ECHA
European Chemicals Agency

General Report 2010

The year of registration

General Report 2010

Reference: ECHA-11-A-01-EN
MB/03/2011 adopted on 24 March 2011
ISBN-13: 978-92-9217-533-7
ISSN: 1831-712X
Publ.date: April 2011
Language: EN

This document will be available in the following 22 languages:

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

If you have questions or comments in relation to this document please send them (quote the reference and issue date) using the information request form. The information request form can be accessed via the Contact ECHA page at: http://echa.europa.eu/about/contact_en.asp

European Chemicals Agency

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Annankatu 18, Helsinki, Finland

Table of contents

ACRONYMS

ABAC	ABAC is the accounting system of the European Commission and ECHA
ACSHW	Advisory Committee on Safety and Health at Work
BC	Business Continuity
BO	Business Owner
C & L	Classification and Labelling
CASPER	IT Characterisation Application for Selection, Prioritisation, Evaluation and Reporting
CEFIC	European Chemical Industry Council
CHESAR	Chemical Safety Assessment and Reporting tool
CLH	Harmonised Classification & Labelling
CMR	Carcinogenic, Mutagenic, Reprotoxic
CLP	Classification, Labelling and Packaging
COM	European Commission
CoRAP	Community Rolling Action Plan
DCG	Directors' Contact Group
DG ENV	Directorate General for the Environment of the European Commission
DG ENTR	Directorate General for Enterprise and Industry of the European Commission
EC	European Commission
ECHA	European Chemicals Agency
ECM	Enterprise Content Management
EC TAIEX	European Commission Technical Assistance and Information Exchange instrument for partner countries
EEA	European Economic Area
EFSA	European Food Safety Authority
ENP	European Neighbourhood Policy
ENVI	European Parliament Committee for Environment, Food Safety and Public Health
EP	European Parliament
ETUC	European Trade Union Confederation
EU	European Union
EU-OSHA	European Agency for Safety and Health at Work
FAQ	Frequently Asked Questions
HELPEX	HelpNet Exchange
HELPNET	REACH and CLP Helpdesk Network
HR	Human Resources
IAC	Internal Audit Capability
IAS	Internal Audit Service of the European Commission
IPA	Instrument for Pre-Accession Assistance
IQMS	Integrated Quality Management System
ICT	Information and Communication Technologies
IT	Information Technologies
IUCLID	International Uniform Chemical Information Database
MB	Management Board
MEP	Member of the European Parliament
MSC	Member State Committee
MSCA	Member State Competent Authority
OECD	Organisation for Economic Cooperation and Development
OR	Only Representative
PBT	Persistent, Bioaccumulative, Toxic
PPORD	Product and Process Oriented Research and Development
QSAR	Quantitative Structure-Activity Relationships
Q&A	Questions & Answers

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
RIPE	REACH Information Portal for Enforcement
RIP-oN	REACH Implementation Projects on Nanomaterials
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SCOEL	Scientific Committee on Occupational Exposure Limits
SEAC	Socio-Economic Analysis Committee
SIDS	Screening Information Data Set
SIEF	Data Sharing & Substance Information Exchange Forum
SME	Small and Medium-sized Enterprise
SVHC	Substance of Very High Concern
TCC	Technical Completeness Check
UNECE SC GHS	Subcommittee of the United Nations Economic Commission for Europe on the Globally Harmonized System for classification and labelling of chemical substances and mixtures
US EPA	United States Environmental Protection Agency
WHO	World Health Organisation
WG	Working Group
W/W	Weight by Weight

FOREWORD BY THE EXECUTIVE DIRECTOR

"The year of registration"

Welcome to the European Chemical Agency's General Report for 2010. I look back at 2010 with great pride and satisfaction – and a little exhaustion. It was an extremely challenging time for us in ECHA but also a momentous year for the European Union as a whole, because we now have the first tangible results of the most ambitious piece of chemicals legislation in the world.

Around the end of 2010, two important deadlines for REACH and the Classification, Labelling and Packaging (CLP) Regulation passed. In response to those deadlines, ECHA received 25 000 registration dossiers on 4 300 chemical substances that are either commonly used in Europe or are the most hazardous; and over 3 million notifications for over 100 000 substances that are classified and have to be labelled to protect the user.

Thanks to this massive effort from industry, the Member States and ECHA, we now have a unique set of information on the chemicals in use in Europe today. This information will grow and improve over time, but already we have access to more knowledge on chemicals than there has ever been before – anywhere in the world. Furthermore, the work of industry in preparing their registration dossiers is already resulting in the safer handling of chemicals due to the assessments undertaken by companies on registered substances, and the resulting implementation of any necessary risk management measures identified during the preparation of registration dossiers. I and all my colleagues here in ECHA are immensely proud to have played our part in this endeavour.

It is clear from the number of registrations and notifications that companies have taken their responsibilities under the law seriously. It also reveals that they have risen to the considerable challenge to work together with their competitors to bring about the aims of the legislation – submitting dossiers and notifications and avoiding unnecessary animal testing by sharing data. This wealth of information on substances has a number of very significant implications for the protection of human health and the environment:

- Better informed regulatory and enforcement action
- More effective risk management for hazardous chemicals
- More consistent classification of hazardous substances
- Greater clarity on the hazards and risks of substances for workers and citizens, and
- Greater understanding amongst civic society of the hazards and risks of substances in use today.

I am delighted to pay tribute to all those that have made 2010 such a significant and successful year.

Geert Dancet
Executive Director

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 the classification of substances and mixtures, and the rules on labelling and packaging. The hazardous properties of chemicals cover 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.

MAIN ACHIEVEMENTS 2010 - SUMMARY

The year 2010 marked a major milestone in the implementation of the REACH Regulation, namely the first registration deadline, on 30 November 2010. By the deadline, ECHA had successfully received 25 000 comprehensive registration dossiers for 4 300 substances – this has never been achieved in the world before. In their dossiers, registrants generated hazard data on the substances they manufacture or import, assessed the risks related to the use of these substances and recommended risk management measures when appropriate.

2010 saw REACH-IT successfully re-engineered to provide improved functionalities and efficiency for registrants and the Agency; IT tools were developed to allow companies to compile their dossiers efficiently, check the completeness of these dossiers and the information from them that will be published on the ECHA website, and to verify their level of fee payment prior to submitting the dossiers. The Technical Completeness Check (TCC) tool in particular was a huge success: after its release in December 2009 the TCC success rate has increased above 98%.

Another major achievement for the Agency was to receive over 3 million classification and labelling notifications from industry by 3 January 2011. ECHA developed three different ways for industry to submit C&L notifications: as a IUCLID dossier; on-line via REACH-IT; or in bulk, covering multiple substances or multiple notifiers. Notifiers could pick the tool of their preference, most suited to their own business needs. The bulk tool, with its extensive help sections, was available in all languages from May 2010.

Important elements in ensuring the smooth submission of registration dossiers and C&L notifications were the Helpdesk services and the necessary guidance provided by the Agency to industry.

As dossier evaluation will be the next major challenge for the Agency following the registration deadline, strong emphasis was put on organising the staff involved into several multidisciplinary teams, which resulted in a significant increase in the number of dossiers under evaluation, while at the same time integrating new staff and reinforcing internal scientific competences. Moreover, ECHA worked on IT tools which should improve the efficiency of the process to allow several hundreds of dossier evaluations per year to be handled simultaneously.

As planned, ECHA updated the Candidate List of Substances of Very High Concern twice in 2010, adding 16 substances to the Candidate List – bringing the total number of substances on the List to 46 – and submitted its second recommendation for the inclusion of priority substances in the Authorisation List to the Commission, in December. Inclusion of eight substances from the Candidate List was recommended and suggestions for the application and sunset dates were made. Both the preparation of the Candidate list and the recommendation concerning the Authorisation List were preceded by public consultations.

Four restriction dossiers were processed during the year, one of which was prepared by ECHA and three by the Member States, and were submitted to RAC and SEAC for opinion.

During 2010 a total of 81 CLH proposals were received, of which almost half of the dossiers were submitted during December. Nevertheless, 30 accordance checks were performed and RAC adopted its scientific opinion on 16 proposals.

The year was a very busy one for all three ECHA Committees: all dossiers were processed by the Committees within the legal timeframe, while opinions or agreements were adopted by consensus or unanimously and were of a high quality.

In 2010, ECHA also concluded its first cooperation agreements with third countries. A Memorandum of Understanding was signed with Environment Canada and Health Canada in May

and a Statement of Intent late in the year with the US EPA Office of Pollution Prevention and Toxics.

One of ECHA's objectives under the REACH Regulation is to publish, free of charge on the internet, information it holds on registered substances. By the end of 2010, the dissemination portal on the ECHA website contained information on 383 substances.

The Agency continued its rapid growth as more than 120 new staff members were recruited during the year. Management and administrative policies and processes were developed and progress was made, in particular, in the fields of security, quality management and risk management.

OPERATIONAL ACTIVITIES – IMPLEMENTATION OF THE REACH AND CLP PROCESSES

Activity 1: Registration, Pre-registration and Data-sharing

Main Achievements in 2010

Registration

The year 2010 marked a major milestone in the implementation of the REACH Regulation, namely the first registration deadline, on 30 November 2010. One of the main goals of the registration process is for manufacturers and importers to generate data on the substances they manufacture or import, to use this data to assess the risks related to these substances, and to develop and recommend appropriate risk management measures, thus contributing to a higher level of protection of human health and the environment throughout the EU. Despite the uncertainties that prevailed both among industry and authorities on the number of registration dossiers expected, as well as on the number of substances that these dossiers would cover, ECHA rose to the challenge and had its staff, procedures, IT tools and support to registrants in place to allow smooth registration.

In order to manage these uncertainties, the Agency began preparations in early 2009 and put contingency plans in place to handle up to 75 000 dossiers during the year. ECHA recruited interim staff for dossier processing and also trained 75 existing staff members to be redeployed swiftly in case of submission peaks. An important watershed was reached early in October when most of the steps in the dossier submission process were automated in REACH-IT, which enabled human intervention to be kept to a minimum.

In addition to ECHA's own preparatory activities, a Directors' Contact Group (DCG) – composed of Directors of the Commission, ECHA, and six industry associations, was established in early 2010 as a temporary structure, to monitor industry's preparedness towards the first registration deadline and to identify solutions when needed to practical problems faced by registrants. In this context, ECHA launched several surveys in close collaboration with the industry associations in order to refine the estimates of the number of phase-in substances covered by the 2010 deadline[1] and of the number of registration dossiers expected to be submitted for those substances. A list of the substances identified in the surveys in 2010 was published on the ECHA website in April 2010, and was updated regularly based on feedback received from manufacturers, importers as well as from Lead Registrants.

By 1 December 2010, ECHA received close to 25 000 registrations covering almost 4 300 distinct substances, of which 3 400 were phase-in substances covered by the deadline. ECHA observed two peaks in the submission of registrations: one in September, when Lead Registrants submitted their dossiers to benefit from a shorter deadline for completeness checks by ECHA, and a steeper one in late November, close to the registration deadline itself. ECHA was able to process the dossiers smoothly even during these peak periods: in September, the Agency was able to rely on interim and existing staff trained for the purposes of temporary redeployment, while in November extra staff input was not required as the majority of the dossier submission processes had been automated in REACH-IT.

[1] Phase-in substances manufactured or imported in quantities greater than 1000 tonnes per year per manufacturer or importer, phase-in substances manufactured or imported in quantities greater than 100 tonnes per year per manufacturer or importer and classified as very toxic to aquatic organisms which may cause long-term adverse effects in aquatic environments and phase-in substances classified as carcinogenic, mutagenic or toxic to reproduction and manufactured or imported in quantities greater than 1 tonne per year per manufacturer or importer.

ECHA also set up the processes to implement a number of solutions identified by the DCG. The solutions were designed for diligent registrants who, due to unexpected circumstances beyond their control, faced practical difficulties in complying with their registrations obligations in time. In the end the situations proved to be exceptional, as foreseen by the DCG, with only a few companies qualifying and benefiting from the solutions established.

The number of registration dossiers received by the November deadline was in line with the baseline scenario foreseen by the Agency, while the number of substances was lower than indicated in the ECHA and industry surveys carried out earlier in the year. Additional registrations were received after the deadline, bringing the overall number of registrations submitted in 2010 to just over 25 600. It was the first time any authority in the world had collected such a large amount of information on the properties of chemical substances, to be disseminated to the general public and utilised in other REACH processes such as evaluation, restriction and authorisation. Overall, the registration process was deemed a success both by authorities and industry.

The vast majority of the registrations were submitted by large companies, as expected, taking into account the affected tonnage bands. Ninety percent of the dossiers concerned substances manufactured or imported in quantities over 1000 tonnes per year, and 25% of the dossiers accounted for substances registered as intermediates solely. Most registrations were submitted as part of joint submissions despite the difficulties reported during the formation and management of SIEFs (cost sharing arguments and communication problems). Only Representatives, acting on behalf of non-EU manufacturers, submitted almost one fifth of the registrations.

While registration dossiers were to be prepared by industry, ECHA put considerable resources into supporting the registrants in this demanding activity. The rate of dossiers accepted for processing and successfully passing the technical completeness check continuously improved throughout the year, bringing the success rates up to 80% and 98% respectively, in the final two months before the deadline. The overall understanding of ECHA is that all companies that were determined to register by the deadline were able to do so, with additional support from the Agency where it was necessary.

Close to the deadline, focus was put on addressing downstream users' uncertainties on whether substances of interest to their supply chains would be registered and whether their uses would be covered by these registrations. To help downstream users monitor the progress of the registration process, a list of phase-in substances for which ECHA had received a dossier was updated weekly on its website.

Data sharing

ECHA has a limited role in settling data sharing disputes according to the REACH Regulation. In the first semester of 2010 ECHA established its procedures and principles, and published them on its website in July. These guidelines affect the data and cost sharing of future registrants up to 2018 and beyond. Throughout the year ECHA was informed that in some cases there were severe problems among the registrants in the areas of data-sharing in general and cost-sharing in particular: very few of these disputes reached ECHA.

While the number of actual data-sharing disputes remained low, the number of inquiries enabling potential and previous registrants of the same substance to be put in contact started to increase rapidly towards the end of the year. Altogether, ECHA received almost 1 600 inquiries in 2010, of which more than 50% arrived in the last quarter of the year. A considerable proportion of these inquiries was for phase-in substances, and hence does not represent new substances on the European market. The peak in the submission of inquiries, combined with problems in the quality of the substance identification information provided by inquirers, resulted in some delays in processing the dossiers. ECHA informed the affected companies about the expected delay and requested that they pay attention to the substance identification requirements for inquiries set by REACH.

Dissemination

One of ECHA's objectives under the REACH Regulation is to publish, free of charge on the internet, information it holds on registered substances. By the end of 2010, the dissemination portal on the ECHA website contained information on 383 substances. Due to the need to focus the Agency's scarce resources on the smooth operation of the first registration deadline, the dissemination project allowing for public access to information on substances via the internet, progressed relatively slowly.

However, a lot of preparatory action took place to ensure swift dissemination of the information in 2011: the strategy for dissemination was reviewed within the Management Board, in particular by its advisory group on dissemination which includes three representatives from interested parties; while two manuals on the topic were also published.

In the last quarter of the year, ECHA also started the assessment of confidentiality claims. About 4% of the registration dossiers received in 2010 contained one or more confidentiality claims. ECHA first verifies whether a claim is made in accordance with Article 119(2) of REACH after which it assesses the justification made by the registrant.

Objectives and Indicators

Objectives

1. All dossiers and data sharing disputes are processed, and PPORD notifications and confidentiality claims evaluated, according to the standard procedures adopted by ECHA and within the deadlines set in the REACH regulation.
2. Inquiries are processed according to the standard procedures adopted by ECHA, within the target timeframe of 20 working days.

Performance Indicators & Targets

Indicator	Target in 2010	Means and frequency of verification	Result 2010
Percentage of registrations, PPORD notifications, and data sharing disputes processed within the legal timeframe.	100%	Time recorded in REACH-IT monthly reporting	100%
Percentage of inquiries processed within the established timeframe (20 working days).	Not less than 90%	Time recorded in REACH-IT monthly reporting	75%
Number of appeals made by registrants and notifiers against decisions.	Not more than 10% of decisions	Monitoring responses to decisions monthly	0%

Main Outputs

- Contingency plans were set up during the first quarter to increase the Agency's capacity to process up to 75 000 of registration dossiers, if needed.
- 26 interim staff were recruited for dossier processing and 75 existing staff trained to be redeployed swiftly in case of submission peaks.
- Detailed and precise specifications were developed for the enhancement of REACH-IT, so that the majority of procedures could be automated.
- Up-to-date manuals, guidance and other information produced for registrants.
- Incoming dossiers were processed, invoices sent and payments received, according to the appropriate deadlines.
- 16 data-sharing disputes were brought to ECHA, which issued decisions on 9 of them.

