Helsinki, 27 April 2010

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GENERAL REPORT OF THE EUROPEAN CHEMICALS AGENCY FOR THE YEAR 2009

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List of Acronyms

AAR	Annual Activity Report
ACSHW	Advisory Committee on Safety and Health at Work
BoA	Board of Appeal
C & L	Classification and Labelling
CASPER	IT Characterisation Application for Selection, Prioritisation, Evaluation and Reporting
CHESAR	Chemical Safety Assessment and Reporting tool
CLP	Classification, Labelling and Packaging
EC	European Commission
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
ENVI	EP's Committee for Environment, Food Safety and Public Health
EP	European Parliament
EU	European Union
EU-OSHA	European Agency for Safety and Health at Work
FAQ	Frequently Asked Questions
HR	Human Resources
IAS	Internal Audit Service of the European Commission
IT	Information Technologies
IUCLID	International Uniform Chemical Information Database
MB	Management Board
MEP	Member of European Parliament
MSC	Member State Committee
MSCA	Member State Competent Authority
OECD	Organisation for Economic Cooperation and Development
PPORD	Product and Process Oriented Research and Development
(Q)SAR	(Quantitative) Structure-Activity Relationships
RAC	Risk Assessment Committee
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
SCOEL	Scientific Committee for Occupational Exposure Limits
SEAC	Socio-Economic Analysis Committee
SIEF	Data Sharing & Substance Information Exchange Forum
SVHC	Substance of Very High Concern
WG	Working Group
WP	Work Programme

Fact sheet 2009

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 and CLP Regulations and to ensure consistency at Community level
Statutory Staff (31.12.2009):	320
Budget:	71.6 million EUR

AGENCY BODIES

Management Board:	5 meetings
Member State Committee:	4 meetings
Risk Assessment Committee:	4 meetings
Socioeconomic Analysis Committee:	3 meetings
Forum:	3 meetings
Board of Appeal:	1 appeal

KEY FIGURES

“Late” pre-registrations:	37 960
Inquiries:	1023
Registrations:	490
PPORD notifications:	211
Proposals for harmonised C&L:	33

Registered substances published on the dissemination website: 129

Dossier evaluations:	15
Proposals for SVHC from MS:	15 (of which 14 included in candidate list in January 2010)
Helpdesk:	6558 questions answered / 4 updates of FAQs published

1 recommendation for inclusion of substances in Annex XIV including a MSC opinion

1 MSC agreement on a draft testing proposal decision

14 MSC agreements on identification of substances of very high concern

1 RAC opinion on one CLH proposal and agreed in principle on 3 others

57 documents translated into 21 official EU languages (17 000 pages)
60 press releases and news alerts
6 Newsletters

Foreword by the Executive Director

Welcome to the European Chemical Agency's General Report for 2009. I look back at 2009 with great satisfaction. It was an eventful and challenging year for everyone involved in REACH - industry, Member States, the European Commission and ECHA. Last year provided a clear demonstration of the shared endeavour that is REACH, with each of us playing our part in starting to make the most ambitious piece of chemicals legislation in the world a reality.

If 2008 was the year of pre-registration, then 2009 was the year of preparations - a race against time to prepare for registration and notification. REACH is not a forgiving piece of legislation – it sets strict deadlines that have to be met by industry and by ECHA and the clock is ticking. Similarly, the new Classification, Labelling and Packaging (CLP) regulation also sets an ambitious imminent target to be met.

In 2009, industry started the demanding business of setting up a SIEF (Substance Information Exchange Forum) with all companies that pre-registered the same chemical substance. The demands placed on industry by REACH are substantial and companies – particularly the Lead Registrants - are to be congratulated for their commitment and determination to comply.

ECHA has responded to the industry's request to assist them in getting SIEFs started and working well. On the second Stakeholder Day in May 2009, we launched the campaign "the clock is ticking – form your SIEF now". We had three aims – to try to remove barriers to effective working in SIEFs; to raise awareness of the urgency for action; and to support Lead Registrants. Chief among our activities to support companies in 2009 has been:

- Tidying up the list of pre-registered substances to make the SIEF groupings more useful and accurate.
- Making the work easier – for example streamlining the submission process; writing manuals and translating more materials; improving REACH-IT with new functionality, improved performance and stability; and launching a Technical Completeness Check IT tool.
- Assisting companies directly – for example by organising workshops and events; contacting registrants directly to assist them with blocked dossiers; and running expert online webinars.
- Planning for a tsunami of dossiers – doing scenario-based planning to reduce the uncertainty over the numbers and timing of dossier submission in 2010 to enable us to better prepare.

In analogy, the Agency has been preparing the guidance, tools and processes for the CLP notifications due by 3 January 2011. On the third Stakeholder Day in December it launched the first stage of its awareness raising on the CLP notification duties with a special websection in 22 EU languages. The restriction title also entered into operation on 1 June and preparations for receiving and processing restriction proposals were completed.

Significant progress has been made on evaluation and authorisation fronts. ECHA has issued a well-appreciated special report on evaluation with recommendations for registrants, has sent a recommendation to the Commission to put seven substances of very high concern (SVHC) on the authorisation list and has finalised all the work to add 15 more SVHCs on the Candidate List.

The world is looking to Europe to see how industry and authorities cope with the new legislations on assessing and labelling chemicals. We are all having a hard time to implement these challenging regulations and I am personally grateful to companies and their associations at EU level for their constructive approach to our collective work. Trusting on continued commitment from all our partners, REACH registrations and CLP notifications will be a success and set a benchmark to the rest of the world, worth following.

Presentation of the European Chemicals Agency

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 (EU), set out in Regulation (EC) No 1907/2006 of the European Parliament and the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). At the beginning of 2009, REACH was complemented by the Regulation on Classification, Labelling and Packaging of substances and mixtures (CLP Regulation (EC) No 1272/2008 of the European Parliament and the Council). These legislative acts are applicable in all EU Member States without the need for transposition into national law.

The purpose of the REACH system is to ensure a high level of protection of human health and the environment; to promote alternative methods to animal testing to assess the hazards of chemicals; to facilitate the free circulation of substances within the single market; and to enhance competitiveness and innovation. In practical terms, the new regime is expected to close a knowledge gap concerning chemicals placed on the European market before 1981; 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 of 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.

The purpose of the CLP Regulation is to ensure a high level of protection of human health and the environment, as well as the free movement of substances, mixtures and articles, by harmonising the criteria for classification of substances and mixtures, and the rules on labelling and packaging. The hazardous properties of chemicals include physical hazards as well as hazards to human health and to the environment, including hazards to the ozone layer. Furthermore, the CLP Regulation constitutes an EU contribution to the global harmonisation of criteria for classification and labelling, the latter having been developed within the United Nations (UN GHS).

Both regulations should contribute to fulfilment of the Strategic Approach to International Chemical Management (SAICM) adopted on 6 February 2006 in Dubai.

ECHA's Mission

ECHA's mission is to manage all REACH and CLP tasks entrusted to it 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 will be recognised as 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 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.

Summary of the Main Achievements

Revision of the list of pre-registered substances

Following the publication of the list of pre-registered substances in December 2008, ECHA recognised that the quality of the list could be improved, in particular for the 40 000 substances not listed on EINECS which included some duplications and other errors. These errors created difficulties for companies attempting to form SIEFs with others who pre-registered the "same" substance. A revised list of around 143 000 substances, incorporating corrections and deletions, as well as improved accessibility, was published in March 2009.

Registration

The preparations for meeting the challenges of the 2010 registration deadline continued. As expected, the number of registrations submitted was still low and a significant part of the registration activity throughout the year was dedicated to streamlining the submission processes and enhancing REACH-IT accordingly. Work also progressed on improving the level of acceptance of dossiers submitted, as dossiers with a wrong format or missing administrative information can not be processed by the system (termed "business rules failure").

To support the registrants in preparing the dossiers, an IT tool ("Technical Completeness Check tool) was developed. The tool enables registrants to verify for themselves the completeness of their dossier before submitting it to ECHA, thus helping them to ensure that they obtain a registration number. The tool was released in December 2009 and should significantly improve the success rate of registration submissions in 2010.

While the low number of registrations had been expected, a greater than expected proportion of the registrations submitted were intermediates. Consequently, the fee income was also lower than expected for the number of registrations received.

SIEF campaign

ECHA provided support for lead registrants and for Substance Information Exchange Fora (SIEF) formation through "The clock is ticking – form your SIEF now" campaign launched in May. The campaign had three elements – trying to remove the barriers to SIEF working; raising awareness of the urgency for companies to make progress; and supporting Lead Registrants. Recognising the need to identify Lead Registrants in order that support could be provided, a webform was set up to enable them to inform ECHA of their nomination. By the end of the year, 2176 Lead Registrants had provided their details to ECHA.

Dissemination website

ECHA aims to establish itself as an authoritative source of information on chemical substances. To support this aim, the Dissemination Portal, which allows the public to have electronic access to information on registered chemicals, was launched on 18 December. Following a review and clearance by the registrants, information on the hazards and safe use of 129 substances was made available. Examination of confidentiality claims had not yet started but solid preparatory work involving stakeholders and the Management Board was under way.

Evaluation

ECHA established the evaluation processes 'compliance check' and 'examination of testing proposals' and took the first decision on a testing proposal after a unanimous agreement at Member State Committee level.

Authorisation

On 1 June 2009 ECHA sent, for the first time, a recommendation for inclusion of priority substances in Annex XIV to the Commission. Inclusion of seven out of the 15 substances from the 2008 Candidate List was recommended and suggestions for the application and sun set dates and for exemptions of uses were made. The recommendation was supported by a positive opinion of the Member State Committee.

In August 2009, ECHA received 15 new dossiers with proposals for identification of Substances of Very High Concern including one dossier prepared by ECHA on request of the Commission. After the public consultation, during which more than 300 different comments were received, the Member State Committee reached agreement in its December meeting on their SVHC status, leading to ECHA's decision to add them to the Candidate List in January 2010.

Harmonised Classification & Labelling

The CLP Regulation, which came into force in the beginning of 2009, identifies a number of tasks for ECHA related to classification and labelling of hazardous substances. Efficient working procedures for processing proposals for harmonised C&L were developed and implemented, and the RAC adopted their first opinion on one substance (Diantimony Trioxide).

