ECHA
EUROPEAN CHEMICALS AGENCY

General Report 2012

The year of evaluation

General Report 2012

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European Chemicals Agency

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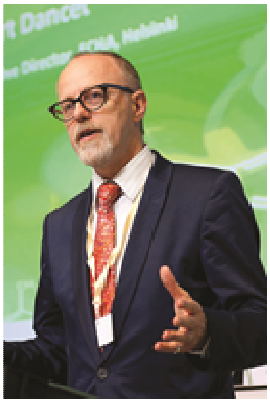
ACRONYMS

AAR	Annual Activity Report
AD	Administrator
ASO	Accredited Stakeholder Organisation
AST	Assistant
C & L	Classification and Labelling
CA	Contract Agent
CHESAR	Chemical Safety Assessment and Reporting tool
CLH	Harmonised Classification and 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
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
EC	European Commission
ECHA	European Chemicals Agency
ECM	Enterprise Content Management
EDC	Endocrine Disrupting Chemical
EEA	European Economic Area
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
ENES	Exchange Network on Exposure Scenarios
EU	European Union
FAQ	Frequently Asked Questions
HELPEX	HelpNet Exchange
HELPNET	REACH and CLP Helpdesk Network
HR	Human Resources
HRMS	Human Resources Management System
IAC	Internal Audit Capability
IAS	Internal Audit Service of the European Commission
ICT	Information and Communication Technologies
IPA	Instrument for Pre-Accession Assistance
IR&CSA	Information Requirements and Chemical Safety Assessment
IT	Information Technologies
IUCLID	International Uniform Chemical Information Database
IUPAC	International Union of Pure and Applied Chemistry
JRC	European Commission Joint Research Centre
MB	Management Board
MSC	Member State Committee
MSCA	Member State Competent Authority
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 and Answers
RAC	Risk Assessment Committee
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
REACH-IT	The central IT system providing support for REACH
RIPE	REACH Information Portal for Enforcement
SEAC	Socio-Economic Analysis Committee
SME	Small and Medium-sized Enterprise
SVHC	Substance of Very High Concern
TA	Temporary Agent
TCC	Technical Completeness Check
UN GHS	United Nations Globally Harmonized System for classification and labelling of chemicals
US-EPA	United States Environmental Protection Agency
UVCB	Substances of Unknown or Variable composition, Complex reaction products or Biological materials
vPvB	Very Persistent and Very Bioaccumulative
W/W	Weight by Weight

FOREWORD BY THE EXECUTIVE DIRECTOR



"The year of evaluation"

Welcome to this report on the European Chemical Agency's work in 2012 – our year of evaluation. In many ways, evaluation is the core of the Agency's work. It provides the reassurance to European citizens that manufacturers and importers of chemicals have taken their registration responsibilities seriously and have complied with the letter and the spirit of the law to enable the safe use of their chemicals. That is also why evaluation is a key element in achieving ECHA's first strategic aim: to improve the quality of information submitted by industry.

The evaluation of registration dossiers requires the involvement of interdisciplinary teams of scientists and lawyers in ECHA and in the Member States Competent Authorities. ECHA is in charge of dossier evaluation - comprising both compliance checks and testing proposals – while the Member States experts review ECHA's draft decisions. The Member States undertake substance evaluations while ECHA reviews their draft decisions. The Member States Committee endeavours to resolve any disagreements on any decision. For the substance evaluation, all three bodies cooperate each year in developing the Community Rolling Action Plan. ECHA has started dossier evaluation in 2008 and has now built up a capacity to process annually 600 dossier evaluations in parallel, while Member States are committed to 50 substance evaluations per year. Getting to a decision takes up to two years. Consequently, the authorities are together evaluating hazard and safety information on hundreds of chemicals at the same time, compared to tens under the Existing Substances Regulation in the past. A key challenge is to deploy the time and effort of our experts where they will have most impact. One key change that we made in 2012 was to speed up compliance checks by selecting specific areas of concern (like genotoxicity) for screening the database of all dossiers with intelligent algorithms that can pick out the potentially deficient dossiers and then to open the relevant dossiers to examine that specific part. We are confident that this new approach is helping us to target dossiers where poor quality represents more of a risk to human health and the environment. I encourage you to look at our latest Evaluation Report to read more about our findings from evaluating dossiers in 2012.

This was also a year of preparation for the next registration deadline and for implementing two new Regulations on Biocidal Products and Prior Informed Consent for the import and export of hazardous substances. Taking on new work is a welcome challenge, but on this occasion it came with some extreme time and resource constraints. The Biocides legislation will enter into operation on 1 September 2013 just about one year after entry into force and the release of the first subsidy. Recruit & train staff and develop & deploy IT systems to receive applications in such a short time sounds to me like 'mission impossible'. To date, we are working hard to be ready, but we risk not having everything in place as we would wish it by September. Next year's report will show how well we managed.

In the meantime, I wish you every success in 2013 - with your registration dossiers ahead of the REACH deadline on 31 May; with your applications for Authorisation; with your Biocidal substances or product applications; and, above all, with our shared goal of a making Europe a safer place for us all.

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.

Introduction

This General Report mirrors the Work Programme (WP) 2012 which outlined the objectives and targets for the year. the first challenge of the year, foreseen in the WP, was to ensure the readiness of ECHA for the second REACH registration deadline of 31 May 2013. A second challenge was for ECHA to live up to the expectations on dossier and substance evaluation. A third challenge was in the area of risk management, with the approaching authorisation application dates for the first substances on the Authorisation List, and the policy target set by the Commission of a Candidate List containing 136 Substances of Very High Concern, by the end of the year. A fourth challenge for ECHA was ensuring its readiness for the expected entry into operation of the new Biocides Regulation in the course of 2013. A fifth challenge, in the same vein as biocides but smaller in extent, was expected to result from the recast of the Prior Informed Consent (PIC) Regulation through which the EU implements the Rotterdam Convention. Through the recast, the technical implementation tasks of this Regulation were expected to be transferred from the Commission to ECHA.

Apart from these five key priorities, many other challenges were expected. The main challenges listed below either intensified the current activities or were totally new:

- Complete the review of all confidentiality claims contained in the dossiers submitted by the first REACH registration deadline.
- Provide the Commission with opinions on several restriction proposals.
- Develop generic criteria to identify when there is a need to require registration by industry or to introduce risk management measures for substances of very high concern used in articles.
- Support Member States in the identification of substances of equivalent concern to SVHCs.
- Provide the Commission with opinions on the high number of dossiers for harmonised classification and labelling received in 2010 and 2011.
- Guidance updates, e.g. on information requirements and chemical safety assessments for nanomaterials under REACH.
- Ensure that the IT system which contains the data submitted by industry is secure, more efficient, and provides Member States Competent Authorities and Enforcement Authorities with user-friendly access to fulfil their legal obligations.
- Work towards the first cooperation agreement(s) with third countries that permit the exchange of confidential information and of full assessments leading to synergy of efforts of authorities implementing REACH-compatible legislations.
- Contribute to the reviews set out in the REACH Regulation which the Commission planned to carry out by 1 June 2012, and assist the Commission in any follow-up.
- Endeavour assisting SMEs to the greatest extent possible.

Furthermore, ECHA was expected to become an agency that is financed from different legislative sources. The new Regulations were expected to enter into force at a moment when the tasks of ECHA under REACH and CLP were still increasing in volume so that any staff to be allocated for the new tasks were not to be deducted from its current workforce.

Main Achievements 2012 - Summary

ECHA has worked intensively to ensure the readiness of the Agency for the second REACH registration deadline of 31 May 2013. In order to ensure that the companies that need to register substances in 2013 have up-to-date information that will help them to comply with their legislative obligations, ECHA provided extended information and support through multiple channels, such as a targeted communication campaign ("REACH 2013 – Act now!") with a specific focus on SMEs; updated guidance documents on registration of substances, also in nanoform; two Lead Registrants workshops and numerous webinars. Additionally, it provided support to potential registrants through its Helpdesk, while the necessary enhancements to the submission processes and IT tools (IUCLID, REACH-IT, Chesar) were carried out. A moratorium on updates to guidance or IT tools was put in place on 1 December 2012, six months before the deadline.

Secondly, the target of examining all testing proposals incorporated in 2010 phase-in registrations by 1 December 2012 was met, with ECHA also continuing compliance checks. ECHA is obliged to carry out compliance checks on at least 5% of the registrations submitted per tonnage band and the Agency is well underway to reaching its goal of achieving the 5% target by the end of 2013 for the highest tonnage band dossiers submitted by the first registration deadline in 2010. Furthermore, the first Community Rolling Action Plan (CoRAP) for substance evaluation by Member States including 90 substances was adopted. The evaluations of the first 36 substances included in the first year have started and should produce draft decisions requesting further information, if needed, by 28 February 2013.

With regard to risk management, the expected first applications for authorisation did not materialise, but intense preparatory and awareness-raising work took place with industry, leading to clarification on the different constituents of the application and the content of public consultations thereof. However, ECHA achieved one of its main priorities of the year by delivering on the policy target of the Commission for the Candidate List, by adding 67 Substances of Very High Concern (SVHCs) during the year, bringing the total number of substances on the Candidate List to 138 by the end of the year. Reaching the target required an intensified effort by the Agency, which had to be compensated by deprioritising other risk management activities.

Throughout the year, several activities were undertaken in preparation for the entry into operation of the new Biocides and PIC Regulations in 2013 and 2014 respectively. This included the recruitment and training of experts, the setting up of the Biocidal Products Committee and the development of working procedures. To assist industry, information was made available on the ECHA website, while new IT submission tools were developed or existing ones adapted, and work on the necessary guidance documents started.

Apart from delivering on these key priorities, ECHA also intensified its efforts in other activities or made a start with new activities, as described below.

With regard to the review of confidentiality claims, ECHA met its target to carry out the assessment of all claims submitted by the end of 2011. Where it was found that no adequate justifications were given, the information was disseminated to the public. At the end of the year, about 30 000 dossiers covering nearly 8 000 substances were published on the ECHA website.

Moreover, ECHA assisted the Commission with restriction proposals and supported Member States in the identification of substances of equivalent concern to SVHCs, which for the first time included endocrine disrupters, PBT-like substances and sensitisers.

ECHA developed different ways to use REACH databases to support the identification of cases where further regulatory actions are needed to address concerns related to SVHCs in articles. The results of this work are fed into the Commission work on the potential use of Article 68(2)

of the REACH Regulation to introduce restrictions on CMR substances in consumer articles.

Although the number of new proposals was less than expected, ECHA provided extensive support to the RAC rapporteurs in developing a record number of 31 opinions and scientific background documents for numerous proposals for a harmonised classification.

The Agency enhanced access to its IT systems that contain the data submitted by industry in a secure and efficient manner to Member State Competent Authorities and Enforcement Authorities to allow them to fulfil their legal obligations. Furthermore, the business continuity level has been considerably improved with the relocation of a second back-up data centre.

The unexpected delay in the adoption by the Commission of the REACH review resulted in less demand for technical scientific support to this review work than originally expected. On the other hand, ECHA has advanced its understanding of the assessment of hazard, exposure and risks as well as risk management and mitigation related to nanomaterials by carefully following and contributing to all the developments and outcomes of EU and international programmes.

Finally, during 2012 ECHA became an agency that is financed from different legislative sources. While it continued to be fully self-financed for its activities under the REACH and CLP Regulations, it received its first EU subsidies for performing its tasks under the Biocidal Products and PIC Regulations. Although ECHA adopted separate accounts for these different tasks, it endeavoured to achieve the highest possible synergies in their implementation.

IMPLEMENTATION OF THE REACH AND CLP PROCESSES

Activity 1: Registration, data-sharing and dissemination

Registration is one of the cornerstones of REACH, and also the first step, for ensuring the safe use of chemicals. In their registration dossiers submitted to ECHA, companies share data, document the properties and uses of their chemicals and demonstrate that they can be used safely. ECHA verifies the completeness of the information provided and the payment of the registration fee, before assigning a registration number. Most of the information is then disseminated to the public via ECHA's website.

Main Achievements in 2012

Registration and dossier submissions

From the registration perspective, the year was marked with two major activities: preparing for the second registration deadline in May 2013 concerning substances in quantities over 100 tonnes per year, and improving the quality of registrations by screening existing dossiers and broadly communicating the findings to the registrants in order to stimulate updates.

As a first step for preparing for the 2013 registration deadline, ECHA conducted a survey among potential registrants together with the Directors' Contact Group (DCG)[1]. The feedback indicated that industry intends to register around 3 000 additional existing (phase-in) substances and send dossiers for around 850 substances which were already registered in 2010. In order to support downstream users in their understanding of their suppliers' intentions, the list of substances, together with the name of the lead registrant, subject to the lead registrants' agreement, was published on the ECHA website and updated monthly throughout the year.

However, considerable uncertainty has remained even after the survey and communication activities, especially for about 700 substances for which the lead registrant is not known to ECHA, raising doubts about their actual intentions in 2013 and the overall number of registration dossiers to be expected. Therefore, building on the experience gained in 2010, ECHA prepared its staff, internal processes and IT tools for three different scenarios up to a level of 30 000 dossiers. Apart from the uncertainty in the numbers, the industry participants of the DCG did not indicate any major issues threatening the registrations of 2013, and the activity in the DCG remained low.

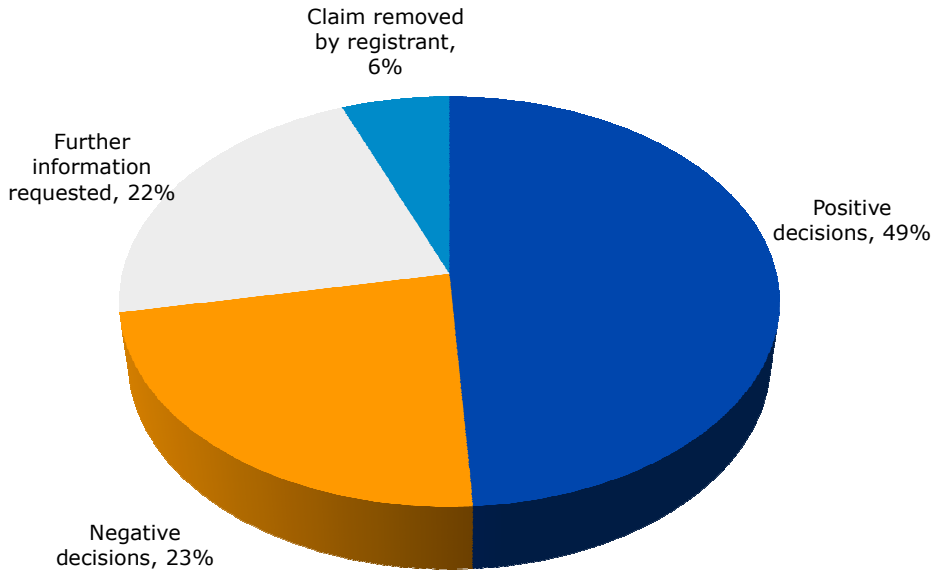
The IT tools relevant for registration, namely IUCLID, REACH-IT and Chesar (CSA/CSR Tool) were upgraded during the year, and then frozen at the end of November 2012, i.e. six months before the deadline, as recommended by the DCG in 2010. This allows industry to prepare their dossiers without having to follow IT updates. The preparation of registration dossiers and the roll-out of IT tools were supported by a series of webinars and two lead registrant workshops. In these events, special attention was given to SMEs with recommendations and best practice adapted to their needs. Furthermore, the Guidance on Registration and all other relevant manuals and supporting documents were updated (see also Activities 5 and 6). An important novel type of support was the publication of an illustrative CSR example together with the respective IUCLID and Chesar files, which allows registrants to trace, in detail, how the chemical safety assessment and the subsequent reporting could best be done.

As planned, ECHA intensified the screening of registrations of intermediates in order to verify whether they meet the conditions imposed by the REACH Regulation. The target group was

[1] The Directors' Contact Group (DCG) consists of representatives from the European Commission, ECHA and industry associations. The objective of the group is to find practical solutions to issues which are seen as barriers to registration.

the 5 500 registration dossiers submitted for substances used as intermediates only. More than 2 300 dossiers covering 760 substances were picked out by the screening algorithms, and the respective registrants received a detailed letter from ECHA explaining the observed anomalies in their dossiers. By the end of the year, almost 80 % of the dossiers were already updated e.g. by further specifying the uses or even by submitting a full registration dossier. In addition to this IT-based exercise, over 70 intermediate dossiers were scrutinised in detail and more information was requested from the registrants to confirm the prerequisites for intermediate registration. Based on the findings of this large-scale exercise and other inconsistencies identified in the dossiers during evaluation activities, ECHA started the development of a Dossier Quality Assistant tool aimed at supporting registrants in the preparation of high quality dossiers, with a first release scheduled in early 2013.

Figure 1: Assessment of confidentiality claims submitted 2008-2011



Although 2012 was expected to be a regular year in terms of incoming dossiers, the intermediate screening led to a heavy increase in arriving dossiers. Further pressure resulted from dossiers being updated with additional confidentiality requests further to the upgrade of certain dissemination rules (see below). Both these phenomena show that REACH is working: ECHA is able to trigger improvement of dossiers and the industry is responding to the regulator's demands. Altogether, ECHA received nearly 10 000 dossiers, of which 70% were for updates of existing registrations.

