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General Report of the

European Chemicals Agency

2008

24 April 2009

(Art. 78(a), 83(3) of Regulation (EC) No. 1907/2006)
(Document adopted by the Management Board)

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List of Acronyms

C&L	Classification and Labelling
CLEEN	Chemical Legislation European Enforcement Network
CLP	Classification, Labelling and Packaging
COM	European Commission
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DG ENTR	European Commission Directorate-General for Enterprise and Industry
DG ENV	European Commission Directorate-General for the Environment
DMS	Document Management System
EC	European Community
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EINECS	European Inventory of Existing Chemical Substances
EMEA	European Medicines Agency
EU	European Union
FAQ	Frequently Asked Questions
Forum	Forum for exchange of enforcement information
HR	Human resources
IAS	Internal Audit Service (of the European Commission)
ID	Identity
IMPEL	EU Network for the Implementation and Enforcement of Environmental Law
ISO	International Organisation for Standardisation
IT	Information Technologies
IUCLID	International Uniform Chemical Information Database
JRC	European Commission Joint Research Centre
MB	Management Board
MS	Member States
MSC	Member State Committee
MSCA	Member States Competent Authorities
OECD	Organisation for Economic Cooperation and Development
PEG	Partner Expert Groups
PPORD	Product and Process Oriented Research and Development
QSAR	(Quantitative) Structure-Activity Relationships [(Q)SARs]; methods for estimating properties of a chemical from its molecular structure
RAC	Committee for Risk Assessment
RCN	Risk Communication Network
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
REACH-IT	REACH-IT is the central IT system providing support for REACH
REHCORN	REACH Helpdesk Correspondent Network
SEA	Socio-Economic Analysis
SEAC	Committee for Socio-economic Analysis
SIEF	Substance Information Exchange Forum
SLIC-CHEMEX WG	CHEMEX Working Group of the Senior Labour Inspectors Committee
SMEs	Small and medium sized enterprises
SVHC	Substance of Very high Concern
UNECE SC GHS	Subcommittee of United Nations Economic Commission for Europe on the Globally Harmonised System for classification and labelling of chemical substances and mixtures

Fact sheet - European Chemicals Agency 2008
www.echa.eu

THE AGENCY

Location:	Helsinki, Finland
Established:	1 June 2007
Founding legal act:	Regulation (EC) 1907/2006 of the European Parliament and the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
Executive Director:	Geert DANCET
Governing body:	ECHA Management Board (Chair: Thomas JAKL)
Mandate:	Managing and in some cases carrying out the technical, scientific and administrative aspects of the REACH Regulation and to ensure consistency at Community level
Statutory Staff (at end 2008):	219
Budget 2008:	63 224 228 EUR

AGENCY BODIES

Management Board	5 meetings in 2008
Member State Committee	6 meetings in 2008
Risk Assessment Committee	4 meetings in 2008
Committee for Socio-Economic Analysis	2 meetings in 2008
Forum:	2 meetings in 2008
Board of Appeal:	No appeals received in 2008

REACH OPERATIONS

Pre-registrations:	> 2 750 000 (pre-registration list published on 19.12.2008)
Inquiries:	243
Registrations:	68
PPORD notifications:	228
Proposals for harmonised C&L:	14
Proposals for SVHC from MS:	16 (of which 15 included in 1st candidate list of 28.10.2008)
Restriction dossiers:	26 transitional dossiers analysed
Helpdesk:	> 15 000 incidents answered / 51 new FAQs published

FOREWORD OF THE EXECUTIVE DIRECTOR

Thank you for taking the time to look at the European Chemicals Agency's first complete General Report. I hope that you find it informative.

Looking back over this first full year of operation I feel a particular sense of pride, gratitude and relief.

Pride for the Agency that, from a standing start, has succeeded in meeting all the high demands placed on it by the REACH Regulation within the tight timeframe set out by the legislators.

Gratitude for the skill, commitment, hard work and long hours spent by my colleagues in ECHA. Gratitude too for the support of the European Commission, the Member States and the European Parliament. And, last but not least, gratitude to the 65 000 companies throughout Europe who worked equally hard to understand the REACH requirements and to fulfil their pre-registration responsibilities, sometimes having to cope with the frustrations of a new IT tool that was not built to handle the unexpectedly high workload.

My relief is that, together, we have managed to give this groundbreaking legislation the promising start that it needed. The aspirations of REACH are extremely important and we can now say that the REACH processes are fully underway:

- The list of pre-registered substances was published on time containing 2 750 000 pre-registrations covering nearly 150 000 substances.
- The first "candidate list" of 15 substances of very high concern was published after having taken account of the views of the public and the opinion of the ECHA Member State Committee.

We are all learning and improving as we go and I fully expect that ECHA will become even more efficient and customer friendly than it is now. REACH implementation is a long journey – for ECHA, our stakeholders, companies and users of chemicals – but together we have made a better start than many of us dared to hope for.

For the following reasons, the coming years will be just as challenging:

- There is a high margin of uncertainty about the number of pre-registrations that will lead to registrations and when they will be submitted, which has implications for ECHA's budget, cash flow and workload.
- It will be challenging for ECHA to further develop REACH-IT to cope with the different and increased demands placed on it and managing the crucial aspect of data security while at the same time establishing the envisaged assessments and delivering the essential outputs.
- ECHA needs to improve on how to communicate to all audiences and disseminate information on chemicals to the public.
- The recruitment targets remain high and ECHA has to work hard to attract the scientific experts needed for its tasks while maintaining the high level of qualification that has been achieved so far.

I am confident that, inspired by the start we have made, ECHA is ready to meet the challenges ahead and I look forward to reporting back to you in one year's time on the progress that we have made.

Geert Dancet
Executive Director

1. GENERAL INTRODUCTION

Established on 1 June 2007, the European Chemicals Agency (ECHA) is at the centre of the new regulatory system for chemicals in the European Union, set out in Regulation (EC) No 1907/2006 of the European Parliament and the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals. At the end of 2008, REACH and the remit of ECHA was complemented by Regulation (EC) No 1272/2008 on the Classification, Labelling and Packaging of substances and mixtures (CLP Regulation).

The purpose of the REACH system is to ensure a high level of protection of human health and the environment, promote alternative methods to animal tests to assess the hazards of chemicals, facilitate the free circulation of substances within the single market, and enhance the competitiveness and innovation of industry.

In practical terms, the new regime is expected to close a knowledge gap for chemicals placed on the European market, to speed up the placing of safe and innovative chemicals on the market and to make the risk management of these substances more efficient, in particular by shifting the burden of proof for identifying and controlling risks from authorities to companies. The successful implementation of REACH requires a well-functioning Agency, capable of delivering independent and high-quality science-based opinions within strict legal deadlines, as well as ensuring that the operational aspects of the legislation function smoothly. However, the efficient operation of REACH also depends on ECHA's institutional partners, in particular the Member States of the EU and the European Commission.

ECHA's Mission

ECHA's mission is to manage all REACH and CLP tasks by carrying out or coordinating the necessary activities, in order to ensure a consistent implementation at Community level and to provide Member States and the European institutions with the best possible scientific advice on questions related to the safety and the socio-economic aspects of the use of chemicals. This is achieved by ensuring a credible decision-making process, using the best possible scientific, technical and regulatory capacities and by working independently in an efficient, transparent and consistent manner.

ECHA's Vision

ECHA's vision is to become *the* internationally recognised Agency on any question related to the safety of industrial chemicals and a source for reliable and high quality information on chemicals. ECHA will be a trustworthy, efficient and transparent regulatory authority and attract highly motivated and talented staff by applying the most modern administrative practices and staff policies. ECHA is a reliable partner providing advice and assistance as needed.

ECHA's Values

As a modern public administration, ECHA's values are transparency, impartiality, accountability and efficiency; it will manage the REACH and CLP operations in a secure, professional and science-based manner. This demonstrates the value that ECHA attaches to its independence from all external interests while at the same time closely cooperating with all stakeholders, the European institutions and Member States. The Agency pursues a strong policy of equal opportunities and environmental friendliness.

More information on ECHA and REACH can be found in ECHA's multi-annual work programme. 2009-2012 and on ECHA's web page www.echa.eu.

2. SUMMARY OF THE MAIN ACHIEVEMENTS 2008

ECHA became financially independent from the European Commission on 1 January 2008 and has since operated as an independent body within the framework of the European Institutions and Agencies.

The timeframe to establish the basic organisational structures and to become ready for the first operational tasks was extremely short. During the year 2008, the Agency more than doubled in size, by growing from 102 statutory staff members to 219, while simultaneously building up operational capacities as well as the supporting infrastructures necessary to perform its regulatory duties.

The successful start of ECHA's activities would not have been possible without the support of the European Commission, which maintained the valuable secondment of experienced officials and provided extensive logistical assistance and strategic advice in 2008.

Entry into operation on 1 June 2008

The major challenge in the first half of the year was to get ready for the entry into operation of REACH on 1 June 2008. ECHA achieved this goal and all companies were able to apply the new regulatory procedures of the REACH Regulation. Importantly, ECHA managed to meet all deadlines and to process all dossiers submitted within the legal timeframe. To support companies ECHA completed relevant guidance documents in due time prior to the entry into operation and provided continuous support to stakeholders, in particular through its helpdesk.

Pre-registration phase from 1 June – 1 December 2008

The priority for 2008 was to inform companies about the crucial pre-registration period for "phase-in" chemical substances[1]. ECHA therefore launched – in collaboration with the Commission – an awareness campaign, which included a dedicated website section, the organisation of stakeholder events and the publication of tools to enable companies to prepare their pre-registrations. Pre-registrations began on time, and by October were being submitted in very large numbers, putting pressure on the systems in place; by the final weeks they were under full control, and the pre-registration period ended successfully on 1 December, the only day the alternative submission system was brought into operation

ECHA's staff coped with an extraordinary workload caused by the high number of pre-registrations as well as the delays in the (external) development of REACH-IT, the main IT system supporting REACH operations. A list of pre-registered substances was published on 19 December 2008 containing more than 2.7 million pre-registrations, a number that vastly exceeded any previous estimates.

First candidate list of substances of very high concern

In the field of the new authorisation procedure, ECHA launched a public consultation on 30 June 2008 on the first dossiers for substances proposed by Member States to be identified as substances of very high concern (SVHC). Based on the comments received, the Member State Committee (MSC) agreed on the first substances to be included on the candidate list of substances for authorisation. ECHA published this candidate list on its website on 28 October 2008.

[1] A phase-in substance is a substance which is either listed in EINECS or which has been manufactured or placed on the market at least once before the entry into force of the REACH Regulation (for a detailed definition see Article 3 (20) of REACH).

Preparing the Agency's bodies for the future work

The three Committees of the Agency met several times in 2008 and established well-defined working procedures for processing scientific dossiers for the various REACH operations. The Forum for exchange of enforcement information adopted its work plan and established several working groups. ECHA also ensured that companies could lodge appeals against Agency decisions, even though no such appeals were received.

Training of Member States officials / Support for international activities

Training of the Member States' Competent Authorities (MSCA) for REACH tasks had already begun in 2007 and continued in 2008. ECHA intensified the cooperation with the MSCAs and with stakeholders and, at the request of the Commission, started to develop its international activities - for which a detailed work programme was agreed between the Commission and the Agency.

3. IMPLEMENTATION OF THE WORK PROGRAMME 2008

Priorities in 2008

In its work programme for 2008, adopted by the Management Board in October 2007[2], ECHA had prioritised its resources for a number of cross-cutting actions, which were expected to determine the success of the Agency's activities in its first full year of operation:

1. Recruiting and training the staff needed to begin operations on 1 June 2008;
2. Establishing working scientific Committees, the Forum and the Board of Appeal;
3. Developing and implementing procedures and IT support tools to ensure a legally sound, user-friendly and efficient execution of the operations;
4. Developing structured relationships with stakeholders and reinforcing the network of competent authorities including the training of national trainers;
5. Ensuring the proper hand-over of chemical "*acquis*" and the IT contracts from the Commission services;
6. Finalising Guidance to help ensure that the network of national helpdesks and the Agency helpdesks could assist registrants in understanding their requirements.
7. Publishing the list of pre-registered substances by 31 December 2008

In the subsequent chapters of this report, explanation on the implementation of these priorities will be provided

Necessity to determine negative priorities

The ECHA Work Programme for 2008 was developed, to a large extent, based on the Commission's Revised Legislative Financial Statement, which sets out the estimates for staff and budgetary needs[3]. The basis for this was the Commission's staff model which estimates the workload for each of the Agency's tasks and the financial model which translated the staff and other resource needs into expenditure.