REACH-IT

Considerable resources were allocated to the further development of REACH-IT during 2009 with two main priority areas: adding new functions essential for the upcoming deadlines of 2010, upgrading the existing system based on the experience gained over the pre-registration phase and recommendations of a benchmark study carried out at the end of 2008. Structural changes were made to improve the performance, stability, and quality of the application. The amount of work involved in specifying and testing the subsequent improvements in REACH-IT was considerable. All changes were documented in end-user manuals published on the ECHA web site.

Entry into force of the CLP Regulation led to considerable work to adjust IUCLID and REACH-IT to make sure that CLP notifications and the C&L inventory can be put into effect. Also the helpdesk network needed to comply with this regulation and ultimately it was decided to merge the national CLP and REACH helpdesks into a single network called HelpNet.

Translations

Translation remained a priority for the Agency, with several guidance documents relevant for SMEs translated in 2009. In late 2009, agreements were signed with ten Member States to participate in the process of validating the translations.

Restrictions

Title VIII of the REACH Regulation, regarding restrictions on the manufacturing, placing on the market and use of certain dangerous substances, preparations and articles, and Annex XVII listing the adopted restrictions entered into force on the 1st of June 2009. ECHA and its Committees are ready to handle the first restriction dossiers that are expected to arrive in spring 2010.

Recruitment and training of staff

Recruitment of qualified staff continued to be a major challenge for the Agency in 2009. The number of statutory staffing grew towards 320 at the end of 2009, which is an increase of 40% compared to the year before. In order to achieve this, the ECHA organised 38 selection procedures, from which 83 temporary and 17 contract agents were recruited in 2009.

The Agency dedicated substantial resources in 2009 to the training of staff, in particular in the field of evaluation, in order to build up and enhance in-house expertise not only in the scientific field but also in administrative and legal issues.

Budget consumption

Regarding budget execution, a high level of 95% in the commitment rate and a satisfactory 67% in the payment rate were achieved as a result of implementing the Agency's work programme 2009. The Agency succeeded in transferring the difference between commitments and payments to the following year so that the results of unfinished contracts could still be honoured in 2010. At the same time, the Agency had a considerable cash balance at the end of the year to bridge the liquidity needs of the first months of the year 2010, before having to call for the extraordinary reimbursable subsidy which the Agency was awarded by the budgetary authority for the year 2010.

1. Operational activities - Implementation of the REACH Processes

1.1 Registration, pre-registration and data-sharing

Priorities in 2009:

- Prepare the ground for the first registration deadline in 2010
- Establish and maintain a final list of substances that had been pre-registered before the deadline
- Facilitate the data sharing process
- Establish ECHA as an authoritative source of information on chemical substances.

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. At the same time, in order to minimise the number of animal tests and reduce costs to industry, REACH provides a number of possibilities to facilitate the sharing of data between registrants. The mechanisms established in REACH to meet this aim are the registration and pre-registration processes.

The publication of the list of pre-registered substances in December 2008 marked the end of the year of pre-registration. However, ECHA recognised that the quality of the list could be improved in particular for the 40 000 substances not listed on EINECS which included some duplications and other errors. These created difficulties for companies attempting to form SIEFs with others who pre-registered the "same" substance. A revised list, with improvements and deletions, as well as improved accessibility, was published in March 2009.

In addition, ECHA subsequently received almost 38 000 'late' pre-registrations from companies manufacturing or importing phase-in substances for the first time in quantities of one tonne or more per year, corresponding to 16 800 substances.

Following an exchange on the major issues faced by registrants in forming SIEFs and getting them functioning, support for lead registrants (i.e. registrants preparing the joint submission with the agreement of the other registrants for the same substance) and support for SIEF formation developed from late March and was organised between ECHA, major industry organisations and the European Commission. Recognising the need to identify the lead registrants, a web form was set up to enable them to inform ECHA of their nomination. By the end of the year, 2176 Lead Registrants had provided their details to ECHA. Further information on the associated awareness campaign is provided in Section 2.3 – Communication.

Manufacturers or importers of non-phase-in substances, or of phase-in substances that have not been pre-registered, must submit an inquiry to ECHA prior to registration to allow ECHA to facilitate data sharing. The main priority in this domain has been to streamline inquiry procedures, which were implemented manually in 2008. The aim was to maintain the level of scientific consistency while improving the throughput in order to help industry reduce time-to-market. By the end of 2009, more than 95% of inquiries were being processed in less than 15 working days. This was achieved despite the number of inquiries received being over 1000 against an anticipated several hundred.

As part of the process improvement, significant effort was made to help inquirers improve the quality of the information submitted. The number of inquiries considered complete increased from 37% in 2008 to 56% in 2009.

Potential registrants who have made an inquiry may request access to studies submitted more than 12 years before[1] from the Agency. The process of accepting and assessing these requests has continued during 2009, when 53 requests for access were made (via the helpdesk).

Finally, the REACH regulation foresees the Agency's involvement in case of disputes in sharing data within SIEFs or further to an inquiry. One request regarding a failure to share data was received at the end of 2009 and was finalised in January 2010. The refinement of these processes continued through the year. However, new priorities were set to support Lead Registrants and SIEF formation, so their completion was delayed to 2010.

Registration

As expected, the number of registrations and requests for exemption from registration for substances used in product and process oriented research and development (PPORD) notifications were relatively low in 2009. While the low number of registrations had been expected, a greater than expected proportion of the registrations submitted were intermediates.

In January 2009, the Agency began accepting electronic-only dossier submissions via the REACH-IT system. ECHA processed 756 registrations, the majority of them (66%) concerning non phase-in substances and updates of dossiers from the transitional measures under Article 24 of the REACH Regulation, for substances notified under Directive 67/548/EEC. Of those, 490 registrations were technically complete and could be given a registration number. Less than 2% of registrations were rejected, with the remaining dossiers carried over into 2010 due to unfinished technical completeness checks.

Table 1: registration dossiers by type of substances and process step

Phase-in	Dossier type description	Accepted for processing	Technically complete	Invoice paid + reg. no. given
1.Phase-in substances	Registration of intermediates	128	93	91
	Standard registrations	123	89	88
	Total	**251**	**182**	**179**
2.Non Phase-in substances	Registration of intermediates	266	187	187
	Standard registrations	239	126	124
	Total	**505**	**313**	**311**
	Overall total	**756**	**495**	**490**

ECHA also received 226 PPORD notifications and 4265 requests for registration numbers for substances notified under Directive 67/548/EEC, which are considered registered under REACH.

A significant part of the registration activity throughout the year was dedicated to streamlining the submission processes and enhancing REACH-IT accordingly. ECHA carried out a review of its submission processes in relation to invoicing, verification of business rules, completeness of dossiers, and the decision making process. Work also progressed on improving the level of acceptance of dossiers submitted, as dossiers with a wrong format or missing administrative information can not be processed by the system (termed "business rules failure").

[1] Under Directive 67/548/EEC- notification of new substances or NONS.

This work resulted in a more reliable and better performing REACH-IT system and in 66% of dossiers being accepted for processing compared with only 46% at the beginning of the year. The quality of registrations and PPORD notifications also improved, with the number considered technically complete increasing from 63% up to 80%.

To help registrants further in preparing their dossiers a new IT tool ("Technical Completeness Check tool) was developed. This tool enables registrants to verify for themselves the completeness of their dossier before submitting it to ECHA, thus helping them to ensure that they obtain a registration number. The tool was released in December 2009 and should significantly improve the success rate of registration submissions in 2010.

Dissemination – public access to electronic information

Continuing the work begun in 2007, ECHA invited a group of stakeholders to share their views about the principles and practicalities of dissemination at a Round Table discussion held in early July. On the basis of the feedback received, the "filter rules" that determine which parts of the registration dossiers are disseminated on ECHA's website, were finalised. Subsequently, a number of registration dossiers were prepared for dissemination and – after review by the registrants – ECHA launched the Dissemination Portal on 18 December enabling public access to electronic information on hazard and safe use information on 129 registered substances. The portal attracted almost 18 000 viewers between its launching day and the end of the year.

Performance Indicator	Result 2009
Percentage of registrations, PPORD notifications, and data sharing disputes processed within the legal timeframe.	100%
Percentage of inquiries processed within the established timeframe (20 working days).	95%
Number of appeals made by registrants and notifiers against decisions.	1*

***** The appeal was subsequently withdrawn following a rectification by ECHA.

1.2 Evaluation

Priorities for 2009:

- Building ECHA's evaluation capacities.
- Ensure efficient decision making with regard to testing proposals and compliance checks.

Quality assessment of the registered dossiers is carried out independently from the registration process, through dossier evaluation (compliance check, testing proposal examination) and substance evaluation processes. Dossier evaluation is the responsibility of ECHA whereas substance evaluation is carried out by Member States. Dossier evaluation is one of ECHA's most demanding tasks due to the volume of information in each dossier and the considerable scientific and technical competence required.

In 2009, the work in the field of evaluation focused on preparing for the peak workload from 2011 onwards, which will come about from the registration deadline for high volume chemicals of 30 November 2010. Consequently, the emphasis of the work was on building

capacities by developing evaluation strategies and expanding the competence base of the staff.

The Agency dedicated substantial resources in 2009 to the training of staff in order to build up and enhance in-house expertise not only in the scientific field but also in administrative and legal issues. The training consisted of different modules relevant for the REACH legal framework, hazard identification, exposure assessment, classification and labelling, and risk assessment. Both basic and advanced seminars were organised during the year and further training will also be provided in the coming years.

In line with ECHA's Work Programme for the year, only a small number of compliance checks were conducted. Out of the 490 completed registration dossiers, evaluation of 35 dossiers (27 compliance checks, 8 examinations of testing proposals) was initiated. For three dossiers a draft decision was prepared and sent to the registrants for comment. Fourteen compliance checks were concluded by the end of 2009: in seven cases a letter was sent to the registrant informing them about shortcomings identified in the dossier and related to the risk assessment and/or the recommended risk management measures; the registrants were asked to revise the dossier and to submit an updated version; in the other seven cases the compliance check was closed without further action.

As expected, the number of first testing proposals received by ECHA in 2009 was low i.e. eight, and five of those concerned non-phase-in substances. Six proposals for studies on vertebrate animals were submitted; the majority requested reproductive toxicity testing, with one proposal for an *in vivo* mutagenicity test and one for a repeated dose toxicity test. The Agency started examining seven testing proposals before the end of 2009. By the end of the year, ECHA took the first decision on a testing proposal after a unanimous agreement in the Member State Committee thus completing, for the first time, the testing proposal process successfully.

