ECHA
EUROPEAN CHEMICALS AGENCY

General Report 2011

The year of dissemination

General Report 2011

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European Chemicals Agency

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ANNEXES

ACRONYMS

AAR	Annual Activity Report
AD	Administrator
AST	Assistant
BC	Business Continuity
C & L	Classification and Labelling
CA	Contract Agent
CASPER	IT Characterisation Application for Selection, Prioritisation, Evaluation and Reporting
CHESAR	Chemical Safety Assessment and Reporting tool
CLH	Harmonised Classification & Labelling
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic, Reprotoxic
CLP	Classification, Labelling and Packaging
CoCAM	Cooperative Chemicals Assessment Meeting (formerly SIAM)
COM	European Commission
CoRAP	Community Rolling Action Plan
CSR	Chemical Safety Report
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
EFTA	European Free Trade Association
EMAS	Eco-Management and Audit Scheme
ENP	European Neighbourhood Policy
EU	European Union
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
ICT	Information and Communication Technologies
IPA	Instrument for Pre-Accession Assistance
IQMS	Integrated Quality Management System
IT	Information Technologies
ITIL	Information Technology Infrastructure Library
IUCLID	International Uniform Chemical Information Database
IUPAC	International Union of Pure and Applied Chemistry
MB	Management Board
MSC	Member State Committee
MSCA	Member State Competent Authority
NGO	Non-Governmental Organisation
NICNAS	National Industrial and Chemicals Notification and Assessment Scheme of Australia.
OECD	Organisation for Economic Cooperation and Development

PBT	Persistent, Bioaccumulative, Toxic
PIC	Prior Informed Consent Regulation
PPORD	Product and Process Oriented Research and Development
PPP	Plant Protection Product
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
SEAC	Socio-Economic Analysis Committee
SME	Small and Medium-sized Enterprise
SVHC	Substance of Very High Concern
TA	Temporary Agent
UN SC GHS	Subcommittee of the United Nations on the Globally Harmonized System for classification and labelling of chemical substances and mixtures
vPvB	Very Persistent and Very Bioaccumulative
WPMN	OECD Working Party on Manufactured Nanomaterials
W/W	Weight by Weight

FOREWORD BY THE EXECUTIVE DIRECTOR

"The year of dissemination

Welcome to this report on the European Chemical Agency's work in 2011 – what I call our year of dissemination. Dissemination is a rather dry word for what is actually an exciting outcome of the work that both we and companies have done over the preceeding years. Our website now plays host to detailed information on more than 100 000 chemical substances coming from over 25 000 registration dossiers and over 3 million classification and labelling notifications. That is a information resource that is unique in the world and an achievement in which we are very proud to have played our part. That said, I am the first to admit that the dissemination challenge is not over yet as we need to extract still more valuable information from the dossiers, as companies will or have to update their dossiers and notifications. We also want to make it more easy to search and understand. We have a clear roadmap on how to make those improvements over time. But an excellent start has been made to fill the information gap on widely used chemicals that REACH was designed to fill.

Last year also marked a significant shift of focus for ECHA, from helping companies to meet the deadlines to the large scale evaluation of registered dossiers. In 2011 the focus was on examining dossiers containing proposals from companies to test substances on animals and we have made considerable progress with that. However, we have been unable to conclude on as many of the test proposals as we had hoped, because the identity of the substances concerned was often unclear, requiring us to do a compliance check. This is an important shortcoming in a large proportion of the dossiers examined so far and needs to be improved upon by companies. If the identity of the substance is not clear, then not only the testing proposal but also the safe handling of the substance(s) are deficient.

During 2011, we have also made progress on managing the risks posed by the most hazardous substances: with 28 Substances of Very High Concern (SVHCs) being added to the Candidate List; thirteen more substances being recommended for Authorisation; and ECHA's scientific committees adopting opinions on the first four restrictions. I know that for a number of stakeholders, action on risk management can never be fast enough, but if we take a moment to reflect on how far we have come in the four short years since ECHA began its work, we can clearly see the enormous progress compared to the past.

Once again, I would like to thank all my colleagues in ECHA for their commitment and hard work, as well as to our stakeholders throughout Europe for their support and participation on the project that is REACH.

I wish you all a successful 2012.

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

ECHA's Mission

ECHA is the driving force among regulatory authorities in implementing the EU's groundbreaking chemicals legislation for the benefit of human health and the environment as well as for innovation and competitiveness. ECHA helps companies to comply with the legislation, advances the safe use of chemicals, provides information on chemicals and addresses chemicals of concern.

ECHA's Vision

ECHA aspires to become the world's leading regulatory authority on the safety of chemicals.

ECHA's Values

Transparent

We are open and transparent in our actions and decision-making. We are easy to understand and to approach.

Independent

We are independent from all external interests and impartial in our decision making. We consult members of the public openly before taking many of our decisions.

Trustworthy

Our decisions are science based, consistent and impartial. Accountability and the security of confidential information are cornerstones of all our actions.

Efficient

We are goal-oriented, committed and we always seek to use resources wisely. We apply high quality standards and respect deadlines.

Committed to well-being

We stimulate the safe and sustainable use of chemicals to improve the quality of life of all citizens in Europe and the environment.

Main Achievements 2011 - Summary

The first achievement of the year was the successful receipt of over three million classification and labelling notifications covering more than 100 000 distinct substances by the CLP deadline of 3 January and the successful processing within the set deadline of 28 February 2011 of all registration dossiers received by the first REACH registration deadline of 30 November 2010.

Subsequently, the focus shifted to making information on the chemicals registered or notified publicly available. By the end of the year, a massive and unique volume of safety information from more than 23 000 registration dossiers covering more than 4 100 substances (or 78% of the registered substances) were freely available via the dissemination portal on the ECHA website. Hereby, it was also instrumental that good progress was made with regard to the assessment of confidentiality claims provided by the registrants for certain parts of the dossiers.

It was planned that the first version of the public inventory with information from C&L notifications would be published during the year. However, the complexity of the task delayed the publication beyond 2011, which was finally achieved in early 2012.

A further shift in focus was towards the evaluation of registered dossiers. In 2011, the primary focus of the dossier evaluation was on testing proposal examinations due to the fixed deadlines for these evaluations. However, unclear substance identity in a significant share of the corresponding dossiers prevented a meaningful examination of testing proposals and a targeted compliance check was necessary first. This almost doubled the number of planned compliance checks, while slowing down the examination of testing proposals. Nevertheless, a remarkable progress was made both with the evaluation of the testing proposals and with the compliance checks of the dossiers.

As planned, the first proposal for the Community rolling action plan (CoRAP), including 91 substances for 2012-2014, was submitted to the Member States and ECHA Member State Committee. This will permit the start of substance evaluation, which aims to verify whether a substance constitutes a risk for human health or the environment and will be undertaken by Member States for the first time in 2012.

During 2011, 28 Substances of Very High Concern (SVHCs) were added to the Candidate List. Among these substances was the first substance that has been identified as an SVHC because of its probable serious effects on the environment giving rise to an equivalent level of concern. By the end of the year, the total number of SVHC substances included in the Candidate List was 73, which is still well below the policy target of 136 for the end of 2012.

ECHA also sent its third recommendation for inclusion of priority substances in the Authorisation List to the Commission. Inclusion of thirteen substances from the Candidate List was recommended. ECHA also finalised its procedures for receiving authorisation applications, but no applications were submitted in 2011. Furthermore, ECHA’s scientific committees adopted opinions on the first four restrictions.

In accordance with the legal requirements of REACH, ECHA delivered its first five-year report on the operation of the REACH Regulation. The first three-year report on the status of implementation and use of non-animal test methods and testing strategies was also produced. Both reports were submitted to the Commission and were made public in the interest of transparency.

ECHA closely followed the developments of the REACH Implementation Projects on nanomaterials and assisted the Commission in compiling information on nanomaterial types and uses. Additionally, ECHA contributed to the further development of OECD test guidelines with a view to ensuring that test methods are developed and updated according to the latest scientific knowledge, while avoiding unnecessary animal testing.

Advice and assistance to industry continued to be provided via guidance and the helpdesk, and all material intended for the general public and SMEs was translated into 22 EU languages. ECHA launched its awareness campaign *REACH 2013 – Act now!* to assist companies in preparing for the second registration deadline in 2013. Guidance has been made more readily accessible to SMEs by the re-design of the guidance web section, by simplifying guidance where practical and by making ECHA's multilingual REACH and CLP terminology database available; facilitating translation and harmonising key REACH terminology.

As expected, the workload of the ECHA Committees increased in 2011, but nevertheless all of the dossiers have been processed within the legal timeframe, were of high quality and most were agreed upon unanimously or adopted by consensus. The ECHA Secretariat provided the necessary support to the Forum that stepped up its activities towards effective and harmonised enforcement of REACH and CLP throughout the EU/EEA.

As the enforcement and implementation of the REACH and CLP processes require a wide range of IT systems, their further development and maintenance continued to be crucial for ECHA's operations in 2011. RIPE, a new tool for enforcement authorities was rolled out and new versions of REACH-IT, IUCLID 5 and Chesar in support of registration by companies were released.

In order to be well prepared for the rapidly increasing volume of technical and scientific tasks demanded of the Agency and to move towards multiple science-based decision and opinion making, ECHA's organisational structure was changed at the beginning of the year. A more horizontal organisation with three new Directorates was created. Implementation of the reorganisation required the adaptation of management processes to the larger organisation and ensuring efficient coordination of cross-Directorate activities. This was complemented later in the year with the launch of a specific corporate identity and a new visual identity that stress the service-orientation and ambitions of ECHA towards all its customers. The new website was launched on 15 December, and is making this very visible to the public.

The activities of ECHA were fully self-financed in 2011, based on the revenue received in 2011, complemented with a balancing amount from the 2010 accumulated reserve. The Agency also repaid the EU subsidy received in 2010 to the Commission.

ECHA continued to attract highly qualified personnel, with 88 new staff recruited during the year. This resulted in filling 98% of the posts in the establishment plan. ECHA also continued to give due attention to the well-being and motivation of the staff, as well as to the induction and professional training of new and existing staff.

OPERATIONAL ACTIVITIES – IMPLEMENTATION OF THE REACH AND CLP PROCESSES

Activity 1: Registration, data-sharing and dissemination

Main Achievements in 2011

Registration and dossier submissions

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. Companies that annually produce or import substances above one tonne are required to document all this information in a registration dossier that must be submitted to ECHA.

The year started with the finalisation of all registrations submitted for the first REACH registration deadline of 30 November 2010, which focused on the registration of high volume substances (1000 tonnes/year) and on certain types of substances of concern. For the registration dossiers submitted in the last two months before the deadline, ECHA had until 28 February 2011 to check that they were technically complete. This was successfully done for all dossiers due to careful planning and the enhancements that had been introduced to the REACH-IT system towards the end of 2010, which enabled the Agency to rely on an automated completeness check and to keep human intervention to a minimum. Based on this, most of the registration dossiers were given a registration number. Only about 1% (some 220) of the dossiers were rejected; with 75% of those rejections due to non-payment of the registration fee. Detailed information on the outcome of the first registration is included in the first report of ECHA to the Commission on the operation of the REACH Regulation, which was finalised in June 2011.[1]

Further to this first wave of registration dossiers received in 2010 but still requiring processing in early 2011, the registration activity settled on a relatively steady level of 6 079 new or updated registration dossiers that were successfully processed by ECHA in 2011. This was a higher workload than had been estimated in the Work Programme, however ECHA managed to verify their completeness within the regulatory deadlines.

As the next registration deadline for substances produced or imported in quantities over 100 tonnes per year is in May 2013, ECHA initiated its preparation activities in the second half of 2011, taking into account the lessons learnt in 2010. The main activities in 2011 were the development and provision of targeted advice for the 2013 registrants via a specific website (See Activity 10)[2], the development of the technical content for the webinar programme to support registrants throughout 2012 and the launch of market surveys to gather a better understanding on substances intended to be registered by 31 May 2013.

In 2011, ECHA also continued the verification of the status of dossiers for substances registered with intermediate uses, only to confirm that these uses are in

[1] See *Report on the Operation of the REACH Regulation* available on the ECHA website at echa.europa.eu/documents/10162/17226/operation_reach_clp_2011_en.pdf.
[2] echa.europa.eu/reach2013.

line with the definition of intermediate use and that strictly controlled conditions are applied. After screening approximately 400 dossiers, ECHA sent more than 40 letters based on Article 36 of the REACH Regulation to the registrants requesting them to clarify the intermediate status of the substance. ECHA will examine the responses to these letters in early 2012.

Although the 2010 registration deadline was a success in terms of timely submission of dossiers by industry and processing by ECHA, concerns regarding the quality of the registration dossiers were rapidly highlighted by ECHA and other stakeholders. Therefore, in addition to meeting a number of formal reporting obligations under REACH, ECHA began developing a range of computational tools and other methods to facilitate more specialised and targeted searches within the registration database. When these are fully developed, they will enable ECHA to screen for those dossiers where safe use is insufficiently demonstrated and require appropriate responses in case of insufficient performance, as well as identify common shortcomings in the registration dossiers that may warrant follow-up outside dossier evaluation. This, together with certain dossier quality issues encountered during the compliance check process (see Activity 2), has resulted in the need to identify algorithms to efficiently and effectively identify dossiers of poor quality from the registration database for evaluation and other purposes.

Regarding temporary exemptions from registration obligations due to product and process oriented reseach and development (PPORD), which aim to stimulate European innovation, a total of 232 notifications were successfully processed in 2011. The number of PPORD dossiers appears to be quite stable throughout the years and is in line with the assumptions. ECHA also has the possibility to impose conditions on the PPORD exemptions, for example to ensure that the substance is handled in reasonably controlled conditions. To this end, ECHA began the development of the assessment process of the PPORD notifications in late 2011. A pilot project was launched in preparation for the full roll out of the process planned in 2012.

New dossier submission types were introduced from 1 April onwards, enabling ECHA to start receiving reports from Downstream Users (for uses not supported by their suppliers as communicated to them in the exposure scenarios attached to the safety data sheets[3]), notifications of substances in articles, applications for authorisation and applications for an alternate name under Article 24 of the CLP Regulation.

During the year, ECHA received a total of 64 Downstream User reports. This is much less than initially expected in the Work Programme, but several reasons were found. Most notably, industry informed ECHA that towards the end of the year only a fraction of the safety data sheets had been updated due to REACH registration, and therefore the reporting obligations for downstream users were not triggered yet or their deadline of six months for reporting was still running at the end of 2011. From 1 June 2011, the submission of notifications of substance in articles became possible via REACH-IT. A total of 203 notifications were received by the end of the year (for details see Activity 3).

Data sharing and substance identification

Companies registering the same substance are required to share their data to minimise registration costs and avoid unnecessary animal testing. ECHA plays no role in the negotiations between the companies. However, if they cannot reach an agreement, they can submit their case to ECHA. The claims submitted to ECHA for

[3] Article 38 of the REACH Regulation.

settling data sharing disputes remained very low in 2011 following the first registration deadline. Five claims, received in 2010, were finalised in early 2011. In three cases, ECHA concluded that the party submitting the claim had not made every effort to reach a data sharing agreement. The two other cases were closed as the parties found an agreement. Two new claims were received in 2011. One of them was also closed while the remaining one is still being processed.

In contrast, the activities around the inquiry process - the step prior to registration that enables potential registrants of non phase-in substances or phase-in substances that were not pre-registered to be put into contact with previous registrants in order for them to share data - were intensive. While the number of incoming inquiries was only slightly higher than predicted (1 900), the total number of inquiries processed in 2011 went over 2 100 due to the backlog of inquiries carried over from 2010. In 2011, 40% of the inquiries were for phase-in substances, and hence do not represent new substances on the European market but rather additional companies manufacturing or importing these substances into the EU.

As the high number of inquiries processed coincided with problems in the quality of the substance identification information provided by the inquirers, the internal target timeframe of handling the inquiries within 20 working days could not be met during the first part of the year. In response to the concerns of the industry on the prolonged response time to their inquiries, ECHA revised the inquiry process during 2011 to improve its efficiency, by streamlining the internal procedure and by supporting companies with an IT tool and an updated Q&A document to enable them to improve the substance identification information prior to submission of their dossier. As a result, since September 2011, 80% of the inquiries were processed within the target of 20 working days.

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. This activity is expected to have a positive impact on health and environmental protection both in Europe and worldwide, as everyone gets the chance to access information on the chemicals they use. Until 2011, the process required a number of procedural steps because ECHA individually communicated with the registrants to confirm the parts of their dossiers for publication. In 2011, ECHA was able to move to a semi-automated dissemination process, thanks to a dedicated IT tool ("dissemination filter tool"), supported by a manual, that enables registrants to check themselves prior to submission which parts of their registration dossiers will be published on the ECHA website.

During 2011, the number of registration dossiers, from which information was made available in the dissemination portal on the ECHA website, was dramatically increased from a few hundred dossiers to more than 23 000 dossiers, corresponding to 88% of all registrations and 78% of the registered substances. The dissemination was done in batches, starting with the data-rich dossiers from Lead Registrants in March, and adding the information from the member dossiers in November.