The verification of the status of companies that had registered as SMEs in 2010 led to the revocation of registration decisions in seven cases (cf. Activity 13). This concerned registrants who had incorrectly claimed to be entitled to a fee reduction and did not pay the remaining fee despite reminders. The decisions were replaced with rejections.

Regarding exemptions from registration for substances used in product and process oriented research and development (PPORD), the number has remained stable with about 230 new notifications processed, including updates. Significant progress was made with regard to assessing whether further information on earlier received PPORD notifications was needed for ensuring safe use at the work place.

In order to secure the REACH-IT readiness for 2013 deadline, it was decided to implement the submission for requests for alternative names under the CLP Regulation via webform for the

time being. Due to the lower than expected number of authorisation applications, the implementation of that submission process in REACH-IT was moved to 2013. Furthermore, in response to strong stakeholder demands, a simpler, web-based submission was setup for receiving downstream user reports and substance in article notifications. Despite the easier way to submit, downstream users reporting their number remained two orders of magnitude lower than expected, which probably reflects both the immature state of interpreting the borderline when is it mandatory to report to ECHA, and the slow update of safety data sheets after registering the substance.

Data sharing and substance identification

ECHA ensured that the registrants of 2013, with a specific focus on SMEs, have the most up-to-date information on both data sharing and substance identity in their use, well in advance of the registration deadline in order to make the process as efficient as possible for them. The corresponding Guidance documents were updated and their publication was supported by a webinar. From ECHA's viewpoint the data sharing activities remained low, as very few disputes were submitted to the Agency. Five cases were handled, four of them were closed upon the claimants' request without the need for ECHA to issue a decision, while the remaining case led to a negative decision. Contrary to expectations, the number of new data sharing requests and disputes remained low despite the upcoming registration deadline.

Progress was also made on substance identity, especially in clarifying the naming of substances and requirements for complex substances such as plant extracts, oleochemicals, etc. with industry associations.

In 2012, ECHA took steps to enhance the inquiry process both within the Agency and among the potential and previous registrants by integrating the handling of inquiries into REACH-IT. For registrants this means that once the substance sameness has been verified by ECHA, the previous and potential registrants can get each other's contact details directly via a co-registrants page in REACH-IT. This new service went live in November 2012, increasing efficiency significantly. In particular, this is seen in communication sending, with a decrease in the number of letters sent each month from around 1000 down to just exceptional cases.

Finally, ECHA received almost 20 000 pre-registrations in 2012, 80% of which were indicating potential registration in 2018.

Dissemination – Electronic public access to information

Making information on chemicals publicly available on the ECHA website has remained a high priority in 2012. The main activities were increasing the number of dossiers published by adding those notified under the previous legislation ('NONS dossiers')[2] for which the registration number had been claimed, and publishing in November 2012 additional information for each substance such as the supplier's names, registration numbers, tonnage bands and results of the PBT assessment (safety data sheet information). This was accompanied by greatly enhancing search functionalities.

At the end of the year, about 30 000 dossiers covering nearly 8 000 substances were published. In addition, detailed statistics on registration were published and updated monthly as of October 2012. Finally, as an established practice, information disseminated on the ECHA website was linked to the OECD eChemPortal without delay, giving users the possibility to also search on properties and effects of chemicals and gain access to additional information stemming from other regulatory databases across the world.

In parallel to adding content, the rate of publication increased significantly with an average

[2] Notification of new substances (NONS) under Directive 76/548/EEC

time of one month for publishing the dossier on the website once it has been verified for completeness.

ECHA launched a survey among its stakeholders on the usability of the dissemination webpages. The objective was to gather, among other things, information on how the various user groups would like to see the disseminated information displayed and what kind of support they would require for using the website more effectively. The results of the survey will be available in 2013 and will feed into the further development of the dissemination section.

Another activity related to dissemination is the assessment of the validity of requests for confidentiality introduced by the registrants in their dossiers. ECHA met its target to carry out the assessment of all claims submitted by the end of 2011. In 271 cases, companies have been formally requested to provide further information.

Objectives and Indicators

Objectives

1. All dossiers, inquiries and data sharing disputes are processed, and confidentiality claims assessed, according to the standard procedures adopted by ECHA and within the legal deadlines or targets set. Decisions are well justified and of a high technical and scientific quality.

2. The public has easy access to information from all dossiers of registered substances within a reasonable time after the registration.

Performance Indicators and Targets

Indicator	Target in 2012	Means and frequency of verification	Result 2012
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 target timeframe (20 working days).	80%	Time recorded in REACH-IT monthly reporting.	88%
Level of assessing the confidentiality requests deriving from the registration dossiers that had received a registration number by the end of 2011.	100%	Assessment recorded in the workflow system. Monthly monitoring.	100%
Percentage of public information published from all registration dossiers received by ECHA since entry into operation.	90%	Rate of publication recorded. Monthly monitoring.	93%
Level of satisfaction of interested parties with the quality of the scientific, technical and administrative support provided.	High	Annual survey.	High

Main Outputs

- Almost 10 000 registrations (of which nearly 7 000 were updates) and 230 PPORD notifications were received and went through completeness check and subsequent rejection/acceptance. 610 PPORDs assessed, of which 446 were closed and 164 require further action.
- Over 1 600 inquiries were received and concluded; five data sharing disputes processed.
- A total of 1 110 confidentiality requests in the registration dossiers assessed, covering submissions until the end of 2011.
- Update requests were sent to over 750 registrants for nearly 2 400 intermediate dossiers.
- An illustrative example of a CSR was published together with the respective IUCLID and Chesar files.

Table 1: Number of dossiers (including updates) received in 2012

Dossier type	Actual	WP 2012 estimates
Registrations	9 773	5 100
Full registrations	6 466	-
Transported Isolated Intermediates	2 351	-
Onsite Isolated Intermediates	956	-
Other types of dossiers		
PPORD notifications	233	200
Inquiries	1 632	1 800
Notifications under Article 7(2)	31	70
DU reports under Article 38	110	11 700
Alternative chemical names requests under CLP Article 24	17	50
Applications for Authorisation	0	30

Table 2: Breakdown of new registrations received in 2012 by dossier type

	Total	Non Phase-in	Phase-in	
			Total	*For 2013 deadline*
Registrations	1 767	305	1 462	677
Transported Isolated Intermediates	584	137	447	337
Onsite Isolated Intermediates	178	44	134	122
Total	2 529	486	2 043	1 136

Table 3: Breakdown of new registrations by company size

Total	Large	Medium	Small	Micro
2 529	80.9%	10.3%	4.5%	4.3%

Table 4: Breakdown of updated registrations received in 2012 by dossier type

	Total	Non Phase-in	Phase-in	NONS
Full registrations	4 049	259	3 220	570
Transported Isolated Intermediates	1 322	124	1 121	77
Onsite Isolated Intermediates	606	33	571	2
Total	5 977	416	4 912	649

Table 5: Breakdown of updated registrations by update type

	Total	Non Phase-in	Phase-in	NONS
Updates following regulatory communication[3]	8%	1%	6%	1%
Spontaneous updates[4]	92%	6%	76%	10%
Total	100%	7%	82%	11%

Table 6: Main reasons identified for spontaneous updates

	REACH	NONS
Change in classification and labelling	9%	14%
Change in composition of the substance	2%	1%
Change in the access granted to information	6%	7%
Change in tonnage band	5%	27%
New identified uses[5]	10%	2%
New knowledge of the risks for human health and/or environment	3%	3%
New or update of CSR and guidance on safe use	16%	4%
Other	49%	42%

[3] Regulatory communication includes evaluation decisions, communication further to confidentiality request assessment.
[4] It includes updates further to the screening of intermediate dossiers.
[5] High percentage probably due to updates further to the screening on intermediate dossiers.

Activity 2: Evaluation

Dossier evaluation comprises both the examination of testing proposals and compliance checks. The purpose of the compliance check is to examine whether registration dossiers are in compliance with the information requirements of the REACH Regulation, while the examination of testing proposals aims to ensure that the generation of information on a given substance is tailored to real information needs and that unnecessary animal testing is avoided.

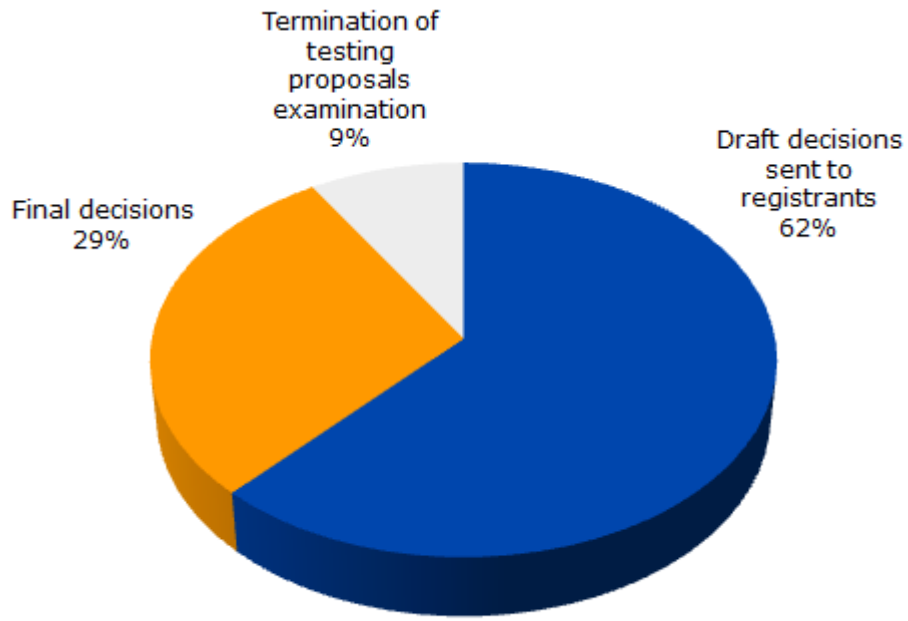
Substance evaluation aims to gather information in order to clarify whether a substance constitutes a concern for human health or the environment. Substance evaluations are performed by the Member State Competent Authorities (MSCAs) and involve an assessment of all available information and requests 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.

Main Achievements in 2012

Dossier Evaluation

In 2012, the main focus of the dossier evaluation was on the examination of testing proposals in order to meet the legal deadline of 1 December 2012 for examining all testing proposals submitted in 2010 registration dossiers. This target was fully met. Public consultations were organised for all testing proposals involving testing on vertebrate animals.

Figure 2: Testing proposal examinations in 2012 by main outcome

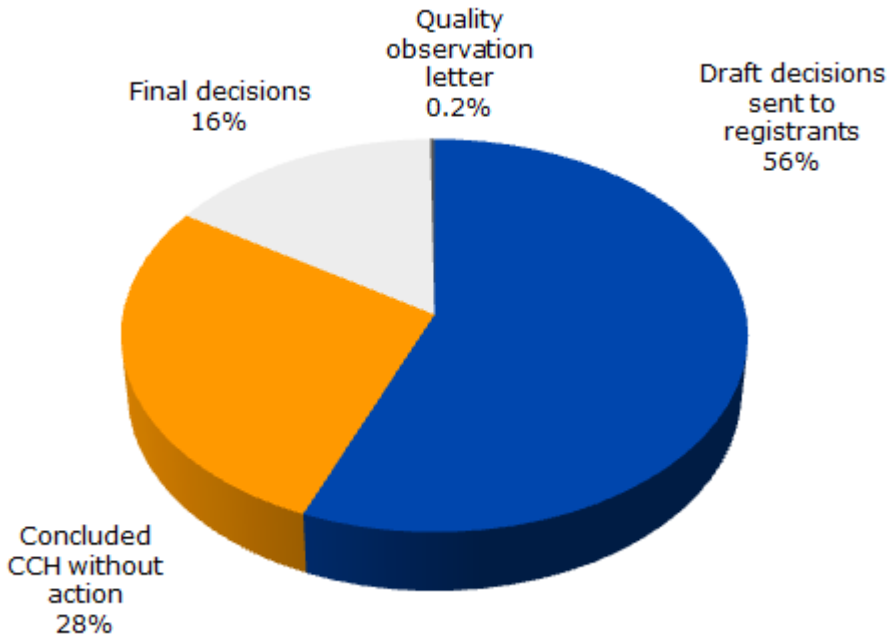


In approximately 20% of the cases, unclear substance identity prevented a meaningful examination of the testing proposal. These dossiers were targeted in compliance checks in 2011 and 2012. A large part of the 2012 compliance check work was allocated to clarify such issues. Priority was also given to testing proposals for non phase-in substances for which a higher number of cases were received than expected. All cases were concluded within the legal deadline of 180 days. In parallel, ECHA continued compliance checks on other dossiers.

With regard to the dossiers submitted by the first registration deadline in 2010, ECHA has committed itself to achieving the 5% target for the highest tonnage band dossiers by the end of 2013. ECHA continued to improve the efficiency of the process and demonstrated its capacity to simultaneously handle over 600 dossier evaluations per year and the target for 2012 (250) was exceeded clearly. The compliance checks also included cases of substances with reference to nanoform.

To respond more effectively and efficiently to the findings on inadequate quality of registration dossiers, , ECHA developed a new approach for compliance checks in close consultation with the Member States. The approach uses advanced data analysis tools to select registration dossiers that potentially contain typical shortcomings for a critical endpoint for the safety of the substance. An IT algorithm is then developed for this endpoint in order to select the most suitable candidate dossiers for the targeted compliance check. This targeted approach is to increase the efficiency of the process and the chances of finding pertinent information gaps in registration dossiers. The first three areas of concern piloted in 2012 covered the physico-chemical parameter used in the pre-assessment of bioaccumulation (n-octanol-water partition coefficient), genotoxicity and aquatic toxicity.

Figure 3: Concluded compliance checks in 2012 by main outcome



In the course of the year, ECHA also developed an approach for systematic follow-up of dossier evaluation decisions endorsed by Member State Competent Authorities and national enforcement authorities. According to the approach, ECHA will issue a statement of non-compliance with the decision to these authorities, if the registrant has not updated its dossier satisfactorily by the given deadline, and hence trigger action by national authorities. Follow-up evaluation was concluded in 2012 on 65 cases, 55 of which led to a second compliance check draft decision. The first nine statements of non-compliance were sent and in one case ECHA concluded that the dossier was brought in compliance with the decision.

Further improvements to the general advice given to registrants regarding evaluation issues were achieved in 2012 by i.a. webinars supporting targeted compliance checks and lead registrant workshops. In the annual progress report on REACH evaluation for 2011, published on ECHA's website in February 2012, detailed recommendations were provided to registrants, mainly focusing on substance identity, testing proposals and justifications for adaptation of information requirements. The report and its layman's version also serve as a general

communication to industry and other stakeholders on evaluation findings. Furthermore, an important step forward for transparency in decision making was taken in December 2012 through the publication of non-confidential versions of ECHA's final evaluation decisions.

Substance evaluation

In 2012, ECHA ensured an effective start to the substance evaluation process by publishing the first Community Rolling Action Plan (CoRAP for 2012-2014) at the end of February 2012 for 90 substances. The evaluations of 36 substances included in the first year have started and should produce draft decisions requesting further information, if needed, by 28 February 2013.

Together with the Member States, ECHA decided that there was no need to refine the criteria set and published in 2011 for selecting CoRAP substances. The process for updating the CoRAP for 2013-2015 included IT based pre-selection of 365 new CoRAP candidate substances, a joint project with 13 volunteering Member States to screen the related registration dossiers and select substances to be included in the draft CoRAP update. The first draft CoRAP update was submitted to the Member States and the ECHA Member State Committee and published in October 2012 with a view to publishing the updated CoRAP by the end of 2013. Altogether, it contains 116 substances including 53 substances that were already included in the first CoRAP and 63 new substances. All in all, the number of substances proposed for 2012 and 2013 fills the evaluation capacity as communicated by the Member States.

To support the substance evaluation process, ECHA finalised the contractual arrangements for the transfer of funds to the evaluating Member States. ECHA also provided aggregated datasets on the dossiers to be evaluated, templates of outcome documents, a checklist to ensure adherence to the procedure and training on drafting substance evaluation decisions.

The provision of general and substance specific advice and the alignment of the approach on legal, procedural and scientific aspects of substance evaluation with the MSCAs was achieved through two workshops, and channels for direct advice. ECHA also offered the possibility to screen draft decisions for consistency and several requests for such screening were received towards the end of 2012.
In the alignment of approach, one main issue was the development of a harmonised policy among MSCAs for interaction with registrants. Recommendations to registrants on how to play their role in substance evaluation have been given through a webinar and a leaflet.

Objectives and Indicators

Objectives

1. Scientifically and legally sound draft decisions on dossier evaluation, in compliance with the legal requirements and the multi-annual planning, are prepared.
2. ECHA has ensured an effective start to substance evaluation by publishing the first CoRAP and has ensured adequate coordination of and support to the MSCAs performing the actual evaluation work.

