Multi-Annual *Work Programme* 2012-2014

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TABLE OF CONTENTS

LIST OF ACRONYMS

BPC	Biocidal Products Committee
C & L	Classification and Labelling
CHESAR	Chemical Safety Assessment and Reporting tool
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic or toxic to Reproduction
COM	European Commission
CSR	Chemical Safety Report
ECHA	European Chemicals Agency
eChemPortal	Global Portal to Information on Chemical substances
EEA	European Economic Area
EEA	European Environment Agency
EEC	European Economic Community
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EMAS	Eco-Management and Audit Scheme
EMA	European Medicines Agency
EU	European Union
EU-OSHA	European Agency for Safety and Health at Work
GHS	Globally Harmonised System of Classification and Labelling of Chemical
HR	Human resources
ICT	Information and Communication Technology
IPA	Instrument for Pre-Accession
ISO	International Organization for Standardisation
IT	Information Technologies
IUCLID	International Uniform Chemical Information Database
JRC	Joint Research Centre of the European Commission
MB	Management Board
MSC	ECHA Member State Committee
MSCA	Member State Competent Authority
OECD	Organisation for Economic Cooperation and Development
PBT	Persistent, Bioaccumulative and Toxic
PIC	Prior Informed Consent Procedure
POPs	Persistent Organic Pollutants
PPORD	Product and Process Oriented Research and Development
(Q)SAR	(Quantitative) Structure-Activity Relationships

RAC	ECHA Risk Assessment Committee
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
REACH-IT	REACH-IT is the central IT system providing support for REACH
RIPE	REACH Information Portal for Enforcement
SAICM	Strategic Approach to International Chemical Management
SDS	Safety data Sheet
SEAC	ECHA Socio-Economic Analysis Committee
SIEF	Data Sharing & Substance Information Exchange Forum
SME	Small and Medium Sized Enterprise
SVHC	Substance of Very High Concern
TA	Temporary Agent
TAIEX	Technical Assistance and Information Exchange instrument managed by the Directorate-General Enlargement of the European Commission
UN	United Nations
UN ECE	United Nations Economic Commission in Europe
vPvB	very Persistent and very Bioaccumulative

FOREWORD BY THE MANAGEMENT BOARD

The REACH Regulation is the most ambitious and comprehensive chemicals legislation in the world. It aims to fill information gaps on the properties of the majority of chemical substances on the EU market and introduces a more rigorous system to minimise the risks to human health and the environment posed by the most hazardous ones. The regulation also aims at enhancing the competitiveness of the EU chemicals industry by creating incentives for innovation and by removing distortions in the internal market.

REACH is complemented by the CLP Regulation, which brings the EU into line with the international Global Harmonised System (GHS) for communicating the hazardous properties of chemical substances and mixtures by harmonising criteria for their classification, labelling and packaging. Both the REACH and CLP regulations clearly place the responsibility on chemical manufacturers and importers to understand the potential adverse effects of chemicals, manage any risks associated with their use and to convey this information to customers and consumers.

At the time of writing this Multi-Annual Work Programme, the REACH and CLP Regulations have resulted in their first tangible outcomes – 25,000 registration dossiers for 3,400 chemical substances that are either commonly used in Europe or are the most hazardous; and more than 3 million notifications for over 100,000 substances that are classified and have to be labelled to protect the user. The European Chemicals Agency (ECHA) – established by REACH – was created as the European centre for coordinating its implementation and harmonising enforcement. As ECHA's Management Board, we are satisfied to have played our part within the Agency over the last four years to enable it to manage its first major legislative challenges. We are happy to to be part of ECHA in its phase as a maturing regulatory agency which is now preparing for new responsibilities.

The number of registration dossiers is a decisive factor in the Agency's workload over the period of this Multi-Annual Work Programme. REACH is admirably clear in the tasks and deadlines that it lays down for ECHA's work – for example the requirement for 5% of the registration dossiers received to be verified as to their compliance as well as taking decisions on all testing proposals received. That means that hundreds of scientific decisions must be taken each year of this reporting period.

However, two additional factors also influence the contents of this Work Programme. The first is the second REACH deadline in 2013, when the Agency will need to repeat its supporting role for business and its registration contingency efforts, as well as taking on the resulting evaluation workload. The second is the Agency's imminent responsibility for the new Biocides and PIC (Prior Informed Consent) Regulations. We in the Management Board remain vigilant that ECHA will have the appropriate financial and staffing means so that it can efficiently prepare for and implement these new pieces of legislation.

OVERVIEW BY THE EXECUTIVE DIRECTOR

The 2012-2014 Multi-Annual Work Programme of the European Chemicals Agency (ECHA) provides you with an overview of the Agency's planned activities during the three coming years. You can find more detailed planning in ECHA's annual Work Programme, which already exists for 2011. The Multi-Annual Work Programme is revised every year and its time-span moved forward by one year.

2012-2014 is an important three-year period. It is the first Multi-Annual Work Programme in which ECHA will operate in all areas of its enlarged responsibilities covering Registration, Evaluation, Authorisation, Restriction, Classification and Labelling as well as managing Biocides and PIC. This represents a tremendous challenge for us. In just one of those areas of activity – the registration process – do we have fully-fledged experience from which to benefit. All the others are new or still in an early stage of implementation, thereby creating pressure for the Agency to deliver over the coming years. We have done that before, but not in so many areas at the same time. However, I am confident that with the support of our Management Board, the European Commission, Member States and our stakeholders, combined with the continued hard work of my colleagues, we will once again succeed in reaching our goals and providing the service that individual companies need and that citizens deserve.

In 2011, ECHA is implementing a new corporate identity – you can read our new mission, vision and values at the start of this document. We believe passionately that working together openly and honestly is the key to the successful implementation of Europe's chemical legislation. We depend on constructive cooperation with all our institutional partners and stakeholder organisations. We very much welcome your continued interest in our work and, in that spirit, would appreciate your feedback on this Multi-Annual Work Programme. We look forward to hearing your views.

Geert Dancet
Executive Director

1 INTRODUCTION

Established on 1 June 2007, the European Chemicals Agency (ECHA) is at the heart of the new regulatory system for chemicals in the European Union set out in the REACH Regulation[1]. It has also been playing an important role in the new Regulation on the Classification, Labelling and Packaging of substances and mixtures (CLP[2]) since 2008. These legislative acts are directly applicable in all Member States without the need for their transposition into national law. Both regulations should contribute to fulfilment of the Strategic Approach to International Chemical Management (SAICM) adopted on 6 February 2006 in Dubai. The purpose of the REACH and CLP system is to ensure a high level of protection of human health and the environment and to facilitate the free circulation of substances within the single market. In addition, the REACH Regulation has as the objective of enhancing competitiveness and innovation and promoting alternative methods to animal tests in order to assess the hazards of chemicals. The REACH Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.

In practical terms, the REACH Regulation is expected to close a knowledge gap in relation to chemicals placed on the European market before 1981. It makes the risk management of these substances more efficient and speeds up the placing of safe and innovative chemicals on the market, in particular, by shifting the burden of proof for identifying and controlling risks from authorities to companies.

The successful implementation of the REACH and CLP Regulations 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 appropriately. However, the efficient operation of the REACH and CLP Regulations also depends on ECHA's institutional partners, in particular the Member States of the EU and the European Commission ("Commission") on the one hand, and on industry to properly implement the Regulations on the other. In addition, contributions by distributors, retailers and consumers as well as workers and their representatives are needed to establish the market-based incentives envisaged by the new chemicals legislation.

From the very beginning, the credibility of the REACH and CLP systems has, for example, been determined by the allocation of sufficient resources at national level and an effective and fair enforcement policy. In addition, since ECHA is responsible for drafting scientific opinions for the Commission, successful implementation depends upon the initiation and appropriate follow-up of these processes by the Commission and/or the Member States.

The planning in this Work Programme is founded upon the baseline figures presented in Annex 3, which are an update of the Commission estimates made when the REACH Regulation was prepared. Having passed two important deadlines for registration and CLP in 2010/2011,

[1] Regulation (EC) No 1907/2006

[2] The CLP Regulation (No. 1272/2008) on classification, labelling and packaging of substances and mixtures was adopted by the European Parliament and the Council in late 2008 and came into force on 20 January 2009. It implements in the EU the international criteria agreed by the United Nation Economic and Social Council (UN ECOSOC) for the classification and labelling of hazardous substances and mixtures - known as the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). The Regulation will gradually repeal Directives 67/548/EEC and 1999/45/EC with effect from 1 December 2010 regarding substances and 1 June 2015 regarding mixtures.

ECHA can base some of its predictions on real data but the baseline numbers remain nevertheless subject to a significant degree of uncertainty, in particular with regard to authorisations and restrictions. The planned resource allocation is based on the revisions made for ECHA's annual Work Programme 2011 taking into account the experience gained and data collected so far. Therefore, constant monitoring of the work volume and potentially a re-allocation of priorities and resources during the years to come will be required.

Alongside the existing REACH and CLP Regulations, the Commission proposed in June 2009 a new Regulation concerning the placing on the market and use of biocidal products[3] which is currently under negotiation by the European Parliament and the Council. The proposed Regulation foresees additional tasks for ECHA – namely, the review of applications for authorisation of certain biocidal products which could in principle start from 2013 onwards. Provided that ECHA receives additional funding for this purpose, prior to the entry into force of the legal base, it will be able to start recruitment procedures, adjusting its IT tools and building up expertise in relation to the Regulation from 2011.

The Commission is currently preparing a recast of the so-called PIC regulation[4] concerning the export and import of dangerous chemicals. It is expected that certain tasks will be transferred from the Joint Research Centre of the Commission to ECHA in the recast as of 2013 and hence it is expected that ECHA will provide the Commission, on request, with technical and scientific input and assistance. Moreover, ECHA expects to start preparing for the processing of dossiers prior to the entry into force of the legislation provided that it receives additional funding for this purpose.

[3] COM(2009)267.

4 Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals

2 THE EUROPEAN CHEMICALS AGENCY IN 2012-2014

2.1 ECHA's Mission, Vision and Values

During 2010, ECHA sought feedback from stakeholders and staff on its performance and values – the services it delivers and how it delivers them. Based on this feedback, and in close consultation with the Management Board and its staff, the Agency has revised its mission, vision and values – providing clearer and more precise descriptions which are more memorable. This new corporate identity is implemented by embedding the values in all services and activities of ECHA and by making improvements to bring them into line.

The main objective is to make sure that the services delivered by the Agency build the kind of reputation that it aspires to. By being clear about where ECHA wants to be as an organisation, it will give clarity to its stakeholders about what they can expect and also to the Agency's staff, thereby enhancing their motivation and commitment to ECHA's work.

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.

Vision

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

Values

Transparent

We actively involve our regulatory partners and stakeholders in our activities and are transparent in our 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 and consistent. 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 human life in Europe and to protect and improve the quality of the environment.

2.2 ECHA's Key Priorities 2012-2014

ECHA has identified the challenges for the years ahead and decided upon its priorities accordingly. These priorities have to be seen in the context of ECHA's legal competence, as laid down in the REACH and CLP Regulations. An overview of the milestones set out in the REACH and CLP Regulations is annexed to this Multi-Annual Work Programme (Annex 1). The key priorities listed below also reflect the expected change of focus in ECHA's activities, mainly in terms of workload.

Key priorities 2012-2014:

- ECHA will optimise its guidance, IT tools and helpdesk functions in order to assist companies more efficiently in their registration and data-sharing tasks to help ensure the safe use of substances. A key aspect is to support registrants in providing high quality dossiers for various types of REACH & CLP dossiers, in particular registration dossiers for the 2013 deadline, taking into account that these registrants are more likely to be smaller companies than in 2010, with less capacity to cope with the obligations of REACH than those who registered for the 2010 deadline. ECHA will also draw on lessons learnt from the registrations submitted in respect of the 2013 deadline for the final 2018 deadline.

- ECHA will complete the dissemination on its website of information on the properties and uses of chemical substances that have been registered by the 2010 and 2013 deadlines. In particular, it will complete the assessment of all confidentiality claims from the 2010 registrations no later than 2012 and for most of the claims arising from the 2013 registrations by 2014.

- ECHA will strive to manage effectively the high number of proposals from MSCAs and industry for harmonised classification and labelling of certain hazardous substances, as well as active substances used in plant protection and biocidal products. ECHA will maintain the C&L Inventory that contains information notified by industry for hazardous substances and from registrations. It will improve further the user friendliness of the

public version of the Inventory. The process of industry harmonising their classifications for substances with differing entries in the Inventory will be facilitated.

- Throughout 2012-2014 ECHA will focus on dossier evaluation activities in order to meet the mandatory deadlines for examining testing proposals submitted by the first and second registration deadline and to reach the minimum compliance check target of 5% of dossiers registered in the highest tonnage bands. Regarding substance evaluation, ECHA will play the central role of prioritising the substances, coordinating the substance evaluation process and supporting the Member State Competent Authorities (MSCAs).

- ECHA will safeguard the smooth implementation of authorisation processes, and has the capacity to develop up to 5 dossiers upon the Commission's request for the identification of substances of very high concern (SVHC) per year. It will biannually update the ever faster growing Candidate List of substances of very high concern and submit an annual recommendation to the Commission for the Authorisation List (Annex XIV – substances subject to authorisation). It will also process the anticipated rapidly-increasing numbers of industry authorisation applications that necessitate timely high-quality committee opinions.

- ECHA will contribute to the reviews set out in the REACH Regulation which the Commission is to carry out by 1 June 2012, and assist the Commission in any follow-up that may follow.