The previous chemical legislation was repealed when REACH entered into operation in June 2007 and the Agency identified about 270 dossiers for which transitional measures apply. Consequently, follow up work needed to be carried out by the Agency in collaboration with the Member States. Additionally, there were many chemicals for which the Member States did not conclude decision-making under the previous legislation. The Agency identified about 60 of such substances and invited the registrants to submit testing proposals. One testing proposal was subsequently received by the end of 2009.

Workshops and webinars were organised to feed-back key findings from the compliance checks to industry, and hence promote the quality of future registration dossiers. In addition, a workshop with Member States was held to develop a common understanding of key elements and challenges in the Evaluation process.

Performance Indicators	Result 2009
Percentage of compliance checks treated within the legal timeframe.	100 %
Percentage of testing proposals examined within the legal timeframe.	100 %
Percentage of the draft decisions accepted unanimously by the MSC.	100 %
Number of appeals lost.	0

1.3 Authorisation and restrictions

Priorities for 2009

- Ensure efficient decision making with regard to the first recommendation to the Commission of Substances of Very High Concern for inclusion in the authorisation list.
- Prepare for adopting the first Committee opinions on restrictions.

From Candidate to Authorisation List

ECHA's tasks relating to authorisation include preparing and updating the so called Candidate List, regularly preparing a recommendation to the Commission on substances from the Candidate List to be included in the so called Authorisation List – the list of substances requiring authorisation (Annex XIV) – and, in the future, handling the authorisation applications.

A key priority for the year was to prepare the recommendation, and on 1 June 2009 ECHA sent, for the first time, a recommendation for inclusion of priority substances in the Authorisation List to the Commission. Inclusion of seven out of the 15 substances from the Candidate List was recommended and suggestions for the application and sun set dates and for exemptions of uses were made. The recommendation was supported by a positive opinion of the Member State Committee and taking into account, where relevant, comments (365) from interested parties following the public consultation process that took place earlier in the year. ECHA also recommended the Commission make a further assessment of the need for exemptions of specific uses covered by existing restrictions. ECHA's recommendation and all background documentation are publicly available on the website.

Whilst waiting for the Commission decision for the first Authorisation List, ECHA initiated a range of preparatory activities for the development of support for the future applicants and of processes and working procedures for handling authorisation applications in order to be ready by mid 2010.

Upon request by the Commission, ECHA worked on the preparation of dossiers for identification of five coal tar derivatives as Substances of Very High Concern. However, only the dossier for one substance, *coal tar pitch high temperature*, could be finalised and successfully subjected to the SVHC identification process commencing in August 2009. For the other four coal tar derivatives not enough information on substance composition could yet be made available to allow for a science-based assessment of their potential SVHC properties. The decision on whether to develop and submit SVHC dossiers for these substances will be taken based on the information provided in the registration dossiers that are expected to arrive later in 2010. In addition, ECHA prepared analyses of the best risk management options for these substances to support possible future decisions on further action.

In August 2009, ECHA received 15 new dossiers with proposals for identification of Substances of Very High Concern. After the public consultation during which more than 300 different comments were received, the Member State Committee reached agreement in its December meeting on their SVHC status, leading to inclusion of 14 of them in the candidate list in January 2010[2]. From the date of inclusion of a substance in the candidate list, EU or EEA suppliers of articles which contain these substances in a concentration above 0.1% (w/w) have to provide sufficient information to allow safe use of the article to their customers or upon request, to a consumer within 45 days of the receipt of the request.

ECHA hosted a workshop on 24 September on prioritisation and grouping of SVHCs for MSCAs and Commission representatives. During this meeting results of work by some

[2] Acrylamide (EC No 201-173-7 and CAS No 79-06-1) was also identified as a Substance of Very High Concern by ECHA's Member State Committee. However, pursuant to an Order of the President of the General Court of the European Union, the inclusion of acrylamide in the Candidate List of substances for eventual inclusion in Annex XIV of REACH was suspended until the President of the General Court had made its order terminating the proceedings for interim relief in Case T-1/10 R. Acrylamide was included in the list in March 2010.

MSCAs on selection of potential SVHCs were discussed and practical experiences with preparing Annex XV dossiers were shared.

Restrictions

Title VIII of the REACH Regulation (Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, preparations and articles) and the List of adopted restrictions (Annex XVII) entered into force on 1st June 2009. Directive 76/769/EEC was repealed with effect from the same day. The main tasks of ECHA related to the Restriction procedure are (1) managing the consultation and opinion-making process for proposals made by the Member States (or by ECHA itself) and (2) preparing, on a request from the Commission, proposals for introducing new restrictions or amending current ones.

During the first part of 2009, ECHA's activities centred on developing the internal and committee working procedures and training staff and members of the RAC and SEAC for their tasks under the restrictions process.

ECHA has revised the format for developing restrictions dossiers and agreed with the MSCAs specific submission dates for their dossiers in order to allow appropriate management of the opinion-making processes. In addition, a dedicated website was developed to provide easier access to data and information that can be helpful in preparing restriction dossiers.

Overall, it can be concluded that ECHA and its Committees are ready to handle the first restriction dossiers that are expected to arrive in spring 2010.

ECHA has itself received a request from the Commission to evaluate new scientific evidence concerning the restrictions of phthalates contained in the Restrictions List. A work plan was developed before the end of the year.

ECHA also received a request from the Commission to prepare a restriction dossier concerning the availability of reliable safer alternatives for mercury-containing sphygmomanometers and other measuring devices. Work has started in 2009.

Performance Indicator	Result 2009
Percentage of SVHC dossiers treated within the legal timeframe.	100 %
Level of satisfaction of the ECHA Committees with the quality of the scientific, technical and administrative support provided.	High

1.4 Classification and labelling (C&L)

Priorities for 2009

- Prepare for the tasks assigned to ECHA under the CLP Regulation.
- Introduce efficient working procedures for managing the first proposals for harmonised classification and labelling of substances.

The CLP Regulation, which came into force in the beginning of 2009, identifies a number of tasks for ECHA related to the classification and labelling of hazardous substances: establishing a Classification and Labelling Inventory, managing proposals from MSCAs and industry for harmonised classification and labelling of substances, and evaluating requests from companies on the use of alternative chemical names.

ECHA developed procedures for the submission of notifications of classification and labelling of hazardous substances by companies, and the processing of these notifications, which would either be submitted as part of a registration dossier or as a separate dossier. ECHA also started to prepare for the development of the classification and labelling inventory.

The activities on handling proposals from Member State Competent Authorities for harmonised C&L that were already initiated under the REACH Regulation with submission of the first 14 dossiers in 2008, were intensified in 2009 as new proposals for 33 substances were received. The appointed RAC rapporteur conducted checks of the dossiers for suitability both for publication for public commenting and for subsequent review in RAC. All of the dossiers received had some shortcomings, either relating to the substance identity or to the scientific documentation for the proposal, which required update and resubmission from the submitting Member State CA. Following resubmission, 12 proposals were published for commenting by parties concerned and Member State Competent Authorities, six of those were subsequently forwarded to RAC, and RAC adopted their first opinion on one of those substances (Diantimony Trioxide).

ECHA started the planning of procedures for reviewing requests from industry for the use of alternative chemical names for substances in mixtures. The basic tasks were identified and served as the basis for input to the Commission's draft CLP Fee Regulation that is scheduled for adoption in 2010.

Performance Indicator	Result 2009
Proposals for Harmonised C&L processed within legal timeframe.	100 %
Level of satisfaction of RAC with the quality of the scientific, technical and administrative support provided.	High

1.5 Advice and assistance through guidance and helpdesk

Priorities for 2009

- Issue further updates of guidance, addressing restrictions, authorisation and classification and labelling as well as major issues raised on registrations
- Provide advice within adequate response times to registrants and others.

Guidance

In 2009, ECHA fully implemented, for the first time since their adoption, the procedures and workflows for developing and updating guidance. Following on from the Guidance Consultation procedure as endorsed by the Management Board in February 2008, an ECHA Framework for Guidance Governance was designed and established to efficiently implement cooperation procedures within and outside ECHA in order to ensure the broadest possible acceptance of guidance.

Guidance work focused on providing advice to industry in view of the first registration and notification deadlines by preparing a number of updates as well as new guidance. Two guidance documents on CLP required for the entry into operation of the CLP Regulation were published in official EU languages following their hand-over from the European Commission. Concerning REACH, several guidance updates covering following topics were launched: registration guidance (Annex V, waste and recovered substances), guidance on information requirements and chemical safety assessment (use descriptor system, exposure scenario format, occupational, consumer and environmental exposure estimation), guidance

on requirements for substances in articles and a new guidance on risk communication. A project to develop new guidance on Safety Data Sheets was initiated, in collaboration with industry stakeholders.

Apart from publishing guidance on ECHA's website, the Agency improved the accessibility of guidance. A new series of "Guidance in a Nutshell" was developed and translated as a way to increase the accessibility of guidance to industry, particularly to SMEs, by summarising complex guidance documents. Guidance Fact Sheets continued to be developed and translated on topics of interest to a more general audience as they provide a structured overview of guidance documents. The guidance website was also improved with direct access from the ECHA website and by creating a new and evolving table containing all on-going consultations on guidance documents.

Helpdesk

After the intensive activities before the pre-registration deadline, in 2009 the Helpdesk continued providing support to industry, with a focus on the upcoming registration and notification processes. Although the quantitative workload was somewhat less than in 2008, statistics on the Helpdesk's activities in 2009 reflect its continuous effort in handling ECHA's contacts with industry, particularly with SMEs and non-EU actors.

Helpdesk support in providing information on the REACH and CLP Regulations as well as on their IT tools (REACH IT, IUCLID 5) was very active throughout the year and mainly consisted of providing information to stakeholders (about 6,600 questions answered in 2009) and formulating and updating FAQs on REACH (overall 88 approved) and CLP (overall 57 published).

To ensure a consistent service to customers/users, the Helpdesk updated its workflow and standard operating procedures by adopting specific working instructions related to incident management and cooperation with the network of national helpdesks.

ECHA continued to promote the close cooperation and exchange of experience and good practice with national helpdesks by means of establishing, in October 2009, the HelpNet, a Network of REACH and CLP Helpdesks (involving a HelpNet Steering Group - previously REHCORN; together with its tool: HelpNet Exchange Platform – HELPEX, previously RHEP). The main aim of the HelpNet is to agree on harmonised answers throughout the EU/EEA and to provide high-quality advice to registrants and notifiers. ECHA organised two meetings of the network during 2009 (in March and October) and held two additional workshops dedicated to CLP and registration and IT tools.