There was also substantial work done to improve the usability and user-friendliness of the dissemination portal. As a first step, the dissemination portal was linked to the OECD eChemPortal[4] in April, giving the users the possibility to search on properties and effects of registered substances. Secondly, an improved layout was introduced based on stakeholders' feedback and was applied to the disseminated dossiers in May. Finally in December – in the context of the renovation of the ECHA website – a new "search for substances" was added. This feature allows users to

[4] Global portal to information on chemical substances, www.echemportal.org/

search for a substance and retrieve in one go all the lists which include this substance (such as the list of registered substances, pre-registered substances, candidate list, registry of intentions, etc.) and a direct link to the information.

Another activity related to dissemination is to assess whether requests for confidentiality introduced by the registrants in their dossiers are justified and valid. The process is in two steps: i) the initial assessment which may lead to either the acceptance of the claim, the direct rejection of it in case the information cannot be made confidential in accordance with REACH or the requirement of the registrants to provide further information; and ii) the final assessment which consists in reviewing the new argumentation provided for the claim in the updated dossier. In case of rejection, the registrant may request a review of the rejection decision.

About 3,5% of the dossiers received before the first registration deadline of 2010 contained one or more requests for confidentiality, leading to an overall number of 1 066 claims to be verified. ECHA's target for 2011 was to focus on the claims received in 2010 and assess 90% of those claims. However, during the development of the process in 2011, it became evident that the most efficient manner to proceed was to group the claims by category instead of following a chronological order. Moreover, the claims on the IUPAC name, which represent about 60% of the claims, had to be prioritised, even if they were received in 2011, in order to ensure that dossiers containing a testing proposal or disseminated dossiers were associated with a clear substance identity. For this reason, only 64% of the 2010 claims underwent the initial assessment. However a fair proportion of 'new' claims received during 2011 were also verified, leading to almost the same volume of assessments as initially planned. With this change introduced, the rate of assessment has become satisfactory and will ensure that ECHA will proceed swiftly with its target for 2012.

In total, there were 1 693 confidentiality claims in the registration dossiers received by the end of 2011. As a result of the grouping of the claims, ECHA had completed the initial assessment for 927 (55%) of these and concluded on 630 (38%) claims, with the majority of the remainder awaiting an update of the registration dossier from the company following a formal request for further information.

With nearly all registration dossiers published, ECHA's dissemination activities during late 2011 turned into the setting up of systems for disseminating other parts of the registration dossiers. Based on an opinion of the European Commission, ECHA concluded that the dissemination provisions of REACH need to be interpreted in a larger way to also include certain information contained in the safety data sheets, such as company name, registration number and the outcome of the PBT and vPvB assessment. These additional elements can only be disseminated in 2012 however, as it requires changes to different IT systems of ECHA and industry needs to have the opportunity to claim these fields partly or completely confidential.

Objectives and Indicators

Objectives

1. All dossiers and data sharing disputes are processed, and PPORD notifications and confidentiality claims assessed, 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.
3. Decisions on registrations and PPORD notifications are of a high technical and scientific quality.

4. Public information from all dossiers of substances registered before the first registration deadline is published on the ECHA website.

Performance Indicators & Targets

Indicator	Target in 2011	Means and frequency of verification	Result 2011
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	48%
Percentage of initial assessments of confidentiality requests in the registration dossiers submitted for the 2010 the registration deadline	Not less than 90%	Recorded in REACH-IT, quarterly reporting	64%
Percentage of assessed confidentiality requests in the registration dossiers submitted for the 2010 the registration deadline.	Not less than 90%	Recorded in REACH-IT, quarterly reporting	44%
Percentage of registration dossiers (non-confidential information) published on the ECHA website.	Not less than 80%	Annual internal report	88%
Number of appeals made by registrants and notifiers against decisions.	Not more than 10% of decisions	Monitoring responses to decisions monthly	1%

Main Outputs

- All dossiers for phase-in substances deriving from the 2010 deadline processed (registrations accepted or rejected and invoices sent); data sharing disputes processed according to the appropriate deadlines.
- Almost 5 000 registration dossiers (of which 2 500 were updates), 2 100 inquiries and 230 Product and Process Oriented Research and Development (PPORD) notifications, received and processed.
- More than 900 initial confidentiality claim assessments done and almost 600 decisions finalised.
- Information from more than 23 000 registration dossiers published on the ECHA website, covering more than 4 100 substances, and this information linked to the OECD eChemPortal.

Table 1: Number of new dossiers received in 2011

Dossier type	Actual	WP 2011 estimates
Registrations	4 376	-
Transported Isolated Intermediates	917	-
On-Site Isolated Intermediates	178	-
Total registration dossiers	**5 471**	**4 500**
PPORD notifications	243	200
Inquiries	1 970	1 800
Notifications under Article 7(2)	218	40
Reports under Article 38	64	45 000

Table 2: Dossier submissions completed by ECHA in 2011

Dossier type	Completeness check successful			Rejected
	Total	Original submission	Updates	
Registrations	4 935	2 394	2 541	199
Transported Isolated Intermediates	938	546	392	26
On-site Isolated Intermediates	206	144	62	3
Total	**6 079**	3 084	2 995	**228**[5]
PPORD notifications	232	187	45	3

[5] Of these, 172 were for non payment of the required fee.

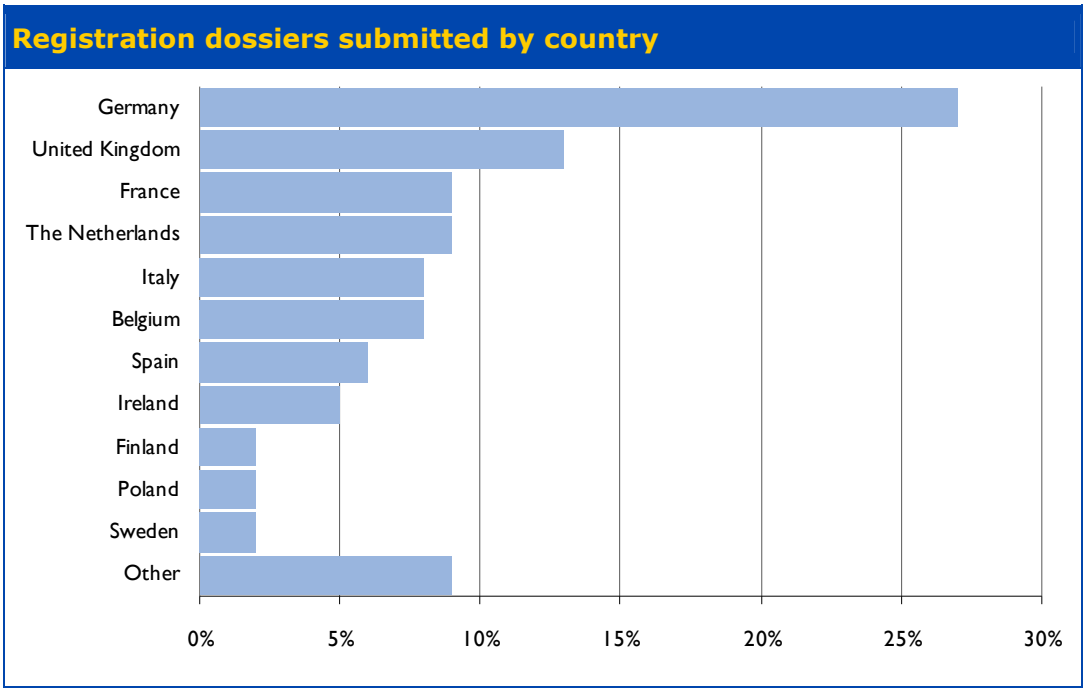
Table 3: Confidentiality claims in 2011

Confidentiality claims	Actual	WP 2011 estimates
Number of new confidentiality claims	627	250
Number of initial assessments	927	-
Number of final decisions	630	960 (90% of 2010 claims)
Positive decisions	229	-
Negative decisions	N/A	20
Decisions: claim out of scope	357	-
Claims removed by the registrant	44	-

Table 4: Dissemination statistics by end 2011

Number of substances disseminated	4 133
Number of dossiers disseminated	23 856

Graph 1: Total of registration dossiers submitted in 2011 by country



Activity 2: Evaluation

Main Achievements in 2011

Dossier Evaluation

After the first registration deadline had passed, the evaluation of the registration dossiers became a key focus of attention for ECHA. Through this activity, ECHA verifies whether the registrants are meeting the standard information requirements set in REACH. The main output of the dossier evaluation are the legally binding decisions requiring registrants to perform further tests or provide other type of information and to update the dossier accordingly.

Based on the information on the number of registrations submitted in 2010 and testing proposals included in the dossiers, a multi-annual plan for Evaluation was prepared and presented to the Management Board in March 2011. The plan aimed to ensure that the targets provided in the REACH text could be met, i.e. to examine all submitted testing proposals in the legal timeframe and to conduct compliance checks for at least 5% of the submitted dossiers. This plan estimated the number of concluded testing proposal examinations for 2011 as 250 and the number of concluded compliance checks as 100. It should be noted that "conclusion" in this context means that a draft decision (not a final decision) or other conclusion by ECHA is issued.

In 2011, the main focus of the dossier evaluation was on testing proposal examinations: it was important to initiate the majority and conclude a significant part of the testing proposals examinations for dossiers submitted for the first registration deadline in 2010, in order to meet the legal deadline of 1 December 2012 for concluding on the proposals. Therefore, a strategy was developed which was targeted on efficiency gains by clustering similar types of proposals or proposals from similar chemical structures and by batching the third party consultation for proposals involving vertebrate animals. The results of the work are presented in table 5. Whilst there was good progress made in processing the testing proposals, the target for testing proposal examinations could not be fully met. The main reason was that when examining the cases, several dossiers with unclear substance identity were found, preventing a meaningful examination of their testing proposals. In these cases, a targeted compliance check had to be conducted first to clarify the substance identity. The need to open such targeted compliance checks almost doubled the number of compliance checks originally planned, which gives an impression of the size of the issue at stake. In parallel, ECHA continued compliance checks also on other dossiers many of which were initiated in 2010 (see table 6).

The specific advice given to registrants resulting from evaluation was improved in 2011. In the annual progress report on REACH evaluation for 2010, published on ECHA's website in February 2011[6], detailed recommendations were provided to registrants. One of the main conclusions of the report was that a significant part of the dossiers evaluated had at least some quality problems – whether they were selected at random or based on some specific concern.

In line with Article 117(3) of REACH and in accordance with the objective of promoting non-animal testing methods, ECHA submitted for the first time a report on the status of implementation and use of non-animal test methods to the European Commission in June 2011. In this report, the registration dossiers received by the first registration deadline were analysed to examine how companies are using alternatives to testing on animals. The main finding of the report is that

[6] http://echa.europa.eu/documents/10162/17221/evaluation_under_reach_progress_report_2010_en.pdf

registrants have in general used all available information and alternative methods before conducting further animal studies or submitting a testing proposal. The report was published in July on the ECHA website[7].

As a prerequisite to handling complex dossiers on high tonnage substances submitted by 1 December 2010, ECHA continued capacity building by recruiting, training (including laboratory visits and hands-on training) and integrating new staff, as well as by reinforcing internal scientific competences, initiating targeted research on questions of immediate relevance to evaluation and networking with external experts.

Moreover, ECHA continued to improve the efficiency of the process in order to simultaneously handle several hundreds of dossier evaluations per year. The expert-based decision support system was put into practice in 2011; it guides evaluators by using standardised questions and instructions and contributes to efficiency gains. Progress has been made towards the specification and implementation of the new document management system that will – once implemented in 2012 - further streamline the workflow and standardise ECHA's approach.

Substance evaluation

Substance evaluation aims to verify whether a substance constitutes a risk for human health or the environment. Substance evaluations are performed by Member State Competent Authorities (MSCAs) and involve an assessment of all available information and requests for further information from registrants, if appropriate. The starting point for substance evaluation is the Community rolling action plan (CoRAP) for substances subject to substance evaluation.

In 2011, the preparations to start the REACH process for the first time in 2012 have been successfully concluded. For that purpose, ECHA continued the dialogue with Member State Competent Authorities, members of the Member State Committee and the Commission, and a consensus view was developed and the process for substance evaluation was agreed. In a workshop organised by ECHA[8], a section was dedicated to validate the criteria for the selection of substances for substance evaluation and to inform the Member States of the planned activities with regard to the development of the draft CoRAP.

The Agency submitted the first proposal for the CoRAP to the Member States and ECHA Member State Committee on 20 October 2011. The draft CoRAP contained 91 substances divided tentatively for the years 2012, 2013 and 2014. Based on the opinion of the Member State Committee, the Agency will adopt the final CoRAP by the end of February 2012.

Objectives and Indicators

Objectives

1. Scientifically sound draft decisions in compliance with the legal requirements are prepared.
2. ECHA has an updated multi-annual plan for evaluation.
3. ECHA has created the foundation for an effective start to substance evaluation.

[7] http://echa.europa.eu/documents/10162/17231/alternatives_test_animals_2011_en.pdf
[8] Workshop on 23 & 24 May 2011. The proceedings are available on the ECHA website.

Performance Indicators & Targets

Indicator	Target in 2011	Means and frequency of verification	Result 2011
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	97%
Number of appeals lost.	0	Annual internal report	N/A

Main Outputs

- The third annual progress report on REACH evaluation was published in February 2011 according to the legal deadline.
- The first tri-annual report on 'The Use of Alternatives to Testing on Animals for the REACH Regulation' has been submitted to the Commission and was published in July 2011.
- New staff members 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.
- An updated multi-annual plan for evaluation has been submitted to the Management Board and was approved in March.
- 393 concluded dossier evaluations (216 testing proposals and 177 compliance checks).
- The criteria for prioritising substances for substance evaluation have been established.
- The first proposal for the Community Rolling Action Plan (CoRAP) was submitted to the Member States and ECHA Member State Committee in October 2011.

Table 5: Number of testing proposal examinations and status of the processes in 2011.

Type	No. of dossiers with testing proposals	Draft decision	Final decision	Terminated	Examination continuing in 2012
Phase-in	542	129	9	48	356
Non-phase-in	45	15	13	10	7
TOTAL	587	144	22	58	363

Table 6: Compliance checks completed or concluded in 2011

Output	No.
Final decisions	105
Withdrawn at the draft decision phase upon further information by the registrant	10
Quality observation letters	19
Concluded without action	12
Draft decisions sent to the registrants (decision making process ongoing at the end of 2011)	146

Activity 3: Authorisations and Restrictions

Main Achievements in 2011

Authorisation

ECHA's tasks relating to authorisation include preparing and updating the Candidate List, regularly preparing a recommendation to the Commission on substances from the Candidate List to be included in the so called Authorisation List – the List of Substances Subject to Authorisation (Annex XIV of the REACH Regulation) – and, in the near future, handling the authorisation applications submitted by industry if they want to continue placing on the market and using these Substances of Very High Concern (SVHCs).

Substances of Very High Concern and Annex XIV

Twice a year, ECHA receives new dossiers with proposals for identification of Substances of Very High Concern (SVHCs) from the Member States. In 2011, ECHA received 28 dossiers. After the public consultations during which nearly 600 comments were received, the Member State Committee (MSC) reached unanimous agreement on the SVHC status of 19 substances. Among these substances was 4-tert-Octylphenol, which is the first substance that has been identified as an SVHC in accordance with REACH Article 57 (f) because of its probable serious effects on the environment giving rise to an equivalent level of concern. For a further nine substances no comments challenging the SVHC properties were received so that these substances where included in the Candidate List without MSC involvement. Overall, eight substances were added to the Candidate List in June and 20 in December 2011, which remained below the internal target of 40 SVHCs that would have been needed to reach the political target of 136 SVHCs by the end of 2012. By the end of 2011, the total number of SVHC substances included in the Candidate List was 73.

On 22 December 2011, ECHA sent its third recommendation for the inclusion of priority substances in the Authorisation List to the Commission. The inclusion of 13 substances[9] from the Candidate List was recommended and suggestions for the application and sunset dates were made. The recommendation was supported by a (large) majority opinion of the Member State Committee and took account, where relevant, of the comments (nearly 1 400) received from interested parties during the public consultation, which took place earlier in the year. Once the Commission has amended the Authorisation List (Annex XIV), industry will ultimately require an authorisation. ECHA's recommendation, the MSC opinion and all background documentation are publicly available on ECHA's website.

ECHA reviewed publicly available data on the uses of and exposures to 35 substances with CMR or PBT profiles to preliminary screen them for the need of SVHC identification/ Candidate listing and potential further risk management measures. On the basis of this preliminary screening, the Commission requested ECHA to prepare dossiers for the identification of eleven substances as SVHCs, which were submitted and passed the two SVHC identification processes carried out in 2011.

Authorisation Applications

In February 2011, the Commission adopted for the first time a Regulation through which the first six substances entered the Authorisation List (Annex XIV). A second such regulation was under preparation in order to add a further eight substances coming from ECHA's recommendation of 2010. The first deadline for industry for submitting applications for authorisation of specified uses for the first substance on the list was set for February 2013. No applications were submitted to ECHA in 2011, but initial inquiries indicate that applications would be made in late 2012.

[9] 7 chromium(VI) compounds, 5 cobalt(II) salts and trichloroethylene (see press release at http://echa.europa.eu/web/guest/view-article/-/journal_content/84f13bf9-d6fd-41ee-aeeb-cdf2e7e9cdee).

