ECHA
EUROPEAN CHEMICALS AGENCY

Multi-Annual Work Programme 2013-2015

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LIST OF ACRONYMS

BPC	Biocidal Products Committee
CA	Contract Agent
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
DU	Downstream User
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 Chemicals
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
MS	(European Union) Member State
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 Chemicals 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

Five years after its adoption, the REACH Regulation is still the most ambitious and comprehensive chemicals legislation in the world. The aims of the legislation are to ensure a high level of protection of human health and the environment while enhancing competitiveness and innovation. The Agency was created to manage and coordinate the implementation of REACH on the EU and Member State level and to harmonise enforcement. REACH is complemented by the CLP Regulation, which brings the EU in line with the UN-wide classification and labelling system for chemicals, which will ensure that the hazards presented by chemicals are clearly communicated to workers and consumers.

Both 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 safety information to customers and consumers.

During ECHA's start-up phase, the Management Board focused on its core tasks, such as establishing the Agency's budget and adopting internal rules. However, the multitude of ECHA's tasks demanded closer monitoring of key challenges such as "planning and reporting"; "the follow-up of audit findings"; "the ambition of and questions regarding dissemination"; and "the transfer of [REACH] fees to reimburse Member States [for tasks they carry out under the legislation]". For these, the Board established specific sub-groups dedicated to in-depth analysis and preparatory decision-making. The modus operandi of the Board, and its interaction with the Agency's management, is an amalgam of commitment, collegiality, transparency, and the strive for efficiency and efficacy. As ECHA's governing board, we are also conscious of our role as ECHA's guardians, in order to seek optimum support for the Agency.

We are proud to have played our part in guiding the Agency over the last five years and can reflect on a job well done, as we see ECHA now as a high-performing, mature agency, ready to take on new responsibilities under the Biocides and PIC legislations – responsibilities that come at a crucial time for the organisational development of the Agency. The difficult economic outlook for all of us – Member States, the EU, and companies throughout Europe – requires the Agency to prioritise its work, taking account of its means i.e. its staff, the budget available from fees and from subsidies awarded by the Budgetary Authority. This prioritisation process is helped by the Agency's founding regulations, which often set clear deadlines by which work should be done. However, as there are still many areas in which subjective decisions need to be taken, the Board agreed upon four strategic aims which have guided the Agency in setting priorities for its activities in this multi-annual work programme.

We are keen to hear your perspective on the strategic aims and on the priorities chosen for the coming three years, and look forward to hearing from you.

Thomas Jakl
Chairman of the Management Board

OVERVIEW BY THE EXECUTIVE DIRECTOR

ECHA's Multi-Annual Work Programme 2013-2015 outlines the Agency's planned activities for the coming three years. We will be providing more detailed plans in due course in our annual Work Programmes. The Multi-Annual Work Programme is revised every year and its time-span is moved forward by one year each time.

2013-2015 is an important three-year period for ECHA. It includes work on four individual pieces of EU legislation – REACH; Classification, Labelling and Packaging; Prior Information Consent on Export and Import of Hazardous Substances; and, last but not least, Biocidal Products. The latter two regulations are entirely new to us and come at a time of peak activity under REACH and CLP. A successful start on these challenging new tasks not just depends on the steering ability of ECHA's management but on the provision of a sufficient staff and financial resources by the Budgetary Authority of the EU and the maintenance of enough expertise in the Member States.

The examination of authorisation applications, an essential new part of REACH, will also begin in this period and is a formidable challenge to all parties concerned. The expectations of this risk management instrument are high for all stakeholders given that a clear pathway will be set for industry to work towards phasing out the use of chemicals of very high concern. However, the opinion and decision making process around authorisation is designed also to take proper account of the socio-economic impact concerns.

Meeting these multitude challenges from four pieces of legislation that lead to actions, the size and intensity of which are entirely demand driven, will require all the skills and flexibility of our expert staff. By agreeing strategic aims with our Management Board we have set ourselves clear targets that will enable us to achieve our vision – to become the world's leading regulatory authority on the safety of chemicals. Together with our partners we can ensure that Europe is in the forefront in safeguarding its citizens and environment from the adverse effects of chemicals.

In achieving our goals, we rely on strong and constructive collaboration with all our stakeholders and we very much welcome your continued interest in our work. With that in mind, I hope that you can find time to give us your feedback on this Multi-Annual Work Programme. I 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 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 implementation of the 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 UN Strategic Approach to International Chemicals Management (SAICM) adopted on 6 February 2006 in Dubai. The purpose of the REACH and CLP Regulations is to ensure a high level of protection of human health and the environment, and to facilitate the free circulation of chemicals within the internal market. In addition, the REACH Regulation aims to enhance competitiveness and innovation, and to promote alternative methods to animal testing to assess the hazards of chemicals. The REACH Regulation is based upon the principle that manufacturers, importers and downstream users should ensure that they manufacture, place on the market or use 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 makes the risk management of chemical 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. It is also expected to close a knowledge gap in relation to so called 'phase-in' substances placed on the European market.

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 upon ECHA's institutional partners, in particular the Member States of the EU and the European Commission (or 'Commission') on the one hand, and on industry to implement the Regulations properly, 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 chemicals legislation.

From the very beginning, the credibility of the REACH and CLP Regulations have, for example, been determined by the allocation of sufficient resources at national level and an effective and fair enforcement policy. Furthermore, since ECHA is responsible for preparing scientific opinions for the Commission, successful implementation depends upon correct initiation work by ECHA, 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 at the time the REACH Regulation was prepared. Having passed two important deadlines for REACH registrations and CLP notifications respectively, in 2010/2011, ECHA can base some of its predictions on real data; the baseline numbers nevertheless remain subject to a significant degree of uncertainty, in particular with regard to authorisation applications. The planned resource allocation is an extrapolation from the revisions made for ECHA's annual Work Programme 2012, apart from resources needed to process authorisation applications, for which 10 expert staff members will be requested for 2013. Minor increases in the number of contract agents are also foreseen in each of these years. Nevertheless, constant monitoring of work

[1] Regulation (EC) No 1907/2006.
[2] Regulation (EC) No 1272/2008.

volumes and a potential re-allocation of priorities and resources during the years to come, will be required.

Alongside the existing REACH and CLP Regulations, the Commission proposed a new Regulation, in June 2009, concerning the placing on the market and use of biocidal products[3] which is currently awaiting final adoption. The proposed Regulation and the amendments agreed by the Parliament and the Council foresee additional tasks for ECHA – namely, the review of applications for authorisation of certain biocidal products, which will start from September 2013. Prior to the entry into force of the legal base, ECHA will have started recruitment procedures, begun to adjust its IT tools, and begun to build up expertise in relation to the Regulation.

In addition to this, the recast of the so-called PIC Regulation[4] concerning the export and import of dangerous chemicals is under negotiation in and between the Parliament and Council. It is expected that certain tasks will be transferred from the Joint Research Centre of the Commission to ECHA from 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 tasks prior to the entry into force of the legislation, based upon the resources foreseen in the budget of 2012.

2 THE EUROPEAN CHEMICALS AGENCY IN 2013-2015

2.1 ECHA's Mission, Vision and Values

ECHA's new mission, vision and values were first adopted in 2011:

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.

[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.

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 Strategic Approach

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. The vision of the Agency is to become the world's leading regulatory authority on the safety of chemicals. The overarching challenge in the coming years will be to make substantial steps towards making this a reality.

The basic foundation for this is an effective and intelligent handling of REACH and CLP instruments. By focusing on the right priorities, this should lead to tangible results and make ECHA an internationally recognised and reliable reference authority.

Furthermore, ECHA will have to take links and synergies with other EU environment legislation into account when implementing its mandate. Close cooperation with the European institutions but also, in particular, with the Member States and their national authorities, are key factors for ECHA's future success. Equally, ECHA has to continue to interact with all stakeholders and develop the networks between industry, MSCAs, EU institutions and civil society.

ECHA has defined its strategic aims to assist in prioritising its actions in order, over time, to achieve its ambitious vision. Whilst these aims go beyond 2015, they thereby provide a steer to the Agency when making choices over resource allocation and over how to motivate staff.

I Maximise the availability of high quality data to enable the safe manufacture and use of chemicals.

REACH places the burden of proof on industry to demonstrate safe use of their chemicals. However, without a solid data set on the hazard properties and uses of a substance it is not possible to ensure appropriate classification and labelling, and ultimately to develop a Chemicals Safety Assessment (CSA) that demonstrates safe use.

Through the first registration deadline for REACH and the more than 3 million CLP notifications, ECHA has collected a wealth of information on substances produced and used in high volumes as well as on those with the most dangerous properties. ECHA will need to maximise the availability and use of this unique pool of data by providing improved access to implementing and enforcement authorities and the general public, in a way that makes it of best use for these respective audiences.

At the same time, given that ECHA's early findings on the quality of the registration dossiers revealed that a significant part have important quality deficiencies, concerted action from all actors involved, in particular industry and authorities, is needed to further improve the quality of the information and of the dossiers for the next registration deadlines; this also includes the Agency addressing implementation issues.

In addition, intensifying feedback and discussion with the broader industry community on the quality of dossiers and related extended Safety Data Sheets will be necessary to enhance safe use throughout supply chains. Providing tools that support industry in generating high quality dossiers – including effective, usable exposure scenarios – and that facilitate the dialogue between the different actors in supply chains to enhance information flows, while enhancing competitiveness and innovation, are key elements in this regard.

Other important actions have to include topical outreach campaigns to industry.