During the first six months of 2008 however, it became clear that ECHA needed to carry out a significant number of additional tasks. In particular, the IT work-arounds developed due to the delays in REACH-IT have resulted in significant re-allocation of resources that were originally intended to prepare and run the operations. These changes have led to the necessity to re-prioritise ECHA's tasks and to identify a number of planned activities as negative priorities.

From an operations point of view, this resulted mainly in rescheduling efforts to build up capacity for dossier evaluation; in postponing the evaluation of PPORD notifications and in delays in the development of operational procedures and of screening and reporting tools. Due to delays in the REACH-IT system, the work on the ECHA public dissemination website section for non-confidential information on chemicals was also unable to advance as planned.

In addition, a report on guidance activities was postponed, and the work with the Commission and other Agencies, aimed at developing structures and rules of procedures to ensure coordination and increase synergy between REACH and related legislations, was reduced or postponed. In addition, work requested by the Commission concerning scientific and technical cooperation with the OECD was reduced, in 2008, to priority tasks.

The Management Board was kept informed of these developments and ECHA took account of the delays when planning for 2009, in order to recover as quickly as possible.

[2] ECHA MB/18/2007
[3] SEC(2006)924 REACH Revised Legislative Statement of 14 July 2006

4. OPERATIONAL ACTIVITIES - IMPLEMENTATION OF THE REACH PROCESSES

Main results

- List of 146 014 pre-registered substances published within legal deadline
- Higher than foreseen number of pre-registrations processed - more than 2.7 million
- 1 538 dossier submissions processed within the legal deadlines resulting in 243 inquiries, 68 registrations and 228 PPORD notifications
- First candidate list drawn up and published, containing 15 SVHCs
- Preparations advanced for dossier evaluation, restriction and C&L tasks
- Provision of effective support to stakeholders through guidance and helpdesk
- Start of the development of further scientific IT tools

The operational part of the REACH Regulation entered into force on 1 June 2008. The main short-term objectives for 2008 were therefore closely linked to this date, to:

- Ensure that the Agency was operational by 1 June 2008, with a high scientific, technical and regulatory capacity;
- Ensure that the Agency's operations were legally compliant, efficient and transparent;
- Have structures in place to ensure consistency with other Community work on chemicals;
- Manage the hand-over of work, mainly from the European Chemicals Bureau (ECB), under the previous chemicals legislation by 31 December 2008.

The REACH operations began on 1 June 2008 with the Agency ready to fulfil its role regarding the following tasks:

- Pre-registration, Registration and inquiry, including requests for data sharing;
- Evaluation with the ability to carry out the examination of testing proposals and compliance check;
- Notification of substances for product and process oriented research and development (PPORD).

The first steps of the authorisation process were undertaken in 2008, namely the identification of Substances of Very High Concern and the establishment of the first candidate list. Preparatory work was also done in the field of Classification and Labelling, covering the harmonised classification and labelling proposals, the forthcoming new C&L legislation and on transitional dossiers linked to the REACH restrictions procedure that comes into force from 1 June 2009.

4.1 Registration, pre-registration and data-sharing

One of the aims of the REACH Regulation is to generate information on chemical substances in order that they can be adequately controlled during their manufacture and use. The main mechanisms established in REACH to meet this aim are the registration and pre-registration processes. These processes depend strongly on the scientific IT-tools available to the agency. The tools were developed externally, and were initially the responsibility of the European Commission prior to handover to ECHA.

When drawing up the REACH Regulation, the Commission estimated that over 130 000 pre-registrations would be received from industry, for more than 70 000 chemical substances and intermediates. By the end of the pre-registration period, ECHA had received 20 times more pre-registrations than expected. Many of these pre-registrations were – for a number of reasons – submitted by companies that will not submit a registration later in the process. However, the high volume of pre-registrations created a significant additional workload for ECHA staff and resulted in a temporary overload of the IT system, which led to an intense period of communication with stakeholders regarding the progress on the system usability.

4.1.1 Pre-registration

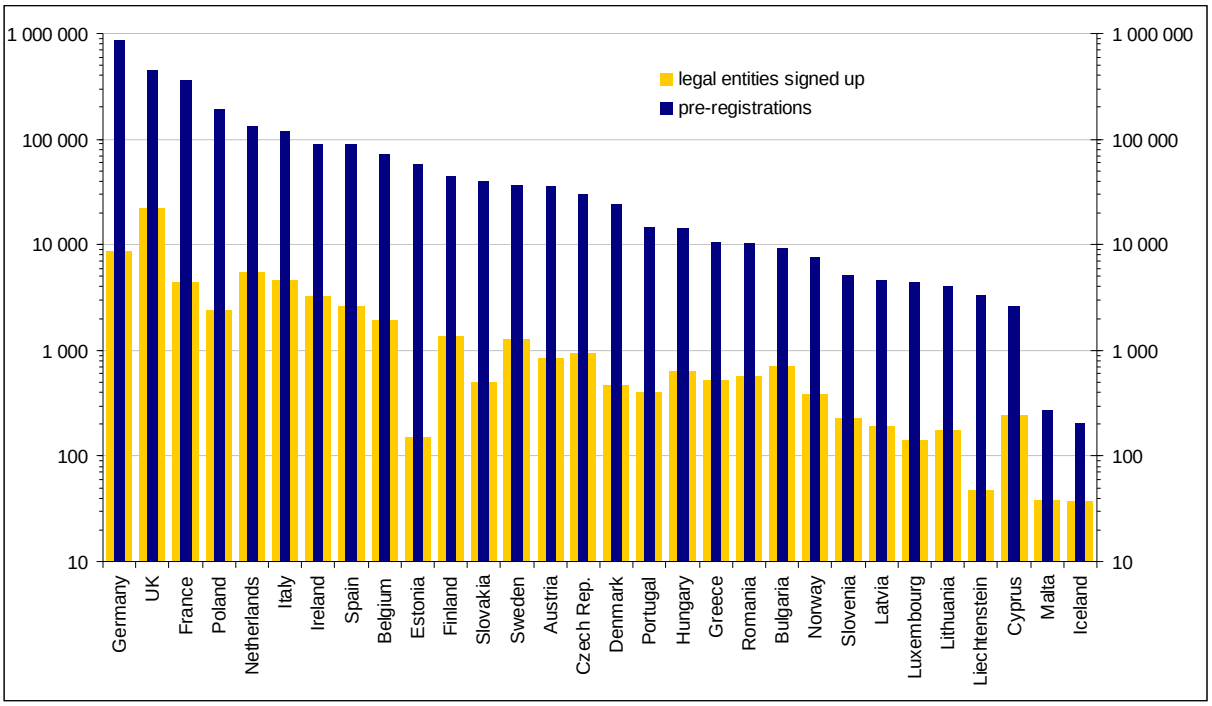
During the six months of the pre-registration period, more than 65 000 companies signed up to REACH-IT, submitting more than 2 750 000 pre-registrations, which covered nearly 150 000 different substances.

Almost half of the pre-registrations were submitted during the last two weeks of the pre-registration period.

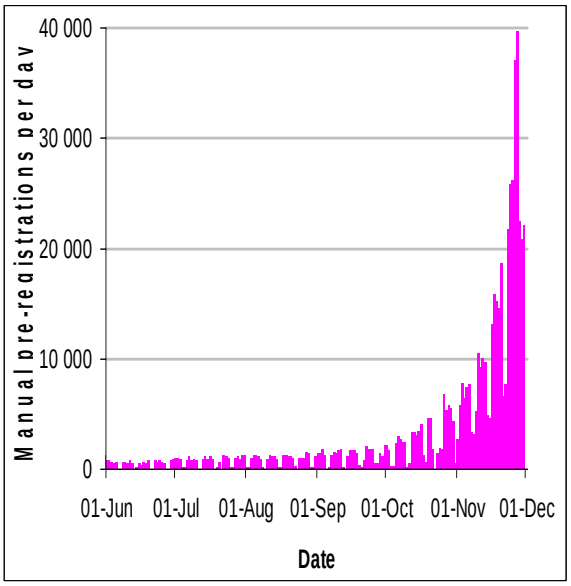
Other notable statistics are that:

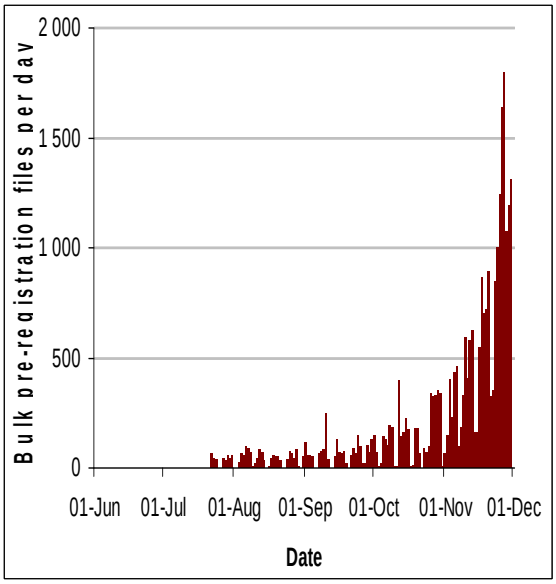
- 82% of companies indicated that they are SMEs;
- 25 000 companies indicated their intention to register before the first deadline of 30 November 2010, which covers approximately 50 000 different substances;
- 18% of substances were pre-registered without indicating an EC number. These include mainly:
    - substances that do not have an EC number, substances presumably manufactured in the Community but not placed on the market by the manufacturer or importer, and which have phase-in status according to Article 3 (20)(b) (so-called “intermediates”);
    - substances that have an EC number, which was not used by the potential registrant. These will be identified by ECHA.
- Almost half of the REACH-IT sign ups and pre-registrations were from companies in Germany and the United Kingdom. Other countries with more than 100 000 pre-registrations were France, Poland, the Netherlands and Italy.

Breakdown of pre-registrations and Legal entities per country



Number of pre-registrations per day from 1 June to 1 December 2008





The list of pre-registered substances

An intermediate list of pre-registered substances was published on 7 October 2008 and was updated on 7 November 2008. A list containing all substances pre-registered by 1 December was published on the ECHA web site on 19 December 2008.

The list published in December consists of 146 014 substances, comprising all the substances listed in the EC inventory (EINECS, ELINCS, NLP) and 41 281 substances without an EC number as an identifier, of these 17 193 are identified by a CAS number, 9 560 by a chemical name and 14 528 submitted as multi-constituent substances.

To improve the quality of the list and facilitate SIEF formation by industry, ECHA screened the substance identity of around 12 000 substances that had been pre-registered without an EC number. More than 9 000 e-mails were sent to companies when issues with the substance identity were noted. The 17 193 substances that were pre-registered using CAS number as the identifier were verified in collaboration with the Chemical Abstract Services (CAS) to ensure that companies had used the correct CAS names.

4.1.2 Registration

By 31 December 2008, 1 538 dossier submissions (810 inquiries, 487 PPORD notifications and 241 registrations covering 28 phase-in substances) had been manually handled and processed within the deadlines set by the legal text.

Data submissions from 1 June 2008 until 31 December 2008

Dossier type	Submitted	Accepted for processing	Technical completeness check passed	Complete
Inquiry	810	619	N/A	243
Registration Intermediates on-site	40	24	12	12
Registration Intermediates transported	107	70	50	46
Regular Registration dossiers	94	36	10	10
PPORD notifications	487	335	234	228
Total	1538	1084	306	539

Approximately 70% of dossiers passed the initial checking procedure (which included a virus check) and were then subject to a technical completeness check. The most common causes for not passing the check included inconsistencies in identification of the dossier, substance or company, or basic errors such as failure to include the requested submission form.

When a dossier failed the initial technical completeness check, ECHA provided the company a responsible for the dossier with a description of the information needed to allow successful re-submission. Duly, many of the submissions, in the above table, concern a second submission of the same dossier.

Inquiries

An “Inquiry” is the process by which every potential registrant of a non phase-in substance (or a phase-in substance which has not been pre-registered) asks ECHA whether a registration has already been submitted for the same substance. “Inquiry” is a requirement of REACH and companies making inquiries must include information on company and substance identity. They must also indicate which information requirements in REACH would require them to carry out new studies, (including new studies involving vertebrate animals) to be carried out by them.