In 2011, ECHA finalised and published its initial formats, technical guidance documents and user manuals for the preparation and submission of industry applications. ECHA was technically ready to receive applications from April 2011 onwards. During the latter part of the year, its procedures to handle authorisation applications were further developed within ECHA and in the Committees for Risk Assessment and Socio-economic Analysis. ECHA also regularly published additional technical advice to potential applicants, for instance on how to describe uses. An implementation plan for further capacity building for 2012 was also prepared.

ECHA's challenge will be to handle the applications in parallel in two committees, manage the public consultation and subsequent opinion-making in the limited time available, especially as the authorisation application process is new not only to ECHA but to all stakeholders. Therefore, in dialogue with NGOs, trade unions and industry stakeholders, in 2011 ECHA started to work on the details of how to carry out the public consultation on broad information on uses. The challenge is to conduct the consultation in an efficient and transparent manner while ensuring that the applications are treated impartially and that no confidential business information is disclosed.

Restrictions

In 2011, the ECHA Secretariat continued to provide high quality and timely support to the RAC and SEAC as they developed their opinions on restriction proposals. RAC and SEAC adopted their opinions on the first four restrictions; (1) the use of Dimethylfumarate (DMFu) in treated articles, (2) Lead and its compounds in jewellery, (3) manufacture, placing on the market and use of Phenylmercury compounds and (4) placing on the market and use of Mercury for sphygmomanometers and other measuring devices in healthcare and in other professional and industrial uses. Following the Committees' opinions, the Commission adopted its decision to restrict the use of DMFu in articles in 2011. The decisions on the three other proposals are expected to be taken in early 2012.

In 2011, ECHA also received a proposal from Denmark to restrict the use of four classified phthalates on which the Committees have started their work to give opinions on the proposal. Based on the Commission's requests, ECHA continued its review of the existing restriction of two non-classified phthalates, started work on a review in relation to the existing restriction on cadmium and initiated the preparation of a restriction proposal on the use of 1,4-dichorobenzene in air fresheners and toilet blocks.

ECHA has collected from the Member States Competent Authorities, Committee members and observers as well as Commission staff their experience gained with the first restriction dossiers with a view to further improve the efficiency and effectiveness of dossier handling procedures, the quality of the Annex XV restriction dossiers and, when relevant, improving the guidance and formats. These suggestions will be followed up in 2012.

Other activities related to regulatory risk management

ECHA provided further support to the Member States in coordinating the information exchange on screening activities and identification of substances that may require risk management (beyond measures currently in place), and on determining the appropriate risk management instruments. Registration data, and in particular CSRs and Exposure Scenarios, are an important new source of information to identify risk management needs and to prepare Annex XV dossiers. To improve the common understanding on how to use this data together with other information sources in an effective way, ECHA organised a data gathering workshop with the Member States.

The planned workshop on the interface between the REACH legislation and occupational health and safety legislation was postponed until 2012 to allow sufficient preparation time

and adequate participation of the authorities in charge of worker protection legislation.

In time for the first notification deadline, 1 June 2011, ECHA provided the necessary tools to enable importers and producers of articles to fulfil their obligations to notify ECHA of Candidate List substances in their articles. In addition to the technical adaptations of REACH IT, supporting documents such as the dossier submission manual and new web pages including questions and answers on the notification obligation were made available on the website. A webinar attracting 560 participants was also organised.

Notifications of substances in articles are required from 1 June 2011 onwards when a substance appears on the Candidate List at least six months beforehand and fulfils the criteria set out in the legislation. By the first deadline, 175 notifications on substances in articles were received. By the end of 2011, this number had only slightly increased to 203 notifications. ECHA has started to prepare principles and procedures for evaluating these notifications with a view to identifying when a full registration will be requested and will communicate these during 2012.

ECHA initiated two methodological study projects on Socio-economic analysis, one on the willingness-to-pay for the reduction of risks of certain health related outcomes of chemicals of concern, and another on the calculation of abatement costs of certain chemicals of concern. The results will become available progressively throughout 2012 and 2013.

Objectives and Indicators

Objectives

Authorisation

1. An updated Candidate List of Substances of Very High Concern (SVHCs) is prepared within five months of receipt by ECHA of dossiers from the Member States, or the finalisation of dossiers prepared by ECHA on the request of the Commission.
2. ECHA provides support of a high technical and scientific quality, and within the legal timeframe, to the Commission, in the selection of substances from the Candidate List for authorisation and in the authorisation application process.
3. ECHA adequately and efficiently manages the authorisation application process within the legal timeframe.

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 2011	Means and frequency of verification	Result 2011
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%

Percentage of applications for authorisation treated within the legal timeframe.	100%	Internal quarterly report	N/A
Level of satisfaction of the Commission, MSCAs and ECHA Committees with the quality of the scientific, technical and administrative support provided.	High	Annual survey	High

Main Outputs

- Development of eleven Annex XV SVHC dossiers at the request of the European Commission.
- Two updates of the Candidate List with new SVHCs in June and December 2011.
- Development of a tool to support Member States in coordinating their activities on identifying substances that may require risk management beyond measures in place.
- ECHA's third recommendation to include 13 SVHCs from the Candidate List in Annex XIV (Authorisation List) submitted to the Commission.
- Support to the Committees in adopting eight opinions (i.e. four RAC and four SEAC opinions) on four restriction proposals.
- Two conformity reports (one negative and one positive) on a new Annex XV restriction dossier produced and submitted to the Committees.
- Establishment of the technical capability of ECHA to receive and process applications for authorisation including the publication of the guidance documents in all EU languages, the formats and technical manuals for the development and submission of applications. ECHA's internal procedures (including those of the Committees) were also established.
- Together with key stakeholders, establishment of the process to make the application for authorisation process efficient, transparent, impartial and trustworthy.
- The setting up of submission tools and support for notification of substances in articles.

Activity 4: Classification and Labelling (C&L)

Main Achievements in 2011

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

Harmonised classification and labelling (CLH)

The main tasks included the management of the proposals for harmonisation of classification and labelling of substances (CLH proposals). Member State Competent Authorities submitted 55 CLH proposals in 2011. In addition, ECHA received the first CLH proposal from industry. The total of 56 proposals was slightly less than expected. The total number of CLH proposals submitted in the period 2008–2011 amounted to 179. For 36 substances a public consultation was completed in 2011.

The procedures to produce the RAC opinion and its annexes have been reviewed in a workshop with the Member States, RAC members and the Commission in February 2011. As a result a new accordance check and drafting procedure and revised formats for the opinion and its annexes were introduced. The new approach is expected to be fully implemented in 2012.

ECHA intensified its cooperation with EFSA on harmonised classification and labelling of plant protection products (PPP). An exchange of information was organised on some of the CLH dossiers dealing with active substances in PPP. A workshop was held in 2011 to discuss the cooperation at European level in the assessment of human health hazards caused by active substances in plant protection products under Regulation (EC) No 1107/2009 and the harmonised classification and labelling of active substances under Regulation (EC) No 1272/2008.

C&L inventory

ECHA is required to establish and manage a C&L inventory based on C&L 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 by 3 January 2011 at the latest. By that deadline, ECHA received over three million notifications covering more than 100 000 distinct substances. During 2011, a further half a million notifications were received bringing the total number of substances to over 110 000. The first version of the inventory with information for the public was planned to be published by mid-December. However, the planned date of publication had to be transferred to early 2012. Finally, the inventory was launched on 13 February 2012.

Different notifiers may indicate different classifications for the same substance. The notifiers will then have to make every effort to come to an agreement on the C&L of the substance. ECHA has investigated the practical possibilities to bring the notifers of same substances together. As a first step in the overall process of setting up a dedicated IT-platform, which would allow and facilitate the discussions between notifiers and registrants on the classification for a particular substance without revealing their identity, it was decided to carry out a technical feasibility study taking into consideration the suitability, workability and security/confidentiality aspects.

Requests for the use of alternative names for substances in mixtures

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

Early in 2011, ECHA organised a workshop with Member State representatives to better understand how requests for alternatives names were handled by the national authorities under the previous legislation. Based among others on the advice provided, ECHA developed the submission tool, manual and process for the request of alternative names for substances in mixtures, which was launched in September 2011.

One such request did not pass the business rules and therefore could not successfully be received before the end of 2011.

Objectives and Indicators

Objectives

1. All proposals for harmonised C&L submitted by MSCAs and industry are processed within the legal timeframe and to a high degree of scientific quality.
2. Any request for the use of an alternative chemical name is processed within the legal timeframe.

Performance Indicators & Targets

Indicator	Target in 2011	Means and frequency of verification	Result 2011
Percentage of proposals for Harmonised C&L processed within legal timeframe.	100%	Internal quarterly report	100%
Percentage of requests for use of alternative chemical name processed within legal timeframe.	100%	Internal quarterly report	N/A
Level of satisfaction of the MSCAs and RAC with the quality of the scientific, technical and administrative support provided.	High	Annual survey	High

Main Outputs

- 78 accordance checks of dossiers containing proposals for harmonised Classification and Labelling.
- Provision of timely support, of a high scientific quality, to both submitters of proposals for harmonised C&L, and to the RAC and its rapporteurs for their development of 30 opinions, and of scientific background documents for such proposals.
- All C&L notifications received by 3 January 2011 and during the rest of the year were successfully processed and made ready for publication in the C&L inventory launched in early 2012.

Activity 5: Advice and Assistance through Guidance and Helpdesk

Main Achievements in 2011

Helpdesk

In the year following the first registration and C&L notification deadlines, the number of questions addressed to the ECHA Helpdesk decreased even more than expected. In 2011, the ECHA Helpdesk replied to 5 362 questions. The average resolution time was seven working days, while 90% of the questions were answered within the established timeframe of 15 working days.

In 2011, the scope of questions addressed to the ECHA Helpdesk has enlarged as other processes than registration kicked-in, such as substances in articles and alternative name requests for mixtures. However, not all expectations related to subject areas of incoming questions materialised as some projects triggering questions to the ECHA Helpdesk have been postponed until 2012, such as the release of the downstream user online notification and the release of the public C&L inventory.

The network of national REACH and CLP helpdesks, HelpNet, remained one of the key activities in 2011. The efforts in the framework of HelpNet to support national helpdesks resulted in building up a sufficient capacity to reply to questions on various subject matters. Only in about 30 cases, did national helpdesks refer their customers to the ECHA Helpdesk. National helpdesks appreciated the HelpNet Visits Programme which continued in 2011. In the context of such visits, specific training was provided to the staff of national helpdesks and national REACH and CLP events were actively supported by speakers from ECHA.

Guidance

The ECHA Secretariat has implemented the experience gathered over the last two years in providing advice to stakeholders in its guidance updates and related stakeholder consultation process. An analysis of lessons learnt from the first registration and notification deadlines and how to apply them to the further development of guidance documents has been made. Furthermore, guidance documents have been published at three specific timeframes per year to enable industry to better plan for changes.

As ECHA's stakeholder consultation process to update or consider new guidance, as well as protracted discussions on scientific, technical or policy issues, had in the past delayed the provision of advice and assistance to industry, the ECHA Management Board adopted a revised guidance consultation process in March 2011. Its revised mechanisms will enable ECHA to carry out the necessary updates of guidance linked to registration in good time ahead of the next registration deadline. These mechanisms will allow the Agency to finalise guidance by taking into account a consideration of majority views if full consensus cannot be achieved.

Throughout 2011, ECHA delivered high-quality guidance documents while ensuring buy-in by stakeholders with a view to provide advice and assistance to industry on the REACH and CLP Regulations. The new procedure has been gradually implemented for those updates that had already been started.

In order to allow industry to concentrate on preparing its dossiers in the period before the forthcoming REACH registration deadline, the ECHA Secretariat initiated the update of the guidance on registration and data sharing in the second half of

2011. The Commission submitted during 2011 the final results of the three REACH Implementation Projects on nano-materials, which permitted ECHA to plan a nano-specific update of the guidance on information requirements and chemical safety assessment for 2012.

To improve the accessibility of the guidance to all stakeholders, ECHA produced 'quasi guidance' documents including five fact sheets and two guidances in a nutshell. The quasi guidance documents aim to explain the key messages of the corresponding parent guidance documents in simple terms and are particularly intended for small and medium size enterprises (SMEs). Furthermore, guidance has been made more readily accessible, by the re-design of the guidance website, by simplifying guidance where practical and by making ECHA's multilingual REACH and CLP terminology database facilitating translation and harmonising key REACH terminology available. Many of these documents and the web pages are provided in the 22 EU official languages to further improve their accessibility.

REACH and CLP training

In 2011, the Agency organised a variety of training events targeted at external stakeholders, covering various topics that are dealt with by different departments of ECHA. About 20 such training events focused on presenting cutting-edge updates on REACH and CLP matters as well as on ECHA's IT tools. The target audiences mainly consisted of representatives of EU Member States, e.g. competent authorities, national helpdesks and enforcement authorities. But also industry representatives followed the Agency's invitation to attend the external training events held during 2011.

In addition to face-to-face training events held at ECHA's premises in Helsinki in the format of topical workshops, the Agency also produced a series of webinars that interested stakeholders can access via the ECHA website at any time of their convenience. Such webinars covered topics such as training on Downstream User reports and Substances in Articles, or tutorials on basic and advanced IUCLID use, to name only a few.

Training events on IT tools focused on developments of the REACH-IT submission tool in particular. Trainers of national enforcement authorities were invited to training on the RIPE tool before it was launched in June.

Although topical workshops on an array of regulatory scientific questions were mainly organised as a means for consulting experts and stakeholders in the process of developing appropriate approaches to specific current regulatory challenges, by spreading knowledge on the current state of debates, they also contained a useful training element. Data sharing, the use of QSAR, the Chesar tool for developing CSRs and the new authorisation processes, are exemplary subjects of such workshops.

Finally, as also mentioned in this report's chapter on advice and assistance, the activities of ECHA's network of national helpdesks (HelpNet) also included a considerable number of hands-on training events, mainly focused on bringing national helpdesk officers up-to-date with ECHA's registration-related IT tools.

Objectives and Indicators

Objectives

1. Industry receives timely and efficient support from the Helpdesk, and through high quality guidance documents, to fulfil its obligations under REACH and CLP.
2. Support is provided for the implementation of REACH and CLP in EU/EEA Member States via the training of trainers.

Performance Indicators & Targets

Indicators	Target in 2011	Means and frequency of verification	Result 2011
Percentage of Helpdesk questions answered within the established timeframe (on average 15 working days).	Not less than 75%	Business Object report / monthly	90%
Number of FAQ updates agreed with HelpNet and published on the web. [10]	At least 3	Annual report	3
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	98%
Percentage of guidance documents published on the web according to the plan.	Not less than 75%	Annual report	86%
Level of satisfaction expressed in feedback from guidance users.	High	Annual survey	High
Level of satisfaction with quality of REACH training events.	High	Participants feedback / Annual	High

[10] 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.

Main Outputs

Helpdesk

- Answers to 5 362 questions regarding ECHA's IT tools (IUCLID, Chesar, REACH-IT and data submission) and REACH and CLP requirements provided.
- Comments on 135 HelpNet Exchange questions on REACH and CLP issues provided to national helpdesks.
- Two REACH FAQs updated by written procedure and three REACH FAQs triggered by a decision of the European Commission. In addition, one CLP FAQ updated by written procedure.
- Two meetings of the HelpNet Steering Group organised: the latter one with a back-to-back training on various types of dossier submission to ECHA. Also two webinars on downstream user reports and notification of substances in articles and two IUCLID 5 tutorials were delivered.
- 11 national helpdesks visited in the context of the HelpNet Visits Programme 2011-2013.
- Contribution to one-to-one Q&A sessions at the ECHA Stakeholders' Day in 2011.

Guidance

- Three new guidance documents and fourteen guidance document updates published:
    - New guidance documents:
        - Guidance on the preparation of an application for authorisation
        - Guidance on Socio-Economic Analysis – Authorisation
        - Guidance on the compilation of Safety Data Sheets
    - Updates or corrigenda :
        - Guidance on requirements for substances in articles
        - Guidance on CLP – labelling criteria
        - Guidance on the scope of exposure assessment
        - Guidance on registration
        - Guidance on substance identification and naming of substances under REACH and CLP
        - Parts A, B and C and chapters R2, R3, R4 and R5 of the Guidance on IR/CSA
        - Guidance on the compilation of Safety Data Sheets
        - Guidance on the application of the CLP criteria
- Five Fact Sheets published:
    - Guidance Fact Sheet on requirements for substances in articles
    - Guidance Fact Sheet on substance identification and naming of substances under REACH and CLP.
    - REACH Fact Sheet on Substance Evaluation
    - REACH Fact Sheet on Safety Data Sheets and Exposure Scenarios
    - REACH Fact Sheet on the application for authorisation
- Two Guidance in a nutshell published:
    - Guidance on requirements for substances in articles
    - Guidance in a nutshell on substance identification and naming of substances under REACH and CLP

REACH and CLP training

- Numerous training events and workshops for targeted audiences organised.
- Six webinars for targeted audience organised and published on the ECHA website.
- Training provided on request during Helpdesk visits.