II Mobilise authorities to use data intelligently to identify and address chemicals of concern.

The data on chemicals that has been created, collected and submitted to ECHA is there to allow ECHA to verify that industry is meeting its duties regarding safe use and to allow the authorities to impose additional risk management measures in case of risks that are regarded as unacceptable. Not only does this data need to be disseminated effectively, in a format that enables citizens to read the information, but it also needs to be used in an intelligent manner so as to target regulatory action as early as possible on priority substances and uses causing risks.

Identified concerns should be addressed through well-informed decisions on regulatory measures which are effective in reducing, as well as proportionate to, the risk. ECHA will focus on quickly identifying dossiers and substances of concern and initiating appropriate action such as dossier and substance evaluation. They will also figure in the Agency's external communications to the general public. Focus should predominantly be on cases which have not yet been adequately regulated.

ECHA is the driving force for effective regulatory chemicals risk management. Through the active and efficient implementation of REACH, in particular the authorisation process, ECHA will contribute significantly to the promotion of the substitution of the most dangerous substances in the EU, thereby increasing innovation. The novelty of the authorisation regime and the high expectations within civil society require that this activity, and that of the identification of Substances of Very High Concern (SVHC) which is closely linked, receive continued high support – in close co-operation with the Member States and the Commission – in order to meet the commonly set ambitious targets. This will also contribute to enhancing the competitiveness of the industrial sector, with special attention given to the needs of SMEs.

III Address scientific challenges by serving as a hub for building the scientific and regulatory capacity of Member States, European institutions and other actors.

ECHA is continuously confronted with new scientific and technical challenges that attract particular (regulatory) attention, such as nanomaterials, endocrine disruptors, use of integrated (alternative) testing strategies and mixture toxicity.

To respond to these evolving and emerging topics, and to provide the Member States and the institutions of the EU with the best possible scientific and technical advice, ECHA not only needs to increase its own scientific capacity but will also need to intensify its function as a hub for building the scientific and regulatory capacity of, and cooperation amongst, Member States, European institutions and other actors. Working together with all actors should help to ensure, by 2020, the production and use of chemicals in ways that lead to the minimisation of significant adverse effects on human health and the environment, while promoting innovation and competitiveness.

ECHA is operating in a field were transparency, credibility and a proactive approach towards potential conflicts of interest are key factors for the successful operation of the Agency. It will be of pivotal importance for the Agency to maintain close co-operation with its partners, such as the Commission, other EU institutions, Member States, industry and other stakeholders. One of the cornerstones of ECHA's values is transparency. This means that regulatory partners and stakeholders have to be closely involved in the Agency's activities and the public well informed of them.

IV Embrace current and new legislative tasks efficiently and effectively, while adapting to upcoming resource constraints.

The combination of anticipated resource constraints in the next multi-annual financial framework 2014–2020, the work on future strategic aims as outlined here, and the assignment of new regulatory tasks to ECHA such as those under the Biocides and PIC Regulations, constitute a major managerial challenge.

The increasing number of tasks will force ECHA to focus on efficiency and on finding (internal) synergies in the way these tasks are implemented. Even in the most optimistic of scenarios, it cannot be ruled out that in the future ECHA will have to manage to operate with less staff than needed, with all the organisational issues that this implies.

Whereas initially, the focus of the work on Biocides and PIC will be on setting up new processes and structures to cope with a rapidly increasing workload, the real challenge will be to demonstrate that by handing over these tasks to ECHA, an overall efficiency gain is indeed achieved, as foreseen by the EU regulator.

ECHA will need to adapt continuously to changing requirements in order to achieve its aim of being a modern European agency that provides **–** to the benefit of citizens **–** quality services to companies, Member States and European institutions.

ECHA recognises that the knowledge, experience and motivation of its staff are key factors in enabling it to achieve its strategic aims. Hence, strategic human resource development is central to sustaining and enhancing organisational performance and achieving increased effectiveness as staff develop their knowledge and experience.

3 IMPLEMENTATION OF THE REGULATORY PROCESSES

3.1 Registration, Data-sharing and Dissemination

Priorities 2013-2015

Contribute to the generation and collection of high quality information on chemicals by, *inter alia*:

- Promoting stakeholder understanding of substance identification requirements and substance sameness concepts, which are essential to the efficient implementation of any REACH or CLP process;
- Stimulating the preparation of high quality dossiers, including chemical safety reports and exposure scenarios, in order to ensure the safe use of chemicals by registrants and, through effective communication, downstream users. This will also provide a good basis for subsequent regulatory work such as evaluation;
- Facilitating the fulfilment by companies of their regulatory obligations and encouraging industry to submit high quality updates to their registration dossiers, where necessary;
- Promoting harmonised and efficient practice amongst all stakeholders when they conduct, document and communicate chemical safety assessments, to ensure the collection and communication of high quality information on the safe use of substances.
- Ensuring that CSR information is technically complete in all new dossiers and updates with the view of enhancing the reporting and disseminating more safety information.

Contribute to the intelligent use of data for effective regulatory management by, *inter alia*:

- Enhancing the dissemination website to make it a user-friendly, one-stop shop for information on the substances in ECHA's databases, and engaging stakeholders in order to better understand and address their needs;
- Developing computational tools and other methods to support efficient and intelligent data-analysis for ECHA processes and for stakeholder data requests.

Contribute to the efficient use of resources by, *inter alia*:

- Seeking synergies across activities and resources to embrace efficiently new dossier submission, dissemination and substance identification tasks linked not only to REACH and CLP but also to the new Biocidal Products and PIC Regulations.

3.1.1 Registration and dossier submissions

Registration

The REACH Regulation places a responsibility on industry to assess and manage the risks arising from the chemical substances it manufactures and imports, and to provide safety information on their use. Companies that manufacture or import substances in quantities over one tonne per year are required to gather data on their properties and recommend appropriate risk management measures. Substances manufactured or imported in quantities above 10 tonnes per year, require a more detailed chemical safety assessment (CSA), documented in a chemical safety report (CSR). Finally, for most of the substances classified as hazardous, use-specific exposure scenarios documenting the conditions of safe use must be reported in a CSR and provided to the registrants' downstream users as attachments to a safety data sheet (SDS).

Companies are required to document all this information in a registration dossier which must be submitted to ECHA. In order to promote harmonised interpretations of data, and reduce registration costs and unnecessary testing on animals, registrants of the same substance have to share their data and submit their registration jointly. The Agency verifies the completeness of the information provided, and the payment of the corresponding fee, before deciding to assign a registration number or to reject a dossier.

Registration obligations for industry started on 1 June 2008. However, a transitional regime was created for so called 'phase-in' substances, which had been pre-registered in 2008. These substances need to be registered in 2010, 2013 or 2018, depending on their hazardous properties and the volumes in which they are produced or imported. Non phase-in substances and phase-in substances that have not been pre-registered must be registered before they can be manufactured or imported into the EU. By the first registration deadline in 2010, ECHA received around 25 000 registration dossiers covering about 3 400 phase-in substances.

The successful management of the next registration deadline of 31 May 2013, by which some 15 000 dossiers are expected to be submitted, will be based upon the experience and know-how built in 2010. These will be used to estimate the adequate level of resources and support ECHA needs to devote to helping registrants, particularly SMEs, in an efficient manner, and to processing registration dossiers in a timely manner. In addition, ECHA will prepare itself to handle pre-registrations and registrations from Croatia[5], in accordance with the transitional arrangements foreseen in their Treaty of Accession to the EU.

Furthermore, ECHA wants to support companies to submit dossiers of as high a quality as possible, given that the analysis contained in dossiers provides the backbone for industry to ensure the safe use of chemicals throughout the supply chain. Indeed, without a solid data set on hazard properties and the uses of a substance, it is not possible to ensure appropriate classification and labelling nor ultimately to develop a Chemicals Safety Assessment (CSA) that demonstrates safe use. Subsequently, the information on registered substances in the Agency's database on chemical substances forms the basis for triggering other regulatory processes and for disseminating information to the public. It is therefore in ECHA's interest to guard the quality of the data to make it as useful as possible for the Agency, the Commission, the Member States and the general public. Unambiguous substance identification and use description, as well as coherent and consistent chemical safety reporting, are among the main areas where the need for better support is currently foreseen.

[5] Croatia is expected to join the EU on 1 July 2013.

To achieve this, ECHA intends to provide technical and scientific support in the development of chemical safety assessments and exposure scenario building, and their communication for the use of substances as such, in mixtures and in articles. ECHA also aims to promote a common understanding of the chemical safety assessments carried out by downstream users. In the coming years, ECHA will intensify its support to industry in their efforts to harmonise the means and practices by which exposure scenarios are produced as part of safety data sheets, to ensure that the producers of mixtures and articles make best use of these exposure scenarios for their assessments and risk management. Moreover, ECHA will work on increasing its internal capacity to evaluate accurately the information presented in chemical safety reports (CSRs) arriving as part of registration dossiers. An element of this is to ensure that the technical completeness check covers exposure and risk information and guidance on safe use. External capacity building will include cooperation with industry but also cooperation with national authorities administering the implementation of REACH, to assist them in evaluating the implementation of risk management measures required to guarantee the safe use of chemicals. Much of the efforts will be devoted to providing companies registering in 2018 with a structured means to undertake their chemical safety assessments. ECHA will also continue to support downstream users, throughout the 2013-2015 period, to assist them in understanding the safety information on registered substances that they will receive in the form of exposure scenarios.