The visiting programme of ECHA Helpdesk staff to national helpdesks, launched in 2008, continued and helped to enhance cooperation as well as the exchange of best practices among helpdesks.

Performance Indicators	Result 2009
Percentage of Helpdesk questions answered within the established timeframe (on average15 days for questions other than those on the user management on REACH IT).	79%
Number of FAQ updates agreed with REACH and CLP helpdesk correspondents and published on the web.	4
Percentage of feedback replies provided by ECHA to questions submitted to RHEP and CLP helpdesk exchange platform by national helpdesks within the timeframe set by the originator of the question.	76%

Level of satisfaction expressed in feedback from guidance users.	High
Level of satisfaction with quality of REACH training events.	High

1.6 IT support to operations

Priorities for 2009

- Consolidate IT support tools, especially REACH-IT and CSR tool, to ensure efficient execution of all operations of the Agency, its bodies and the MSCA
- Enhancing the interface and dialogue with the general public via the dissemination website.

ECHA is developing a wide range of IT systems for supporting the REACH operations. The main existing systems in this domain are REACH-IT (online system managing the communication between industry, ECHA, Member States and the European Commission and the dissemination of information over the Internet), complemented by a case and document management system supporting the work of ECHA Secretariat and its Committees, IUCLID 5 (main system developed for industry for preparing registrations and notifications), Chesar (Tool to assist registrants in the production of the Chemical Safety Reports) and RIPE (REACH Information Portal for Enforcement).

Considerable efforts were allocated to the further development of REACH-IT during 2009 with two main priority areas: adding new functions essential for the upcoming deadlines of 2010 and improving the performance of the existing system based on the experience gained over the pre-registration phase and recommendations of a benchmark study carried out at the end of 2008. Changes were made to improve speed, stability, and quality of the application. The amount of work involved in specifying and testing the subsequent improvements in REACH-IT was significant. All changes were documented in end-user manuals published on ECHA website.

Part of the industry functionality was not released in 2009 as initially planned, due to the shift of priorities to preparing for the 2010 load. These concerned the Classification and Labelling (C&L) module covering the online creation of C&L notification and building the C&L inventory; and the Legal entity change functionality supporting the transfer of registration rights in case of merge/split of legal entities. The specifications and the design however were fully completed in 2009, and the releases are scheduled for early 2010.

Access to three Member States Competent Authorities was enabled by the end of the year.

Cooperation with stakeholders has continued in the form of a Workshop dedicated to IT tools (March 2009), webinars, testing sessions organised with industry users, meetings and presentations with industry organisations, the MSCA Security Officers Network, and Management Board Advisory Group meetings.

For IUCLID 5, two maintenance releases (v5.1 and v5.1.1) were released during 2009, together with four new modules (“plug-ins”) which added new functions to the system. The most important development was however related to the preparation of a much improved version, IUCLID 5.2, to be released in early 2010. The main improvements include adapting IUCLID 5 to the needs of the CLP regulation and updating the management of information on substance use for generating the Chemical Safety Report in accordance with the Guidance on Information requirements.

The Chesar project aimed to deliver the first version of the tool by the end of 2009 and considerable progress was made in the development with delivery of three prototypes in September, October and November 2009. However, valuable time lost in the outsourced project in the first quarter of the year could only partially be recovered by subsequent in-house development. Moreover, a key challenge and difficulty has been the lack of experience in the stakeholder community on best practice in preparing exposure scenarios. ECHA has worked in very intense collaboration with the industry to overcome this challenge.

The development of several systems supporting other REACH processes has been initiated. It includes two genuinely new scientific IT-systems (Casper and Odyssey) for the identification of dossiers for evaluation and supporting and documenting the decision-making process, and an Enterprise Content Management solution to support workflows (to be tested on the workflow for the identification of substances of very high concern). Work also began on a system (RIPE) to support the work of national REACH enforcement authorities.

Following the intense discussion on the likely number of dossiers that ECHA should expect in 2010, resulting from the REACH and CLP deadlines and on the outcome of the REACH-IT risk audit, a decision was made to build a back-up IT system for REACH-IT (Secondary Business Contingency System / Plan B) to take over certain key functions should REACH-IT not operate as planned.

Finally, the dissemination website was developed. Making non-confidential information available to the public is a key commitment under REACH and the website and associated filtering tools have ensured that such information is made accessible to the general public.

Performance Indicator	Result 2009
Percentage of individual software deliverables for the different IT tools completed according to schedule.[3]	78 %

1.7 Other scientific and technical advice on questions relating to chemicals

Priorities for 2009

- Advice on nanomaterial and the way their specificities need to be addressed in the registration dossiers.
- Advise on the revision of the Biocides Directive.

As planned in the Work Programme 2009, ECHA contributed to and commented on the Commission documents prepared for the meetings of the Competent Authorities in the area of nanomaterials. ECHA also contributed to the Commission REACH Implementation Projects on Nanomaterials that started to evaluate how to improve existing guidance to better address the specific challenges and concerns related to nanomaterials. At international level, ECHA followed, in particular, the work of the OECD Working Party on Manufactured Nanomaterials, and the relevant parts of the International Organisation for Standardisation work on nanomaterials. Furthermore, ECHA established an internal task force to ensure a coordinated and well planned capacity building and actions related to this work.

[3] All delivered versions for IUCLID, REACH-IT, Dissemination, Chesar, and Casper**.** The calculation includes, in addition to production versions, also interim versions for testing foreseen by the project planning.

Regarding development of test methods, including alternative test methods, ECHA started, though still with very limited resources, to build up its expertise and capacities to provide scientific and technical advice. Following a request from the Commission, ECHA started to participate and contribute to the activities of the OECD Working group of National Coordinators for the Test Guidelines Program, including the EU mirror group. This included commenting on proposals for new test guidelines, covering also the proposed new protocol for an extended one-generation reproductive toxicity study.

ECHA continued to provide scientific advice to the Commission in the preparation of the proposal for the new Biocides Regulation. This work also covers the planning of ECHA's future biocide tasks, including preparatory activities to ensure appropriate staffing, IT-tools, and processes to be in place early enough. As no specific funding was yet available for ECHA, these activities were so far relatively limited.

Performance Indicator	Result 2009
Level of satisfaction with the quality of the scientific, technical and administrative support provided to Commission.	High

2. ECHA's bodies and supporting activities

2.1 Committees and Forum

Priorities for 2009

- Efficient handling of the dossiers using the working procedures developed.
- Prepare for the first restriction proposals.

The Committees are an integral part of ECHA and play an essential role in carrying out its tasks. The Committees are of paramount importance to the smooth and efficient functioning of the REACH Regulation and the credibility of ECHA in ensuring its independence, scientific integrity and transparency.

Member State Committee (MSC):

The MSC held four plenary meetings and two working group meetings in the course of 2009. Fifteen further proposals on Substances of Very High Concern (SVHCs) were treated and agreed unanimously for inclusion in the Candidate List. The MSC opinion on ECHA's recommendation for priority-setting of candidate substances for authorisation was adopted by consensus, allowing ECHA to submit its recommendation by the legislative deadline (1 June 2009). The Committee also agreed on its working procedure on draft decisions on testing proposals and compliance checks and revised the working procedure on preparation of the opinion on ECHA's draft recommendation for inclusion of prioritised substances in the Authorisation List (Annex XIV). The Committee unanimously took its first decision on a testing proposal following dossier evaluation.

Committee for Risk Assessment (RAC):

The RAC held four plenary meetings, one of which was held in-part jointly with the Committee for Socio-economic Analysis. The Committee adopted its first opinion on a Harmonised Classification & Labelling (CLH) proposal and concluded in principle on the classification and labelling of a further three CLH proposals. The complementary roles of SEAC and RAC in handling restriction dossiers was further clarified and the Committee agreed, in cooperation with SEAC, on a procedure to process restriction dossiers and on templates for opinions as well as the accompanying background document. The RAC also received its first mandate under Article 77(3)(c) concerning boric acid and borate compounds in photographic applications and established a process to deliver its opinion through an accelerated procedure by early 2010.

Committee for Socio-economic Analysis:

The Committee held three plenary meetings, one of which was held partially jointly with the RAC. Pending the dossier work to start, SEAC progressed on methodological issues related to the handling of restriction dossiers. The Secretariat organised a course on SEA and a crash course on Risk Assessment for SEAC members to further build up the capacity of the Committee to meet its challenging tasks forthcoming in 2010.

Forum for exchange of information on enforcement:

The Forum met three times in plenary and held eleven WG meetings in 2009. Based on its work plan, the Forum focused on clarifying the roles of REACH enforcers and on elaborating best practices. The first coordinated enforcement project on pre-registration, registration and safety data focused on the enforcement of the "no data, no market" rule, and was implemented in 25 EU-EEA Member States. Furthermore, the Forum decided on its second

coordinated project for 2010/2011, focusing on formulators of mixtures who are the first-level Downstream Users in the supply chain. Based on the information requirements determined by the Forum, the Secretariat launched the project called RIPE (REACH Information Portal for Enforcement) to develop a separate data base with information from REACH IT adapted to the purposes of inspectors. It also prepared a concept for an electronic information exchange procedure for REACH enforcers, in analogy to market surveillance. It dealt with the advice on enforceability of proposals for restrictions and testing methods for restricted substances. The Forum developed basic elements for minimum criteria for REACH inspections and initiated its cooperation with customs authorities.

All three Committees and the Forum continued to provide for an active involvement of ECHA stakeholder organisations in their work. Moreover, the publication of their preliminary draft agendas on ECHA's website increased the transparency of the work.

Performance Indicators	Result 2009
Percentage of opinions / agreements delivered in time.	100 %
Percentage of unanimous MSC agreements.	100 %
Percentage of Committee opinions adopted by consensus.	100 %
Level of satisfaction of the Members and other participants with the support (including training and chairing) provided by ECHA to the Committees and the Forum.	High
Level of satisfaction of Members of the Committees with the overall transparency and publication of the outcomes of Committee processes and the Forum activities.	High

2.2 Board of Appeal

Priorities for 2009

- Take high quality decisions in a timely manner
- Finalise the appointment procedure for the Board of Appeal
- Adopt procedural rules and practices for the appeal procedure.

The Board of Appeal (BoA) achieved full operability in 2009, including the basis for coordination and engagement of alternate and additional members in appeal cases. The BoA started its preparations for dealing with future appeals in a structured manner by defining its mission and vision. Within the framework of the Rules of Organisation and Procedure (Regulation (EC) No 771/2008), the BoA has refined its decision-making process with the aim of ensuring high quality and consistent decisions. Several procedural decisions were prepared and adopted, for example with respect to the rules on publication of announcements of appeals and on costs of taking evidence. The BoA has also participated in selected stakeholder events.