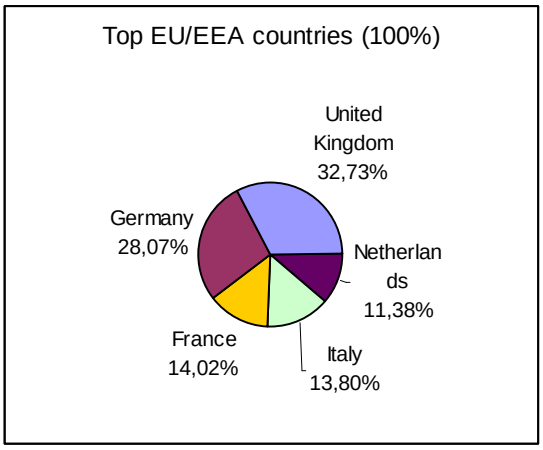
Table 7: Number, percentage and average resolution time of questions resolved during 2011

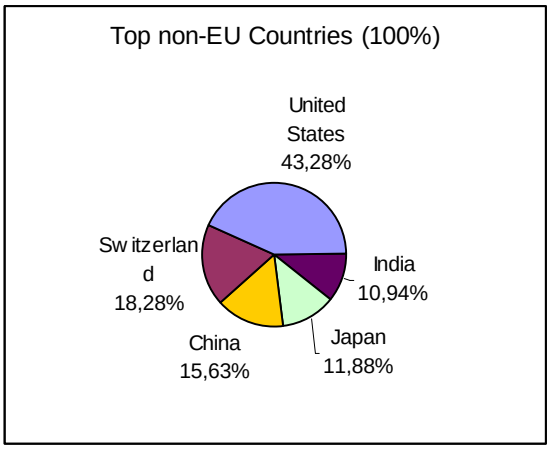
Topic	Number of questions resolved	%	Average resolution time (no. of working days)
REACH	1 227	22,9%	9.6
CLP	192	3,6%	5.7
IUCLID 5	590	11%	8
CHESAR	207	3,9%	10.9
REACH-IT	452	8,4%	6.4
REACH-IT User mgmt	1 414	26,4%	2.6
Submissions	1 280	23,9%	7.8
Total	**5 362**	100%	**7.3**

Table 8: Comments provided in HelpEx
Comments provided by ECHA to questions opened in HelpEx by national helpdesks during 2011 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	100	97	**97%**	162.25	310.5
CLP	35	35	**100%**	0	0
Total	135	132	**98%**	-	-

Graphs 2 and 3: Top countries from which questions were received





Activity 6: Scientific IT tools

Main Achievements in 2011

The implementation of the REACH processes requires a wide range of IT systems; their further development and maintenance continued to be crucial for ECHA's operations in 2011.

More than three million C&L notifications were successfully processed in REACH-IT by the January 2011 deadline. A new version 2.2 of REACH-IT was released in early April including the adaptation to IUCLID 5.3, a migration tool and the integration of workflow support for the assessment of confidentiality claims in the registration dossiers.

Additional developments of REACH-IT planned to be released before the end of 2011 concerning the management of downstream user notifications, increasing the automation level and building interfaces with other systems were delayed due to difficulties that arose from the change of contractor. Corrective actions were taken to ensure the timely implementation in 2012 of these and all other functionalities needed for the 2013 deadline and for improvement in the workflows.

To further support industry with the preparation of registrations, ECHA continued to develop two key systems: IUCLID 5, the main tool for industry to prepare their REACH and CLP dossiers and Chesar, a tool designed to help companies to prepare chemical safety assessments and produce their chemical safety reports and exposure scenarios to be added to the safety data sheets.

IUCLID 5.3 was released in February, including updates to harmonised OECD templates, support for new submission types (downstream user report, notification of substance in articles, application for authorisation). Version 5.4 with the enhancements for publishing company names and other Safety Data Sheet information on the dissemination website was to a large extent developed and tested so that it can be released in 2012.

The user consultation for the next generation of IUCLID (6) was started and progressed steadily into a user requirements preparation phase, which will be followed by implementation starting in 2012.

Chesar was developed further and two releases were published during the year. Version 1.2 introduced exposure scenarios for the downstream user communication as part of the safety data sheet and support for creation of a full Chemical Safety Report (CSR). Development has continued and intensified towards the end of the year with the aim of introducing a major new revision of the tool by summer 2012.

As a follow-up of an Enterprise Architecture (EA) study performed in 2010, ECHA identified the integration of its IT systems and the accessibility of its databases as cornerstone components to further support the foreseeable future developments in its business processes. A project (Data Integration Project) was started to improve the accessibility to relevant dossier and registration data. The project aims in particular at improving the usability of ECHA's systems used in the work performed by MSCAs. In the first phase, a pilot was started on providing MSCAs access to a centralised IUCLID database containing the registration dossiers received by ECHA.

To provide tools and information for the enforcement work performed by the Member States, ECHA released the RIPE portal where enforcement authorities can check information on substances registered in their respective countries. Information security played an important role in the architecture and

implementation of the system as disclosure of confidential information beyond intended audiences needs to be strictly prevented.

Complementary to REACH-IT, an Enterprise Content Management (ECM) programme was already started in 2010 to provide fundamental support to ECHA's operational processes. The ECM programme was extended in 2011 to support the dossier evaluation process (so called ECM-DEP); the overall entry into production is foreseen in May 2012. ECM-DEP will be integrated with REACH-IT to allow the sharing of registration data and the channelling of all communication to industry through a central "hub".

The Dissemination publication process is supported by an IT system for automated publishing. The level of automation was further improved in 2011 and the portal was revised for enhancing usability.

Development for publishing the inventory of C&L notifications continued throughout the year. The technical implementation took longer than anticipated; the first version of the software was ready for internal testing at the end of the year and ultimately published with some delay in February 2012.

ECHA further developed tools for internal use: Casper (priority setting and reporting tool) and Odyssey (decision-support system for evaluation activities).

The final production version of Casper was available in early 2011. The tool has been used for selecting dossiers to be evaluated, for providing statistics to various purposes, including the Art. 117 reports and for supporting the preparation of the CoRAP list. Enhancements were introduced throughout the year.

The first version of the scientific dossiers evaluation decision-support system Odyssey was put into production in February 2011. Three subsequent minor versions were released during the year. The user survey conducted at the end of the year showed that the system has been fully and successfully used, especially to support compliance checks. First signs of reducing the evaluation time were already noticed. The system has proven to assist especially in tracking the decision-making process and in guiding the preparation of the decision-support documents.

Preparatory activities started under a service contract with the European Commission to analyse the operational processes stemming from the new Biocides Regulation. Such analysis focused in particular on the IT support needed to enable the adaptation and implementation of the Registry for Biocidal Products (R4BP), which will start for ECHA at the entry into application scheduled for September 2013.

ECHA has provided some assistance to the Commission in their study to analyse the requirements for information systems support to the new tasks foreseen for ECHA according to the re-cast of the PIC Regulation.

Objectives and Indicators

Objectives

1. ECHA receives and successfully processes all registration dossiers and C&L notifications with the assistance of a well functioning, upgraded REACH-IT.
2. Specialised IT tools (IUCLID5, C&L submission tools and Chesar) and targeted user manuals and workshops have efficiently supported registrants in preparing their dossiers and meeting their legal obligations.

3. An advanced screening tool (Casper) and an efficient decision-support system (Odyssey) are efficiently supporting ECHA in its goal of conducting compliance checks on 5% of dossiers per tonnage band.

Performance Indicators & Targets

Indicators	Target in 2011	Means and frequency of verification	Result 2011
Project success rate in terms of time, budget and scope.	80%	Each project is evaluated as part of its closure activities. Summary reports prepared quarterly for follow-up.	77%
Level of satisfaction of external users of the IT tools (IUCLID, REACH-IT, Chesar and RIPE).	High	Annual survey	High

Main Outputs

REACH-IT

- REACH-IT was successfully supporting registrants and ECHA in processing incoming dossiers throughout the year.
- System was updated to adapt to the IUCLID changes and to support the assessment of confidentiality claims in registration dossiers.

Dissemination website

- Information from both lead and member registration dossiers was published by the end of the year.
- Dissemination web section has been integrated with eChemPortal so that the same information can be searched from both systems.
- Search for information from pre-registration and registration dossiers as well as from testing proposals is possible through the revised ECHA website.

IUCLID 5

- Stakeholder driven upgrades undertaken, including several updates to OECD harmonised templates.
- New functionality introduced for the preparation of new dossier types under REACH like downstream user report, notification of substance in articles and application for authorisation.

RIPE

- First version of the portal for MS enforcement authorities was published.

Document Management System

- Support for the SVHC process was available throughout the year.
- Dossier evaluation process support progressed to testing phase.

Chesar

- New functionality was introduced for preparing exposure scenarios for user communication and ability to prepare a full CSR.

Casper

- Final production version of the datawarehousing and reporting tool was delivered and it was used to support selecting dossiers for evaluation, providing information to other systems, preparation of the CoRAP list and reporting needs like Art. 117 of REACH.

Odyssey

- Scientific dossiers evaluation decision-support system was developed and users started to use it. First signs of reduced evaluation time were already noticed.

General

- Based on the Enterprise Architecture Study, a Data Integration Project has been established to improve data and application integration and to enhance usability and access to the data for the Agency and for MSCAs.

Activity 7: Scientific and technical advice to EU institutions and bodies

Main Achievements in 2011

In accordance with the legal requirements of REACH, ECHA delivered its first five-year report according to Article 117(2) of REACH on the operation of the REACH and CLP Regulations. The first three-year Article 117(3) report on the status of implementation and use of non-animal test methods and testing strategies was also produced. Both reports were submitted to the Commission and were made public in the interest of transparency.

Cooperation with Member States continued using the meetings of the Competent Authorities for REACH and CLP (CARACAL) as the main platform for informing and consulting MSCAs.

ECHA participated in the Preliminary Assessment of Regulatory Relevance of *in vitro* test methods (PARERE), which was established by the European Centre for the Validation of Alternative Methods (ECVAM). This work will help to focus the work on development of alternative methods on the areas of highest regulatory relevance.

In 2011, ECHA closely followed the developments of the REACH Implementation Projects on Nanomaterials (RIP-oN), and in particular for the RIP-oN 2 on information requirements, and RIP-oN 3 on exposure and risk characterisation. Comments and input on the RIP-oN 1 report on substance identification and its related case studies had already been provided in the previous year. The RIP-oN project reports were then handed over to ECHA in early November for consideration in future guidance updates. In November, important progress was made when the European Commission adopted a recommendation on the definition of nanomaterials that can now be used for regulatory purposes. In addition, ECHA assisted the Commission in compiling information on nanomaterial types and uses. The information included safety aspects reported by the chemical companies either in their registration dossiers submitted under the REACH Regulation or in notifications to the Classification and Labelling Inventory submitted under the CLP Regulation. Finally, ECHA started in cooperation with the DG Joint Research Centre (JRC) to assess the type of information on nanomaterials currently available in the received registration and notification dossiers - for those that include information on nanomaterials - and aimed from this to conclude on the adequacy of REACH requirements for nanomaterials in early 2012.

ECHA contributed to the further development of OECD test guidelines with a view to ensuring that test methods are developed and updated according to the latest scientific knowledge while avoiding unnecessary animal testing. The priority areas in 2011 were genotoxicity, *in vitro* tests (e.g. for skin and eye irritation/corrosion and sensitisation), reproductive toxicity, especially the Extended One-Generation Reproductive Toxicity study, endocrine disrupters, ecotoxicity (aquatic, sediment, soil), and bioaccumulation.

With the view of supporting registrants and downstream users in (i) efficiently carrying out their Chemical Safety Assessments (CSAs) and generating good quality Chemical Safety Reports (CSRs), and (ii) setting up efficient mechanisms for communication on the safe use of chemicals in the supply chain, ECHA set up an internal CSA Development Programme. Good quality information in the CSRs and extended Safety Data Sheets is not only beneficial for industry but also for ECHA and the Member States when implementing the REACH processes following registration, such as evaluation, authorisation and restriction. One of the main achievements in 2011 was setting up the Exchange Network on Exposure Scenarios

(ENES) between ECHA and stakeholders to align expectations among all players in the field. ECHA also identified, in cooperation with the stakeholders, what information is missing for downstream users to understand the exposure scenarios they will receive from their suppliers and produced the first publications to support them. Another main achievement was the specification of requirements for the update of IUCLID (version 5.4) to support registrants in reporting on conclusions from the hazard assessment, on identified uses, on safe conditions of use and on the related exposure estimates.

Finally, ECHA provided technical advice to the Commission during the second reading of the proposal for the new Biocidal Products Regulation. Planning and initial preparation was launched, with support of specific funding by the Commission, in relation to ECHA's anticipated future tasks under the proposed regulation, so that ECHA will be able to take up these tasks from the foreseen date of application (1 September 2013). Detailed planning started on procedures and workflows, establishment of the foreseen Biocidal Products Committee and Coordination Group, IT-tools, guidance, and staffing.

Objectives and Indicators

Objectives

1. ECHA has improved its capacity to provide scientific and technical advice on the safety of chemicals, nanomaterials and testing methods.
2. ECHA delivers timely, high quality reports that help the Commission in assessing and improving the workability of the REACH Regulation and in promoting the availability of non-animal testing methods (Art. 117).

Performance Indicators & Targets

Indicator	Target in 2011	Means and frequency of verification	Results 2011
Level of satisfaction with the quality of the scientific, technical and administrative support provided to Commission.	High	Annual survey	High
Timely delivery of the REACH Art. 117 reports.	1 June 2011	Internal report	Done

Main Outputs

- Article 117 reports on operation of REACH and CLP Regulations, and on the status of implementation and use of non-animal test methods and testing strategies were delivered in a timely manner.
- Scientific and technical input was given to the Commission to support the legislative procedure on Biocidal Products Regulation, including the revised Financial Fiche and the Commission's preparation of implementing rules.

- Preparatory work launched on all tasks foreseen to be performed by ECHA under the new Biocidal Products Regulation, including development of workflows, IT-tools and establishment of the Biocidal Products Committee.
- Establishment of relationships with Member States and stakeholders, regular reporting via existing fora such as the Biocides Competent Authority meetings and international meetings.
- First meeting of ENES organised.
- Publication of exposure scenario examples for the professional use and the consumer use of a chemical substance.
- Contribution to the specifications of IUCLID 5.4.

ECHA'S BODIES AND SUPPORTING ACTIVITIES

Activity 8: Committees and Forum

Main Achievements in 2011

2011 has been another year of intense activity for the ECHA Committees and the Forum in which the workload has risen from the previous year as most of the REACH and CLP processes became an operational reality. At the start of the year, the term of office ended for many of the members that were appointed at the establishment of the Committees and hence a major renewal and replacement programme occurred. This took place smoothly and a sufficient number of memberships were renewed to guarantee continuity of the work at this important time. A more detailed account of the activities of each of the Committees is given below.

Member State Committee (MSC)

The MSC held six plenary meetings in 2011, several working group meetings back-to-back with the plenary meetings, as well as a number of meetings via video conference.

As expected, the workload of the Committee increased in 2011, but nevertheless all of the dossiers under the evaluation and authorisation processes have been agreed upon within the legal timeframe, were of high quality and most were agreed upon unanimously.

The MSC unanimously agreed on the identification of 19 substances as Substances of Very High Concern (SVHCs) that were later included in the Candidate List. For the first time a substance with endocrine disrupting properties (4-tert-octylphenol) was identified by the Committee as an SVHC due to an equivalent level of concern (Article 57(f) of REACH).

The MSC also adopted its opinion on the third ECHA draft recommendation for prioritisation of substances for inclusion in Annex XIV by a majority vote in December 2011, allowing ECHA to submit its recommendation for 13 substances to the European Commission.

The MSC unanimously agreed on 32 ECHA draft compliance check decisions on registration dossiers and on 19 testing proposal draft decisions. In another two testing proposal cases (where two-generation reproduction toxicity testing were proposed), the MSC did not manage to come to a unanimous agreement, mainly due to legal uncertainties. In accordance with the legal requirement, the full documentation was submitted to the Commission for their further decision-making.

Since the update of the working procedures of the MSC on dossier evaluation in early 2011, the regular stakeholder observers and case owners (registrants) have been able to follow the first MSC discussions on dossier evaluation. During 2011, 15 case-owners made use of this opportunity and participated in the Committees' discussions.

In relation to the initiation of the substance evaluation process in 2011, the Committee also began preparatory activities for the development of an opinion on the Community Rolling Action Plan (CoRAP). The MSC opinion on the ECHA draft CoRAP is scheduled to be adopted in February 2012.

Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC)

RAC met five times during 2011 while SEAC met four times. Two of these meetings were conducted in parallel in order to strive for a coherent opinion-making process between the two committees. It is expected that the two committees will have even more interaction in the future.

RAC made a substantial improvement in efficiency during 2011 when processing proposals for harmonised classification and labelling, despite the high level complexity of several dossiers related to in particular carcinogenicity/mutagenicity and reprotoxicity. This efficiency gain has been reflected in RAC adopting twice the number of opinions on harmonised classifications and labelling compared to 2010. The discussions in RAC focused on 39 CLH proposals, of which an opinion was adopted for 30 proposals. Despite these successes, the RAC working procedure for processing harmonised classification and labelling is currently being reviewed to look for further ways of improving the process.

In addition, two fairly complex requests from the Commission[11] were dealt with – one for an opinion on the proposed harmonised classification of epoxiconazole and the other for an opinion on the proposed harmonised classification of gallium arsenide in relation to carcinogenicity.