Computational tools and methods

ECHA will refine its computational tools and other methods in order to screen, through smart and targeted means, for those dossiers where safe use is insufficiently demonstrated and which require appropriate responses in case of insufficient performance. The Agency will also identify common shortcomings in registration dossiers that may warrant follow-up outside dossier evaluation. For example, the screening of registrations for substances used as intermediates will continue to verify whether the uses specified are in line with the definition of intermediate use and that strictly controlled conditions are applied. Unjustified registration of a substance as an intermediate results in a lack of information relevant to ensure the identification and control of risks. Furthermore, such unjustified registration may result in a substance being given undue low priority as one for which further information should be generated or for which further regulatory risk management may be required. Such problems could result in distortions of the market. The findings from screening, as well as best practice developed in cooperation with industry, will be communicated to registrants with the aim of encouraging the spontaneous updating and improvement of dossiers. These activities will continue throughout the 2013-2015 period, as they are of direct relevance to preparations for the final registration deadline under REACH, in 2018. Furthermore they also have an immediate impact on improving the quality of information that is communicated up and down the supply chain, via safety data sheets (including exposure scenarios for most of the substances classified as hazardous) and thus, on the safe handling of substances at workplaces – as well as on protecting consumers and the environment.

ECHA will also further develop its capacity for data mining and data-analysis in order to assess accurately the information presented in registration dossiers and in order to be able to serve the interests of other REACH and CLP processes, such as targeted evaluation and risk management activities. This will also facilitate the use of registration data for EU regulatory needs other than those under the REACH and CLP legislations, as further explained in Section 3. Furthermore, it will help the Agency to reply more efficiently to requests made according to Regulation 1049/2001/EC, for access to documents; these requests are expected to become more complex and time-consuming as the amount of information the Agency holds increases.

Other types of dossier submissions

With a view to stimulating European innovation, companies can request temporary exemption of registration obligations for substances used in product and process oriented research and development (so-called 'PPORD notifications'). The first PPORD exemptions expire in 2013, at which time assessment of their prolongation will begin. Informed decisions on the potential extensions of PPORDs will be based on assessment of the original applications from 2008, which will be completed by early 2013.

In addition to handling registrations and PPORD notifications, ECHA receives information on substances in the form of downstream user reports (if a downstream use is not covered by a supplier's exposure scenario) and notifications of substances in articles. ECHA will provide downstream users of substances registered in 2013 with practical support in the fulfilment of their reporting obligations via simple guides and examples, and user-friendly tools.

Although dossier submission is a largely automated process, especially for the handling of registrations and C&L notifications, 2013 will be a challenging year, as ECHA will start to receive new types of dossiers related to the Biocidal Products and PIC Regulations. They will be handled by the same team, adequately staffed in order to exploit fully the synergies between legislations and to make the best use of resources. Biocides dossiers and PIC export notifications should arrive just as all dossiers from the second REACH registration deadline have been processed. However, preparatory activities will run in parallel to handling the registration peak and this will require careful planning and monitoring in order to avoid any disruption. It is expected that the streamlining of processes will continue over 2014 and 2015 in order to achieve a high level of automation.

3.1.2 Data sharing and substance identification

Data-sharing is a REACH process which precedes the joint submission of registration information by companies who manufacture or import the same substance. The aim of data-sharing is to minimise registration costs for companies, to prevent duplication of animal tests, and to facilitate the common classification and labelling of substances. Data-sharing is obligatory for studies in which vertebrate animals are used. ECHA facilitates data-sharing between potential registrants and has an arbitration role in settling potential data-sharing disputes.

There are two separate routes foreseen for data-sharing: the establishment of Substance Information Exchange Fora (SIEFs) for pre-registered phase-in substances, and the inquiry process for other substances.

Pre-registration of phase-in substances was designed to bring companies interested in registering the same substance into the SIEF of that substance. While the SIEF is formed without ECHA, the Agency has facilitated the start-up of the SIEF discussions by providing a secured pre-SIEF environment under its submission software REACH-IT. Third parties holding information on a given substance can also make themselves known to the respective SIEF via REACH-IT. Pre-registration is still possible until 31 May 2017 for companies who start to manufacture or import a phase-in substance for 100 tonnes or less per year, and ECHA will continue to put these new pre-registrants into contact with existing SIEFs in 2013-2015. ECHA will also review the pre-SIEF pages of REACH-IT after the 2013 registration deadline and develop them to serve the communication and data-sharing of 2018 registrants in the best possible way.

For non phase-in substances and phase-in substances that have not been pre-registered, the inquiry process is the data-sharing step preceding registration. As ECHA holds

information on previous registrations, it will continue to facilitate contact between the previous and potential registrant(s) of a given substance, enabling them to start negotiations on available information and related cost-sharing. The Agency workload associated with inquiries is expected to increase over time, as there will be more and more previous registrants for substances.

ECHA has a limited arbitration role in data sharing disputes where previous and potential registrants cannot reach agreement. Although the number of these disputes has remained low until now, ECHA expects there to be an increase in requests for arbitration regarding disputes on phase-in substances in early 2013, and is readying its capacity to solve these prior to the registration deadline in May. Based on experience from the 2010 registration deadline, ECHA also expects the number of inquiries for phase-in substances to peak in the first half of 2013, as companies become aware of the approaching deadline. Finally, new data sharing and substance identification tasks will kick off in 2013 with the application of the new Biocidal Products Regulation; synergies with REACH processes should enable the Agency to implement these new tasks efficiently, however, ECHA will still seek to streamline processes and make efficiency gains throughout 2014-2015.

The key to meaningful data sharing lies in correct substance identification. While substance identification for phase-in substances is established by industry during SIEF discussions by potential registrants, the situation is more complex for substances to which the inquiry process applies, as ECHA needs to make a judgement on whether the substances are the same based on the documentary evidence provided by companies. ECHA will work actively, in 2013-2015, towards a better understanding by all stakeholders of the concept of substance identity and related issues. It is important that these issues are settled as early as possible in order to promote the efficient and timely formation of SIEFs for the 2018 deadline, when many more substances are expected to be registered. Finally, ECHA will also perform targeted substance identity checks on registration dossiers for groups of substances to ensure that the substance identification indicated therein is meaningful for other regulatory processes, such as evaluation.

In addition, ECHA has assigned list numbers to the substances for which there has been no EC number available. In order to build a reliable REACH inventory and to give a solid regulatory status to these chemicals it is necessary to validate the adequacy of their identification information. A feasibility study for this work will be conducted in 2013 with a view to starting validations in the following years.

3.1.3 Dissemination

ECHA is obliged to make information on registered substances publicly available on its website. This activity is expected to have a positive impact on health and environmental protection both in Europe and worldwide, as everyone has the possibility to consult information on the chemicals they use.

Activities pertaining to the dissemination of information range from publishing, in large volumes, information on chemicals contained in registration dossiers and the classification and labelling inventory (see details in section 3.4), to the assessment of justifications provided by registrants that request that certain information they provide to ECHA remains confidential, in accordance with the provisions laid down in REACH. Further to the second wave of registrations in 2013, ECHA will have received and stored information from an estimated additional 15000 registration dossiers for substances manufactured or imported in quantities of 100-1000 tonnes per year. Dissemination of information from these dossiers will be one of the core activities of ECHA, and will continue until 2014. In addition, these dossiers are expected to contain nearly 800 confidentiality claims, and ECHA will promptly assess the justifications provided by the registrants. Priority will be given to

assessing confidentiality claims in dossiers that contain testing proposals involving vertebrate animals, so that the largest possible amount of information on a substance can be made public at the time when interested parties are requested to comment on the necessity of a testing proposal. If the chemical name of a substance is claimed confidential, ECHA will verify that the proposed public name reveals enough of the intrinsic properties of the substance even though it masks its complete chemical identity.

Recognising the strategic importance of its dissemination website towards achieving long-standing international commitments to make information on chemical properties publicly available, ECHA is seeking to engage better its stakeholders to enhance content and improve access to information. Above and beyond publishing information directly from registration dossiers, the goal is to develop the dissemination website as a central point of access for all the regulatory information contained in ECHA databases on a given substance, including information stemming from the Biocidal Products and PIC Regulations.

By 2013, ECHA should have completed a feasibility study aimed at better defining and prioritising stakeholders' needs. Specifically, the needs of the general public, i.e. an audience that is not familiar with the technical format or the English language currently used for publication, will be taken into consideration. The resulting changes will be implemented over the 2013-2015 period in synchronisation with IT development of a portal (see Activity 6) so that, in 2015, the dissemination website will have been fully revamped both in terms of enriching its content and enhancing its usability. Finally, ECHA will also seek to improve the quality of the information disseminated in particular with regard to safety information coming from the chemical safety report by encouraging registrants to update their registration dossiers, which will have to pass from 2014 onwards a more comprehensive completeness check.

3.2 Evaluation

Priorities 2013-2015

Contribute through dossier evaluation to the improvement of the quality of registration dossiers, specified as compliance with information requirements, by, *inter alia*:

- Maximising the impact of compliance checking, the core regulatory process that ECHA has at its disposal to instil confidence in the quality of registration dossiers. This is done by using IT tools to screen dossiers for compliance systematically, by selecting an appropriate mix of dossiers for targeted or full compliance check, and by preparing scientifically and legally sound draft decisions to request additional information, where necessary;
- Conducting, in an efficient manner, an increasing number of examinations of updated dossiers, further to evaluation decisions, and providing a solid basis for MS enforcement authorities to take action, and conducting further compliance checks as appropriate;
- Using the annual evaluation report and other channels of communication with registrants and industry to highlight the main areas for improvement in submissions; and to encourage the spontaneous and voluntary updating of registration dossiers.