About 20% of the successfully processed inquiries refer to previous registrations (substances notified under Directive 67/548/EEC regarded as registered under REACH). As a standard procedure, ECHA informs the potential registrants and the previous registrants, about each other, and reminds them of their obligations to share data.

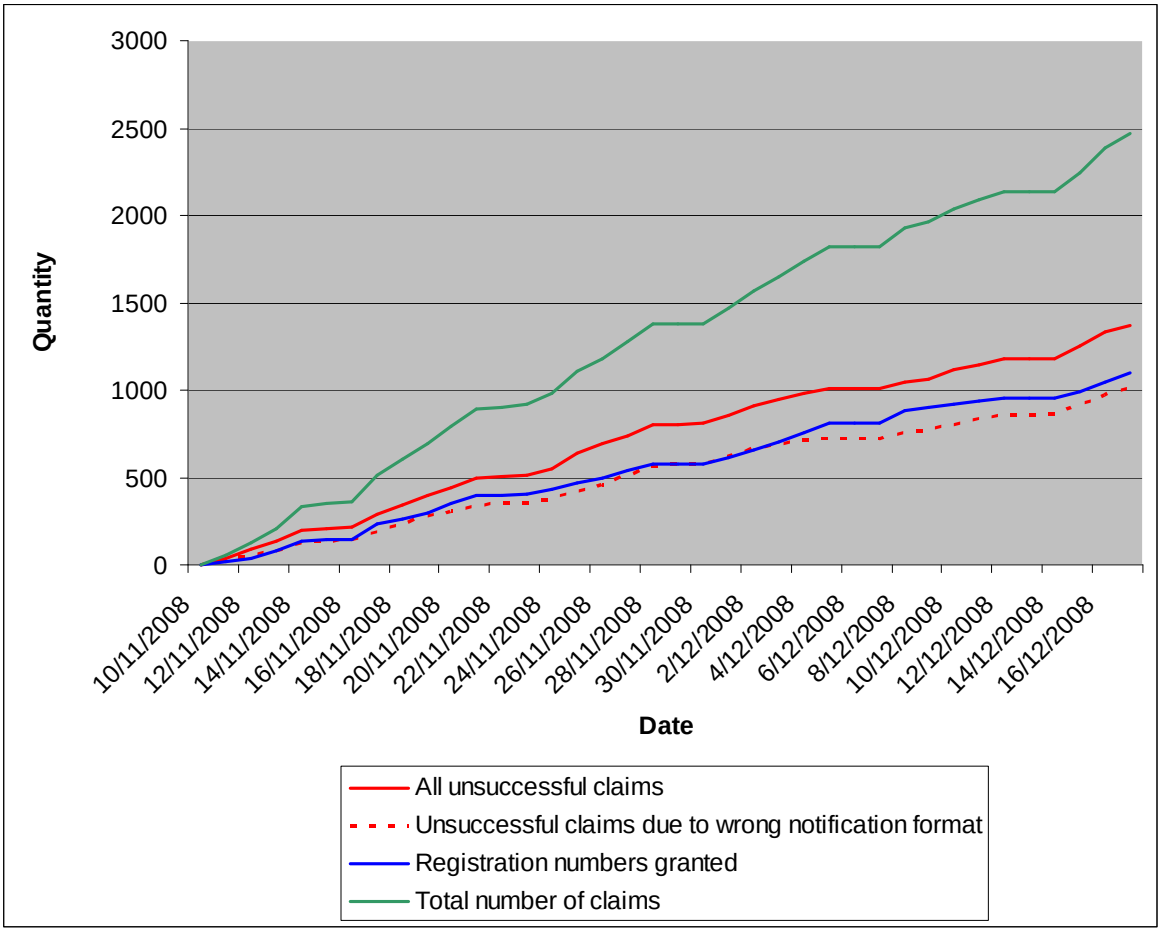
Registration numbers for substances notified under Directive 67/548/EEC

Substances notified under Directive 67/548/EEC (NONS) are regarded as registered under REACH. As required by REACH, ECHA assigned registration numbers to these substances by 1 December 2008.

From 11 November 2008, following a procedure endorsed by the Member State Competent Authorities (MSCA), notification owners could, upon request, claim their registration numbers via REACH-IT.

Provided that the company details specified in REACH-IT match those listed in the appropriate notification, ECHA provides the registration number to the requesting party: 1096 such numbers were provided by the end of the year. Should the details not match, ECHA does not distribute the registration number and the requesting party is advised to contact the relevant Member State Competent Authority (MSCA) to resolve the issue.

Overview of distribution of registration numbers for NONS



4.1.3 Data-sharing

Data sharing for registration purposes is mandatory in REACH in order to reduce both the need for testing on vertebrate animals and the costs for industry. As a follow-up to inquiries, where potential registrants are informed that data older than twelve years is available from ECHA for the registration purposes, and because the dissemination web site is not in place, procedures were put in place in 2008 to address requests received via the helpdesk. In these cases (five of which were received between October and December 2008), ECHA provided access to (robust) study summaries of data older than twelve years (under the "12 year rule" laid down in the REACH Regulation).

4.2 Evaluation

As the Agency's tasks related to the evaluation of registration dossiers and chemical substances will mainly occur after the first registration deadline of 30 November 2010, the work in 2008 consisted mainly of establishing up procedures for handling compliance checks for registration dossiers, testing proposals and building up expert capacity.

Seven low volume (1-10 t/year), non phase-in substance registration dossiers passed the technical completeness check in 2008. The compliance checks for three dossiers of low volume (1-10 t/year), non phase-in substance registration dossiers were started and Member States Competent Authorities (MSCAs) were informed as such. No registration dossiers which included testing proposals were received in 2008.

A software-based workflow system was developed and used for both managing the filing of documents, as well as for following the order of processes and monitoring the progress of tasks during compliance checks and testing proposals. The system is used to maintain historical records of the work carried out and to support time management.

4.3 Authorisation and Restrictions

4.3.1 Authorisation

During the first half year of 2008, working instructions and procedures were developed for ECHA's tasks linked to the authorisation procedure. In particular, the mechanisms for handling of Annex XV dossiers for Substances of Very High Concern (SVHC) were developed to facilitate the exchange of information between ECHA and MSCAs and to gather comments from interested parties through the public website.

The second half of the year focused on handling the first Annex XV dossiers, development and publication of the first candidate list of SVHC and preparation for the first draft recommendation of substances to be included in Annex XIV of REACH (the "authorisation list"). ECHA received sixteen SVHC dossiers from Member States in 2008. After the public consultation of interested parties, the Member States Committee (MSC) unanimously agreed on the identification of fourteen SVHC. MSC involvement was unnecessary for the identification of a further substance as no comments on its intrinsic properties were received from interested parties. For one other substance the MSC unanimously concluded that there is currently not enough information to identify that substance as a SVHC. ECHA has therefore included fifteen substances in the candidate list of SVHC for inclusion in the authorisation list. The list was published on 28 October 2008 on ECHA's website (cf. Annex 3).

In June 2008, the Commission asked ECHA to prepare dossiers proposing that five coal tar derivatives be identified as SVHC. ECHA started work on these substances with a view to submitting the corresponding Annex XV dossiers in 2009.

In relation to the development of the first recommendation of priority substances for inclusion in Annex XIV of REACH (the "authorisation list") which has to be submitted to the Commission by 1 June 2009, ECHA presented its prioritisation approach, as well as its suggested approach towards developing the Annex XIV entries at the fifth meeting of the MSC, in November 2008. Subsequently, ECHA has developed a first draft priority list and draft recommendation for Annex XIV and discussed these at the MSC meeting in December. During this meeting, the MSC appointed a rapporteur, charged with drafting a Committee opinion on the recommendation, and set up a working party to assist the rapporteur in preparing the opinion.

4.3.2 Restrictions

The REACH procedure for restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles will enter into force on the 1st June 2009. In 2008, ECHA prepared most of the necessary written procedures and related letter and and document templates as well as procedures for the Risk Assessment and Socio-economic Analysis Committees (RAC & SEAC) to manage restriction proposals. The work done and experiences gained from the work on C&L and SVHC dossiers were used as a basis.

Where the work prioritised substances under the Existing Substances Regulation (93/793/EEC) was not finalised by the 1 June 2008, the respective rapporteur Member States had to submit transitional dossiers in accordance with the REACH Regulation. Such dossiers were received for all 26 non-finalised substances by the deadline of 1 December 2008. ECHA began its assessment of the dossiers with a view to making non-

confidential information publicly available and to inform the RAC and SEAC on the conclusions, in particular with respect to whether a need for restrictions under REACH had been identified. None of the dossiers examined resulted in a recommendation for a restriction.

4.4 Classification and Labelling

In 2008, ECHA received dossiers proposing harmonised Classification and Labelling (C&L) for fourteen substances. Four of these proposals were received during June and July 2008 and have undergone a check of whether they were prepared in accordance with the requirements of the REACH Regulation. Based on the findings in these accordance checks the dossiers were or will be updated by the submitting Member States.

In addition, ECHA received 21 notifications of intention to prepare dossiers proposing harmonised C&L. Most of these are expected to arrive in the course of 2009[4]. The RAC nominated rapporteurs and co-rapporteurs for all substances for which notifications of intention had been received from MSCAs.

ECHA analysed and started preparing for the implementation of the new tasks under the new CLP Regulation which entered into force in January 2009 and contributed to Commission's work on the development of guidance on this new legislation.

4.5 Advice and Assistance through Guidance and Helpdesk

4.5.1 Guidance

In early 2008, in particular, ECHA's work on guidance focused on supporting the Commission in finalising guidance documents which were subsequently made available on the Agency's website. ECHA also developed first updates of guidance documents. This effort was undertaken in various stages throughout the year. The full list of Guidance Documents can be accessed via ECHA's website[5]:

Furthermore, a number of Guidance Fact Sheets providing an overview of the corresponding guidance documents were developed and published in the Community languages on ECHA's website.

In 2008, ECHA also prepared several guidance updates by developing respective roadmaps and issuing calls for tenders. This work pertained to the following topics:

- Annex IV/V of the REACH Regulation
- Substances in articles
- Scoping of guidance on the extended Safety Data Sheet (e-SDS)
- CSA/CSR
- CLP Regulation

Apart from publishing guidance on ECHA's website, the Agency improved the accessibility of guidance through maintaining and updating the "Navigator" IT tool and by enabling a key-word search. With the aim of further facilitating the use of guidance, ECHA commissioned a scoping study focusing on the harmonisation of key REACH terminology.

[4] All intentions received by Member State with regard to the planned submissions of scientific dossiers for C&L, restrictions or the identification of substances of very high concern were indicated in the Registry of Intentions published on ECHA's web page.

[5] http://guidance.echa.europa.eu/

In February 2008, the Management Board endorsed a document establishing a Consultation Procedure on Guidance; the procedure aims at ensuring transparency and at minimising the period during which guidance containing identified shortcomings remains publicly available on ECHA's website. On an internal level, ECHA implemented appropriate workflows for this procedure.

With a view to the pre-registration deadline of 1 December 2008, ECHA coordinated a specific project, in cooperation with the European Commission, on overall guidance and awareness-raising actions on pre-registration, aimed at providing industry with practical information (e.g. brochures and leaflets) and support tools (e.g. IT manuals, standard questions and answers, a video-tutorial for REACH-IT and IUCLID). This resulted in a "one-stop shop" for information on pre-registration available to all users of ECHA's website.

ECHA also developed and managed an expert database to support the work of the Agency, for instance with regard to convoking Partner Expert Groups (PEGs) as foreseen in the consultation procedure on guidance. This database was established in consultation with Member State Competent Authorities and stakeholder organisations.

With a view to ECHA's task to elaborate guidance on risk communication, the Agency commissioned a scoping study to identify issues to be covered by a guidance document addressing communication to the general public on risk and the safe use of chemical substances. In June 2008, ECHA held a workshop gathering expertise on risk communication from other Community agencies and from individual experts in this field.

4.5.2 Helpdesk

The year 2008 provided an intensive workload for ECHA's helpdesk. The periods ahead of the entry into operations of the Agency on 1 June 2008 and ahead of the deadline for pre-registrations on 1 December 2008 presented the Helpdesk with the particular task of adjusting its communication to these two REACH milestone. The statistics on the Helpdesk's activities in 2008 also reflect the intensity of the workload involved in handling ECHA's contacts with industry, particularly with SMEs and non-EU actors.