An additional activity for RAC included the requirement to cooperate with other EU committees and bodies dealing with risk assessment. The CLH dossiers for active substances in Plant Protection Products (PPP) are based on dossiers handled by risk assessment bodies outside ECHA. Cooperation with the European Food Safety Agency (EFSA) for coordinating the identification of CMR properties of PPP active substances has started in 2011 and will need to be continued in 2012.

In 2011, the cooperation between both Committees has been put in practice for the first time when adopting the first opinions of RAC and SEAC on the following restriction proposals: dimethylfumarate, lead and its compounds in jewellery, mercury in measuring devices and phenylmercury compounds. The processing of the Annex XV proposal from Denmark on four classified phtalates (DIBP, DBP, BBP and DEHP) started during the year and the opinions from RAC and SEAC are expected to be adopted in 2012. Based on the experience gained from processing the first restriction dossiers, RAC and SEAC, jointly with the ECHA Secretariat, initiated a review of how restriction proposals are processed by the Committees, which will be finalised in 2012.

In relation to the authorisation process, both RAC and SEAC continued their preparatory activities for processing applications for authorisation. These included capacity-building activities (such as information sessions and training) for RAC and SEAC members. Preparatory activities will continue in 2012 as the first applications for authorisation are expected to be submitted in the second half of 2012. The aim is to be prepared to deliver a large number of opinions to the Commission within a tight timeframe, while preserving good scientific quality.

Forum for exchange of information on enforcement

The Forum met twice in plenary and held ten Working Group meetings in 2011. In addition, it organised a Stakeholders Workshop to strengthen its liaison with them. The Forum also finalised and published the report of the prolongation phase of its first coordinated enforcement project on pre-registration, registration and safety

[11] Article 77(3)(c) of the REACH Regulation.

data sheets (with a focus on enforcement of the "no data, no market" rule). The Forum started the implementation of the second coordinated project for 2011/2012, on formulators of mixtures who are the first level downstream users in the supply chain. Furthermore, a third coordinated enforcement project has been agreed focusing on registration, only representatives and cooperation with customs.

Effective, harmonised and equal enforcement throughout the EU is of crucial importance for the credibility and success of REACH and CLP. Therefore, the Forum has started to identify and describe the interlinks between ECHA, Member State Competent Authorities (MSCAs) and National Enforcement Authorities (NEAs) with a view to setting out the Forum's position on the communication channels, the division of tasks and the working procedures between ECHA, MSCAs and NEAs which are relevant for the enforcement of the REACH and CLP Regulations. A pilot project was set up in order to gather experience on communication channels related to only representatives and PPORDs.

As the incorrect registration of a substance as an isolated intermediate may have a very significant impact on the achievement of the objectives pursued by the REACH Regulation, such as relevant safety information and appropriate risk management measures, several national enforcement authorities joined forces in setting up a pilot project on intermediates, taking due account of the experience ECHA has acquired on the verification of the intermediate status of registrations.

In early 2011, the Forum Working Group participated in the user testing of the REACH Information Portal for Enforcement (RIPE) tool – an IT tool that will allow inspectors in Member States to access data from submissions to ECHA. The tool itself was released by ECHA in June 2011 and four further upgrades with new features and reports were released by the end of December 2011.

Furthermore, the Forum published a document outlining the minimum criteria for REACH and CLP inspections and agreed the basic procedures for cooperation with customs authorities. The Forum adopted its work programme 2011-2013 and a general template for the reporting by Member States of the results of the official controls and other enforcement measures according to Art. 46 (2) of the CLP Regulation. Finally, the Forum advised RAC and SEAC, the ECHA Secretariat and the European Commission on the enforceability of five proposals for the restriction of substances.

Objectives and Indicators

<u>Objectives</u>

1. The Secretariat will support the work of the Committees efficiently and effectively so that the Committees 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 Secretariat will support and facilitate the work of the Forum efficiently and effectively and in a transparent manner so that it will have been able to strengthen and harmonise further the enforcement of the REACH and CLP Regulations in the EU/EEA Member States, while ensuring the necessary confidentiality.
3. 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.

Performance Indicators & Targets

Indicators	Target in 2011	Means and frequency of verification	Result 2011
Percentage of opinions / agreements delivered in time.	100%	Annual internal report	100%
Percentage of unanimous MSC agreements.	Not less than 80%	Annual internal report	97%
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	High
Feedback from the Member States enforcement authorities and ECHA stakeholders on the added value of the Forum activities.	Positive	Annual survey	High
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
Occurrence of conflicts of opinions with Scientific Committees of other EU bodies.	Only in well justified cases	Internal evaluation report	None

Main Outputs

Member State Committee

- 19 SVHC proposals were refered to the MSC, all of which were agreed for inclusion in the Candidate List.
- Opinion on ECHA's draft recommendation for inclusion of priority substances from the Candidate List to Annex XIV ("authorisation list") adopted on 19 December 2011.
- Unanimous agreements on draft decisions on 32 compliance checks and 19 draft decisions on testing proposals.
- Draft decisions on two testing proposals for two generation reproductive toxicity testing were sent to the European Commission, as unanimous agreements on them were not reached.
- One workshop on Article 57(f) cases was hosted by the MSC Secretariat.

Committee for Risk Assessment

- Four RAC opinions on restriction proposals.
- RAC adopted 30 opinions (in 32 dossiers) on harmonised classification and labelling of substances.
- 39 proposals on harmonised classification and labelling were discussed.
- 87 accordance checks of dossiers for harmonised classification and labelling were performed.
- Agreement by RAC on a new framework for accordance check of CLH dossiers replacing the RAC working procedure on the accordance check.
- RAC adopted two opinions on Article 77(3)(c) mandates.
- Joint workshop with European Commission and Member States on procedural aspects of opinion development of harmonised classification and labelling dossiers 'On the way to CLH'.
- Joint workshop with European Commission, EFSA and Member States on 'Harmonised Classification and Labelling in Plant Protection Products'.

Committee for Socio-economic Analysis

- Four SEAC opinions on restriction proposals.
- Joint workshop for SEAC and RAC on impact assessment (refinement of risk assessment for use in socio-economic impact assessment).

Forum

- One stakeholder workshop, one training event for enforcement trainers on CLP, one training event for national coordinators of the REF-2 project and one training event on RIPE for MS RIPE Administrators and Single Points of Contact.
- Final report from Forum project REACH-EN-FORCE-1 taking into account the compliance with the first REACH deadline.
- Forum document on "Strategies for Enforcement of REACH and CLP" (update).
- Forum document on "Minimum Criteria for REACH and CLP Inspections" (update).
- Forum guide on enforceability of restrictions.
- Five reports on advice of enforceability on proposed restrictions.
- Release of RIPE and some additional versions prepared by ECHA with the assistance of the Forum.

Table 7: Number of Committee decisions, opinions, agreements adopted[12]

	SVHC agreements	Restriction opinions	Opinion on draft Recommendation for Annex XIV	CLH opinions	Testing proposal agreements	Compliance check agreements	Article 77(3)(c) opinions[13]
MSC	19	Not applicable	1	Not applicable	19	32	Not applicable
RAC	Not applicable	4 (5)	Not applicable	30 (32)	Not applicable	Not applicable	2
SEAC	Not applicable	4 (5)	Not applicable	Not applicable	Not applicable	Not applicable	0

[12] The figures between brackets refer to the number of dossiers received.
[13] 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."*

Activity 9: Board of Appeal

Main Achievements in 2011

In 2011, the Board of Appeal had its first opportunity to consider a number of appeals that went through the complete appeal process and to make a greater number of decisions (both final and procedural). Whilst the number of appeals was lower than estimated, six cases were closed with a final decision and in addition 10 other procedural decisions were taken by the Board. The appeals lodged in 2011 contested a variety of ECHA decisions including the rejection of registrations, the requirements for data sharing, and the evaluation of registration dossiers. The considered appeal cases have generally been very different and, without exception, proven to be more complicated than expected, both in terms of the legal and scientific issues raised and the procedural measures to be taken.

The Board of Appeal published its first two final decisions on appeal cases that went through the whole appeal process in 2011. Both of these final decisions on registration rejections, one of which was in favour of the appellant and one in favour of the Agency, raised important issues of principle for stakeholders; for example, the importance of good administration and in particular the requirement for clear communications from ECHA to registrants. All final decisions have been made available on the ECHA website.

A further two appeal cases were withdrawn by the appellant and two were withdrawn by the appellant following rectification of the appealed decision by the Executive Director of ECHA. Prior to the withdrawal of each appeal a considerable amount of work was undertaken to assess the issues raised and to progress the case. For example, several confidentiality decisions were adopted by the Chairman of the Board; procedural measures were taken, and the merits of the cases examined in considerable detail. The fact that these cases did not need to go through the entire appeal process can be taken as a positive indication that the appeals process works well in protecting the interests of the parties, not only when the case is decided upon by the Board of Appeal, but also by allowing the Agency to reconsider its decisions and to rectify decisions if appropriate.

The 10 procedural decisions addressed confidentiality requests, intervention requests, a request to change the language of a case, and a request for rectification. The range and complexity of the issues arising from these decisions has been invaluable in helping the Board of Appeal and its Registry to ensure that the procedures that were put in place are working efficiently.

Dealing with multiple confidentiality claims and requests for a leave to intervene and the actions subsequent to such requests have proven to be particularly challenging; not only because of the number of such claims and requests but also because of the complexity of the issues raised. This and additional experience with new appeal cases and of different issues will help to further improve the working methods in the future.

More generally, the Board of Appeal and its Registry have put in place systems (e.g. working methods, processes, formats and IT-systems) to help in the effective management of appeal cases and have also achieved a great deal in interacting with stakeholders. Communication systems have been put in place to improve two-way communication with the alternate and additional members of the Board of Appeal.

Actions to raise the awareness of stakeholders to the possibility of making appeals and the appeals procedure have been increased. The Board of Appeal has also

worked actively with others in ECHA to ensure that, whilst ensuring the independence and impartiality of the Board of Appeal and its members, the Board of Appeal understands ECHA's processes so that it can work as efficiently and effectively as possible in the interests of all stakeholders.

Objectives and Indicators

Objectives

1. High-quality decisions adopted by the Board without undue delay.
2. Maintain stakeholder confidence in the REACH provisions for legal redress.

Performance Indicators & Targets

Indicators	Target in 2011	Means and frequency of verification	Result 2011
Percentage of cases concluded within target time[14] set for each type of appeal	90%	Annual report of the Board	100%
Percentage of Board of Appeal decisions appealed before the General Court	Less than 20%	Annual report of the Board	0
Level of stakeholder confidence in the appeal procedure.	High	Survey among stakeholders	Medium

Main Outputs

- Six final decisions and 10 procedural decisions were taken by the Board of Appeal in 2011:
  - Two final decisions on appeal cases were adopted and published;
  - Two appeal cases were withdrawn by the appellant following rectification of the original decision by the Executive Director of ECHA and final decisions were adopted and published;
  - Two appeal cases were withdrawn by the appellant and final decisions were adopted and published;
  - Six confidentiality (procedural) decisions were adopted and notified to the parties concerned;
  - Two (procedural) decisions on requests for intervention were adopted and notified to the parties concerned;
  - One (procedural) decision on a request for rectification of a decision was adopted and notified to the parties concerned; and
  - One (procedural) decision on a request to change the language of a case was adopted and notified to the parties concerned.

[14] Target time is defined as the time within which 75% of previous cases of the type of appeal have been closed (minimum 10 cases being closed to define target time).

Activity 10: Communications

Main Achievements in 2011

The first challenge for the year was to rebuild ECHA's website - the primary communication vehicle of the Agency. The new website was launched in December 2011. It was designed with the needs of the stakeholders and public in mind and is now offering clearer content, improved navigation and better search functionality. In addition, it provides easier access to information on chemicals and a new section *Chemicals in our life* that reaches out to the general public with easy to understand information.

The second challenge was to continue to provide material which is accessible to all by producing it in 22 EU languages. This practice continued with around 100 new documents translated and the vast majority of the new website available in 22 languages too. In addition, the Agency launched a multilingual online database, ECHA-term, to provide stakeholders with accurate REACH and CLP terminology. Currently, the database contains around 900 terms, phrases and definitions in 22 EU languages. At the end of the year, based on survey feedback, the Agency took the view that validation of translated material by Member States was no longer needed – the quality of translations having reached a sufficient quality. Finally, the Agency completed its study to gauge the need for additional multilingual communication and the feasibility of providing it – for example, enabling multilingual use of IT tools like REACH-IT. The study, which also refers to a survey of successful registrants undertaken last year and published separately, concluded that limited further multilingualism could be explored, but only after the 2013 deadline. The Management Board concurred that the risk of large scale modification of the IT tools before the deadline outweighed the benefits.

The third challenge was the completion of an EU wide study on the communication of information to the general public on the safe use of chemicals and potential need for additional information on labels (Article 34 of the CLP regulation). The study was carried out in consultation with the Member State Competent Authorities and stakeholders and consisted of a Eurobarometer survey that assessed consumers' perception of chemicals in all EU Member States (27 000 members of the public across all member states were interviewed) and follow up research on consumer behaviour in relation to household chemicals. In line with the CLP Regulation, the final report was submitted to the Commission on 20 January 2012.

The final challenge was to ensure effective internal communication. In 2011, internal communications played a pivotal role in the implementation of ECHA's new corporate identity aiming to improve services for stakeholders. In addition, to ensure effective internal communication throughout the Agency, knowledge-sharing tools were further developed and the first survey on internal communications was conducted to help the Agency to meet the information needs of staff.

Objectives and Indicators

<u>Objectives</u>

1. ECHA's external audiences are communicated with effectively, and ECHA benefits from an accurate and balanced media presence.
2. Stakeholders are involved in ECHA's work and are satisfied that their views are heard and taken into account.
3. All material (whether online or offline) that is produced for small and medium sized enterprises or the general public will be published in 22 official EU languages.
4. ECHA staff are well informed, have a sense of belonging, and feel part of a common corporate endeavour.

Performance Indicators & Targets

Indicators	Target in 2011	Means and frequency of verification	Result 2011
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 reader satisfaction with publications	Good	Annual customer surveys	High
Level of stakeholder satisfaction with their involvement.	Very good	Stakeholder survey on Stakeholder Days	High
Publication of translations of new documents relevant for small and medium sized enterprises or the general public (within an average period of three months after the original document, without validation).	100%	Internal quarterly report	95%

Main Outputs

- Communications campaigns *REACH 2013 – Act now*! and the downstream user campaign *Use chemicals? – Use them safely!* in support of the Chemicals Safety Assessment Programme were launched.
- ECHA's website re-built and launched in December. This coincided with the launch of the new corporate identity and visual identity of ECHA.
- All material (whether online or offline) that is produced for SMEs or the general public published in 22 official EU languages.
- Study on the need for additional multilingual communication and the feasibility of doing it completed.
- Weekly internal e-newsletters (ECHAexchange) were produced, quarterly internal newsletter (ECHO) printed, daily updates of internal information screens and intranet (ECHAnet) provided.
- A study of the public's perception on the safe use of chemicals (Article 34 of the CLP Regulation) completed, ready for submission in January 2012.
- *Ad hoc* Press Releases and weekly e-news bulletins produced, two press briefings organised.
- One Stakeholders' Day in May was attended by 430 participants with an additional 500 viewing the web-stream live, while the second Stakeholders' Day was replaced by the REACH conference *What did we achieve in 2010? How can we ease the way for 2013?*, which was organised jointly with the European Commission.
- The Agency's first strategic workshop with Accredited Stakeholders was held to facilitate their input to ECHA's work programme.
- The eligibility criteria for Accredited Stakeholder Organisations were revised to better reflect the organisations that are relevant to the work of the Agency.

- Numerous activities under the auspices of the *2011 International Year of Chemistry* including the inauguration of a new conference centre as the Marie Skłodowska Curie room to honour the hundredth anniversary of Ms. Curie's Nobel prize.
- Small and medium size enterprise (SME) outreach activities included ECHA stands at the European Enterprise Network annual conference in Warsaw and the SME week in Brussels. In addition, a leaflet for small companies in relation to the 2013 deadline was produced jointly with the Commission and UEAPME – one of ECHA's Accredited Stakeholders.
- The external communication strategy was revised and a strategy for stakeholder engagement was established.

Table 9: Communication statistics

Activity	Output
Stakeholder events	2
Webinars	6
Publications	70
Translations	260 documents
Press inquiries	1 050
Press releases	27
News alerts	55
Newsletters	6
Website visits	2 877 824

Activity 11: International Cooperation

Main Achievements in 2011

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 ECHA Management Board.

Concerning multilateral activities, ECHA actively contributed to OECD activities, particularly in work areas which are of direct relevance to the REACH programme. The three main areas of collaboration relate to the development of eChemPortal[15] and of the OECD QSAR Toolbox[16], as well as the gathering of user requirements for the further development of IUCLID, including the implementation of new or updated OECD Harmonised Templates.

Regarding eChemPortal, ECHA continued funding the hosting and the maintenance of the portal, which now provides access to information on more than 670 000 industrial chemicals, pesticides and biocides. One essential contribution of ECHA in 2011, as a participating database, was to synchronise its dissemination website with eChemPortal in order to enable the searching of the REACH dossiers by chemical property directly on the portal. This led to a significant increase in the overall number of visits to the portal. ECHA also participated in the gathering of users' needs for preparing the further development of eChemPortal, such as tracking chemicals assessments carried out by regulatory authorities worldwide, with the aim of avoiding duplication of work and thus saving resources.