Contribute through substance evaluation to the intelligent use of data for effective regulatory chemicals management by, *inter alia*:

- Selecting, in collaboration with Member States, substances for the annually updated Community Rolling Action Plan which are suspected to pose risks but for which there is a lack of conclusive information.

The REACH Regulation distinguishes between dossier and substance evaluation. Dossier evaluation is performed by ECHA, whilst substance evaluation relies on Member States to perform the evaluation work. Both evaluation processes are integrally linked to registration and EU-wide risk management processes, and therefore require close coordination with those activities.

3.2.1 Dossier Evaluation

Dossier evaluation, subdivided into compliance checking of registration dossiers and the examination of testing proposals[6], is the core regulatory process that ECHA uses to instil confidence in the general quality of registrations and their compliance with REACH requirements. This task has become more important given that ECHA has identified the improved quality of data as one of the key strategic aims.

Registrants submit testing proposals to ECHA as part of their registrations and seek permission from ECHA to undertake tests that are needed to meet the information requirements for high volume substances[7], if the information requirements of the REACH Regulation cannot otherwise be fulfilled. Testing proposals which include vertebrate animal tests, undergo third party consultation before a decision is taken. 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 so that animal testing is required only when there is a broad consensus that such testing is indeed necessary.

The purpose of compliance checks is to ensure that the information requirements under the REACH Regulation are met in the registration dossiers received. In this regard, the compliance check is the main tool for requesting the standard information required by the REACH Regulation, but not submitted by registrants. This information forms the basis for the safe use of substances.

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. Therefore, one of the main challenges for the period 2013-2015 is to maintain ECHA's scientific, technical and legal capacity and further optimise its efficient use over the whole period of evaluation work on dossiers received by the 2010 and 2013 deadlines. Furthermore, ECHA needs to increase its capacity to address effectively new scientific challenges embedded in dossier evaluation work, such as those posed by nanomaterials or newly adopted test guidelines.

In accordance with REACH Article 41(6), any third party may submit electronically to the Agency, information relating to registered substances for consideration by ECHA when selecting and evaluating dossiers for compliance check. To support this element of inclusive

[6] Articles 40 and 41 of the REACH Regulation.
[7] REACH Regulation Annexes IX and X.

governance, ECHA – as part of its coordinating role – has created a single point of access on the website with regard to third party contributions.

Each ECHA draft decision is referred to Member State Competent Authorities in order for them to propose possible amendments. Should Member States propose amendments, the draft decision is referred to the Member State Committee to seek agreement. Therefore, efficient and effective interaction and communication with Member States and the Member State Committee is critical for meeting the quantitative and qualitative objectives of dossier evaluation.

All testing proposals have to be evaluated within a certain deadline[8], whereas compliance checks have a quantitative target of at least 5 % per tonnage band. By the end of 2013, ECHA plans to have conducted compliance checks on 5% of all dossiers registered by the 2010 deadline. Dossiers will be selected for compliance check both randomly and based upon concern. Random selection is important in order to compensate, to some extent, the bias of concern-based selection, and to send a clear signal that in principle, all dossiers are subject to scrutiny. In these cases, a comprehensive evaluation is normally performed. In the case of concern-driven compliance checks, evaluation can be targeted. To improve efficiency, it is envisaged that IT-tools will be used to pre-screen dossiers regarding whether key information on environmental or human health hazards has been submitted, and then to process targeted draft decisions in a standard manner, in order to gain efficiency. Another important basis for the prioritisation of dossiers is the envisaged or planned substance evaluation and the needs of risk management processes.

With the resources currently planned, ECHA expects to be able to handle between approximately 400-600 dossier evaluations per year in 2013-2015. Due to the overall reduction in ECHA staff foreseen, measures will be taken to improve continuously the efficiency of the respective evaluation processes.

Follow-up to Dossier Evaluation

Dossier evaluation will in many cases result in a request to the registrant to provide further information in an updated dossier by a deadline set by ECHA. The deadlines set range from 3 months to 3 years, depending upon the information requested. After the deadline has passed, ECHA has to examine whether the dossier has been updated and whether the update meets the requirements. As a result of the follow-up, further compliance checks may need to be performed. In case of continued incompliance, ECHA and the Member States will consider appropriate measures, including withdrawal of registration number, to ensure the correct implementation of REACH.

The increasing amount and complexity 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 to verify whether a substance constitutes a risk to human health or the environment. Member State Competent Authorities (MSCAs) are responsible for performing substance evaluations in accordance with the Community Rolling Action Plan (CoRAP). This work involves an assessment of all available information relevant for the

[8] Testing proposals for phase-in substances registered by the second registration deadline in May 2013 will have to be evaluated by 1 June 2016. Proposals for non-phase-in substances must be evaluated within six months of the date of registration.

evaluation, and the preparation of requests for further information from registrants, if appropriate. These requests can go beyond the standard information requirements provided in the Annexes of the REACH Regulation. Substance evaluation is meant to bring added value to the REACH system by bringing together data on the properties and uses of a substance from individual registration dossiers and thereby feeding into the preparation of Community-level risk management measures.

Substance evaluations which lead to requests for further data will contribute to improving the data on chemicals. Furthermore, substance evaluation will add value to REACH processes by helping to ensure that the right substances are selected for relevant EU-level risk management measures.

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 was adopted in February 2012 and contains the list of substances per Member State to be evaluated in 2012-2014. The CoRAP will henceforth be updated annually.

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. To ensure the added value of substance evaluation, ECHA will interlink prioritisation and ranking with the needs of EU-wide regulatory risk management measures, authorisation, restrictions, and harmonised classification and labelling.

ECHA will ensure 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 them and to the Member State Committee. The registry of notifications will facilitate information-sharing and the allocation of substances among Member States. In cases where more than one Member State expresses an interest in evaluating a given substance, the ECHA Secretariat will initiate an informal "negotiation" procedure to reach agreement, with the aim of avoiding referring the matter to the Member State Committee, as would otherwise be required.

Cooperation with Member States will also include discussion and potential revision of the criteria agreed in 2011, for the prioritisation of substances for substance evaluation. This review is planned to take place in 2014, when first experiences from the substance evaluation process will be available.

ECHA estimates that up to 150 substances will be included in the updated CoRAP and evaluated between 2013 and 2015 by Member States, i.e. approximately 50 substances per year. This is less than originally estimated by the Commission, but due to careful pre-screening and priority setting, it is expected that 90% of evaluations will lead to a draft decision and subsequently to decision making and follow-up work, therefore requiring the same level of resources as originally estimated by the Commission.

Substance Evaluation Process

Whilst MSCAs perform the actual evaluation work, ECHA plays a coordination role in the overall substance evaluation process. As an end result of the evaluation process, a Member State will in most cases prepare a draft decision, to be adopted by ECHA, which is addressed to the registrants of a substance and which requests information to clarify any concerns detected. ECHA must ensure that draft decisions on information requirements are completed within the legal time frame and that they are scientifically consistent and legally sound.

ECHA will continue to provide support to MSCAs for substance evaluation by providing training and advice and by screening draft decisions. This is regarded as necessary to ensure the consistency and efficiency of the process. The process will be fully put in practice for the first time in the 2012-2013 period and further developments on the basis of initial experience will be considered, in a pragmatic dialogue with the MSCAs.

It is also up to ECHA to communicate with registrants and with the general public on the purpose, status and achievements of substance evaluation. In 2013-2015, the updated CoRAP will be published, as will the outcomes of the substance evaluations completed by MSCAs.

Although substance evaluation is conducted by Member States, a significant administrative and legal workload is nonetheless foreseen for the Agency. Simultaneous facilitation of the identification of good CoRAP candidates, of updates of the CoRAP, as well as coordination of the evaluation of substances - including follow-up work and decision making on the information requested by MSCAs – will be a continuous challenge for ECHA.

Reporting and communication of the results

The general results of the dossier and substance evaluation processes are published in the annual progress report delivered by ECHA in line with Article 54 of the REACH Regulation. This report includes general recommendations to registrants in order to improve the quality of registration dossiers and invites registrants to update their dossiers voluntarily and improve their quality. It also illustrates the possibilities and conditions for using alternative testing methods and assessment approaches to avoid unnecessary animal testing in cases where alternatives can be applied.

In 2014, ECHA will publish the second three-year report on the status of 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. The report will require statistical analysis of the registration dossiers submitted for the 2013 deadline, for which further development of certain IT tools will be necessary.

3.3 Risk Management

Priorities 2013-2015

Mobilise authorities to use data intelligently to identify and address chemicals of concern whilst at the same time taking into account the need to carry out an increasing workload efficiently and effectively by, *inter alia*:

- Further developing methods and approaches that allow the effective use of REACH data to identify those substances which need further regulatory risk management, and which have not yet been adequately addressed by Community legislation;
- Ensuring the optimal use of the different REACH processes to address and reduce adequately the risks from chemicals of concern.

Identification of Substances for Further Risk Management Work

Data from registration, from other REACH processes, as well as from other sources, are used to identify substances and their uses i) for which further data is needed to confirm or refute concerns and ii) that require further regulatory risk management, including harmonised classification. Although new data should be generated only when needed for well founded decision-making, it is recognised that in many cases, the screening of substances results in requests for new information. Therefore, during this planning period it is important to further develop a common understanding with Member States on the interactions between screening activities, dossier and substance evaluation, and risk management, and how to use these processes for effective regulatory risk management. Furthermore, it is anticipated that in the longer term the efforts directed at improving the quality of Chemicals Safety Reports included in registration dossiers will also contribute to more effective identification of new regulatory needs.