The provision of information by the Helpdesk on the REACH Regulation as well as on the REACH-IT and IUCLID 5 tools essential to the registration process mainly consisted of providing information to stakeholders (more than 15 000 incidents were answered in 2008) and formulating and updating Frequently Asked Questions (51 FAQs approved).

ECHA began helpdesk support on REACH-IT industry functionalities in May 2008 and established a single entry point for helpdesk questions on the ECHA website. To provide continuous service to customers/users, the Helpdesk implemented workflow and standard operating procedures to effectively run a three-level helpdesk. This also necessitated consultations with the European Commission and with software suppliers.

In the two weeks prior to the pre-registration deadline, the Helpdesk provided a special Rapid Response Service (RRS). This allowed ECHA to deal with prioritised questions related to pre-registration by directly telephoning "customers" in different Community languages. ECHA provided this service to interlocutors in EU and EEA countries wishing to pre-register phase-in substances. During the two-week RRS period, the Helpdesk handled almost 3 500 responses. All enquiries relevant to pre-registration were answered before the pre-registration deadline, and the effective response time for replies was shortened to two/three days.

For the purposes of in-house consultation, and to run RHEP (the REACH Helpdesk Exchange Platform with national REACH helpdesks), ECHA further developed the helpdesk IT tool and accommodated the transfer of the respective IT-Server from the European Commission (Joint Research Centre at Ispra in Lombardy) to Helsinki. ECHA's Helpdesk was also involved in developing user manuals and training material.

The ECHA Helpdesk closely cooperated with national REACH helpdesks by means of the network "REACH-Helpnet" which aims at agreeing upon harmonised answers and providing high quality advice to registrants. ECHA organised three REHCORN meetings during 2008 (in February, April and September, respectively) and held dedicated workshops on information exchange, best practice and the identification of common answering strategies. The Helpdesk also organised a training session for national helpdesks on the REACH-IT industry functionality in advance of the pre-registration period.

A visiting programme of ECHA helpdesk staff to national helpdesks, launched in 2008, also helped to enhance cooperation, as well as the exchange of best practice, among helpdesks.

Overall, the year 2008 has provided invaluable experience from which a number of lessons learnt can be identified. These are, for example, the need to deliver targeted information in a timely and more proactive manner well in advance of the deadlines, dealing with a high workload before important deadlines and having the sufficient capacity building in place. These lessons will serve to develop further the support provided by the helpdesks with a view to accomplish successfully the challenges ahead.

Annex 4 features tables with a statistical overview of the output of ECHA's Helpdesk during 2008.

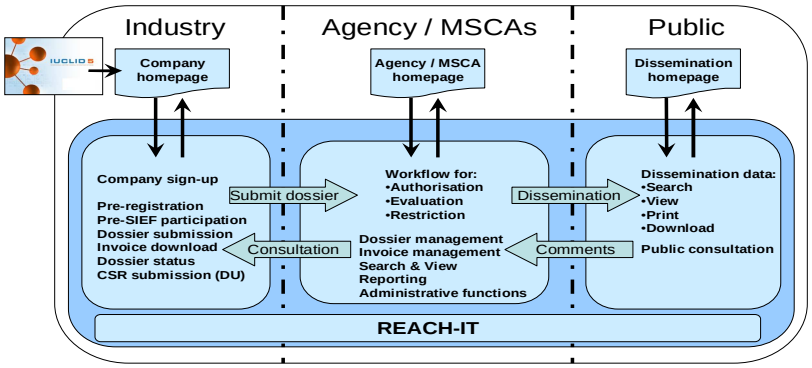
4.6 IT tools supporting operations

4.6.1 REACH-IT

REACH-IT is the main IT system of ECHA, and will, from early 2009, also be accessible to Member States Competent Authorities (MSCAs). REACH-IT is intended to automate REACH workflows: from submission of information (e.g. registration dossiers submitted by companies), through processing of the information by ECHA and the MSCAs, to eventual publication of non-confidential data on the ECHA website. REACH-IT is therefore essential for the successful implementation of REACH.

The future development of REACH-IT has been, and remains, a major challenge for ECHA - in terms of scope, resources and time constraints; these have proved to be much more demanding than originally expected. One reason for this is the need to incorporate new requirements e.g. new user demands, arising from the development of standard operating procedures by ECHA's personnel, or from lessons learned from handling the dossiers submitted since 1 June 2008, or even from requirements coming from new, related legislation - such as the Fee Regulation published on 16 April 2008 or the Classification and Labelling regulation (CLP) published on 31 December 2008.

Overview of REACH-IT modules



Note: Agency **=** ECHA, MSCA = EU Member State Competent Authority

The construction of the REACH-IT application started in early 2007, when the core functions for industry were developed; some of these were ready for initial testing in September 2007.

Given that the first main deadline under REACH was for pre-registration (the pre-registration period ran from 1 June to 1 December 2008), the majority of resources were focused towards securing the pre-registration process - providing companies with the basic necessary functions to allow them to pre-register in REACH-IT. Additionally, ad-hoc tools were developed to allow companies to prepare their pre-registrations in large numbers, off-line.

Recognising the need to focus on pre-registration, the Agency decided in May to postpone the online dossier submission via REACH-IT until September. Consequently, temporary submission procedures were put in place. These procedures relied on IUCLID 5 for the preparation of the dossiers, which were then submitted to ECHA by registered mail or by courier services. Approximately 1 500 dossiers (registrations, inquiries, PPORD notifications and proposals for harmonised classification and labelling and identification of substances of very high concern) were received via this temporary system.

Bulk pre-registration became possible on 22 July, and from September to November REACH-IT was upgraded, and capacity added several times, in order for it to cope with an exponential increase in use for pre-registration. The upgrades resulted in an adequately performing system, in spite of its very high usage by industry. At the same time, the online submission of dossiers was again postponed to January 2009. As noted earlier, 65 000 legal entities signed up in REACH-IT, submitting 2 750 000 pre-registrations - far above the original Commission estimate of over 130 000 pre-registrations.

On 11 November 2008, the functionality for distributing registration numbers for the notified substances under Directive 67/548/EEC was made available.

4.6.2 IUCLID 5

IUCLID 5 is a software application used by industry to manage information on the properties and uses of their chemicals and to create their registration dossiers. It was developed by the European Commission and made available to stakeholders in June 2007. The project management was handed over to the Agency from the Joint Research Centre of the Commission in Ispra (Italy) over the course of 2008.

A IUCLID Management Group (IMG) has been established by ECHA, and in 2008 its responsibilities included management of the IUCLID 5 helpdesk and further development and release of changes to the system. The IMG also participated in the OECD IUCLID User Group Expert Panel, where stakeholders' requirements were collected and prioritised. ECHA set up a new contract in December 2008 for the maintenance and further development of IUCLID 5.

Several add-ons were released in 2008, in particular two critical modules for industry: the pre-registration module enabling companies to prepare and submit pre-registrations in large numbers ("bulk" pre-registration), and the SNIF migration module - enabling companies to transfer into IUCLID 5, data collected under the notification scheme of New Substances under the former legislation.

4.6.3 CSR tool

The REACH Regulation states that ECHA should provide guidance and tools, in particular to assist the development of Chemical Safety Reports (CSR). Consequently, the Agency has committed itself to building a tool to assist registrants and downstream users with the production of Chemical Safety Assessments (CSA) and with documenting the results in a CSR.

The CSA tool is aimed at supporting industry in following the core elements of the Guidance on information requirements and chemical safety assessment (available on the ECHA website) when carrying out a CSA for standard cases.

A contract for the development of the tool was awarded in October 2008 by ECHA.
In order to provide support to industry in time for the first registration deadline in 2010, the objective is to roll out a first version of the tool before the end of 2009.

4.7 Scientific and practical advice to the further development of legislation

Upon the request of the Commission, ECHA examined the option of taking over scientific, technical and administrative tasks regarding the authorisation of biocidal products, and contributed to the drafting of the legislative proposal for a new EC Biocides Regulation.

In addition, ECHA contributed to the development of the annexes to the new CLP Regulation, in collaboration with the JRC and other stakeholders.

ECHA also provided support to the Commission during the review process of several annexes to the REACH legislation: in particular with respect to Annex V on exemptions from the obligation to register; Annex XI.3 on Substance-tailored Exposure-driven testing; and Annex XIII on criteria for identification of PBT and vPvB substances. ECHA scientific support was also provided to the REACH CA subgroup on nanomaterials.

5 ECHA'S BODIES AND SUPPORTING ACTIVITIES

Main results

- All Committees and the Forum established and ready for forthcoming tasks
- Member State Committee exercised a crucial role in establishing the candidate list and developed criteria for Annex XIV recommendations
- Registry of the Board of Appeal ready to receive appeals
- Three stakeholder events organised and a pre-registration campaign carried out
- Support to the Commission on international, activities mainly related to the OECD

All three ECHA Committees held inaugural meetings in early 2008. To prepare for what will be substantial work, the Committees as well as the Forum, agreed on their respective draft Rules of Procedure, prior to the entry into operation of ECHA on 1 June 2008, and duly submitted them to the Management Board for approval and adoption.

The Committees and the Forum also started to establish co-operation procedures with each other.

Following the entry into force of the EEA Joint Committee Decision (No 25/2008) on 5 June 2008 concerning the REACH Regulation, Iceland, Liechtenstein and Norway appointed members to the Forum and to the Member State Committee. Norway also nominated candidates for the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC). Members nominated or appointed by these countries have the same rights and obligations as those from EU Member States with one exception – they do not enjoy the right to vote.

Major steps were taken to ensure the transparency of the Committees and the Forum, and all the bodies decided to publish their key documents on ECHA's website. Following a policy decision by the Management Board and an open call for expressions of interest, each Committee selected 15 to 16 stakeholder organisations to join their work as observers. The Forum decided to invite stakeholder organisations to an open session at least once a year. An ECHA code of conduct for observers from stakeholder organisations was consequently adopted in September 2008.

In addition to stakeholder observers from within the EU, the OECD Secretariat was invited to participate in the Committee meetings as a regular observer.

5.1 Member State Committee (MSC)

The MSC held its inaugural meeting in February and met six times in 2008.

Prior to addressing specific cases, the MSC established a practice to adopt working procedures for each of the processes in which it is involved (i.e. the authorisation and evaluation processes). The working procedures were then published on ECHA's website to reflect the transparency of the Committee's procedures.

In 2008, the MSC played a crucial role in the establishment of the first candidate list of SVHC (cf. above 4.3.1) as well as in reviewing ECHA's proposal for the first draft recommendation of priority substances for Annex XIV (the "authorisation list").

5.2 Risk Assessment Committee (RAC)

Having been established in December 2007, the RAC met for the first time in February 2008. It held a total of four meetings in 2008. After agreeing on Rules of Procedure, the RAC concentrated on understanding its tasks as designated by REACH, the need for interaction with other ECHA bodies, and the ways in which the Committees would operate.

The Committee agreed on the basic content and format of an opinion on a C&L proposal, as well as on the procedure for developing and agreeing on the Committees opinion, as specified in the CLP Regulation.

A procedure on how to conduct a conformity check on a restriction dossier within both the RAC and SEAC in parallel was agreed by both Committees. Discussions have started on the form an opinion should take and the content of both an opinion and its supporting documentation, as well as the procedure to ensure finalisation of the opinion within the legal timeframe.

5.3 Committee for Socio-economic Analysis (SEAC)

The Management Board appointed the first members of the SEAC in February 2008, and the Committee then met twice in plenary and once in an inter-session working group meeting. The reason for the SEAC only convening its first meeting in 2008 was due to the fact that it can only receive its first REACH dossiers from June 2009. The SEAC thus enjoyed a longer period to establish its working procedures, than the other two Committees.

The Committee's first meetings focused on its Rules of Procedure and on working procedures on restriction dossiers. As the SEAC has no evident predecessor in the earlier legislative framework, defining the role and the tasks of the Committee led to thorough discussion. This discussion identified the particular challenges related to forming a SEAC opinion on the socio-economic aspects of a restriction proposal, and the socio-economic impacts, such as a possible lack of actual socio-economic analysis and/or lack of socio-economic data and the validation of the quality of the data, stringent timelines and their relationship with the opinion that the SEAC will have to prepare in parallel with the RAC.

In October 2008, ECHA organised a workshop in Helsinki on applying socio-economic analysis as part of restriction proposals under the REACH Regulation. Its purpose was to build a common understanding on how to prepare a restriction proposal (particularly, from the point of view of socio-economic analysis) and to understand how interested parties can contribute to the opinion-making process during the consultation period.