ECHA also co-manages the development of the QSAR Toolbox with the OECD. Two new updates of the application with improved profiling, additional modules and data and improved interface were released to the public in 2011. ECHA also organised, in collaboration with the OECD, a workshop where the use of the Toolbox – with some emphasis on the use for REACH purposes - and future needs and requirements were discussed with industry users. The feedback gathered will feed into the preparation of a future release scheduled for 2012 and beyond.

Significant progress was also made on gathering user requirements for the further development of IUCLID in 2012. This includes additional reporting possibilities for example on exposure and risk information. New standard formats (OECD Harmonised Templates) were developed and agreed for reporting results of studies done on pesticides or for wood preservatives.

Other OECD-related activities in which ECHA was involved, as appropriate, included contributing to the work of the Cooperative Chemicals Assessment Meeting (CoCAM, formerly SIAM); the Task Force on Exposure assessment; the OECD Working Party on Manufactured Nanomaterials (WPMN); the Expert Group on the Electronic Exchange of Pesticide Data and the Test Guidelines Programme.

ECHA also supported the European Commission delegation at the Review Committee of the Stockholm Convention on Persistent Organic Pollutants. At the request of the European Commission, ECHA has also appointed contact persons for a number of correspondence groups within the framework of the UN SC GHS.

Based upon the Memorandum of Understanding with Environment Canada and Health Canada, ECHA held a number of telephone and video conferences with these institutions. A dialogue between regulatory scientists as well as risk managers started to find its format. A similar cooperation also took place with the US EPA counterparts based on the common

[15] Global portal to information on chemical substances allowing simultaneous searching of information by chemical name or chemical across more than 24 participating databases (http://www.echemportal.org/)
[16] 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 (www.qsartoolbox.org)

Statement of Intent. During 2011, ECHA further concluded a Statement of Intent with Japan and a Memorandum of Understanding with the National Industrial and Chemicals Notification and Assessment Scheme (NICNAS) of Australia.

A number of activities supported by the European Commission Instrument for Pre-Accession Assistance to support candidate countries and potential candidates for EU accession to prepare for REACH implementation and participation in ECHA were carried out in Croatia, Turkey and the former Yugoslav Republic of Macedonia, as well as in the potential candidate countries.

Concerning other bilateral cooperation, the ECHA Secretariat participated in activities to increase the knowledge of REACH for candidate countries and potential candidates as well as ENP (European Neighbourhood Policy) partners mainly arranged by the EC TAIEX office.

Objectives and Indicators

Objectives

1. The Commission receives high-quality scientific and technical support for its international activities, especially in multilateral bodies.
2. ECHA, within the scope of its responsibilities, builds up and maintains its bilateral relations for scientific and technical cooperation with those third country regulatory agencies that are useful for the implementation of REACH and CLP.
3. Awareness of the OECD eChem Portal and the QSAR Toolbox has been raised.
4. The QSAR Toolbox development progresses in accordance with the plan and budget.

Performance Indicators & Targets

Indicators	Target in 2011	Means and frequency of verification	Result 2011
Level of satisfaction of the Commission with the support given by ECHA on international activities	High	Annual survey	High
Increase in the visits to the OECD eChemPortal from previous year.	20%	Internal annual report	896%
Level of implementation of the annually planned modules of the OECD QSAR Toolbox.	90%	Internal annual report	100%

Main Outputs

- Scientific and technical cooperation with the OECD:
    - eChemPortal: hosting by ECHA and updated to handle information prepared with the IUCLID 5.3 version
    - QSAR Toolbox: releases in February (version 2.1) and July (version 2.2)
    - IUCLID: IUCLID 5.3 released in February, two maintenance releases, versions 5.3.1 and 5.3.2, respectively in August and December
    - Task force on hazard assessment
    - Task force on exposure assessment
    - Working Party on manufactured nano-materials
    - Working Group of the National Coordinators for the Test guidelines Programme.

- Memorandum of Understanding on cooperation with NICNAS Australia agreed and signed.
- Statement of Intent with Japan agreed and signed.
- First IPA-project for Candidate countries concluded.
- Various delegations from third countries received and participation in a number of workshops and seminars on REACH and CLP on the invitation of different organisers in third countries.

MANAGEMENT, ORGANISATION AND RESOURCES

Activity 12: Management

Main Achievements in 2011

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 a revised policy for managing potential conflicts of interest and criteria for third country participation.

The Executive Director is responsible for the day-to-day administration of the Agency. The further development of management and administrative processes continued at a 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 and to move towards multiple science-based decision and opinion making, ECHA's organisational structure was changed at the beginning of the year. A more horizontal organisation with three new Directorates was created following preparations initiated in 2010. Implementation of the reorganisation required adapting management processes to the larger organisation and ensuring efficient coordination of cross-Directorate activities. Planning of activities at each level of the organisation was strengthened to enable better performance monitoring and risk management.

From March 2011, ECHA chaired the Troika of the European Agencies Network, which involved a lot of coordination activities.

ECHA had regular contact with the authorities of the Member States and the Executive Director, together with expert staff, visited partner authorities in Belgium, Finland, Germany, Ireland, Italy, Poland, Slovenia and future Member State Croatia. The Executive Director also met with Polish and Danish authorities to discuss the respective priorities of their EU presidencies. To further improve the communication and collaboration with the Member States, a first MSCA Directors' planning meeting was organised in December. In addition, delegations from German and French authorities visited ECHA. Other high-level visitors included Commissioners Janez Potočnik and Antonio Tajani, as well as Members of the European Parliament. Framework Agreements for the transfer of fees to Member States linked to work undertaken for substance evaluation and to support rapporteurs on restrictions and authorisation applications were signed with 27 countries.

ECHA has continued the implementation of an Enterprise Content Management system (ECM) and developed a new procedure regarding control of documents and records, thus ensuring that all processes leading to a decision and/or opinion are standardised, documented, auditable and transparent and the documentation related to them is handled securely, efficiently and in compliance with all applicable legislation.

In 2011, ECHA continued to implement its information security management system, with an increase of the collaboration on security with Member States Competent Authorities and their security teams. In addition, emphasis was placed on business continuity management, in parallel with the procurement of a new external data centre. ECHA also developed collaboration with the Commission and the Member States for the use of data in the REACH-IT database.

The Agency continued the implementation of its Integrated Quality Management System (IQMS) with a specific focus on activities in development, such as dossier evaluation and applications for authorisation. Internal quality audits were started with an assessment of the IQMS implementation in connection with a gap analysis against ISO 9001 requirements, which will allow a roadmap leading to the certification of the Agency's IQMS

to be produced in 2012. The preparation for integrating the Eco-Management and Audit Scheme (EMAS) commenced with targeted awareness and information sessions.

ECHA continued to reply in a timely way to applications submitted on the basis of Regulation (EC) No 1049/2001 on public access to documents. In addition, it fulfilled its obligations in the field of personal data protection, following the advice of the European Data Protection Supervisor (EDPS) and of its own Data Protection Officer (DPO).

According to ECHA's Financial Regulation, the Internal Auditor for ECHA is the Internal Auditor of the European Commission (IAS). The IAS performed an IT risk assessment and an audit on IT project management in 2011. An action plan has been developed in response to the recommendations of the IAS on IT project management. The IAS also confirmed the strategic three-year audit plan undertaken last year as the basis for the selection of the 2012 audit topic.

The local "Internal Audit Capability" (IAC) undertook two assurance audits (IQMS Process documentation; and Planning, reporting and monitoring of the Dossier evaluation process) and four follow-up audits. Action plans have been developed in response to the recommendations of the assurance audits.

ECHA monitored the implementation of the 2011 risk mitigation plan and improved its business continuity plans and its capability to face crises. All risk mitigation measures were taken during the year, except the development of a long term staff retention strategy.

Objectives and Indicators

Objectives

1. The Agency is governed through efficient and effective management, which ensures proper planning of activities, allocation of resources, assessment and management of risks, safety of staff and security of assets and information and provides a quality assurance for outputs.

Performance Indicators & Targets

Indicators	Target in 2011	Means and frequency of verification	Result 2011
Percentage of statutory documents submitted to the Management Board within legal deadlines.	100%	Quarterly internal report	100%
Level of implementation of the annual risk mitigation plan.	100%	Annual internal report	80%
Percentage of quality procedures released to the public according to plan.	Not less than 90%	Quality Manager's annual report	100%
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 13 meetings involving Management Board members were organised.
- Two Inter-Agency network meetings were organised of which one took place in ECHA's premises.
- The Quality Management System was further developed and 150 effective documents were in place by the end of the year.
- Legal support was provided to ensure that ECHA's decisions are in line with legal requirements; provision of legal defence or action in 13 court proceedings and 7 appeal proceedings.
- 93 initial and five confirmatory "access to documents" requests, some of which addressed dozens of documents, were answered in accordance with the applicable legislation.
- 70% of processing operations listed in the inventory entered into the Data Protection register.
- The first MSCA Directors' planning meeting was organised.
- Access to the data in the REACH-IT database was established for 15 MSCAs, bringing the total to 35.
- One Security Officer's Network meeting was organised.

Activity 13: Finance, Procurement and Accounting

Main Achievements in 2011

The total budget revenue for ECHA in 2011 amounted to €37.6 million, an amount that stemmed from registrations, interest income from the reserve, the special biocides preparatory contribution from the Commission as well as from SME verification work conducted during the year. This revenue, which was considerably higher than estimated, was complemented with a balancing amount from the 2010 accumulated reserve, in order to finance the activities of ECHA in 2011. The Agency's cash reserves from 2010 were managed by two external, highly rated custodians, with the objective of ensuring the safe-keeping of the funds and sufficient risk diversification. They permitted ECHA to reimburse the 2010 subsidy of €36 million plus interest earnings to the European Commission. The remaining reserve will allow ECHA to fund its activities until the start of the next EU Financial framework of 2014-2020.

The initial budget of €99.8 million was reduced by the management Board by €7.1 million to assure the alignment between the budgeted and the real expenditure. This reduction was driven by the postponement of some IT projects, a rigorous policy in terms of annuality of budget expenditure, as well as by the fact that no salary indexation took place in 2011. The total budget execution amounted to 96% for the budget's commitment appropriations and 81% for the payment appropriations. The 96% budget execution is 2% below the 2011 target, but compares well with the 95% targets as set for 2010 and 2012. The 81% payment execution is above the target of 75%. The carry-over rate was 16%, which is well below the target of 25%.

The Agency started a systematic verification of the status of companies that had registered as SME's in 2010 and had consequently benefited from SME reductions. A total of 326 companies were contacted in 2011 and 245 verifications were completed. Of those, 80% had wrongly stated the size of their company, which was well above the anticipated outturn. As a result from this work, a total of €6.6 million of fees and charges have been invoiced during the year 2011.

The Agency also started preparations for the anticipated responsibilities related to the financial implementation of the new regulations in the fields of biocides and – later – PIC, requiring separate budgetary and accounting reporting. Therefore, during the year, the Agency started a pilot project on cost accounting, with the aim to establish a technical basis for activity based management as well as to ensure that different activities of the Agency can be accounted for on a transparent basis. The preparatory work was completed during the year and the methodology as well as the IT application was tested. From the beginning of 2012 the cost accounting approach will be implemented on a systematic basis for all of the Agency's activities.

With reference to procurement activities, around 350 procurement actions have been carried out in 2011, with a main focus on IT-related contracting. Several new framework contracts have been established, notably in the areas of security, catering, IT hosting, scientific services and others. A large number of specific contracts have been established during the year for different types of IT services, equipment and scientific studies as well as the contracting required for the administrative needs of the Agency.

Objectives and Indicators

<u>Objectives</u>

1. The Agency has sound and efficient financial management.
2. Fee invoices are efficiently generated and cashed, and cash reserves securely and effectively managed.

Performance Indicators & Targets

Indicators	Target in 2011	Means and frequency of verification	Results 2011
Number of reservations in the annual report of the European Court of Auditors.	0	ECA reports/ annual	0
Commitment rate.	Not less than 98%	Monthly financial report / annual	96%
Payment rate.	Not less than 75%	Monthly financial report / annual	81%
Carry over rate (of committed funds).	Not more than 25%	Annual internal report	16%
Number of Court rulings against ECHA procurement procedures.	0	Annual internal report	0
Compliance with MB guidance on cash reserves (MB/62/2010 final)	100%	Quarterly internal report	100%

Main Outputs

- Rigorous budget and liquidity management including repayment to the Commission of the EU subsidy received in 2010.
- Mechanism for managing and investing the Agency's cash reserves in operation.
- Verification of the SME status of companies started.
- Cost accounting system developed.
- Regular reportings to the management and Governing Board.
- Correct closure of the 2010 accounts.

Activity 14: Human Resources and Corporate Services

Main Achievements in 2011

Human resources

ECHA continued to attract highly qualified personnel, with 88 new staff recruited during the year. This resulted in the completion of 98% of the Establishment Table of the Agency.

ECHA also continued to give due attention to the induction and training of new staff upon their entry into the service. Following a year of less focus on learning and development in 2010, the ambitious target of 10 training days per staff member was reached in 2011. The HR administrative services were reorganised during the year to cope with the increase in staffing and payroll and the performance management, the leave administration and other core HR functions were upscaled to the capacities required.

Jointly with operational services, preparatory work for the new regulatory tasks for ECHA in the field of Biocides and PIC was undertaken by the Human Resources Unit. A feasibility study on the development of an integrated Human Resources management system has been initiated in 2011.

Several steps have been taken towards enhancing staff retention, which will lead towards the development of an overall policy. In 2011, various measures have been implemented to increase job mobility, foster wellbeing at work, improve work/life balance and develop leadership competencies for senior and middle management, as foreseen in the work programme for 2011. Turnover of TA staff was 3%, which was within the target of maximum 5%.

ECHA management and the Human Resources Unit maintained a continual dialogue and working relationship with the staff representatives.

Infrastructure

Infrastructure management and facility services were further strengthened to cope with the growing number of staff and the increase in the operational activities of the Agency. Following the adoption of a new organisational structure in early 2011, a reallocation of work spaces was done and the required removals took place with minimal disturbance during the first half of the year.

A total of 179 official meetings or workshops with a total of 6 382 external participants (+23%) were organised in ECHA's conference premises. These activities have also resulted in an increased number of travel related services provided to external experts.

Meeting organisers at ECHA have adopted well and taken advantage of the new virtual conferencing techniques. The number of videoconferences and other web based conferences organised have increased over 60% compared to 2010. Virtual conferencing has proved to be very cost effective and it is also to be expected that the use of this technique will increase remarkably in 2012.

In order to continue to support the growing number of events, the meeting facilities of the Agency were extended with a fully equipped meeting room with a capacity of 550 participants – the Marie Skłodowska Curie room – which was inaugurated in November 2011.

Physical security, a major task under the Corporate Services and a key priority of the Agency, continued to received due attention in 2011. Other corporate services functions such as mail handling, logistics, library, physical archiving and travel management

continued to provide reliable and high level support. The envisaged digitalisation of the archives was postponed and will be considered in the context of an overall digital document management approach.

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 2011	Means and frequency of verification	Result 2011
Percentage of establishment plan posts filled at the end of the year.	Not less than 95%	Annual internal report	98%
Percentage of selection procedures planned for the year completed.	100%	Annual internal report	128%
Turnover of the Temporary Agents.	Not more than 5%	Annual internal report	3%
Average number of training days per staff member.	10	Annual internal report	10
Level of satisfaction of the Committee, Forum and MB members with the functioning of the conference centre.	High	Annual survey	N/A
Level of satisfaction of staff with the office facilities and logistics services.	High	Annual survey	N/A

Main Outputs

HUMAN RESOURCES

- Payroll for statutory staff and other payments to staff, SNEs and trainees, overall some 550 persons.
- 22 reserve lists were adopted based on the selection procedures carried out.
- 88 recruitments completed.
- Average of 10 training days per staff member delivered.
- Performance appraisal and reclassification exercise for over 400 statutory staff managed.
- Advice and assistance to staff and management on HR matters, in particular individual rights and wellbeing provided.
- Staff survey carried out.
- Active development of the people and performance management processes and methods.

CORPORATE SERVICES

- Completion of the equipping of the 600 workstations in ECHA's premises.
- Space allocation plan for 2011 and complete reorganisation of offices carried out in the second quarter of the year.
- Timely purchase of equipment, materials and services through appropriate procurement procedures.
- Timely calculations and reimbursements of mission and travel reimbursements.
- Secure office facilities.
- Good support for meetings and conferences provided.
- Well-functioning audio-visual equipment with good technical support provided.
- Mail services provided efficiently.
- Library and archive services managed well and correctly.
- Facilities inventory carried out correctly and up-to-date.

Activity 15: Information and Communication Technology

Main Achievements in 2011

The main focus throughout the year was put on ensuring that the ICT infrastructure capacity – which was reaching its limits during 2011 – could be enhanced to further support several new releases of software applications (Odyssey, RIPE, C&L Inventory), as well as support the resources demand of the already existing production sites of REACH-IT, Dissemination Portal and IUCLID. In addition, new software releases – as well as the new ECHA website - were supported by delivering systems and *multi-tier* server environments including hardware, databases, middleware, and application software for development, testing, and production purposes.