Table 1: Number of submissions successfully completed in 2010[2]

Dossier type	Successfully completed
	Total
Registrations	18 956
Transported Isolated Intermediates	3 425
On-site Isolated Intermediates	1 373
Total	**23 754**

Table 2: Breakdown of submissions in 2010

Type	% Successfully Completed
Joint – Lead Registrant	12%
Joint – Member Registrant	81%
Individual Registrant	7%
	100%

Table 3: Percentage of registration dossiers by company size (successfully completed)

Company size	Successfully completed
	Total 2010
Large	87%
Medium	8%
Small	4%
Micro	1%
Total	100%

[2] Successfully completed: dossiers that successfully went through the registration process and received a registration number. The total number of dossiers submitted by industry in 2010 is thus even higher, at 25,616.

Main Achievements in 2010

In 2010, an increasing number of registration dossiers were submitted by registrants covering mostly phase-in substances that were to be registered by the November deadline. Dossiers submitted in 2009 or in the first semester of 2010 were used to build further ECHA's knowledge on the quality of dossiers through the execution of compliance checks and the examination of testing proposals, while an increasing number of dossiers were dealt with under dossier evaluation. However, most of the dossiers arrived only in the last three months before the deadline and therefore only a limited number of dossier evaluations on phase-in substances were concluded in 2010. Nevertheless, 70 compliance checks and 4 testing proposal examinations were completed in 2010.

As a prerequisite to handling complex dossiers on high tonnage substances, ECHA continued capacity building by recruiting, training and integrating new staff, as well as by reinforcing internal scientific competences and networking with external experts. Moreover, ECHA worked to improve the efficiency of the process in order to handle simultaneously several hundreds of dossier evaluations per year. The expert-based decision support system was further developed in 2010 to support the work in 2011: it will guide evaluators by using standardised questions and instructions and will increase the time available for scientific decision making.

Both dossier evaluation processes comprise tasks where the ECHA secretariat makes scientific and legal judgments. The information contained in registration dossiers is compared with the requirements in the legal text. Substance identity, physical-chemical properties, structure activity relationships, toxicology, epidemiology, occupational hygiene, environmental effects and fate, classification and labelling, exposure assessment, risk characterization and management, are scientific elements that are needed in order for science based and robust evaluation decisions to be reached.

Based on the experiences in dossier evaluation up to the spring of 2010, it was concluded that communication with registrants on the evaluation outcome would facilitate the evaluation process. ECHA decided to provide registrants with the opportunity to receive additional scientific and legal background information on draft decisions via informal interaction in a pilot project. This interaction does not replace the formal process for a registrant to comment, and the obligation to provide further information via an updated dossier. Overall, the interaction has been perceived positively by registrants.

Further improvements to the general advice given to registrants regarding evaluation issues have been achieved in 2010: for example, in the annual progress report on REACH evaluation for 2009, published on ECHA's website in February 2010, detailed recommendations were provided to registrants.

A common understanding of the relationship between the examination of testing proposals and compliance check is essential for the functioning of the decision making within the regulatory framework of the REACH Regulation. A workshop was organised by ECHA in April 2010 on the scope of the examination of testing proposals. Agreement was reached that the decision on a testing proposal *per se* should address only the end point addressed by the testing proposal. The examination of the testing proposal should also, as appropriate, include the examination of the results of tests that are directly interlinked with the test proposed. ECHA should not open a compliance check automatically when a testing proposal is being examined. However, observed data gaps should not be ignored and they could possibly lead to compliance check decisions.

ECHA started to prepare for a major new sub-activity in 2010, namely substance evaluation. In October, it hosted a workshop to discuss the scope of substance evaluation, the criteria to be

used for prioritising and selecting substances for substance evaluation, and the process for the establishment of the Community Rolling Action Plan (CoRAP). An agreement on the general scope of substance evaluation was reached between Member State representatives and ECHA, and with regard to the prioritisation criteria for substance evaluation, there was a general agreement that the criteria should cover hazard and exposure aspects, and that they should be flexible and simple in the initial stage of the CoRAP development. With experience, the criteria will be further refined and developed. There was also general agreement with regard to the process and the timelines proposed for the establishment of the first CoRAP. The CoRAP will cover a period of three years and will be updated every year. Member States were invited to reflect on their substance evaluation capacity for the coming years.

In the same workshop, ECHA addressed its systematic approach for selecting dossiers for compliance checks based on a pragmatic set of criteria. Such criteria have been developed and used increasingly in 2010, as dossier numbers submitted for registration increased. The criteria are flexible and allow an evolution over time. ECHA is currently prioritising dossiers for compliance check based on criteria set out in REACH, random selection, and concern driven selection. With respect to concern driven selection, ECHA developed two types of criteria: criteria linked to the likelihood of incompliance and criteria related to the relevance for safe use in case of a potential incompliance. The criteria can be combined and optimised, in order to make best use of the available resources.

Objectives and Indicators

Objectives

1. Scientifically sound draft decisions in compliance with the legal requirements are prepared.

Performance Indicators & Targets

Indicator	Target in 2010	Means and frequency of verification	Result 2010
Percentage of compliance checks treated within the legal timeframe.	100%	Quarterly internal report	100%
Percentage of testing proposals examined within the legal timeframe.	100%	Quarterly internal report	100%
Percentage of the draft decisions accepted unanimously by the MSC.	90%	Annual internal report	100%
Number of appeals lost.	0	Annual internal report	0

Main Outputs

- The annual progress report on REACH evaluation was published in February 2010.
- New staff were recruited and integrated using specifically designed scientific and administrative/legal training, complemented by on-the-job training for junior staff. Advanced seminars and workshops were organised to maintain the scientific competence of more senior staff.
- Establishment of the criteria for prioritising substances for substance evaluation was successfully initiated.
- Tables 4 and 5 report on the statistics of the dossier evaluation processes in 2010. Detailed analysis of the 2010 evaluation statistics were provided in the annual progress report on REACH evaluation published on the ECHA website by 28 February 2011.

Table 4: An overview of the examination of testing proposals in 2010

Total[3]	Dossiers with vertebrate studies	Draft decisions[4]	Final decisions	Terminated[5]	Carry over to 2011[6]
123	99	8	4	3	116

Table 5: Compliance check overview

Output	Total	Break-down
Compliance checks completed in 2010	**70**	
• Final decisions		12
• Quality observation letters		33
• Concluded without action		25
Compliance checks ongoing at the year end and carried over from 2010 to 2011	81	
• **Of which draft decisions sent to the registrants**		**21**

[3] Total number of examinations of testing proposals in 2010, notwithstanding their current status.
[4] Draft decisions which did not become final by 31 December 2010.
[5] Terminated at the decision-making stage upon further information provided by the registrant (e.g. cease of manufacture, tonnage downgrade or withdrawal of a testing proposal).
[6] Examination of testing proposals which were not finalised by the end of 2010 and will continue in 2011.

Main Achievements in 2010

Authorisation

ECHA's tasks relating to authorisation include preparing and updating the so called 'Candidate List' of Substances of Very High Concern (SVHCs); regularly preparing a recommendation to the European Commission on substances from the Candidate List to be included in the so called 'Authorisation List' – the List of Substances Subject to Authorisation (Annex XIV); and, in the future, handling authorisation applications.

Work on screening and selecting substances which could be identified as SVHCs is developing well, in close collaboration with the Member States and the European Commission. Identifying substances for which Candidate listing and possible inclusion in Annex XIV are effective regulatory instruments to protect human health and the environment, appears to require considerable effort. The number of substances that have been added to the Candidate List in 2010 may not be sufficient to reach the objective expressed by the European Commission in March 2010.

ECHA received 19 new proposals for the identification of Substances of Very High Concern from MS, which was less than expected. After the public consultations, during which more than 620 different comments were received, the Member State Committee reached an agreement on the SVHC status of these substances, leading to eight of them being included in the Candidate List in June and eight in December 2010. Three substances were not included in the Candidate List because the Member State Committee considered that based on the information available it was not possible to conclude on the identification of these substances as SVHCs in accordance with Article 57(f) of the REACH Regulation. By the end of 2010 the overall number of SVHCs included in the Candidate List was 46.

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 to their customers or, upon request, to a consumer, sufficient information as is available to them, to allow safe use of the article.

Companies brought actions for annulment before the General Court challenging the identification by ECHA of 7 Substances of Very High Concern. In response, ECHA has prepared and filed with the General Court objections challenging the admissibility of these actions. An action by a company for interim measures in one case was rejected by the General Court[7].

As planned, ECHA sent its second recommendation for inclusion of priority substances on the Authorisation List to the Commission in December. Inclusion of eight substances from the Candidate List was recommended and suggestions for the application and sunset dates were made. The recommendation was supported by a positive opinion of the Member State Committee and took into account, where relevant, comments from interested parties – following the public consultation process that had taken place earlier in the year.

ECHA reviewed publicly available data on the uses of and exposures to 35 substances with CMR or PBT profiles to screen them preliminarily regarding the need to identify them as SVHCs / include them on the Candidate List, and regarding potential further risk management measures. On the basis of this preliminary screening, the Commission requested that ECHA

[7] Case T-1/10 R: Order of the President of the General Court of 26 March 2010.

work towards preparing dossiers for the identification of five substances as SVHCs: ECHA started to work on these substances in autumn 2010.

Whilst waiting for the Commission decision on the first Authorisation List, ECHA conducted a range of preparatory activities in order to provide the necessary support (guidance, formats and IT tools) to potential applicants, and to put in place internal processes and working procedures for handling authorisation applications. The aim is to be ready for processing applications for authorisation from the date of entry into force of the amended Annex XIV of REACH (21 February 2011).

Restrictions

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, upon the request of the Commission, proposals for introducing new restrictions or amending current ones.

ECHA prepared, on the basis of a request from the Commission, an Annex XV restriction dossier on the placing on the market and use of mercury in measuring devices. This dossier, which was submitted in June 2010, focused on the availability of safer, technically and economically feasible alternatives based on the review clause included in the current restriction on certain mercury containing measuring devices and the Commission's request.

Following the conformity checks by the Risk Assessment (RAC) and Socio-economic Analysis (SEAC) Committees, ECHA launched consultations on four restriction dossiers[8]. The public consultations were finalised in December and resulted in 60 comments in total. In parallel to the public consultation, the development of RAC and SEAC opinions on these four suggested restrictions was ongoing and will be finalised in 2011.

Upon a further request from the Commission, ECHA evaluated new scientific evidence concerning the restrictions on six phthalates contained in the Restrictions List[9] and submitted its review reports to the Commission in March. On the basis of comments received from Member States and stakeholders, ECHA finalised the review reports and published them on its website. The conclusion of these reviews was that the available information does not indicate a need for an urgent re-examination of the existing restrictions and that the Commission should decide whether further action is needed after the first registration deadline has passed. Following this recommendation the Commission requested in December 2010 that ECHA continue its work on phthalates.

Objectives and Indicators

Objectives

Authorisation

1. An updated candidate list of substances of very high concern (SVHC) is prepared within five months of receipt by ECHA of dossiers from Member States, or the submission of dossiers prepared by ECHA on the request of the Commission.
2. ECHA provides support to the Commission, of high technical and scientific quality and within the legal timeframe, in the selection of substances for authorisation and in the authorisation application process.

[8] France submitted restriction dossiers for the placing on the market and use of DMFu in articles and for the placing on the market and use of lead in jewellery in April 2010. Norway submitted a restriction dossier for the manufacturing, placing on the market and use of five phenylmercury substances in polyurethane applications in June 2010.

[9] Annex XVII of REACH

Restrictions

1. ECHA prepares restriction proposals at the request of the Commission and handles all dossiers in the restriction process to a high degree of scientific and technical quality and within the legal timeframe.

Performance Indicators & Targets

Indicator	Target in 2010	Means and frequency of verification	Result 2010
Percentage of SVHC dossiers treated within the legal timeframe.	100%	Internal quarterly report	100%
Percentage of restriction dossiers treated within the legal timeframe.	100%	Internal quarterly report	100%
Level of satisfaction of the Commission, MSCAs and ECHA Committees with the quality of the scientific, technical and administrative support provided.	High	Annual survey	MSCA: Medium COMMITTEES: High COM: High

Main Outputs

- The Candidate List was updated twice.
- Eight substances were prioritised from the Candidate List and a recommendation for their inclusion in Annex XIV was submitted to the Commission.
- Conformity checks on the three restriction dossiers submitted to ECHA were carried out and the public consultations and opinion forming were initiated.
- A restriction dossier for mercury in measuring devices was prepared by ECHA and the public consultation and opinion forming on the suggested restrictions were initiated.
- Review reports on 6 restricted phthalates were prepared and submitted to the Commission.
- Examples for industry on the exposure scenarios were developed and published on ECHA's website.
- Workshops on the health and environmental impacts and on abatement costs of chemicals were organised.
- To support the Member States in preparing restriction reports guidance on how to calculate compliance costs was published.

Main Achievements in 2010

Classification reflects the hazards of chemicals, and labelling helps providing the necessary information to ensure that substances and mixtures are manufactured, used and disposed of safely.

Harmonised classification and labelling (CLH)

The main tasks under this activity in 2010 were to manage proposals for the harmonisation of the classification and labelling of substances (CLH proposals). An increasing number of CLH proposals were received from Member State Competent Authorities. In addition, ECHA received the first CLH proposal from industry. In total, 81 proposals were received in 2010, which was very close to what was estimated. The total number of CLH proposals submitted in the period 2008 – 2010 amounted to 128.

During 2010, 30 accordance checks were performed. As almost half of the 81 dossiers were submitted during December, the accordance checks for most of the substances will only be finalized in 2011. For 30 substances, public consultation was launched and completed. The RAC discussed CLH proposals for 26 of these substances and was able to conclude discussions with an opinion for 16 substances.

C&L inventory

ECHA is required to establish and manage a C&L inventory based on the notifications from industry. All hazardous substances placed on the market on 1 December 2010 and all substances subject to REACH registration (independently of their hazardous properties or respective deadlines) had to be notified at the latest on 3 January 2011. For substances already registered under REACH, no additional notification was required. ECHA received about 3.1 million notifications covering about 107 000 different substances. The number of notifications exceeded expectations by 50%. Several IT tools for submission of notifications were developed, tested and made available to industry during the year. Originally, it was foreseen that the first version of the inventory would be published during the year; however, as most notifications were received late in the year, and the development of the IT specifications for the inventory needed to be postponed, it was decided that the first version be published in 2011.

Requests for the use of alternative names for substances in mixtures

ECHA is also charged with handling requests for the use of alternative names of substances in mixtures according to Article 24 of the CLP Regulation. Companies can make such requests for substances with certain hazardous properties to protect confidential business information.

The processes for the request for use of alternative names were further developed during the year. As expected, at the time of writing ECHA was yet to receive any requests.

Objectives and Indicators

Objectives

1. All proposals for harmonised C&L sent by the Member State Competent Authorities (MSCAs) and industry are processed within the legal timeframe and to a high degree of scientific quality.
2. An intermediary C&L inventory will be published in December 2010.

Performance Indicators & Targets

Indicator	Target in 2010	Means and frequency of verification	Result 2010
C&L Inventory is operational and published.	December 2010	Through project management	Postponed to May 2011
Proposals for Harmonised C&L processed within legal timeframe.	100%	Internal quarterly report	100%
Level of satisfaction of the MSCAs and RAC with the quality of the. scientific, technical and administrative support provided.	High	Annual survey	MSCA: Medium RAC: High

Main Outputs

- C&L notification tools were elaborated and technical advice was provided to industry on the notification of substances to the C&L inventory. A public awareness raising campaign on the notification tools was successfully completed.
- 3 114 835 notifications for 107 067 substances were successfully received.
- The processes for the evaluation of requests for the use of alternative names were further developed. Development of a web form for dossier submission was launched and work on a IUCLID submission manual was almost completed.
- 30 CLH dossiers processed by ECHA.

Activity 5: Advice and Assistance through Guidance and Helpdesk

Main Achievements in 2010

Helpdesk

In the run-up to the first registration and C&L deadlines, the number of questions addressed to the Helpdesk was expected to increase considerably from the previous year. This expectation did indeed materialise, with the ECHA Helpdesk providing answers to nearly 10 000 questions regarding REACH and CLP requirements, and IT-related issues, submitted by different EU and non-EU customers during the year. The average resolution time was 10.1 working days and 84% of questions were answered within the established timeframe.