Substances in articles may pose risks to human health or the environment. While emissions to air, water or soil during the service-life and waste stage of articles are only some of the sources of exposure, these deserve specific focus during this planning period. This is the case given that there are new information sources, in particular, registration dossiers, substance in articles notifications and DU reports, which will support the assessment of whether more regulatory actions are warranted to control the potential risks resulting from the use of substances in articles. ECHA will 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 and if so, to consider the need for restricting such uses.

Initiating action at EU level, including the use of the restriction or authorisation mechanisms under REACH, requires resources from 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 efficiently contributes to the 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. During this planning period, the first experiences from the new processes (e.g. substance in articles notifications, authorisation applications) will be used to refine and to develop further the assessment of risk management options and to increase common understanding of the optimal use of REACH processes.

While authorisation and restriction are the main regulatory risk management instruments under REACH, the information generated by REACH processes can also be used when considering and designing measures under other relevant EU legislation. To ensure effective use of information and regulatory coherence, it is important to develop well-functioning channels for transferring such information to the authorities responsible for the implementation of other EU legislation.

3.3.1 Authorisation

The authorisation procedure aims to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies, where these are economically and technically viable.

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[9];
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.

SVHCs are identified by placing them on a Candidate List based on their intrinsic properties. ECHA subsequently issues recommendations to the Commission for some of these substances to be placed on the Authorisation List (REACH Annex XIV) following a priority-setting approach agreed with the Member State Committee, and which uses the priority setting criteria included in REACH. To be able to continue placing on the market and/or using these substances, companies must apply to ECHA for an authorisation – subject to time-limited review for specific uses – whilst at the same time providing an analysis of available alternatives. Through the active and efficient implementation of the authorisation process, ECHA contributes significantly to the promotion of the substitution of some of the most dangerous substances in the EU. By using an evidence-based approach, it is anticipated that the active transfer to safer alternative substances or technologies will also contribute to the increased competitiveness of EU industry.[10]

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 for justifying the identification of the substance as an SVHC in accordance with the criteria mentioned above. ECHA will continue providing support to Member States, for instance through expert meetings on risk management, the further improvement of formats and guidance, and, when needed, training. In collaboration with the Commission and MSCAs, ECHA will work on further developing a common understanding of the principles and minimum requirements that should apply when identifying a substance as an SVHC via the REACH Article 57 (f) route. Work done during this planning period is particularly important in view of the fact that substance evaluation is expected to generate new information which can be used to identify substances as PBTs, vPvBs or as substances of equivalent concern in 2015 and beyond.

ECHA is prepared to develop five Annex XV SVHC dossiers per year at the request of the Commission. In addition, it is anticipated that a substantial number of SVHC dossiers developed by MSs will also enter the process in the coming years. The Candidate List, which contained 73 substances at the end of 2011, is expected to grow steadily in the period 2013-2015, with an increasing focus on PBTs, vPvB substances, and substances of equivalent concern to these.

Inclusion of Substances in the Authorisation List (Annex XIV)

Based on ECHA's recommendation of 17 December 2010, the Commission amended the Authorisation List for the second time in February 2012. ECHA will use the experience gained during the elaboration of the first recommendations, in particular with respect to setting transitional periods, to develop future recommendations on an annual basis. Working closely with the Member State Committee, ECHA will continue to develop its priority-setting approach for selecting substances from the Candidate List, taking particular account of the growing number of substances on that list.

[9] 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).

[10] It should be noted that the use of SVHCs in articles imported from outside the EU is not covered by the authorisation provisions. If there are human health or environmental risks identified from such uses, ECHA will consider the development of specific proposals for restricting such uses.

Applications for Authorisation

Applications for authorisation can be made by manufacturers, importers, downstream users and/or Only Representatives, and need to be submitted to ECHA. An application can cover the applicants' own uses and/or those of their downstream users.

ECHA's Committees on Risk Assessment and Socio-economic Analysis provide the Commission with opinions on each application for authorisation. Subsequently the Commission decides on the granting or refusal of these authorisations, taking into account the risks to human health and/or the environment of the use applied for and, where relevant, the socio-economic benefits and availability of suitable alternative substances or technologies.

The Commission adopted the first list of substances requiring authorisation (i.e. Annex XIV) in February 2011. In 2011, no applications for authorisation of the use of any of the substances listed on Annex XIV of REACH were received. Based on indications from industry stakeholders, the first applications are expected to be submitted in late 2012. ECHA has re-estimated the number of authorisation applications and is currently preparing to receive about 100 per year by 2015, compared to a previous estimate of 400 per year. The complexity of individual and, in particular, joint applications, would nevertheless require similar staffing as originally estimated by the Commission. This number, which is very uncertain, will be refined on the basis of the experience obtained with the first substances to be included in the authorisation list. Furthermore, as an overall reduction in ECHA staff is foreseen, ECHA will design the whole opinion-making process on authorisation applications to ensure it is as lean as possible and runs effectively in the Secretariat and its two Committees; this also includes a feedback system to allow staff to learn from opinion-making pertaining to the first applications received, and thus to improve the efficiency of the Agency's operations.

ECHA is planning to provide support to potential applicants in advance of their actual submissions in order to ensure that their applications include all relevant information. ECHA is also planning to publish pertinent information to ensure the efficiency of public consultations on possible alternatives.

The successful and effective management of the authorisation application process, duly resulting in scientifically-sound and robust RAC and SEAC opinions, will constitute a very important challenge for ECHA during this programme period.

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. Any such decision has to take into account the socio-economic impacts of the restriction, including the availability of alternatives.

Proposals for restrictions are either developed by the Member States, or by ECHA on request of the Commission. The RAC and SEAC give their opinions on suggested restrictions within 9 and 12 months respectively. During that period, interested parties have the opportunity to comment on a case and on the draft opinion of the SEAC. The opinions and supporting documentation delivered by ECHA to the Commission will need to be scientifically sound and comprehensive in order to allow the Commission, where appropriate, to draft an amendment to the REACH Regulation.

Depending on the complexity of the proposals, ECHA is prepared to develop between two and four restriction proposals annually for the Commission in 2013-2015. As per information gathered in 2011, the Member States and ECHA are planning to submit between five and 10 restriction dossiers in total, per year.

Based on the experience from opinion-making for the first Annex XV restriction reports, ECHA will continue to issue additional information, advice and, where relevant, provide training, to Member States to support them in the preparation of effective restriction proposals. The Agency will also further streamline processes so that the RAC and SEAC can concentrate on giving scientifically and technically sound opinions to underpin the Commission's decisions on restrictions.

3.3.3 Other Activities Related to Risk Management Measures

Socio-economic Analysis

To the extent permitted by its resources, 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 has started to develop methodologies and to collect estimates of disability/quality adjusted life years and willingness-to-pay to avoid negative health impacts from substances. It will continue this development to better support its risk management activities. 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. These activities will help Member States and ECHA in the preparation of Annex XV restriction reports as well as in RAC and SEAC opinion-making on incoming restriction proposals and applications for authorisation.

ECHA will also collaborate with Member States and stakeholders to improve their capacity to use different analytical tools, including socio-economic analysis, with the aim of having well-targeted and relevant risk management measures identified in restriction and authorisation processes.

3.4 Classification and Labelling

Priorities 2013-2015

Contribute to increasing the availability of high quality data by:

- Further optimising the user friendliness of the Classification and Labelling Inventory;
- Facilitating the process by which industry can align diverging classifications for the same substance.

Contribute to mobilising all authorities to use C&L data intelligently to identify and address chemicals of concern by:

- Further improving the quality of proposals for the harmonised classification and labelling of hazardous substances and the preparation of opinions.

Chemical substances or mixtures to be placed on the market need to be classified. Where a substance or mixture is classified as hazardous, the proper labelling and packaging shall be

ensured; for some substances, legally binding classification exists (harmonised at EU level). Substances with certain properties (classified as carcinogenic, mutagenic or reprotoxic (CMRs)), respiratory sensitisers and, if justified, substances classified for other hazards) are prioritised for harmonised classification and labelling (CLH). Self-classification by suppliers of substances is obligatory for those hazards where no harmonised classification exists and for mixtures. For active substances used in plant protection products or biocidal products, Member States Competent Authorities consider all hazard classes when drawing up proposals for harmonised classification and labelling.

The CLP Regulation identifies a number of tasks for ECHA that are related to the classification and labelling of hazardous substances; the main tasks being the establishment and maintenance of a Classification and Labelling Inventory; developing opinions on proposals from MSCAs and industry for the harmonised classification and labelling of substances; and processing requests from companies for the use of alternative chemical names.

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

The C&L inventory will improve the information basis on chemical substances. Industry has to submit notifications for all hazardous substances and those subject to registration, placed on the market. More than three million notifications for over one hundred thousand substances have so far been submitted and stored in the C&L Inventory. The first public version was made available on ECHA's website in February 2012 and will be improved and extended through subsequent updates.

It is anticipated that several thousands new notifications will continue to arrive each year and that existing entries to the Inventory will need to be updated by industry. Therefore, an important task for ECHA will be to maintain the Inventory and further improve its usefulness. The information has to be available for the public, the industry and Member States in a manner that is as useful and user friendly as possible while ensuring that confidentiality is maintained.