- ECHA will actively contribute to and support the effective enforcement of the REACH and CLP Regulations by the national enforcement authorities, by ensuring that the Forum fulfils its obligations, so that chemicals circulating on the single European market comply with the requirements of REACH and CLP.

- ECHA will further develop its scientific knowledge and expertise and interact and engage with the academic and regulatory science communities. Hence it will enhance its role as the leading expert in chemicals, ensuring it is also able to provide scientific and technical advice for new and emerging issues. Key areas relevant to REACH and CLP are the development of hazard and risk assessment methodologies for nanomaterials and the use of alternative test methods, including non-test methods, to assess the properties of substances without the need for animal testing.

- ECHA will enhance communications with the general public and SMEs and reinforce the involvement of stakeholders in ECHA's work.

- ECHA will prepare for and upon adoption start the implementation of the new Biocides Regulation and the Prior Informed Consent Regulation. Any preparation prior to the adoption of the legal base is subject to the availability of additional resources.

3 IMPLEMENTATION OF THE REGULATORY PROCESSES

3.1 Registration, Data-sharing and Dissemination

Priorities 2012-2014

- Develop means to support fair, transparent and non-discriminatory data-sharing among registrants and promote best practices of data-sharing among registrants;
- Provide user-friendly means and adequate support to downstream users who report their use to the Agency;
- Ensure to the extent possible that the substance identity of the submitted dossiers is correct so that information and data sharing on substances is targeted and well understood by industry and authorities;
- Ensure that companies are able to fulfil their registration obligations as efficiently as possible and stimulate the submission of high quality registration dossiers in order to provide a good basis for subsequent work, such as evaluation;
- Effectively assess the confidentiality claims in the registration dossiers and ensure that the non-confidential information is swiftly made publicly available over the Internet.

3.1.1 Registration

The REACH Regulation is based upon the principle that the responsibility for the identification and management of risks from a substance lies with the company that manufactures, imports, places on the market, or uses the substance. Registration provisions therefore require all manufacturers and importers of substances in quantities of 1 tonne or more per year to collect or generate data in respect of each substance. In order to promote harmonised interpretations of data, reduce costs and unnecessary testing on vertebrate animals, registrants of the same substance are required to share their data. They also have to implement appropriate on-site risk management measures and recommend appropriate risk management measures to their customers. Information on the intrinsic properties of the substance and on the safe use of the substance must be documented in a registration dossier and submitted to ECHA; the Agency then verifies the completeness of the information provided and the payment of the corresponding fee, before assigning a registration number.

For substances manufactured or imported in quantities above 10 tonnes per year, companies have to complete a chemical safety report (CSR) that includes exposure scenarios, leading to more precise estimates of risks and risk management measures.

Registration under REACH began on 1 June 2008; however, the Regulation creates a transitional regime for substances which, under certain conditions, were already manufactured, imported or placed on the market before the entry into force of the Regulation on 1 June 2007, and which did not have to be notified under the previous legislation[5]. These substances are known as ‘phase-in substances’, and there are later deadlines for their registration (in 2010,

[5] Directive 67/548/EEC.

2013 and 2018) depending on the tonnages being manufactured or imported and upon specific hazard characteristics. In order to benefit from the transitional regime, phase-in substances had to be pre-registered between 1 June and 1 December 2008. Non-phase-in substances, and phase-in substances, which were not pre-registered, cannot be manufactured, imported or placed on the market without the successful submission of a registration dossier.

By the first registration deadline in 2010 ECHA received approximately 25 000 registration dossiers covering about 3400 phase-in substances and about 900 non-phase-in substances. While the number of dossiers coincides with the Commission's original estimates, the number of substances registered was somewhat lower than expected. ECHA will work together with its partners to analyse the discrepancy between the predictions and the outcome of the first registration deadline in order to refine the estimates for the forthcoming deadlines. At the time of writing this document, ECHA expects to receive some 25 000 registration dossiers in 2012-2014, with approximately half of these dossiers being updates of existing registrations[6].

Based on the experiences gained so far, in 2012 ECHA will have a full overview of the registration process including the workload resulting from requests from registrants to complete or update dossiers. ECHA will have also gained understanding on what kind of support the registrants need in order to successfully submit a complete registration dossier. All this know-how will be used to streamline both the registration process and support mechanisms for the registrants of 2013 and the review will be repeated in 2014. Special attention will be paid to the fact that the registrants for the second and third deadline are expected to be smaller companies than those of the 2010 deadline and will face higher challenges in submitting their registrations. This will be the starting point to prepare efficiently for the last registration deadline of 2018, for which the volume of registrations is expected to represent three times the 2010 volume.

In addition to the registration obligations for substances as such and those contained in mixtures, there is also a registration obligation for substances in articles in certain cases. Moreover, ECHA processes notifications for temporary exemptions from registration for substances that are used in product and process related research and development (PPORD). The first requests for prolongation of the initial five-year exemptions will start in 2013. It is also foreseen that a substantial number of downstream users will report to ECHA their use not covered by the registration of their supplier or because of a different classification of the substance. A user-friendly means and adequate support for them will be provided.

3.1.2 Data Sharing

Registration requires the submission of available and relevant data on intrinsic properties and uses of substances. If this data is not available it needs to be generated, by testing where necessary. The REACH Regulation has several provisions to facilitate data sharing between registrants in order to minimise costs, prevent duplicate animal testing, and facilitate the common classification and labelling of substances. Data sharing is obligatory for studies involving tests on vertebrate animals.

For phase-in substances, the pre-registration system was established to enable registrants of a same substance to get in contact to form a Substance Information Exchange Forum (SIEF), in which they can co-operate; receive an overview of which studies are available; agree on the generation of new test data; and jointly prepare their registration. A SIEF is formed without the involvement of ECHA. However, to facilitate the data-sharing process, ECHA maintains an IT system via which the pre-registrants of the same phase-in substance can find each others' contact details on secure "pre-SIEF" web pages. Third parties holding information on those

6 Assuming phase-in substances updated at a rate of 10% per year, non-phase in at a rate of 20% per year.

substances can make themselves known on the corresponding pre-SIEF web pages, if they intend to share their data.

Pre-registration took place between 1 June and 1 December 2008, but it remains open for companies in certain situations until up to one year before the relevant submission deadline. In practice this means that first-time manufacturers and importers of a phase-in substance for more than 100 tonnes /year will have to pre-register their substance on 31 May 2012 at the latest in order to benefit from the extended registration deadline of 31 May 2013. They then have the opportunity to join existing SIEFs in order to be part of a joint registration. In 2012-2014 ECHA will continue to handle these “late” pre-registrations. In order to smooth the process of data sharing, ECHA will review its support to the (pre-)SIEF activities based on the feedback received around the first registration deadline. Consideration will also need to be given as to whether additional support can be provided to newcomers to facilitate their data-sharing obligation within the SIEFs following the lessons learned during the 2008 pre-registration period and subsequent 2010 registration period.

For non-phase-in substances and for phase-in substances that were not pre-registered, an inquiry process prior to registration will allow ECHA to facilitate data sharing. ECHA expects to receive approximately 1800 inquiries (initial submissions and updates) per year. Consideration will also be given in this area to reach out to potential registrants in order to clarify the type of information needed in this process to ensure that previous registrants of the same substance can be correctly identified.

ECHA has a limited arbitration role when the potential registrants cannot reach agreement on the sharing of a study. If no data has been submitted, ECHA will take a decision on whether or not the test needs to be repeated by another potential registrant. Given the overarching aim of REACH to avoid unnecessary animal testing, this is a very unlikely measure in case of tests on (vertebrate) animals. At the time of writing, ECHA assumed that the number of data sharing decisions would be small in 2012 and in 2014 increasing to a fairly high number in 2013 due to the second registration deadline in the middle of the year.

Based on lessons learned around the registration deadlines, ECHA will systematically review its data-sharing procedures in the 2012-2014 period and make them more effective for all involved parties.

The data-sharing decisions taken on dossiers submitted around the registration deadlines of 2010 and 2013 may result in a number of appeals, requiring input from the scientific staff to support the legal experts preparing the defence on behalf of ECHA.

Understanding the substance identity is highly important in data-sharing activities, but it is also required in all types of registrations and notifications, including proposals for harmonised classification and labelling, and for authorisations and restrictions. The workload related to substance identification will remain high in 2012-2014.

3.1.3 Dissemination

Making information on chemicals publicly available is expected to have a positive impact on health and environmental protection both in Europe and worldwide. Dissemination activities require a balance between citizens’ right to know the properties of the chemicals they may be exposed to and companies’ right to protect their confidential business information. Further to the second wave of registrations in 2013, ECHA will have an even more complete database of information on substances which are present on the European market. In addition to the substances manufactured and imported in large quantities, with specific hazardous properties, information on substances manufactured and imported in quantities of 100-1000 tonnes per

year will be available. One core activity in 2013 will be to disseminate all non-confidential information submitted in the registration dossiers earlier that year, swiftly and reliably.

Dissemination activities will range from publishing, in large volumes, the non-confidential information contained in the registration dossiers, to the assessment of justifications provided by the registrants in order to keep certain information confidential in accordance with the REACH Regulation. The assessment of the confidentiality claims submitted in the context of the 2010 deadline will be completed for the most part in 2011 and fully completed by mid 2012. ECHA foresees that the assessment of the confidentiality claims submitted by the 2013 deadline will be completed by the end of 2014. Confidentiality claims on the IUPAC name will also lead to additional work for ECHA as the public name proposed by the company needs to be verified by ECHA in order to ensure that it provides sufficient understanding of the intrinsic properties of the substance even though it masks its complete chemical identity. Therefore, ECHA will have achieved the dissemination of the maximum amount of information on each of the substances supplied by each registrant.

Priority is given to the assessment of confidentiality claims for dossiers containing testing proposals so that interested parties can provide useful hazard information on the substance under examination for which the largest possible amount of information is made public already at that point in time.

In order to increase the user friendliness of the dissemination website, ECHA will continuously cooperate with its stakeholders to better understand the needs of the various users. Specifically the needs of the general public, i.e. an audience that is not familiar with the technical format the data is displayed in, will be examined and taken into consideration when further developing the dissemination website in 2012-2014.

3.2 Evaluation

Priorities 2012-2014

- Ensure that all testing proposals incorporated in the registration dossiers are handled within the legal deadlines and lead to scientifically and legally sound decisions;
- Conduct compliance checks on 5% of all dossiers by the end of 2013 registered by the 2010 deadline; and prepare, where appropriate, scientifically and legally sound draft decisions to encourage companies to deliver good quality dossiers and to ensure that standard information requirements are met;
- Conduct increasing numbers of follow-up examinations of updated dossiers following evaluation decisions;
- Ensure establishment of the first Rolling Action Plan and its annual updates;
- Provide adequate support to Member States to ensure that the substance evaluation process is efficient, meets its legal deadlines and, where appropriate, leads to scientifically and legally sound decisions;
- Prepare the annual evaluation report and use it and other communication pathways with registrants and industry to point out the main areas for improvement in the submission and update of registration dossiers with the aim to support the submission of high quality registration dossiers, in particular in view of the subsequent registration deadline.

The REACH Regulation distinguishes between dossier and substance evaluation. Dossier evaluation is performed by ECHA whilst substance evaluation relies on the Member States to perform the evaluation work. Dossier evaluation is further subdivided into the examination of testing proposals and the compliance check.

3.2.1 Dossier Evaluation

Dossier evaluation is one of ECHA's most demanding tasks due to the number of dossiers submitted, the volume of information in each dossier, and the considerable scientific and technical competence required. One of the main objectives for the year 2012 is to increase ECHA's scientific, technical and legal capacity and further optimise its efficient use over the whole period for the evaluation work on dossiers received by the 2010 and 2013 deadlines.

Dossier evaluation is subdivided into compliance checks of registration dossiers and examinations of testing proposals[7]. Both processes use the same decision-making process and follow-up process[8].

In evaluating dossiers, the ECHA Secretariat produces scientific and legal judgments. These judgments have to be based on sound science and require well-trained and experienced staff. A number of scientific disciplines, such as (eco)toxicology, chemistry, epidemiology, occupational hygiene, environmental fate and behaviour, exposure assessment, as well as risk characterisation and management, are needed in order to arrive at scientifically robust

[7] Articles 40 and 41 of the REACH Regulation.
[8] Articles 42, 51 and 52 of the REACH Regulation.

evaluation results. As a second step, the scientific judgments as to whether the registration dossiers, and the CSRs are in compliance with the information requirements of REACH, have to be transformed into legally binding documents.

High volume chemicals are generally the most complex substances to evaluate, on account of the comprehensive information requirements and the large number of uses. Following a prioritisation exercise completed in 2011, ECHA will strive to handle hundreds of dossiers in an efficient manner and to ensure scientific quality and legal robustness.

With the resources currently planned, and under current assumptions, ECHA expects to be able to handle approximately 600 dossier evaluations per year in 2012-2014. The 2012 priority is to conclude the remaining 2010 testing proposals by the legal deadline of 1 December 2012. The 2013 priority is to conclude the up to 1000 compliance checks necessary to achieve the 5% target. The 2014 target is to achieve good progress in the evaluation of testing proposals submitted by the 2013 deadline (related to Annex IX endpoints).

The examination of all testing proposals and, in certain case, the compliance checks leads to evaluation decisions requiring registrants to undertake certain tests or address serious shortcomings of the registration. The growing volume of evaluation decisions may also result in a number of appeals by registrants requiring input from the scientific staff in support of the legal experts preparing the defence on behalf of ECHA. Later on, decisions of the Board of Appeal may also result in a number of actions for annulment before the General Court requiring input from the scientific staff in support of the legal experts preparing the defence on behalf of ECHA.