Performance Indicators and Targets

Indicator	Target in 2012	Means and frequency of verification	Result 2012
Percentage of compliance checks treated within the legal timeframe.	100%	Monthly internal report.	100%
Percentage of testing proposals examined within the legal timeframe.	100%	Monthly internal report.	100%
Proportion of compliance checks concluded to reach the 5% target for the highest tonnage band dossiers submitted by the 2010 deadline.	35%	Quarterly internal report.	46%
Percentage of the draft decisions accepted unanimously by the MSC.	90%	Monthly internal report.	77%
Level of satisfaction of MSCAs with ECHA's support for substance evaluation.	High	Annual survey.	High

Main Outputs

- 416 cases on dossiers with testing proposals concluded and 171 final decisions on testing proposals issued.
- 354 compliance checks concluded and 66 final decisions on compliance checks issued.
- The third annual progress report on REACH evaluation was published in February 2012 in accordance with the legal deadline.
- Approach for a systematic follow-up of dossier evaluation decisions endorsed by Member State Competent Authorities and national enforcement authorities; first 65 follow-up evaluations concluded.
- Further advice and communication to 2013 registrants via i.a. annual evaluation report, webinars and lead registrants' workshops.
- The first Community Rolling Action Plan (CoRAP), including 90 substances to be evaluated in the years 2012-2014, was adopted on 28 February 2012.
- Substance evaluation started for 36 substances included in the CoRAP for 2012.
- A draft CoRAP update for the years 2013-2015, including a total of 116 substances, submitted to the Member States and Member State Committee in October 2012.
- Administrative support, advice and training provided to the MSCAs according to Work Programme 2012. Two workshops with Member State representatives on dossier and substance evaluation organised.

Table 7: Compliance checks and (CCH) testing proposal examinations (TPE) completed or concluded in 2012

Output	TPEs	CCH
Final decisions issued in 2012	171	66
Concluded testing proposal examinations / compliance checks	**416**	**354**
Draft decisions sent to the registrants	364	236
Quality observation letters	n.a.	1
Termination of testing proposals examination / Concluded compliance check without action	52	117

Activity 3: Risk Management

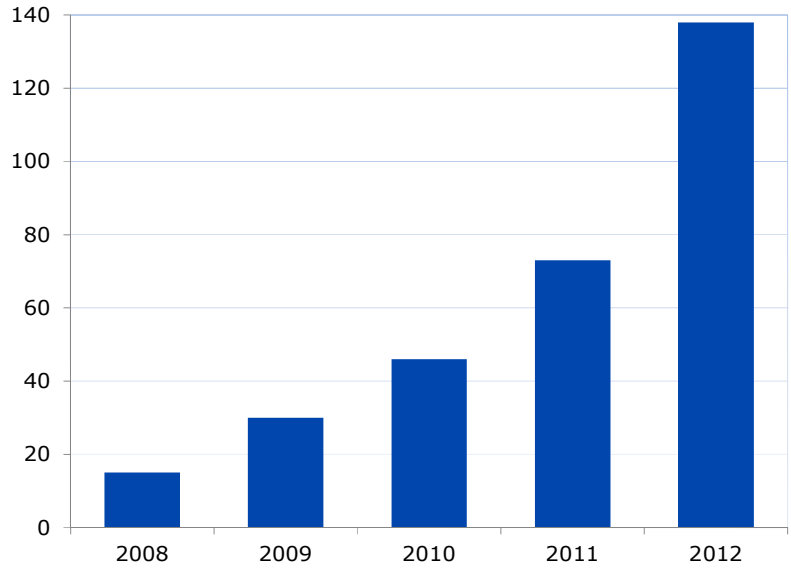
ECHA's tasks relating to risk management include preparing and updating the Candidate List of Substances of Very High Concern (SVHCs), regularly preparing a recommendation to the Commission on substances from the Candidate List to be included in the Authorisation List – the list of substances subject to Authorisation (Annex XIV) – and, in the future, handling the authorisation applications. Substances of concern that pose unacceptable risks at EU level are restricted for particular uses or banned altogether.

Main Achievements in 2012

Identification of SVHCs and Annex XIV recommendations

By request from the European Commission, ECHA prepared 43 dossiers proposing identification of Substances of Very High Concern (SVHCs), which exceeded the plans dramatically. With this high number, the Commission wished to achieve its policy target of 136 SVHCs on the Candidate List by the end of 2012. ECHA informed the Commission and its Management Board of the risk management activities it deprioritised in order to achieve this target.[6] In January and August 2012, ECHA received a further 24 dossiers from the Member States. These included the first three substances identified as SVHCs because there is scientific evidence of probable serious effects to human health due to their respiratory sensitising properties. Two further substances were identified because there is scientific evidence of probable serious effects to the environment: one on the basis of its endocrine disrupting properties and the other since it degrades to an endocrine disruptor already identified as an SVHC.

Figure 4: Number of SVHC substances on the Candidate List



Furthermore, these new SVHCs included five PBT and/or vPvB substances.[7] These developments provide a good basis for future work on identifying new SVHCs on the basis of their equivalent level of concern. Overall, 13 substances were added to the Candidate List in June and 54 in December 2012. By the end of 2012, the total number of SVHC substances

[6] The finalisation of the fourth Annex XIV recommendation was postponed until January 2013. In addition, it was decided that the prioritisation for the fifth Annex XIV draft recommendation would not include the additional 37 substances that the Commission requested ECHA to work on and that the Risk Management Option analyses for these substances would also be handled in 2013.

7 PBT: persistent, bioaccumulative and toxic; vPvB: very persistent and very bioaccumulative.

included in the Candidate List was 138, slightly exceeding the policy objective of the Commission.

By the end of the year, ECHA finalised its fourth recommendation to the Commission for inclusion of priority substances in the Authorisation List. Inclusion of ten substances from the Candidate List was recommended and suggestions for the application and "sunset dates" were made. The recommendation was supported by the Member State Committee and took account, where relevant, of the comments received from interested parties during the public consultation taking place earlier in the year.

ECHA continued screening of the REACH and CLP databases to support the identification of substances for further regulatory work. ECHA developed a framework to support the assessment whether certain substances pose equivalent concern to CMRs[8] using respiratory sensitisers as an example. Furthermore, ECHA continued to facilitate the sharing of information between Member States to enhance coordination and cooperation in regulatory risk management. To this end, ECHA further developed and kept up-to-date technical tools and organised regular meetings (e.g. to support PBT identification). Moreover and not foreseen, ECHA provided substantial input to the Commission and Member States for the development of the roadmap for SVHC identification and implementation of REACH risk management measures from now to 2020.

Authorisation Applications

In February 2012, the Commission adopted a regulation through which the second batch of eight substances entered into the Authorisation List (Annex XIV). Although the first deadline for submitting applications is January 2013, ECHA did not receive any applications in 2012. However, five requests were received to hold a pre-submission information session (PSIS). The first such meeting was held in November 2012. ECHA placed much effort in explaining the authorisation process to industry and other stakeholders. A seminar was held for potential applicants, as well as a workshop on socio-economic analysis (SEA) and the analysis of alternatives. ECHA also participated in numerous events organised by industry or other stakeholders to clarify different aspects of applications. ECHA clarified many open questions concerning how to deal with the language regimes of applications, confidentiality of information, and how applicants and stakeholders would provide information and follow the opinion making of RAC and SEAC. ECHA also increased the technical capacity of its staff to use the tools to receive authorisation applications.

Restrictions

In 2012, the Commission adopted decisions on the first four restriction dossiers[9] for which the opinions of RAC and SEAC were forwarded to the Commission in 2011. ECHA provided technical support to the Commission during this adoption process, in particular for the restriction on the use of lead and its compounds in jewellery.

Additionally, ECHA supported the Commission in identifying possible substances for which the Agency will prepare restriction dossiers. This was carried out in particular in the context of the review of the restriction on cadmium in paints, plastics and for specific safety uses for which ECHA prepared and published five review reports in 2012.

ECHA provided technical and scientific support to the ECHA Committees for their work on three opinions on Annex XV restriction dossiers: the use of classified phthalates in consumer

[8] CMR: carcinogenic, mutagenic, reprotoxic.
[9] These proposals relate to (1) the use of dimethylfumarate 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.

articles, the use of 1,4-dichlorobenzene in toilet blocks and the use of chromium VI in leather products. The opinions on phthalates were finalised and provided to the Commission in 2012. The opinions of the other two dossiers will be completed and sent in early 2013. ECHA also reviewed the existing restriction of two phthalates in children's toys and requested RAC to give an opinion of the draft review report that it has prepared. This work will be completed in 2013.

In late 2012, ECHA received two requests from the Commission to prepare an Annex XV restriction report. These were cadmium in plastics and cadmium in paints. It also received a request to investigate the risks related to certain uses of five cobalt salts in the EU, which ECHA had recommended for the Authorisation List, but could, in the Commission's view, be better suited for restriction proposals.

Other activities related to regulatory risk management

ECHA continued to increase the knowledge on the practical application of socio-economic analysis. The projects on willingness-to-pay and costs of using alternative substances as well as estimates for quality/disability adjusted life years progressed well. ECHA received the results of the costs study and plans to make this available on the website in early 2013. ECHA also helped to achieve progress in the discussion on the approach to analyse economic feasibility in the context of applications for authorisation.

ECHA continued to develop approaches for and enhance assessment of the most appropriate risk management options. This work included development of an analysis grid to support the assessment and decisions, and organising a workshop on regulatory risk management in May. The Agency developed different ways to use REACH databases to support the identification of cases where further regulatory actions are needed to address concerns related to SVHCs in articles. The results of this work are fed into the Commission work on the potential use of Article 68(2) to introduce restrictions on CMR substances in consumer articles. Furthermore, the work is used to identify complementary information sources and means of screening substances in articles.

To support registrants in preparing chemical safety reports (CSRs), ECHA developed an illustrative example of a Chemical Safety Report (CSR) addressing in particular the commonly identified shortcomings in the submitted CSRs. Additionally, ECHA published a practical guide for downstream users on how to comply with their obligations in relation to exposure scenarios. Downstream users may choose to carry out a chemical safety assessment if they use a substance outside the conditions described in the exposure scenario provided by the supplier. To further facilitate the downstream users to comply with their obligation to report these uses to ECHA, a specific web-form was released to submit these reports. A webinar attracting 600 participants was organised.

ECHA, together with six industry stakeholder organisations, supported the functioning and organised two meetings of the Exchange Network on Exposure Scenarios (ENES) to identify good practices on preparing and implementing exposure scenarios, and to develop an effective communication exchange between supply chain actors. Main themes that were addressed in 2012 were exposure scenarios for the environment and how to deal with exposure scenarios when handling and placing mixtures on the market.

Objectives and Indicators

Objectives

1. All dossiers related to the authorisation and restriction processes are prepared and processed with a high degree of scientific, technical and legal quality according to the standard approaches and procedures adopted by ECHA and within the legal deadlines or targets set.

2. Industry, Member States and the Commission are provided with the best possible scientific and technical support and advice to identify substances that require further risk management and to define the best risk management approach, including further development of the use of Exposure Scenarios.

Performance Indicators and Targets

Indicator	Target in 2012	Means and frequency of verification	Result 2012
Percentage of SVHC dossiers treated within the legal timeframe.	100%	Monthly internal report.	100 %
Percentage of restriction dossiers treated within the legal timeframe.	100%	Monthly internal report.	100%
Percentage of applications for authorisation treated within the legal timeframe.	100%	Monthly internal report.	n/a (no applica-tions received)
Level of satisfaction of the Commission, MSCAs, ECHA Committees and other interested parties with the quality of the scientific, technical and administrative support provided.	High	Annual survey.	High

Main Outputs

- Two updates of the Candidate List published, bringing the total number of SVHCs to 138 entries (see Annex 3).
- Development of 43 Annex XV dossiers for SVHCs at the request of the Commission.
- Overviews of the registered substances and analyses of the work carried out on groups of substances provided to the Commission and Member States to support identification of substances for further work. Three meetings of risk management experts organised in cooperation with Member States. Three meetings of the PBT Expert Group organised.
- ECHA's fourth recommendation to include ten SVHCs from the Candidate List in Annex XIV (Authorisation List) finalised.
- Workshop for the Member States and the Commission on regulatory risk management and a workshop on the interface between the REACH legislation and occupational health and safety legislation organised.
- Two meetings of the ECHA-stakeholder Exchange Network on Exposure Scenarios organised.
- Support to the Commission during the adoption of the first four restrictions under the REACH Regulation.
- At the request of the Commission, work on two Annex XV restriction dossiers initiated.
- At the request of the Commission, five review reports on cadmium in plastics, paints, spectacle frames and safety applications prepared and published.
- At the request of the Commission, a draft review report on restriction of two non-classified phthalates prepared and submitted to the Risk Assessment Committee for opinion.
- The procedure that will be followed during opinion making in the application for authorisation process published.

Activity 4: Classification and Labelling (C&L)

Classification reflects the hazards of chemicals and labelling helps to ensure that substances and mixtures are manufactured, used, transported and disposed of safely. ECHA's main tasks are to develop scientific opinions on proposals for harmonisation of classification and labelling of substances (CLH proposals), to develop and maintain the classification and labelling inventory and to decide on requests for the use of alternative names for substances in mixtures.

Main Achievements in 2012

Handling proposals for harmonised Classification and Labelling (CLH)

In 2012, Member State Competent Authorities submitted 23 CLH proposals and additionally four proposals from industry were received. This total of 27 new proposals was less than expected. In the period from 2008 to 2012, a total amount of 206 proposals have been submitted. For 31 substances, a public consultation was completed in 2012. ECHA provided extensive support to the RAC rapporteurs in developing final opinions and scientific background documents on 31 proposals for a harmonised classification. In addition, the two specific requests of the Agency's Executive Director[10] for reviewing the classification of epoxiconazole and galliumarsenide generated a substantial additional workload for the ECHA secretariat.

The quality of the scientific underpinning of opinions on CLH proposals is increasingly important as the legislation aims to harmonise difficult hazard classes (carcinogenicity, mutagenicity, reproduction toxicity, respiratory sensitisation) and classification may have far reaching consequences.

ECHA took the next steps in establishing cooperation with the European Food Safety Authority (EFSA) on harmonised classification of Plant Protection Products (PPP) in order to synchronise timelines and scientific opinion development as much as possible. The first CLH dossier under Regulation (EC) No 1107/2009 on Plant Protection Products arrived. In addition, the alignment of work practices of harmonised classification with the Biocidal Products Regulation (EC) No 528/2012, which will enter into operation 1 September 2013, began.

Classification & Labelling Inventory (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 (independent of their hazardous properties or respective deadlines) had to be notified at the latest on 3 January 2011. The public inventory was successfully launched in February 2012. The inventory provides a wealth of information from industry on how they have self-classified chemicals and shows how some companies have classified the same substance differently. The inventory was updated in late September, to include all notifications for hazardous substances (including non-hazardous notifications), as well as all notifications for EINECS[11] substances, regardless of classification.

Since 2010, ECHA received 5.7 million notifications covering about 121 000 distinct substances, of which almost 110 000 are included in the publicly disseminated notifications. This makes it the largest database of self-classified substances available globally. The inventory database is refreshed on a regular basis with new and updated notifications. Every month, approximately 200-300 new substances are added to the database and on average about 15 000 updates per months are carried out.

[10] Requests under Article 77(3)(c) of the REACH Regulation.
[11] EINECS: European INventory of Existing Commercial chemical Substances

For approximately 30 000 substances, the inventory contains entries for which different notifiers have indicated different classifications. The notifiers will then have to make every effort to come to an agreement on the classification and labelling of the substance. In order to facilitate notifiers to come to an agreement, ECHA completed a feasibility study and the technical preparations for setting up a dedicated IT-platform, which would allow discussions between notifiers and registrants on the classification for a particular substance without revealing their identity. This platform is to be launched by the end of January 2013.

Evaluating requests for the use of alternative chemical names

In 2012, the first requests for the use of alternative names for substances in mixtures according to Article 24 of the CLP Regulation were submitted to ECHA. These were all addressed within the legal deadline of six weeks. In total, 13 requests were accepted for processing, which is a lower number than expected. Eight decisions were completed, of which three requests were rejected and five were accepted.

Communication to the general public on the safe use of substances and mixtures

In January, ECHA submitted a study to the Commission on communication to the general public on the safe use of substances and mixtures and the potential need for additional information on labels, as stipulated by Article 34(1) of the CLP Regulation. This study concluded more than two years of preparatory work by ECHA, which included a Eurobarometer survey of European citizens' recognition of CLP hazard pictograms and their attitudes towards handling various household and other products with respective labels as well as in-depth deliberations by national experts of the Agency's Risk Communication Network (RCN). The study provided key input to the Commission's subsequent report to the European Parliament and Council of 29 October 2012, in accordance with Article 34(2) CLP. The Commission's report followed ECHA's conclusions that changes to the CLP pictograms should not be envisaged, instead giving the general public time to increase its knowledge of the new global system, and to accompany the deadline of June 2015 at which CLP labelling obligations will apply to mixtures with respective awareness-raising activities.

Objectives and Indicators

Objectives

1. All dossiers related to the harmonised C&L process are processed with a high degree of scientific, technical and legal quality according to the standard approaches and procedures adopted by ECHA and within the legal deadlines or targets set.
2. Any request for the use of an alternative chemical name is processed within the legal timeframe.
3. The C&L Inventory is maintained and kept updated.