The adequacy of the BoA and Registry procedures was demonstrated during the processing of the first appeal. In its first decision, the BoA partially granted on the appellant's request that certain information be regarded as confidential. The appeal was however subsequently withdrawn by the appellant following the rectification of the contested decision by the Executive Director in a way which met its concerns. Information on the appeal was published on the BoA's websection on ECHA's website. There was fluent communication with the parties and the procedure was conducted in an expeditious way by the Registry. The transparency of the appeal process (publicly available on internet) has and will contribute to creating trust in the appeal system.

Performance Indicators	Result 2009
Percentage of cases concluded within 12 months of their introduction.	100%

2.3 Communication

Priorities for 2009

- Further strengthen ECHA's primary means of communication – its website.
- Translate key materials to enable companies to understand their responsibilities under REACH.

ECHA's external website was maintained and updated, with new sections provided in 22 official EU languages. During 2009, the decision was taken to rebuild the site completely by 2011, due to the limited room for improvement of the current site caused by its structure and design.

Translation remained a priority and a challenge for the Agency – a priority because of the need to reach out particularly to small and medium size enterprises to support them in fulfilling their responsibilities under REACH; a challenge because of the volume and the logistics involved in managing translations and also because of the technical nature of much of ECHA's documentation and their validation. In late 2009, ECHA signed agreements with ten Member State Competent Authorities to validate the technical wording of translations.

All Guidance and Guidance in a Nutshell documents established in 2009 as well as fact sheets and leaflets relevant for SMEs and the general public were published in 22 official EU languages. Furthermore, the CLP web-pages were also published in 22 language versions. Finally, ECHA's terminology project completed its first phase in 2009, providing critical REACH and CLP terms in 22 languages for all potential users

The most significant achievement was unplanned at the time of writing the 2009 Work Programme – the awareness-raising campaign to support the work in Substance Information Exchange Fora (SIEFs) and to try to encourage the early and high quality submission of dossiers, called "The clock is ticking – form your SIEF now" - launched in May. The campaign had three elements – trying to remove the barriers to SIEF working; raising awareness of the urgency for companies to make progress; and supporting Lead Registrants. A variety of actions were taken in 2009 (and will continue into 2010) as part of that campaign. These ranged from webinars, workshops and an online discussion-forum for Lead Registrants, to joint activities with Associations and Member States to try to raise awareness of the urgency.

With a view to the first C&L notification deadline of 3 January 2011, ECHA launched a new campaign at its third Stakeholder Day in December, aimed at making industry, and in particular SMEs, aware of their imminent notification obligations. For that purpose ECHA developed a new section on CLP on its website, in official EU languages, alongside practical information in the form of brochures and leaflets, and frequently asked questions.

Internal communications became a priority in 2009 – the growing size and complexity of the Agency made effective internal communication essential. With full cooperation of all staff, a strategy and an action plan were developed and activities launched. ECHA now has a number of high-quality communication tools that are enabling us to make sure that all ECHA

staff have the information they need to do their jobs. Key among these tools is the newly built and launched intranet site (ECHAnet).

The Risk Communications Network has continued to develop, with the members now also playing a role in the production of Risk Communication Guidance for Member States' authorities.

Stakeholder engagement took a number of forms in 2009. At its most intense, many of the 45 official stakeholder organisations[4] were invited to participate in ECHA's formal Committee meetings as regular observers. At the other extreme, over 1200 participated in ECHA's two Stakeholder days – both in person and online (watching the web stream). Throughout the year, thousands have participated in the numerous workshops and webinars that have been organised.

ECHA has continued to respond to requests from journalists in a helpful and timely fashion. ECHA's profile is reasonably pronounced in the sectoral media where the degree of interest in REACH and CLP is very high. During 2009 however, ECHA began to receive enquiries also from a wider media audience – for example on the issues of testing substances on animals to determine their potential hazard for humans and on chemical substances in cosmetics.

Performance Indicators	Result 2009
Level of website customer satisfaction.	High
Level of staff satisfaction with internal communications.	High
Level of stakeholder satisfaction with their involvement.	High (measured after each of the two Stakeholder Days)

2.4 Relations with EU institutions and international cooperation

Priorities for 2009

- Maintain and consolidate its close contact effective collaboration with the European institutions, in particular the European Commission and the European Parliament, as well as other European Agencies and the Member State competent authorities.
- Respond to requests of the Commission for scientific/technical support of its bi- and multilateral international activities.

EU institutions and other bodies

The Executive Director and the senior management of ECHA liaised regularly with the European institutions, in particular the Parliament, Council as well as Member States and the Commission.

The Executive Director appears annually in the European Parliament's (EP) Committee for Environment, Food Safety and Public Health (ENVI). Regular information on ECHA's activities is provided to the EP's liaison person, Satu Hassi MEP, as well as to MEPs from specialised Committees.

[4] Those meeting the four criteria agreed by the Management Board – available on the website

ECHA had regular contacts with the authorities of the Member States and the Executive Director, together with expert staff, visited partner authorities in Denmark, Lithuania, the Netherlands, Poland and Spain.

ECHA had continuous and frequent contacts with the Commission. Occasionally, high level meetings were held at Director General level and with Cabinet staff. ECHA staff has continuous working level contacts with Commission officials from DG ENTR and DG ENV. Moreover, Vice-President Wallström and Commissioner Dimas visited ECHA in 2009.

Cooperation with other Community bodies' scientific committee

The Management Board, subject to agreement by the Commission, adopted rules of procedures for cooperation between ECHA and EFSA in December 2009. Similar rules were drafted for the cooperation between ECHA and the Scientific Committee for Occupational Exposure Limits (SCOEL) but due to a need to formally consult the Advisory Committee for Safety and Health at Work (ACSHW), their finalisation and adoption was postponed to 2010.

In addition, ECHA agreed on a Memorandum of Understanding with EFSA. Preparation of a Memorandum of Understanding with EU-OSHA was on its way in 2009. High level delegation visits from EFSA and EU-OSHA to ECHA took place in order to prepare the Memoranda of Understanding and intensify the scientific-technical cooperation.

International cooperation

The international activities of ECHA were mainly based on the request of the European Commission and were detailed in the ECHA Work Plan for International Activities. This plan was prepared in close consultation with the Commission and was then endorsed by the Management Board.

Concerning multilateral activities, the main focus was on the OECD activities. ECHA Secretariat contributed to the task force on hazard assessment (including planning for revision of the OECD existing chemicals cooperation after 2010), the SIDS programme (as a commenting party) and to the discussions on extended one generation reprotoxicity study.

Three work packages of the OECD eChemPortal – a joint project between ECHA and the OECD initiated in 2008 - were delivered and accepted by the OECD Steering Group according to the agreed planning in February ("Inception Phase"), June ("Design model") and December ("Beta version"). The ECHA Dissemination database was also integrated as a participating database in the beta testing phase enabling search on identity and properties of registered substance via the eChemPortal.

Two work packages of the OECD (Q)SAR Application Toolbox – another joint project between ECHA and the OECD initiated in 2008 - were delivered and accepted by the OECD Management Group according to the agreed plan. The first in March ("Inception Phase") and the second in November ("Development beyond Version 1.0 of the Toolbox – software modules and reports"), these cover the full specifications of the next modules to be integrated in the Toolbox.

Under the leadership of ECHA, the OECD IUCLID User Group Expert Panel prioritised new features for IUCLID (discussed at a meeting in 2008) to be implemented in IUCLID 5.2., which include new functionalities and Harmonised Templates for pesticides.

The Agency contributed to the implementation of the OECD Programme on High Production Volume Chemicals on behalf of the European Commission and in line with the international work plan agreed between ECHA and the Commission. In this context, the Agency assessed nine OECD dossiers (three categories and six single substances) with relevance to the REACH Regulation (e.g. pre-registered, high tonnage in the EU-region, potential risk for human health and/or the environment, and exposure concerns).

ECHA also supported the European Commission delegation at the fourth Conference of the Parties to the Stockholm Convention as well as at the Persistent Organic Pollutant Review Committee. Furthermore, ECHA supported the Commission at the second International Conference on Chemicals Management.

Concerning bilateral cooperation, the ECHA Secretariat participated in activities to increase the knowledge of REACH for candidate countries and potential candidates as well as ENP (European Neighbourhood Policy) partners mainly arranged by the EC TAIEX office. It received a number of representatives from embassies, government authorities and industry organisations from countries outside the EU. The highest number of visits originated from Asia. ECHA also participated in a number of workshops and seminars on REACH and CLP on the invitation of EC Delegations and other organisers in countries outside the EU.

A project plan for financial support from the European Commission Instrument for Pre-Accession for activities to support candidate countries for EU accession to prepare for REACH implementation and participation in ECHA was prepared and the contract with the European Commission was signed in October 2009.

Indicators	Result 2009
Level of satisfaction of the Commission with the support given by ECHA on international activities.	High

3. Management, organisation and resources

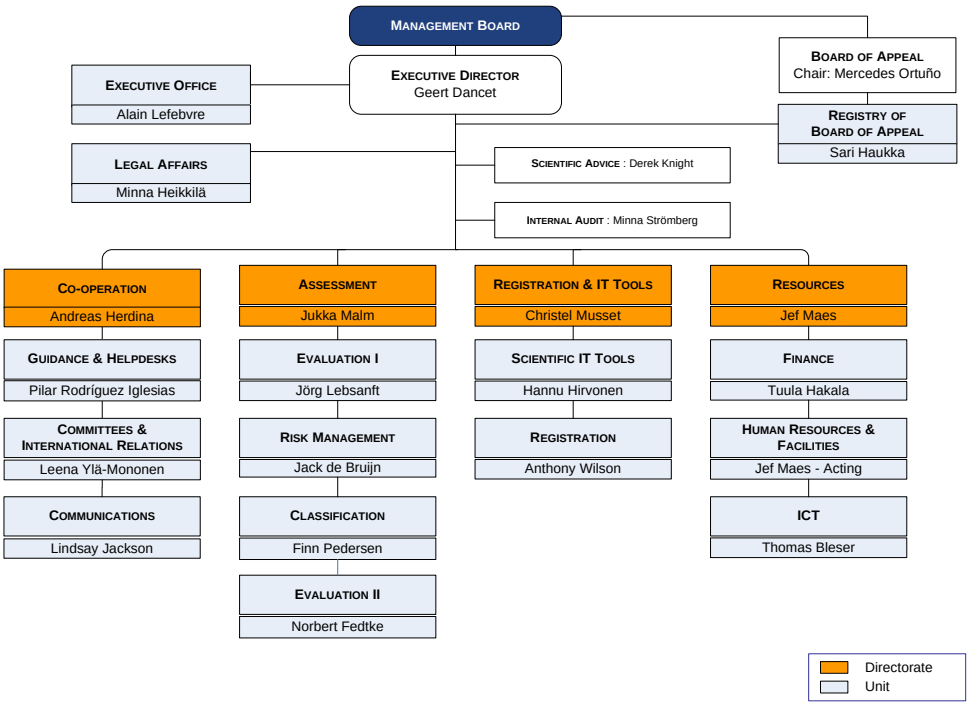
3.1 Management

Priorities for 2009

- Consolidate, improve and develop operational structure, procedures and the management of the Agency
- Consolidate internal control systems to ensure efficient resource management
- Finalise or improve ECHA's Standard Operating Procedures.
- Maintain and develop professional management skills of the middle and senior management.