In October 2009, the ECHA Helpdesk had established a special service for registrants. As a part of the service, the Helpdesk addressed questions raised at several Lead Registrant webinars. In the context of the special service for registrants, a new activity was introduced from 15 June 2010 onwards – specifically, an outbound phone service to assist registrants and notifiers close to the first registration and notification deadlines.

The Network of REACH and CLP helpdesks (HelpNet) was used to promote the harmonisation of answers, particularly by promoting the use of the HelpEx tool (HelpNet Exchange) and also by organising harmonised updates of FAQ documents (REACH and CLP FAQs). The ECHA Helpdesk provided feedback to 204 HelpEx questions created by the national helpdesks and carried out 4 REACH and 5 CLP FAQ updates[10].

The HelpNet Secretariat organised two formal meetings of the HelpNet Steering Group in 2010, and developed a closer cooperation with the national REACH and CLP helpdesks, e.g. by visiting several of them. In addition, several training webinars were organised, with a specific session organised on C&L notifications and the different IT tools used for submitting notifications, to prepare the national helpdesks for the notification deadline.

Guidance

Throughout 2010, ECHA delivered high-quality guidance documents while ensuring the buy-in of stakeholders, with a view to providing advice and assistance to industry on the REACH and CLP Regulations. It was agreed in the Director's Contact Group in the first half of 2010 however, that the issuance of several guidance documents would be postponed until after the first registration deadline; this was done given that a strong need for stable guidance in the run-up to the deadline was detected, and as industry needed to focus their resources on registering and notifying in time – which would prevent them from contributing to consultation processes on guidance documents. Despite ECHA's decision on a moratorium on guidance updates (June - November 2010), most guidance updates and several new guidance documents were published as planned, either before or after the moratorium.

[10] ECHA publishes Frequently Asked Questions (FAQs) on REACH and CLP on its website, which address general situations and aim at assisting those who do not have detailed knowledge on REACH, CLP and ECHA's IT tools.

The accessibility of guidance was improved via the publication of two new *Fact Sheets*, several new dedicated internet pages for specific REACH and CLP processes and via the development of REACH terminology. ECHA also published 10 Practical Guides providing companies with practical information on best practice regarding REACH and CLP requirements. Furthermore, the REACH Navigator and some guidance related web pages were made available in 22 EU languages.

REACH and CLP training

REACH and CLP training was largely provided in the form of webinars in 2010, with the ECHA Helpdesk mainly contributing to the administration and follow up of Q&A sessions. The implementation of a training programme with special focus on the training of MSCAs (e.g. on access to REACH-IT MSCA functionalities) was postponed to 2011. Emphasis was then put on training national REACH and CLP helpdesks (via HelpNet trainings) due to the upcoming REACH registration and CLP notification deadlines.

During the Stakeholders' Day in October, training sessions on C&L notification tools and on the submission of registration dossiers were delivered.

Awareness raising activities on C&L notification and the IT tools to be used were highly promoted by ECHA in the Member States in 2010.

Objectives and Indicators

Objectives

1. The industry receives timely and efficient support from the Helpdesk, and through high quality guidance documents, for submission of their registration dossiers and CLP notifications.
2. Support is provided to the implementation of REACH in the Member States by the training of trainers.

Performance Indicators & Targets

Indicators	Target in 2010	Means and frequency of verification	Result 2010
Percentage of Helpdesk questions answered within the established timeframe (on average 15 days for questions other than those on the user management on REACH IT).	Not less than 75%	Business Object report / monthly	84%
Number of FAQ updates agreed with REACH and CLP helpdesk correspondents and published on the web. [11]	At least 3	Annual report	4
Percentage of feedback replies provided by ECHA to questions submitted to HelpEx by national helpdesks, within the timeframe set by the originator of the question.	Not less than 75%	Business Object report / monthly	86%
Percentage of guidance documents published on the web according to the plan.	Not less than 75%	Annual report	100%
Level of satisfaction expressed in feedback from guidance users.	High	Annual survey	Medium
Level of satisfaction with quality of REACH training events.	High	Participants feedback / Annual	High[12]

[11] Four FAQ updates were published on the ECHA website after agreement with the REACH and CLP helpdesk correspondents, while five more FAQ updates were published after the issues were addressed to the European Commission, without further consultation of the HelpNet Steering Group.
[12] The feedback stems from the REACH and CLP related training events for the HelpNet.

Main Outputs

Helpdesk

- Answers to 9 953 questions regarding REACH and CLP requirements and regarding IT-related issues provided.
- Comments on 204 HelpEx questions provided.
- Two REACH FAQs updated by written procedure and two REACH FAQs triggered by a European Commission decision. In addition, two CLP FAQs updated by written procedure and three CLP FAQs triggered by a European Commission decision.
- Two meetings of the HelpNet Steering Group organised; the latter one with a back-to-back training workshop on C&L notification providing hands-on advice. Also a REACH training workshop on Joint Submission for member registrants was delivered in the form of a webinar.
- Nine national Helpdesks visited in the context of the Helpdesks visits programme which ended in 2010.
- Organisation of one to one Q&A sessions to answer to individual questions at the two ECHA Stakeholders' Days in 2010.

Guidance

- Twelve guidance document updates and two new guidance documents published:
  - > Guidance on Use Descriptor System
  - > Guidance for Annex V
  - > Guidance on waste and recovered substances
  - > Guidance for intermediates
  - > Guidance on information requirements and chemical safety assessment
    - - Guidance on the Exposure Scenario Format
    - - Exposure scenarios describing strictly controlled conditions and conditions controlling releases from article matrices
    - - Guidance on exposure based adaptations
    - - Exposure scenario building and environmental release estimation for the waste life cycle stage
    - - Guidance on derivation of DNELs/DMELs from human data
    - - Tier 1 exposure estimates
      - - environmental exposure
      - - occupational exposure
      - - consumer exposure
  - > Guidance on Risk Communication
  - > Guidance on the preparation of dossiers for harmonised classification and labelling (CLH dossiers).

- Two Fact Sheets published:
  - > Fact Sheet on waste and recovered substances
  - > Fact Sheet on Use Descriptor System.

- Ten Practical Guides published:
  - > How to report in vitro data
  - > How to report weight of evidence
  - > How to report robust study summaries
  - > How to report data waiving
  - > How to report (Q)SARs
  - > How to report read-across and categories
  - > How to report changes in identity of legal entities
  - > How to notify substances in the C&L Inventory
  - > How to do a registration as a member of a Joint submission
  - > How to avoid unnecessary testing on animals.

- REACH Navigator and some guidance related web pages made available in the official EU languages as a way to increase the accessibility of guidance documents to industry, particularly to SMEs.

REACH and CLP training

- Seventeen webinars for targeted audiences organised and published on the ECHA website, with the presentations made available in the 22 official EU languages.
- Three webinars for REACH and CLP national helpdesks organised.
- Presentations and trainings provided on request during Helpdesk visits.

Table 6: Number, percentage and average resolution time of questions resolved during 2010

Topic		Number of questions resolved	%	Average resolution time (nr. of days)
REACH		1503	15.1%	15.5
CLP		374	3.8%	13.3
IUCLID 5		1829	18.4%	9.0
CHESAR		169	1.7%	9.1
REACH-IT		1197	12.0%	7.4
REACH-IT	User mgmt	2842	28.6%	4.1
Submissions		2039	20.5%	11.8
Total		**9953**	100%	**10.1**

Main Achievements in 2010

The focus of 2010 was on developing and/or enhancing IT tools to ensure the smooth submission and processing of registration dossiers and notifications to the C&L inventory. To this end, the main ECHA system, REACH-IT, was re-engineered to increase efficiency and scaled up to allow the receipt of up to 75 000 registrations and several million C&L notifications. All functions needed for industry users were delivered and frozen half a year before the registration deadline, while the milestone in the development of Agency functions was reached in early October when the majority of the dossier processing steps were automated. ECHA was also preparing for the eventuality that REACH-IT would not be able to handle a sudden peak in the incoming dossiers and developed a back-up system. Ultimately, the back-up system was not used as REACH-IT was able to process all submitted data without problems.

The IT tools for registrants and notifiers were also intensively developed throughout the year. IUCLID was adapted to the new CLP Regulation and the new version, IUCLID 5.2, was published in February 2010. It was complemented with plug-ins that allow registrants to check the completeness of their REACH registration dossiers; the information that will be disseminated on the ECHA website from their dossiers; and their registration fees, prior to submitting the dossiers. Of these, the technical completeness check plug-in in particular proved to be of high importance, as the success rate of the completeness check quickly rose above 90% after publication of the tool, and reached 98% by the deadline.

The ECHA tool for chemical safety assessment and reporting, CHESAR, was also published in 2010. Although the publication in May, followed by an update allowing full chemical safety report generation in July, was rather late for many companies preparing for the 2010 registration deadline, the feedback received from industry was very positive.

As the obligation to notify to the C&L inventory touched many more companies than the 2010 registration, and the companies were of a wide variety, it was important to offer different tools that suited the different business needs of notifiers. ECHA provided three tools altogether: thus, it was possible to submit notifications either as a IUCLID file via REACH-IT; directly on-line in REACH-IT; or by using a bulk submission tool allowing submission of notifications for multiple substances by multiple notifiers in one go. The bulk submission tool with its extensive help functionalities was made available in 22 EU languages in May 2010.

Focussing on ensuring successful registration and notification had the drawback that resources were withdrawn from other projects. Therefore, IT development related to dissemination activities progressed somewhat slowly until late 2010, preventing the publication of registration data in large quantities. However, planning was made to publish the necessary information from all registrations received in 2010 gradually throughout the year. Importantly, the information on the dissemination website was successfully linked to the OECD eChemPortal to allow international use of the information on chemical substances collected by ECHA.

Similarly, reallocation of resources delayed the development of the RIPE portal for Member State enforcement authorities. Nevertheless, the Agency started development of the application in summer 2010 and the first iteration of the application was ready by the end of 2010. The final release for the application is foreseen for Q2 of 2011.

While 2010 was the year to receive and handle registrations and notifications it was also the year to prepare for evaluation tasks set by the REACH Regulation. To this end, ECHA developed and tested a first version of its screening and prioritisation tool, Casper, which by the end of 2010 was in place to support efficiently the evaluation tasks. Moreover, the development of the evaluation decision support tool, Odyssey, was largely completed by the end of 2010 so that the first version can be taken into production in early 2011. This tool, effectively an expert-based decision support system, provides scientific officers an accessible way to the Guidance documents and allows a traceable procedure for evaluation of registration dossiers, therefore guaranteeing an efficient and consistent evaluation function.

Finally, IT document management support was developed for the workflows related to the management of Substances of Very High Concern (SVHCs) as the initial pilot project in the context of a wider Enterprise Content Management (ECM) programme that will span most of ECHA's operational processes. The analysis for extending ECM to cover the workflows related to evaluation was concluded at the end of the year and implementation is planned in 2011.

Objectives and Indicators

Objectives

1. ECHA is able to receive and process all registration dossiers for phase-in substances and all C&L notifications, subject to the first registration deadlines in 2010 and early 2011, with the assistance of a well functioning, upgraded REACH-IT tool and databases, and registrants are supported by specialised IT-tools (IUCLID 5 and CHESAR).

Performance Indicators & Targets

Indicator	Target in 2010	Means and frequency verification	Results 2010
Percentage of software modules for the different IT tools completed according to schedule.	Not less than 80%	Project planning: Monthly activity reporting	80%

Main Outputs

REACH-IT

- REACH-IT was re-engineered, scaled and tested to handle three to four times the number of registration dossiers and C&L notifications expected in the baseline scenario, i.e. up to 75 000 registration dossiers and several million C&L notifications.
- A backup system was put in place to receive submissions in case of unavailability of the REACH-IT system.
- A set of tools was provided to cover for the different needs of industry to submit their C&L notifications. The REACH-IT system was updated to receive and process the incoming notifications.

IUCLID 5

- Stakeholder driven upgrades undertaken, including the introduction of new OECD harmonised templates for reporting study results; new requirements arising from the CLP Regulation; and improved interfaces between IUCLID 5 and other IT systems

in particular REACH-IT and CHESAR. A series of plug-ins were created to facilitate the preparation of registration dossiers.

CHESAR

- First release in May 2010, followed by subsequent upgrades throughout the year, notably regarding the automated generation of the chemical safety report and a distributed version.

CASPER

- First release enabling the automatic identification and prioritisation of registration dossiers that are suitable candidates for compliance check and testing proposal examination.

ODYSSEY

- Development of the first version was completed by the end of 2010, enabling the start of production in early 2011.

ECM

- IT document management support was developed for the workflows related to the management of SVHCs as the initial pilot project in the context of a wider Enterprise Content Management programme.

Activity 7: Scientific and Practical Advice for the further development of legislation

Main Achievements in 2010

According to its mission, ECHA shall 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 role also covers, beyond what is described under other operational activities, certain horizontal and general scientific issues, as well as the scientific and technical support ECHA will give to the Commission and other institutions in the development or revision of chemicals legislation.

The main areas of work in 2010 covered nanomaterials, the development of test methods, and the draft Biocides Regulation[13].

ECHA closely followed the development of the REACH Implementation Projects on Nanomaterials (RIP-oN). Substantial input was particularly provided to the RIP-oN-1 project on substance identification and its related case studies, where one study on carbon nanotubes was jointly led by ECHA and CEFIC. In addition, developments on the other two RIP-oN projects regarding information requirements and chemicals safety assessment were closely followed with the aim of evaluating the outcome in terms of a potential update to ECHA guidance in the near future. Finally, ECHA provided the Commission services with technical and scientific advice during the development of the draft Commission recommendation on the definition of the term "nanomaterial", as well as participating in the SCENIHR[14] Working Group on the scientific elements of the nanomaterial definition.

Regarding the development of test methods, including alternative test methods, ECHA continued to build up its expertise and capacities to provide scientific and technical advice. ECHA participated and contributed 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, also covering the proposed new protocol for an extended one-generation reproductive toxicity study.

Moreover, with a view to developing a common understanding on the use of non-test methods in the regulatory context, ECHA organised a workshop for relevant stakeholders in September 2010. The workshop helped to clarify the concepts, possibilities and the restrictions of non-test methods, and serves as a starting point for the further capacity building scheduled for 2011.

ECHA provided technical advice to the Commission during the first reading of the proposal for the new Biocides Regulation. Initial planning was begun in relation to ECHA's future tasks under the proposed regulation, taking into account the amendments proposed by the European Parliament and the political agreement reached by the Council. ECHA's main interest was to ensure that appropriate staffing, IT-tools, and processes can be in place early enough in order to start the effective implementation of the new activities. As no specific funding was yet available for ECHA, these preparatory activities were so far relatively limited.

[13] Proposal for a regulation of the European Parliament and the Council concerning the placing on the market and use of biocidal products (COM(2009)267 final).
[14] Scientific Committee on Emerging and Newly Identified Health Risks

Objectives and Indicators

Objectives

1. ECHA has improved its capacity to provide scientific and technical advice on the safety of nanomaterials and the development of alternative testing methods and has provided scientific and technical advice to the Commission (and if appropriate to the other co-legislating institutions) on the proposed Biocides Regulation.

Performance Indicators & Targets

Indicator	Target in 2010	Means and frequency of verification	Results 2010
Level of satisfaction with the quality of the scientific, technical and administrative support provided to Commission.	High	Annual survey	High

Main Outputs

- Close follow-up of the development of the REACH Implementation Projects on Nanomaterials (RIP-oN) and technical and scientific advice provided to the Commission services during the development of the draft Commission recommendation on the definition of the term "nanomaterial".
- OECD program on test guidelines was supported. ECHA experts contributed considerably, particularly to discussion on the new protocol for an extended one-generation reproductive toxicity study.
- Support was provided for the co-decision procedure on the proposed Biocides Regulation and initial work was started to prepare for the new tasks, with a view to ensuring effective implementation.

ECHA'S BODIES AND SUPPORTING ACTIVITIES

Activity 8: Committees and Forum

Main Achievements in 2010

MSC, RAC and SEAC

The Member State Committee (MSC), the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) are an integral part of ECHA. Together they play an essential role in ensuring the smooth and efficient functioning of the REACH Regulation and the credibility of ECHA with respect to its independence, scientific integrity and transparency.