Performance Indicators and Targets

Indicator	Target in 2012	Means and frequency of verification	Result 2012
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.	100%
Level of satisfaction of interested parties with the C&L Inventory.	High	Annual survey.	High
Level of satisfaction of Commission, MSCAs and RAC with the quality of the scientific, technical and administrative support provided.	High	Annual survey.	High

Main Outputs

- 37 accordance checks of dossiers containing proposals for harmonised classification and labelling carried out.
- Provision of timely support, of a high scientific quality, to both submitters of proposals for harmonised C&L, and to RAC and its rapporteurs for their development of 31 final opinions and of related scientific background documents.
- All notifications and updates included in the C&L database.
- Launching and major update of the public C&L inventory.
- C&L platform prepared to be ready to be launched in early 2013.
- 13 dossiers with requests for an alternative name processed.
- Study on the communication of information to the general public on the safe use of substances and mixtures delivered to the Commission.

Activity 5: Advice and Assistance through Guidance and Helpdesk

The ECHA Helpdesk provides advice to those who have obligations under the REACH and CLP Regulations, supports users of the scientific IT tools of ECHA, and helps with information on individual submissions to ECHA. Additionally, ECHA provides technical and scientific guidance and tools for the operation of those regulations for industry, especially SMEs and other interested parties. Furthermore, ECHA must provide assistance to registrants and explanatory information on REACH to other interested parties.

Main Achievements in 2012

Helpdesk

In 2012, the ECHA Helpdesk achieved its goals by replying to over 5 000 questions related to REACH or CLP submitted by individual duty holders (companies) and national authorities. Additionally, it responded to hundreds of enquiries arising in other contexts, such as the platform (HelpEx) used by the network of national helpdesks (HelpNet), which ECHA manages for discussing specific questions to harmonise replies across the EU/EEA; webinar Q&A sessions and one-to-one sessions with individual stakeholders visiting the two lead registrant workshops and the Stakeholders' Day that the Agency organised during the course of the year.

The average resolution time of helpdesk enquiries was about six working days, due to the Helpdesk answering about 90% of the questions within the established timeframe of 15 working days. As the implementation of REACH and CLP advances, however, some questions have become very complex and thus require nuanced replies from the second and third helpdesk levels, which need to be elaborated by topical experts over a longer timeframe.

In 2012, the scope of questions addressed to the ECHA Helpdesk was very much focused on subject matters related to the 2013 REACH registration deadline, such as identifying registrants of the same substance, data sharing obligations, the co-registrants' functionality in REACH-IT, and similar topics. The Agency's progress in disseminating information from registration dossiers also kept the ECHA Helpdesk busy, as well as the deployment of the new version of the REACH-IT, IUCLID and Chesar tools.

Managing the network of national REACH and CLP helpdesks (HelpNet) remained one of the key activities of value to streamlining the advice and assistance provided to duty holders in all 30 EU and EEA countries in which REACH and CLP apply. In 2012, the HelpNet Steering Group decided upon various means to speed up finding solutions to identified issues. This initiative resulted in a significant efficiency gain for the network by successfully reducing the number of such issues by nearly half. As part of this work, the ECHA Helpdesk also helped national helpdesks strengthen their capacity to reply to questions on various subject matters. Apart from sharing information, one full day of practical training for national helpdesk correspondents on the scientific IT tools of ECHA provided further insight into using these tools and the processes applied for REACH and CLP implementation.

Guidance

The main focus of guidance activities during 2012 was on providing updated guidance on those aspects of REACH that are particularly relevant to the 2013 registration deadline.

In accordance with its commitment to maintain a "guidance moratorium" spanning the last six months ahead of the second REACH registration deadline (thus from 1 December 2012 until 31 May 2013) to allow industry to concentrate on preparing its dossiers during that period, ECHA published updates of the guidance documents on registration, on data sharing and on monomers and polymers. A large number of further updates and corrigenda to other existing guidance documents were also published in advance of the voluntary moratorium. This

particular achievement was of notable help to industry and reflected, once again, that the Agency lives up to its values of being trustworthy and efficient by making every effort of holding itself accountable for reaching demanding deadlines.

Moving swiftly to ensure the efficient and rapid implementation of the recommendations on which there was consensus among authorities in the final results of the three REACH Implementation Projects on nanomaterials, ECHA generated a series of six new appendices to the Information Requirements and Chemical Safety Assessments (IR&CSA) guidance. The Agency conducted the related consultations in the format of a fast-track update procedure that also allowed their publication over one year ahead of the 31 May 2013 REACH registration deadline. A further seven minor corrigenda to other parts of the IR&CSA guidance, which also achieved an alignment with the new annexes on nanomaterials, were published before the moratorium.

To improve the accessibility of the guidance for the benefit of its stakeholders, ECHA further produced several "quasi guidance" documents. In particular, the new REACH Fact Sheet on *"Communication obligations for certain substances exempted from registration under REACH"* should be of benefit to small and medium size enterprises in the recovery sector as it explains why they do not necessarily need to include a registration number in their safety data sheets for certain recovered substances. The launch of an updated version of the Guidance Navigator had to be postponed until 2013, for technical reasons; the new version of this multilingual tool will now be launched after the current moratorium.

ECHA also published several important updates to the guidance on CLP. Publishing the updated version 3 of the "*Guidance on the Application of the CLP Criteria"* in particular complied with the requirement of Article 10(7) of the CLP Regulation for the Agency to provide further guidance on the setting of specific concentration limits (SCLs).

REACH and CLP training

ECHA continued to put emphasis on external training activities with the aim of providing high quality training for national REACH and CLP helpdesks in order to enable them to reply to questions and to foster a common understanding of the REACH and CLP Regulations. During the year, the Agency organised a variety of training events targeted at external stakeholders, focusing 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. However, industry representatives also followed the Agency's invitation to attend the external training events held during 2012.

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, with a specific focus on topics relevant to the 2013 REACH registration deadline.

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 and Targets

Indicators	Target in 2012	Means and frequency of verification	Result 2012
Percentage of resolved Helpdesk questions answered within the established timeframe (15 working days).	80%	Business Object report / monthly.	91%
Level of satisfaction with quality of Helpdesk services provided to interested parties.	High	Annual survey.	High
Number of FAQ updates agreed with HelpNet and published on the web.	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.	80%	Business Object report / monthly.	96%
Percentage of guidance documents published on the web according to the plan.	80%	Annual report.	155%[12]
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

Main Outputs

Helpdesk

- Answers to 5 184 questions regarding REACH and CLP requirements, as well as ECHA's IT tools (IUCLID, Chesar, REACH-IT and data submission) provided.
- Comments on 122 HelpNet Exchange questions on REACH and CLP issues provided to national helpdesks.
- Three FAQ updates agreed with HelpNet and published on the website. Furthermore, the entire set of REACH FAQs available on ECHA's website was reviewed to align them with ECHA's updated Guidance documents.
- Two meetings of the HelpNet Steering Group and training on the scientific IT tools organised.
- Seven national helpdesks visited in the context of the HelpNet Visits Programme 2011-2013.

Guidance

Updates (13) and corrigenda (17 marked with *) published:

- Guidance for identification and naming of substances under REACH and CLP*

[12] The number of documents published in 2012 was exceptionally higher than projected as additional appendices and corrigenda concerning nanomaterials were published which were not foreseen in the original planning.

- Guidance on Data sharing
- Guidance for Monomers and polymers
- Guidance on Registration
- Guidance on the Application of the CLP Criteria, version 2 and version 3
- Guidance for Annex V *
- The following parts and chapters of the *Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA)*:
    - Part D: Exposure scenario building *
    - Part E: Risk Characterisation
    - Part G: Extending the SDS *
    - Chapter R.7a: Endpoint specific guidance
    - Appendix R.7-1 to Chapter R.7a on nano-materials
    - Chapters R.7b* and R.7c*: Endpoint specific guidance
    - Appendix R.7-1 to Chapter R.7b on nano-materials
    - Appendix R.7-2 to Chapter R.7c on nano-materials
    - Chapter R.8: Characterisation of dose [concentration]-response for human health *
    - Appendix R.8-15 to Chapter R.8 on nano-materials
    - Appendix R.10-2 to Chapter R.10 on nano-materials
    - Chapter R.11 PBT Assessment *
    - Chapter R.13. RMM library *
    - Chapter R.14. Occupational exposure assessment *
    - Appendix R.14-4 to Chapter R.14 on nano-materials
    - Chapter R.15 Consumer exposure estimation *
    - Chapter R.16 Environment exposure estimation *
    - Chapter R.17 Estimation of exposure from articles *
    - Chapter R.18: Exposure scenario building and environmental release estimation for the waste life stage *
    - Chapter R.19: Uncertainty analysis *
    - Chapter R.20: Table of terms and abbreviation *
    - Exposure Scenario Format in Part D and Part F *

Nine "quasi-guidance" documents published:

- Practical Guide 1: How to report *in vitro* data
- Practical guide 3: How to report robust study summaries
- Guidance in a nutshell on data sharing
- Guidance Fact Sheet on data sharing
- REACH Fact Sheet on Communication obligations for certain substances exempted from registration
- Practical guide 7: How to notify substances in the Classification and Labelling Inventory
- Practical Guide 13: How downstream users can handle exposure scenarios
- Practical Guide 14: How to prepare toxicological summaries in IUCLID and how to derive DNELs
- Practical Guide 15: How to undertake a qualitative human health assessment and document it in a chemical safety report

REACH and CLP training

- Numerous trainings on REACH and CLP and on IT tools provided and workshops for targeted audiences, including two lead registrant workshops, organised.
- Sixteen webinars on REACH and CLP related topics organised, half of which were targeted at lead registrants.
- Training on the scientific IT tools of ECHA, webinar on "Dissemination overview with IUCLUD 5.4" and two refresher trainings on HelpEx tool delivered to the HelpNet members.

Table 8: Number, percentage and average resolution time of questions resolved during 2012 in Levels 1 and 2

Topic		Number of questions resolved	%	Average resolution time (no. of working days)
REACH		1 227	23.9%	7.94
CLP		141	2.7%	4.8
IUCLID 5		717	13.9%	6.82
CHESAR		172	3.3%	8.81
REACH-IT		514	10.0%	5.99
REACH-IT	User management	1 306	25.4%	1.9
Submissions		1 063	20.7%	5.77
Total		**5 140 (*)**	**100%**	**5.55**

(*) The ECHA Helpdesk also resolved 44 more questions that were escalated to Level 3 for the IT tools' contractors or the Commission for consultation.

Table 9: Top countries from which questions were received

EU/EEA Countries from where the ECHA Helpdesk received questions	Number of questions received	Percentage of questions received
Germany	903	21.09%
United Kingdom	772	18.03%
France	369	8.61%
Netherlands	345	8.06%
Italy	310	7.24%
Other EU/EEA countries	1 583	36.97%
EU/EEA total	**4 282**	**100%**

Non-EU countries from where the ECHA Helpdesk received questions	Number of questions received	Percentage of questions received
United States	251	28.85%
Hong Kong	110	12.64%
China	89	10.23%
Switzerland	87	10%
India	66	7.59%
Other non-EU countries	267	30.69%
Non-EU countries total	**870**	**100%**

Activity 6: Scientific IT tools

The REACH and CLP Regulations impact a significant number of companies - more than 70 000 legal entities are registered in REACH-IT – and require submission, processing and the sharing of enormous amounts of data between industry and authorities. Therefore, ECHA has to be an IT-based agency and timely delivery of fully functional IT systems for industry, Member States and the Agency's own use are the key to ECHA's success.

Main Achievements in 2012

During 2012, ECHA focused its activities related to scientific IT tools on the preparation for the 2013 REACH registration deadline, on enhancing the breadth and width of the disseminated information on chemicals, on the integration of the data on chemicals stored in separate databases and on the preparation for the entry into operation of the Biocidal Products Regulation in 2013.

In advance of the 2013 deadline and in order to assist industry in preparing high quality dossiers, IUCLID 5.4 was released in June providing improved ability to report exposure, PBT (Persistent, Bioaccumulative and Toxic chemicals) and human hazard assessment data. The related plug-ins (technical completeness check, fee-calculation, dissemination, query tool) were updated and released simultaneously with the compatible REACH-IT version in July. Work also started on a major technical revision of the IUCLID application, i.e. IUCLID 6. IUCLID 6 specifications were developed and presented to the relevant OECD groups.

Based on the experience and feedback from the initial versions of Chesar, the application underwent a considerable redesign and development. Industry will benefit from such redesign in the usability of the tool, the simplification of functionality and increased maintainability. Version 2.0 was released in June providing registrants with the ability to start preparing their chemical safety assessments (CSAs) based on a IUCLID 5.4 dataset and to generate chapters 9 and 10 of the chemical safety report (CSR). In October, version 2.1 provided an exposure estimation tool for consumers completing the functionality needed for CSA. Preparation of exposure scenarios for communication in the supply chain was partly covered in the September release and work continued to deliver the full functionality in a release in early 2013.

Two new easy to use online forms were introduced for downstream users to report their uses to the Agency and for notifying Substances of Very High Concern in articles.

Corrective actions were successfully taken to bring REACH-IT development back on track from the difficulties encountered in 2011. Two versions were released during the year, one in July to accommodate the changes in IUCLID 5.4 and another one in November, which introduced greatly enhanced support for the internal inquiry process, benefiting both ECHA and registrants.

Enhancements to the user interface, including support for multiple languages, were piloted in the context of the development of the biocides IT project (Cf. infra) with the aim of introducing the functionality to the next major version of REACH-IT. In this way, ECHA is already preparing to facilitate SMEs – estimated to register in higher numbers for the 2018 deadline – in the utilisation of the submission tools. This next major version of REACH-IT is planned to also incorporate other structural improvements to the application and integration of the currently separate solutions for some types of dossier submission into the main application in 2014.

To support the work of the MSCAs under REACH, ECHA established a system and the related services for MSCAs to access a centralised database - the ECHA MSCAs IUCLID database - offering the same functionalities used by ECHA staff.

Dissemination of the information received from the classification and labelling notifications – C&L Inventory – was introduced in two phases: February and September. The dissemination portal was updated three times during the year to publish additional information from the REACH dossiers: in June (production volumes), July (NONS information), and November (safety data sheet information).

The Registration Information Portal for Enforcement authorities (RIPE) was maintained throughout the year by adding new information and adapting to the changes in the incoming information (specifically the new IUCLID version). A functionality was added enabling communication between different enforcement authorities.

Two Odyssey versions were released during the year, one in early March providing improved functionalities for the testing proposal evaluations and compliance checks, and another one in October which greatly extended the scope of the decision support tool to the scientific assessment of inquiry dossiers.

These developments were achieved in parallel with the outsourcing of Odyssey to an external contractor, in accordance with the chosen sourcing strategy.

Considerable efforts were allocated to understanding the various business needs and planning the technical implementation of integrated access and management of the substance related data currently spread over several systems and databases. Initial solutions were delivered for internal use, but the bulk of the development phase will take place in 2013 as initially planned. Data integration will be an overarching initiative impacting the future roadmaps of the key information systems like REACH-IT, IUCLID and others.

Objectives and Indicators

Objectives

1. ECHA receives and successfully processes all dossiers and notifications and disseminates the public information, in accordance with the legislation, with the assistance of well-functioning IT tools.
2. Specialised IT tools and targeted user manuals and workshops have efficiently supported the stakeholders in meeting their legal obligations.

Performance Indicators and Targets

Indicators	Target in 2012	Means and frequency of verification	Result 2012
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.	88%
Level of satisfaction of external users with the IT tools (IUCLID, REACH-IT, Chesar and RIPE).	High	Annual survey.	High

Main Outputs

- All REACH-IT modifications impacting registrants of the 2013 deadline implemented by November 2012, more than six months in advance.
- IUCLID version required for 2013 deadline (V5.4) published in June 2012, 12 months in advance.

- A major revision of the Chesar tool (V2.0) for chemical safety assessment released in June 2012 enabling registrants to prepare their chemical safety reports for environmental and workers assessment. Version 2.1 added the functionality for consumer assessment in October 2012.
- Technical access and a related service for MCSAs to access a centralised ECHA MSCAS IUCLID database established in summer 2012.
- Major versions of Odyssey (V2.0 and V3.0) delivered on time, enabling ECHA to perform the scientific assessment of inquiry dossiers.
- Services established for the maintenance of the existing IT systems in production.

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

It is ECHA's strategic aim to become a hub for the scientific and regulatory knowledge building of Member States, European institutions and other actors, and to use this new knowledge for improved implementation of the chemicals legislation.

Main Achievements in 2012

ECHA continued contributing to the development of test methods, including alternatives to animal testing, with a view of promoting the availability of alternative test methods in order to make them available beyond the 2013 deadline, since more data gaps can be expected than for the first registration deadline. The main focus was on test methods for eye irritation, skin sensitisation and skin irritation/corrosion. In particular, ECHA contributed to the development of OECD integrated testing strategies (ITS) for skin and eye irritation/corrosion.

ECHA wants to promote the use of data available for substances from the 2010 registration deadline to avoid unnecessary (animal) testing for the 2013 and 2018 registrations by applying alternative methods. To this end, a selection of relevant data received during the 2010 deadline has already been incorporated in the OECD QSAR Toolbox Version 3.

ECHA has strengthened its expert knowledge on non-test method approaches, and continued integrating them in ECHA processes such as evaluation and risk management. This has supported prioritisation activities, such as identification of substances to be placed on the Community Rolling Action Plan, the assessment of read-across proposals and the establishment of the Read Across Assessment Framework.