As multiple notifications of the same substance have and will be made by different manufacturers or importers, there is the potential for differences in the classifications notified. There can be valid reasons for such differences, such as different contents in impurities, but as notifiers of diverging classifications for the same substance have the duty to undertake all efforts to come to an agreement, over time such differences should decrease. Based on work that started in 2012, ECHA will further develop the tools to facilitate contact between companies placing the same substances on the market which will support them in fulfilling their obligation to undertake all reasonable efforts to come to an agreed entry in the inventory.

Handling Proposals for Harmonised Classification and Labelling

The harmonisation of classification and labelling in Annex VI of the CLP Regulation makes it legally binding. The process leading to harmonisation is resource-demanding and can only be applied to a limited number of substances. Efficient use of available administrative resources is ensured by applying this instrument predominantly to substances of very high concern, and active substances used in plant protection products and biocides, where a correct classification is crucial. Member State Competent Authorities (MSCAs) submit proposals for harmonised C&L for substances that are CMRs or for respiratory sensitisers, and for substances that have other hazardous effects where there is a justification for action on an EU-wide basis. Member State Competent Authorities, manufacturers,

importers and downstream users may submit proposals for harmonised C&L for hazard classes of substances for which no harmonised entry exists. Amendments of existing harmonised C&L may only be proposed by Member State Competent Authorities.

Proposals for harmonised C&L which provide the scientific basis for evaluating whether a substance fulfils the criteria for classification are published for comments by MSCAs and concerned parties; subsequently, they are 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 prepare a decision to include the harmonised C&L into Annex VI of the CLP Regulation resulting in a harmonised C&L for that substance.
All draft decisions have to receive the positive opinion of the REACH Committee.

ECHA expects about 70 proposals for harmonised classification to arrive in each year of the 2013-2015 period.

In order to handle this number of proposals, ECHA will need to improve further the effectiveness of the development of opinions on these proposals, based on improvements to the process already initiated in 2011-2012. In addition, ECHA, in collaboration with the European Food Safety Agency (EFSA), the Commission, and MSCAs, will work further on the alignment of the C&L process with the approval process for active substances used in plant protection products.

It is expected that further analysis of the information included in the C&L inventory and available through the registration and evaluation processes will allow MSCAs and industry to identify substances for which launch of the process of developing a harmonised classification and labelling entry in the CLP Regulation could be considered.

Evaluating Requests for the Use of Alternative Chemical Names

Manufacturers, importers and downstream users of mixtures may submit a request to ECHA for the use of an alternative chemical name for a substances in a mixture(s) 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 has to evaluate, within six weeks, whether the criteria for the use of the alternative name are fulfilled. Based on experience obtained by Member States in the past, and taking into account that companies that wish to classify their mixtures according to the CLP Regulation can no longer send their requests to the individual Member States, ECHA expects to receive an increasing number of requests in each year (up to 250 requests in 2015) of this programme period.

Preparations for the Changes Entering into Force on 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; it will also no longer be possible to classify substances according to the previous legislation. ECHA will, from 2014, initiate activities in collaboration with MSCAs and the Commission to ensure that relevant companies are fully aware of this important change in their obligations, and in good time.

3.5 Advice and Assistance through Guidance and the Helpdesk

Priorities 2013-2015

ECHA's advice and assistance to industry will remain the most pivotal means by which the Agency stimulates the submission of high quality data:

- Publishing new and updated guidance documents, drawing on experience further gained during the 2013 REACH registration process, as, for instance, the potential update of ECHA's Guidance on Information Requirements and Chemical Safety Assessment, will contribute to this goal;
- The ECHA Helpdesk and the national helpdesks conduct the most immediate interaction with duty holders in jointly working towards the safe manufacture and use of chemicals; they provide harmonised answers through the HelpNet managed by the Agency, and the ECHA Helpdesk provides support regarding ECHA's registration-related IT tools;
- In preparation of the 2018 REACH registration deadline, ECHA's guidance and helpdesk work will progressively adapt the formats of tools, guidance and messages to the needs of SMEs, as well as of companies with less experience of EU chemicals legislation. Furthermore, the HelpNet will involve national helpdesks in related awareness-raising activities.

3.5.1 Guidance

Publishing new and updated guidance on the ECHA website represents a critical pathway in spreading knowledge on the sound application of the EU's chemicals safety legislation to duty holders. This spread of knowledge contributes to ensuring the provision of comprehensive information and high-quality data that the Agency requires to fulfil its role in contributing to the safe manufacture and use of chemicals.

By 2015, ECHA's guidance is expected to have tangibly advanced the knowledge and capacity of duty holders and public authorities to implement the REACH and CLP Regulations in accordance with the most up-to-date reference framework made available via the ECHA website. The launch of this website in a totally revised format in December 2011, will already have brought about a significant improvement in the accessibility of ECHA's respective documents, by grouping ECHA's guidance and so-called "quasi-guidance" (i.e., Practical Guides, User Manuals, FAQs, etc.) together more logically and by providing a capable search engine. Through 2013 to 2015, ECHA will make full use of this communication capacity, by publishing its guidance in 23 official EU languages (i.e., including Croatian, in view of Croatia's accession to the EU, expected by mid-2013).

ECHA's guidance work will see a number of important milestones within the period from 2013 to 2015, outlined here.

Following the precedent set in 2010, this period will commence with a further "moratorium" of at least six months on the release of registration-related guidance and quasi-guidance updates in the run-up to the second REACH registration deadline, on 31 May 2013 – thus providing registrants with the requisite stability of guidance to facilitate their work in finalising their dossiers for submission.

ECHA will extend its guidance to providing advice on the implementation of the new Biocidal Products Regulation which will enter into force in 2013; as will be the case with regard to the forthcoming recast PIC Regulation.

The Agency will also embark on providing more refined guidance on the registration of substances in nano-form. ECHA's own guidance in this regard will take into account new developments on nano-materials. Some elements of the recommendations from the information provided by the REACH Implementation Projects on Nano-materials (RIP-oNs) will have been implemented into appendices to the current guidance in 2012. This will be followed by further updates in subsequent years, to provide further detailed advice reflecting the state-of-the-art in regulatory science in this respect.

After the 2013 REACH registration deadline, ECHA will again harvest feedback from registrants and other actors to draw upon lessons learned for the further development of related guidance. This may trigger further updates of the 'Guidance on Information Requirements and Chemical Safety Assessment'. Furthermore, authorisation-related guidance will be updated on the basis of experience gained from the first wave of applications for authorisation which will be analysed in 2015.

New and updated guidance will gradually be populated with additional examples and explanations from the continually growing experience of applying EU chemicals safety legislation. Such guidance will also support duty holders in fulfilling their legal obligations when updating their dossiers to improve quality. Whilst ECHA will endeavour to generate guidance which will be as helpful as possible to duty holders, it will never, however, intend such guidance to be as prescriptive as to replace the case-specific judgement that is to be exercised by duty holders on whom the REACH and CLP Regulations have ultimately imposed the burden of proof.

Given the growing number of companies with little experience of REACH and who will become subject to the 2013 and 2018 registration deadlines, and ECHA's expectation that SMEs will represent the largest category of registrants submitting dossiers for the latter, ECHA will – from 2013 through 2015 – also focus on providing more information in easily accessible formats, such as "Guidance in a Nutshell" or "Practical Guides".

Lastly, the further development of the Navigator as well as the ECHA-terminology tools will provide additional help to duty holders; this development will increase incrementally over 2013-15.

3.5.2 Helpdesk

By 2015, the Helpdesk will have further expanded its activities to support duty holders in fulfilling their obligations, and will have helped those with duties for the 2013 REACH registration deadline in particular, to submit their dossiers in due time and in the correct form.

With this effort, the Helpdesk will be one of the Agency's key players in achieving its strategic goal of elevating the quality of information and data on the safe manufacture and use of chemicals.

In 2013, the challenges that the Helpdesk will face are mainly two-fold: it will face a peak workload ahead of the 31 May 2013 REACH registration deadline and will, drawing on experience from its analogous activities in autumn 2010, provide a special service to registrants in the immediate run-up to the deadline. This service will again include two-way

contacts with companies, including by telephone. The other challenge will be to extend its activities to include advice on implementing the Biocidal Products Regulation and to introduce the topic of biocides to its network of national helpdesks.

Throughout the period 2013-2015, the Helpdesk will continuously adapt its responses to ongoing developments in the implementation of European chemicals safety legislation. The Agency will continue its practice of updating its FAQs and providing Question and Answer documents on the ECHA website. These will take account of new legislative obligations taking effect, such as the inclusion of mixtures into the duties of manufacturers to affix C&L pictograms in accordance with the CLP Regulation. Moreover, the Helpdesk not only has the task of providing help on relevant legislation and its application, but also of supporting the users of the IT tools that the Agency provides to duty holders. The Helpdesk will continue to make use of webinars to address its customer audiences.

ECHA manages the network of national REACH and CLP helpdesks (HelpNet) which allows the national helpdesks of EU/EEA countries (as well as industry helpdesks which participate in the network as observers) to harmonise their responses to questions from industry, as well as to exchange best practice and other information relevant to their work. The HelpNet Steering Group, under the chairmanship of the Agency, will regularly convene to give support to this activity. Whilst this network currently includes all national REACH and CLP helpdesks, in 2013, the Agency will need to devise appropriate means to integrate national Biocide helpdesks which EU/EEA competent authorities may establish at their discretion (as the Biocides Product Regulation will not make such national helpdesks mandatory), into the work of the HelpNet.