5.4 Forum for Exchange of Information on Enforcement

After its inaugural meeting in December 2007, the Forum met twice in 2008 and allocated part of its business to various working groups (WGs). In addition to admitting stakeholders to an open session of its meeting in December 2008, the Forum initiated a discussion of possible forms of cooperation with other enforcement networks, namely SLIC-CHEMEX WG, CLEEN and IMPEL.

The work of the Forum proceeds mainly through WGs which report to the plenary; the latter then adopts the documents produced by the WGs. In 2008, a total of eight Forum WGs were active, and held a maximum of four meetings in the course of the year. At its third plenary meeting in December 2008, the Forum established or prolonged the mandate of five WGs.

During 2008, the Forum shifted its focus from procedural issues towards issues more directly related to enforcement. At its second meeting in May 2008, the Forum agreed on its work programme for 2008-2010, which has been published on ECHA's website[6]. Work also started on developing advice regarding the enforceability of the revision of Annex XVII, identification of enforcement issues to be covered by the Member State report under Article 117 of the REACH Regulation, a strategy for the enforcement of REACH, and a first enforcement project.

At its third meeting in December 2008, just after the pre-registration deadline, the focus of the Forum's work further shifted to the discussion of more detailed aspects of enforcement. The Forum established specific working groups to investigate requirements for the IT information exchange system for inspectors, and to identify common minimum criteria for REACH inspections – both are aimed at improving the coordination of REACH enforcement. The first coordinated enforcement project on pre-registration, registration and SDS was adopted and will be implemented in 2009. A further new working group will prepare the second Forum project for 2010. Forum members also discussed the practicalities of enforcing the submission of pre-registration, and the Forum welcomed ECHA's proposal for the access of inspectors to data from REACH-IT as a necessary precondition for enforcement; a working group to examine the details of this proposal was duly established.

5.5 Board of Appeal

The main priority in 2008 was the appointment of the members of the Board of Appeal who are appointed by the Management Board on the basis of a list of candidates proposed by the Commission.

The Management Board selected and appointed the members and alternates of the Board of Appeal at its June and September meetings respectively. However, the appointments were subject to the acceptance and availability of the persons concerned. The candidates appointed as the Chair, alternate Chair of the Board of Appeal, and as a legally qualified member, did not accept their respective appointments. The candidate appointed as a technically qualified member, along with three further candidates, accepted their appointments to the positions of alternate/additional legally qualified members.

To remedy the situation, new calls for expressions of interest for the positions of Chair of the Board of Appeal, legally qualified member and alternates, and additional technical members, were published in the Official Journal. Furthermore, a new call for expressions of interest for the position of an alternate Chair of the Board of Appeal was published.

The rules governing the appeal procedure before the Board of Appeal were adopted by Commission Regulation (EC) No 771/2008 of 1 August 2008, which lays down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency.

In addition, a Registry of the Board of Appeal was established, which assists the Board of Appeal in its functions by providing administrative support for the proceedings and by keeping a register of all procedural acts. The Registry is also the repository of all procedural documents and serves as a link between the appellants, other interested parties, and the Board of Appeal. In this respect, and aside from the practicalities for receiving appeals, prior to the Commission adoption of the above-mentioned Regulation on Rules of Procedure, the Registry of the Board of Appeal prepared a set of temporary guidelines to provide assistance to the parties in appeal proceedings, in order to guarantee their access to justice as from the entry into operation of the REACH Regulation. After the publication of the Rules of Procedure, the temporary guidelines still

[6] See http://echa.europa.eu/doc/about/organisation/forum/forum_wp_2008_2010.pdf

serve the function of providing practical help to the parties and also compensate for the temporary lack of definitive implementing rules, until such time as the Board of Appeal is in a position to adopt them. In addition, a dedicated “Appeals” section was introduced to the ECHA website in June 2008.

Thus, at the end of 2008, the Registry of the Board of Appeal was ready to receive potential appeals and to proceed with the procedural formalities of an appeal. However, no appeals were received in 2008.

5.6 Communications and REACH training

Throughout 2008, efforts in this field followed ECHA’s Communication Strategy endorsed by the Management Board in February 2008.

ECHA focused on maintaining and further developing its website as the key communication channel of the Agency. Publishing news and ECHA documents online ensured timely access to information and stakeholders’ awareness of topical issues. In the course of the year, ECHA added several new sections to the website: Pre-registration; Consultations; ECHA CHEM (for information on chemicals); Publications; REACH-IT; and the Board of Appeal. A system to collect statistics was also developed.

ECHA published several key documents in 22 Community languages, such as guidance on the web pages for pre-registration, the multi-annual work programme, and the General Report 2007.

ECHA has been producing a bi-monthly Newsletter since July 2008 and has published various documents including the General Report 2007, several brochures and REACH awareness-building material.

Three stakeholder events were (co-)organised during the year. The first, co-organised with the European Commission, took place in Brussels in April 2008. It focused on the pre-registration requirements of REACH. The formal inauguration of the Agency on 3 June 2008 constituted the second event. The third was ECHA’s first formal “Stakeholders’ Day” at the Finlandia Hall in Helsinki in October 2008, which gathered 237 participants, representing international organisations, associations, and companies. 85% of participants came from EU countries, and 15 % from outside the European Union. The April and October events were web-streamed and several hundred people followed them online from around the world.

The Agency also provided a major contribution to the Helsinki International Conference on Chemical Safety held in May 2008. This conference mainly targeted third country chemical industries, and was attended by about 600 participants from 39 countries worldwide.

In 2008, the Agency took its first steps in the area of communication on the risks of chemicals, as did Member States’ Competent Authorities. To provide a platform to exchange experience and best practice with a view to coordinate efforts, ECHA’s Executive Director convened a new network - the Risk Communication Network (RCN) - which held its first meeting in Helsinki in September 2008.

To support the implementation of REACH in the Member States, the Agency organised three training seminars for Member State trainers (in March, May, and October, respectively), reaching out to a total of 151 participants. The main themes of the seminars where REACH IT and IUCLID. In addition, ECHA organised a training seminar on REACH-IT for REHCORN members in April.

Induction training was organised for new staff and a comprehensive general training catalogue was also provided.

Communication statistics:

- Replies to information requests, incl. Rapid Response Service: 3626
- Press inquiries processed: 1401
- News alerts and Press releases published: 59
- Press memos: 3
- REACH case stories: 7
- Brochures and other information leaflets: 17
- Subscriptions to news alerts and press releases: 4713
- Press interviews given: 50
- Speeches delivered: 116 (97 in the EU, 19 outside)
- Visits to ECHA (mainly after 1 September): 21 (14 from within the EU, 7 from outside the EU)
- Website (4 June – 31 December): 1 561 012 hits by 619 227 visitors, 6 943 738 pages viewed.

In collaboration with the EU publications office, OPOCE, ECHA also took steps to develop the Agency's visual identity. Components of this visual identity (e.g. logos, colours, layouts) were used for ECHA's publications, exhibition roll-ups and promotional material.

Internal communication

ECHA's focus during 2008 was to establish and ensure a sufficient information flow within the rapidly growing Agency. The Intranet, supported by e-mails to all staff, regular staff assemblies after Management Board meetings, and an intensification of the link between the Directors' coordination meetings convening senior management, and Unit meetings chaired by middle management, served as the principle channels of communication.

5.7 Relations with EU institutions and international cooperation

5.7.1 Relations with other EU institutions and EU bodies

The Agency intensified its links with the European Commission and took measures, where appropriate, to provide efficient scientific and technical support to the Commission in the execution of its tasks under REACH. In particular, the services of the Commission were supported in their work with:

- The REACH Competent Authority (CA) Meeting
- The REACH Comitology Committee
- REACH stakeholder information activities.

ECHA further consolidated its cooperation with the European Parliament in 2008. For example, the Executive Director presented the Agency's work to the Committee for Environment, Public Health and Food Safety and the Committee's contact person for ECHA, MEP Satu Hassi, visited ECHA and regularly received information about important developments, in particular with regards to the activities of the Management Board.

Concerning the cooperation of ECHA Committees and the other relevant scientific Community bodies, first steps were taken by the Secretariat on the development of cooperation procedures referred to in Articles 95 and 110 of REACH. As had already been the case in 2007, ECHA participated in a Commission-led annual meeting of the Chairs and Secretariats of the Commission and Agency Scientific Committees/Panels involved in Risk Assessment in 2008. This initiative provides a platform for the exchange of best practice. ECHA contributed to a shared inter-Agency/Commission paper on practical

arrangements for sharing scientific data between scientific committees and panels, which is to be tested in 2009. ECHA also agreed to participate in a project to compile an inventory of the practices of Commission and Agency panels and committees.

First contacts were established with EFSA with regard to sharing best practice and procedures, which may lead to an Inter-Agency Memorandum of Understanding identifying specific topics of cooperation. ECHA also started to work with EFSA on the specific aim of establishing effective cooperation with Member States and the Commission to optimise procedures for achieving harmonised classification and labelling of pesticide-active substances of plant protection products.

5.7.2 International Activities

The European Commission requested the ECHA Secretariat to provide technical and scientific support in steps to improve cooperation between the Community, its Member States, international organisations and third countries on scientific and technical issues related to the safety of substances. The details of this support are reflected in an annual work plan for international activities. ECHA's respective work plan for 2009 was endorsed by the Management Board in December 2008 and was subsequently published on ECHA's website.

In 2008, the main focus of ECHA's international work was related to OECD activities. In particular, ECHA participated actively and contributed financially to two major OECD tasks, namely the further development of the Global Portal to Information on Chemical Substances (eChemPortal) and of the (Q)SAR Application Toolbox.

A project was launched in November to support the development of the Second Phase of eChemPortal, which aim is to improve the availability of hazard data on chemicals coming from different sources around the globe.

In November, ECHA also began work on the (Q)SAR Application Toolbox project, the aim of which is to develop a software application intended to be used for the identification of categories of discrete organic chemicals, and the filling of data gaps for toxicological, ecotoxicological and physico-chemical endpoints. The Toolbox shall facilitate the identification of similar chemicals to form categories and facilitate the application of the (Q)SAR methodology in order to provide a common framework for the chemical industry, ECHA and other stakeholders.

Concerning other OECD activities, ECHA supported the Commission in the following groups:

- New Chemicals Task Force
- Globally Harmonised System for C&L
- Task Force on Exposure Assessment
- Test Guidelines Programme
- Nanomaterials.

With respect to other multilateral activities, ECHA, again at the request of the Commission, supported work on the Stockholm Convention Persistent Organic Pollutants Review Committee (POP RC), by making delegating a technical expert to the 4th POP RC meeting.

In the course of 2008, several other third countries approached ECHA, seeking possibilities to participate in the work of its Committees and of the Forum. Formal requests for such participation were received from Turkey and Switzerland. The Management Board endorsed a general policy towards third countries in December.

In 2008 ECHA participated in over 30 meetings, workshops and conferences organised in third countries (i.e. China, the Russian Federation, USA), providing information on the implementation of REACH and the role and tasks of ECHA. ECHA also received approximately twenty visits from third country government and industry representatives, as well as from other organisations and from academia.

6 MANAGEMENT, ORGANISATION AND RESOURCES

Main results

- Management Board steered ECHA successfully through first year of independence
- New senior management recruited to replace seconded Commission officials
- Internal audit capability established and first review of the Agency by IAS
- Integrated Quality & Internal Control strategy established and implementation begun
- Security rules and procedures established and implemented
- Recruitment targets met
- REACH-IT operations successfully supported

6.1 Management and Organisation

6.1.1 Management Board

The Management Board held five meetings in 2008 and helped to steer ECHA and its management through its first year of financial independence. 2008 was 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 finalised the arrangements for making the Agency's Committees operational, and took several decisions in order to overcome the difficulties encountered in the establishment of the Board of Appeal. Furthermore, a series of important rules and procedures for the functioning of the Agency were put in place. The Management Board was regularly informed and also provided advice to the Executive Director on the challenges encountered by ECHA during the first seven months of its operations.

In particular, the following decisions were taken:

- Adoption of the General Report 2007;
- Approval of the budget 2009;
- Adoption of ECHA's new Financial Regulation;
- Adoption of the Multi-annual work programme 2009–2012 and of the work programme 2009;
- Adoption of the scale of fees for performing tasks for the Agency (Committee members, experts);
- Adoption of the Internal Control Standards;
- Adoption of the Agency's internal rules of procedures, including rules on good administration, transparency, access to documents and on the application of the Aarhus Convention;
- Approval of the Rules of Procedure of the Committees and the Forum.