Examination of Testing Proposals

Registrants submit testing proposals to ECHA as part of their registrations and seek permission from ECHA to undertake tests required by REACH Annexes IX and X, if they identify a data gap and cannot otherwise fulfil the information requirements of the REACH Regulation. ECHA examines all testing proposals to ensure that the proposed tests will generate reliable and appropriate data, and that all available information has been considered. In this regard, the examination of testing proposals may be regarded as a specific type of compliance check. Moreover, a proportion of testing proposals cannot be processed before having had a targeted compliance check on the substance identity. Testing proposals, which include vertebrate animal tests, undergo third party consultation before a decision is taken. The draft decision on testing proposals examines the grounds for conducting the proposed test taking into account the dossier information and all relevant scientifically valid information received from third parties.

The decision-making process involves consultation with the registrants that submitted the testing proposal, the Member State Competent Authorities, and, if necessary, ECHA's Member State Committee (MSC). If unanimous agreement cannot be reached in the MSC, ECHA refers the draft decision to the Commission and the Commission prepares the draft decision to be taken in the Committee procedure referred to in Article 133(3) of REACH. This procedure was established to make sure that the best possible use is made of existing information, and that animal testing is required only when there is a broad consensus that such testing is indeed necessary.

Deadlines for the evaluation of testing proposals differ for phase-in and non-phase-in substances. Proposals for phase-in substances registered by the first registration deadline in November 2010 will have to be evaluated by 1 December 2012. Proposals for non-phase-in substances must be evaluated within six months of the date of registration. ECHA received 580 dossiers with testing proposals by the 2010 registration deadline, covering about 1500 hazard endpoints. A large proportion of these testing proposals will be examined in 2011 but a

significant number will remain to be concluded in 2012. ECHA also expects to receive about 400 testing proposals for phase-in substances by the 2013 deadline, which will lead to decisions to be adopted in 2014-2016. In addition, on the basis of the 2009 and 2010 numbers, about 10 testing proposals for non-phase-in substances are expected each year.

Compliance Checks

The purpose of the compliance check is to ensure that the information requirements under the REACH Regulation are met in the registration dossiers. In this regard the compliance check is the main tool for requesting standard information required by the REACH Regulation, but not submitted by registrants. This information forms the basis for the safe use of substances. Identification of non-compliance issues will lead to a draft decision, requesting the missing information from the registrant and setting a deadline for the submission of this information. The decision-making process is the same as that described for the evaluation of testing proposals. The Agency may also identify shortcomings, which are not necessarily related to the lack of information. For example, the risk management measures proposed by the registrant may be inadequate if the proposed classification and labelling does not reflect the reported study results. Quality observation letters are therefore also used by ECHA to invite the registrant to update the dossier in such cases. Another outcome may be that the compliance check is closed without action towards the registrant.

ECHA is obliged to select a percentage of the received registration dossiers, not lower than 5% for each tonnage band, for compliance checks. A draft decision has to be prepared by ECHA within 12 months from the start of the compliance check. Relevant for the 5 % target with regard to the 2010 deadline are:

- Dossiers submitted in 2008, 2009 and 2010 by companies for phase-in substances meeting the criteria for the 2010 deadline (not containing updates and dossiers submitted for later registration deadlines);

- Dossiers on transported isolated intermediates submitted by companies for phase-in substances meeting the criteria for the 2010 deadline.

Almost 20,000 such dossiers have been submitted by the 2010 deadline, meaning that ECHA needs to carry out 1000 compliance checks to meet the 5 % target[9]. With the planned resources, this will be a major challenge for ECHA. The legislator has not defined a timeframe within which the 5% target should be met, but ECHA has planned to complete compliance checks up to the stage of the draft decision, observation letter or a conclusion document on up to 1000 dossiers by the end of 2013. These dossiers include not only lead registrants' dossiers but also member dossiers. The ratio between the two types of dossiers selected for compliance checks is envisaged to be the same as the average ratio of lead and member dossiers in joint submissions (i.e. 1:7). Furthermore, compliance checks can be either full checks or targeted to certain parts of the dossier.

Follow-up to Dossier Evaluation

The general results of the evaluation processes are published in the annual progress report provided by ECHA in line with Article 54 of the REACH Regulation. This report will include general recommendations to potential registrants in order to improve the quality of registration dossiers. It will also illustrate the possibilities and conditions for using alternative testing methods and assessment approaches to avoid unnecessary animal testing in cases where alternatives can be applied.

[9] Art 23 of the REACH Regulation.

As of early 2011, experience showed that testing proposal examinations, in almost all cases, and compliance checks, in most cases, result in a request to the registrant to provide further information in an updated dossier by a deadline set by ECHA. The updated dossiers are examined in a follow-up process[10] and the deadlines set range from 3 months to 3 years, depending on the information requested. Therefore, an increasing number of updated dossiers containing new information are expected in the years 2012 to 2014 based on the requests sent to registrants in 2009-2011. The number of follow-up examinations could reach 350 – 400 in 2014 and beyond. This increasing amount of follow-up activities may mean that fewer resources are available for the evaluation of new registration dossiers received in relation to the 2013 registration deadline.

3.2.2 Substance Evaluation

Substance evaluation aims at verifying whether a substance constitutes a risk to human health or the environment. Substance evaluations are normally performed by Member State Competent Authorities (MSCAs) and involve an assessment of all available information relevant for the evaluation and requests for further information from registrants, if appropriate. This request for further information can go beyond the standard information requirements provided in the Annexes of the REACH Regulation.

Community Rolling Action Plan

ECHA has a principal role in establishing and updating the Community Rolling Action Plan (CoRAP) for the substances to be evaluated. The first CoRAP will be adopted in early 2012 and will contain the list of substances per Member State to be evaluated in 2012-2014. The CoRAP shall be updated annually thereafter.

For each annual update ECHA will apply a stepwise prioritisation and ranking procedure, which will largely rely on the application of IT prioritisation tools to be further refined in the coming years. ECHA will ensure adequate an interlinking of the CoRAP development in general with other processes which could lead to establishing (EU-wide) risk management measures.

ECHA will support the active involvement of Member States by giving them the possibility to notify substances of interest and to comment on ECHA proposals before the draft annual CoRAP update is formally submitted to the Member States and the Member State Committee. The establishment and maintenance of a registry of notifications will facilitate the information sharing and the allocation of substances among Member States. In cases when more than one Member State expresses an interest to evaluate the same substance, the ECHA Secretariat will initiate an informal “negotiating” procedure to reach an agreement, which may in many cases avoid the otherwise required referral of the matter to the Member State Committee.

The cooperation with Member States will also include the discussion and revision of the criteria for prioritising substances for substance evaluation as they have been agreed in 2011.

ECHA estimates that 140 substances will be evaluated between 2012 and 2014 by Member States - 40 substances in 2012, and 50 substances annually thereafter.

Substance Evaluation Process

ECHA also plays a coordination role in the overall substance evaluation process. As an end result of the evaluation process the Member States may propose a draft decision requesting information requirements to clarify the detected concern. The decision-making process involves all Member States and also the Member State Committee, in cases where Member

[10] Article 42 of the REACH Regulation.

States propose amendments to the draft decision. The final outcome of the process however will be an ECHA decision. ECHA must therefore ensure that the draft decisions on information requirements are completed within the legal time frame and that they are scientifically consistent and legally sound.

During 2012 ECHA will continue to provide clear support for substance evaluation. In 2012 the process will be fully deployed in practice and further developments on the basis of experience will be foreseen in a pragmatic dialogue with the Member States. It is anticipated that in 2013 most of the draft decisions from the first list of substances will be processed to a final decision together with the responsible Member State. In 2013 and 2014 the Member States will start new evaluations from the updated CoRAP. Further follow-up on the additional information requested from registrants in the substance evaluation process may start from 2014 onwards.

Communication to registrants and to the general public on achievements of substance evaluation is also an ECHA task. As a first step, the criteria for prioritising substances and the adopted CoRAP will be published in 2012. In 2013-2014 the updated CoRAP will be published as well as outcomes of the finished substance evaluations by MSCAs.

Although substance evaluation is in principle conducted by Member States, a significant administrative and legal workload is in any case foreseen for the Agency. The challenge will be to facilitate simultaneously the updating of the CoRAP as well as coordinating the evaluation of substances, including follow-up work and decision making on the requested information by MSCAs.

3.3 Risk Management

Priorities 2012-2014

- Prepare scientifically and legally sound Annex XV dossiers for identification of SVHCs and for restrictions on request of the Commission;
- Provide scientific, technical and legal support in the identification of substances that require further risk management, including further development of the Candidate List and the preparation of new recommendation(s) for priority substances for authorisation;
- Successfully manage the process of handling the applications for authorisation;
- Ensure a high degree of scientific, technical and legal quality in processing the dossiers;
- Provide support to industry in building its capacity to develop good quality exposure scenarios to be included in the CSR and SDS.

Authorisations and restrictions can be used as risk management measures at EU level in order to address risks arising from chemicals for which the other REACH procedures are not considered sufficient. Authorisation is intended to ensure that risks from the identified substances of very high concern (SVHC) are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically and viable. Viable alternatives reduce the overall risk, while ensuring the good functioning of the internal market. Restrictions may be imposed where there is an unacceptable risk that needs to be addressed on an EU-wide basis.

These procedures should be applied coherently to ensure that they contribute effectively to achieving the objective of the REACH Regulation which is to ensure a high level of protection of human health and the environment, while enhancing competitiveness and innovation. Regulatory coherence and effectiveness can be enhanced by i) efficient identification of substances and uses which may require further scrutiny and potentially further action, and ii) systematic assessment of the different risk management options early in the process. These tasks are carried out by the Member States and by ECHA (on their own or in co-operation). To avoid gaps and overlapping work on substances, there is a need for co-ordination and ECHA is best placed to provide this co-ordination. To ensure that the steps taken in the authorisation and restrictions procedures are scientifically and legally coherent and adopted within the relevant legal timeframes, ECHA will use the scientific capacity as well as the technical and legal support at its disposal.

3.3.1 Authorisation

The authorisation procedure concerns Substances of Very High Concern (SVHCs). These are substances which are: a) Carcinogenic, Mutagenic or toxic to Reproduction (CMR) 1A or 1B[11]; b) Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) according to the criteria set out in the REACH Regulation; and c) substances of an equivalent level of concern identified on a case-by-case basis.

Identification of Substances of Very High Concern (SVHC)

The identification procedure for SVHCs starts with the preparation of a dossier by an MSCA or ECHA, the latter at the request of the Commission. These dossiers provide the grounds justifying the identification of the substance as a SVHC in accordance with the criteria mentioned above. The preparation of such dossiers is a challenging task. The Commission together with ECHA has stimulated discussion and cooperation between Member States which, since autumn 2010, has taken place through meetings of experts from the Competent Authorities on Risk Management. The ECHA Secretariat will continue providing support to the Member States, for instance through further improvement of formats and guidance and, when needed, training. Further development of guidance (or a 'code of practice') may be needed in relation to the application of Article 57(f) which relates to substance properties that could give rise to an equivalent level of (very high) concern. In collaboration with the Commission and the MSCAs a common understanding should be developed of the principles and minimum requirements that should apply when identifying a substance as SVHC via the Article 57 (f) route.

ECHA expects the Commission to request it to develop 5 Annex XV SVHC dossiers per year in order to contribute to the objective expressed by Commission's Vice-President Tajani and Commissioner Potočnik to substantially accelerate the speed by which SVHCs are identified and included in the Candidate List with the aim of having 136 SVHCs on the List by 2012. Once finalised, these dossiers will be submitted in accordance with the agreed submission dates for new Annex XV dossiers. It is anticipated that a substantial number of SVHC dossiers will enter the process in the coming years – leading to an increased workload in this area. The Candidate List, which contained 46 substances at the end of 2010, is expected to grow by approximately 30 to 40 substances per year in the period 2012-2014.

ECHA's decisions to add substances to the Candidate List may also result in a number of actions for annulment before the General Court requiring input from the scientific staff in support of the legal experts preparing the defence on behalf of ECHA.

[11] Classification in accordance with Table 3.1 of Annex VI (List of harmonised classification and labelling of hazardous substances) of the CLP Regulation (Regulation (EC) No 1272/2008). This corresponds to a classification as carcinogenic, mutagenic or toxic to reproduction, categories 1 or 2 in accordance with Annex I to Directive 67/548/EEC (Table 3.2 of Annex VI to Regulation (EC) No 1272/2008).

Inclusion of Substances in the List of Substances Subject to Authorisation (Annex XIV)

Based on ECHA's recommendation, the Commission adopted the first Authorisation List or amendment to Annex XIV of the REACH Regulation in February 2011. ECHA will use the experience gained during the elaboration of the first recommendations to develop future recommendations on an annual basis. Working closely together with the Member State Committee, ECHA will further shape its priority setting approach for selecting substances from the Candidate List. ECHA will continue to develop, for each substance included in its recommendations, a dossier specifying the details that apply in respect of the authorisation requirement (e.g. the application dates, "sunset dates", and proposed exemptions, if applicable) and the justifications for these entries.

Applications for Authorisation

Substances on the Authorisation List (Annex XIV) may only be placed on the market and used after the sunset date if an authorisation has been granted by the Commission. Applications for authorisation can be made by manufacturer(s), importer(s) and/or downstream user(s) and can be submitted separately or jointly to ECHA. An application can cover the applicants' own and/or their downstream users' uses. The content of an application may vary but certain minimum requirements apply, such as a chemical safety report (unless already submitted as part of a registration) and an analysis of alternatives.