While approaching a more mature state with regard to its management and administration, 2009 was still a year in which management tools and internal procedures were further developed. In particular, significant progress was made in developing the tools used for planning and security, both with respect to information and physical security. A global filing plan for ECHA has been defined, as the basis for a common information system. A reform of the Agency's organisational structure – to be implemented by January 2011 – was also designed and shared with the staff and the Management Board.

ORGANISATION CHART OF ECHA – 31.12. 2009



The Management Board met regularly and to ensure proper preparation of its decision making, it had five Working Groups (WG): WG on Planning and Reporting, WG on Dissemination, WG for the selection of the BoA members and two WG's for the performance appraisal of the Executive Director and the BoA members. Altogether 11 WG meetings were held.

As part of its risk management, in 2009 ECHA recognised that it faced a great deal of uncertainty about the number of registrations it would receive before the first registrations deadline of 30 November 2010. An internal analysis of the pre-registration data suggested that the number of registrations in 2010 would probably be close to the original Commission estimate of 25 000. However, based on experiences from the pre-registration phase, ECHA management decided to be ready to face up to three times that number. To ensure that it

would be properly prepared, ECHA set up a task force to plan the relevant mitigating measures. Based on three different scenarios contingency plans were prepared covering not only the submission process but also e.g. IT issues, human resources, officer space, communications and helpdesk.

Quality control

In 2009 the Agency stabilised its Integrated Quality Management System. The quality management function assisted management in defining and implementing the Agency's Quality Policy.

A scrutiny of the process inventory established in 2008 revealed the need for further refinement of the approach to reflect the complexity of the Agency's processes, their dependencies and interfaces. A process hierarchy was introduced and the Agency's quality management system documentation, hitherto consisting in Standard Operating Procedures (SOP), was changed to a modular tier scheme.

The documentation of operational and support processes and activities was continued. The revision of existing SOPs according to the new documentation scheme is underway. New procedures, work instructions and pertaining documents were drafted with a focus on processes with special relevance for the Agency's performance in 2010. Process maps were established and detailed process descriptions were elaborated for the planned development of automated workflows for document control.

The conception of procedures for the handling of non-conformities and corrective action as well as the internal auditing of the quality management system was started. Research for tools with suitable functionality for realising an IT assisted workflow for these procedures is ongoing. Surveys were carried out to assess the needs and expectations of stakeholder groups and their satisfaction.

Awareness for the principles of quality management was raised amongst staff. An event, dedicated to communicate and explain ECHA's Quality Policy, was organised. In response to the continued rapid growth of the Agency, induction training was offered to newcomers on a regular basis. Training in quality management system documentation was repeated regularly and targeted coaching also covered further specific aspects. The creation of a permanent Quality Network with a representative from each Directorate strengthened the horizontal character, capacity building and a harmonised approach of quality management throughout the Agency.

Internal audit

According to ECHA's Financial Regulation, the Internal Auditor for ECHA is the Internal Auditor of the European Commission (IAS). The IAS performed an audit on "Planning and Monitoring" in 2009. The audit focused on strategic planning and monitoring as well as on operational and financial monitoring. Based on the results of this audit, the IAS raised eight recommendations, three of which were rated as "very important"; three as "important"; and two as "desirable" – and all of which were accepted by ECHA's management. The action plan in response to the recommendations of the IAS, is being implemented.

The IAS also updated the first strategic audit plan for ECHA, adopted in 2008, as a result of the risk assessment which the IAS conducted in October 2009. The new strategic audit plan, which was endorsed by the Management Board in December, is established for three years on a rolling basis and foresees a consultative audit of the registration activities of ECHA.

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 resource, adds value by providing the Executive Director with additional assurance and consulting activities.

In 2009, the IAC carried out audits on “Management of IT service contracts” and “Implementation of ECHA/2008/02 framework contract”. The main recommendations from these two audits concerned: efficiency of the monitoring aspects of IT service contracts; development of procurement procedures; and training. Based on the results of these audits, the IAC raises 16 recommendations, eight of which are rated as “very important” and eight as “important”. ECHA management developed in 2009 action plans to respond to the recommendations of the IAC.

Performance Indicators	Result 2009
Percentage of statutory documents submitted to the Management Board within legal deadlines.	100 %
Number of “critical” findings by the auditors relating to the internal control system in place.	0
Percentage of audit recommendations implemented within the deadline.	100 %

3.2 Finance, Procurement and Accounting

Priorities for 2009

- Monitor closely the fee revenues and expenditure so as to achieve a high proportion of budget consumption and identify any potential shortfall of revenue in advance.

In the area of budget planning, the main achievement was the ability to safeguard the prospect for uninterrupted implementation of the essential REACH tasks during 2010 through a temporary community subsidy of 44,7 million EUR. In view of the fact that the date of the first registration deadline was shifted late in the legislative procedure for the adoption of REACH, and was not accommodated by a consequential increase in the subsidy planning for the Agency, ECHA had to seek a bridging subsidy to compensate for the late inflow of expected fee income in 2010.

Regarding budget execution, satisfactory levels of 95% in the commitment rate and 67% in the payment rate were achieved as a result of implementing the Agency’s work programme 2009.

As regards preparations for the expected invoicing peak in 2010, a substantial range of improvements to the REACH-IT invoicing system have been proposed with the aim of making the invoicing and the processing of payments more efficient. These need to be implemented in 2010.

With reference to procurement activities, two high-value multi-annual framework contracts with several lots were established, e.g. in the areas of IT consulting and projects, and several inter-institutional framework contracts for ICT hardware and software were entered into.

A high volume of contracting was carried out either through direct contracts or specific contracts under existing framework contracts in the field of communication and IT, scientific, technical, environmental and socio-economic questions related to REACH. Finally, a large amount of procurement was carried out to cover various administrative needs of the Agency.

No new formal complaints were raised by tenderers in any procurement procedure of ECHA in 2009.

Budget outturn account

EUR

		2009	2008
REVENUE			
Commission subsidy	+	68 051 042,35	62 856 195,89
IPA funds	+	136 410,00	0,00
Fee income	+	2 658 572,25	365 429,58
Other revenue	+	503 194,89	2 602,96
TOTAL REVENUE (a)		**71 349 219,49**	**63 224 228,43**
EXPENDITURE			
Title I: Staff			
Payments	-	31 180 604,56	20 208 389,51
Appropriations carried over	-	1 272 735,44	1 605 826,16
Title II: Administrative Expenses			
Payments	-	9 088 290,54	12 391 335,50
Appropriations carried over	-	6 478 379,99	4 652 805,82
Title III: Operating Expenditure			
Payments	-	6 636 641,65	7 379 854,79
Appropriations carried over	-	12 402 108,54	6 359 119,92
TOTAL EXPENDITURE (b)		**67 058 760,72**	**52 597 331,70**
OUTTURN FOR THE FINANCIAL YEAR (a-b)		**4 290 458,77**	**10 626 896,73**
Cancellation of unused payment appropriations carried over from previous year	+	2 658 578,48	0,00
Adjustment for carry-over from the previous year of appropriation available at 31.12. arising from assigned revenue	+	1 458,27	0,00
Exchange differences for the year (gain +/loss -)	+/-	-3 224,26	-1 362,94
BALANCE OF THE OUTTURN ACCOUNT FOR THE FINANCIAL YEAR		**6 947 271,26**	**10 625 533,79**
Balance year N-1	**+/-**	8 702 945,23	
Positive balance from year N-1 reimbursed in year N to the Commission	**-**	-8 702 945,23	-1 922 588,56
BUDGET OUTTURN		**6 947 271,26**	**8 702 945,23**

Performance Indicators	Result 2009
Commitment rate.	95%
Payment rate[5].	67%
Number of complaints against ECHA procurement procedures.	0

[5] Executed payments against payment appropriations.

3.3 Human resources and infrastructure

Priorities for 2009

- Recruit and train staff needed to execute the operational tasks in 2009 and to prepare for the first registration deadline in 2010.

Timely and legally correct recruitment of qualified staff continued to be a major challenge for the Agency in 2009. The number of statutory staffing grew towards 320 at the end of 2009, which is an increase of 40% compared to the year before. In order to achieve this, the Human Resources unit organised 38 selection procedures, from which 83 temporary and 17 contract agents were recruited in 2009. ECHA continued to provide entry programmes and supported the integration and installation of the new staff in both the Agency and Helsinki.

Human resources 31.12.2009[6]

Activities (Title III of the Budget)	**Human resources**	
The numbering below refers to the General Report 2009, not to the numbering in the budget	**AD and AST**	**CA+SNE***
Management, incl. Management Board and Legal Advice	23	3
Operations General coordination, management and support	26	
1.1 Registration, pre-registration and data-sharing	23	4
1.2 Evaluation	27	1
1.3 Authorisation and Restrictions (incl. SVHC)	20	1
1.4 Classification and labelling	8	
1.5 Advice and Assistance	33	2
1.6 IT support the operations	23	
2.1 Committees and Forum	18	2
2.2 Board of Appeal	10	1
2.3 Communication, including translations	10	8
2.4 Relations with EU institutions and international cooperation	7	
Total	**228**	22
Administrative and support staff	65	10
Total	**293**	**32**
In Establishment plan:	**324**	

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

Focus was given to further developing the Human Resources infrastructure, including the conclusion of a set of implementing rules, a streamlined personnel and salary administration, the setting up of the medical services, the implementation of an HR IT system to manage leave and missions and an extended learning and development programme for staff including management training and coaching. In this, due focus was given to aspects of data protection, sound and correct financial management and quality systems.