In the context of its CSA Development Programme, ECHA intensified its support to supply chain communication in cooperating closely with its stakeholders on such issues as standardising the communication of conditions of use in the supply chain and interpreting the boundaries of exposure scenarios (scaling). While the scientific and technical discussions continued throughout the year, the two meetings of the ECHA-Stakeholder Exchange Network on Exposure Scenarios (ENES) served as checkpoints to take stock on the progress made and to exchange and disseminate best practice.

ECHA has advanced its understanding of the assessment of hazard, exposure and risks as well as risk management and mitigation related to nanomaterials by carefully following all the developments and outcomes of EU and international programmes. An inventory of nanomaterials from screening the IUCLID database has been sent to the Commission and published as an Annex to the "Staff Working paper on nanomaterial types" (part of the Communication on the Second Regulatory Review on Nanomaterials). ECHA has also participated in the steering committee of Task II of the NANOSUPPORT project; participated in the GAARN project and the first meeting on Substance Identity and phys-chemical aspects. ECHA has commented on the OECD guidance for nanomaterials, and followed MSCA initiatives for proposals to modify REACH for nanomaterials and national initiatives to establish nanomaterial product inventories.

Regarding endocrine disrupting substances (EDC), ECHA has participated in the Expert Advisory Group on Endocrine Disruptors of the European Commission, developing criteria for EDC's, and in a working group of the European Food Safety Authority (EFSA) developing opinions on scientific aspects related to EDC's. Likewise, ECHA is participating in the Commission Adhoc working group on combination effects of chemicals as a follow-up to the Commission communication on that topic from May 2012. These activities are contributing to ECHA's internal capacity building to deal with EDC's and mixture toxicity under ECHA's regulatory processes.

Objectives and Indicators

Objectives

1. ECHA has good capacity to provide scientific and technical advice on the safety of chemicals, including nanomaterials and endocrine disruptors, exposure assessment, testing methods and the use of alternative methods.

Performance Indicators and Targets

Indicator	Target in 2012	Means and frequency of verification	Results 2012
Level of satisfaction with the quality of the scientific, technical and administrative support provided to the Commission and MSCAs.	High	Annual survey.	High

Main Outputs

- CSR improvement activities kicked off with a contract to support the analysis and the further development of risk assessment methodologies for "complex" substances such as UVCBs. Project initiated to exemplify exposure scenarios for article service life. Remaining aspect, i.e. "Practical methods to address conversions products of substances reacting on use in the CSA" were postponed to 2013.
- A selection of relevant data received during the 2010 deadline incorporated in the OECD QSAR Toolbox Version 3.
- Computational methods routinely applied in support of the different processes, most notably the targeted compliance check, but also other selection of dossiers or prioritisation of substances.
- Software procured allowing developing advanced screening and data analysis methods as well as capacity building to support evaluation and risk management
- Publication of "Best practices on physicochemical and substance identity information for nanomaterials".
- OECD expert meeting hosted where testing strategy for skin irritants was drafted.
- Publication in September of a study about the cost and practicalities of two new OECD toxicity tests.
- Contributions provided to the development of core genotoxicity test methods foreseen in REACH integrated testing strategies and to the work of PARERE[13].
- The unexpected delay in the adoption by the Commission of the REACH review resulted in less demand for technical scientific support to this review work than originally expected.

[13] PARERE Network (Preliminary Assessment of REgulatory RElevance)

ECHA'S BODIES AND CROSS-CUTTING ACTIVITIES

Activity 8: Committees and Forum

The Committees – the Member State Committee (MSC), Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) - are an integral part of ECHA and play an essential role particularly in providing valuable scientific and technical advice (i.e. agreements and opinions) as a basis for ECHA and Commission decision-making. The Forum for Exchange of Information on Enforcement provides a network of Member State authorities responsible for the enforcement of the REACH and CLP Regulations, with the aim of harmonising their approach to enforcement.

Main Achievements in 2012

A remarkable increase in the overall output of the ECHA Committees has been seen in 2012. The number of opinions and agreements delivered has doubled, while the high quality and respect for the legal timeframes has been maintained. The Committees' procedures and functioning were adapted to efficiently manage the increased workload.

Member State Committee (MSC)

As expected, the workload of the Committee was high in 2012, 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. This was achieved by improving working methods such as increasing the number of written procedures, organising video conferences and preparatory meetings.

The MSC unanimously agreed on the identification of 28 substances as Substances of Very High Concern (SVHCs) that were referred to it for agreement seeking. For the first time, three substances with respiratory sensitising properties were identified by the Committee as SVHCs due to equivalent level of concern having probable serious effects to human health. Two substances with endocrine disrupting properties were identified as SVHCs based on equivalent level of concern having probable serious effects to the environment.[14] Following from the revision of Annex XIII of the REACH Regulation and applying these new criteria for the first time, the MSC also agreed on the identification of three Very Persistent and Very Bioaccumulative (vPvB) substances as SVHCs using read-across and the weight of evidence approach.

The MSC also adopted its opinion on ECHA's fourth draft recommendation for prioritisation of substances for inclusion in Annex XIV by consensus in December 2012, allowing ECHA to submit its recommendation for 10 additional substances to the European Commission.

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

In relation to the substance evaluation process, the Committee adopted its first opinion on ECHA's draft CoRAP in February 2012. A working group and a rapporteur were appointed to start preparing the MSC opinion on the first annual update of the CoRAP and the work is set to be completed by February 2013.

[14] Based on Article 57 (f) of the REACH Regulation.

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

Overall, the Committees handled a similar number of dossiers as in 2011, including those carried over from the previous year (Harmonised Classification & Labelling opinions, 'CLH'), restriction proposals and specific requests from the Executive Director). As foreseen, RAC was especially placed under a high level of demand. Besides handling the restriction dossiers, both RAC and SEAC continued their preparatory activities for processing applications for authorisation. The procedural aspects related to the involvement of stakeholders and case-owners in the process of applications for authorisation were discussed and agreed in the both Committees.

RAC adopted a total of 31 CLH opinions in 2012. A new framework for RAC opinion development on substances for harmonised classification & labelling was also agreed upon, outlining the general principles and clarifying the roles and responsibilities of the different parties. In line with the framework, the first two additional targeted consultations with the parties concerned were held during 2012.

Opinions on two Annex XV restriction proposals were adopted by RAC; one on the proposal from Denmark on four classified phthalates concluding that the dossier did not demonstrate that there is a risk from the use of the four substances and therefore the restriction was not justified, and one on the proposal from Denmark on Chromium VI in leather articles for which RAC demonstrated a risk to consumers and recommended restriction. Based on the RAC opinions, SEAC subsequently concluded not to support the restriction on the four classified phthalates and agreed on the SEAC draft opinion concerning the restriction proposal for Chromium VI in leather articles.

The opinion-making on the Commission proposal submitted by ECHA on dichlorobenzene started during the year and the opinions from RAC and SEAC are expected to be adopted in 2013. A dossier proposing restriction of nonylphenol and its ethoxylates in textiles by Sweden was found to not be in conformity by RAC and SEAC.

In addition, RAC and SEAC have jointly agreed on a revision of the working procedures for restriction, and more in particular regarding the process of elaborating the Forum advice.

RAC concluded on one request from the Executive Director of ECHA under Article 77(3)c of the REACH Regulation concerning an additional information report for the fungicide epoxiconazole, prepared by industry and upheld the earlier RAC decision regarding classification for reproduction.

In this respect, the agreement of the rules of procedure for cooperation with other Community bodies in accordance with Article 110 of REACH on matters related to food safety and worker protection, which was accomplished at the end of the year by the Management Board, constitutes an important achievement that paves the road to foster cooperation activities with other scientific bodies. These rules define the framework for cooperation between ECHA and other Community bodies with a view to ensuring coherence in the work, sharing of relevant information and avoiding potential conflicts of scientific opinions.

Forum for exchange of information on enforcement

In 2012, the Forum finalised its work on establishing enforcement-related interlinks between ECHA, MSCAs and National Enforcement Authorities. This important project identified the most appropriate communication channels, clarified the responsibilities of all bodies involved in the wide scope of different tasks that make up enforcement, and streamlined the working procedures between all actors.

The Forum published a comprehensive report on its first coordinated enforcement project. The scope of this project was to verify the compliance of manufacturers and importers of substances with the REACH obligations on pre-registration, registration and safety data sheets. The Forum released a preliminary report on its second coordinated project pertaining to inspections of formulators of mixtures. This project focuses on the compliance of this group of downstream users with the legal requirements imposed by REACH and CLP such as the supply chain communication and the content of the safety data sheets. Concurrently, the Forum agreed on a third coordinated REACH enforcement project focusing on registration, only representatives and cooperation with customs.

Several national enforcement authorities continued to join forces in the Forum's pilot project on intermediates, making best use of ECHA's experience when verifying the intermediate status of chemicals claimed in submitted registrations. A related workshop and web-conferences increased the mutual understanding amongst the enforcement authorities and ECHA of the role of downstream users in relation to strictly controlled conditions (SCCs), of the definition of intermediates and of the requirements for SCCs regarding hazardous properties, such as the use of personal protection equipment and local exhaust ventilation.

The Forum appreciated the updates of the REACH Information Portal for Enforcement (RIPE), an IT tool which will allows inspectors in Member States to access data extracted from submissions to ECHA. More and more inspectors are now using the tool before and during inspections.

The Forum also agreed upon and published a Manual of Conclusions (MoC) which compiles all conclusions on REACH and CLP practical enforcement issues drawn during the Forum plenary meetings. The aim of this tool is to spread good practice, harmonise enforcement and to inform Forum members on lines to take by the national inspectors.

The Forum organised its third annual "Training for the Enforcement Trainers", which serves to promote a common understanding to serve harmonised enforcement. Additionally, in a first coordinated exchange project, inspectors from smaller and larger Member States shared and exchanged best practice in checking compliance with registration and downstream user obligations.

At the outset of the year, in accordance to Article 46(2) of the CLP Regulation, Member States submitted their reports on the results of their CLP-related official controls and other enforcement measures. ECHA submitted a consolidated summary to the Commission in the run-up to the 2012 REACH Review. This input is bound to strengthen the proper implementation and enforcement of the REACH and CLP Regulation.

Finally, the Forum advised RAC, SEAC and the ECHA Secretariat on the enforceability of proposals for the restriction of phthalates, chromium(VI) in leather articles and dichlorobenzene, taking due account of the content of its dialogue with the Committee members as well as their questions and opinions.

Objectives and Indicators

Objectives

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 be able to further strengthen and harmonise the enforcement of the REACH and CLP Regulations in the EU/EEA Member States, while ensuring the necessary confidentiality.
3. Conflicts of opinion with Scientific Committees of other Community bodies are prevented through the sharing of information and the coordination of activities of mutual interest.

Performance Indicators and Targets

Indicators	Target in 2012	Means and frequency of verification	Result 2012
Percentage of opinions/agreements delivered within the legal timeframe.	100%	Annual internal report.	100%
Percentage of unanimous MSC agreements.	80%	Annual internal report.	81%
Percentage of Committee opinions adopted by consensus.	80%	Annual internal report.	100%
Degree of Committee opinions taken on board in the final decision of the Commission.	High	Annual internal report.	High
Level of satisfaction of ECHA stakeholders on the added value of the Forum activities.	High	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	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 Forum activities.	High	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

- 28 SVHC proposals were referred to the MSC, all of which were agreed for inclusion in the Candidate List.
- Opinion on ECHA's draft recommendation for inclusion of 10 priority substances from the Candidate List to Annex XIV ("Authorisation List") adopted.
- Unanimous agreements on draft decisions on 16 compliance checks and 134 draft decisions on testing proposals.
- Draft decisions on 41 testing proposals for two generation reproductive toxicity testing were sent to the European Commission, as unanimous agreements on them were not reached.
- Opinion on draft CoRAP adopted.

Committee for Risk Assessment

- Two opinions on restriction proposals.
- Agreement on the conformity of two restriction proposals and agreement on the non-conformity of one restriction proposal.
- 31 opinions (in 31 dossiers) on harmonised classification and labelling substances.
- 38 accordance checks of dossiers for harmonised classification and labelling performed.
- Agreement by RAC on a new framework for RAC opinion development on substances for harmonised classification and labelling.
- One opinion on an Article 77(3)c request.

Committee for Socio-economic Analysis

- One opinion on a restriction proposal.
- Agreement on one draft restriction opinion.
- Agreement on the conformity of two restriction proposals and agreement on the non-conformity of one restriction proposal.
- Revision of the SEAC Manual of Conclusions and Recommendations.

Forum

- One stakeholder event, one training event on REACH and CLP for enforcement trainers, one web conference on training for national coordinators of the REF-3 project, one meeting for testing RIPE by end users, one meeting on the testing of EIES, two workshops (workshop on SCCs and workshop on Interlinks) with experts from ECHA and MSCAs.
- Submission of the Forum report on the functioning of the CLP Regulation (Article 46(2) CLP report).
- Final report on the Forum project REACH-EN-FORCE-1 taking into account the compliance with the first REACH deadline by the working group on horizontal methodology.
- Interim report on the second Forum enforcement project on compliance of formulators with REACH and CLP.
- Forum "Manual of Conclusions" adopted.
- Forum document on Interlinks and related inventory.
- Establishment of an ECHA and Member State focal points to handle enforcement of ECHA decisions.
- Three dossiers and four reports on advice of enforceability on proposed restrictions.

Table 10: Number of Committee decisions, opinions, agreements adopted

	SVHC agreem.	Restriction opinions	Opinion on draft Recom. for Annex XIV	CLH opinions	Testing proposal agreem.	Compliance check agreem.	Article 77(3)(c) opinions
MSC	28	NA	1	NA	134	16	NA
RAC	NA	2	NA	31	NA	NA	1
SEAC	NA	1	NA	NA	NA	NA	0

Activity 9: Board of Appeal

The Board of Appeal was established by the REACH Regulation to provide interested parties with the possibility of legal redress. It does this by considering and making decisions on appeals against certain decisions of the Agency (see Article 91 of the REACH Regulation).

Main Achievements in 2012

In 2012, eight new appeal cases were lodged and one appeal from 2011 continued to be examined. Whilst in 2011 most appeals were related to registration, appeals lodged in 2012 mainly concerned dossier evaluation (89%) and were highly complex from a scientific point of view. The appeals against compliance check decisions covered a variety of issues including substance identity and the use of read-across and waiving arguments to fulfil data requirements. One appeal was made against a decision imposing an administrative charge following a check of the company size (SME check). More detailed information on all appeal cases can be found in the announcement of each case which can be found on the Board of Appeal section of the ECHA website.

During 2012, one appeal was withdrawn by the appellant following the rectification of the contested decision by the Executive Director. The remaining appeals are still pending due to the following circumstances: in four appeal cases, three of which were lodged during the last quarter of the year, the written part of the proceedings is still open. In three cases, the written part of the proceedings was closed with parties, in particular the appellants, requesting a hearing. An oral hearing is held on the request of either party to the case or if the Board of Appeal considers one to be necessary. This gives the parties the opportunity to present the arguments in defence of their interests directly to the Board of Appeal and allows the Board of Appeal to ask questions to the parties and interveners, if present. The first oral hearing was held in 2012 and was open to the public. In addition to the final decision, a large number of other decisions need to be made by the Board of Appeal in each case. In 2012, in addition to the large number of procedural decisions made to generate the information needed to decide each case (for example, requests for observations on submissions, requests for specific information, requests for responses to particular questions) important decisions have been made on confidentiality requests, applications for leave to intervene, requests for extension of deadlines, and for a stay of proceedings.

The Board of Appeal also has alternate/additional members, as foreseen in Article 89(2) of the REACH Regulation. In 2012, alternate members have been called upon to work as members of the Board of Appeal in five different appeals.

Actions to raise the awareness of stakeholders on the work of the Board of Appeal and the appeals process have continued in 2012 largely through presentations at conferences and similar events, information on the Board of Appeal section of the ECHA website, and the production of information explaining the work of the Board of Appeal in straightforward terms.

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 and Targets

Indicators	Target in 2012	Means and frequency of verification	Result 2012
Percentage of cases concluded within target time[15] set for each type of appeal.	90%	Annual report of the Board.	N/A
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.	High

Main Outputs

- Six procedural decisions and one final decision adopted.
- A robust body of high-quality decisions published online.
- Effective (clear, accurate and timely) communication with the (potential) parties to appeal proceedings.

[15] 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

In order to achieve the goals of the REACH and CLP Regulations, the Agency needs to ensure effective communication towards its stakeholders on the correct implementation of these regulations.

Main Achievements in 2012

ECHA has reached out to – and largely satisfied – many organisations representing different categories of duty holders under REACH and CLP, with a particular focus on the 2013 REACH registration deadline. In order to ensure that the companies who need to register substances in 2013 have up-to-date information that will help them to comply with their legislative obligations, ECHA provided extended information and support through multiple channels. This included a targeted communication campaign ("REACH 2013 – Act now!") with a specific focus on SMEs, while extended support was provided to lead registrants and other potential registrants via up-to-date guidance documents, two lead registrant workshops and numerous webinars.

ECHA's website, newly launched at the end of 2011 has been further developed throughout the year. It now includes significantly more information on chemicals, provides an enhanced search function for chemicals extended to new substances, more accessible and user-friendly web forms, and additional features such as the possibility to query evaluation decisions, thereby making it more easily accessible to interested audiences. A survey conducted at the end of 2012 indicated that the majority of users were satisfied with the website's new structure, look-and-feel and features. The content of the website is also largely available in 22 official EU languages. The high number of weekly additions in the working language of the Agency (English), however, makes it a continuously challenging task to maintain the full language service.