Two main lines of action, tightly linked were pursued: upgrading the core ICT infrastructure to achieve an increase in performance, operability, extensibility and efficiency, as well as a more effective High Availability architecture to support Business Continuity. The overall design of the upgrading and the procurement were completed and the initial set-up started, while the migration from the old infrastructure is planned to be finalised by mid 2012.

The strategic decision to outsource hosting services - already taken in 2010 but delayed due to unsuccessful tendering – was carried through in 2011 as a framework contract was signed at the end of the year. Two high standard offsite data centres located in the greater Helsinki area will be ensured through the outsourcing contract. Network and system architectures, as well as back-up systems, will exploit the multiple data centres for business continuity and disaster recovery.

Encrypted connectivity to information on substances registered, employing secure two-factor authentification, was provided to the Member State enforcement authorities via the RIPE portal. In the last quarter of 2011, a pilot for giving MSCAs access to a central IUCLID dossiers database was started. The pilot – continued in the first quarter of 2012 - covers both implementing the secure remote access solution used for REACH-IT to access the central IUCLID database and the actual use of the central IUCLID instance to perform scientific tasks. Upon successful conclusion of the pilot, full deployment to all MSCAs will be performed.

In 2011, particular attention was given to the implementation of new services and enhanced IT security in the usage of ICT facilities for end users: two-factor authentication was introduced for remote access to webmail, as well as encryption of data stored locally on laptops. In this area, ECHA started to build a Catalogue of ICT Services inspired by the industry standard ITIL. The Catalogue will be the basis for engineering the provisioning of services and will serve the purpose of triggering a quality improvement cycle (defining, measuring, improving).

In the context of administrative applications, the Project Portfolio Office prepared a time tracking tool coherent with the Activity Based Management set-up and the IT Governance Framework methodology. The tool – piloted at the end of the year – will be used by ECHA's personnel to record the time spent allowing the separation of staff costs by Activity and Process in the context of the cost accounting system of the Agency.

New applications have been implemented for the Board of Appeal and HR processes, while the existing applications were timely maintained.

Finally, the management of a ticketing system used in particular by the ECHA Helpdesk and national helpdesks was revised and a complete overhaul and update of the platform was performed, giving way to a better support for the ECHA Helpdesk, ICT helpdesk and new users like the helpdesk for General Inquiries.

The Enterprise Architecture (EA) function focused on the integration and consolidation project originated by the EA study performed at the end of 2010 to improve the overall accessibility, searchability and maintainability of ECHA's business information systems landscape, while preparing for the future integration of new functionalities in particular for providing IT support to Biocides.

Objectives and Indicators

Objectives

1. To operate the technical ICT infrastructure of the Agency at a high service level and maximise continuity, efficiency and security for all supported business operations.
2. To assure a consistent and common corporate architectural approach as well as to foster best practice in governance and management of IT projects, and to ensure professional, competent and timely responses to any of the planned or recurring business activities.

Performance Indicators & Targets

Indicators	Target in 2011	Means and frequency of verification	Result 2011
Availability of operational systems for external customers (uptime).	99%	Data centre statistics	98%
Level of user satisfaction with internal IT services.	High	Annual customer survey and *ad hoc* feedback	High
Level of implementation of fully featured ICT business continuity and plan.	100%	Annual internal report	50%

Main Outputs

- ICT infrastructure upgrade designed and set-up started.
- Outsourced hosting services framework contract signed.
- IT security measures for usage of ICT facilities by end users deployed.
- ICT Service catalogue initiated.
- Time tracking tool ready to be deployed.
- Effective support to IT project management and governance.
- Support and maintenance of administrative IT applications.
- Stable operations of ICT infrastructure.
- ICT infrastructure support to new releases of software applications.
- Monitoring and maintenance of core business applications.

Annexes

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

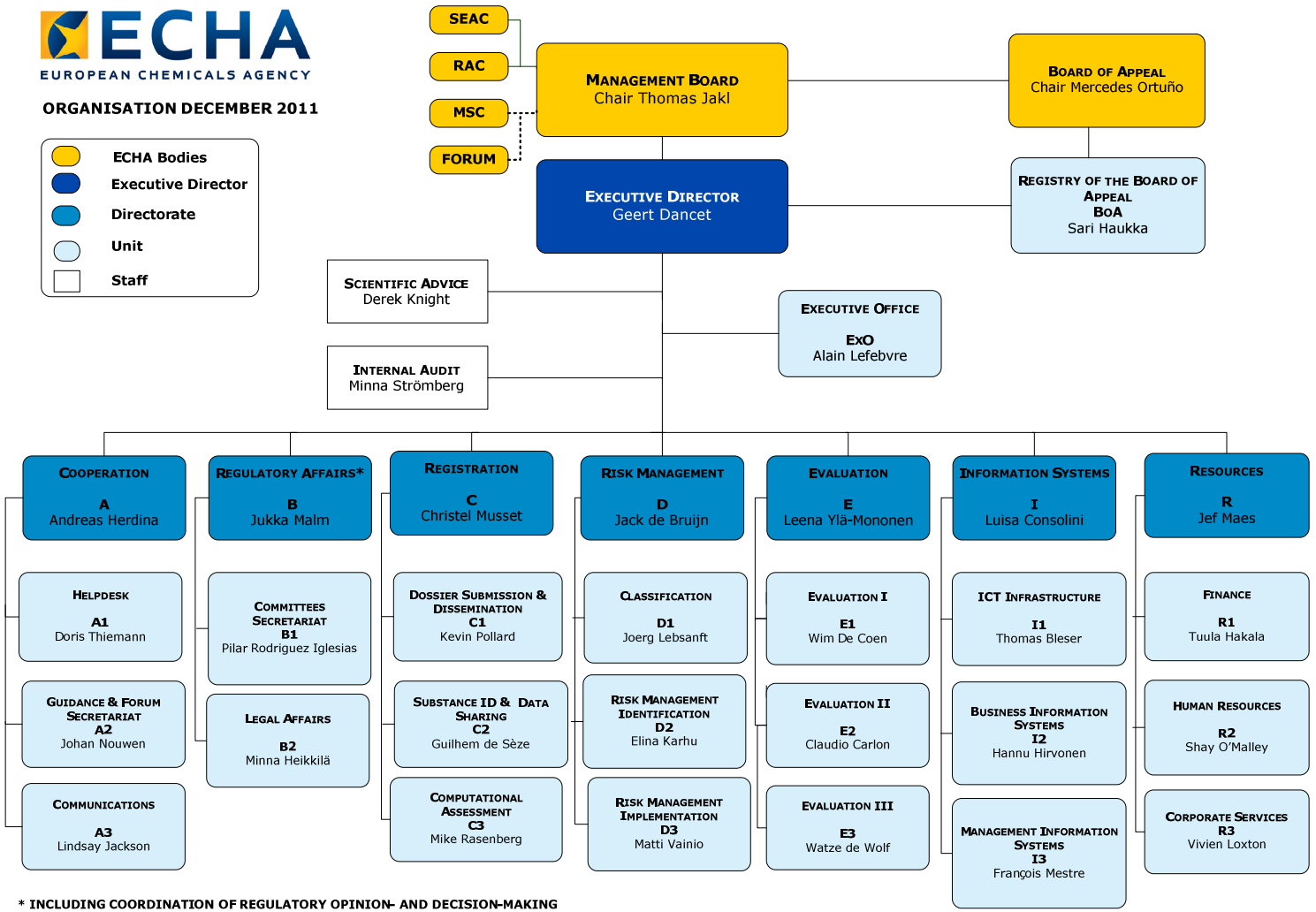
Annex 2: Financial and Human Resources 2011

Annex 3: Candidate List of Substances of Very High Concern

Annex 4: Substances recommended for the Authorisation List

Annex 5: Analysis and assessment of the AAR of the Authorising Officer for 2011

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



Members of the Management Board on 31 December 2011

Chair: Thomas JAKL

Members	
Thomas JAKL	Austria
Helmut DE VOS	Belgium
Boyko MALINOV	Bulgaria
Leandros NICOLAIDES	Cyprus
Karel BLAHA	Czech Republic
Eskil THUESEN	Denmark
Aive TELLING	Estonia
Pirkko KIVELÄ	Finland
Catherine MIR	France
Alexander NIES	Germany
Kassandra DIMITRIOU	Greece
Zoltan ADAMIS	Hungary
Martin LYNCH	Ireland
Antonello LAPALORCIA	Italy
Armands PLATE	Latvia
Maria TERIOSINA	Lithuania
Claude GEIMER	Luxembourg
Francis E. FARRUGIA	Malta
Jan-Karel KWISTHOUT	Netherlands
Edyta MIEGOC	Poland
Mário GRÁCIO	Portugal
Ionut GEORGESCU	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)
Gertraud LAUBER	European Mine, Chemical and Energy Workers' Federation (EMCEF)
Martin FÜHR	University of Darmstadt

Observers from EEA/EFTA countries	
Kristin Rannveig SNORRADOTTIR	Iceland
Henrik ERIKSEN	Norway

Members of MSC - Member State Committee on 31 December 2011

Chair: Anna-Liisa SUNDQUIST

Members	Nominating state
Helmut STESSEL	Austria
Kelly VANDERSTEEN	Belgium
Parvoleta Angelova LULEVA	Bulgaria
Tasoula KYPRIANIDOU-LEONTIDOU	Cyprus
Pavlina KULHANKOVA	Czech Republic
Henrik TYLE	Denmark
Enda VESKIMÄE	Estonia
Jaana HEISKANEN	Finland
Sylvie DRUGEON	France
Helene FINDENEGG	Germany
Aglaia KOUTSODIMOU	Greece
Szilvia DEIM	Hungary
Majella COSGRAVE	Ireland
Pietro PISTOLESE	Italy
Arnis LUDBORZS	Latvia
Lina DUNAUSKINE	Lithuania
Arno BIWER	Luxembourg
Tristan CAMILLERI	Malta
René KORENROMP	Netherlands
Linda REIERSON	Norway
Michal ANDRIJEWSKI	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 2011

Chair: José Tarazona

Members	Nominating state
Annemarie LOSERT	Austria
Karen VAN MALDEREN	Belgium
Zhivka HALKOVA	Bulgaria
Gera TROISI	Cyprus
Marian RUCKI	Czech Republic
Frank JENSEN	Denmark
Peter Hammer SØRENSEN	Denmark
Urs SCHLÜTER	Estonia
Riitta LEINONEN	Finland
Elodie PASQUIER	France
Annick PICHARD	France
Helmut A. GREIM	Germany
Norbert RUPPRICH	Germany
Nikolaos SPETSERIS	Greece
Christina TSITSIMPIKOU	Greece
Katalin GRUIZ	Hungary
Thomasina BARRON	Ireland
Yvonne MULLOOLY	Ireland
Paola DI PROSPERO FANGHELLA	Italy
Pietro PARIS	Italy
Normunds KADIKIS	Latvia
Jolanta STASKO	Latvia
Lina DUNAUSKIENE	Lithuania
Hans-Christian STOLZENBERG	Luxembourg
Betty HAKKERT	Netherlands
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
Radu BRANISTEANU	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 2011

Acting Chair: Pilar Rodríguez Iglesias

Members	Nominating State
Simone FANKHAUSER	Austria
Georg KNOFLACH	Austria
Catheline DANTINNE	Belgium
Jean-Pierre FEYAERTS	Belgium
Elina Velinova STOYANOVA-LAZAROVA	Bulgaria
Georgios BOUSTRAS	Cyprus
Jiri BENDL	Czech Republic
Lars FOCK	Denmark
Johanna KIISKI	Finland
Jean-Marc BRIGNON	France
Karine FIORE-TARDIEU	France
Franz-Georg SIMON	Germany
Karen THIELE	Germany
Angela LADOPOULO	Greece
Dimosthenis VOIVONTAS	Greece
Endre SCHUCHTÁR	Hungary
Marie DALTON	Ireland
Frederica CECARELLI	Italy
Silvia GRANDI	Italy
Vitalius SKARZINSKAS	Lithuania
Cees LUTTIKHUIZEN	Netherlands
Magnus Utne GULBRANDSEN	Norway
Zbigniew SLEZAK	Poland
Joao ALEXANDRE	Portugal
Liliana Luminita TIRCHILIA	Romania
Robert CSERGO	Romania
Janez FURLAN	Slovenia
Maria Jesus RODRIGUEZ DE SANCHO	Spain
Asa THORS	Sweden
Stavros GEORGIOU	United Kingdom

Members of the Forum for Exchange of Information on Enforcement on 31 December 2011

Chair: Szilvia Deim

Members	
Eugen ANWANDER	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 VOM HOFE	Germany
Elina FOUFA	Greece
Szilvia DEIM	Hungary
Bergþóra Hlíðkvist SKÚLADÓTTIR	Iceland
Sinead MCMICKAN	Ireland
Mariano ALESSI	Italy
Parsla PALLO	Latvia
Manfred FRICK	Liechtenstein
Viktoras SESKAUSKAS	Lithuania
Jil WEBER	Luxembourg
Shirley MIFSUD	Malta
Jos VAN DEN BERG	Netherlands
Maren WIKHEIM	Norway
Rui CABRITA	Portugal
Mihaiela ALBALESCU	Romania
Dušan KOLESAR	Slovakia
Vesna NOVAK	Slovenia
Pablo SANCHEZ-PENA	Spain
Agneta WESTERBERG	Sweden
Mike POTTS	United Kingdom

Annex 2: Financial and Human Resources 2011

Total number of TA positions occupied at 31.12.2011: 441

Total number of CA positions occupied at 31.12.2011: 62

Other staff (Seconded National Experts, interims, trainees) at 31.12.2011: 46

Financial and human resources per Activity (excluding 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	28	11	8	415 615
Activity 2: Evaluation	78	13	3.5	324 092
Activity 3: Authorisations and restrictions	31.5	5	3.5	481 496
Activity 4: Classification and labelling	12.5	3	1	19 870
Activity 5: Advice and assistance through guidance and helpdesk	22	11	5.5	309 768
Activity 6: IT support to operations	33.5	9	0	10 396 487
Activity 7: Scientific and practical advice to the further development of legislation	9.5	1	0	19 448
ECHA's bodies and supporting activities				
Activity 8: Committees and Forum	20	7	3	1 134 156
Activity 9: Board of Appeal	6	3	1	25 823
Activity 10: Communications	10	10	5	5 343 270
Activity 11: Relations with EU institutions and international cooperation	4	0	0	117 131
Management, organisation and resources				
Activity 12: Management	22	16	3.5	1 351 926
Total	**277**	**89**	**34**	
Activities 13-15: Title II (Infrastructure and operating expenditure)	21	54	28	12 589 579
Title I (staff expenditure)				56 340 503
Total	**298**	**143**	**62**	**88 869 164**
In Establishment plan:	**456**		**70**	

Annex 3: Candidate List of Substances of Very High Concern

Nr.	Name	EC number	Date inclusion	Reason inclusion
1	Sodium dichromate	234-190-3	2008/10/28	Carcinogenic, mutagenic and toxic for reproduction (articles 57a, 57b and 57c)
2	5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	201-329-4	2008/10/28	vPvB (article 57e)
3	4,4'- Diaminodiphenylmethane (MDA)	202-974-4	2008/10/28	Carcinogenic (article 57a)
4	Bis(tributyltin)oxide (TBTO)	200-268-0	2008/10/28	PBT (article 57d)
5	Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	287-476-5	2008/10/28	PBT and vPvB (articles 57 d and 57 e)
6	Triethyl arsenate	427-700-2	2008/10/28	Carcinogenic (article 57a)
7	Dibutyl phthalate (DBP)	201-557-4	2008/10/28	Toxic for reproduction (article 57c)
8	Diarsenic trioxide	215-481-4	2008/10/28	Carcinogenic (article 57a)
9	Anthracene	204-371-1	2008/10/28	PBT (article 57d)
10	Lead hydrogen arsenate	232-064-2	2008/10/28	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
11	Benzyl butyl phthalate (BBP)	201-622-7	2008/10/28	Toxic for reproduction (article 57c)
12	Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified: Alpha-hexabromocyclododecane Beta-hexabromocyclododecane Gamma-hexabromocyclododecane	247-148-4 and 221-695-9	2008/10/28	PBT (article 57d)
13	Diarsenic pentaoxide	215-116-9	2008/10/28	Carcinogenic (article 57a)
14	Bis (2-ethylhexyl)phthalate (DEHP)	204-211-0	2008/10/28	Toxic for reproduction (article 57c)
15	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)
16	Anthracene oil, anthracene-low	292-604-8	2010/01/13	Carcinogenic[2], mutagenic[3], PBT and vPvB (articles 57a,