In view of the REACH registration deadline of 2018, for which more SME registrants can be expected, the advice provided by national REACH and CLP helpdesks becomes even more important. ECHA will therefore reinforce its efforts to keep national helpdesks up to date and to build, by means of training, their capacity to provide good advice. Via the HelpNet, the Agency will involve national helpdesks in related awareness-raising activities.

Ensuring that the required quality of information is gathered by ECHA not only involves reaching out to duty holders by giving advice in response to their queries, but also ensuring that the ECHA Helpdesk is closely involved within the Agency in developing and releasing scientific IT tools available to external users. The ECHA Helpdesk will become an even more integral part of the Agency's work in testing such tools ahead of their release and in drawing up user manuals. This involvement of the ECHA Helpdesk in the quality assurance of tools will equip its staff with the skills and knowledge that are a prerequisite to subsequently support industry users. The ECHA Helpdesk will also evaluate the needs of external users for training and guidance on the application of these tools and arrange such training in close coordination with the IT project teams of the Agency. Such training is particularly important in view of the registration deadline of 2018, as it can be expected that SMEs will face difficulties with the complexity of the software applications they are required to use to register successfully.

3.6 Scientific IT Tools

Priorities 2013-2015

To enable intelligent use of data to identify and address chemicals of concern, ECHA will:

- Enhance the integration of its IT systems to provide an easy, customizable, secured and unique access to information held by ECHA to internal and remote users (MSCAs and Commission);

- Enhance ECHA's dissemination portal to develop the concept of a "single point of access", to improve the format, and to build more powerful searches on the properties and uses of chemicals.

To contribute to making high quality data available, ECHA will:

- Continue enhancing IT tools that support registrants such as the Chemical safety assessment and reporting tool (Chesar), to create the conditions to make its formats and algorithms for exposure scenario generation the industry norm for new and updated registrations.

To embrace current and new legislative tasks efficiently and effectively, while adapting to upcoming resource constraints, ECHA will:

- Enhance and implement information systems to enable it to manage the expected (increase and in some respect peak) workload levels, and ensuring that ECHA's regulatory action can be indispensably traced, audited and is accountable, while concurrently facing stringent resource constraints;
- Prepare IT support for the implementation of tasks under the new Biocidal Products legislation, leveraging the experience and the components developed in existing IT systems.

ECHA has developed a wide range of IT systems to support REACH and CLP operations. Over time, focus has moved from submission and dissemination processes (the REACH-IT system, IUCLID, Chesar, and Dissemination) to supporting the workflows which begun after completion of submission for the first registration deadline. These workflows are largely related to decision-forming/decision-making in evaluation and risk management.

Further to the Enterprise Architecture study carried out in 2010, which disclosed risks associated to the fragmentation of data across several systems, ECHA launched a data integration project in 2011, with a view to integrating better its business applications. An area of innovation in 2013 and 2014 will be the release of a new generation of IT tools implementing integrated models for data management, for security and access management, and for communication between industry, ECHA, Member States and the Commission. Although the primary systems concerned by the project are REACH-IT and IUCLID, the outcome of the work will have an impact on other systems, such as ECHA's Data warehouse (CASPER) and RIPE, and the dissemination portal.

One of the core components of the new generation system will be a portal which will represent a single point of access to ECHA systems and the platform for a revised approach to the publication of information on chemicals (dissemination). In this respect the portal – the completion of which is planned for 2015 - will focus on enhancing the usability of the published information, as well as the information sources and the search functionalities available to the public.

In 2013, ECHA has to face the second REACH registration deadline, and in 2013 and 2014, a foreseeable peak in post-registration tasks (dissemination and evaluation) has to be sustained while the Agency handles an increasing number of authorisation applications. Current regulatory tasks under REACH and CLP require the constant optimisation of ECHA's operational processes to meet legal obligations with an increased level of effectiveness and efficiency.

Preparations for the 2018 REACH registration deadline will have to begun in 2014. These registrations are estimated to be by far the highest in numbers – as compared to the earlier deadlines – and it is expected that there will be more SMEs among the registrants

than for previous deadlines. ECHA's processes and systems will, therefore, be considerably strained and need to be adapted to meet the expected workload. Moreover, ECHA will continue enhancing IT tools for registrants that support the generation of high quality dossiers, such as the Chemical safety assessment and reporting tool (Chesar) or the OECD QSAR Toolbox - which enables data gaps to be filled in a structured and fully transparent manner. In order to put into place usability enhancements to ease SMEs' interaction with REACH-IT in 2018, ECHA will carry on a technical study of REACH-IT to assess the impact and the feasibility to operate it in 23 languages.

Most ECHA processes involve collaboration with external regulatory partners (specifically MSCAs and COM). This calls for rethinking ECHA's systems and processes as well as secure data access policies and solutions. Such an outward looking approach will also be substantiated by involving MSCAs, industry representatives and the Helpdesk in working groups aimed at gathering requirements and at the verification and validation of IT tools.
In 2013, ECHA will have a set of enhanced systems for supporting the new registration deadline (IUCLID 5.4, REACH-IT 2.4, and CHESAR 2), and it will focus on operating them at a very high level of availability and performance under peak conditions. Offering an adequate level of IT support for the post-registration tasks will also be a priority.

To ensure higher levels of efficiency and the indispensable traceability of ECHA's regulatory action, ECHA will pursue the implementation of IT support for workflow management and document management in the context of the Enterprise Content Management (ECM) programme. During the period 2013-2015, the ECM Programme will further develop ECHA's processes. A workflow will be developed for Substance Evaluation, covering CoRAP updates and Substance Evaluation. Collaboration capabilities will be progressively developed to support the work of MSCAs, and the MSC, RAC and SEAC. The ECM Programme will also develop the use a document management platform for the management of Agency documents and records, and additional modules will complement existing applications for SVHC and dossier evaluation process, with reporting functionalities and support for the MSC secretariat and the legal unit.

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 from 2013 onwards. Given the extensive needs, this IT development will be a gradually evolving multi-annual project. The current databases and functionalities will be modified in an integrated way as far as possible to benefit from common mechanisms and building blocks.

To support the operational tasks under the biocides legislation, 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.

As responsibilities for regulatory processes are more widely distributed under the biocides legislation, an enhancement of ECHA's Information Systems will be required to adapt them to involve "partner" authorities beyond its organisational borders.

3.7 Scientific Activities and Technical Advice to EU Institutions and Bodies

Priorities 2013-2015

To become a hub for the scientific and regulatory capacity building of Member States, European institutions and other actors, ECHA will pro-actively seek to:

- Address new challenges in fields such as nanomaterials, endocrine disruptors, test methods (including alternative methods), mixture toxicity and other scientifically complex areas, and use this new knowledge to improve implementation of chemicals legislation.

To pursue intelligent use of data, ECHA will:

- Support the Commission in the further development of the REACH and CLP regulations and any other related legislation on chemicals;
- Foster collaboration and good relations with EU institutions, and relevant bodies within the EU, that are internationally active on chemicals.

To contribute to improving the quality of data, ECHA will:

- Solidify harmonised and efficient practice in conducting, documenting and communicating chemical safety assessments among all stakeholders to ensure the collection of high quality information in this area.

The REACH legislation establishes that the Agency must provide the Member States and the EU institutions with the best scientific and technical advice on questions relating to chemicals which fall within its remit. Now that the first registration deadline has passed, bringing substantial information, i.a. on the properties and effects of chemicals placed on the market, there is an increasing expectation for closer interaction and collaboration between European regulators to use this information. Moreover, the scientific capacity of ECHA and its scientific Committees has achieved a degree of maturity allowing the Agency to increase its contribution in questions of a scientific nature relevant to policy-makers.

In the period 2013-2015, ECHA will further enhance its co-operation with the EU institutions, in particular the European Parliament and the Commission, for the further development of the REACH and CLP Regulations. The expertise and know-how gained with the implementation of these two legislations will be used, whenever appropriate, to provide advice on any related legislation concerning chemicals, as well as on measures related to their implementation. As a consequence, the number of specific requests for scientific opinions by ECHA Committees, under Article 77(3)(c) of REACH, is likely to increase, and ECHA will respond to these requests, resources allowing.

With regard to nanomaterials, ECHA aims to ensure that the regulatory requirements of REACH and CLP can be fully implemented to address the hazards and risks of substances in nano-form. ECHA will further extend its internal capacities in the area of the characterisation, hazard and safety assessment and risk management of nanomaterials; the Agency will also enable Member States' experts to participate in capacity building and will share experience with stakeholders. ECHA will participate in various scientific and regulatory activities at the EU and OECD level with the aim of developing appropriate guidance for industry, as well as to be able to evaluate registration dossiers that contain information on the hazards, risks and risk management of nanomaterials, effectively.

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

Besides these planned activities, ECHA faces other significant scientific challenges which are embedded in the execution of its tasks, related, for example, to endocrine disruptors or mixture toxicity. Therefore, the Agency will seek constantly to develop its scientific capacity in order to be able to tackle these challenges within existing legislative frameworks. This will be achieved by creating, within the Agency, a knowledge management approach and by increasing efficiency through coordinated efforts with other EU institutions and Member States.

Indeed, 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 and MS authorities involved in the implementation of sector-specific legislation on the assessment and management of the risks from chemicals (such as legislation on specific product types, or on environment or worker protection). 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 (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 will continue to contribute to creating synergies between REACH and other EU legislation.

There is also cooperation needed 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 order to achieve synergies at the EU level. 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.

Finally, ECHA will also continue its specific reporting activities to the Commission, as required by REACH, during the 2013-15 period. ECHA will, in particular, draw up the second three-year report[11] 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 start preparing for the second five-year report on

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

REACH and CLP implementation, due by June 2016. In addition, and if duly 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 endocrine-disrupting substances, in relation to the authorisation procedure.