ECHA's Accredited Stakeholder Organisations (ASOs) continued to grow in number, reaching 63 at the end of 2012. Later in the year, the Agency started to convene a specific discussion group with public interest NGOs, in recognition of their particular perspective on making REACH and CLP work as well as their role in representing and communicating with the public.

Furthermore, the Agency launched a targeted communications vehicle for Accredited Stakeholder Organisations to ensure a transparent and efficient flow as well as regular update of information of interest to ECHA's partners. Similarly to 2011, in November the Agency held a dedicated meeting in Brussels with Accredited Stakeholder Organisations where most of the European Union-focused organisations have their seat.

During 2012, ECHA's staff continued to benefit from a wide range of opportunities to be informed about the Agency's work and the environment within which they work. The main platform for this remained ECHAnet, the Agency's intranet which was being upgraded at the end of the year by an enhanced search engine, new news layout, automated templates and routing slips for financial processes in-house, etc. The annual survey of staff on internal communication revealed a very high rate of satisfaction.

Objectives and Indicators

Objectives

1. ECHA's external audiences are communicated with effectively, in 22 EU languages where necessary, and ECHA benefits from an accurate and proportionate media presence.
2. Stakeholders are involved in ECHA's work and are satisfied that their views are heard and taken into account.

3. ECHA staff are well informed, have a sense of belonging, and feel part of a common corporate endeavour.

Performance Indicators and Targets

Indicators	Target in 2012	Means and frequency of verification	Result 2012
Level of website customer satisfaction.	High	Annual user survey, quarterly web statistics.	High
Level of staff satisfaction with internal communications.	High	Annual staff survey.	High
Level of reader satisfaction with publications.	High	Annual customer surveys.	High
Level of stakeholder satisfaction with their involvement.	High	Stakeholder Day surveys and Annual Stakeholder survey.	High
Publication of translations of new documents relevant for small and medium sized enterprises or for the general public (within an average period of three months after publication of the original document, without validation).	100%	Internal quarterly report.	95%

Main Outputs

- Communications campaign towards industry carried out for the 2013 deadline.
- All material (whether online or offline) that was produced for SMEs or the general public published in 22 official EU languages.
- Internal information provided daily on the intranet and internal information screens. Weekly internal highlights (ECHAnet Exchange) produced.
- Press Releases and weekly e-News bulletins produced, two press briefings organised.
- Stakeholder Day and *adhoc* Stakeholder events held.
- A bi-monthly e-bulletin *Stakeholder update* for Accredited Stakeholder Organisations established.
- A general enquiries response team established.
- New ECHA website further enhanced.
- ECHAnet (ECHA's intranet) further improved.
- Crisis Communications Strategy produced.
- Annual Corporate Day and quarterly staff assemblies organised.

Table 11: Communication statistics

Activity	Output
Stakeholder events (Stakeholder Day, Accredited Stakeholder Workshop, Lead Registrant Workshop)	4
Stakeholder updates	5
New Accredited Stakeholder organisations	5
Webinars	16
Publications	92
Translations	276 documents
Press releases	39
News alerts	62
Press enquiries	~600
Newsletters	6
Website visits	~ 3 000 000 (1 000 000 unique visitors)
New mailing list subscribers	1 200 (Total: 15 400)

Activity 11: International Cooperation

ECHA strives to live up to its international profile as a leading regulatory agency worldwide, mandated with the management of the advanced and sophisticated EU chemicals safety regime. This entails interaction with actors and authors beyond the confines of the European Union.

Main Achievements in 2012

The main field of ECHA's international cooperation continued to be the Agency's involvement in numerous OECD activities, its contribution to the preparation of the candidate countries for accession to the EU, as well as its contacts with individual OECD Member States.

ECHA actively contributed to OECD activities, particularly in work areas which are of direct relevance to the REACH programme. In particular, ECHA continued to be an active partner in developing tools and methods for the harmonised collection of information on chemical substances with the view to facilitating electronic submission and data exchange across regulatory programmes worldwide. Regarding IUCLID, ECHA continued to chair the IUCLID User Group Expert Panel and submitted proposals for developing IUCLID 6 to the group for their consideration. A considerable number of harmonised templates were also developed and submitted for review by the OECD prior to integration into IUCLID. These included specific templates to report results of studies done on pesticides and nanomaterials. This should bring a clear benefit for improving the understanding of the properties of nanomaterials in the future registration dossiers. ECHA continued to secure the maintenance and hosting of eChemPortal for the time being.

Finally, the QSAR Toolbox project reached an important milestone in October 2012 with the release of version 3.0 which concluded a four-year project launched in 2008. Among many new functions proposed was the inclusion of the data stemming from REACH registration dossiers, thus increasing significantly the amount of experimental data in the toolbox supporting data gap filling. An architecture review was performed to set the foundation for the further development of the toolbox.

Based upon the Memorandum of Understanding established with Environment Canada and Health Canada, a dialogue between regulatory scientists focused on specific substances and technical topics of mutual interest. A similar cooperation also took place with the US Environmental Protection Agency.

Throughout the year, the Agency continued its work in support of candidate countries and potential candidates, focusing on Croatia after the signature of its Accession Agreement in December 2011. In October, ECHA started implementing the second two-year element of an EU-funded project which is managed by the European Commission under the Instrument for Pre-Accession Assistance (IPA). It provides capacity building on REACH, CLP, and the Biocidal Products Regulation and acquaints authorities of its beneficiary countries with the knowledge needed to participate in ECHA's work.

During 2012, ECHA further provided scientific and technical assistance to the European Commission in conducting its multilateral work, in particular related to the International Conference on Chemicals Management in Nairobi.

The worldwide interest in the EU chemicals legislations continued to increase as shown by the demand for explanatory meetings with ECHA management and staff and delegations from several countries visiting ECHA to gain a better understanding of the preparatory activities the EU took when preparing and subsequently implementing the new EU legislation.

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, and supports EU candidate countries and potential candidates within the framework of the IPA programme in an effective and efficient way.

Performance Indicators and Targets

Indicators	Target in 2012	Means and frequency of verification	Result 2012
Level of satisfaction of the Commission with the support given by ECHA on international activities.	Medium	Annual survey.	Medium
Increase in the visits to the eChemPortal from previous year.	20%	Internal annual report.	20%
Level of implementation of the annually planned modules of QSAR Application Toolbox.	90%	Internal annual report.	100%

Main Outputs

- In total, 23 new and 15 updated harmonised templates were/are under review with the OECD, including specific templates for nanomaterials.
- OECD QSAR Toolbox version 3 was released in October 2012.
- Specifications for IUCLID 6 architecture accepted in the OECD IUCLID User Group Expert Panel.
- First IPA-project for candidate countries and potential candidates for EU accession concluded and second project initiated.
- Technical support to the European Commission in relation to three bilateral agreements with a chemicals component, with Korea, Russia and Turkey.
- ECHA presence through an information stand and a joint side-event with the European Commission at the third session of the International Conference on Chemicals Management (ICCM-3).
- Technical input to the European Commission in relation to several UN GHS correspondence groups.
- First Director level video conference with NICNAS Australia and virtual or physical meetings with US-EPA, Japanese and Canadian counterparts.
- Six delegations from Asia visited ECHA.
- ECHA participated in 13 workshops and seminars for third country audiences.

MANAGEMENT, ORGANISATION AND RESOURCES

Activity 12: Management

The Agency strives to ensure efficient management, including integration of new activities to the Agency's organisation.

Main Achievements in 2012

The Management Board, ECHA's governing body, met quarterly during the year. The Management Board thereby duly discharged all its statutory obligations as set out in the legislation. In addition, a number of important decisions were taken to further implement the REACH Fee Regulation and the EU Staff Regulations. The Board also determined the future leadership of the Agency by prolonging the mandate of the Executive Director for a second term of five years and by selecting a new Chairperson for 2012-2014. Other strategic decisions taken in 2012 concerned a contemporary policy on managing conflicts of interest and connected implementation decisions, and conditions for an improved direct access of Member State authorities to confidential data contained in the Agency's databases.

The policy concerning the management of potential conflicts of interest, adopted by the Management Board in September 2011, has been further implemented with specific decisions of the Executive Director, integrated in the ECHA processes and largely communicated within the Agency. The Management Board formally established the Conflict of Interest Advisory Committee and adopted a Code of Conduct and eligibility criteria for the members of all ECHA bodies. Compulsory trainings and workshops on conflicts of interest and ethics have been organised for all staff, and the main recommendations of the European Court of Auditors, based on the findings made during their audit in October 2011, had been implemented even before the publication of the Court's special report in October 2012.

Relations with other EU institutions were strengthened during 2012. A collaboration agreement has been signed with the Joint Research Centre of the European Commission in order to link the technical and scientific capacities of the two institutions on chemicals for the benefit of European citizens. ECHA also continued its active participation in the EU Agencies Network.

In addition to these activities, the Agency received several high-level visits over the course of the year, including from the Ministers of the Environment for Finland and Sweden, the European Ombudsman, European Commission Vice President Tajani, and a delegation from the European Parliament Committee on the Environment, Public Health and Food Safety (ENVI). Regular liaison with the ENVI Committee was maintained throughout 2012, including via the annual exchange of views between the Committee and the ECHA Executive Director, which took place in November.

In 2012, the Agency further developed its contacts with Member States through Executive Director visits and by organising a meeting with MSCA Directors to further improve the joint planning of substance evaluation and risk management related tasks for 2013-2016.

The Agency has continued to use the development of its integrated Quality Management System to improve its management and internal processes. After the prioritisation of operational processes in the past years, the focus was now put on the management and support processes, mainly the Human Resources process area, and a full review of the architecture of the ICT processes was undertaken. The Management approved a roadmap leading towards ISO 9001 certification. The Quality Organisation, internal communication and training in quality related matters were strengthened.

The multi-annual planning of the Agency has been developed to a more strategic level and a revision of the Multiannual Work Programme concept was approved by the Management Board

in September. There was also a specific focus on planning the integration of biocides preparatory activities to achieve maximum synergies between the different legislations. The Agency has also worked to implement a better internal information management, and a project to improve records management is ongoing.

ECHA's Management Board adopted a new security model based on a model approach for its IT system IUCLID, in order to facilitate exchanges with Member States and other partners. Generally, there has been an increased need for the secure exchange of information with external partners, as the REACH implementation progresses, which has been an increasing concern for the Agency. Furthermore, the business continuity level has been considerably improved with the procurement of a secure external data centre (cf. infra).

The high numbers of decisions taken by the Agency gave rise to an increased demand for internal legal support for decision-making. The Agency also provided dozens of procedural submissions in defence of its decisions in proceedings at the European General Court, the Court of Justice and the Board of Appeal.

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. The total number of requests went down from the previous year but the requests mainly concerned industry owned data of a complex scientific nature, requiring a work-intensive consultation procedure. In addition, ECHA 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).

Objectives and Indicators

Objectives

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

Performance Indicators and Targets

Indicators	Target in 2012	Means and frequency of verification	Result 2012
Percentage of statutory documents submitted to the Management Board within legal deadlines.	100%	Quarterly internal report.	100%
Percentage of quality documents in place according to annual plan.	80%	Quality Manager's annual report.	113%
Number of "critical" findings by the auditors relating to the internal control system in place.	0	Internal auditor's annual report.	0
Percentage of important audit recommendations implemented within the deadline.	100%	Internal auditor's 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.	1

Main Outputs

- Four Management Board meetings and 14 meetings involving Management Board members organised.
- All regulatory plans and reports produced.
- One EU Agency Network meeting organised.
- The Quality Management System was further developed and implemented following the roadmap leading towards ISO 9001 certification.
- Legal support provided to ensure that ECHA's decisions are in line with legal requirements.
- 70 initial and six confirmatory "access to documents" requests, covering about 650 documents, answered in accordance with the applicable legislation.
- The Data Protection register contained 95% of the processing operations involving personal data identified by the Data Protection Officer.
- One MSCA Directors' planning meeting organised.
- One Security Officer's Network meeting organised.
- 29 framework agreements for the transfer of fees to the Member States in place.
- Internal Auditor of the European Commission (IAS) performed an audit on "Stakeholder relations and external communication", while the Agency's Internal Audit Capability (IAC) undertook three assurance audits ("Business continuity management"; "Compliance with rules of classification of documents and Data Protection"; and "Handling proposals for harmonised classification and labelling").

Activity 13: Finance, Procurement and Accounting

The overall objective of ECHA's financial management continued to be assuring the best use of available financial resources in line with the principles of economy, efficiency and effectiveness.

Main Achievements in 2012

The revenue for ECHA's REACH activities in 2012 amounted to €30.7 million, stemming from fee income on REACH registrations, SME verification work and interest income from the reserve built up from the fees and charges linked to the first REACH registration deadline of 2010. This revenue was complemented with a balancing amount from the accumulated reserve, in order to finance the REACH activities of ECHA in 2012. The Agency's reserve was managed by the European Investment Bank and by the Central Bank of Finland, with a continued objective to ensure the safe-keeping of the funds and a sufficient risk diversification. The reserve assures that ECHA is able to fund its REACH activities until the start of the next EU Financial framework of 2014-2020, while from then on it is expected for ECHA to enter into a mixed regime of funding with both own income and EU subventions for REACH.

The initial REACH expenditure budget of €102.6 million was reduced to €93.5 million by the Management Board to assure the alignment between the budgeted and the real expenditure. This reduction was partly driven by the postponement of some projects in order to comply with the annuality principle of the budget. In addition, some cost savings were achieved due to the fact that no salary indexation took place in 2012, no retroactive indexation had to be applied for 2011 and finally by the fact that no employers pension contribution has been paid in the second half of the year due to the receipt of an EU subsidy.

In 2012, the Agency deployed its cost accounting approach on a systematic basis for all its activities, specifically also to separate the budget and cost allocation for the different regulations that ECHA is responsible for. Specific emphasis was laid on adapting the accounting system to accommodate ECHA's responsibilities under these regulations and for which separate accounts have to be maintained and reported.

The Agency continued its systematic verification of the status of companies that had registered as SMEs and had consequently benefited from SME reductions. The verification was completed on a total of 315 companies, of which 38% complied with the rules while 62% turned out to be incorrect. As a result from this work, a total of €3.9 million of fees and charges were invoiced during 2012.

With reference to procurement activities, around 460 procurement actions were carried out in 2012, with the main emphasis again on IT related contracting. More specifically, a new generation of IT framework contracts have been established for IT consulting services, accompanied by several framework contracts in the area of scientific services, communication and administrative services.

Objectives and Indicators

Objectives

1. The Agency has sound and efficient financial management.

2. Cash reserves are managed diligently.

3. The Agency has effective financial systems to manage and report on several financially segregated legal bases.

Performance Indicators and Targets

Indicators	Target in 2012	Means and frequency of verification	Results 2012
Number of reservations in the annual report of the European Court of Auditors.	0	ECA reports/ annual.	0
Commitment rate.	95%	Monthly financial report / annual.	98%
Payment rate.	75%	Monthly financial report / annual.	85%
Carry over rate (of committed funds).*	< 20%	Annual internal report.	13%
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%

* REACH and CLP

Main Outputs

- Rigorous budget and liquidity management.
- Mechanism for managing and investing the Agency's cash reserves in operation.
- 315 verifications of the SME status of companies continued.
- Cost accounting system implemented.
- Correct closure of the 2011 accounts.
- Reporting established to ensure segregation of funds under different legislations.

Activity 14: Human Resources and Corporate Services

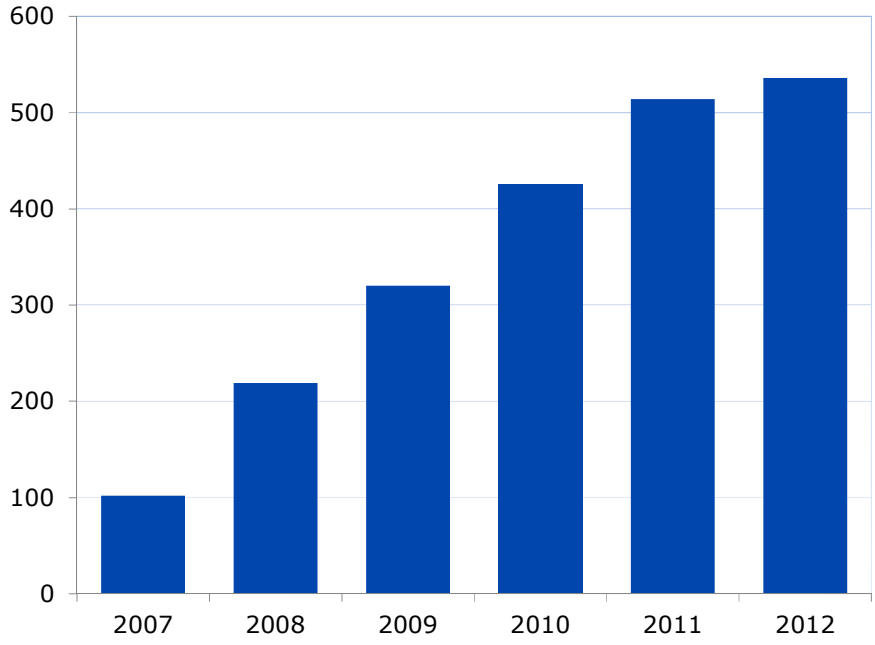
The human resource strategy is evolving from an initial focus on growth towards enabling a more stable organisational environment that is effective, efficient and that maintains the flexibility to assume and integrate new tasks. With regard to corporate services the strategic aim is to provide sufficient, well maintained and secured premises that offer an efficient and safe working environment for the staff and that can support the meeting and communication requirements for the Agency's bodies and stakeholders.