The main challenges expected for 2010 were an increasing workload for the Committees which in turn was dependent upon the actual number and complexity of restriction and harmonised classification and labelling (CLH) dossiers and evaluation decisions received.

Furthermore, preparations for receiving authorisation applications were largely completed by drawing up and agreeing the key Committee procedures with close cooperation between RAC and SEAC.

In general, the actual numbers of dossiers received were high and several were particularly complex and required additional work. RAC delivered its opinion on the first *ad hoc* request, i.e. a mandate under Article 77(3)(c) of the REACH Regulation, which presented an additional challenge. Taken together, there was a considerable workload during 2010 compared to the previous year. Despite this, all of the dossiers were or are being processed by the Committees within the legal timeframe; opinions or agreements were adopted by consensus or unanimously, respectively and have been of a high quality.

In December 2010, or early 2011, many of the Committee members reached their full three year term of office. To ensure the continuity of the work of the Committees a process was put in place to ensure the successful renewal or replacement of these members.

Stakeholder organisations continue to play an active role in the work of the Committees. Currently each of the Committees has invited up to 19 eligible stakeholder organisations, representing different types of general interests, to nominate a regular observer to follow and contribute to the work of the Committee. Stakeholder organisations have become more actively involved in the work of the Committees during 2010 now that the focus of their work has shifted to dossiers, rather than the establishment of the Committees themselves. The participation of observers has in general been very positive and members of the Committees have appreciated the added value of involving the regular stakeholder observers in their work. In addition, the Member State Committee also reviewed its working procedure on draft decisions on testing proposals and compliance checks which will allow, with the agreement of the Management Board, case-owners and stakeholder observers to participate in discussions on compliance check and testing proposal decisions when the dossiers are presented and initially discussed. ECHA has initiated actions to further improve the efficiency of the Committee procedures with the aim to ensure that all relevant

information is available and all relevant comments from stakeholders have been addressed at the time when the opinion-making process needs to be finalised.

Forum for exchange of information on enforcement

The Forum met two times in plenary and held ten working group meetings in 2010. In addition, it organised a Stakeholders workshop to strengthen its liaison with them. In accordance with its work programme, the Forum concentrated on the finalisation of its first coordinated enforcement project on pre-registration, registration and safety data (with a focus on enforcement of the "no data, no market" rule), which was implemented in 25 EU-EEA Member States. Beside this, the Forum prepared the second coordinated project for 2010/2011, on formulators of mixtures who are the first level Downstream Users in the supply chain.

In early 2010, the Forum assisted ECHA in finalising the required specifications for the REACH Information Portal for Enforcement (RIPE) – an IT tool which will allow inspectors in Member States to access data from submissions to ECHA. The Forum working group on RIPE provided its preliminary feedback on the first iteration of the application in December 2010 and also discussed the RIPE Security Recommendations that govern the rules of secure access to RIPE and handling of the data found therein.

The Forum has also discussed the necessity for another IT tool for REACH enforcement authorities – an Electronic Information Exchange System that would allow inspectors from different countries to exchange information and experiences easily and smoothly. In late 2010, the Forum established a working group to define the general functional requirements for such a platform, which will be used by ECHA in 2011 to assess the optimal way of implementing the required system.

Furthermore, the Forum published its basic elements for minimum criteria for REACH inspections and initiated cooperation with customs authorities. It arranged a training session on REACH for national trainers, and also prepared for the enforcement of the CLP Regulation by organising a training event for CLP inspectors as well as evaluating its work programme and working documents in terms of the needs for the enforcement of CLP. In addition, the Forum cooperated and shared information with RAC and SEAC, the ECHA Secretariat and the European Commission, regarding advice on the enforceability on proposals for the restriction of substances.

Objectives and Indicators

Objectives

1. The work of the Committees will be supported efficiently and effectively so that they will be able
   - to respect the timelines given in the legislation, and
   - to deliver high quality scientific and technical opinions and agreements that support the final decision-making

in a transparent manner while ensuring the necessary confidentiality.

2. The work of the Forum will be supported efficiently and effectively so that it is able to strengthen and harmonise further the enforcement of the REACH and CLP Regulations in the Member States in a transparent manner while ensuring the necessary confidentiality.

Performance Indicators & Targets

Indicators	Target in 2010	Means and frequency of verification	Result 2010
Percentage of opinions / agreements delivered in time.	Not less than 90%	Annual internal report	100%
Percentage of unanimous MSC agreements.	Not less than 80%	Annual internal report	100%
Percentage of Committee opinions adopted by consensus.	Not less than 70%	Annual internal report	100%
Degree of Committee opinions taken on board in the final decision of the European Commission.	High	Annual internal report	Not applicable
Feedback from the Member States enforcement authorities and ECHA stakeholders on the added value of the Forum activities.	Positive	Annual survey	Positive
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	Annual survey	High
Level of satisfaction of stakeholders, Competent Authorities and Members of the Committees with the overall transparency and publication of the outcomes of Committee processes and the Forum activities.	High	Annual survey	High

Main Outputs

General

- Written contracts with rapporteurs and experts serving the working groups were established in accordance with Article 87(3) of the REACH Regulation.
- Renewal of appointment or replacement of the RAC, SEAC and MSC members having served for three full years was accomplished successfully.

Member State Committee

- Five plenary meetings and 2 working group meetings were held.
- Nineteen further proposals on Substances of Very High Concern (SVHCs) were received, out of which it was agreed that 16 be included in the Candidate List, while agreement was reached on the remaining 3 that information was not available to be able to conclude on SVHC status.
- Opinion on ECHA's draft recommendation for inclusion of priority substances from the Candidate List to Annex XIV (the 'Authorisation List') was adopted by consensus, allowing ECHA to submit its recommendation for 8 substances to the European Commission.
- Unanimous decisions on 4 draft decisions on compliance checks and 3 draft decisions on testing proposals were reached.

Committee for Risk Assessment

- Six plenary meetings were organised, one of which was held in part jointly with SEAC.
- Fifteen opinions on harmonised classification & labelling (CLH) proposals were adopted.
- An opinion was adopted at the Executive Director's request concerning boric acid and borate compounds in photographic applications.
- The first 4 restrictions dossiers were received and opinions are scheduled to be adopted in 2011.

Committee for Socio-economic Analysis

- Four plenary meetings were organised, one of which was held in part jointly with RAC.

- The first 4 restrictions dossiers were received and opinions are scheduled to be adopted in 2011.
- Two workshops related to the assessment of health and environmental impacts were organised by the Secretariat to build up the capacity of the Committee further to meet its challenging tasks in 2011.

Forum for Exchange of Information on Enforcement

- Two plenary Forum meetings, 10 Forum working group meetings, 1 enforcement workshop with stakeholder organisations and 1 training event for REACH enforcement trainers were organised.
- Forum finalised its first coordinated enforcement project, and decided on its continuation until spring 2011 taking into account the compliance with the first REACH deadline.
- Forum REACH-EN-FORCE-1 project report.
- Forum document on "Minimum Criteria for REACH Inspectors" produced.
- Manual for REACH-ENFORCE-2 project produced.
- Forum adopted six advice on the enforceability of the proposed restrictions.
- Functional Requirements Specification for RIPE prepared by ECHA with the assistance of the Forum.

Table 7: Number of Committee decisions, opinions, agreements adopted[15]

	SVHC agreements	Restriction opinions	Opinion on draft Recommendation for Annex XIV	CLH opinions	Testing proposal agreements	Compliance check agreements	Article 77(3)(c) opinions[16]
MSC	19	Not applicable	1	Not applicable	3	4	0 (0)
RAC	Not applicable	0 (4)	Not applicable	15[17] (29)	Not applicable	Not applicable	1 (0)[18]
SEAC	Not applicable	0 (4)	Not applicable	Not applicable	Not applicable	Not applicable	0 (0)

[15] The figures between brackets refer to the number of dossiers received, while in the last column the number between brackets refers to the mandate (Executive Director request) received.
[16] Article 77(3)(c) of the REACH Regulation: *"The Committees shall undertake the following tasks: (…) at the Executive Director's request, drawing up an opinion on any other aspects concerning the safety of substances on their own, in preparations or in articles."*
[17] The opinions cover 16 dossiers.
[18] The mandate (Executive Director request) for this opinion was received in 2009.

Main Achievements in 2010

One of the main goals for 2010 was to increase awareness of the appeals process and to build stakeholder confidence in the Board of Appeal. With this in mind, communication with potential appellants and other stakeholders was improved through the making available of new practical tools and new website content in 22 EU languages. In particular, Practice Directions to parties to appeal proceedings before the Board of Appeal and supporting tools were prepared and published to help parties act in compliance with the legal requirements and prepare appeals in the most effective manner. The Board of Appeal has also participated in selected stakeholder events.

The essential elements of the appeals process have also been defined in more detail through implementing decisions based on the Rules of Procedure. Furthermore, quality management has been set up and standardized in a series of documented working instructions which reinforces the efficiency of the Board and the Registry. Internal quality tools related to appeal procedures and the drafting of decisions were also developed.

As indicated in the Work Programme 2010, there was considerable uncertainty regarding the number of registration dossiers that would be submitted to ECHA by the 30 November deadline, and therefore also regarding the number of appeals that would be received. Consequently, contingency measures were planned for 2010 in case a large number of appeals would have arisen from decisions related to registration and data sharing. However, only one appeal was lodged in 2010. It was received at the very end of the year and therefore will be processed in early 2011. In fact, data sharing disputes appear not to have materialised as foreseen. Furthermore, it is apparent that the efforts of ECHA to assist companies in the registration process, for instance with the TCC tool, resulted in a lower than expected number of registration rejections. In addition, many of those decisions were taken after the registration deadline and still had, therefore, the possibility of being appealed after the end of 2010.

Considerable work was also carried out to ensure that the alternate/additional members were prepared should the need for their designation arise. This included the annual meeting between the regular and alternate/additional members.

During 2010 there were some changes in the Board of Appeal's composition with the Technically Qualified Member retiring and assuming the position of alternate/additional member. The appointment process for a new member also began. In addition, three new alternate Chairs were appointed by the Management Board.

Objectives and Indicators

Objectives

1. High-quality decisions are adopted by the Board without undue delay.

Performance Indicators & Targets

Indicators	Target in 2010	Means and frequency of verification	Result 2010
Percentage of cases concluded within 12 months of their introduction.	90%	Annual report of the Board	Not applicable
Level of stakeholder confidence in the appeal procedure.	High	Survey among stakeholders	Not applicable

Main Outputs

- The procedures which took place in the course of 2010 and related to the new appeal case (lodged in December 2010) were conducted in an effective manner.
- Several decisions on procedural rules were prepared and adopted by the Board of Appeal, e.g.:
  - Decision adopting Practice Directions to parties to appeal proceedings before the Board of Appeal;
  - Decision adopting the Code of Conduct of the (Regular/Alternate/Additional) Members of the Board of Appeal;
  - Decision laying down Instructions to the Registrar of the Board of Appeal.
- Legal and practical framework for the engagement of alternate/additional members was fully established, e.g.:
  - Decision setting out the rules on the designation of Alternate and Additional Members;
  - Decision adopting the General Terms for Alternate and Additional Members of the Board of Appeal designated to act in proceedings before the Board of Appeal.
- Registry procedures were finalised and working instructions clearly defined in standardized documents reflecting high standards of quality. The Board of Appeal's work process for "Deciding on Appeals" was defined and the first quality tools relating to decision making were developed.

Main Achievements in 2010

In 2010, extensive support was provided to industry in building up their capacity to submit complete registration dossiers via various communication tools in the form of webinars, industry workshops, two stakeholder days with one-to-one sessions for individual companies, and targeted materials in 22 EU languages. The Agency also ran a multi-lingual campaign on CLP (under the slogan, "CLP - Notify in time") to increase awareness among all companies impacted by the regulation, about the deadline for classification and labelling notifications. The campaign included: a video; webinars; targeted materials for downstream users, research organisations and importers; workshops in Member States in the respective national language(s); Stakeholders' Day presentations; and intensive press activities. The Agency also worked together with the European Trade Union Confederation (ETUC) and the European Agency for Safety and Health at Work (EU-OSHA) to highlight the importance of the new chemical legislation and the deadlines around the end of the year.

Translating material with a target audience of small and medium sized companies (SMEs) or the general public continued to be a priority throughout 2010. In total, 175 documents were translated and published in 22 languages, including: guidance documents, user manuals, Practical Guides, the bulk CLP notification tool, news alerts, and press releases. Furthermore, web pages for SMEs on data sharing and Classification and Labelling were made available in 22 languages. To promote the use of our translations, a mini-campaign (under the slogan, "In your language") was launched in autumn 2010 and accompanied by a leaflet and web-banner.

In 2010, ECHA further developed its press and media relations service: providing its first multi-media press release on the occasion of the first REACH deadline; and introducing a new weekly e-News communication. ECHA's profile is already strong in sector-specific media where the degree of interest in REACH and CLP is very high. However, 2010 saw an increasing number of enquiries and interview requests from more mainstream media, for instance on the outcome of the REACH deadline and its implications for industry and society as a whole.

A review of ECHA's reputation – how the Agency is seen, both internally and externally – was undertaken during 2010 and is leading, in 2011, to the implementation of a clear corporate identity. This will include a refocusing of the Agency's mission, vision and values; improved services (both internal and external); a new website; and a new visual identity.

As the number of staff in ECHA continues to increase rapidly, effective internal communication is ever more important. Focus in 2010 was therefore placed on managing, evaluating and further developing the communication tools to enhance both on-line communications as well as two-way dialogue with staff.

Objectives and Indicators

Objectives

1. ECHA's external audiences are communicated with effectively, and ECHA benefits from an accurate and balanced media presence.
2. All material (whether online or offline) that is produced for large numbers of small and medium sized enterprises or the general public will be translated into 21 official EU languages.

3. With the help of effective internal communication, ECHA staff are well informed, have a sense of belonging, and feel part of a common corporate endeavour.

Performance Indicators & Targets

Indicators	Target in 2010	Means and frequency of verification	Result 2010
Level of website customer satisfaction.	Very Good	Annual user surveys, quarterly web statistics	High
Level of staff satisfaction with internal communications.	Good	Annual staff survey	High
Level of satisfaction expressed in customer surveys of publications readerships – newsletter, internal newsletter.	Good	Annual customer surveys	High
Level of stakeholder satisfaction with their involvement.	Very good	Stakeholder survey on Stakeholder Days	High
Publication of translations of guidance documents relevant to large numbers of small and medium sized enterprises (within an average period of three months after the original document, without validation).	100%	Internal quarterly report	91%

Main Outputs

Internal Communication

- Internal communications vehicles – ECHAExchange, ECHO, information screens, Communications Network etc – were evaluated and further developed.
- First Staff Survey was held.

Digital Communication

- ECHA's website and intranet were updated and enhanced.
- Customer Insight research project on the website was completed.

External

- ECHA's brand was reviewed and a new Corporate Identity is under development, for implementation in 2011.
- All materials targeted at small firms and the general public were translated and language revisions of guidance documents were co-ordinated with 13 Member States.
- ECHA terminology project – two prototypes of the online portal were developed and assessed with test users.
- CLP "Notify in time" campaign was launched and co-ordinated, including first joint campaign with stakeholders.
- "In Your Language" campaign to promote ECHA translations was launched.
- Risk Communications Network was managed and further developed.
- Crisis Communications strategy was developed.
- CLP Eurobarometer study was completed.
- Two Stakeholders' Days were organised (May and October).
- ECHA's first Stakeholder Survey was completed.
- Seventeen webinars for targeted audiences were organised.