In September 2008, the Management Board elected a new Chair (Dr. Thomas JAKL, AT) following the resignation of the former Chair.

Due to the lack of a clear provision in the EEA Joint Decision on the REACH Regulation as regards the nominations of Members of the Management Board, no representatives of EEA-EFTA countries could yet be nominated by their Member States. Therefore, the Board decided in September 2008 to admit observers from these countries pending formal appointments.

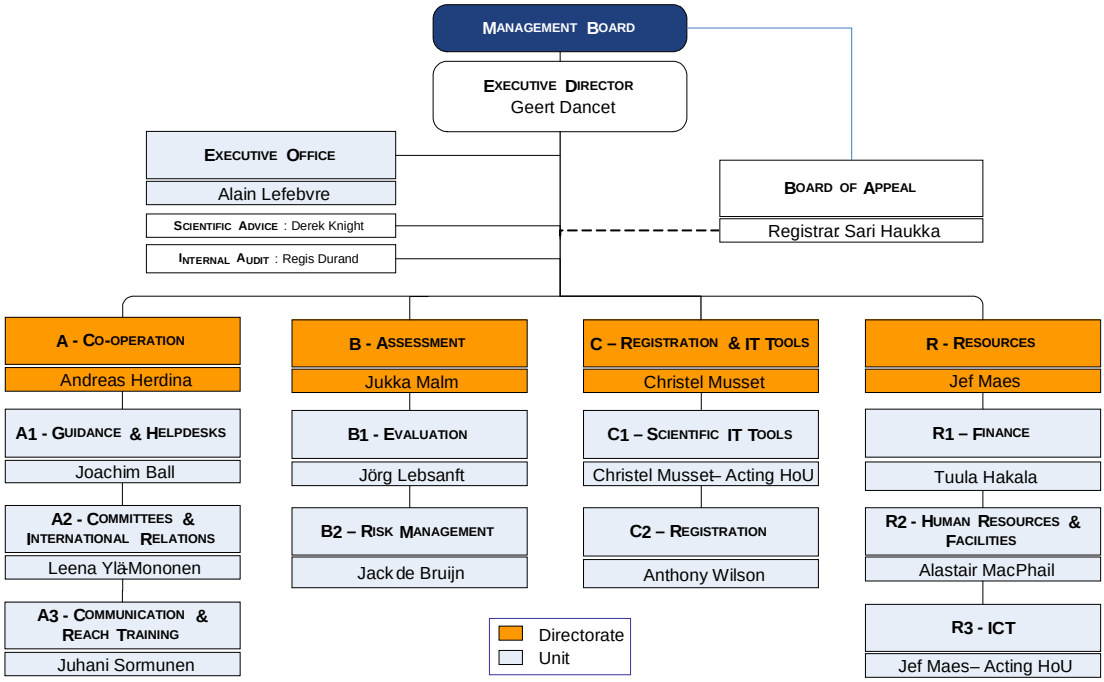
6.1.2 Organisation

The overall challenges for the management of the Agency in 2008 were:

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

As the Agency doubled its staff in 2008, it was also necessary to adapt its structure to this growth in size. Thus, in September 2008 a fourth Directorate was created by splitting the former Directorate for Operations into a Directorate for Assessment and a Directorate for Registrations and IT-tools.

Organisation Chart of ECHA December 2008



6.2 Internal Audit and Quality Control

6.2.1. Internal Audit

According to ECHA's Financial Regulation, the Internal Auditor of ECHA is the Internal Auditor of the European Commission (IAS). In addition, the Agency has an internal audit function. In line with the Quality and Internal Control Standards and considering the Agency's risk profile, the local "Internal Audit Capability" (IAC), as a permanent function, adds value by providing the Executive Director with additional assurance and consulting activities.

During 2008, ECHA's IAC had a broad consulting role during the start-up phase, in particular in initiating the set up of the Agency's quality system. In December 2008, the Management Board approved the IAC Charter, which specifies the role and status of this function in the Agency, as prescribed by international standards for the professional practice of internal auditing.

As part of his duties, the Internal Auditor drew up the first strategic audit plan for ECHA. It is the result of a risk assessment which the IAS conducted for the first time in July 2008. All results were discussed and agreed with ECHA management and the IAC. The audit plan, which was endorsed by the Management Board in December, is established for three years on a rolling basis.

The IAS will once a year perform an audit engagement in the Agency. In ECHA's first year, the IAS carried out a limited review of the implementation of Internal Control Standards as of July 2008. The review focused on the recruitment of staff, procurement procedures and financial circuits. The review report and the action plan in response to the IAS recommendations were presented to the Management Board in December 2008. The auditor concluded that the overall process, structure and management of the setting up of the Agency can be considered best practice.

6.2.2 Quality Control

In 2008 the Agency started developing its quality system, first of all by encouraging a quality culture from the early stage of operations. In line with ECHA's Quality Plan, operational and support processes were identified and a mapping of key and sub processes was started in the first months of the year. In the course of the year, these process lists were updated according to the Agency's organisational development. The combined process lists now represent a process inventory that will serve as a basis for the establishment of the Agency's process-oriented integrated quality management system.

Processes have been analysed in order to identify critical operations and process steps that need to be secured by written procedures. After prioritisation, "Standard Operating Procedures" (SOPs) were produced for processes bearing on the present implementation phase of the REACH legislation. Training in quality related topics such as Internal Control and drafting of SOPs was delivered to existing staff and to newcomers in order to raise awareness of the requirements and the competent documentation of ECHA's Quality System.

In the current start-up phase, it is still very likely that procedures need frequent adaptation and revision, in particular considering that not yet all functionalities of the Agency's IT systems in support of the REACH processes are available. Therefore, it was deemed preferable to postpone the publication of available SOPs until these systems are more stabilised and an overall policy on the publication of documented procedures has been established.

A comparison of the requirements set out by the Commission's ICS with those of the ISO 9001 quality management system standard revealed substantial similarities and the existence of complementing elements. An aggregate of both standards resulted in the combined quality and internal control standards (Q&ICS). Adopted by the Management Board in September 2008, these Q&ICS form the normative basis to be applied to ECHA's Integrated Quality Management System (IQMS). The adherence to the ISO 9001 standard requirements entails the need for adapting the documentation scheme to a hierarchical documentation structure, including, as the main structural elements, a Quality Manual, process descriptions, written procedures and work instructions. This structure, validated by ECHA's senior management in December 2008, will be applied henceforth. The newly recruited Quality Manager will steer the implementation of the revised quality system.

6.2.3 Security

In the field of security, rules and procedures were established in 2008 to achieve a higher level of physical and information security. A successful disaster recovery test of the ECHA ICT infrastructure was also performed in 2008.

A Security Working Group, bringing together all the services of the Agency, was set up early in 2008 and collected relevant good practice - learning from the experience of other EU Agencies. ECHA has worked rapidly to establish a higher level of physical and information security and to obtain the commitment from staff that is needed to sustain high standards in this area. ECHA has established four security perimeters as a first step to ensuring physical security, restricting access to the building and controlling access to floors occupied by ECHA staff.

2008 also saw the launch and implementation of a global ECHA information security project based on ISO 27001 standards, including a risk assessment exercise following the "health check" performed in 2007. The main steps of the project were the following:

1) Preparing an inventory of information assets at ECHA.
2) Assessing the risks threatening the security of those information assets.
3) Defining a risk treatment plan to implement appropriate controls using the ISO 27001 standard as a framework.
4) Commencing work on those controls given top priority.

Based on this analysis, ECHA has prepared a decision for determining the organisation of security-related issues, including the creation of a security committee, and nominated the Head of the Executive Office as security manager. It has launched the initial projects under the 27001 framework, such as a detailed inventory of security assets, which is the base for the information classification, the systematic security training of staff, and the reporting of security events. In addition, specific actions have been implemented, such as testing of the IT back-up systems.

6.3 Risk management

In early 2008, ECHA identified a list of key projects linked to the start-up activities presented in its annual work programme. For each project, the most relevant immediate risks were gathered in order to identify, coordinate and prioritise corresponding mitigating actions.

From the very beginning, guaranteeing a high level of information security had been identified as a major area of concern and transformed into an important project in the Agency. Therefore, a pilot exercise was conducted in the context of the still on-going "ISO

27001 project". It involved a more systematic and detailed analysis and assessment of business risks linked to information security, gathered through questionnaires addressed to management, and discussed in a well-attended workshop. Whereas the exercise aimed at prioritising further action in that particular field, it also served as a pilot to develop methodology and practice adapted to the Agency's specific control environment.

In the meantime, and as required to support its strategic audit plan, the Internal Auditor conducted a high level auditors' risk assessment of ECHA in July 2008, which was issued under the IAS' own responsibility. Nevertheless, the conclusions of the Internal Auditor constitute a document of reference broadly endorsed by the management. The risk assessment will be complemented by a specific exercise covering IT aspects. Furthermore, given the start-up nature of many of ECHA's activities, annual updates will be necessary.

The development of a formalised risk management system will start in 2009, with an Agency-wide risk assessment exercise. The next step - the design of a structured risk management system linked to follow-up actions, and fully owned by the management - is planned for 2010.

6.4 Budget, finance and procurement

On 1 January 2008, the Agency became financially independent from the Commission based on a detailed financial cut-off agreement signed by the Agency and the Directorate General (DG) for Enterprise and Industry - the 'parent DG' of the Agency.

Upon signature of the agreement, a number of contracts and commitments which had been procured and signed by the Commission on behalf of the Agency in the course of 2007, were transferred to the Agency. Support from the Commission to the financial activities of the Agency continued, with experienced procurement personnel being sent on missions to the Agency in order to help develop the most urgent procurement procedures. In addition, the Commission still carried out a large number of payments on commitments which had not been transferred to the Agency, as these related to 2007 activities only.

These challenges required the establishment of internal financial and accounting procedures consistent with the Agency's Financial Regulation.

The principal objectives and tasks in the budget area were the development and the timely and accurate management of ECHA's financial resources, including budget estimation, budget implementation and reporting. An annex has been added to the Work Programme that details the use of the operational budget by the different Directorates in 2008. By 1 January 2008, setting up of the ABAC financial/accounting system was completed.

With the entry into force of the Fee Regulation of the European Commission, the fee and invoicing system that was developed in-house to support the operations of REACH was completed and operational, in order to enable the collection of registration fees to the Agency.

Budget outturn account

		2008
REVENUE		
Commission subsidy 2008	+	60 933 607,33
Commission subsidy Dec 2007 (reimbursed in 2008)	+	1 922 588,56
Fee income	+	365 429,58
Other revenue	+	2 602,96
TOTAL REVENUE (a)		**63 224 228,43**
EXPENDITURE		
Title I: Staff		
Payments	-	20 208 389,51
Appropriations carried over	-	1 605 826,16
Title II: Administrative Expenses		
Payments	-	12 391 335,50
Appropriations carried over	-	4 652 805,82
Title III: Operating Expenditure		
Payments	-	7 379 854,79
Appropriations carried over	-	6 359 119,92
TOTAL EXPENDITURE (b)		**52 597 331,70**
OUTTURN FOR THE FINANCIAL YEAR (a-b)		**10 626 896,73**
Cancellation of unused payment appropriations carried over from previous year	+	0,00
Exchange differences for the year (gain +/loss -)	+/-	-1 362,94
BALANCE OF THE OUTTURN ACCOUNT FOR THE FINANCIAL YEAR		**10 625 533,79**
Reimbursed in year 2008 to the Commission	-	-1 922 588,56
BUDGET OUTTURN 2008		**8 702 945,23**

Work was also started to put in place a system for reimbursing the rapporteurs of the scientific committees that should set limits on 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 required close involvement of the Finance unit:

- Continuous monitoring of the spending related to the conference centre building project on 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;
- 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;
- Internal procurement guidelines were developed and published;
- The system of financial delegations and processes was revised in order to improve efficiency;
- An assets and inventory management system was implemented;
- Procedures for fee income were developed and implemented (REACH-IT invoicing module);
- Significant effort was made regarding the financial training of staff;

- o Procurement was organised efficiently (95 % of the planned procurement done, and procurements not foreseen achieved);
- o The Revision of the Financial Regulation was adopted;
- o Commitment rate of 77 % of the actual income received, payment rate of 55 %.