Main Achievements in 2012

Human resources

In 2012, ECHA continued to attract highly qualified personnel, with 54 new staff recruited during the year. With 44 recruitments for the REACH activities, the establishment table of REACH was completed up to the level of 96% and it can now be considered that the REACH activities are at cruising speed. The activities related to the new responsibilities of ECHA in the field of biocides and PIC, which kicked in during the second half of the year, were supported with the recruitment of 11 staff members for biocides and a further two for PIC.

Figure 5: Number of ECHA staff (2007-2012)



ECHA continued to give considered attention to the induction and training upon entry into the service of new staff. The target to reach an average of 10 training days per year for all staff members was also almost reached. ECHA continued its focus on developing its management capability with the commencement of a new organisation-wide team leader development programme in 2012 and the adoption of a proposal to conduct an external development programme for senior management in 2013. The HR administrative services accommodated the growing number of staff in terms of payroll, performance management, leave administration and other core HR functions. ECHA also commenced the implementation of its new contract renewal procedure and focused on the retention of its technical and scientific staff.

The ECHA graduate scheme is to help graduates to become better qualified as regulatory scientists and regulatory affairs professionals to work in the field of chemicals dealing with REACH and CLP. A mapping study has been completed to make an inventory of the courses

relevant to REACH and CLP that are already available and to suggest options for possible improvements. A dedicated section was made available on the ECHA website, including an indicative list of universities with courses, which is periodically updated.

Throughout 2012, continued dedicated attention has been given to the well-being and motivation of the staff of the Agency. The Human Resources unit supported dialogue with the staff and their representatives in the Staff Committee. The turnover of staff for 2012 was within the target range of 5%.

Corporate Services

Infrastructure management and facility services were further developed in 2012 to cope with the growing number of staff and the start of the biocides and PIC activities for ECHA.
A total of 279 official meetings or workshops with a total number of 7 025 external participants (+25 %) were organised in ECHA's conference premises. These activities were also supported by providing travel related services.

An increasing number of meetings and contacts were supported with webinars and ECHA continued to take advantage of its excellent virtual conferencing techniques. The number of videoconferences/web based conferences organised have increased by 18 % compared to 2011. Virtual conferencing and webinars have proven again to be a cost effective way of conferencing and it is to be expected that the use of this technique will increase further in the coming years.

Further emphasis was given to reinforcing business continuity through further cabling, network connections and other infrastructural measures. Physical security remained a key priority of the Agency and continued to receive due attention in 2012.

ECHA's library services continued to provide its services to the operational units with a variety of books and journals as well as with access to databases and online subscriptions.
Other corporate service functions, such as mail handling, logistics, physical archiving, as well as travel management for the staff continued to provide reliable and high level support.

The option to purchase the ECHA building from the landlord has been considered, but given the context of the Multi-annual Financial Framework (2014-2020) it is unlikely that this route would be further pursued.

Objectives and Indicators

Objectives

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

Performance Indicators and Targets

Indicators	Target in 2012	Means and frequency of verification	Result 2012
Percentage of establishment plan posts filled at the end of the year.	95%	Annual internal report.	96%

Percentage of selection procedures planned for the year completed.	90%	Annual internal report.	96%
Turnover of Temporary Agents.	< 5%	Annual internal report.	5%
Average number of training and development days per staff member.	10	Annual internal report.	9
Level of satisfaction of the Committee, Forum, and MB members with the functioning of the conference centre.	High	Annual survey.	High
Level of satisfaction of staff with the office facilities and logistics services.[16]	High	Annual survey.	High

Main Outputs

Human Resources

- Payroll for statutory staff and other payments to staff, SNEs and trainees, overall some 600 persons.
- 23 reserve lists adopted based on the selection procedures carried out.
- 54 external recruitments completed.
- Performance appraisal and reclassification exercise for some 500 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

- Maintenance of the 650 workspaces in ECHA's premises.
- 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 audiovisual equipment with good technical support provided.
- Mail services provided efficiently.
- Library and archive services managed well and correctly.
- Facilities inventory carried out and up-to-date.

[16] The survey covered all corporate services.

Activity 15: Information and Communication Technology

The ICT function in the Agency covers a wide range of services, and supports a wide range of business needs. The aim is to achieve operations in a paperless and data-secure fashion, and to meet the needs for IT tools.

Main Achievements in 2012

An extensive upgrade programme for the ICT infrastructure has significantly advanced in 2012. By June, a new architecture based on state-of-the art network, storage and server technology was deployed to sustain the growth of the Agency's IT and to enhance operability and availability. A redundant fully symmetrical configuration was set up and tested for high availability by the end of September. In parallel, an external data centre was connected to the ECHA data centre located in the premises. Consequently, by the end of November, ECHA managed to co-locate its upgraded core infrastructure over two, geographically separated data centres, the external one operated by an external service provider.

The immediate benefit is resilient infrastructure architecture for fail-over, ready to support the Agency business continuity plans. At the same time, the data assets of the Agency are now stored symmetrically in the two data centres, reinforcing the safeguard against loss and disaster.

In the context of IT security, ECHA modernised its solution for remote secure access to restricted IT applications (e.g. IUCLID Database, REACH-IT), simplifying the set up and the operability to its external users, mainly MSCAs. Such a solution has proven suitable for all equivalently restricted IT applications delivered remotely by ECHA.

Considerable progress has been made on the project to implement an integrated Human Resources Management System (HRMS). After completing the feasibility study and requirements for the new solution, the procurement process of an off-the-shelf HRMS solution was initiated. The scope of the target application will automate new business areas not currently covered or sufficiently integrated, such as staff planning and reporting, recruitment and selection, performance and career management, learning and development.

In April, the Enterprise Content Management (ECM) initiative released the first version of the IT support for the dossier evaluation process workflows, supporting the testing proposal examination and compliance checks with automated processes, decision-support and document management in compliance with the REACH Regulation. The ECM platform has been designed and built in such a manner that future requirements and solutions can be incrementally added to the platform. In 2012, the platform has already been accommodated for the needs of the substance evaluation CoRAP process.

In the context of the ECM programme, a new project was initiated to re-engineer the internal document management system (DMS) based on SharePoint, providing improved performance and maintainability, as well as higher availability of the related services. The management of the re-factored platform will be outsourced in 2013. This project required extensive work for the preparation of the infrastructure and migration of the applications and the content which was not foreseen in the planning and will be continued in 2013. Conversely, the plans for using an off-the-shelf module of the ECM platform for external collaboration was jeopardised by the sudden change in the product strategy of the vendor; ECHA analysed possible alternatives to prepare a fall-back plan which was postponed until 2013.

Objectives and Indicators

Objectives

1. The technical ICT infrastructure of the Agency is operated at a high service level and continuity, efficiency, and security is maximised for all supported business operations.
2. A consistent and common corporate architectural approach is assured; best practice in governance and management of IT projects, fostered; and professional, competent and timely responses to any of the planned or recurring business activities, ensured.

Performance Indicators and Targets

Indicators	Target in 2012	Means and frequency of verification	Result 2012
Availability of mission-critical systems for external customers (i.e. uptime during attended service hours).	99%	Data centre statistics.	99%
Level of internal user satisfaction with IT services, relative to staff/support ratio.	High	Annual customer survey and *adhoc* feedback.	High
Level of coverage of mission-critical systems in the business continuity solution involving external data centres.	REACH-IT, the ECHA website, the email system and Internet connectivity are covered.	Annual internal report.	80%

Main Outputs

- ICT infrastructure upgraded and ready for business continuity.
- Migration of all the end-user workstations prepared and deployment started.
- Updated remote secure access solution delivered.
- Target corporate architecture for business information systems defined and progressively applied: consistency ensured at project initiation by an architecture assessment.
- Target Enterprise Architecture for business information systems defined.
- Service Oriented Architecture guidelines defined.
- Dossier Evaluation Process V1.0 released, enabling ECHA to streamline the testing proposal examination and compliance check.
- Document Management System for the substance evaluation CoRAP released.
- Document Management System services contract awarded and knowledge transfer started.
- Procurement of an HRMS initiated.
- Time Tracking system released and supported.
- Services were established for the maintenance of the existing IT systems in production.
- Preparation of centralised management of user's credentials, groups and distribution lists through an Identity Management System (IDM). Activation of the system postponed to early 2013.
- Decision on external collaboration processes postponed to 2013.

Activity 16: Biocides – preparatory work

The purpose of the new regulation is to harmonise the European market for biocidal products and their active substances while providing a high level of protection for humans, animals and the environment.

Main Achievements in 2012

The Biocidal Products Regulation was adopted and entered into force on 17 July 2012. The Agency continued its preparatory activities throughout the year, and intensified them in particular in the second half of the year with the support of the specific biocides resources (both subsidy and new staff) made available. After the adoption of the Regulation, the EU subsidies of €3.2 million were activated. The budget implementation rate was high and amounted to 99%.

ECHA continued analysing and designing the new IT tools (Register for Biocidal Products, R4BP, and adaptation of IUCLID) to support the development and submission of dossiers by industry, and their processing by ECHA and the Member State authorities.

IUCLID 5 has been further developed to accommodate the additional information needed by the new Regulation. This new version will be released in early 2013. A technical proof of concept was successfully conducted for R4BP in autumn 2012 and development of the application started towards the end of the year. As part of the R4BP development, ECHA will introduce a new application architecture that will be gradually rolled out to other relevant systems. The new architecture includes identification of common components that can be shared with several applications.

The development of internal processes, working methods, and workflows started to enable the Agency to receive and process biocides dossiers from September 2013 for all relevant processes (approval of active substances, establishment of technical equivalence, alternative suppliers, authorisation of biocidal products, data sharing). The development of new guidance documents to assist both industry and national authorities was also progressing further.

Preparatory activities were initiated to be ready for submissions of biocides dossiers and for publishing dossiers starting with those submitted under the current Biocidal Products Directive.[17]

In addition, ECHA contributed to the development of implementing legislation (including the Biocides Fee Regulation) by the European Commission. ECHA launched the preparations for the new Biocidal Products Committee and invited Member States to appoint their members to it. The Agency appointed the Chair of the new Committee. Preparations were also started for the Coordination Group dealing with disputes under the process of mutual recognition of national authorisations.

Objectives and Indicators

Objectives

1. Ensure preparedness of ECHA to start new biocides operations from the date of application in an effective and successful way.

2. Setting up of new procedures, tools, and organisational structures as well as selection and capacity building of new biocide experts.

[17] Directive 98/8/EC

Performance Indicators and Targets

Indicators	Target in 2012	Means and frequency of verification	Result 2012
Not applicable in 2012			

Main Outputs

- Technical proof of concept for the Registry for Biocidal Products (R4BP) conducted and development of the system started.
- Incorporation of biocides features in the foreseen IUCLID5 release has well progressed and is foreseen to be finalised in Q1 2013.
- First draft key guidance documents developed, a comprehensive program for developing other biocides guidance established.
- Launch of development of procedures to carry out the tasks of the ECHA Secretariat to handle applications, including cooperation with Member States and industry.
- Draft procedures and necessary documentation have started to be developed to deal with tasks related to data sharing, alternative suppliers, and technical equivalence.
- Preliminary work plan for the Biocidal Products Committee established.
- Member States have been invited to appoint members; provision of the Chair and Secretariat for the new Committee started, as well as preparations for the Coordination Group.
- The Biocides Unit created in February 2012.
- ECHA's website has been updated to include information on the new legislation.

Activity 17: PIC – preparatory work

The PIC Regulation applies for banned and severely restricted chemicals and provides for information exchange mechanisms regarding the export and import of these chemicals. It also contains a Prior Informed Consent (PIC) procedure for chemicals that are specifically identified as PIC chemicals under the Rotterdam Convention, and which are also listed in the Regulation. The export of PIC chemicals requires an explicit consent of the importing country.

Main Achievements in 2012

The recast of the Regulation concerning the export and import of dangerous chemicals (the PIC Regulation) entered into force on 16 August 2012, with a foreseen handover of the PIC tasks from the Joint Research Centre of the European Commission to ECHA on 1 March 2014. After the adoption of the PIC Regulation, the EU subsidies of €1.5 million were activated. These budgets allowed ECHA to continue the preparatory activities for PIC in order to ensure the entering into force of the Regulation in 2014. The budget implementation rate was high and amounted to 99%. Considering the delay in the entry into operation from 2013 to 2014, ECHA's preparations to take on the PIC tasks are still at an early stage. The negotiations for the handover from JRC both with regard to the content and IT tools were kicked off in late 2012, and a joint plan for the necessary work in 2013 was agreed upon. The preparation of the necessary guidance documents has also started, and a roadmap has been established for producing up-to-date documents in a timely manner.

On the date of entry into force, ECHA published a dedicated section for the PIC Regulation on its website in order to highlight the forthcoming handover and to familiarise affected stakeholders with it. In 2012, ECHA also started to participate in the Designated National Authorities' meetings to give an overview on ECHA's activities and the Agency's plans for further implementing measures. The PIC Regulation was also introduced to the Enforcement Forum, as their tasks will be expanded to coordinating enforcement of the PIC Regulation.

Objectives and Indicators

Objectives

1. Preparations well underway to start implementing the new PIC tasks from entry into operation, in an effective and successful way.
2. Ensure setting up of new procedures and tools, as well as the capacity building of staff implementing the new tasks.

Performance Indicators and Targets

Indicators	Target in 2012	Means and frequency of verification	Result 2012
Not applicable in 2012			

Main Outputs

- Modest progress in the development of export notification submission procedures, IT tools, and related manuals for export notifications procedures in cooperation with Designated National Authorities.
- Significant progress in developing procedures to deal with the explicit import consent procedure.
- Necessary contacts with the Member States and third countries established.
- Recruitment of new staff and capacity building initiated.

Annexes

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

Annex 2: Baseline assumptions

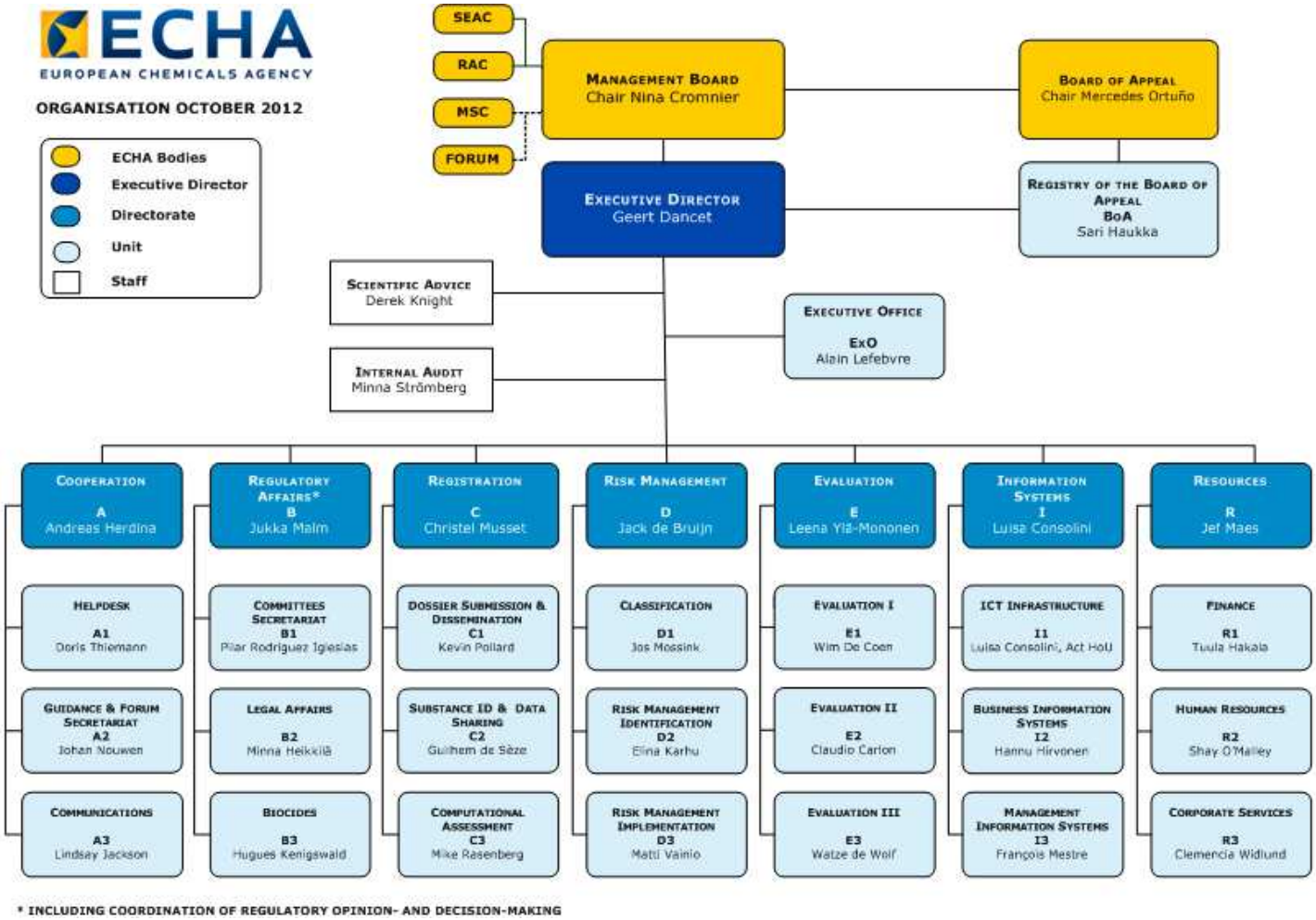
Annex 3: Financial and Human Resources 2012