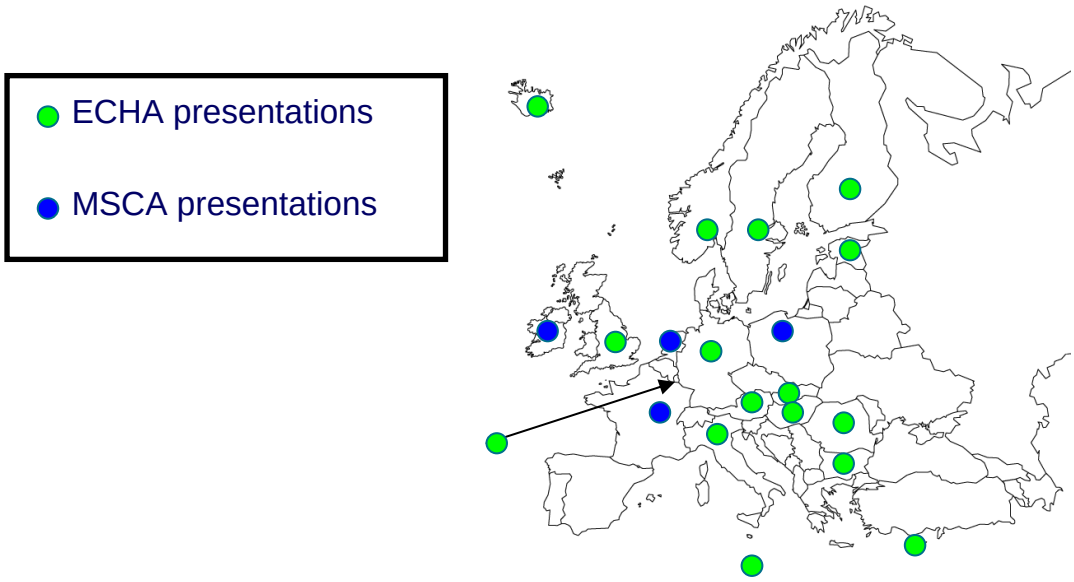
Press and Media Services

- News disseminated in press releases, news alerts, weekly and monthly newsletters.
- Management of press conferences and press briefings, interviews and external visits.
- A daily media monitoring system was put into place together with weekly and monthly analyses.
- A first multi-media press pack was produced following the first registration deadline.

Table 8: Communication statistics

Activity	Output
Two stakeholder days	700 participants and 1000 via web streaming, 140 one-to-one sessions with individual companies and 150 participants trained on CLP and REACH submission
Lead registrant webinars	Over 3000 participants and 10 000 viewings after the event
Publications	More than 60 original publications
Translations	2279 pages translated into 21 languages
Press inquiries	2979
Press releases	29
News alerts	82
Newsletters	6
Website visits	2 477 479 visits from 200 countries

Figure 1: Presentations delivered in national workshops as part of C&L notification campaign roadshow



Main Achievements in 2010

EU institutions and other bodies

The Executive Director and the senior management of ECHA liaised regularly with the European institutions in 2010, in particular the Parliament and Council as well as Member States and the Commission.

The Executive Director appears annually in front of the European Parliament's (EP) Committee for Environment, Food Safety and Public Health (ENVI), and 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. A large delegation from the Parliament, lead by the Chair of the ENVI Committee, also visited ECHA in April 2010.

ECHA had continuous and frequent contacts with the Commission, and occasional, high level meetings were held at Director General-level and with Cabinet staff. ECHA staff have continuous working level contacts with Commission officials from DG ENTR and DG ENV. Moreover, Vice-President Tajani and Commissioner Potočnik visited ECHA in March 2010.

Furthermore, Article 95 and 110 of the REACH Regulation require the cooperation of the Agency with other relevant Community scientific bodies to ensure mutual support and to identify potential sources of conflict between scientific opinions. This year a significant amount of work was carried out to put in place agreements between ECHA and EFSA[19], SCOEL[20] and the ACSHW[21]. The first agreement with EFSA has nearly been completed and is expected in 2011. The other agreements are under development.

Ad hoc interactions have also occurred with other scientific bodies and EU agencies: for example members of the Committees have provided input into specific EU-wide activities and contacts between the Committee Secretariat and other EU Committees have ensured that good cooperation has taken place on a dossier-specific basis.

Through the Committee Secretariats, ECHA started the process of establishing standard practices to identify, prevent and handle potential divergences between the opinions of the ECHA Committees and those of the Scientific Committees and Panels which provide advice to other EU Agencies and the Commission. The early identification of mandates related to the same substance or group of substances, is a key element in this process. During 2010 several opinions were considered for a screening evaluation and no conflicts in the opinions were identified.

International cooperation

The international activities of ECHA were mainly based on the requests 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 as in the previous two years, was on OECD activities. ECHA continued to collaborate with the OECD on the eChemPortal project (Global portal to information on chemical substances) by funding the development and by taking over

[19] European Food Safety Authority.
[20] Scientific Committee on Occupational Exposure Limits.
[21] Advisory Committee on Safety and Health at Work.

the hosting of the portal. In December 2010, ECHA and the OECD successfully launched a new version of the portal, which significantly enhances the search options available and improves public access to information on the intrinsic properties of chemicals collected by regulatory bodies worldwide in the context of their chemical review programmes. Information on more than 600 000 industrial chemicals, pesticides and biocides is now accessible via the portal, including data from REACH registration dossiers.

ECHA also successfully co-managed the development of the QSAR Toolbox[22] with the OECD and version 2.0 was released to the public in November 2010. This expert software was downloaded more than 800 times between November and December 2010. ECHA also observed that the QSAR Toolbox was already being used for the filling of data gaps in a number of registration dossiers.

Other OECD-related activities in which ECHA was involved, as appropriate, included contributing to the work of the Task Force on Hazard Assessment – including the SIDS-programme; the Task Force on Exposure Assessment; the Harmonised Templates Project; the OECD Working Party on Manufactured Nanomaterials (WPMN); and the Test Guidelines Programme. ECHA also participated in one of the OECD Joint Meetings of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology (generally referred to as the Joint Meeting).

ECHA also supported the European Commission delegation at the Review Committee of the Stockholm Convention on Persistent Organic Pollutant. On the request of the European Commission, ECHA also participated in the WHO Meeting on Strengthening Global Collaboration in Chemical Risk Assessment and in the 20th session of the UNECE SC GHS.

During 2010, ECHA concluded its first cooperation agreements with third countries. Following a visit of the Executive Director to Canada and the United States, a Memorandum of Understanding was concluded with Environment Canada and Health Canada in May, on the occasion of the second Helsinki Chemicals Forum; while a Statement of Intent was signed late in the year with the US EPA Office of Pollution Prevention and Toxics.

Concerning other bilateral cooperation, the ECHA Secretariat participated in activities to increase the knowledge of REACH in candidate countries and potential candidate countries, as well as among ENP (European Neighbourhood Policy) partners, which were mainly arranged by the EC TAIEX office. ECHA 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 upon the invitation of different organisers in countries outside the EU.

The first activities to support candidate countries for EU accession to prepare for REACH implementation and participation in ECHA were carried out, supported by the European Commission Instrument for Pre-Accession Assistance. Fact-finding missions to the three candidate countries, Croatia, Turkey and the Former Yugoslav Republic of Macedonia were the starting points of the project. As a result of this, a first seminar for representatives from the competent authorities in these three countries was held at ECHA, where *i.a.* the work of the Management Board and the different committees were introduced.

[22] A tool to facilitate estimation of the properties of a chemical from its molecular structure, which has the potential to provide information on hazards of chemicals, while reducing the time, monetary cost and animal testing currently needed.

Objectives and Indicators

Objectives

1. Conflicts of opinions with Scientific Committees of other Community bodies are prevented through the sharing of information and through the coordination of activities of mutual interest.
2. The European Commission receives high-quality scientific and technical support for its international activities, especially in multilateral bodies.

Performance Indicators & Targets

Indicators	Target in 2010	Means and frequency of verification	Result 2010
Occurrence of conflicts of opinions with Scientific Committees of other Community bodies.	Only in well justified cases	Internal evaluation report	Not applicable
Level of satisfaction of the Commission with the support given by ECHA on international activities.	High	Annual survey	Medium
Joint IT projects (eChem portal and IUCLID 5) with the OECD completed successfully.	New release of eChem portal has been delivered to ECHA and a new release of IUCLID 5 published by the end of 2010	Annual report	Completed

Main Outputs

- Continuous liaison with the key EU institutions and the Member States.
- Four visits of the Executive Director and expert staff to partner authorities in the Member States.
- A significant amount of work was carried out to put in place agreements between ECHA and EFSA, SCOEL and the ACSHW. The first agreement with EFSA has nearly been completed and is expected in 2011. The other agreements are under development.
- First IPA-project for Candidate countries was begun.
- Memorandum of Understanding on cooperation with Canada was agreed and signed.
- Statement of Intent with US EPA was agreed and signed.
- Scientific and technical cooperation with the OECD continued:
  - *The new version of eChemPortal was launched in December 2010. Portal hosted by ECHA.*
  - *Second version of the QSAR Toolbox was released at the end of 2010.*
  - *All requirements prioritised by the OECD IUCLID User Group Expert Panel in its meeting of September 2008 were incorporated in IUCLID 5.2. New harmonised templates were developed and incorporated into IUCLID.*
  - *Task force on hazard assessment.*
  - *Task force on exposure assessment.*
  - *Working party on manufactured nanomaterials.*
  - *Task force on Harmonized classification and labelling.*

MANAGEMENT, ORGANISATION AND RESOURCES

Activity 12: Management

Main Achievements in 2010

The Management Board, which is ECHA's highest decision-making body, met regularly during the year in plenary sessions or in a smaller composition within one of its working groups. Apart from the tasks foreseen by the REACH regulation, agreement was reached on some important topics, including on the administrative charges to be levied for the verification of a registrant's SME status, in case false information has been submitted; on stakeholder observer and case-owner participation in dossier evaluation-related MSC debates; on the review of criteria for the selection of stakeholder observers; and on the transfer of fees to Member States in the context of the authorisation procedure. The ECHA Secretariat ensured the smooth functioning of all meetings.

The Executive Director is responsible for the day-to-day administration of the Agency. The further development of management and administrative processes continued at the pace reflective of a growing Agency. In order to be well prepared for the rapidly increasing volume of technical and scientific tasks demanded of the Agency, changes to its organisational structure were prepared in 2010, which were to take effect on 1 January 2011.

ECHA had regular contacts with the authorities of the Member States, and the Executive Director, together with expert staff, visited partner authorities in Austria, Slovakia, France and Luxembourg. Moreover, a visit to ECHA by the President of Finland, which is the Agency's host country, took place in September 2010. Framework Agreements for the transfer of fees to Member States were also initiated.

In 2010, ECHA continued to implement its security plan, as defined in 2008, with emphasis placed on establishing business continuity management. The following high-level policies and plans approved in 2010 define the framework for business continuity and security in ECHA: the Internal Classification and Handling of information and documents policy; the Information Security policy; the Business Continuity Management policy; and the Crisis Management Plan. ECHA also managed requests from Member States for access to data in the REACH-IT database and organised two meetings of the Security Officers Network, which is a cooperative network of representatives of the Member States and the European Commission advising the ECHA Secretariat on any security issues related to the secure exchange of information regarding the REACH and CLP Regulation.

In the course of 2010 the Agency continued the implementation of its Integrated Quality Management System. The elaboration of relevant documentation was focused on processes related to Registration; Helpdesk and HelpNet activities; Restrictions and SVHCs; as well as Dossier Evaluation, in order to prepare for the Agency's tasks determined by the timeline of the Regulation. As a result, the foreseen publication of the main operational procedures progressed relatively slowly. Training and coaching, primarily directed to capacity building among staff, continued. The expansion of the Quality Organisation was prepared in conjunction with the Agency's re-organisation, leading to the introduction of Quality Assurance functions in each Directorate in 2011.

Managing the risks relating to the functioning of the Agency was enhanced through the adoption of the principles and methodology relating to risk assessment.

According to ECHA's Financial Regulation, the Internal Auditor for ECHA is the Internal Auditor of the European Commission (IAS). The IAS performed an advisory audit on "Preparedness for registration" in 2010, and the major part of the action plan developed in response to the recommendations of the IAS was implemented in 2010, in order to ensure registration ran smoothly. The IAS also updated the strategic audit plan for ECHA, which is established for a three-year period, on a rolling basis.

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.

Objectives and Indicators

Objectives

1. The Agency fulfils all its statutory obligations with regard to the Management Board and the EU institutions.
2. The Agency continues the development of a structured quality and internal control system, having reviewed its risks and has a comprehensive security system as well as a solid information management system in place.

Performance Indicators & Targets

Indicators	Target in 2010	Means and frequency of verification	Result 2010
Percentage of statutory documents submitted to the Management Board within legal deadlines.	100%	Quarterly internal report	100%
Level of implementation of the risk mitigation plan.	Not less than 90%	Annual internal report	100%
Percentage of quality procedures released to the public.	Not less than 70%	Quality Manager's annual report	44%
Number of "critical" findings by the auditors relating to the internal control system in place.	0	Internal auditors annual report	0
Percentage of audit recommendations implemented within the deadline.	100%	Internal auditors annual report	100%
Number of security incidents for which an inquiry by ECHA's security services identified a leak of confidential information.	0	Internal reports	0

Main Outputs

- Four Management Board meetings and 18 meetings involving Management Board members (including teleconferences and meetings of the reporting officers of the Executive Director and the members of the Board of Appeal) were organised.
- Regulatory documents for planning and reporting were provided and adopted according to the agreed schedule.
- The Quality Management System was developed and some of the main operational procedures published on the ECHA website.
- 85 effective IQMS documents were in place at the end of December 2010.
- A decision on Risk Management in ECHA was adopted by the ED, including a methodology for risk assessment, and the first risk assessment exercise conducted accordingly.
- The Internal Audit Capability's annual work plan for 2010 was implemented: the IAC carried out 2 assurance audits, 1 consultative audit and 1 follow-up audit.

- Legal support was provided to ensure that ECHA's decisions are in line with legal requirements; provision of procedural documents in 10 court proceedings, provision of effective defence with a positive outcome in case T-1/10 R.
- 107 "Access to documents" requests were answered in accordance with the applicable legislation.
- 18 Framework Agreements for the transfer of fees to Member States were signed.
- Access to the data in the REACH-IT database was established for 20 MSCAs.

Main Achievements in 2010

With regard to the Agency's fee revenue operations, the main achievement in 2010 was the efficient processing of close to 23 000 incoming fee payments linked to the first registration deadline, which resulted in cashed fee income of €349.7 million. This accomplishment also safeguarded the repayment of the temporary EU contribution of €36 million that was needed to enable the smooth continuation of essential REACH tasks throughout 2010 until the accumulation of sufficient independent revenue. Moreover, an arrangement with an external, highly rated custodian was set up and a second arrangement is under preparation to ensure the safe-keeping and risk diversification of the accumulated cash reserves that should principally finance the Agency until the start of next Financial Perspectives Period in 2014.

In the area of budget implementation, the year was characterised by caution in order not to put strain on the Agency's cash position and to ensure better alignment to the principle of budget annuality. As a result, two budget amendments were made, revising the Agency's budget downwards by a total of €11 million (12.7%) during the year.

The Agency also started a pilot project to verify the status of companies that had registered as SMEs and had thus benefited from SME fee reductions. The first results demonstrated that a considerable proportion of companies could not prove their SME status or accepted that they erroneously classified themselves as SMEs. In the latter cases, supplementary invoices were dispatched to the companies concerned. This experience enabled ECHA to submit a proposal to the Management Board and the Commission, as foreseen in the Fee Regulation, to fix administrative charges to be claimed from companies that make false declarations regarding company size.

With reference to procurement activities, around 350 procurement actions were carried out in 2010, including multi-annual framework contracts for IT, security, quality and management consulting services, for different communication-related matters, and for language training.

A high volume of contracting was carried out under existing framework contracts in the field of IT consulting services, as well as for scientific, technical, environmental and socio-economic questions related to REACH. In addition, a large amount of procurement was processed to cover the administrative needs of the Agency.

Objectives and Indicators

Objectives

1. The Agency has sound and as efficient as possible financial management.
2. Invoices are efficiently generated and cashed in order to reduce the need for subsidy during the entire year.

Performance Indicators & Targets

Indicators	Target in 2010	Means and frequency of verification	Results 2010
Number of reservations in the annual report of the European Court of Auditors.	0	ECA reports/ annual	0
Commitment rate.	Not less than 98%	BO report on ABAC/ annual	95%
Payment rate.	Not less than 70%	BO report on ABAC/ annual	79%
Cashed fee income.	€106.8 million	REACH report / annual	€349.7 million
Number of complaints against ECHA procurement procedures.	0	Annual internal report	0
Surplus necessary for the reimbursement of the Community subsidy.	100% of the value of subsidy	2010 accounts	Achieved

Main Outputs

- Securing of the Agency's budget for 2010-2013 and the repayment of the temporary reimbursable Community subsidy through efficient collection of fee revenue.
- Launching of procurement for major framework contracts in the areas of IT, security, quality and management consulting services, various communication-related matters and language training.
- Implementation of one contractual arrangement and preparation of a second contract to manage and invest the Agency's cash reserves.
- Carrying out of a pilot project on the verification of registrant SME status and the establishment of consequential procedures in case of false declarations.