The Risk Assessment Committee (RAC) and Socio-Economic Analysis Committee (SEAC) have to give their draft opinions on the application within 10 months of the date that ECHA receives the payment of the related fee. This draft opinion shall take into consideration further information submitted by third parties, in particular on alternative substances or technologies, through the public consultation process. Before becoming final, applicants are given the opportunity to provide comments on the draft opinions. The ECHA Secretariat supports the rapporteurs of the Committees in developing opinions, it coordinates the process through which comments can be submitted and forwards final opinions to the Commission for the decision-making process.

The first applications to authorise the use of any of these substances are expected to be submitted during 2011. The original estimates of the Commission suggested that the number of authorisation applications would grow by up to 400 per year. ECHA reassessed this estimate in late 2010 concluding that the actual number, although still uncertain, will most likely follow this growth path but with a one-year delay. The estimates will be refined on the basis of the experience obtained with the first substances to be included in the authorisation list. ECHA is also planning to provide support for potential applicants in advance of their actual submissions to ensure that applications include all relevant information.

3.3.2 Restrictions

A restriction is any condition for, or prohibition of, the manufacture, import, placing on the market or use of a chemical. New restrictions can be introduced, or existing restrictions can be amended, when there is an unacceptable risk to health or the environment which needs to be addressed on an EU/EEA-wide basis. Any such decision has to take into account the socio-economic impacts of the restriction, including the availability of alternatives. New restrictions will be included in Annex XVII to the REACH Regulation, which already includes 'old' restrictions adopted under the Limitations Directive[12] that the REACH Regulation replaced on 1 June 2009.

[12] Directive 76/769/EEC.

The restrictions process is initiated by a notification of intent to prepare a scientific dossier. Restriction dossiers can be prepared by a Member State or by ECHA at the request of the Commission. The dossiers have to include, among other things, information on the hazards and risks which give rise to concern, available information on alternatives, and justifications that action is needed on an EU-wide basis and that a restriction is necessary beyond any measure already in place.

RAC and SEAC give their opinions on the suggested restrictions within 9 and 12 months respectively. During that period, interested parties have the opportunity to comment on the dossier and the draft opinion of SEAC. ECHA will coordinate these consultation processes. The opinions and supporting documentation delivered by ECHA to the Commission will need to be scientifically sound and comprehensive to allow the Commission, if appropriate, to draft an amendment to the REACH Regulation, within three months of receiving the opinions.

The original Commission estimate was that ECHA would process a growing number of restriction dossiers submitted by Member States. Based on the information that ECHA has received so far, there are no indications that the number is going to increase from the current four dossiers per year although this situation may evolve once the information from the first registration deadline has been assessed by Member States in more detail. It is also possible that more dossiers for groups of substances will be submitted, following the example of a first notification of this type that was received in autumn 2010. ECHA therefore continues to plan for handling up to ten dossiers per year. Subject to possible requests from the Commission, ECHA is prepared to develop up to three restriction proposals annually from 2012-2014.

Based on the experience in opinion making for the first four Annex XV restriction reports, ECHA plans to issue additional information, advice and where relevant, training, to Member States to support them in the preparation of restriction proposals.

3.3.3 Other Activities Related to Risk Management Measures

Socio-economic Analysis

ECHA will continue its activities to improve the knowledge of methodologies and estimates of the health and environmental impact of identified risks, for instance through better understanding of the population at risk. ECHA will also develop methodologies and collect estimates of disability/quality adjusted life years and willingness-to-pay to avoid negative health impacts from substances. Furthermore, ECHA will continue its activity to increase its knowledge and capability of assessing abatement and other costs related to restricting or not authorising the use of substances. All these activities will help Member States and ECHA in the preparation of Annex XV restriction reports as well as in the opinion making of RAC and SEAC on incoming restriction proposals and applications for authorisation.

Exposure Scenarios

ECHA has developed, over the past few years, practical examples of exposure scenarios and exposure estimations for different uses of substances. In the coming years, further examples will be developed to increase the capacity of industry and Member States to develop good quality exposure scenarios, for instance for substances used in mixtures, for dispersive use of substances and for substances in articles. ECHA will also work on increasing its internal capability to accurately evaluate information presented in the CSRs that arrive as part of the registration dossiers. External capacity building will include cooperation with industry but also cooperation with national authorities administering the implementation of REACH to assist them in the evaluation of the implementation of risk management measures required to guarantee the safe use of chemicals.

Substances in Articles

Substances in articles may pose risks to human health or the environment during their service-life or waste stage and warrant action at EU level. The obligation of article producers and importers, under specified conditions, to register or notify substances that are on the Candidate List in their articles starts in 2011 and the number is expected to grow in this planning period. Other REACH processes (registration, evaluation, authorisation) will also generate information relevant for the work on substances in articles, although the main focus of these processes is on the use of substances on their own and in mixtures.

During this planning period ECHA will develop approaches and tools for using this REACH information and other available information to identify cases where further risk management on substances in articles, in particular restrictions, may be needed. This will include the screening of registration data and the development of generic criteria as to when to require registration of substances in articles. ECHA will also prepare for the legal obligation to conclude, after the sunset date, whether substances included in the authorisation list pose a risk to human health or the environment in articles. While the restriction process is the main instrument under REACH to address the risks related to substances in articles, the information generated by REACH processes can also be used when considering and designing measures under other relevant Community legislation. To ensure effective use of the information and regulatory coherence, it is important to develop well-functioning channels for transferring such information to the implementation of other legislation.

Identification of Substances for Further Work on Risk Management

The effective use of the Candidate List as the first step of the authorisation process and as a trigger for information requirements on substances in articles requires identification of those substances for which the inclusion in the Candidate List is an appropriate EU wide measure. The same applies to the effective use of restrictions and other EU-wide measures. To this end ECHA will, together with the Member States, further develop screening approaches, using as one of the new information sources the registration dossiers that have arrived by the first and second registration deadlines. Where the conclusion from screening is that further information is needed to confirm or refute the concern, use of the evaluation process can be considered.

Initiating action at EU level, including the use of the restriction or authorisation mechanisms under REACH, requires resources from the authorities and industry. Furthermore, initiating one process will affect the possibility of and the willingness to take other actions. Therefore, to ensure that the different EU-wide measures are used in a manner which effectively contributes to elimination or reduction of risks related to the use of substances, the most appropriate risk management action to address the identified concern needs to be assessed early in the process. The Commission, together with ECHA, has created an approach and platform to stimulate discussion and cooperation between Member States on the most appropriate risk management options. ECHA will continue providing support to the Commission and Member States, for instance through further improvement of formats and guidance and, if needed, training.

3.4 Classification and Labelling

Priorities 2012-2014

- Maintain the Classification and Labelling Inventory and optimise the user friendliness of the Inventory;
- Facilitate the process for industry to align diverging classifications for the same substances;
- Manage effectively proposals from MSCAs and industry for harmonised classification and labelling of certain hazardous substances, as well as active substances used in plant protection and biocidal products;
- Decide on requests from industry on the use of alternative chemical names of substances in mixtures.

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

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

Maintenance and Further Development of the Classification and Labelling Inventory (C&L Inventory)

By early 2011, industry was required to send in notifications for all hazardous substances and substances subject to registration, if placed on the market before or on 1 December 2010. More than three million notifications were submitted and stored in the C&L Inventory. A public version containing the non-confidential information will be made available on ECHA's website in 2011 and the user friendliness of the technical system will be improved by the end of that year.

It is anticipated that several thousands of new notifications will continue to arrive each year and that existing entries to the Inventory will need to be updated by industry. Therefore, a major task for ECHA will be to maintain and improve the user friendliness of the Inventory. The information has to be available for the public, industry and the Member States in a manner that is as user friendly as possible while ensuring that confidentiality is maintained. Major efforts are needed to enable management of the complex database with minimum manual intervention but without compromising the correctness and reliability of the information in the database.

While multiple notifications of the same substance may be made by different manufacturers or importers, with the potential for differences in the classifications notified, over time this should provide the stimulus for suppliers to liaise with each other in order to agree on a single entry. The fulfilment of the obligation for industry to come to an agreed entry may be hampered by the fact that the Inventory does not reveal the identity of the companies. Having explored in 2011 options to bring companies placing the same substances on the market into contact with

each other, ECHA will implement some initial measures to assist companies seeking common entries in the Inventory.

ECHA will ensure that industry remains aware that for substances placed on the market for the first time after 1 December 2010, notifications of the classification and labelling information are to be submitted to ECHA within 1 month of the date of placing on the market.

Handling Proposals for Harmonised Classification and Labelling (C&L)

Member State Competent Authorities (MSCAs) submit proposals for harmonised C&L for substances that are CMRs, for respiratory sensitisers, and, if justified, for substances that have other hazardous effects with a justification for the need of action on an EU-wide basis. For active substances used in plant protection products or biocidal products, full harmonisation of the C&L is required. The procedure for submitting the proposals is comparable to that described under Activity 3 above for identifying SVHCs.

In addition, manufacturers, importers and downstream users may submit proposals for harmonised C&L for hazard classes of substances for which no harmonised entry exists, which will be particularly relevant for cases where companies placing on the market the same substances cannot agree among themselves on the correct C&L.

The dossier from the MSCA or the manufacturer, importer or downstream user provides the scientific basis for evaluating whether a substance fulfils the criteria for classification. The proposal is published by ECHA for comments from the other MSCAs and parties concerned. Subsequently, it is discussed within the RAC, which delivers an opinion on the proposed C&L. The opinion of the RAC is forwarded to the Commission. Where the Commission finds that the harmonisation of that substance is appropriately justified, it will submit a decision via comitology, resulting in a harmonised C&L for that substance.

ECHA expects about 60 proposals for harmonised classification to arrive each year in this reporting period, which will be submitted for opinion to RAC following a public consultation process.

Evaluating Requests for the Use of Alternative Chemical Names

Manufacturers, importers and downstream users of substances in mixtures may submit a request to ECHA for the use of alternative “generic” chemical names in cases where it can be demonstrated that the disclosure of the identity of the substance puts the confidential nature of the business at risk. For each request, ECHA will evaluate within six weeks whether the criteria for the use of the alternative name are fulfilled. ECHA expects to receive an increasing number of requests each year (up to 200 requests in 2014) during the reporting period.

Preparations for the Changes Entering into Force 1 June 2015

After 1 June 2015 industry will need to comply with the CLP Regulation not only with regard to substances but also to mixtures and will no longer be allowed to classify substances according to the previous legislation. Preparatory work for ensuring that industry is well-informed before these changes become effective will start during 2014.

3.5 Advice and Assistance through Guidance and the Helpdesk

Priorities 2012-2014

- Delivery of high-quality guidance documents while ensuring buy-in by stakeholders;
- Review of the guidance on information requirements and chemical safety assessment, integrating experience from the 2010 registration deadline in advance of the 2013 registration deadline;
- Further improve accessibility to these guidance documents;
- Develop guidance on biocides;
- Provision of advice and assistance to industry as well as harmonised answers across the EU, via the network of national helpdesks, on the REACH, CLP and Biocides Regulations.

3.5.1 Guidance

Guidance describes commonly agreed ways for industry and MSCAs to fulfil their obligations under the REACH and CLP Regulations, with the aim of facilitating the implementation of these regulations. Guidance serves as an accurate reference framework, helping companies and industry associations to develop tailor-made and sector-specific solutions to fulfil obligations that both pieces of legislation place on them. With regard to information requirements, ECHA guidance follows the balance in the legislation which aims at generating reliable and high quality information to ensure the safe use of substances while minimising the need for additional animal testing.

Based on the feedback collected and work initiated in 2010-2011, relevant parts of the guidance will be updated for the 2013 deadline and new feedback will be sourced afterwards for the next deadline before starting further updating work.

ECHA aims at freezing the development of registration guidance sufficiently early in order to ensure that registrants can work on the basis of stable and translated guidance documents published at least 6 months before the 2013 registration deadline.

The existing guidance will also be kept aligned with new developments on nanomaterials, and subject to progress made by the Commission, new guidance may be developed throughout the 2012 -2014 timeframe.

In order to ensure the broadest possible acceptance of guidance, ECHA has developed a Consultation Procedure on Guidance to ensure transparency in the process of updating/developing guidance, while maintaining close stakeholder involvement and access to high-level expertise. For this purpose, ECHA maintains a comprehensive database of scientific experts and stakeholder organisations.

The accessibility of guidance will be improved via explanatory documents and guidance access tools, such as *Frequently Asked Questions*, *Fact Sheets*, *Guidance in a nutshell*, *Practical guides* and dedicated internet pages for each REACH and CLP process, the REACH Navigator, and via REACH terminology development in 22 Community languages.

3.5.2 Helpdesk

The ECHA Helpdesk gives advice on provisions of the REACH and CLP Regulations as well as providing support in relation to ECHA's software applications IUCLID 5, Chesar and REACH-IT.

In 2012-2014, an important part of the work of the ECHA Helpdesk will be to promote a common understanding of the REACH and CLP Regulations with a view to providing harmonised answers to industry by national REACH and CLP helpdesks. ECHA will continue strengthening its cooperation with the national helpdesks with a special focus on making the HelpNet activities more proactive in delivering the best possible service in a timely manner. Besides the harmonisation of answers to questions on the REACH and CLP Regulations, further training events will ensure capacity building at the national and European level, and the further development of common knowledge that is easily accessible for all relevant actors.