Annex 4: Candidate List of Substances of Very High Concern (SVHCs)

Annex 5: Analysis and assessment of the AAR of the Authorising Officer for 2012

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

Organisation Chart



Members of the Management Board on 31 December 2012

Chair: Nina CROMNIER

Members	
Thomas JAKL	Austria
Jean-Roger DREZE	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
Krisztina CSENGODY	Hungary
Martin LYNCH	Ireland
Antonello LAPALORCIA	Italy
Armands PLATE	Latvia
Marija TERIOSINA	Lithuania
Claude GEIMER	Luxembourg
Francis E. FARRUGIA	Malta
Jan-Karel KWISTHOUT	Netherlands
Edyta MIĘGOĆ	Poland
Paulo LEMOS	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
Christina RUDEN
Anne LAPERROUZE

Representatives appointed by the European Commission

Antti PELTOMÄKI	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

Observers from accession countries

Biserka Kokić BASTIJANČIĆ	Croatia

Members of the MSC - Member State Committee on 31 December 2012

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
Petteri TALASNIEMI	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
Ana Lúcia CRUZ	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 2012

Chair: Tim BOWMER

Members	Nominating state
Annemarie LOSERT	Austria
Sonja KAPELARI	Austria
Safia KORATI	Belgium
Gera TROISI	Cyprus
Marian RUCKI	Czech Republic
Frank JENSEN	Denmark
Peter Hammer SØRENSEN	Denmark
Urs SCHLÜTER	Estonia
Riitta LEINONEN	Finland
Elodie PASQUIER	France
Stéphanie VIVIER	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
João CARVALHO	Portugal
Radu BRANISTEANU	Romania
Helena POLAKOVICOVA	Slovakia
Agnes SCHULTE	Slovenia
Benjamin PIÑA	Spain

José Luis TADEO	Spain
Bert-Ove LUND	Sweden
Stephen DUNGEY	United Kingdom
Andrew SMITH	United Kingdom

Members of SEAC - Committee for Socio-economic Analysis on 31 December 2012

Chair: Tomas ÖBERG

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 LADOPOULOU	Greece
Dimosthenis VOIVONTAS	Greece
Endre SCHUCHTÁR	Hungary
Marie DALTON	Ireland
Federica CECCARELLI	Italy
Silvia GRANDI	Italy
Vitalius SKARZINSKAS	Lithuania
Cees LUTTIKHUIZEN	Netherlands
Magnus Utne GULBRANDSEN	Norway
Zbigniew SLEZAK	Poland
Joao ALEXANDRE	Portugal
Liliana Luminita TIRCHILA	Romania
Robert CSERGO	Romania
Janez FURLAN	Slovenia
Maria Jesus RODRIGUEZ DE SANCHO	Spain
Åsa THORS	Sweden
Stavros GEORGIOU	United Kingdom

Members of the Forum for Exchange of Information on Enforcement on 31 December 2012

Chair: Szilvia DEIM

Members	
Eugen ANWANDER	Austria
Paul CUYPERS	Belgium
Parvoleta LULEVA	Bulgaria
Tasoula KYPRIANIDOU-LEODIDOU	Cyprus
Oldrich JAROLIM	Czech Republic
Birte Nielsen BØRGLUM	Denmark
Nathali PROMET	Estonia
Annette EKMAN	Finland
Vincent DESIGNOLLE	France
Katja VOM HOFE	Germany
Eleni FOUFA	Greece
Szilvia DEIM	Hungary
Bergþóra Hlíðkvist SKÚLADÓTTIR	Iceland
Sinead MCMICKAN	Ireland
Mariano ALESSI	Italy
Parsla PALLO	Latvia
Manfred FRICK	Liechtenstein
Donata PIPIRAITE-VALIŠKIENE	Lithuania
Jil WEBER	Luxembourg
Shirley MIFSUD	Malta
Jos VAN DEN BERG	Netherlands
Gro HAGEN	Norway
Marta OSÓWNIAK	Poland
Rui CABRITA	Portugal
Mihaiela ALBALESCU	Romania
Dušan KOLESAR	Slovakia
Vesna NOVAK	Slovenia
Pablo SÁNCHEZ-PEÑA	Spain
Agneta WESTERBERG	Sweden
Mike POTTS	United Kingdom

Annex 2: Baseline assumptions

Baseline figures for 2012			
Main drivers of ECHA activities	**Estimate for 2012**	**Total**	**Actual %**
Dossiers arriving in 2012			
Registration dossiers (including updates)	5 100	9 773	**192%**
Testing proposals	10	26	**260%**
Confidentiality requests (new claims -flags- received in 2012)[18]	320	619	**193%**
Access to data older than 12 years[19]	120	109	**91%**
PPORD notifications	200	233	**117%**
Inquiries	1 800	1 632	**91%**
Number of notifications under Article 7(2)	70	31	**44%**
Number of reports and notifications under Article 38	11 700	110	**1%**
Restriction proposals (Annex XV)	10	5	**50%**
Proposals for harmonised classification and labelling (Annex VI of CLP Regulation)	60	25	**42%**
Proposals for identification as SVHC (Annex XV)	40	67	**168%**
SVHC dossier developed by ECHA	5	43	**860%**
Authorisation applications	30	0	**0%**
Alternative name requests	50	17	**34%**
Substances on the CoRAP to be evaluated by MS	40	36	**90%**
ECHA decisions in 2012			
Dossier evaluation			
no. of concluded testing proposal examinations	360	416	**115%**
no. of concluded compliance checks	250	354	**142%**
- out of which draft decisions (estimated 30%)	75	336	**315%**
Final decisions on testing proposals	-	171	**-**
Final decisions on compliance check	-	66	**-**
Decisions on data sharing	10	1	**10%**
Decisions on completeness check (negative, i.e. rejections)[20]	10	3	**30%**
Decisions on access to documents requests[21]	300	70	**23%**
Decisions on confidentiality requests (negative)	30	276	**920%**
Appeals submitted in 2012			
Appeals submitted in 2012	20	8	**40%**
Others			
Draft CoRAP for substances subject to evaluation	1	1	**100%**
Recommendations to the Commission for the Authorisation List	1	0	**0%**
Questions to be answered/harmonised answers (REACH Advice, REACH-IT, IUCLID 5, others)	7 000	5 417	**77%**
SME checks	300	315	**105%**
Management Board meetings	4	4	**100%**
MSC meetings	6	6	**100%**
RAC meetings	7	4	**57%**

[18] Only the number of flags detected in the initial dossiers is reported. Under Article 119.2(d) of the REACH Regulation, only flags on uses are detected (flags on company name, registration number, PBT assessments are not detected).
[19] Access to data older than 12 years: this information is now retrievable in the inquiry process. This is the number of inquiries containing such requests for information that the Data Sharing team handles.
[20] It covers only rejections due to failure in TCC (=fee paid + TCC failed).
[21] One request typically concerns several documents – more than 600 documents were handled.

SEAC meetings	4	4	**100%**
Forum meetings	3	3	**100%**
New CA positions to be filled REACH/CLP	17	22	**129%**
Recruitment due to turnover	25	17	**68%**
New TA/CA posts to be filled for Biocides	19	16	**84%**
New TA/CA posts to be filled for PIC	4	2	**50%**

Annex 3: Financial and Human Resources 2012

Total number of TA positions occupied at 31 December 2012: **447**

Total number of CA positions occupied at 31 December 2012: **82**

Other staff (Seconded National Experts, interims, trainees) at 31 December 2012: **71**

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

	Work Programme 2012					REACH					BIOCIDES					PIC					ECHA (Total)				
	Staff Resources 2012				Initial Budget 2012	Staff Resources 2012				Budget 2012	Staff Resources 2012				Budget 2012	Staff Resources 2012				Budget 2012	Staff Resources 2012				Budget 2012
The numbering below refers to the WP 2012, not to the numbering in the budget	AD	AST	CA	Total	Total	AD	AST	CA	Total	Total	AD	AST	CA	Total	Total	AD	AST	CA	Total	Total	AD	AST	CA	Total	Total
Implementation of the Regulatory Processes (Operational Budget)																									
Activity 1: Registration, Data-sharing and Dissemination	33	11	8	52	1 035 200	29.5	12.1	9.8	51	7 556 320	1.0			1	82 245				0	0	31	12	10	52	7 638 564
Activity 2: Evaluation	85	13	4	102	2 652 150	78.0	13.4	3.2	95	16 734 442				0	0				0	0	78	13	3	95	16 734 442
Activity 3: Risk Management	35	7	7	49	975 700	30.4	4.8	2.0	37	6 432 183				0	0				0	0	30	5	2	37	6 432 183
Activity 4: Classification and Labelling	14	3	4	21	223 500	13.6	3.3	1.9	19	2 923 096				0	0				0	0	14	3	2	19	2 923 096
Activity 5: Advice and Assistance through Guidance and Helpdesk	22	11	7	40	475 560	22.2	8.6	3.6	34	5 152 973				0	29 390				0	0	22	9	4	34	5 182 364
Activity 6: IT Support to Operations	27	9	2	38	11 561 650	26.6	8.3	2.8	38	14 634 458	4.8	1.1	0.2	6.1	1 639 779	0.3	0.4		0.7	1 370 363	32	10	3	45	17 644 599
Activity 7: Scientific Activities and Technical Advice to EU Institutions and Bodies	7	0	3	10	589 700	11.3	0.7	1.0	13	2 042 427				0	10 000				0	0	11	1	1	13	2 052 427
ECHA's Bodies and Supporting Activities																									
Activity 8: Committees and Forum	21	8	4	33	1 870 120	19.8	7.4	5.0	32	5 916 828				0	0				0	5 700	20	7	5	32	5 922 528
Activity 9: Board of Appeal	6	4	2	12	80 000	6.0	3.0	1.6	11	1 570 527				0	14 695					0	6	3	2	11	1 585 222
Activity 10: Communications	9	9	8	26	6 040 280	9.2	10.0	6.0	25	8 103 321				0	70 659				0	18 333	9	10	6	25	8 192 313
Activity 11: International Cooperation	4	0	0	4	655 640	3.1	0.0	0.0	3.1	810 453				0	9 183				0	0	3	0	0	3	819 636
Management, Organisation and Resources																									
Activity 12: Management	24	15	4	43	1 971 100	21.7	15.4	3.8	41	6 973 048	1.0			1	99 301				0	0	23	15	4	42	7 072 349
Activities 13-15: Organisation and Resources (Title II: Infrastructure)	24	55	30	109	14 619 700	21.5	50.5	35.5	108	12 393 886			2.5	2.5	139 895				0	9 206	22	51	38	110	12 542 987
Staff cost - REACH / CLP (only for 2012)					59 915 700					0				0					0		0	0	0	0	0
Activity 16: Biocides	11	0	8	19	3 256 500						6.0		3.1	9.1	598 156				0		6	0	3	9	598 156
Activity 17: PIC	1	2	1	4	1 471 300											1.0	1.0	0.2	2.2	39 166	1	1	0.2	2.2	39 166
Total	323	147	92	562	107 393 800	293	138	76.2	506.6	91 243 962	12.8	1.1	6	20	2 693 303	1.3	1.4	0	2.9	1 442 767	307	140	82.2	529.2	95 380 032
In Establishment plan:	**470**					**456**		**83**																	

Annex 4: Candidate List of Substances of Very High Concern (SVHCs)

Overall, 13 substances were added to the Candidate List in June and 54 in December 2012. By the end of 2012, the total number of SVHC substances included in the Candidate List was 138. The complete Candidate List of Substances of Very High Concern can be found here:

http://echa.europa.eu/web/guest/candidate-list-table

Annex 5: Analysis and assessment of the AAR of the Authorising Officer for 2012

Dublin, 22 March 2013 MB/10/2013 final

ANALYSIS AND ASSESSMENT OF THE ANNUAL ACTIVITY REPORT OF THE AUTHORISING OFFICER FOR THE YEAR 2012

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 2012 adopted by the Management Board at its meeting of 30 September 2011 and updated on 15 December 2011,

Having regard to the Annual Activity Report of the Authorising Officer of the European Chemicals Agency for the year 2012 as submitted to the Board on 11 March 2013,

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 59 out of the 66 ambitious performance targets set in the Work Programme 2012 were met.

2. Congratulates ECHA for the operational work performed in 2012 and, in particular, for the achievements in:

(a) Raising awareness for the 2013 registration deadline, particularly with its "REACH 2013 – Act Now!" campaign targeting SMEs. The planned guidance updates and new versions of REACH-IT, IUCLID 5 and Chesar for industry were released in time prior to the moratorium on 30 November 2012.

(b) Continuing to make the information on the chemicals registered or notified publicly available. By the end of the year a massive and unique volume of information from about 30 000 registration dossiers covering nearly 8000 substances was freely available on the ECHA website.

(c) Making progress in processing inquiries and in processing confidentiality claims thus meeting ECHA's annual targets as a result of the measures put in place in 2011.

(d) Making progress both with the evaluation of the testing proposals, thereby meeting the legal deadline of 1 December 2012, and with the compliance checks of registration dossiers.

(e) Publishing as planned, the first Community rolling action plan (CoRAP) for substance evaluation, including 90 substances for 2012-2014 and supporting Member States in the evaluations of 36 substances.

(f) Adding 67 Substances of Very High Concern (SVHCs) to the Candidate List, including 43 substances for which ECHA had prepared the Annex XV dossier, bringing the total number of substances on the Candidate List to 138 by the end of the year.

(g) Preparing the fourth recommendation for inclusion of priority substances in the authorisation list; raising the level of preparation to receive applications for authorisation.

(h) Adopting 2 RAC and 1 SEAC opinions on restriction proposals and adopting 31 opinions in RAC on CLH proposals.

(i) Considerably increasing the output of the three committees, while maintaining quality and respecting the legal deadlines.

(j) Publishing a well functioning C&L inventory in February 2012 following the notification deadline of January 2011 and orocessing a further 1.4 million C&L notifications in 2012 thus bringing the total number of processed notifications since 2010 to 5.7 million and the total number of different substances on the inventory to 121,000.

(k) Supporting industry in building up capacity, particularly for registration and authorisation, 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; engaging national helpdesks via the Helpnet in this effort.

3. Notes the high quality of the scientific advice provided by the Agency, in particular in relation to the development of test methods, including alternatives of animal testing, chemical safety assessment, nanomaterials, PBT substances and endocrine disruptors.

4. Welcomes that the Agency continues to work transparently, that the Committees involve stakeholders and case owners as appropriate and that a workshop with those organisations was held in Brussels to facilitate their input in ECHA's work programmes.

5. Welcomes that in December 2012, the Agency took an important step towards increased transparency by publishing non-confidential versions of ECHA's final evaluation decisions as well as additional information stemming from the registrations such as supplier's names, registration numbers, tonnage bands and results of the PBT assessment.

6. Welcomes the Agency's efforts to improve dossier quality, including with regard to intermediates, through the development of a compliance check strategy and encouraging registrants to proactively update their dossiers.

7. Notes that the MSC did not to reach unanimous agreement on any of the proposals for testing reproductive toxicity and that over 40 dossiers have been referred to the Commission.

8. Supports the annual meeting with heads of MSCAs, which delivers elements of effective planning and use of authorities' resources across the EU.

9. Welcomes the work of the Forum in harmonising the approach to enforcement and in particular in concluding the interlinks project, which provides a basis for the enforcement of regulatory decisions.

10. Acknowledges the work of the Board of Appeal and its Registry in processing 9 appeals and that the first oral hearing open to the public took place in December 2012.

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

12. Appreciates the Agency's substantial efforts, recruiting 54 staff members and filling 96% of the posts in the establishment plan.

13. Appreciates the Agency's continuing efforts in verifying the SME status of registrants.

14. Congratulates the Agency for exceeding its targets with a rate of execution of commitment appropriations of 98% and payment execution of 85%.

15. Congratulates the Agency on reducing its carry-over rate to 13% and encourages the Agency to continue its efforts to reduce carry over in as far as possible.

16. Notes the Agency's continuing work to support the access of Member State authorities to the REACH-IT and IUCLID systems, as well as the secure use of the information in that system.
17. Notes that in 2012 ECHA upgraded its ICT infrastructure and set up outsourced services to secure an IT Business Continuity Plan for the IT systems necessary to support the registration deadline.
18. Notes the intensifying preparations for the developing role of the Agency for the biocides and PIC regulations, after their entry into force.
19. Notes the report of the Court of Auditors on conflicts of interest and the response of the Agency in developing its procedures to address the recommendations of the Court.

Dublin, 22 March 2013

Signed

For the Management Board
Nina Cromnier

ISBN