[6] The figures include the staff employed. Several recruitments, in particular in Evaluation, had been finalised but the recruits did not start before the end of the year.

The office environments were created for an additional 250 desks, which were required for the growing number of staff but also for incoming trainees, seconded national experts, consultants and other contract types.

After consultation with the Management Board and the Budgetary Authority, a major renovation project was concluded in 2009 which will provide ECHA with extra offices, meeting rooms and a library. ECHA continued to manage its contemporary conference facilities for its committees, governance boards, staff as well as stakeholders and other meetings. Several other facilities and services were upgraded during 2009, such as the physical security, travel services and internal logistics.

Performance Indicators	Result 2009
Percentage of establishment plan posts filled at the end of the year.	90% filled 9% in process
Percentage of selection procedures for the new posts for the year completed.	100%
Turnover of the Temporary Agents.	3%
Level of satisfaction of the Committee, Forum and MB members with the functioning of the conference centre.	High
Average number of training days per staff member.	9,36

3.4 Information and Communication Technology

Priorities for 2009

- Review and consolidation of the overall REACH-IT architecture
- Performance review and enhancement of ECHA data centre
- Support to the proper functioning, use and further enhancement of the REACH-IT system
- Extension and maintenance of secure network connections with MS

In ECHA's data centre, centralised storage systems were upgraded and backup systems streamlined to prepare for increased and future load. New REACH-IT application servers were installed and brought online, centralised logging was implemented and monitoring improved. Office automation server systems were scaled up in line with growing staff numbers.

The rapid growth of ECHA's staff was supported by the provisioning of the necessary ICT tools, facilities and end-user help-desk support. During 2009, the data networks were extended to cover newly occupied premises, including the newly established Conference Centre. Wireless networks for visiting stakeholders were installed, and systems brought online to provide appropriate levels of security.

Secure connections with the Member States Competent Authorities (MSCA's) were made possible in 2009 and by the end of the year three of them had been granted access to the application once the required and signed security declarations had been received.

Support to office applications, to operational systems and to document management projects has been provided. REACH-IT applications were maintained, including the hosting and

installation of new versions/upgrades as well as the testing, tuning and monitoring of the application.

In 2009, the majority of IT projects, applications and major systems have been managed in accordance with the Agency's newly established standard governance process, including architectural guidelines and quality standards for projects. A review of the architecture of REACH-IT led to major structural improvements in the system, upgrading of the hardware, and a major testing plan for performance testing to be undertaken in the first semester of 2010 in advance of the peak activity in registration and CLP notification.

Performance Indicators	Result 2009
Availability of operational systems for external customers (uptime).	99.4%

Annexes

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

Annex 2: Candidate list of substances of very high concern

Annex 3: Useful links in ECHA website

Annex 4: Helpdesk statistics

Annex 5: Analysis and Assessment of the AAR of the Authorising Officer for 2009

Annex 1 List of members of the Management Board, Committees and Forum

Members of the Management Board on 31 December 2009

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	**Jan Karel KWISTHOUT**	**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	**Catherine MIR**	**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 (process of replacement ongoing in 2009).

- **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 **Gustaaf BORCHARDT**	**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 MSC – Member State Committee on 31 December 2009

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

Members

o	**Helmut STESSEL**	**Austria**	o	**Arnis LUDBORZS**	**Latvia**
o	**Kelly VANDERSTEEN**	**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**	**Norway**
o	**Enda VESKIMÄE**	**Estonia**	o	**Jerzy MAJKA**	**Poland**
o	**Jaana HEISKANEN**	**Finland**	o	**Maria do Carmo Ramalho Figueira PALMA**	**Portugal**
o	**Sylvie DRUGEON**	**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	**Gary DOUGHERTY**	**United Kingdom**
o	**Pietro PISTOLESE**	**Italy**			

Members of the RAC – Committee for Risk Assessment on 31 December 2009

Chair: José TARAZONA
ECHA contact: José TARAZONA

Members	Nominating State		Nominating State
o **Annemarie LOSERT**	**Austria**	o **Paola DI PROSPERO FANGHELLA**	**Italy**
o **Erich A. POSPISCHIL**	**Austria**	o **Normunds KADIKIS**	**Latvia**
o **Karen VAN MALDEREN**	**Belgium**	o **Lina DUNAUSKIENE**	**Lithuania**
o **Zhivka HALKOVA**	**Bulgaria**	o **Hans-Christian STOLZENBERG**	**Luxembourg**
o **Maria ORPHANOU**	**Cyprus**	o **Marianne VAN DER HAGEN**	**Norway**
o **Milan PAULOVIC**	**Czech Republic**		
o **Marian RUCKI**	**Czech Republic**	o **Boguslaw BARANSKI**	**Poland**
o			
o **Frank JENSEN**	**Denmark**		
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 **José L. TADEO LLUCH**	**Spain**
o **Helmut A. GREIM**	**Germany**	o **Eugenio VILANOVA**	**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 **Thomasina BARRON**	**Ireland**		

Members of the SEAC – Committee for Socio - economic analysis on 31 December 2009

Chair: Leena Ann THUVANDER
ECHA contact: Adriana LIPKOVA

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

Members for Forum for Exchange of Information on Enforcement on 31 December 2009

Chair: Richard BISHOP
Vice chair: Joop BLENKERS and Nikolay STANIMIROV SAVOV
ECHA contact: Maciej Baranski, Pablo CALVO TOLEDO

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	**Jill WEBER**	**Luxembourg**
o	**Oldrich JAROLIM**	**Czech Republic**	o	**Shirley MIFSUD**	**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	**Guido GRUNWALD**	**Germany**	o	**Dušan KOLESAR**	**Slovakia**
o	**Ioanna ANGELOPOULOU**	**Greece**	o	**Mojca JERAJ PEZDIR**	**Slovenia**
o	**Szilvia DEIM**	**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

Candidate list of substances of very high concern

Substance name	EC (CAS No.)	Date of inclusion	Reason for inclusion
2,4-Dinitrotoluene	204-450-0	13.01.2010	Carcinogenic (article 57a)
4,4'- Diaminodiphenylmethane (MDA)	202-974-4	28.10.2008	Carcinogenic (article 57a)
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	201-329-4	28.10.2008	vPvB (article 57e)
Acrylamide	201-173-7	30.03.2010	Carcinogenic and mutagenic (articles 57a and b)
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	287-476-5	28.10.2008	PBT and vPvB (article 57d - e)
Aluminosilicate Refractory Ceramic Fibres *are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.2 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the two following conditions:* *a) Al_2O_3 and SiO_2 are present within the following concentration ranges:* • *Al_2O_3: 43.5 – 47 % w/w, and SiO_2: 49.5 – 53.5 % w/w,* *or* • *Al_2O_3: 45.5 – 50.5 % w/w, and SiO_2: 48.5 – 54 % w/w,* *b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm).*	-	13.01.2010	Carcinogenic (article 57a)
Anthracene	204-371-1	28.10.2008	PBT (article 57d)
Anthracene oil	292-602-7	13.01.2010	Carcinogenic[1)], PBT and vPvB (articles 57a, 57d and 57e)
Anthracene oil, anthracene paste	292-603-2	13.01.2010	Carcinogenic[2)], mutagenic[3)], PBT and vPvB (articles 57a, 57b, 57d and 57e)
Anthracene oil, anthracene paste, anthracene fraction	295-275-9	13.01.2010	Carcinogenic[2)], mutagenic[3)], PBT and vPvB (articles 57a, 57b, 57d and 57e)
Anthracene oil, anthracene paste,distn. lights	295-278-5	13.01.2010	Carcinogenic[2)], mutagenic[3)], PBT and vPvB (articles 57a, 57b, 57d and 57e)
Anthracene oil, anthracene-low	292-604-8	13.01.2010	Carcinogenic[2)], mutagenic[3)], PBT and vPvB (articles 57a,

			57B, 57D AND 57E)
BENZYL BUTYL PHTHALATE (BBP)	201-622-7	28.10.2008	TOXIC FOR REPRODUCTION (ARTICLE 57C)
BIS (2-ETHYLHEXYL)PHTHALATE (DEHP)	204-211-0	28.10.2008	TOXIC FOR REPRODUCTION (ARTICLE 57C)
BIS(TRIBUTYLTIN)OXIDE (TBTO)	200-268-0	28.10.2008	PBT (ARTICLE 57D)
COBALT DICHLORIDE	231-589-4	28.10.2008	CARCINOGENIC (ARTICLE 57A)
DIARSENIC PENTAOXIDE	215-116-9	28.10.2008	CARCINOGENIC (ARTICLE 57A)
DIARSENIC TRIOXIDE	215-481-4	28.10.2008	CARCINOGENIC (ARTICLE 57A)
DIBUTYL PHTHALATE (DBP)	201-557-4	28.10.2008	TOXIC FOR REPRODUCTION (ARTICLE 57C)
DIISOBUTYL PHTHALATE	201-553-2	13.01.2010	TOXIC FOR REPRODUCTION (ARTICLE 57C)
HEXABROMOCYCLODODECANE (HBCDD) AND ALL MAJOR DIASTEREOISOMERS IDENTIFIED: ALPHA-HEXABROMOCYCLODODECANE BETA-HEXABROMOCYCLODODECANE GAMMA-HEXABROMOCYCLODODECANE	247-148-4 AND 221-695-9 (134237-50-6) (134237-51-7) (134237-52-8)	28.10.2008	PBT (ARTICLE 57D)
LEAD CHROMATE	231-846-0	13.01.2010	CARCINOGENIC AND TOXIC FOR REPRODUCTION (ARTICLES 57A AND C)
LEAD CHROMATE MOLYBDATE SULPHATE RED (C.I. PIGMENT RED 104)	235-759-9	13.01.2010	CARCINOGENIC AND TOXIC FOR REPRODUCTION (ARTICLES 57A AND C)
LEAD HYDROGEN ARSENATE	232-064-2	28.10.2008	CARCINOGENIC AND TOXIC FOR REPRODUCTION (ARTICLES 57A AND C)
LEAD SULFOCHROMATE YELLOW (C.I. PIGMENT YELLOW 34)	215-693-7	13.01.2010	CARCINOGENIC AND TOXIC FOR REPRODUCTION (ARTICLES 57A AND C)
PITCH, COAL TAR, HIGH TEMP.	266-028-2	13.01.2010	CARCINOGENIC, PBT AND VPVB (ARTICLES 57A, 57D AND 57E)
SODIUM DICHROMATE	234-190-3 (7789-12-0 AND 10588-01-9)	28.10.2008	CARCINOGENIC, MUTAGENIC AND TOXIC FOR REPRODUCTION (ARTICLES 57A, 57B AND 57C)
TRIETHYL ARSENATE	427-700-2	28.10.2008	CARCINOGENIC (ARTICLE 57A)
TRIS(2-CHLOROETHYL)PHOSPHATE	204-118-5	13.01.2010	TOXIC FOR REPRODUCTION (ARTICLE 57C)
ZIRCONIA ALUMINOSILICATE REFRACTORY CERAMIC FIBRES *ARE FIBRES COVERED BY INDEX NUMBER 650-017-00-8 IN ANNEX VI, PART 3, TABLE 3.2 OF REGULATION (EC) NO 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 16 DECEMBER 2008 ON CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES, AND FULFIL THE TWO FOLLOWING CONDITIONS:* *A) AL_2O_3, SIO_2 AND ZRO_2 ARE PRESENT WITHIN THE FOLLOWING CONCENTRATION RANGES:*	-	13.01.2010	CARCINOGENIC (ARTICLE 57A)