More difficult questions related to the CLP Regulation are expected, triggered especially by the publication of the C&L Inventory in 2011. The subject areas of the ECHA Helpdesk will cover all REACH processes, i.e. registration, evaluation, authorisation and restrictions, as well as downstream user activities. In 2012, it is expected that the number of questions on authorisation will progressively increase.

From the end of 2012, the workload is expected to increase before the second deadline for registration under REACH in 2013, leading to a peak in the number of questions that year. The ECHA Helpdesk will be proactive in adapting its activities to take account of such fluctuations.

The ECHA Helpdesk is also in charge of coordinating topical training events on REACH and CLP – and in future, potentially also on biocides – matters for external audiences (such as MSCAs etc.). This activity will remain needs-based, will seek synergies with training events organised in more specific contexts, such as through the HelpNet for national helpdesks etc., and will be planned on an annual basis. This activity will make use of e-learning tools (such as webinars) which allow for wider dissemination of training content.

3.6 Scientific IT Tools

Priorities 2012-2014

- Further develop ECHA scientific applications to extend IT support to all business processes shifting focus from the submission processes to the decision-forming/decision-making processes in evaluation and risk management;
- Enhance integration of the scientific applications by consolidating a common and consolidated models for data management, security management, users management and communication;
- Enhance functionalities for accessing, retrieving and querying ECHA databases taking into account the needs of different target audiences: MSCAs, enforcement authorities, stakeholders, and the general public;
- Build business intelligence systems on ECHA databases to support scientific work;
- Enhance IT support for collaborative work involving ECHA and external stakeholders (Committees, MSCAs, Enforcement authorities, Industry etc.).

ECHA has developed a wide range of IT systems to support the REACH and CLP operations. In 2011 the focus has been moving from submission processes to supporting the workflows starting after completion of the submission for the first registration deadline. These workflows are largely related to the decision forming/decision making in evaluation and risk management. In 2012 the coverage of IT systems applied in these processes will be incremented. An area of development will then be to enhance the integration of the IT tools by consolidating integration models for data management, for security and access management and for communication between industry, ECHA, Member States and the Commission.

A strong accent on integration will be the basis for enhancing IT support for accessing, retrieving and querying ECHA databases, taking into account the needs of different target audiences. A major focus will remain to improve IT support for MSCAs in the performance of their tasks.

Having passed two critical milestones for the REACH-IT system at the end of 2010 and early 2011, with the handling of the first wave of registrations and of C&L notifications, ECHA will move into the 2012-2014 period with the experience gained from that work and will be in a position to efficiently prepare for the second registration deadline in 2013. In this context ECHA will particularly address issues identified in the feasibility and needs assessment carried out in 2011. The study will be conducted to get an overview of how to enhance SME communication with the Agency, including via its IT tools in the various EU languages.

Furthering the coverage of ECHA platform for document and record management system to most administrative workflows will continue in 2012-2014 and will be extended to collaboration processes mostly related to the work of the ECHA Secretariat and its Committees.

ECHA will analyse the C&L inventory to look for best approaches to improve its usability and the level of support achievable through IT to C&L harmonisation.

ECHA will also continue to develop or enhance a number of additional specialised applications, such as the Chemical Safety Assessment and Reporting tool (CHESAR), screening and predictive systems (e.g. the (Q)SAR toolbox), information retrieval and business intelligence systems applied to ECHA databases to help make better use of alternative computational approaches to animal testing.

Based on the experiences gained in 2010 ECHA will review its IT Manuals and revise them from the viewpoint of user-friendliness. Specific attention is given to the fact that the 2013 registrants will be smaller companies than 2010 registrants and have less resources and experience in using regulatory IT tools.

In parallel to new development, activities will also be dedicated to the operations and support of the existing systems to the agreed service levels.

3.7 Scientific Activities and Technical Advice to EU Institutions and Bodies

Priorities 2012-2014

- Establish ECHA's role as a leading European regulatory expert and provide methods, tools and other support in the areas of alternative testing methods and chemical safety assessment;
- Support the Commission in the further development of the REACH and CLP regulations;
- Maintain the network for collaboration and good relations with EU institutions and relevant bodies within the EU that are internationally active on chemicals;
- Develop further ECHA's capacity to provide scientific and technical advice in the areas of testing methods (including alternative test methods) and on nanomaterials.

In 2012-2014, ECHA will further enhance its co-operation with the EU institutions, in particular the European Parliament and the Commission. The scientific capacity of ECHA and its scientific committees have achieved a degree of maturity allowing the latter institution to request ECHA's input in questions of a scientific nature relevant to policy-makers.

ECHA will in particular provide appropriate advice to the Commission for the further development of the REACH and CLP Regulations, and any related legislation concerning chemicals, as well as measures related to their implementation.

In 2012-2014, ECHA will continue its co-operation with the Joint Research Centre (JRC) of the Commission. Co-operation with the Institute for Health and Consumer Protection (IHCP) will be particularly strengthened in the areas of alternatives to animal testing and Nanotechnology. Due to this co-operation ECHA will develop its capacity to provide the best possible scientific and technical advice in fast-advancing scientific areas such as *in vitro* and *in silico* testing methods, (Q)SAR methods and in nano-safety.

Chemical safety assessment (CSA) is a core element of REACH, as it describes the conditions of safe use of a substance throughout its lifecycle. Hence, it affects all REACH processes (registration, evaluation, restriction and authorisation) and related decisions, and works also as a link between REACH and other legislation. ECHA aims at further establishing the concepts and methods related to CSA in order to develop a consistent approach to CSA throughout the supply chain and provide adequate support to companies. This work will continue in the period of 2012-2014. It will also cover the further development of exposure estimation tools. In addition, ECHA will start developing methods for the assessment of difficult substances, degradation products and transformation products from substances reacting on use, and for developing exposure scenarios (ES) for the waste life stage based on the initial analysis carried out in 2011.

Under certain conditions REACH requires new testing of chemical substances with vertebrate animals in order to fill the data gaps in knowledge on the potential hazards of these substances. At the same time, it is also an aim of REACH to promote alternative methods for the replacement, reduction and refinement of methods based on animal testing while maintaining a high level of protection. In the EU, the Commission is responsible for the regulatory acceptance of new methods. ECHA provides scientific and technical support to these activities. Specifically, as more data on substances becomes available there will be more opportunities for registrants to rely on alternative testing methods such as *in vitro* methods and (Q)SAR (quantitative and qualitative structure-activity relationship) for the safety assessment of their substances. ECHA will promote the scientifically justified use of non-test methods. This will be achieved by taking into account already existing experience and advancements in *in vitro* approaches within Europe and at international level, further development and integration of non-test methods in internal procedures and by actively contributing to the further progress in this area.

Based on the priorities set out in the Work Plan developed in 2009, ECHA will further extend its internal capacities in the area of the characterisation, hazard and safety assessment and risk management of nanomaterials. ECHA will participate in various scientific and regulatory activities at EU and OECD level with the ultimate aim of developing appropriate guidance to industry, as well as to be able to effectively evaluate registration dossiers that contain information on the hazards, risks and risk management of nanomaterials. With this in mind, ECHA and the Commission have set up cooperation agreements that will facilitate the transfer of know-how in both directions.

ECHA will also continue its specific reporting activities to the Commission as required by REACH during the 2012-14 period. ECHA will in particular draw up the second three-year report[13] for the Commission on the status of the implementation and use of non-animal test methods and testing strategies used to generate information on intrinsic properties and for risk assessment to meet the requirements of the REACH Regulation. Furthermore, ECHA will contribute to the first review of the Agency, which is due by June 2012. In addition, and if so requested by the Commission, ECHA will prepare a contribution to support the review being carried out by the Commission related to REACH in accordance with Art. 138 of the Regulation and in particular concerning the endocrine disrupting substances in relation to the authorisation procedure under (Art.138.7).

The REACH Regulation provides for a horizontal framework which applies to most of the chemical substances manufactured in or placed on the European market. On many occasions, therefore, ECHA's work affects European Union bodies involved in sector-specific legislation on the assessment and management of the risks from chemicals. For this reason, the REACH Regulation requires ECHA to cooperate with these entities, in order to avoid duplication of work and conflicting scientific opinions, and in particular with the European Food Safety Authority

[13] REACH Regulation Art. 117(3).

(EFSA), and with the Commission's Advisory Committee on Safety, Hygiene and Health Protection at Work – where worker protection issues are concerned. Through this work the Agency contributes to creating synergies with other EU legislations and will continue to do so.

There is also cooperation with the European Agency for Safety and Health at Work (EU-OSHA, the European Medicines Agency (EMA), the European Environment Agency (EEA), the Commission's Joint Research Centre (JRC), and the Commission's non-food Scientific Committees. In addition, contacts will be reinforced with research policy and funding bodies, including the Commission, with the aim of communicating the scientific needs arising from the REACH Regulation, or receiving the results of science projects that may have regulatory implications. Where appropriate, ECHA will structure these partnerships, e.g. by creating a network for collaboration with similar bodies in the EU or developing further Memoranda of Understanding.

3.8 Biocides

Priorities 2012-2014

- Build up ECHA capacities to deal with new responsibilities under the future Biocides Regulation and prepare the implementation thereof;
- Ensure effective start of implementing the new tasks assigned to ECHA under the Biocides Regulation.

The European Commission adopted in June 2009 a proposal for a new Regulation concerning the placing on the market and use of Biocidal Products with the aim of revising the existing regulatory framework (Biocidal Product Directive 98/8/EC). 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.

Biocidal products contain or generate active substances and are used against harmful organisms such as pests and bacteria. They include household products such as disinfectants, rodenticides, repellents, and insecticides. Others are used in more industrial applications, such as wood and material preservatives, anti-fouling paints, and embalming products to avoid damage to natural or manufactured products.

In the proposal, the Commission has foreseen a new role and additional tasks for ECHA in the evaluation of active substances and the authorisation of biocidal products. The proposal is currently in the legislative process, with its entry into force being possibly as early as 2012 and its application starting from 2013. Within the period 2012-2014 ECHA has to therefore ensure that it can start implementing the new biocide tasks in an efficient and timely manner once the revised legislation has been adopted and ECHA has been given additional resources to cope with these tasks. The description of future ECHA tasks below is based on the political agreement reached by the Council in December 2010. The description of the tasks and their impact will be revised based on further progress in the legislative process.

3.8.1 Implementation of the Regulatory Processes

Evaluation and Approval of Active Substances

Active substances can be used in bioicidal products if they are approved and thereby listed in Annex I of the future regulation. ECHA will be responsible for receiving applications for approval of active substances. ECHA will verify that the application is submitted in the correct format and will collect the application fee. Thereafter the Member State Competent Authority will carry out the scientific evaluation of the application. ECHA will receive the assessment report from the Competent Authority and a new committee (Biocidal Product Committee) of ECHA will prepare an opinion on the report. The committee's opinion will be submitted to the Commission, who will decide on the application for approval. Applications for renewal will be reviewed following a similar procedure.

If the active substance is a candidate for substitution, ECHA will open a public consultation to receive information from third parties e.g. on possible alternative substances.

ECHA will also take over the Commission responsibility of managing the Review Program of existing active substances under the current Biocidal Products Directive.

ECHA will prepare itself to receive and manage applications as from 2013 and manage the current Review Programme as from 2014. The foreseen number of applications for approval is expected to be relatively low, whereas the number of dossiers in the Review Programme is over 500.

Evaluation and Authorisation of Biocidal Products

Biocidal products can be marketed only if they are authorised and they must contain only approved active substances. Authorisation processes can vary depending on the case and at what level the company wants to apply for the authorisation. The different possibilities include: a simplified procedure (for 'low-risk' products), national authorisation, mutual recognition of national authorisations, or Union authorisation. ECHA will play a role in the mutual recognition of individual products. ECHA will provide the Secretariat for a new coordination group of Member States authorities which will examine questions related to mutual recognition. Eventually, the Commission may request ECHA's opinion if the coordination group cannot resolve disagreements between Member States. In the Union authorisation procedure the applications will be submitted to ECHA which will verify that the application is submitted in the correct format and collect the application fee. The evaluation by an MSCA, the ECHA opinion and the authorisation by the Commission follows the same steps as for active substances. The scope of the EU authorisation is foreseen to start with seven product types and will widen to other product types in 2020 (with certain product types exempted from EU authorisation).

Data Sharing, Free Riders, and Technical Equivalence

Similar to REACH, the proposed Biocides Regulation will also contain provisions about facilitating data sharing with a view to avoiding unnecessary animal testing. In respect to Biocides, ECHA will also have a limited arbitrator role through the possibility of granting an applicant the right to refer to a study with vertebrate animals even without agreement of the data owner. ECHA may also allow an applicant to refer to data owned by another company for which the data protection period has expired, provided that the technical equivalence of the active substances could be established. These Agency decisions will be appealable.

The Regulation will also force all companies marketing active substances in the EU to apply for approval for them either by sending a separate application, or joining the application of another applicant. This procedure is meant to solve the problem of so called free riders, i.e. companies

that so far have been able to continue marketing biocidal active substances without an application for approval and related investment. ECHA will have to publish the list of applicants who wish to continue marketing in the future.

To promote the above described processes there will be a procedure for establishing technical equivalence of active substances. For this, an application with a fee will have to be sent to ECHA, who will decide whether the active substances in question are considered to be technically equivalent. This decision will also be open to appeal. ECHA will need to prepare for these tasks, and will also need to provide guidance for industry in implementing these procedures.

Register for Biocidal Products

ECHA will have to establish and maintain a Register for Biocidal Products. This register will be an information system for industry to generate and submit their applications, and for applicants, ECHA, Member States, and the Commission to have access to the applications and to exchange information related to them and to authorisations. Non-confidential information in the register will be made publicly available by the Agency.