6.5 Human resources and infrastructure

6.5.1 Human resources

Recruiting high quality staff, on time, in a transparent, impartial, objective and equitable manner was one of the Agency top priorities in 2008. In addition to the 110 new posts on the 2008 establishment plan, the contracts of 38 seconded Commission officials, many of them occupying key management posts, ended in 2008. At the request of the Agency, the Commission agreed to extend six secondments. The Agency drew on reserve lists resulting from selections launched in 2007 and concluded 43 new temporary agent selections, recruiting a total of 139 temporary agents in 2008.

The doubling of staff numbers meant a significant increase in the HR administration workload, in particular payroll and financial management activities, probation period reporting, entry into service and induction training.

In addition to on-the-job training, new ECHA staff members received a training curriculum focusing on the knowledge and skills they need most urgently to run the operations of the Agency, and in particular their specific tasks in their respective directorate/unit. The Agency also provided training for 151 trainers sent by the Member State Competent Authorities to acquire the necessary knowledge and know-how to be able to deliver REACH-related training in their own institutions ("training for trainers"). For that purpose, two training sessions of three days were organised in spring 2008.

<u>Human resources' main achievements</u>

- o 139 recruitments, with a 95% execution of the establishment plan;
- o 54 selection procedures for Temporary Agents launched, 44 completed;
- o 12 selection procedures for Contract Agents from EPSO's reserve lists initiated, 10 completed;
- o 20 interim staff, engaged in support functions, in place at the end of 2008;
- o Renewal of the management (replacement of seconded commission officials), 15 posts published, 13 filled;
- o Traineeship programme launched and first selection of trainees completed (to start in March 2009);
- o Number of staff in payroll doubled, procedures for recoveries and regularisations put in place;
- o Financial management of missions taken over in summer, over 200 mission cost claims reimbursed;
- o Contracts for travel agency services and assistance in selection procedures concluded;
- o Drafting of implementing rules for staff (first package);
- o Election and establishment of the Staff Committee;
- o Development of training (priority on language training, security training and newcomers training);
- o Training delivery: 85 courses, 363 days of training, 12 days of training per person (including language training).

6.5.2 Infrastructure

The infrastructure tasks encompass the management of the Agency's premises in co-operation with the building owner, who continued to occupy the majority of the building until the end of August 2008. The departure of the owner triggered many infrastructure measures and the procurement of renovation works, goods and services that required careful planning and implementation. The finalisation of the lease agreement created long term stability regarding the location of the Agency and holds also a purchase option.

Long term security nevertheless needed to be ensured, and the Agency implemented a series of recommendations resulting from the security health check, in conformity with ISO 27001, realized in 2007.

The conference centre was completed in October 2008, and subsequently handed over to ECHA, which had closely monitored the progress and costs of the project throughout the year, with the assistance of a external expert

Main achievements on facilities:

- Facility Management team established;
- Take over of the building from the owner;
- Contracts for canteen services, security, reception and cleaning services concluded;
- Renovation contract with the owner concluded for front hall and 2nd floor renovation;
- Completion and bringing into operation of the Conference Centre;
- Adoption of security rules (access control, restricted areas, ID cards);
- Establishment of contacts with Finnish authorities based on seat agreement.

6.6 Informatics and Communications Technology

Main achievements on ICT:

- Migration of the European Commission applications;
- IT Support for launching REACH-IT and for pre-registration;
- Development of a back-office environment for database and operating systems applications;
- Implementation of IT Governance and project management framework;
- Deployment of a document management system and workflows for REACH processes;
- Development of interim WEB applications facilitating the communication of ECHA with the Public;
- Creation and good functioning of the REACH-IT operations team.

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 was installing new Agency software applications (in particular REACH-IT) and creating a dedicated team in charge of REACH-IT operations. Other applications were also purchased to cover specific needs, in particular the document management system, system integration for all the applications needed to run on the Agency's servers, security improvements, as well as the establishment and monitoring of secure networks with the Member States Competent Authorities.

7. ANNEXES

Annex 1: List of Members of the Management Board, the Committees and the Forum
Annex 2: First candidate list of substances of very high concern
Annex 3: Useful information and links
Annex 4: Helpdesk statistics 2008

Annex 1: List of Members of the Management Board, the Committees and the Forum

Members of the Management Board on 31 December 2008

Chair: Thomas JAKL
ECHA contact: Frank BÜCHLER

Members

o	Thomas JAKL	Austria	o	Armands PLATE	Latvia
o	Marc LEEMANS	Belgium	o	Aurelija BAJORAITIENE	Lithuania
o	Ekaterina Spasova GECHEVA-ZAHARIEVA	Bulgaria	o	Claude GEIMER	Luxembourg
o	Leandros NICOLAIDES	Cyprus	o	Francis E. FARRUGIA	Malta
o	Karel BLAHA	Czech Republic	o	Arnoldus VAN DER WIELEN	Netherlands
o	Per NYLYKKE	Denmark	o	Katarzyna KITAJEWSKA	Poland
o	Maria ALAJÕE	Estonia	o	Fernanda SANTIAGO	Portugal
o	Pirkko KIVELÄ	Finland	o	Teodor OGNEAN	Romania
o	Odile GAUTHIER	France	o	Edita NOVAKOVA	Slovakia
o	Alexander NIES	Germany	o	Marta CIRAJ	Slovenia
o	Maria-Miranda XEPAPADAKI-TOMARA	Greece	o	Ana FRESNO RUIZ	Spain
o	Zoltan ADAMIS	Hungary	o	Ethel FORSBERG	Sweden
o	Martin LYNCH	Ireland	o	John ROBERTS	United Kingdom
o	Antonello LAPALORCIA	Italia			

Independent persons appointed by the European Parliament

- Alexander De Roo
- Bernd Lange

Representatives appointed by the European Commission

o	Heinz ZOUREK	Directorate General Enterprise and Industry	o	Alain PERROY	European Chemical Industry Council (CEFIC)
o	Grant LAWRENCE	Directorate General Environment	o	Tony MUSU	European Trade Union Confederation (ETUC)
o	Elke ANKLAM	Directorate General Joint Research Centre (JRC)	o	Martin FÜHR	University Darmstadt

Observers from EEA/EFTA countries

o	Kristin Rannveig SNORRADOTTIR	Iceland
o	Anne Beate TANGEN	Norway

Members of the RAC – Committee for Risk Assessment on 31 December 2008

Chair: Sharon MUNN
ECHA contact: Sharon MUNN

Members	Nominating State		Nominating State
o Annemarie LOSERT	Austria	o Roberto MEZZANOTTE	Italy
o Erich A. POSPISCHIL	Austria	o Margita TOMSONE	Latvia
o Daphné HOYAUX	Belgium	o Normunds KADIKIS	Latvia
o Karen VAN MALDEREN	Belgium	o Lina DUNAUSKIENE (LUKINSKIENE)	Lithuania
o Zhivka HALKOVA	Bulgaria	o Hans-Christian STOLZENBERG	Luxembourg
o Maria ORPHANOU	Cyprus	o Marianne VAN DER HAGEN	Norway
o Frank JENSEN	Denmark	o Boguslaw BARANSKI	Poland
o Poul Bo LARSEN	Denmark	o CÉU NUNES	Portugal
o Helen SULG	Estonia	o Maria Teresa BORGES	Portugal
o Paul KREUZER	Finland	o Mariana-Elena ZGLOBIU	Romania
o Riitta LEINONEN	Finland	o Helena POLAKOVICOVA	Slovakia
o Annick PICHARD	France	o Agnes SCHULTE	Slovenia
o Olivier LE CURIEUX-BELFOND	France	o Eugenio VILANOVA	Spain
o Helmut A. GREIM	Germany	o Jose V. TARAZONA	Spain
o Norbert RUPPRICH	Germany	o Alicja ANDERSSON	Sweden
o Chrysanthi NAKOPOULOU	Greece	o Bert-Ove LUND	Sweden
o Maria MELANITOU	Greece	o Marja PRONK	The Netherlands
o Katalin GRUIZ	Hungary	o Andrew SMITH	United Kingdom
o Yvonne MULLOOLY	Ireland	o Stephen DUNGEY	United Kingdom
o Paola DI PROSPERO	Italy		

Members of the MSC – Member State Committee on 31 December 2008

Chair: Anna-Liisa SUNDQUIST
ECHA contact: Anna-Liisa SUNDQUIST

Members

o	Helmut STESSEL	Austria	o	Arnis LUDBORZS	Latvia
o	Jeanine FERREIRA MARQUES	Belgium	o	Lina DUNAUSKIENE	Lithuania
o	Parvoleta Angelova LULEVA	Bulgaria	o	Joëlle WELFRING	Luxemburg
o	Tasoula KYPRIANIDOU-LEODIDOU	Cyprus	o	Tristan CAMILLERI	Malta
o	Erik GEUSS	Czech Republic	o	René KORENROMP	Netherland
o	Henrik TYLE	Denmark	o	Linda Reierson REIERSON	Norway
o	Enda VESKIMÄE	Estonia	o	Jerzy MAJKA	Poland
o	Katariina RAUTALAHTI	Finland	o	Maria do Carmo Ramalho Figueira PALMA	Portugal
o	Emmanuel MOREAU	France	o	Mariana MICHALCEA UDREA	Romania
o	Elmar BÖHLEN	Germany	o	Peter RUSNAK	Slovakia
o	Ioanna ANGELOPOULOU	Greece	o	Simona FAJFAR	Slovenia
o	Szilvia DEIM	Hungary	o	Esther MARTíN	Spain
o	Gunnlaug EINARSDOTTIR	Iceland	o	Sten FLODSTRÖM	Sweden
o	Majella COSGRAVE	Ireland	o	Steve FAIRHURST	United Kingdom
o	Pietro PISTOLESE	Italy			

Members of the SEAC – Committee for Socio - economic analysis on 31 December 2008

Chair: Leena YLÄ-MONONEN (substitute until chair is appointed)
ECHA contact: Adriana LIPKOVA

Members	Nominating State		Nominating State
o Simone FANKHAUSER	Austria	o Kristof KOZAK	Hungary
o Stephan SCHWARZER	Austria	o Endre SCHUCHTÁR	Hungary
o Catheline DANTINNE	Belgium	o Sharon McGUINNESS	Ireland
o Jean-Pierre FEYAERTS	Belgium	o Franco DE GIGLIO	Italy
o Aristodemos ECONOMIDES	Cypros	o Luca Maria RECCHIA	Italy
o Rut BÍZKOVÁ	Czech Republic	o Kristina BROKAITE	Lithuania
o Franz-Georg SIMON	Germany	o Cees LUTTIKHUIZEN	The Netherlands
o Karen THIELE	Germany	o Espen LANGTVET	Norway
o Lars FOCK	Denmark	o Izabela RYDLEWSKA - LISZKOWSKA	Poland
o Aive TELLING	Estonia	o João LOURENÇO	Portugal
o Maria THEOHARI	Greece	o Ion COSTEA	Romania
o Dimosthenis VOIVONTAS	Greece	o Mats FORKMAN	Sweden
o Maj-Britt LARKA ABELLAN	Spain	o Lars GUSTAFSSON	Sweden
o Heikki SALONEN	Finland	o Janez FURLAN	Slovenia
o Henri BASTOS	France	o Martin HAJAŠ	Slovakia
o Jean-Marc BRIGNON	France	o Stavros GEORGIOU	United Kingdom

List of Members for Forum for Exchange of Information on Enforcement on 31 December 2008

Chair: Ulrike KOWALSKI
Vice chair: Joop BLENKERS and Nikolay STANIMIROV SAVOV
ECHA contact: Maciej Baranski

Members

o	Gernot WURM	Austria	o	Parsla PALLO	Latvia
o	Paul CUYPERS	Belgium	o	Manfred FRICK	Liechtenstein
o	Nikolay Stanimirov SAVOV	Bulgaria	o	Viktoras SESKAUSKAS	Lithuania
o	Tasoula KYPRIANIDOU-LEODIDOU	Cyprus	o	Gaston SCHMIT	Luxemburg
o	Eva RYCHLIKOVA	Czech Republic	o	Ingrid BUSUTTIL	Malta
o	Birte Nielsen BORGLUM	Denmark	o	Maren WIKHEIM	Norway
o	Natali PROMET	Estonia	o	Edyta MIEGOC	Poland
o	Annette EKMAN	Finland	o	Álvaro António BARROQUEIRO	Portugal
o	Stéphanie VIERS	France	o	Mihaiela Emilia ALBULESCU	Romania
o	Ulrike KOWALSKI	Germany	o	Dušan KOLESAR	Slovakia
o	Ioanna ANGELOPOULOU	Greece	o	Mojca JERAJ PEZDIR	Slovenia
o	Jenö MAJOR	Hungary	o	Rosario ALONSO FERNÁNDEZ	Spain
o	Sigridur KRISTJANSDOTTIR	Iceland	o	Karin THORAN	Sweden
o	Tom O' SULLIVAN	Ireland	o	Joop BLENKERS	The Netherlands
o	Mariano ALESSI	Italy	o	Richard BISHOP	United Kingdom