Main Achievements in 2010

Human resources

In 2010, ECHA continued its efforts to attract highly qualified staff, and more than 120 new staff members were recruited during the year. A strong focus was placed on recruiting expert staff and to enhance the scientific capacity of the Agency; while the recruitment of middle and senior management was also prioritized in order to ensure the implementation of the new organisational structure from January 2011 onwards.

Alongside the recruitment of new staff, continued dedication was given to induction and initial training upon the entry into service of new employees. The capacity of HR administration, including payroll, the performance management system, leave management and other core HR functions, were under pressure to cope with the growing number of staff.

In anticipation of the new organisational structure of ECHA from 2011 onwards, a high number of selection procedures for director and head of unit positions was organised. The registration deadline and the related recruitment of necessary interim personnel, the redeployment of existing staff and the contingency measures were a further, particular challenge in 2010. After a problem of stress and burn out was detected among a high number of staff, an action plan was designed to enhance staff well-being and to mitigate as much as possible, related risks.

Due to the high recruitment rate and the impact on HR services of the registration deadline, training activities were de-prioritised and several HR projects such as competence-based HR management, broadening the learning and development programme and management development were postponed or managed at a lower level than initially foreseen.

Infrastructure

Facility and infrastructure management was strengthened by creating a new corporate services unit in 2010, with responsibilities for facility management, conference and meeting services, logistics, mail handling, physical archiving and travel management. The building premises were further extended in 2010 in order to accommodate the increasing number of staff and other workers at ECHA – based upon a decision taken in 2009. This required a major renovation project within which a new assembly hall was also constructed.

Tasks relating to maintaining the high requirements for information and physical security continued to be key areas of activity: overall relevant services were extended in line with the increased number of staff in the Agency.

Objectives and Indicators

Objectives

1. The Agency has a sufficient number of skilled staff in order to secure the implementation of the work plan and offers them a well functioning working environment.
2. The Agency has sufficient, secure and safe office premises that provide an efficient and safe working environment for the staff, and well functioning meeting facilities for the Agency bodies and external visitors.

Performance Indicators & Targets

Indicators	Target in 2010	Means and frequency of verification	Result 2010
Percentage of establishment plan posts filled at the end of the year.	Not less than 95%	Annual internal report	90%
Percentage of selection procedures for the new posts for the year completed.	100%	Annual internal report	87%
Turnover of the Temporary Agents.	Not more than 5%	Annual internal report	2.6%
Level of satisfaction of the Committee, Forum and MB members with the functioning of the conference centre.	High satisfaction	Annual survey	HIGH
Average number of training days per staff member.	10	Annual internal report	6

Main Outputs

- 35 Selection procedures were finalised in 2010 (including 3 for Directors posts and 8 for Head of Unit positions), which involved the screening of around 1000 candidates.
- 98 Temporary Agents and 23 Contract Agents were recruited.
- 30% increase in the number of staff on the payroll, with a corresponding increase in the workload for HR services.
- Although training was de-prioritized in the second half of the year, due to the registration deadline, a total of 1800 training days for ECHA staff were organised and followed.
- Several well-being initiatives and project were prioritized in 2010.
- Office capacity was increased to 650 desks, including for contingency staff.
- Meeting room capacity was extended, including a renovated assembly hall for 400 participants.
- Services for over 450 staff on office requirements, travel, stationary, etc were provided.
- Horizontal services on mail registration, physical archiving were provided.

Main Achievements in 2010

While in 2010 the Agency, as a whole, faced its biggest challenge after the pre-registration period two years earlier, this was particularly true for its ICT and IT-Operations teams. Hence, focus throughout the year was put on ensuring that the technical handling of the expected registration peak load ran smoothly, and this required major investment in the development of REACH-IT and IUCLID, and in performance optimisation and testing activities. The high-availability of both the databases and of custom-built applications such as REACH-IT and its related systems had to be assured. To mitigate the residual risk associated with the technical handling of the deadline peaks, the Agency decided to implement and make available an additional back-up system to which industry could upload dossiers in the case of any prolonged failure of REACH-IT.

In addition, many other new software projects were supported by delivering systems and *multi-tier* server environments including hardware, databases, middleware, and application software for development, testing, and production purposes. The server farms hosting the virtualisation platform had to be expanded so as to accommodate needs.

To improve technical resiliency, and to enable demand-driven infrastructure growth, ECHA's internal data-centre facilities were upgraded, for example, with regard to electrical power supply and cooling systems.

In the context of administrative applications, the Human Resources application suite was further enhanced in order to better match the leave and mission management needs of the Agency, and to automate certain processes related to the management of HR master data. To address the particular requirements of small- and medium-sized enterprises when checking the compliance of applications, a SME-tool was developed and deployed.

To prepare for future system developments, external hosting and architectural assessment were initiated in 2010 and are to be completed in 2011. The procurement of a contractor to provide external hosting failed in the second restricted stage and needs to be repeated in 2011, thereby causing considerable delay in business continuity planning. The systems architecture project specifically aims at establishing a structured and harmonised information base for ECHA's database and applications portfolio in view of, and as a basis for, the taking of informed decisions on the Agency's future IT strategy.

Objectives and Indicators

Objectives

1. The staff, stakeholders and external clients are provided with continuous IT services including operational back-up systems.

Performance Indicators & Targets

Indicators	Target in 2010	Means and frequency of verification	Result 2010
Availability of operational systems for external customers (uptime).	99%	Data centre statistics	99.4% (excluding maintenance)

IT business continuity & disaster recovery plan operational in August 2010.	100%	Annual disaster recovery, business continuity tests and management reporting	BC: 50% Disaster recovery: 25%
Level of user satisfaction with internal IT services.	High	Annual customer survey and *ad hoc* feedback	Medium

Main Outputs

- 100 new desktop workspaces were rolled out for the Registration Unit.
- ICT help desk capacity was further extended alongside the growth of the organisation.
- During the first half year, 3 new versions of REACH-IT were developed.
- Construction of 3 new database server clusters and a corresponding farm of application servers was completed.
- Around-the-clock network perimeter monitoring was deployed.
- A centralised monitoring system was installed to cover essentially all ICT systems.
- Automated Disaster Recovery (DR) and Business Continuity tools were created.
- Project management support and project governance was provided for 30 IT projects.

Annexes

Annex 1: ECHA organisation chart; MB, Committee, and Forum members

Annex 2: Financial and Human Resources 2010

Annex 3: Registration and CLP statistics

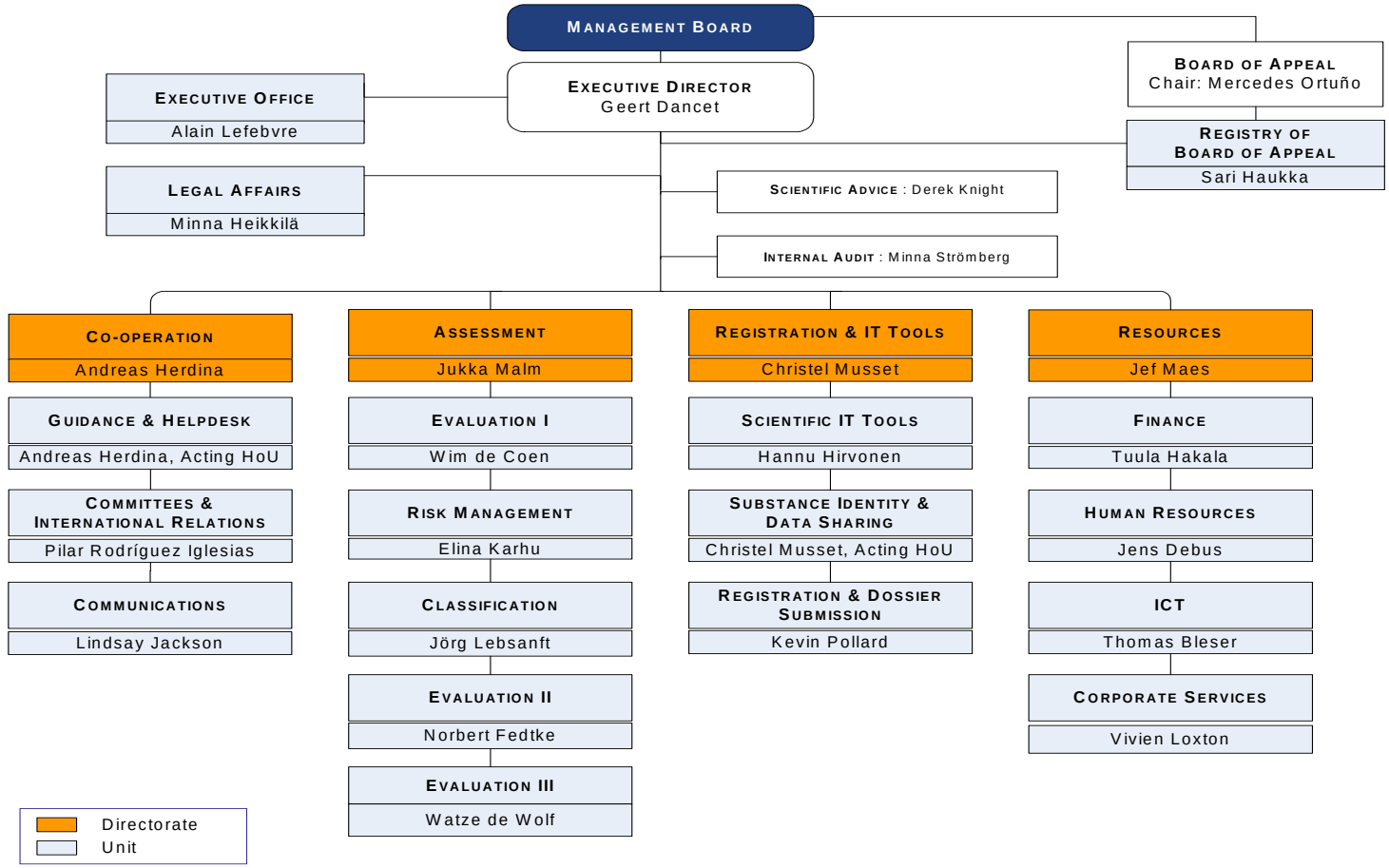
Annex 4: Helpdesk statistics

Annex 5: Candidate List of Substances of Very High Concern

Annex 6: Substances recommended for the Authorisation List

Annex 7: Analysis and assessment of the AAR of the Authorising Officer for 2010

Organisation Chart for ECHA – December 2010



Members of the Management Board on 31 December 2010

Chair: Thomas JAKL
ECHA contact: Frank BÜCHLER

Members	
Thomas JAKL	Austria
Helmut DE VOS	Belgium
Boyko MALINOV	Bulgaria
Leandros NICOLAIDES	Cyprus
Karel BLAHA	Czech Republic
Eskil THUESEN	Denmark
Maria ALAJÕE	Estonia
Pirkko KIVELÄ	Finland
Catherine MIR	France
Alexander NIES	Germany
Maria-Miranda XEPAPADAKI-TOMARA	Greece
Zoltan ADAMIS	Hungary
Martin LYNCH	Ireland
Antonello LAPALORCIA	Italy
Armands PLATE	Latvia
Aurelija BAJORAITIENE	Lithuania
Claude GEIMER	Luxembourg
Francis E. FARRUGIA	Malta
Jan-Karel KWISTHOUT	Netherlands
Katarzyna KITAJEWSKA	Poland
Mário GRÁCIO	Portugal
Teodor OGNEAN	Romania
Edita NOVAKOVA	Slovakia
Simona FAJFAR	Slovenia
Ana FRESNO RUIZ	Spain
Nina CROMNIER	Sweden
Arwyn DAVIES	United Kingdom

Independent persons appointed by the European Parliament
Hartmut NASSAUER
Guido SACCONI

Representatives appointed by the European Commission	
Heinz ZOUREK	Directorate General for Enterprise and Industry
Gustaaf BORCHARDT	Directorate General for Environment
Elke ANKLAM	Directorate General Joint Research Centre (JRC)
Hubert MANDERY	European Chemical Industry Council (CEFIC)
Tony MUSU	European Trade Union Confederation (ETUC)
Martin FÜHR	University of Darmstadt

Observers from EEA/EFTA countries	
Kristin Rannveig SNORRADOTTIR	Iceland
Anne Beate TANGEN	Norway

Members of MSC - Member State Committee on 31 December 2010

Chair: Anna-Liisa SUNDQUIST

Members

Helmut STESSEL	Austria
Kelly VANDERSTEEN	Belgium
Angelova LULEVA PARVOLETA	Bulgaria
Tasoula KYPRIANIDOU-LEODIDOU	Cyprus
Erik GEUSS	Czech Republic
Henrik TYLE	Denmark
Enda VESKIMÄE	Estonia
Jaana HEISKANEN	Finland
Sylvie DRUGEON	France
Helene FINDENEGG	Germany
Ioanna ANGELOPOULOU	Greece
Szilvia DEIM	Hungary
Gunnlaug EINARSDÓTTIR	Iceland
Majella COSGRAVE	Ireland
Pietro PISTOLESE	Italy
Arnir LUDBORZS	Latvia
Lina DUNAUSKINE	Lithuania
Joëlle WELFRING	Luxembourg
Tristan CAMILLERI	Malta
René KORENROMP	Netherlands
Linda REIERSON	Norway
Jerzy MAJKA	Poland
Maria do Carmo Ramalho Figueira PALMA	Portugal
Mariana MIHALCEA UDREA	Romania
Peter RUSNAK	Slovakia
Tatjana HUMAR-JURIČ	Slovenia
Esther MARTÍN	Spain
Sten FLODSTRÖM	Sweden
Gary DOUGHERTY	United Kingdom

Members of RAC - Committee for Risk Assessment on 31 December 2010

Chair: José TARAZONA

Members	Nominating state
Annemarie LOSERT	Austria
Robert WINKER	Austria
Karen VAN MALDEREN	Belgium
Zhivka HALKOVA	Bulgaria
Maria ORPHANOU	Cyprus
Marian RUCKI	Czech Republic
Frank JENSEN	Denmark
Poul Bo LARSEN	Denmark
Riitta LEINONEN	Finland
Elodie PASQUIER	France
Annick PICHARD	France
Helmut A. GREIM	Germany
Norbert RUPPRICH	Germany
Katalin GRUIZ	Hungary
Thomasina BARRON	Ireland
Yvonne MULLOOLY	Ireland
Paola DI PROSPERO FANGHELLA	Italy
Pietro PARIS	Italy
Normunds KADIKIS	Latvia
Lina DUNAUSKIENE	Lithuania
Hans-Christian STOLZENBERG	Luxembourg
Marja PRONK	Netherlands
Christine BJØRGE	Norway
Marianne VAN DER HAGEN	Norway
Boguslaw BARANSKI	Poland
Maria Teresa BORGES	Portugal
Maria do Céu NUNES	Portugal
Maria OLTEANU	Romania
Helena POLAKOVICOVA	Slovakia
Agnes SCHULTE	Slovenia
Benjamin PIÑA	Spain
José Luis TADEO	Spain
Alicja ANDERSSON	Sweden
Bert-Ove LUND	Sweden

Stephen DUNGEY	United Kingdom
Andrew SMITH	United Kingdom

Members of SEAC - Committee for Socio-economic Analysis on 31 December 2010

Chair: Ann THUVANDER

Members	Nominating State
Simone FANKHAUSER	Austria
Catheline DANTINNE	Belgium
Jean-Pierre FEYAERTS	Belgium
Aristodemos ECONOMIDES	Cyprus
Jiri BENDL	Czech Republic
Lars FOCK	Denmark
Aive TELLING	Estonia
Heikki SALONEN	Finland
Henri BASTOS	France
Jean-Marc BRIGNON	France
Franz-Georg SIMON	Germany
Karen THIELE	Germany
Maria THEOHARI	Greece
Dimosthenis VOIVONTAS	Greece
Endre SCHUCHTÁR	Hungary
Marie DALTON	Ireland
Mark FAHERTY	Ireland
Franco DE GIGLIO	Italy
Silvia GRANDI	Italy
Kristina BROKAITE	Lithuania
Cees LUTTIKHUIZEN	Netherlands
Espen LANGTVET	Norway
Izabela RYDLEWSKA-LISZKOWSKA	Poland
Paulo Eurico Alves VARIZ	Portugal
Liliana Luminita TIRCHILIA	Romania
Janez FURLAN	Slovenia
Maj-Britt LARKA ABELLÁN	Spain
Lars GUSTAFSSON	Sweden
Mats FORKMAN	Sweden
Stavros GEORGIOU	United Kingdom

Members of the Forum for Exchange of Information on Enforcement on 31 December 2010