It is crucial that ECHA starts preparing for the IT aspects of biocide tasks as early as possible, in order to be able to deal with the first applications possibly from 2013 onwards. Given the extensive needs, this IT development will be a gradually evolving multi-annual project.

In 2012 and 2013 ECHA expects to modify its IT systems to support the new biocides legislation, extending the current databases and functionalities in an integrated way as far as possible to benefit from common mechanisms and building blocks.

Support to Industry

ECHA needs to provide support to industry which is similar to that which it provides under the REACH and CLP Regulations. Thus guidance and helpdesk services on biocides will be added to the scope of its work. It is crucial for ECHA to start building up expertise in relation to this Regulation as soon as possible and to prepare for the hand over from the Commission of the existing guidance documents related to biocidal substances and products.

3.8.2 ECHA's Bodies and Cross-cutting Activities

The Biocidal Products Committee

As part of the implementation of the new tasks under the future Biocides Regulation a new Biocidal Products Committee (BPC) will be established. It will be responsible for preparing Agency opinions in particular on applications for approval for active substances, identification of active substances that are candidates for substitution, and applications for authorisation of Biocidal Products, including the periodical renewal of above applications.

Each Member State will be entitled to appoint a member to the BPC. The modalities and operational rules of the BPC will follow very closely those of the other ECHA Committees. As the workload on biocides will strongly increase over the years there will also be a possibility to create parallel committees by a decision of the Management Board.

ECHA will have to establish the new Committee very soon after the entry into force of the Biocides Regulation, and prepare it to carry out its tasks and dealing with the rapidly growing workload.

Other Cross-cutting Activities

Under the proposed Regulation, the Board of Appeal will be competent to decide on appeals against certain ECHA decisions adopted pursuant to that Regulation. Prior to the date of application of the Regulation, the Board of Appeal will be required to adapt its working procedures to accommodate these new tasks.

ECHA will need to set up new communication activities to support the effective implementation of the new tasks. This will require specific awareness raising campaigns, particularly soon after the entry into force of the new Regulation, as well as designing tailor-made communication to specific industry sectors and stakeholders to inform them about the new rules and ECHA's role.

An extension of ECHA's international activities to cover OECD biocides program is foreseen.

3.8.3 Management, Organisation and Resources

New biocides tasks of ECHA will also have an effect on ECHA's general governance activities such as management, planning and reporting, quality control, security, HR, and finance. Setting up and operating a proper activity-based budget management and cost-accounting system is a key objective in order to make sure that subsidies and/or fees received under this regulation are not mixed up with the activities and revenues coming from REACH and CLP. While the active recruitment period for REACH and CLP is calming down, another challenging exercise is ahead in order to ensure the rapid recruitment of high quality staff, especially during the years 2012-2014. A major new challenge will be to decide from which point in time ECHA will need additional space to cater for the additional staff needs resulting from the final Biocides Regulation, which is expected to allocate more tasks to ECHA than originally foreseen by the Commission when the last modifications to the lease were agreed.

3.9 PIC Regulation

Priorities 2012-2014

- Prepare for the new responsibilities under the future PIC Regulation and begin the preparation for the implementation thereof, provided that additional resources are made available by the Commission;
- Assuming that the legislation enters into force well before 2014, start implementing the revised PIC Regulation.

The Commission is currently preparing a recast of the so called PIC Regulation (Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals) implementing the Rotterdam Convention into EU law, which should be adopted by the College before the Summer 2011. The Regulation applies for banned and severely restricted chemicals and provides for information exchange mechanisms regarding the export and import of these chemicals. These mechanisms include the export notification for the banned and severely restricted chemicals listed in the Annex of the Regulation. It also contains a Prior Informed Consent (PIC) procedure for chemicals that are specifically identified as PIC chemicals under the Rotterdam Convention, and which also are listed in the Regulation. The export of PIC chemicals requires an explicit consent of the importing country.

It is expected that certain tasks regarding the implementation of this Regulation will be transferred from the Joint Research Centre of the Commission to ECHA in the recast and hence it is expected that ECHA will provide the Commission, on request, with technical and scientific input and assistance with respect to the role of the Commission as common designated national authority of the European Union and to the participation of the Union in the Convention.

The consequences for ECHA's functioning are similar to those related to implementing the Biocides Regulation, although on a much smaller scale. ECHA will first prepare to develop IT tools and working procedures to process dossiers resulting from this legislation and then start to implement these processes. It is important for ECHA that the preparatory activities and entry into force date does not coincide with REACH/CLP deadlines and follows the biocides start-up.

4 ECHA'S BODIES AND CROSS-CUTTING ACTIVITIES

4.1 Committees and Forum

Priorities 2012-2014

- Deliver opinions on time, to allow the Commission or the Executive Director of ECHA to reach regulatory decisions on a legally and scientifically sound and well-argued basis;
- Provide a solid basis for decision making by delivering RAC and SEAC opinions as well as MSC agreements and, in particular, ensure that the Candidate List of substances of very high concern is updated biannually and that ECHA's draft decisions on testing proposals and compliance checks are of high scientific quality and provided in a timely and transparent manner;
- Significantly promote the harmonisation of REACH and CLP enforcement, in the Member States, by coordinating of Forum's harmonised enforcement projects and by facilitating communication amongst enforcement authorities.

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

Chapters 4.1.1 and 4.1.2 describe the activities of the three ECHA Committees in a general manner. The type and number of throughputs to be handled by the Committees is directly determined by the various REACH and CLP processes and driven by the expected number of dossiers relating to Evaluation, Authorisation and Restrictions and C&L Activities. Chapter 4.1.3 refers to the work of the Forum.

4.1.1 RAC and SEAC

The members of these two Committees are experts appointed by ECHA's Management Board on the basis of proposals from the Member States. Both Committees can also co-opt a number of independent scientists as additional members because of their specific competences.

The Risk Assessment Committee (RAC) has to deliver opinions on: 1) proposals for harmonised classification and labelling of substances; 2) proposals for restrictions of substances; 3) applications for authorisation; and 4) any other question that arises from the operation of the REACH Regulation relating to risks to human health or the environment.

The Socio-Economic Analysis Committee (SEAC) has to give opinions on: 1) the availability and technical and economic feasibility of alternatives and on proposed restrictions and their socio-economic impact; 2) the socio-economic factors related to applications for authorisation; and 3) any other question that arises from the operation of the REACH Regulation relating to the socio-economic impact of possible legislative action on substances.

During 2012-2014, the ECHA Secretariat will continue to prepare and to chair Committee meetings and *ad hoc* working groups in order to facilitate their coordination. Good coordination is particularly important when dealing with restriction proposals and authorisation applications where a common understanding amongst both Committees is essential. Dealing with the different legal deadlines represents an additional challenge. As required, the Secretariat will provide support to the Committee members who have been appointed as (co-)rapporteurs for specific dossiers. In addition, the Committee members need full scientific and technical support from the Member State Competent Authorities, especially when serving as (co-)rapporteurs.

The number of Committee opinions will depend on future dossiers and it is expected to rise continuously, even dramatically. The number of plenary meetings is estimated to be six per year in the case of the RAC, and four to five in the case of the SEAC. It is already discernable that more than six plenary meetings a year will not be feasible for the Committee members or for the Secretariat. In the years 2012–2014, both Committees are expected to hold an increasing number of working group meetings to support the rapporteurs and to prepare the conclusions of the Committee. The Committees will therefore need to adapt their working procedures to be able to cope with a sharply increasing workload as the number of authorisation applications in particular is expected to grow significantly as of 2012. In addition, RAC and SEAC will need to consider the feedback received from the Commission, Member States, stakeholder organisations and other concerned parties on their opinions and should review their processes on the basis of this acquired experience.

Coordination with other EU scientific committees, dealing with the same or similar substances under different regulatory frames will represent an additional challenge; with early identification of potential divergences in opinions being a critical issue. In addition, the hazard-based conditions imposed by the plant protection products legislation, and also foreseen for the Biocidal Products legislation currently under discussion, will need to be specifically addressed in the RAC work programmes. As a consequence, the coordination of RAC with the scientific committees involved in risk assessment supporting other Agencies and European Union bodies will need to be expanded, covering not only the identification of potential divergences, but also developing procedures for cooperation among Committees working on the basis of the same dossier.

4.1.2 MSC

The Member State Committee (MSC) consists of members appointed by each Member State. Its core function is to resolve potential differences of opinion on draft decisions for dossier evaluation and substance evaluation, and on proposals for identification of substances of very high concern (SVHC). Where the MSC fails to find unanimous agreement, its opinion will be forwarded to the Commission for a final decision. The Committee also gives its opinion on ECHA proposals for prioritisation of SVHCs for authorisation, and on the Community Rolling Action Plan on substances to be evaluated.

The tasks of the MSC require detailed scientific deliberations on a broad range of scientific fields – ranging from the best use of different test methods for obtaining information on the hazards of substances and the assessment of the environmental persistence of substances, to agreeing on priorities for SVHCs to be included in the “authorisation list”. That is why members are assisted in each meeting by experts from their competent authorities.

It is currently estimated that 20-30% of the draft decisions will require agreement to be sought in the MSC. Therefore, it is expected that between 2012 and 2014, the MSC will be informed of 60-100 draft decisions annually and will potentially seek unanimous agreement on them, once at least one Member State submits respective proposals for amendments to the draft decisions. From 2012 to 2013, dossier evaluation draft decisions will form a major part of the

workload for the MSC. The Committee is expected to start work on substance evaluation in 2012.

Furthermore, the Candidate List of SVHCs will need to be regularly updated and an opinion given at least every second year on ECHA's draft recommendation on inclusion of substances in Annex XIV ("the authorisation list"). This increasing workload will have a corresponding impact on the number of Committee meetings and on their length.

4.1.3 Forum

The REACH Regulation requires each Member State to set up a system of official controls and other activities as appropriate to the circumstances. Effective, harmonised and equal enforcement throughout the EU is of crucial importance for the credibility and success of REACH. The Forum for Exchange of Information on Enforcement is the coordinating network of EU/EEA Member States authorities responsible for the enforcement of the REACH and the CLP Regulations. The Forum is an integral part of ECHA and plays an essential role in ensuring harmonised enforcement activities; the REACH Regulation places a number of duties on the Forum. The Forum functions as a network for Member States to exchange information on and to coordinate their enforcement activities of REACH and CLP. Member State representatives are in charge of chairing the meetings and the working groups while being supported by a secretariat of ECHA staff.

As the implementation of REACH will continuously gather momentum with the increasing volume of data held by ECHA and the growing number of decisions and opinions taken within the different REACH processes, the ECHA Secretariat will devote increasing attention and effort to promoting enforcement and to ensuring that the Forum fulfils its duties effectively.

The impact of the conclusions or initiatives of the Forum will depend upon the involvement of the members and their ability to mobilise the resources of the national authorities responsible for enforcement. As ECHA believes that the success of the REACH and CLP Regulations depends upon effective enforcement in the Member States, the Secretariat will step up its efforts to support the Forum in its harmonised enforcement activities, to the extent possible.

The Forum works in accordance with the provisions set out in the REACH Regulation and its Rules of Procedure. The Forum undertakes activities included in a regularly updated three-year Forum Work Programme, available on the ECHA website, which are in compliance with its legal mandate. The core documents are the "Strategies of Enforcement of REACH" and the "Minimum Criteria for REACH Inspections". The Forum focuses its activities on the clarification of the tasks of REACH enforcement officers, and the elaboration of best practice. The involvement of the Forum in a number of coordinated harmonised enforcement projects, e.g. on enforcing the "no data, no market" rule with regard to (pre-) registration or on supply chain-related obligations of REACH vis-à-vis substances in mixtures that are prepared by formulators, will be of particular importance.

The Forum will regularly update its enforcement strategies and minimum criteria for REACH enforcement by undertaking harmonised projects and preparing guidance and training materials for local inspectors. Another tool for inspectors which will be developed further is RIPE (REACH Information Portal for Enforcement), which has been developed in accordance with their needs and will be expanded with new features. In addition, it will cooperate with RAC and the SEAC to give advice on the enforceability of proposed restrictions on substances. The activities of the Forum will be conducted with good coordination when dealing with restriction proposals, taking into account the dialogue with the Committee members and the questions and opinions of RAC and SEAC. The Forum will have an open session with stakeholders once per year to discuss specific enforcement-related topics.

To increase the effectiveness of the harmonisation of enforcement the Forum will continue to develop information portals and exchange tools to facilitate communication amongst the enforcement authorities until 2013. Activities regarding the coordination of the exchange of inspectors and study visits will stimulate and intensify, from 2012 onwards, the information exchange. This will be an asset to the work of the Forum. At the same time the Forum will continue to develop and implement in 2012 indicators to allow effective measurement of the progress of the work of the Forum.

4.2 Board of Appeal

Priorities 2012-2014

- Tackle the lodged appeals, in particular on more complex scientific topics deriving from dossier evaluations;
- Based on the additional experience gained during this period, provide further input to the Commission for the purposes of adjusting the Rules of Procedure after the first few years of experience in order to enhance the procedural effectiveness and efficiency of the appeal system. This may also imply making recommendations to better match the organisational structure of the Board with the emerging workload characteristics;
- Provide adequate legal redress to potential appellants following the 2013 registration deadline when a much higher share of the registrations is expected to be introduced by SMEs.