Annex 2: First candidate list of substances of very high concern for eventual inclusion in the authorisation list

Substance name	EC (and/or CAS number)	Basis for Identification as a SVHC
Triethyl arsenate	427-700-2	Carcinogenic (article 57a)
Anthracene	204-371-1	PBT (article 57d)
4,4'- Diaminodiphenylmethane (MDA)	202-974-4	Carcinogenic (article 57a)
Dibutyl phthalate (DBP)	201-557-4	Toxic for reproduction (article 57c)
Cobalt dichloride	231-589-4	Carcinogenic (article 57a)
Diarsenic pentaoxide	215-116-9	Carcinogenic (article 57a)
Diarsenic trioxide	215-481-4	Carcinogenic (article 57a)
Sodium dichromate	234-190-3 (7789-12-0 and 10588-01-9)	Carcinogenic, mutagenic and toxic to reproduction (articles 57a, 57b and 57c)
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	201-329-4	vPvB (article 57e)
Bis (2-ethylhexyl)phthalate (DEHP)	204-211-0	Toxic to reproduction (article 57c)
Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified: α- hexabromocyclododecane β- hexabromocyclododecane γ-hexabromocyclododecane	247-148-4 and 221-695-9 (134237-51-6) (134237-50-7) (134237-52-8)	PBT (article 57d)
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	287-476-5	PBT and vPvB (article 57d)
Bis(tributyltin)oxide (TBTO)	200-268-0	PBT (article 57d)
Lead hydrogen arsenate	232-064-2	Carcinogenic and Toxic to reproduction (articles 57a and c)
Benzyl butyl phthalate (BBP)	201-622-7	Toxic to reproduction (article 57c)

Annex 3: Useful information and links

ECHA web site: http://echa.europa.eu

ECHA CHEM: http://echa.europa.eu/chem_data_en.asp

List of pre-registered substances
Candidate List
Substances of interest for downstream users
Registry of Intentions

Consultations: http://echa.europa.eu/consultations_en.asp

SVHC proposed for the candidate list
Draft recommendations for priority substances for inclusion in Annex XIV

REACH-IT portal: http://echa.europa.eu/reachit/portal_en.asp

Dossiers submissions
Late pre-registration & pre-SIEF
Joint submission
Registration numbers for NONS
REACH-IT Industry User Manuals

IUCLID 5 website: http://iuclid.eu/

Software application for preparing REACH compliant dossiers

REACH Guidance: http://guidance.echa.europa.eu/

Annex 4: Helpdesk statistics 2008

ECHA Helpdesk Statistics 2008

Number of incidents received and resolved during the year 2008:

Incidents received:

Month	ECHA Info Support	ECHA Web Support	IUCLID 5 Support	REACH Advice	REACH-IT Support	Submission Support	Sum:
2008.01			195	163			358
2008.02			249	196			445
2008.03			228	174	1		403
2008.04			317	321			638
2008.05			289	380	33		702
2008.06			262	405	259	58	984
2008.07			241	510	280	57	1118
2008.08			181	291	246	33	751
2008.09			192	296	385	40	913
2008.10			245	422	654	50	1371
2008.11	5		302	1433	2055	45	3840
2008.12	62	2	60	201	441	36	802
Sum:	67	2	2761	4822	4354	319	12325

Incidents resolved:

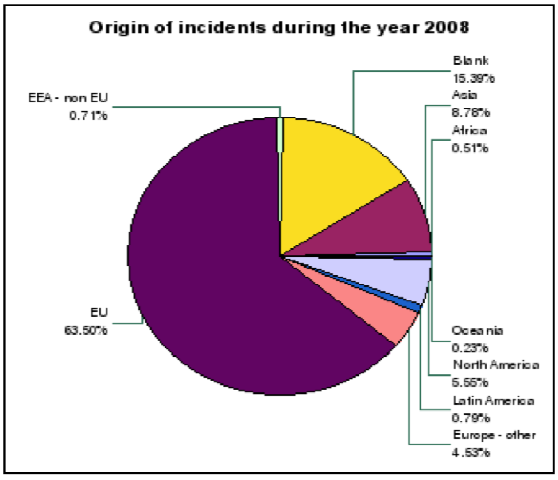
Month	ECHA Info Support	ECHA Web Support	IUCLID 5 Support	REACH Advice	REACH-IT Support	Submission Support	Sum:
2008.01			158	109			267
2008.02			271	172			443
2008.03			221	166			387
2008.04			257	261	1		519
2008.05			281	315	13		609
2008.06			346	396	216	42	1000
2008.07			203	456	288	54	999
2008.08			187	425	186	28	826
2008.09			204	244	391	57	896
2008.10			232	438	575	42	1287
2008.11	5		366	1595	2202	43	4211
2008.12	53	2	64	204	436	36	795
Sum:	58	2	2790	4781	4306	302	12239

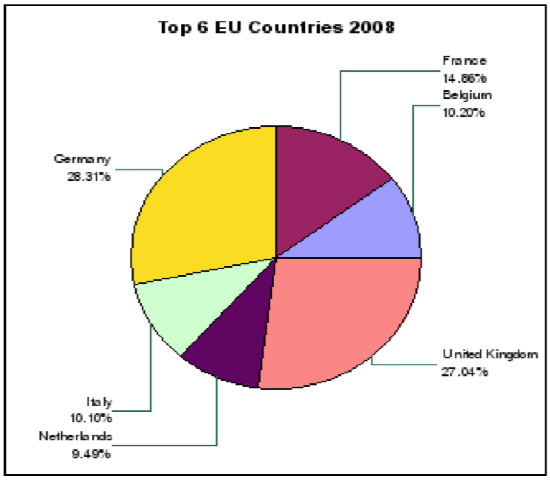
Average resolution time for resolved incidents in working days:

Month	IUCLID 5 Support		REACH Advice		REACH-IT Support		Submission Support	
	Incident Count	Average working days	Incident Count	Average working days	Incident Count	Average working days	Incident Count	Average working days
2008.01	158	5.9	109	8.9				
2008.02	271	6.1	172	11.7				
2008.03	221	5.5	166	13.1				
2008.04	257	5.5	261	11.9	1	10.1		
2008.05	281	9.6	315	11.2	13	1.4		
2008.06	346	8.2	396	11.7	216	5.0	42	4.1
2008.07	203	5.7	456	14.2	286	5.0	54	5.9
2008.08	187	9.8	425	12.9	186	5.2	28	8.3
2008.09	204	8.0	244	16.1	391	6.5	57	8.0
2008.10	232	8.4	438	16.0	575	6.0	42	4.9
2008.11	366	5.8	1,595	4.9	2,202	2.6	43	6.4
2008.12	64	5.4	204	8.9	436	2.4	36	5.0

Number of incidents resolved and their average resolution time in working days during the Rapid Response Service period (from 17 Nov to 1 Dec 2008):

#MULTIVALUE	Average working days	Sum:
3443	2.8	3443





It is not mandatory to indicate the origin of IUCLID 5 Support questions

Annex 5: Analysis and Assessment of the Annual Activity Report of the Authorising Officer for the Year 2008

Helsinki, 23 April 2009
Doc.: **MB/18/2009 final**

ANALYSIS AND ASSESSMENT OF THE ANNUAL ACTIVITY REPORT OF THE AUTHORISING OFFICER FOR THE YEAR 2008

THE MANAGEMENT BOARD,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006,

Having regard to the Financial Regulation of the European Chemicals Agency (MB/53/2008) and in particular Article 40 thereof,

Having regard to the Work Programme of the European Chemicals Agency for the year 2008 adopted by the Management Board at its meeting of 17 October 2007,

Having regard to the Annual Activity Report of the Authorising Officer of the European Chemicals Agency for the year 2008 signed by the Executive Director on 8 April 2009,

1. Welcomes the results presented in the Annual Activity Report of the Authorising Officer and the strong commitment and contribution of the European Chemicals Agency to beginning efficiently the operations of the REACH Regulation (EC) 1907/2006 in 2008.

2. Congratulates the management and staff of the Agency for the extraordinary hard work performed in 2008 and, in particular, for its achievements in:

   (a) Ensuring that all companies could electronically submit their pre-registrations by the legal deadline, and publishing the list of pre-registered substances on 19 December 2008;

   (b) Establishing and publishing, on 28 October 2008, the first candidate list of substances of very high concern for eventual inclusion into Annex XIV of the REACH Regulation (EC) 1907/2006;

   (c) Ensuring that companies could, from 1 June 2008, submit registration dossiers for chemical substances, enquiries and notifications for product and process orientated research and development (PPORD), and handling all incoming submissions within the legal deadlines;

(d) Resolving the high number of enquiries submitted to the Agency's helpdesk and providing a rapid response service at the end of the pre-registration phase in order to ensure that all pre-registrations could be completed;

(e) Preparing the work of the Agency's Committees and the Forum in anticipation of their future tasks, and providing for capacity-building in other relevant areas, such as dossier evaluation and socio-economic analysis.

3. Notes the flexibility that the Agency has shown in reorienting its priorities and reallocating staff when faced with difficulties or high workloads to meet deadlines, whilst stressing at the same time the importance of some of the postponed activities, in particular the work on the public dissemination of non-confidential information via the Agency's website in accordance with Article 119 of Regulation (EC) No 1907/2006.

4. Congratulates the management and staff of the Agency on its capacity to face the unforeseen number of pre- registrations in 2008 (over 2.7 million); and acknowledges the efforts made and the patience shown by industry to cooperate with the Agency in order to finalise the pre-registration phase successfully. Notes that the efficient and frequent communication from the Agency's Secretariat towards stakeholders and towards the Management Board facilitated this cooperation.

5. Welcomes the fact that the Agency virtually met its recruitment target in 2008, including the replacement of the managers seconded from the Commission for the initial start-up phase, and notes that the timely recruitment of qualified staff and their integration remains an ongoing challenge for the coming years.

6. Welcomes the first contributions of the Agency to international cooperation regarding the management of chemical substances, particularly the work done with the OECD at the request of the European Commission.

7. Notes the level of budget execution, which was achieved, inter alia, through the transfer between budget titles approved by the Board for the financing of the conference centre.

8. Welcomes the results of the limited audit performed by the Commission's Internal Audit Service, in particular the reference made to the establishment of the Agency as "best practice", which stands as an important achievement.

9. Commends the important efforts of the European Commission in continuing to support the Agency in its first year of financial independence, in particular through the ongoing support by seconded officials and the smooth hand-over of relevant documentation from the previous legislation at the Joint Research Centre to the Agency.

10. Welcomes the risk analysis contained in the report and invites the Agency to use the analysis of the problems that occurred in 2008 to face future challenges, particularly in terms of activity-planning, by adapting its IT systems to deal with a possibly higher than expected number of registration dossiers, thus helping to avoid delays in implementation.

11. Acknowledges the progress made by the Agency in 2008 in terms of implementing comprehensive measures for IT security and physical security - about which the Management Board has been regularly informed – and notes that challenges remain justifying continuous, if not increased, efforts to cope with in the years to come.

12. Emphasises the importance of the Agency's cooperation and communication with the Member States and commends, in particular, the training and coordination activities undertaken in the context of the network of national helpdesks, the Committees, and the REACH Competent Authorities.

13. Stresses the importance of effective enforcement and welcomes the support given by the Secretariat of the Agency to ensure the successful start of the Forum's activities. Congratulates the Agency for ensuring that the three scientific Committees were established in a timely manner, and that their rules of procedure were submitted, together with those of the Forum, in due time for adoption by the Management Board.

14. Welcomes the Agency's transparency policy, which the Board has validated and which permits the involvement of stakeholder observers in the Committees and the Forum. Congratulates the Agency for the organisation of the first Stakeholder Day and for the many channels of communication that it has established with these stakeholders.

Helsinki, 23 April 2009

signed
For the Management Board
Thomas JAKL