Acting Chair: Nikolay STANIMIROV SAVOV (Bulgaria)

Members

Gernot WURM	Austria
Paul CUYPERS	Belgium
Nikolay Stanimirov SAVOV	Bulgaria
Tasoula KYPRIANIDOU-LEODIDOU	Cyprus
Oldrich JAROLIM	Czech Republic
Birte Nielsen BORGLUM	Denmark
Nathali PROMET	Estonia
Annette EKMAN	Finland
Luc MAURER	France
Katja VAM HOFE	Germany
Elina FOUFA	Greece
Szilvia DEIM	Hungary
Sigriður KRISTJANSDOTTIR	Iceland
Tom O' SULLIVAN	Ireland
Mariano ALESSI	Italy
Parsla PALLO	Latvia
Manfred FRICK	Liechtenstein
Viktoras SESKAUSKAS	Lithuania
Jil WEBER	Luxembourg
Shirley MIFSUD	Malta
Maren WIKHEIM	Norway
Rui CABRITA	Portugal
Mihaiela ALBALESCU	Romania
Dušan KOLESAR	Slovakia
Mojca Jerai PEZDIR	Slovenia
Pablo SANCHEZ-PENA	Spain
Agneta WESTERBERG	Sweden
Mike POTTS	United Kingdom

Total number of TA positions occupied at 31.12.2010: 382
Other staff (CAs, Seconded National Experts, interims, trainees) at 31.12.2010: 90

Financial and human resources per Activity (including vacant posts and those being filled):

Activities	Human Resources			Budget execution
	AD	AST	CA	
Operational activities (Title III of the Budget)				
Operational activities – Implementation of the REACH and CLP Processes				
Activity 1: Registration, pre-registration and data-sharing	41	15	7	866 957
Activity 2: Evaluation	61	8	2	72 870
Activity 3: Authorisations and restrictions	27	5	1	177 398
Activity 4: Classification and labelling	10	2	2	29 450
Activity 5: Advice and assistance through guidance and helpdesk	28	12	5	326 322
Activity 6: IT support to operations	28	4	0	9 264 790
Activity 7: Scientific and practical advice to the further development of legislation	3	0	0	0
ECHA's bodies and supporting activities				
Activity 8: Committees and Forum	20	8	0	1 276 482
Activity 9: Board of Appeal	9	5	3	34 512
Activity 10: Communications	10	9	7	4 704 645
Activity 11: Relations with EU institutions and international cooperation	4	0	1	81 800
Management, organisation and resources				
Activity 12: Management	19	11	2	1 487 245
Total	**262**	**80**	**30**	
Activities 13-15: Title II (Infrastructure and operating expenditure)	26	58	22	10 739 961
Title I (staff expenditure)				42 214 050
Total	**288**	**138**	**52**	**71 276 483**
In Establishment plan:	**426**			

Registration dossier submission report at the close of the first registration deadline on 30 November 2010[23]

Number of dossiers by dossier type

Dossier type	Accepted for Processing		Successfully completed	
	Total	Deadline 2010	Total	Deadline 2010
Registrations	19 702	17 174	14 265	12 312
Transported Isolated Intermediates	3 544	2 692	2 699	1 979
On-site Isolated Intermediates	1 429	857	1 037	492
Total	**24 675**	**20 723**	**18 001**	**14, 783**

Percentage of dossiers split by Joint Submission Lead and Members plus Individuals

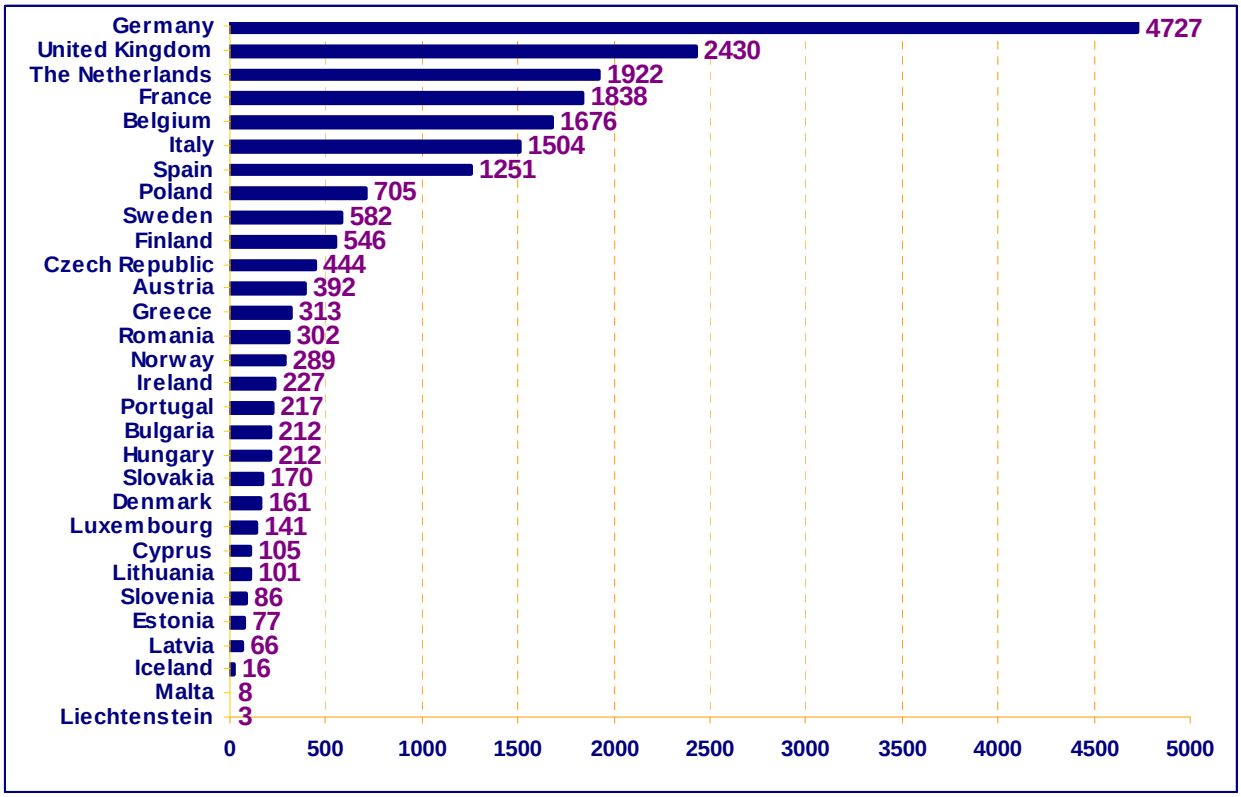
Type	% Accepted for Processing	Ratio of Members to Lead	% Successfully Completed	Ratio of Members to Lead
Lead	12%	-	16%	-
Member	82%	6.7	78%	5.0
Individual	6%	-	7%	-
	100%		100%	

Failure rates by dossier type

Dossier type	Pre-Processing		Technical Completeness Check	
	Total	Deadline 2010	Total	Deadline 2010
Registrations	19%	13%	1%	1%
Transported Isolated Intermediates	18%	10%	3%	2%
On-site Isolated Intermediates	15%	9%	2%	1%

[23] ***Notes***
The report includes registration dossier data from 2010 only. Dossier numbers include updates (spontaneous, by request) unless indicated. Percentages are rounded up to the nearest whole number.
Accepted for processing: dossiers that successfully passed Business Rules validation.
Successfully completed: dossiers that successfully went through the registration process and received their registration number.
Deadline 2010: dossiers submissions of phase-in substances, as indicated by industry, affected by the 30 November 2010 legal deadline

Number of dossiers Accepted for Processing by country



Percentage of dossiers by company size

Company size	Accepted for Processing		Successfully completed	
	Total	Deadline 2010	Total	Deadline 2010
Large	86%	86%	90%	91%
Medium	9%	9%	7%	6%
Small	4%	4%	2%	2%
Micro	1%	1%	1%	1%
	100%	100%	100%	100%

Percentage of dossiers submitted by an Only Representative

Roles	Accepted for Processing		Successfully completed	
	Total	Deadline 2010	Total	Deadline 2010
Only Representative	19%	19%	18%	18%

Percentage of registrations by tonnage band

Registrations

Tonnage	Accepted for Processing		Successfully completed	
	Total	Deadline 2010	Total	Deadline 2010
1-10	6%	4%	7%	3%
10-100	5%	2%	4%	2%
100-1000	8%	4%	7%	4%
1000 +	81%	90%	82%	91%
	100%	100%	100%	100%

Transported Isolated Intermediates

Tonnage	Accepted for Processing		Successfully completed	
	Total	Deadline 2010	Total	Deadline 2010
1-10	7%	3%	7%	2%
10-1000	25%	14%	25%	11%
1000 +	68%	83%	68%	87%
	100%	100%	100%	100%

On-site Isolated Intermediates

Tonnage	Accepted for Processing		Successfully completed	
	Total	Deadline 2010	Total	Deadline 2010
1-10	3%	1%	4%	1%
10 +	97%	99%	96%	99%
	100%	100%	100%	100%

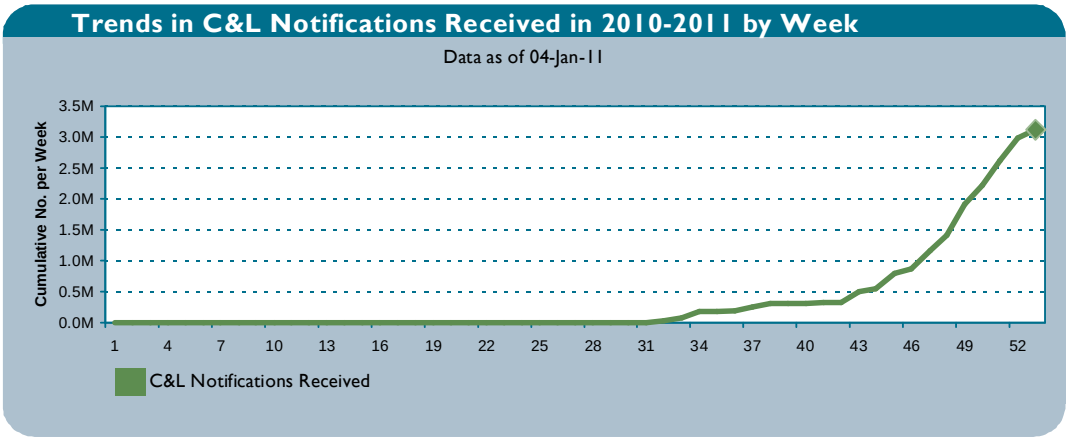
Spontaneous updates are excluded.

Number of testing proposals received

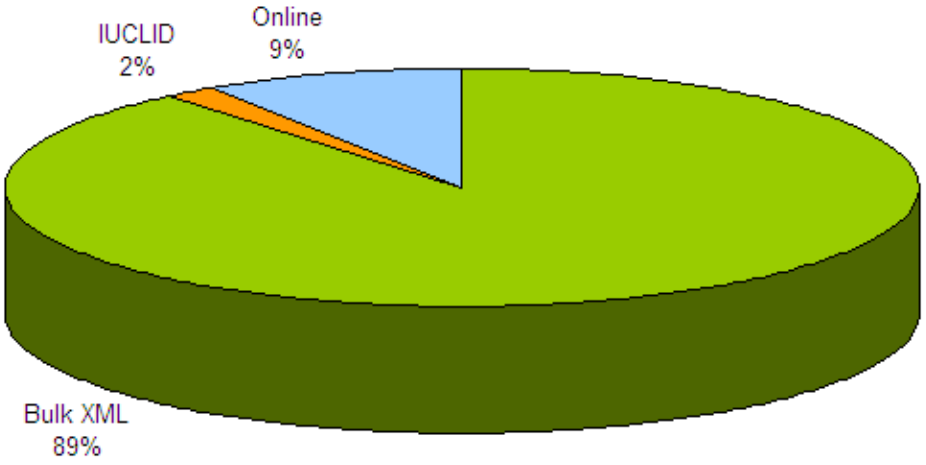
Dossiers with testing proposal(s): 580
Testing proposals: 1 548

CLP deadline report on 3 January 2011[24]

Number of notifications received: 3 114 835
Number of distinct substances: 107 067

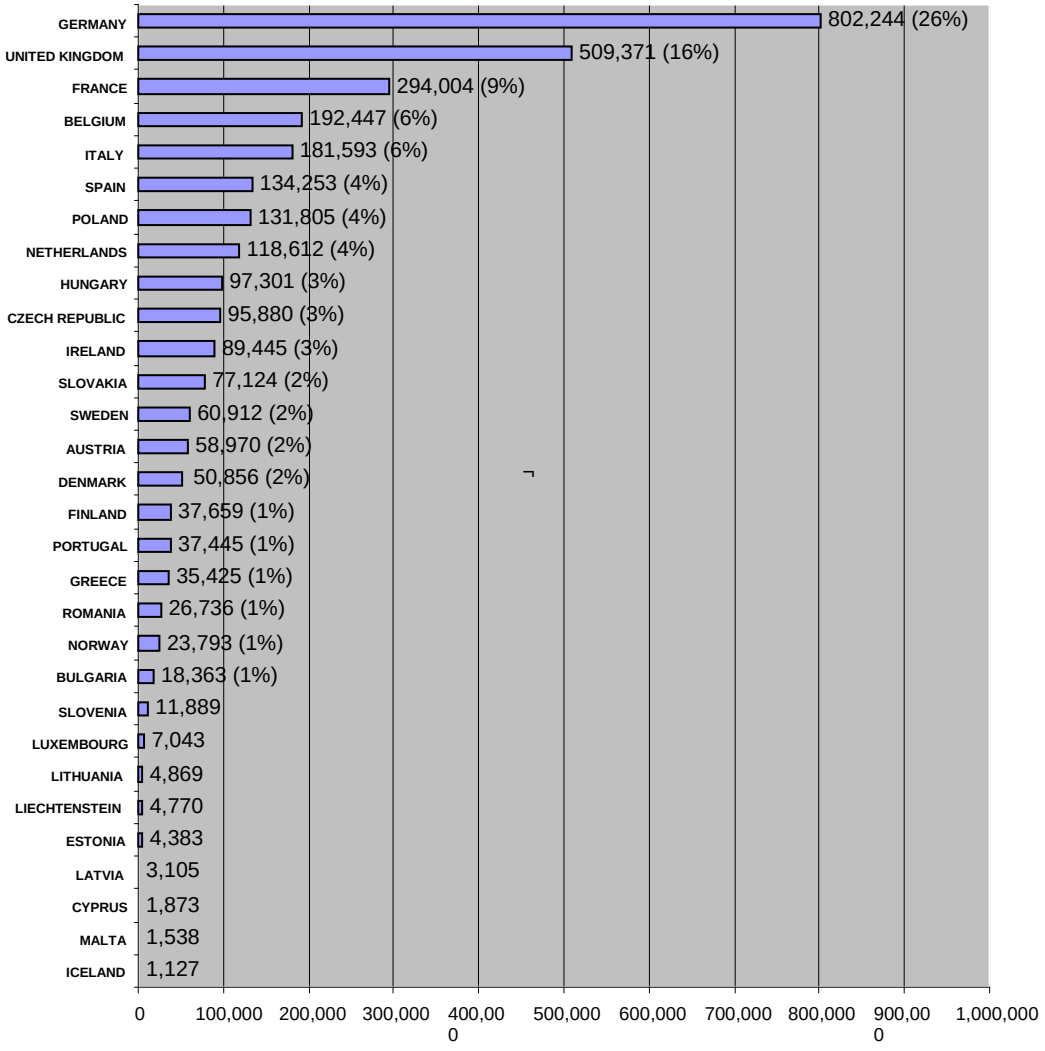


Total number of notifications received by way of submission



[24] ***Notes***
C&L data received since 1 January 2009. Data does not include notifications received via registration dossiers. Percentages are rounded up to the nearest whole number.