Nr.	Name	EC number	Date inclusion	Reason inclusion
				57b, 57d and 57e)
17	2,4-Dinitrotoluene	204-450-0	2010/01/13	Carcinogenic (article 57a)
18	Lead chromate	231-846-0	2010/01/13	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
19	Anthracene oil, anthracene paste, anthracene fraction	295-275-9	2010/01/13	Carcinogenic[2], mutagenic[3], PBT and vPvB (articles 57a, 57b, 57d and 57e)
20	Anthracene oil	292-602-7	2010/01/13	Carcinogenic[1], PBT and vPvB (articles 57a, 57d and 57e)
21	Tris(2-chloroethyl)phosphate	204-118-5	2010/01/13	Toxic for reproduction (article 57c)
22	Aluminosilicate Refractory Ceramic Fibres *are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.2 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the two following conditions: a) Al2O3 and SiO2 are present within the following concentration ranges: Al2O3: 43.5 – 47 % w/w, and SiO2: 49.5 – 53.5 % w/w, or Al2O3: 45.5 – 50.5 % w/w, and SiO2: 48.5 – 54 % w/w, b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm).*	-	2010/01/13	Carcinogenic (article 57a)
23	Anthracene oil, anthracene paste,distn. lights	295-278-5	2010/01/13	Carcinogenic[2], mutagenic[3], PBT and vPvB (articles 57a, 57b, 57d and 57e)
24	Zirconia Aluminosilicate Refractory Ceramic Fibres *are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.2 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil*	-	2010/01/13	Carcinogenic (article 57a)

Nr.	Name	EC number	Date inclusion	Reason inclusion
	the two following conditions: a) Al2O3, SiO2 and ZrO2 are present within the following concentration ranges: Al2O3: 35 – 36 % w/w, and SiO2: 47.5 – 50 % w/w, and ZrO2: 15 - 17 % w/w, b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm).			
25	Pitch, coal tar, high temp.	266-028-2	2010/01/13	Carcinogenic, PBT and vPvB (articles 57a, 57d and 57e)
26	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))
27	Diisobutyl phthalate	201-553-2	2010/01/13	Toxic for reproduction (article 57c)
28	Anthracene oil, anthracene paste	292-603-2	2010/01/13	Carcinogenic[2], mutagenic[3], PBT and vPvB (articles 57a, 57b, 57d and 57e)
29	Acrylamide	201-173-7	2010/03/30	Carcinogenic and mutagenic (articles 57 a and 57 b)
30	Disodium tetraborate, anhydrous	215-540-4	2010/06/18	Toxic for reproduction (article 57 c)
31	Ammonium dichromate	232-143-1	2010/06/18	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
32	Tetraboron disodium heptaoxide, hydrate	235-541-3	2010/06/18	Toxic for reproduction (article 57 c)
33	Potassium dichromate	231-906-6	2010/06/18	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
34	Trichloroethylene	201-167-4	2010/06/18	Carcinogenic (article 57 a)
35	Sodium chromate	231-889-5	2010/06/18	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
36	Potassium chromate	232-140-5	2010/06/18	Carcinogenic and mutagenic (articles 57 a and 57 b).
37	Boric acid	233-	2010/06/18	Toxic for reproduction

Nr.	Name	EC number	Date inclusion	Reason inclusion
		139-2, 234-343-4		(article 57 c)
38	Acids generated from chromium trioxide and their oligomers. Group containing: Chromic acid, Dichromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid	231-801-5, 236-881-5	2010/12/15	Carcinogenic (article 57a)
39	Cobalt(II) carbonate	208-169-4	2010/12/15	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
40	Cobalt(II) diacetate	200-755-8	2010/12/15	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
41	2-Methoxyethanol	203-713-7	2010/12/15	Toxic for reproduction (article 57c)
42	Chromium trioxide	215-607-8	2010/12/15	Carcinogenic and mutagenic (articles 57 a and 57 b)
43	Cobalt(II) dinitrate	233-402-1	2010/12/15	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
44	Cobalt(II) sulphate	233-334-2	2010/12/15	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
45	2-Ethoxyethanol	203-804-1	2010/12/15	Toxic for reproduction (article 57c)
46	1,2,3-Trichloropropane	202-486-1	2011/06/20	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
47	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	271-084-6	2011/06/20	Toxic for reproduction (article 57c)
48	1-Methyl-2-pyrrolidone	212-828-1	2011/06/20	Toxic for reproduction (article 57c)
49	Hydrazine	206-114-9	2011/06/20	Carcinogenic (article 57a)
50	Strontium chromate	232-142-6	2011/06/20	Carcinogenic (article 57a)
51	2-Ethoxyethyl acetate	203-839-2	2011/06/20	Toxic for reproduction (article 57c)
52	1,2-Benzenedicarboxylic acid, di-	276-	2011/06/20	Toxic for reproduction

Nr.	Name	EC number	Date inclusion	Reason inclusion
	C6-8-branched alkyl esters, C7-rich	158-1		(article 57c)
53	Cobalt dichloride	231-589-4	2011/06/20 - 2008/10/28	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
54	Zirconia Aluminosilicate Refractory Ceramic Fibres *are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions: a) oxides of aluminium, silicon and zirconium are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm). c) alkaline oxide and alkali earth oxide (Na2O+K2O+CaO+MgO+BaO) content less or equal to 18% by weight*		2011/12/19	Carcinogenic (article 57 a)
55	Calcium arsenate	231-904-5	2011/12/19	Carcinogenic (article 57 a)
56	Bis(2-methoxyethyl) ether	203-924-4	2011/12/19	Toxic for reproduction (article 57 c)
57	Potassium hydroxyoctaoxodizincatedichromate	234-329-8	2011/12/19	Carcinogenic (article 57 a)
58	Aluminosilicate Refractory Ceramic Fibres *are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions: a) oxides of aluminium and silicon are the main components present (in the fibres) within variable*		2011/12/19	Carcinogenic (article 57 a)

Nr.	Name	EC number	Date inclusion	Reason inclusion
	concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm) c) alkaline oxide and alkali earth oxide (Na2O+K2O+CaO+MgO+BaO) content less or equal to 18% by weight			
59	N,N-dimethylacetamide	204-826-4	2011/12/19	Toxic for reproduction (article 57 c)
60	Arsenic acid	231-901-9	2011/12/19	Carcinogenic (article 57 a)
61	Lead dipicrate	229-335-2	2011/12/19	Toxic for reproduction (article 57 c)
62	1,2-dichloroethane	203-458-1	2011/12/19	Carcinogenic (article 57 a)
63	2-Methoxyaniline; o-Anisidine	201-963-1	2011/12/19	Carcinogenic (article 57 a)
64	Trilead diarsenate	222-979-5	2011/12/19	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
65	Pentazinc chromate octahydroxide	256-418-0	2011/12/19	Carcinogenic (article 57 a)
66	4-(1,1,3,3-tetramethylbutyl)phenol	205-426-2	2011/12/19	Equivalent level of concern having probable serious effects to the environment (article 57 f)
67	Formaldehyde, oligomeric reaction products with aniline	500-036-1	2011/12/19	Carcinogenic (article 57 a)
68	Bis(2-methoxyethyl) phthalate	204-212-6	2011/12/19	Toxic for reproduction (article 57 c)
69	Lead diazide, Lead azide	236-542-1	2011/12/19	Toxic for reproduction (article 57 c),
70	Lead styphnate	239-290-0	2011/12/19	Toxic for reproduction (article 57 c)
71	2,2'-dichloro-4,4'-methylenedianiline	202-918-9	2011/12/19	Carcinogenic (article 57 a)
72	Phenolphthalein	201-004-7	2011/12/19	Carcinogenic (article 57 a)
73	Dichromium tris(chromate)	246-356-2	2011/12/19	Carcinogenic (article 57 a)

1) The substance does not meet the criteria for identification as a carcinogen in situations where it contains less than 0.005 % (w/w) benzo[a]pyrene (EINECS No 200-028-5)

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

3) The substance does not meet the criteria for identification as a mutagen in situations where it contains less than 0,1 % w/w benzene (EINECS No 200-753-7).

Annex 4: Substances recommended for the Authorisation List

Recommendation of the European Chemicals Agency (ECHA) of 20 December 2011 for the inclusion of substances in Annex XIV (the list of substances subject to authorisation) of Regulation (EC) No 1907/2006

					Transitional arrangements				
Nr.	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	**Trichloroethylene**	201-167-4	79-01-6	Art. 57 (a); Carcinogen 1B	Date of inclusion in Annex XIV plus 18 months [1)]	Latest application date plus 18 months	None	None	None
2	**Chromium trioxide**	215-607-8	1333-82-0	Art. 57 (a) & (b); Carcinogen 1A, Mutagen 1B	Date of inclusion in Annex XIV plus 21 months [2)]	Latest application date plus 18 months	None	None	None
3	**Acids generated from chromium trioxide and their oligomers** Group containing: Chromic acid Dichromic acid Oligomers of chromic acid and dichromic acid	231-801-5 236-881-5 not yet assigned	7738-94-5 13530-68-2 not yet assigned	Art. 57 (a); Carcinogen 1B	Date of inclusion in Annex XIV plus 21 months [2)]	Latest application date plus 18 months	None	None	None
4	**Sodium dichromate**	234-190-3	7789-12-0 10588-	Art. 57 (a), (b) & (c); Carcinogen 1B; Mutagen 1B;	Date of inclusion in Annex XIV plus 21 months [2)]	Latest application date plus 18 months	None	None	None

			Transitional arrangements						
Nr.	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
			01-9	Toxic for reproduction 1B					
5	**Potassium dichromate**	231-906-6	7778-50-9	Art. 57 (a), (b) & (c); Carcinogen 1B; Mutagen 1B; Toxic for reproduction 1B	Date of inclusion in Annex XIV plus 21 months [2)]	Latest application date plus 18 months	None	None	None
6	**Ammonium dichromate**	232-143-1	7789-09-5	Art. 57 (a), (b) & (c); Carcinogen 1B; Mutagen 1B; Toxic for reproduction 1B	Date of inclusion in Annex XIV plus 21 months [2)]	Latest application date plus 18 months	None	None	None
7	**Potassium chromate**	232-140-5	7789-00-6	Art. 57 (a) & (b); Carcinogen 1B, Mutagen 1B	Date of inclusion in Annex XIV plus 21 months [2)]	Latest application date plus 18 months	None	None	None
8	**Sodium chromate**	231-889-5	7775-11-3	Art. 57 (a), (b) & (c); Carcinogen 1B, Mutagen 1B, Toxic for Reproduction 1B	Date of inclusion in Annex XIV plus 21 months [2)]	Latest application date plus 18 months	None	None	None
9	**Cobalt(II) sulphate**	233-334-2	10124-43-3	Art. 57 (a) & (c); Carcinogen 1B; Toxic for	Date of inclusion in Annex XIV plus 24 months [3)]	Latest application date plus	None	None	None

				Transitional arrangements					
Nr.	**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**
				reproduction 1B		18 months			
10	**Cobalt dichloride**	231-589-4	7646-79-9	Art. 57 (a) & (c); Carcinogen 1B; Toxic for reproduction 1B	Date of inclusion in Annex XIV plus 24 months [3)]	Latest application date plus 18 months	None	None	None
11	**Cobalt(II) dinitrate**	233-402-1	10141-05-6	Art. 57 (a) & (c); Carcinogen 1B; Toxic for reproduction 1B	Date of inclusion in Annex XIV plus 24 months [3)]	Latest application date plus 18 months	None	None	None
12	**Cobalt(II) carbonate**	208-169-4	513-79-1	Art. 57 (a) & (c); Carcinogen 1B; Toxic for reproduction 1B	Date of inclusion in Annex XIV plus 24 months [3)]	Latest application date plus 18 months	None	None	None
13	**Cobalt(II) diacetate**	200-755-8	71-48-7	Art. 57 (a) & (c); Carcinogen 1B; Toxic for reproduction 1B	Date of inclusion in Annex XIV plus 24 months [3)]	Latest application date plus 18 months	None	None	None

Reference is made to the identified SVHC properties in accordance with Article 57 of the REACH Regulation and to the corresponding 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.

1) Assuming the Commission Regulation including the substances of this third Recommendation in Annex XIV would enter into force in February 2013, the latest application date would be August 2014

2) Assuming the Commission Regulation including the substances of this third Recommendation in Annex XIV would enter into force in February 2013, the latest application date would be November 2014

3) Assuming the Commission Regulation including the substances of this third Recommendation in Annex XIV would enter into force in February 2013, the latest application date would be February 2015

Annex 5: Analysis and assessment of the AAR of the Authorising Officer for 2011

Helsinki, 22.03.2012
MB/07/2012 final

ANALYSIS AND ASSESSMENT OF THE ANNUAL ACTIVITY REPORT OF THE AUTHORISING OFFICER FOR THE YEAR 2011

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 2011 adopted by the Management Board at its meeting of 30 September 2010 and updated on 16 December 2010,

Having regard to the Annual Activity Report of the Authorising Officer of the European Chemicals Agency for the year 2011 as submitted to the Board on 12 March 2012,

1. Welcomes the results presented in the Annual Activity Report of the Authorising Officer as well as the high performance level achieved with regard to discharging the tasks under the REACH Regulation (EC) 1907/2006 and the CLP Regulation (EC) No 1272/2008. This is reflected in the fact that 52 out of the 66 ambitious performance targets set in the Work Programme 2011 were met.

2. Congratulates ECHA for the operational work performed in 2011 and, in particular, for the achievements in:

   (a) Processing over 3 million C&L notifications covering over 100 000 different substances by the 3 January 2011 deadline, which exceeded expectations by 50%. The Management Board notes that the C&L inventory was not published in 2011, but shortly afterwards.

   (b) Finalising the processing of all registration dossiers submitted by the first registration deadline in 2010 and having its staff, procedures, IT tools and support to registrants in place to allow smooth registration with proportionally few rejections and consequently only few appeals launched.

   (c) Making most of the information on the chemicals registered or notified publicly available. By the end of the year a massive and unique volume of information from more than 23 000 registration dossiers covering more than 4 100 substances (or 78% of the registered substances) were freely available via the dissemination portal on the ECHA website.

(d) Making progress both with the evaluation of the testing proposals and with the compliance checks of the dossiers, supported by the large number of unanimous agreements by the Member State Committee.

(e) Submitting, as planned, the first proposal for the Community rolling action plan (CoRAP) for substance evaluation, including 91 substances for 2012-2014, to the Member States and ECHA Member State Committee.

(f) Adding 28 Substances of Very High Concern (SVHCs) to the Candidate List, including 11 substances for which ECHA had prepared the Annex XV dossier.

(g) Sending its third recommendation for inclusion of priority substances in the Authorisation List to the Commission. Inclusion of thirteen substances from the Candidate List was recommended. Being prepared to receive applications for authorisation.

(h) Adopting opinions in RAC and SEAC on the first four restriction proposals.

(i) Delivering, in accordance with the legal requirements of REACH, its first five-year report on the operation of the REACH Regulation; producing the first three-year report on the status of implementation and use of non-animal test methods and testing strategies; submitting both reports to the Commission and making them public in the interest of transparency.

(j) Supporting the implementation of REACH and CLP by rolling out a new tool RIPE for enforcement authorities, as well as releasing new versions of REACH-IT, IUCLID 5 and Chesar for industry.

(k) Supporting industry in building up capacity via various communication tools in the form of webinars and targeted materials in 22 EU languages.

(l) Providing direct support to registrants via the ECHA 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.

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 Agency continues to work transparently, that the Committees involve stakeholders and case owners as appropriate, that the eligibility criteria for accredited stakeholder organisations were improved and that the first workshop with those organisations was held in Brussels to facilitate their input in ECHA's work programmes.

5. Notes that progress in processing inquiries did not meet ECHA's annual target but that measures were put in place to meet such target from the fourth quarter of 2011.

6. Notes that the progress in processing confidentiality claims did not meet the target but that measures have been put in place to deliver a satisfactory performance in future. Encourages the Agency to make up the backlog in terms of confidentiality claims and additional information to be published, following the Commission's advice.

7. Welcomes the initiative of meeting with heads of MSCAs, which will deliver benefits of more effective planning and use of authorities' resources across the EU.

8. Welcomes the progress in implementing internal control standards, an integrated quality management system as well as the continuing analysis and management of risks.

9. Welcomes the results of the feasibility and needs assessment with regard to enhancing SME accessibility to communication with the Agency, including via REACH-IT, in different languages and encourages ECHA to implement the recommendations.

10. Acknowledges the work of the Board of Appeal and its Registry in processing 6 appeals.

11. Appreciates the Agency's substantial recruitment efforts, recruiting 88 staff members and filling 98% of the posts in the establishment plan.

12. Acknowledges that the Agency repaid the temporary 2010 subsidy to the Commission and was able to collect a higher amount of revenue in 2011 than planned. Appreciates the Agency's efforts in verifying the SME status of registrants.

13. Congratulates the Agency for a high rate of execution of commitment appropriations of 96% and notes that the payment execution reaches 81%.

14. Notes that the global carryover rate remains at nearly the same level as in 2010, but encourages the agency to take measures to reduce carry over in as far as possible.

15. Notes the Agency's continuing work to support the access of Member State authorities to the REACH-IT system, as well as the secure use of the information in that system.

16. Welcomes the new staff model and encourages the Agency to complement it with the financial aspects.

17. Welcomes the new corporate identity and user-friendly website.

18. Notes the reorganisation to align the structure of the Agency with its developing role, including for biocides and PIC.

19. Strongly appreciates the efforts of management and the entire staff in achieving the ambitious goals set by the regulations; approves of the measures taken to address the high levels of staff stress seen in 2010, as this is key to maintaining high staff morale and retaining the highly qualified staff.

Helsinki, 23 March 2012

signed
For the Management Board
Thomas JAKL

ISBN