The Board of Appeal is an integral part of ECHA but takes its decisions independently. It currently consists of a full-time Chair and two full-time members, who may not perform any other duties in ECHA. Additional and alternate members have been appointed and can be called upon, on a part-time basis, to cope with fluctuations in the volume of work and absences of the full-time members. The members of the Board of Appeal are appointed by ECHA's Management Board on the basis of a list of candidates proposed by the Commission. The Board of Appeal is assisted in its functions by the Registry.

The Board of Appeal is responsible for deciding on appeals lodged against certain decisions taken by ECHA. The decisions against which an appeal may be lodged include rejections of registrations, data sharing, examinations of testing proposals, compliance checks of registration dossiers, substance evaluations, and exemptions from the general obligation to register for product and process orientated research and development (PPORD).

The number of appeals lodged before the Board of Appeal will depend upon the number of decisions taken by ECHA and the subsequent decisions of affected parties as to whether or not to appeal. Consequently, the Board of Appeal cannot itself define its own workload but must address all the appeals brought before it. Thus, the baseline figures for appeals used for resource planning for the period 2012 – 2014 are derived from a hypothetical relatively steady reference scenario.

The Board of Appeal has to be able to take high quality decisions in a timely manner without developing major backlogs and to build up a consistent body of case-law. It is expected that a much higher share of registrations before the 2013 deadline will be introduced by SMEs than was the case before the 2010 deadline. It therefore has to be anticipated that, in the aftermath

of the 2013 registration deadline, any appeals would to a great extent reflect the typical problems SMEs may have with registrations.

It is foreseen that from 2012 onwards appeals will be focused more on dossier and substance evaluations. This gradual shift probably implies that the scientific complexity of cases will increase. It will also require that the focus of the Board of Appeal's knowledge management is adapted accordingly.

During the 2012-14 period, the Board of Appeal will also need to analyse systematically, on the basis of experience gained, whether there are needs to modify the adopted ways of working or the procedures in place.

4.3 Communications

Priorities 2012-2014

- Continue to improve communications to better support the achievement of ECHA's objectives;
- Enhance communications, in particular, with the general public and with small and medium sized enterprises (SMEs) including by providing translations;
- Further develop and deepen the involvement of stakeholders in ECHA's work.

ECHA will continue to develop and improve the ways in which it communicates. The primary vehicles will remain online, ie. the website and intranet, both of which will be further developed. In 2012, the new website will allow ECHA's customers better access to the services that ECHA provides. It will have a simpler and clearer user interface and improved navigation, making it easier for customers to find what they are looking for. In addition, more targeted vehicles will include: Stakeholder Days, workshops, and other tailor-made events; press releases, news alerts, articles, interviews and press briefings; external newsletters; e-newsletters; and publications including the annual General Report and Work Programme.

A key audience will be the media, where ECHA's relationship with the press will be managed both proactively and reactively – seeking to explain ECHA's work to the media as well as responding in a helpful, timely and efficient way to enquiries and media reports.

In the aftermath of the first REACH registration deadline of November 2010, of the CLP notification deadline and – even more so after the second REACH registration deadline of May 2013 – the wealth of information held by ECHA on the properties of chemical substances is continuously and significantly increasing. Part of ECHA's communications work will consist of promulgating this knowledge beyond industry – looking more towards the general public and stakeholders.

As from 2011, the REACH dissemination database and C&L inventory on chemical substances will provide interested audiences with access to yet more information on chemicals and how to use them more safely that they have ever have before. This work will be continued in 2012 and beyond in partnership with ECHA's stakeholders and will be further enhanced from the end of 2013 as additional information from registration dossiers becomes available.

Communication with the general public and stakeholders will also be a priority as more substances of very high concern are identified and become subject to authorisation and restriction. Similarly, networking with stakeholders representing health and environmental interest groups will be prioritised.

A further key audience will be the media, where ECHA's relationship with the press will be managed both proactively and reactively – seeking to explain ECHA's work to the media as well as responding in a helpful, timely and efficient way to enquiries and media reports.

Building on the efforts planned for 2011, ECHA will maintain in 2012-2014 its practice of publishing documents of relevance particularly to the general public and to companies, in particular SMEs, in 22 official EU languages. This is enabled by dedicating considerable budgetary and operational means to ECHA's translation efforts.

ECHA will further develop its work on communicating chemical risks to the public. This work will be undertaken together with the Risk Communication Network and other EU institutions. ECHA will support them as they apply the new Risk Communication Guidance and will gather feedback on its use.

4.4 International Cooperation

Priorities 2012-2014

- Contribute to the REACH and CLP related work of the OECD and the UN;
- In close co-operation with the Commission establish and continue bilateral cooperation or working agreements with agencies similar to ECHA in major third countries;
- Acquaint IPA beneficiary countries with the operations as well as scientific work of various ECHA bodies, and support capacity-building measures in partner countries, in anticipation of their possible future accession to the EU (if further funds are made available from the IPA-programme).

Respective provisions in the REACH Regulation entrust the Management Board with deciding on the participation of third countries and international organisations in the work of ECHA [14], while other types of cooperation are based on requests from the Commission[15]. Moreover, Article 120 of the REACH Regulation stipulates that for any exchange of information received by the Agency with third countries or international organisations, a specific agreement between the EU and the third party has to be laid down.

It is foreseen that after the first registration deadline in 2010, ECHA will start receiving requests from third countries or international organisations for confidential data. Therefore ECHA plans, in cooperation with the Commission, to assess the need for and remit of possible confidentiality agreements, in the coming years.

[14] Articles 106 and 107.
[15] Article 77(2)(l).

4.4.1 Multilateral Activities

EU cooperation with international organisations in the field of chemicals policy falls within the remit of the Commission. ECHA provides support for these international activities at the request of the Commission.

ECHA has been asked to participate in a number of OECD activities which are of relevance to the implementation of the REACH and CLP Regulations: OECD activities in which ECHA will continue to be involved during the period 2012-2014 include contributing to the revised Programme on Cooperation on the Assessment of Chemicals which is steered by the Task Force on Exposure Assessment; to the OECD IUCLID Expert Panel, to the Working Party on Manufactured Nanomaterials, to the Test Guidelines Programme; to the work of the Task Force on Harmonisation of Classification and Labelling, and to the Task Force on Exposure Assessment, and the subgroups or projects under these, if appropriate.

ECHA will continue in particular to contribute to the project management of the Global Portal to Information on Chemical Substances (eChemPortal), the hosting of which will be ensured by ECHA from 2011, and the further development of the QSAR Toolbox, which will be rolled out in 2012[16].

In addition to OECD related activities, ECHA will continue supporting the Commission's work on the Stockholm Convention on Persistent Organic Pollutants (POPs). Another international activity for which the Commission is likely to continue requesting support from ECHA relates to the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). Considering the role and various tasks that the CLP Regulation gives to ECHA, the Agency expects to take part in the work of the UN ECE Sub-Committee of Experts on the GHS and its correspondence groups, whenever their work is of a scientific and technical nature.

4.4.2 Working Relations with Third Countries

In line with the general request from the Commission, ECHA organises or attends meetings and conferences with third countries on the requirements of the REACH Regulation, and supports the provision of adequate training in this regard (for instance, within the framework of TAIEX seminars). ECHA has been regularly charged with helping to improve cooperation between the EU and third countries, by participating in the exchange of best practice in fields covered by its remit. In line with the decision of the Management Board on a general approach to cooperation with third countries taken in December 2008, ECHA focuses particularly on EU candidate countries and potential candidates for EU accession. Overall, ECHA will intensify its relations with these countries in a manner commensurate with their alignment with the REACH Regulation.

As from 2010, ECHA has been able to draw on funds allocated from a transitional programme funded through the EU's external assistance Instrument for Pre-Accession Assistance (IPA). ECHA expects that further funds will be allocated to ECHA beyond 2011, when the current programme expires. This programme allows ECHA to acquaint IPA beneficiary countries with the operations as well as the scientific work of various ECHA bodies, and to support capacity-building measures in partner countries, in anticipation of their possible future accession to the EU.

[16] The version 1.0 of the OECD (Q)SAR Application Toolbox was released in March 2008. The version 2.0 including additional databases for grouping chemicals and for data gap filling was developed in collaboration with OECD and released in November 2010 under the new brand QSAR Toolbox. The software is available for free download at www.qsartoolbox.org

The large amount of data from the registration dossiers that ECHA will disseminate to the public in 2011 and the C&L inventory is likely to increase the attention and interest of third countries in the work of the Agency. The ECHA Secretariat will expand its cooperation with chemical safety regulatory authorities outside the EU/EEA area, mainly in OECD member countries with equivalent expertise as ECHA, and – where appropriate – formalise these relations by concluding Memoranda of Understanding in addition to those already concluded. However, any activity related to the exchange of data will only be possible on the basis of formal agreements referred to in REACH Article 120.

To ensure appropriate coordination with the Commission in these areas, ECHA will base its activities on an annual work plan agreed with the Commission. The Commission may at any time request further support from ECHA.

5 MANAGEMENT, ORGANISATION AND RESOURCES

5.1 Management

Priorities 2012-2014

- Ensure efficient management of the Agency, including integration of new Activities to the Agency's organisation;
- Prepare for compliance with ISO 9001;
- Prepare for EU Eco-Management and Audit Scheme (EMAS)

ECHA's highest decision-making body is the Management Board, consisting of 32 voting members representing each of the 27 EU Member States, as well as the Commission and Parliament. In addition, three non-voting members represent stakeholders, and three observers the EEA-EFTA countries.

The recurring tasks of the Management Board include the adoption of strategic documents, such as the work programmes, the annual report, as well as adoption of the budget and the delivery of an opinion on the final accounts. The Board also appoints the Executive Director, the Board of Appeal and the members of the Committee for Risk Assessment and the Committee for Socio–economic Analysis, and may accept stakeholder organisations that can be invited by the Committees, the Forum or other Agency networks as observers.

The day-to-day management of ECHA is a task of the Executive Director. He carries out his duties independently, without prejudice to the respective competences of the Commission and the Management Board. The Executive Director maintains regular contacts with the European institutions, Member States, other EU Agencies and other stakeholders.

Apart from integrating the new activities, which might become part of ECHA's mandate, the organisational structure of the Agency will be stable from 2012 onwards. Ensuring cooperation across directorates will, however, remain essential for the Agency's success. In order to ensure the efficient functioning of the Agency, ECHA will continue the development and implementation of tools to integrate planning, resource allocation, performance monitoring and risk management. In view of the progressive expansion of its core areas of operation it is important that the enhancement of the corporate risk management system continues in 2012. By 2013 the risk management systems should have reached a mature state and risk management should have become a continuous, well integrated part of each manager's tasks.

In 2012-2014, ECHA will continue the implementation of its Integrated Quality Management System (IQMS), including the documentation of the process system and related procedures, and will advance the incorporation of the Eco-Management and Audit Scheme (EMAS). The assessment of the maturity of the system, and its compliance with requirements, will stimulate its optimisation and continual improvement. The internal audit conclusions will also provide essential information for defining the roadmap leading to the certification according to ISO 9001.

Security and business continuity will continue to represent a major challenge for the Agency, and will stay a priority in order to ensure that the Agency's personnel, information assets (in particular registration data), buildings and equipment are adequately protected. In particular,

secure IT systems, able to ensure business continuity in case of a major crisis, and mature security procedures and business continuity plans shall be in place.

ECHA's Data Protection Officer will ensure that the Agency complies with all its statutory obligations to protect individuals with regard to the processing of their personal data. The initial notification of all processing operations will be finalised in 2012 after which the work will involve updates and notifications of new processes.

The development of knowledge management will be one of the important new developments, in order to support ECHA's mission to provide information on chemicals and address chemicals of concern as well as supporting its vision of becoming the world's leading regulatory authority on the safety of chemicals.

Legal expertise is further strengthened in order to guarantee that the growing numbers of ECHA's decisions and contracts are legally sound and in order to be able to manage the possible complaints and court proceedings, including those related to ECHA's intellectual property.

5.2 Finance, Procurement and Accounting

Priorities 2012-2014

- Provide reliable activity-based budget planning and reporting and foster compliance with applicable rules and regulations;
- Ensure that the fee regulations are correctly implemented, and that income and the cash reserves are adequately managed.

ECHA's means of financing include a subsidy granted by the budgetary authority from the EU budget, income generated from fees and charges and any voluntary contributions from the Member States and EEA-EFTA countries. In addition, ECHA may receive funding from the EU's external assistance Instrument for Pre-Accession Assistance (IPA).

With the fee income received from the first registration wave in the year 2010, ECHA can cover its REACH and CLP operations up to the end of year 2013. The second registration deadline in June 2013 is expected to yield considerably less income compared to the first one. It is therefore anticipated that from 2014 onwards ECHA will enter into a mixed funding regime, with part of the expenditure covered by fee income and the rest balanced by an EU subsidy.

The overall objective of ECHA's financial management is to assure the best use of available financial resources in line with the principles of economy, efficiency and effectiveness. Reimbursements to Member States with regard to substance evaluation will be a new task requiring some additional resources. As regards procurement and contracting, ECHA will continue to outsource part of its operational activities to ensure the efficient implementation of the REACH Regulation. Establishing the contractual basis for ICT developments, logistics and other services will continue to impose demands for efficient procurement and contracting in the period 2012-2014. Emphasis will be given, as in the past, to prudent financial management that complies with the relevant EU rules and regulations. Managing and safeguarding the cash reserves built up in 2010 will be a main objective.

ECHA will continue giving weight to its control function and will, in particular, carry on checking, amongst other matters, SME reductions granted based on the self-declared size of the companies and hence the correctness of the fees paid to ECHA.