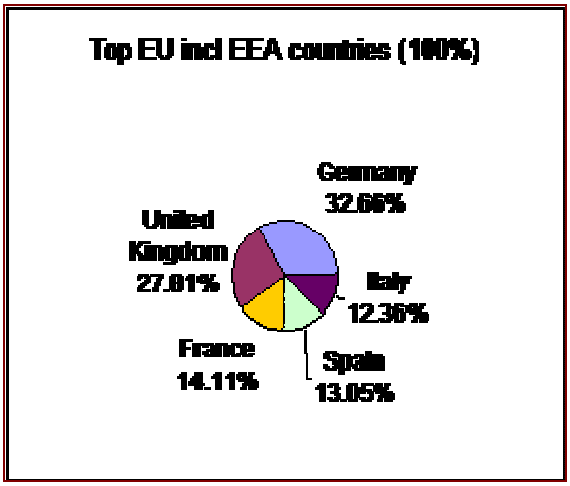
Total number of notifications received by country

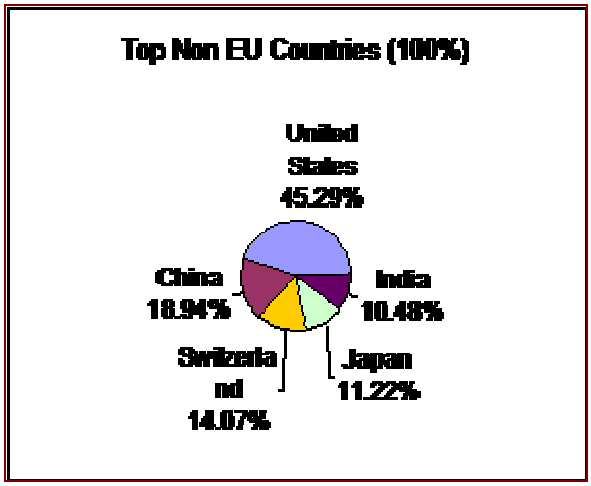


Total number of incidents received on the subject areas REACH, CLP, IUCLID 5, REACH-IT, CHESARand Submissions: 9782

Total number of questions resolved on the subject areas REACH, CLP, IUCLID 5, REACH-IT, CHESAR and Submissions: 9953

Top countries from which questions were received





Comments provided in HelpEx

Comments provided by ECHA to questions opened in HelpEx by national helpdesks during 2010 and number of comments provided within the deadline specified by the owner of the respective questions

Topic	Number of questions commented	Number on time	% on time	Average Delay working days	Maximum Delay working days
REACH	139	122	**88%**	18.18	134
CLP	51	41	**80%**	40.5	125
OVERALL	190	163	**86%**	-	-

Annex 5: Candidate List of Substances of Very High Concern

Nr.	Name	EC number	Date inclusion	Reason inclusion
1	Trichloroethylene	201-167-4	2010/06/18	Carcinogenic (article 57 a)
2	Boric acid	233-139-2 / 234-343-4	2010/06/18	Toxic for reproduction (article 57 c)
3	Disodium tetraborate, anhydrous	215-540-4	2010/06/18	Toxic for reproduction (article 57 c)
4	Tetraboron disodium heptaoxide, hydrate	235-541-3	2010/06/18	Toxic for reproduction (article 57 c)
5	Potassium dichromate	231-906-6	2010/06/18	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
6	Ammonium dichromate	232-143-1	2010/06/18	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
7	Potassium chromate	232-140-5	2010/06/18	Carcinogenic and mutagenic (articles 57 a and 57 b).
8	Sodium chromate	231-889-5	2010/06/18	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
9	2,4-Dinitrotoluene	204-450-0	2010/01/13	Carcinogenic (article 57a)
10	Acrylamide	201-173-7	2010/03/30	Carcinogenic and mutagenic (articles 57 a and 57 b)
11	Aluminosilicate Refractory Ceramic Fibres	-	2010/01/13	Carcinogenic (article 57a)
12	Anthracene oil	292-602-7	2010/01/13	Carcinogenic, PBT and vPvB (articles 57a, 57d and 57e)
13	Anthracene oil, anthracene-low	292-604-8	2010/01/13	Carcinogenic, mutagenic, PBT and vPvB (articles 57a, 57b, 57d and 57e)
14	Anthracene oil, anthracene paste	292-603-2	2010/01/13	Carcinogenic, mutagenic, PBT and vPvB (articles 57a, 57b, 57d and 57e)
15	Anthracene oil, anthracene paste, anthracene fraction	295-275-9	2010/01/13	Carcinogenic, mutagenic, PBT and vPvB (articles 57a, 57b, 57d and 57e)
16	Anthracene oil, anthracene paste,distn. lights	295-278-5	2010/01/13	Carcinogenic, mutagenic, PBT and vPvB (articles 57a, 57b, 57d and 57e)
17	Diisobutyl phthalate	201-553-2	2010/01/13	Toxic for reproduction (article 57c)
18	Lead chromate	231-846-0	2010/01/13	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
19	Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	235-759-9	2010/01/13	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
20	Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	2010/01/13	Carcinogenic and toxic for reproduction (articles 57 a and 57 c))
21	Pitch, coal tar, high temp.	266-028-2	2010/01/13	Carcinogenic, PBT and vPvB (articles 57a, 57d and 57e)
22	Tris(2-chloroethyl)phosphate	204-118-5	2010/01/13	Toxic for reproduction (article 57c)
23	Zirconia Aluminosilicate Refractory Ceramic Fibres	-	2010/01/13	Carcinogenic (article 57a)
24	4,4'- Diaminodiphenylmethane (MDA)	202-974-4	2008/10/28	Carcinogenic (article 57a)
25	5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	201-329-4	2008/10/28	vPvB (article 57e)
26	Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	287-476-5	2008/10/28	PBT and vPvB (articles 57 d and 57 e)
27	Anthracene	204-371-1	2008/10/28	PBT (article 57d)
28	Benzyl butyl phthalate (BBP)	201-622-7	2008/10/28	Toxic for reproduction (article 57c)
29	Bis (2-ethylhexyl)phthalate (DEHP)	204-211-0	2008/10/28	Toxic for reproduction (article 57c)
30	Bis(tributyltin)oxide (TBTO)	200-268-0	2008/10/28	PBT (article 57d)

Nr.	Name	EC number	Date inclusion	Reason inclusion
31	Cobalt dichloride	231-589-4	2008/10/28	Carcinogenic (article 57a)
32	Diarsenic pentaoxide	215-116-9	2008/10/28	Carcinogenic (article 57a)
33	Diarsenic trioxide	215-481-4	2008/10/28	Carcinogenic (article 57a)
34	Dibutyl phthalate (DBP)	201-557-4	2008/10/28	Toxic for reproduction (article 57c)
35	Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified:	247-148-4 and 221-695-9	2008/10/28	PBT (article 57d)
36	Lead hydrogen arsenate	232-064-2	2008/10/28	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
37	Sodium dichromate	234-190-3	2008/10/28	Carcinogenic, mutagenic and toxic for reproduction (articles 57a, 57b and 57c)
38	Triethyl arsenate	427-700-2	2008/10/28	Carcinogenic (article 57a)
39	Cobalt(II) sulphate	233-334-2	2010/12/15	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
40	Cobalt(II) dinitrate	233-402-1	2010/12/15	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
41	Cobalt(II) carbonate	208-169-4	2010/12/15	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
42	Cobalt(II) diacetate	200-755-8	2010/12/15	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
43	2-Methoxyethanol	203-713-7	2010/12/15	Toxic for reproduction (article 57c)
44	2-Ethoxyethanol	203-804-1	2010/12/15	Toxic for reproduction (article 57c)
45	Chromium trioxide	215-607-8	2010/12/15	Carcinogenic and mutagenic (articles 57 a and 57 b)
46	Chromic acid, Oligomers of chromic acid and dichromic acid, Dichromic acid	231-801-5 - 236-881-5	2010/12/15	Carcinogenic (article 57a)

Recommendation of the European Chemicals Agency (ECHA) of 17 December 2010 for the inclusion of substances in Annex XIV (the list of substances subject to authorisation) of Regulation (EC) No 1907/2006

					Transitional arrangements				
#	Substance	EC number	CAS Number	SVHC-relevant intrinsic properties	Latest application date pursuant to Art. 58 (1) (c) (ii)	Sunset date	Review periods	Exempted (categories of) uses	Exemptions for PPORD
1	**Diisobutyl phthalate (DIBP)**	201-553-2	84-69-5	*Article 57(c)* Repr. 1B # Repr. Cat. 2; R61##	01/07/2013 *	Latest application date plus 18 months	None	None	None
2	**Diarsenic trioxide**	215-481-4	1327-53-3	*Article 57(a)* Carc. 1A # Carc. Cat. 1; R45 ##	01/10/2013 **	Latest application date plus 18 months	None	None	None
3	**Diarsenic pentaoxide**	215-116-9	1303-28-2	*Article 57(a)* Carc. 1A # Carc. Cat. 1; R45 ##	01/10/2013 **	Latest application date plus 18 months	None	None	None
4	**Lead chromate**	231-846-0	7758-97-6	*Article 57(a) and 57(c)* Carc. 1B Repr. 1A # Carc. Cat. 2; R45 Repr. Cat. 1; R61 ##	01/10/2013 **	Latest application date plus 18 months	None	None	None
5	**Lead sulfochromate yellow (C.I. Pigment Yellow 34)**	215-693-7	1344-37-2	*Article 57(a) and 57(c)* Carc. 1B Repr. 1A # Carc. Cat. 2; R45 Repr. Cat. 1; R61 ##	01/10/2013 **	Latest application date plus 18 months	None	None	None
6	**Lead chromate molybdate sulfate red (C.I. Pigment Red 104)**	235-759-9	12656-85-8	*Article 57(a) and 57(c)* Carc. 1B Repr. 1A # Carc. Cat. 2; R45 Repr. Cat. 1; R61 ##	01/10/2013 **	Latest application date plus 18 months	None	None	None

#	Substance	EC number	CAS Number	SVHC-relevant intrinsic properties	Transitional arrangements		Review periods	Exempted (categories of) uses	Exemptions for PPORD
					Latest application date pursuant to Art. 58 (1) (c) (ii)	Sunset date			
7	**Tris (2-chloroethyl) phosphate (TCEP)**	204-118-5	115-96-8	*Article 57(c)* Repr. 1B # Repr. Cat 2; R60 ##	02/01/2014 **	Latest application date plus 18 months	None	None	None
8	**2,4 – Dinitrotoluene (2,4-DNT)**	204-450-0	121-14-2	*Article 57(a)* Carc. 1B # Carc. Cat. 2; R45 ##	02/01/2014 **	Latest application date plus 18 months	None	None	None

Classification in accordance with Annex VI, Table 3.1 (*List of harmonised classification and labelling of hazardous substances) 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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Classification in accordance with Annex VI, Table 3.2 *(The list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) 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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

* The sunset date for diisobutyl phthalate should be set as close as possible to the sunset dates for the phthalates included in the Commission Regulation amending Annex XIV to the REACH Regulation for the first time. The Commission is invited to take into account the principles set out in Annex I of this Recommendation in order to determine the appropriate latest application dates.

** The recommendation of the latest application dates is based on the assumption that the Commission Regulation amending Annex XIV to the REACH Regulation for the first time will enter into force in January 2011 and that the substances mentioned in the present Recommendation will be included in Annex XIV in January 2012. The Commission is invited to take into account the principles set out in Annex I of this Recommendation in order to determine the appropriate latest application dates.

Helsinki, 25 March 2011

Doc: MB/05/2011 final

ANALYSIS AND ASSESSMENT OF THE ANNUAL ACTIVITY REPORT OF THE AUTHORISING OFFICER FOR THE YEAR 2010

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 2010 adopted by the Management Board at its meeting of 29 September 2009 and updated on 17 December 2009,

Having regard to the Annual Activity Report of the Authorising Officer of the European Chemicals Agency for the year 2010 as submitted to the Board on 14 March and subject to the signing of the declaration of assurance,

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 2010 and, in particular, for the achievements in:

   (a) Rising to the challenge of processing almost 25 000 registrations covering some 4 300 distinct substances by the first registration deadline, despite the uncertainties that prevailed on the number of registration dossiers expected; planning and preparing well for this major milestone in the implementation of the REACH Regulation and having its staff, procedures, IT tools and support to registrants in place to allow smooth registration with very few rejections and consequently almost no appeals launched.

   (b) Processing over 3.1 million CLP notifications covering over 107,000 different substances by the 3 January 2011 deadline, which exceeded expectations by 50%.

   (c) Re-engineering REACH-IT and IUCLID5 to obtain efficiency gains for the registrants and the Agency, including improved functionalities; developing IUCLID plug-in tools to allow companies to check completeness of dossiers before

submission, the information which will be disseminated on the ECHA website and to verify their invoice before submitting the dossier; publishing CHESAR, the ECHA tool for chemical safety assessment and reporting ahead of the registration deadline.

(d) Supporting industry in building up capacity to submit complete registration and notification dossiers via various communication tools in the form of webinars and targeted materials in 22 EU languages.

(e) Investing substantial work and resources in providing direct support to registrants via the helpdesk and in producing updated and new guidance documents for industry and making a substantial number of these available in 22 EU languages well ahead of the registration deadline.

(f) Publishing detailed instructions for data sharing and setting up procedures for settling data sharing disputes as data sharing in SIEFs posed a major challenge to industry, contributing to a low number of notified disputes; also, putting potential and previous registrants of the same substance in contact, as the number of inquiries peaked ahead of the registration deadline.

(g) Defining the strategy for dissemination, publishing information on 383 substances on the dissemination portal and starting the assessment of confidentiality claims.

(h) Rapidly building up capacities in relation to the evaluation tasks with a focus on setting up small multidisciplinary teams to ensure efficient dossier evaluation of a high number of registrations coming from the first registration deadline.

(i) Completing two updates of the Candidate List of Substances of Very High Concern, adding 16 substances to the Candidate List, bringing thereby the total number of substances on the List to 46; submitting to the Commission its second recommendation for inclusion of a further 8 priority substances in the Authorisation List and submitting 4 restriction dossiers to RAC and SEAC for opinion, of which one proposal was developed by ECHA on request of the Commission.

(j) Concluding the first cooperation agreements with third countries (Canada and the US) and assisting the Commission effectively in international chemicals work undertaken by OECD and the UN.

3. Notes the high quality of the scientific advice provided by the Agency on request by the Commission, in particular in relation to the first reading 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.

4. Welcomes that the scientific Committees work transparently and involve observers from stakeholder organisations and that these observers and case owners will now have the opportunity to attend the Member State Committee discussions on draft decisions on dossier evaluation; also, commends the Committees in finding in all instances unanimous agreements and RAC in arriving at 15 opinions on harmonised classification and labelling proposals; encourages RAC to further ensure the participation of observers from any sector affected by a particular C&L proposal for harmonisation.

5. Notes the progress in revising the stakeholder policy, which is sent to the Commission for agreement.

6. Supports the management in its commitment taken during the adoption process of the 2011 Work Programme to conduct a feasibility and needs assessment with regard to enhancing SME accessibility to communication with the Agency, including via REACH-IT, in different languages.

7. Acknowledges the work of the Board of Appeal and its Registry to establish an effective and efficient appeals procedure through the adoption of the necessary implementing rules, the creation of helpful guidance in 22 languages and the development of internal quality tools.

8. Appreciates the Agency's substantial recruitment efforts, managing a notable increase of staff compared to the year before by recruiting more than 120 staff members.

9. Acknowledges the Agency's efforts to put the necessary procedures and staff in place to be able to cash fee incomes of € 349.7 million, but also appreciates the Commission's temporary 2010 subsidy, which was not fully used but helped to bridge the many months when fee revenue was below payments.

10. Notes that 2010 was an unusual budgetary year for the Agency due to the uncertainties attached to the size and timing of fee income and therefore understands the need for prudent budgeting and the timely planning of two budget reductions.

11. Highly welcomes the Agency's choice to accept or organise three important audits on registration-related topics and its responsiveness to the results of these audits, and acknowledges the further development of an Integrated Quality Management System, while stressing the need for balancing between the flexibility of procedures and the need for proper documenting of the processes.

12. Welcomes the efforts undertaken towards addressing business continuity issues, especially with a view to ensuring the success of the first registration deadline by developing and putting into place a back-up system for REACH-IT.

13. Appreciates the Agency's endeavour to successfully resolve the difficulties related to the access of Member State authorities to the REACH-IT system; also appreciates the implementation of a strong protection of physical and information security, and encourages the Agency to further improve the user-friendliness of the access to dossier information.

14. Notes the Agency's efforts in providing more detailed multi-annual planning of its activities and its commitment to revise the Commission's staff and finance model of the Agency.

15. Strongly appreciates the efforts of management and the entire staff in achieving the ambitious goals set by the regulations; also takes note of the high levels of stress measured due to the heavy workload and therefore encourages the Agency in identifying and resolving the main factors behind this problem, as it is key to maintaining high staff morale and retaining the highly qualified staff.

Helsinki, 25 March 2011

signed
For the Management Board
Thomas JAKL

European Chemicals Agency
P.O. Box 400, FI-00121 Helsinki
http://echa.europa.eu