• *Al_2O_3: 35 – 36 % w/w, and* • *SiO_2: 47.5 – 50 % w/w, and* • *ZrO_2: 15 - 17 % w/w,* *b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm).*			

1) The substance does not meet the criteria for identification as a carcinogen in situations where it contains less than 0.005 % (w/w) benzo[a]pyrene (EINECS No 200-028-5)
2) The substance does not meet the criteria for identification as a carcinogen in situations where it contains less than 0.005 % (w/w) benzo[a]pyrene (EINECS No 200-028-5) and less than 0,1 % w/w benzene (EINECS No 200-753-7).]
3) The substance does not meet the criteria for identification as a mutagen in situations where it contains less than 0,1 % w/w benzene (EINECS No 200-753-7).]

Annex 3 Useful links to the ECHA website

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

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

Registry of Intentions
List of pre-registered substances
Registered substances
Candidate List
First Annex XIV Recommendation
Evaluation – Annual progress reports
Substances of interest for downstream users

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

Testing proposals
Harmonised C&L
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
PPORD
Inquiry
Registration numbers for NONS
Notification to the C&L inventory
REACH-IT Industry User Manuals

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

Software application for preparing REACH compliant dossiers

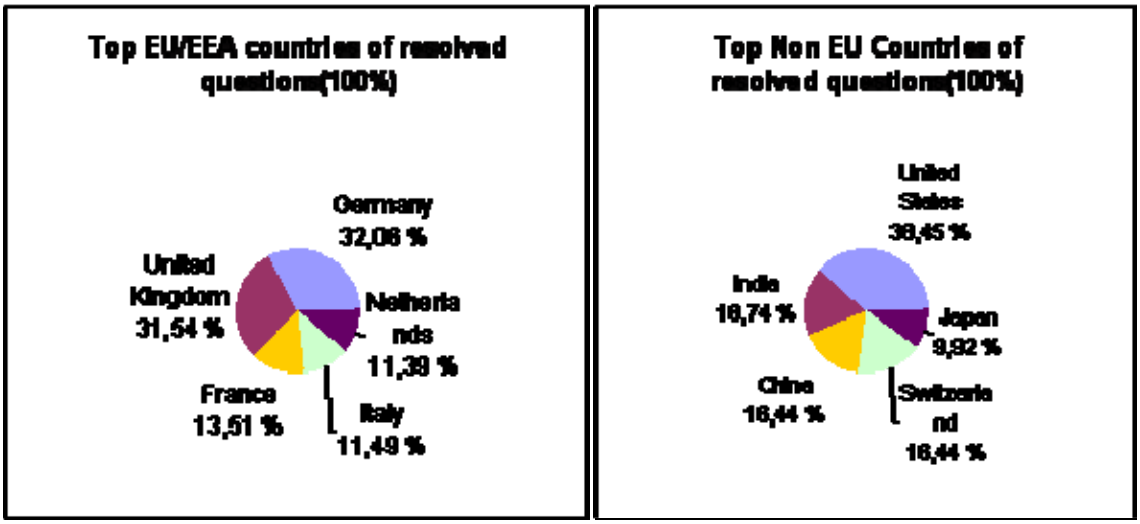
REACH and CLP Guidance: http://guidance.echa.europa.eu/

Publications: http://echa.europa.eu/publications_en.asp

Annex 4 Helpdesk statistics

Incidents received

Topic		Number of Qs Resolved	Number of Qs Resolved within Resolution Time <= 15 WD	Number of Qs Resolved within Resolution Time > 15 WD	% of Resolved with in Timeframe	Avg Resolution Time of Qs Resolved
REACH		1521	1027	494	68	14
IUCLID 5		1020	727	293	71	12
REACH-IT	Other	2788	2281	507	82	8
REACH-IT	User Account	1164	1031	133	89	5
Submissions	1st Level	65	63	2	97	4
Submissions	2nd Level	768	542	226	71	14
Total		7326	5671	1655	79	9



RHEP / HELPEX

Number of posted / opened questions by Member States	112			
Number of comments by ECHA those that were posted	110	- >	76	% of comments provided within the timeframe
Average deadline of posted question	41.2	days		
Average time to comment by ECHA	27.6	days		

Annex 5

Analysis and Assessment of the AAR of the Authorising Officer for 2009

Helsinki, 27 April 2010

Doc: MB/13/2010 final

ANALYSIS AND ASSESSMENT OF THE ANNUAL ACTIVITY REPORT OF THE AUTHORISING OFFICER FOR THE YEAR 2009

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 2009 adopted by the Management Board at its meeting of 25 September 2008,

Having regard to the Annual Activity Report of the Authorising Officer of the European Chemicals Agency for the year 2009 signed by the Executive Director on 12 April 2010,

1. Welcomes the results presented in the Annual Activity Report of the Authorising Officer as well as the performance level achieved with regard to discharging the tasks under the REACH Regulation (EC) 1907/2006 and the CLP Regulation (EC) No 1272/2008.

2. Congratulates the ECHA Secretariat for the operational work performed in 2009 and, in particular, for the achievements in:

   (a) Improving the quality of the list of pre-registered substances which facilitated the Substance Information Exchange Fora (SIEF) creation process of companies that have pre-registered the same substance.

   (b) Proactively supporting the process for establishing SIEFs between companies through a comprehensive awareness-raising campaign, a SIEF websection, dedicated helpdesk support as well as the organisation of conferences and workshops.

(c) Providing enhanced technical assistance to companies in fulfilling the obligations related to the registration of chemicals. Important elements of this were the release of an IT tool to allow verifying the technical completeness of a registration dossier before submission to the Agency and the high number of REACH-IT manuals for industry.

(d) Building up capacities in relation to the evaluation and classification and labelling tasks; and making a credible start with these new procedures, in particular by taking the first decision on a testing proposal following unanimous agreement in the Member State Committee and adopting the first scientific opinion on a harmonised classification and labelling for one substance of concern.

(e) Making progress with the further development of the authorisation process for substances of very high concern by submitting, in time by 1 June 2009, the first recommendation to the Commission for inclusion of substances into the authorisation list (Annex XIV of the REACH Regulation). Moreover, the right for the public to know about substances of very high concern was enhanced as a result of the unanimous agreement in the Member State Committee to add 15 new substances on the candidate list for authorisation, taking into account over 300 comments received during public consultations.

(f) Assisting the Forum for exchange of information on enforcement in its first coordinated enforcement project on pre-registration, registration and safety data.

3. Appreciates the commitment demonstrated by the ECHA management and staff in taking up the new tasks under the CLP Regulation which entered into force on 20 January 2009, especially by promptly establishing Helpdesk support for CLP and merging the two helpdesk networks into a single HelpNet.

4. Welcomes that ECHA Secretariat has invested substantial work and resources to start making guidance documents available in all Community languages but recognises that significant further efforts are necessary and therefore supports the management in its commitment to further expand the manuals on tools and documentation available to industry in the languages of the European Union.

5. Acknowledges the launch of the public dissemination webpage containing non-confidential information on chemical substance and encourages the Agency to continue the efforts towards bringing the provisions of Article 119 of the REACH Regulation to full effect.

6. Notes the high quality of the scientific advice provided by the Agency on request by the Commission, in particular in relation to the preparation of a legislative proposal for a regulation on biocidal products, the technical work on developing a regulatory framework for chemical substances on nano-scale and on alternative testing methods that may reduce the use of test animals.

7. Welcomes that the scientific Committees are smoothly working and involving, to the extent possible, observers from the stakeholder organisations, and commends the Member State Committee's success in finding unanimous agreements in its field of competence.

8. Expresses its satisfaction with the progressive stakeholder policy applied by ECHA and the efficient communication tools developed for interacting with stakeholders.

9. Notes that the appeal procedure provided for in the REACH Regulation is functional and attains its purpose of avoiding, to the extent possible, unnecessary court proceedings.

10. Congratulates the Agency meeting again its recruitment target in 2009, managing to increase the staff by 40% compared to the year before by recruiting 83 temporary and 17 contract agents.

11. Appreciates the Agency's efforts to achieve a high execution rate of the budget and securing the reimbursable 2010 subsidy, which will help it to bridge the period when fee revenue will be below payments.

12. Welcomes the results of the audits performed in 2009 and the determined follow-up of these audits by the management which demonstrates that the risk management mechanisms are functioning efficiently; acknowledges the establishment of an Integrated Quality Management System and the steps undertaken towards addressing business continuity issues.

13. Notes that – despite tight time tables - the Agency has implemented most of the planned scientific IT-projects either on time or with acceptable delays, including several upgrades of the central REACH-IT system. Highlights that the timely further development of the system prior to the first registration deadline of the REACH Regulation remains a crucial task for ECHA in 2010.

14. Emphasises the importance of the Agency's endeavour to successfully resolve the difficulties related to the access of Member State authorities to the REACH-IT system, and appreciates the Agency's commitment to strong protection of physical and information security.

15. Notes that in line with the risks identified, the Agency has undertaken every reasonable effort to reassess the estimated number of registration dossiers that will be submitted by industry in 2010; and, as this exercise has not yielded sufficiently comforting results, diverted resources to prepare detailed contingency plans for 2010.

Adopted by the Management Board in a written procedure on 27 April 2010.