5.3 Human Resources and Corporate Services

Priorities 2012-2014

- Introduce and implement a competency management framework, and organisational and management development;
- Continue to ensure a high quality working environment for ECHA staff and its visitors, in line with the highest health, safety and environmental standards.

Human Resources

ECHA's Human Resources policy for the period 2012-2014 is set out in the Multi-Annual Staff Policy Plan covering the same period.

The first years in the establishment of the Agency were characterised by a very fast growth in staffing. A further, more modest growth with 20 new posts is foreseen for the year 2012 in the Multi-Annual Staff Policy Plan for 2012-2014, after which staffing requirements for CLP and REACH will stabilise. The registration and C&L notification deadlines of November 2010 and early 2011 respectively have revealed and reconfirmed these initially identified needs in staffing for the coming years as well as the requirement to sustain this capacity at the same level for the full period of 2012 – 2014. In addition, new staff are foreseen for the new tasks of the Agency, with biocides tasks requiring another period of relatively rapid growth.

The HR strategy in this period will strongly focus on the management of staff competencies. This will establish the basis for deploying and orienting expert skills where required in the Agency and for creating a context of continuous learning and development for the staff in order to foster career perspectives for staff as well as helping steer the long-term competency basis of the Agency.

Specific further efforts will be dedicated in 2012, and sustained in the subsequent years, to management support. The aim is to support managers in the fulfilment of their people management responsibilities and to contribute to the organisational development of ECHA.

During the reporting period, considerable effort will continue to be devoted to optimising human resource administration, management processes, systems and quality management.

The Human Resources policy will, in close partnership with the Staff Committee and Joint Committees, aim at fostering and promoting the wellbeing of staff and their families.

Corporate Services

The Agency's infrastructure tasks include the management of its premises, for which the Agency has established a long term lease agreement. The agreement also holds out the prospect of a purchase option which may be considered. Before any decision in this regard is taken the Agency will submit a comprehensive assessment to the European Parliament and Council so that both institutions may provide their opinions.

Some refurbishing of the Agency's premises will take place in 2012 following decisions taken in 2011 linked to the reorganisation. Further improvements in the technical infrastructure will also be necessary in order to ensure the operability of the premises.

The key objective of the infrastructure and corporate services function is to assure a high level of service provision to the staff and visitors to the Agency. Adhering to the highest safety, health, and environmental standards will continue to be a main driver in pursuing this objective.

5.4 Information and Communication Technology

Priorities 2012-2014

- Operate the technical ICT infrastructure of the Agency at a high service level and maximise continuity, efficiency and security for all supported business operations;
- Increase efficiency in the administrative processes of the Agency by applying management information systems;
- Enhancing the programming and control capacity of the Agency's management by introducing management reporting systems;
- Assure a consistent and common corporate architectural approach as well as foster best practice in governance of IT projects.

The ICT function in the Agency covers a wide range of services, and supports a wide range of business needs. In order to achieve the aim of operating in a paperless and data-secure fashion, and to meet the needs for IT tools described in the previous chapters, the ICT function specifically provides the following services:

- the management of the technical infrastructure and provision of basic services;
- oversight and support to operations in the execution of large projects;
- establishment, implementation and maintenance of Agency-wide architectural guidelines with regard to infrastructure, applications, business processes and workflows;
- management, support and maintenance of administrative applications;
- monitoring and maintenance of operational applications; and
- implementation and enforcement of IT security policies.

In 2012-2014 the capacity of ECHA's infrastructure will be further enhanced by outsourced hosting services - which started being deployed in the last quarter of 2011 - in order to support the increased and evolving needs of ECHA and to achieve Business Continuity for the mission critical services.

IT Security management in relation to network connections, data access, monitoring and incidents management and designing secure software will be constantly upgraded to meet ECHA's challenging confidentiality obligations vis-à-vis the constant evolution of our systems and external threats.

Because of the size of the Agency and the need for even more accurate programming and control over the use of resources in 2012-2014, ECHA will further deploy management information systems to support its administrative processes and management reporting.

Engineering of ICT processes and services will be an on-going effort for the Directorate of Information Systems which was established in 2011 in order to meet the challenges of providing high quality IT support to a complex and modern administration.

6 ANNEXES

6.1 Annex 1: Overview of the Milestones from REACH and the CLP Regulations, 2011-2014

	Milestones from the Regulations
2011	▪ Classification & Labelling notifications in accordance with CLP Regulation, Art. 40 by 3 January ▪ Progress report on evaluation by 28 February 2011 (Art. 54) ▪ Notifications for SVHCs in articles start from 1 June, six months after a substance is put on the Candidate List (Art. 7.2) ▪ First 5 year ECHA-COM report on the operation of REACH by 1 June (Art. 117.2) ▪ First 3 year ECHA-COM report on non-animal test methods and strategies by 1 June (Art. 117.3) ▪ First draft Community Rolling Action Plan for substance evaluation to be submitted to MS by 1 December (Art. 44.2)
2012	▪ Study on the communication of information to the general public on the safe use of substances and mixtures (Art. 34 of the CLP Regulation) by 20 January ▪ Progress report on evaluation by 28 February 2012 (Art. 54) ▪ Adoption of the first Community Rolling Action Plan for substance evaluation ▪ Possible submission of the draft annual update of the Community Rolling Action Plan by 28 February 2012 (Art. 44(2). ▪ First 5 year COM general report on the operation of REACH and funding for development and evaluation of alternative test methods to be published by 1 June (Art. 117.4): this report to include COM review of registration requirement 1-10t/y as basis for possible legislative proposals (Art. 138.3) ▪ COM review of scope of the REACH Regulation, as basis for possible legislative proposals by 1 June (Art. 138.6) ▪ Review of ECHA by 1 June (Art. 75.2) ▪ Deadline for ECHA's draft decisions on testing proposals for registrations received by 1 December 2010, on 1 December (Art. 43.2.a)
2013	▪ Progress report on evaluation by 28 February 2013 (Art. 54) ▪ Submission of the draft annual update of the Community Rolling Action Plan by 28 February 2013 (Art. 44(2). ▪ Registration deadline for phase-in substances ≥100 t/y by 1 June
2014	▪ Tests for physical hazards in accordance with the CLP Regulation to be carried out from 1 Jan 2014 (Art. 8(5) ▪ Submission of the draft annual update of the Community Rolling Action Plan by 28 February 2014 (Art. 44(2) ▪ Second 3-year ECHA-COM report on non-animal test methods and strategies by 1 June (Art. 117.3) ▪ COM review in accordance with REACH Art 138(1).

6.2 Annex 2 : Estimated ECHA Revenue and Expenditure 2012-2014 (including staffing plan[17])

Proposed resources in draft budget 2012

Activities	Human Resources			Draft budget	Revenue
	AD	AST	CA		
Implementation of the REACH and CLP Processes (operational budget)					
Activity 1: Registration, data-sharing and dissemination	34	9	5	1.100.000	4.500.000
Activity 2: Evaluation	88	16	6	1.750.000	
Activity 3: Risk management	36	9	3	1.600.000	2.700.000
Activity 4: Classification and labelling	15	3	2	200.000	300.000
Activity 5: Advice and assistance through guidance and helpdesk	23	10	6	700.000	
Activity 6: Scientific IT tools	28	8	1	12.000.000	
Activity 7: Scientific activities and technical advice to EU institutions and bodies	9	1	1	300.000	
ECHA's bodies and cross-cutting activities					
Activity 8: Committees and Forum	21	9	3	2.700.000	
Activity 9: Board of Appeal	8	5	4	300.000	200.000
Activity 10: Communications	10	9	8	6.000.000	
Activity 11: International cooperation	5	1	0	700.000	
Management, organisation and resources					
Activity 12: Management	25	15	4	1.600.000	
Total (REACH and CLP)	302	95	43	28.950.000	
Activities 13-15: Organisation and resources (Title II: Infrastructure)	24	55	30	16.000.000	1.700.000
Title I (staff expenditure)				57.800.000	
Total	**326**	**150**	**73**	102.750.000	**9.400.000**
In Establishment plan:	**476**				
Activity 16: Biocides *(total budget)*	22	8	4	5.385.000	
Activity 17: PIC *(total budget)*	3	1	-	1.778.000	

Estimated resources for 2013

[17] ECHA will undertake, during 2011, a review of the staff model produced by the Commission when the REACH Regulation proposal was made in order to update the estimates for staff needs based on the experiences gained until now.

Activities	Human Resources			Draft budget	Revenues
	AD	AST	CA		
Implementation of the REACH and CLP Processes (operational budget)					
Activity 1: Registration, data-sharing and dissemination	34	11	7	1.400.000	36.800.000
Activity 2: Evaluation	86	14	6	3.500.000	
Activity 3: Risk management	41	10	5	1.600.000	18.000.000
Activity 4: Classification and labelling	14	3	1	200.000	700.000
Activity 5: Advice and assistance through guidance and helpdesk	23	12	6	700.000	
Activity 6: Scientific IT tools	26	6	1	11.000.000	
Activity 7: Scientific activities and technical advice to EU institutions and bodies	9	1	1	300.000	
ECHA's bodies and cross-cutting activities					
Activity 8: Committees and Forum	21	9	4	6.500.000	
Activity 9: Board of Appeal	8	5	4	300.000	200.000
Activity 10: Communications	10	9	9	7.500.000	
Activity 11: International cooperation	5	1	0	700.000	
Management, organisation and resources					
Activity 12: Management	25	15	4	1.600.000	
Total (REACH and CLP)	300	97	43	35.300.000	
Activities 13-15: Organisation and resources (Title II: Infrastructure)	24	54	30	16.400.000	800.000
Title I (staff expenditure)				58.500.000	
Total	**326**	**150**	**78**	**110.200.000**	**56.500.000**
In Establishment plan:	**476**				
Activity 16: Biocides *(total budget)*	57	14	9	13.600.000	
Activity 17: PIC *(total budget)*	4	3	0	1.560.000	

Estimated resources for 2014

Activities	Human Resources			Draft budget	Revenue
	AD	AST	CA		
Implementation of the REACH and CLP Processes (operational budget)					
Activity 1: Registration, data-sharing and dissemination	34	11	7	1.000.000	400.000
Activity 2: Evaluation	86	14	6	3.500.000	
Activity 3: Risk management	44	11	6	1.600.000	36.000.000
Activity 4: Classification and labelling	14	3	1	200.000	900.000
Activity 5: Advice and assistance through guidance and helpdesk	22	10	6	600.000	
Activity 6: Scientific IT tools	24	5	1	10.500.000	
Activity 7: Scientific activities and technical advice to EU institutions and bodies	9	1	1	300.000	
ECHA's bodies and cross-cutting activities					
Activity 8: Committees and Forum	21	11	4	11.000.000	
Activity 9: Board of Appeal	8	5	4	300.000	200.000
Activity 10: Communications	10	9	8	5.000.000	
Activity 11: International cooperation	5	1	0	700.000	
Management, organisation and resources					
Activity 12: Management	25	15	4	1.600.000	
Total				36.300.000	
Activities 13-15: Organisation and resources (Title II: Infrastructure)	24	54	30	16.800.000	300.000
Title I (staff expenditure)				59.400.000	
Total (REACH and CLP)	**326**	**150**	**78**	**112.500.000**	**37.800.000**
In Establishment plan:					
Activity 16: Biocides *(total budget)*	55	19	10	15.400.000	
Activity 17: PIC *(total budget)*	3	3	0	1.280.000	

6.3 Annex 3: Baseline Figures for 2012-2014

ECHA's main activity drivers	Estimate for 2012	Estimate for 2013	Estimate for 2014
Dossiers arriving[18]			
Registration dossiers (including updates)	5100	13 300	6500
Testing proposals	10	410	10
Confidentiality requests	320	650	240
Access to data older than 12 years	120	120	120
PPORD notifications	200	315[19]	315
Inquiries	1800	1800	1800
Number of notifications under REACH Art. 7(2)	70	70	70
Number of reports/notifications under Article 38	11700	370	4400
Restriction proposals (REACH Annex XV)	10	10	10
Restriction proposals developed by ECHA	3	3	3
Proposals for harmonised classification and labelling (REACH Annex XV)	60	60	60
Proposals for identification as SVHC (CLP Annex VI)	40	30	30
SVHC dossiers developed by ECHA	5	5	5
Authorisation applications	30	200	400
Alternative name requests	50	150	200
Substances on the CoRAP to be evaluated by MSs	40	50	50
ECHA decisions			
Evaluation - No of dossier evaluations initiated - No. of decisions on TP - No. CCH concluded - Out of which CCH decisions - No of substance evaluation decisions	610 360 250 80 -	570 10 560 190 30	500 100 90 30 40
Decisions on data sharing	75	75	75
Decisions on completeness check (negative)	10	30	10
Decisions on confidentiality requests (negative)	30	30	20
Decisions on access to documents requests	300	400	500
Appeals	40	40	40
Others			
(Updates of the) draft CoRAP for substances subject to substance evaluation	1	1	1
Recommendations to the European Commission for the authorisation list	1	1	1

Questions to be answered/harmonised answers (REACH Advice, REACH-IT, IUCLID 5, others)	7 000	10 000	7000
SME checks	300	350	400
Management Board meetings	4	4	4
MSC meetings	6	6	6
RAC meetings	7	7	7
SEAC meetings	4	5	5
Forum meetings	3	3	3
New TA posts to be filled REACH/CLP	20	0	0
Recruitment due to turnover	25	25	25
New TA posts to be filled for Biocides[20]	30	41	3
New TA posts to be filled for PIC[21]	4	3	-

21 ECHA estimate.
22 ECHA estimate.