3.8 Biocides

Priorities 2013-2015

Embrace current and new legislative tasks efficiently and effectively by:

- Building up ECHA's capacity to deal with new responsibilities under the future Biocidal Products Regulation and preparing the implementation thereof;
- Ensuring that the implementation of the new tasks assigned to ECHA under the Biocidal Products Regulation begins effectively, by developing efficient processes as well as by integrating them into ECHA's organisational structure efficiently.

In June 2009, the European Commission adopted 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 foreseen for mid-2012 and its application starting from September 2013. Within the period 2013-2015, ECHA has therefore to ensure that it can begin implementing its new biocides 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.

Alongside this biocides-specific chapter, the Agency's various biocides-related activities are described in other chapters, in order to demonstrate how ECHA will attempt to maximise the synergies between these tasks and those under other legislation, e.g. by fully integrating its processes.

Evaluation and Approval of Active Substances

Active substances can be used in biocidal products if they are approved. The approval process aims at ensuring that active substances do not result in unacceptable effects on human or animal health or on the environment.

After submission of an application for approval from industry, and payment of related fees, a 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 ECHA committee (the Biocidal Product Committee) will prepare an opinion on the report. The committee's opinion will be submitted to the Commission, who will decide upon approval of the application. 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's responsibility for 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 September 2013. This requires finalisation of the ongoing preparatory work where the processes and workflows are designed. Management of the handover of the current Review Programme by the end of 2013 will require close coordination with the Joint Research Centre of the Commission. 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. This is to ensure that biocidal products do not result in unacceptable effects on human or animal health, or on the environment.

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.

In the Union authorisation procedure, applications will be submitted to ECHA who 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 six product types and will widen to three additional product types in 2017, and to all remaining product types in 2020 (with certain product types exempted from EU authorisation).

ECHA will play a role in the mutual recognition of individual products, and will provide the Secretariat for a new coordination group of Member State authorities which will examine questions related to mutual recognition. Eventually, the Commission may request ECHA's opinion should the coordination group not be able to resolve disagreements between Member States.

Data Sharing, Alternative Suppliers and Technical Equivalence

In a similar manner to REACH, the proposed Biocidal Products 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 arbitration 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 can be established. These are decisions for which an appeal can be brought in front of ECHA's Board of Appeal.

The Regulation will also require all companies marketing active substances in the EU to show that they have access to the required data, either by providing a letter of access or a dossier. This procedure is meant to solve the problem of so-called alternative suppliers, i.e. companies that have so far been able to continue marketing biocidal active substances without an application for approval and the related investment. ECHA will have to publish a list of manufacturers who wish to continue marketing in the future.

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

3.9 PIC Regulation

Priorities 2013-2015

Embrace current and new legislative tasks by:

- Efficiently and effectively preparing for the new responsibilities under the future PIC Regulation and begin implementation.

In 2011, the Commission adopted a proposal for the 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). The PIC Regulation implements the international Rotterdam Convention into EU law; it applies to banned or severely restricted chemicals and provides for information exchange mechanisms regarding the export and import of those chemicals. Those mechanisms include an export notification for banned or severely restricted chemicals listed in Annex I to the Regulation. The Regulation also contains a Prior Informed Consent (PIC) procedure for chemicals that are specifically identified as PIC chemicals under the Rotterdam Convention, and which are also listed in the Regulation itself. The export of PIC chemicals requires the explicit consent of the importing country.

The Commission has proposed in the recast that certain tasks regarding the implementation of the Regulation will be transferred from the Joint Research Centre of the Commission to ECHA: it is duly expected that ECHA will manage the practical functioning of the PIC mechanisms and will provide the Commission, upon request, with technical and scientific input and assistance with respect to the latter's role as commonly designated 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 implementation of tasks under the new Biocidal Products Regulation, although on a much smaller scale. ECHA will first prepare development of IT tools and working procedures to process export notifications and to deal with other tasks resulting from this legislation, and then begin to implement these procedures.

4 ECHA'S BODIES AND CROSS-CUTTING ACTIVITIES

4.1 Committees and Forum

Priorities 2013-2015

To contribute to securing a high quality of data and promoting the intelligent use thereof, and to address scientific challenges in an efficient way, ECHA will:

- Provide a solid basis for MSC agreements on evaluation and SVHC processes by investing further both in the scientific content of its work and in the efficiency of procedures and working methods;
- Provide a solid basis for Commission decisions on regulatory risk management by further investing in RAC and SEAC regarding the scientific content of their opinions, and regarding the transparency and efficiency of procedures and working methods, including close coordination between the RAC and SEAC;
- Significantly promote enforcement of evaluation decisions in the Member States and selection of enforcement projects that contribute to the Agency's strategic aims.

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, CLP and Biocidal Product Regulations and to the credibility of ECHA in ensuring its independence, scientific integrity, and transparency.

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, as well as by any additional requests made by the Executive Director of ECHA.

4.1.1 RAC and SEAC

The Risk Assessment Committee (RAC) delivers opinions on: 1) proposals for the harmonised classification and labelling of substances; 2) proposals for the restriction 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 to the environment.

The Socio-Economic Analysis Committee (SEAC) gives opinions on: 1) proposed restrictions, their socio-economic impact and on the availability and technical and economic feasibility of alternatives; 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 2013-2015, 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 an efficient interaction and common understanding amongst both Committees is essential. Dealing with the different legal deadlines for the two Committees 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 is expected to rise continuously, or even dramatically. The number of plenary meetings is estimated to rise to up to six per year in the case of the RAC, and four to five in the case of the SEAC. In the years 2013–2015, both Committees are expected to hold an increasing number of working group meetings to support the (co-)rapporteurs and to prepare the conclusions of the Committee. The use of written procedures will also increase to limit the need for plenary meetings. The Committees will therefore need to maximise efficiency and streamline working procedures when dealing with specific dossiers in order to be able to cope with a sharply increasing workload as the number of authorisation applications, in particular, is expected to grow significantly. In addition, the RAC and SEAC will need to consider 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 acquired experience.

Coordination with other EU scientific committees dealing with the same or similar substances under different regulatory frameworks, will represent an additional challenge; with early identification of potential divergences in opinions being a critical issue. As a consequence, the coordination of the RAC with scientific committees involved in risk assessment that support other Agencies and European Union bodies, will need to be expanded – covering not only the identification of potential divergences, but also the development of 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 and substance evaluation, and on proposals for identification of substances of very high concern (SVHCs). Where the MSC fails to reach unanimous agreement, its opinion are 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 agreement on priorities for the SVHCs to be included in the Authorisation List (Annex XIV) That is why members are assisted in each meeting by experts from their competent authorities.

Draft evaluation decisions require agreement to be sought in the MSC if at least one Member State submits proposals for amendment of the decision (the latter is prepared by ECHA). Given that several hundred draft decisions will be concluded by ECHA each year, it

is expected that between 2013 and 2015, the MSC will seek unanimous agreement on well over 100 draft decisions each year. Draft dossier evaluation decisions will continue to form a major part of the MSC workload; the Committee is expected to start work on substance evaluation in 2012, and during 2013-2015, it will need to seek agreement on the first draft decisions on substance evaluation.

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 the authorisation list.

This increasing workload requires frequent and efficient use of written procedures; use of working groups; and in addition, Committee meetings every two months. New tasks from substance evaluation will require more time for discussion – at least over the first years of the process – which will lead to longer MSC meetings despite their frequency not being expected to grow.

4.1.3 Biocidal Products Committee

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

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

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

4.1.4 Forum

Each EU/EEA Member State is required to set up a system of official controls to implement REACH and CLP Regulations. Effective, harmonised, and equal enforcement throughout the EU is of crucial importance. The Forum for Exchange of Information on Enforcement ("Forum") is the coordinating network of EU/EEA Member States authorities responsible for enforcement. The Forum is an integral part of ECHA, with an essential role in ensuring harmonised enforcement activities; and the REACH, CLP and PIC Regulations[12] place a number of duties on the Forum. Member State representatives chair the meetings and the working groups of the Forum; the latter is supported by a Forum Secretariat composed of ECHA staff.

As the implementation of the REACH and CLP Regulations advances, enforcement is progressively taking an ever-more prominent role in mobilising duty holders to effectively use chemicals safely and to address chemicals of concern. By 2013-2015, the Forum, as the appropriate body of ECHA, will take on an increasingly operative role in facilitating the

[12] The Forum shall be used to coordinate activities of the Member States' authorities responsible for enforcement of the PIC Regulation.

information flow allowing the enforcement of ECHA decisions; this will be in addition to its traditional tasks of promoting generic approaches to harmonising enforcement practices between EU/EEA countries with the longer-term aim of levelling the playing field across Europe. The launch of the RIPE tool (REACH Information Portal for Enforcement) in mid-2011 marked a key milestone in this regard. The finalisation of the Interlinks Project in 2012 will be another.

As the implementation of legislation 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's efforts will increasingly encompass operational functions linked to enforcing individual decisions via inspections in Member States.

The impact of the conclusions or initiatives of the Forum will, however, depend upon the involvement of its members and their ability to mobilise the resources of the national authorities responsible for enforcement. Ultimately, the success of the REACH, CLP and PIC Regulations depends on effective enforcement in Member States; in this context, the Secretariat will continue its efforts to support the Forum in its activities on harmonised enforcement, to the fullest extent possible.

The Forum undertakes its activities according to a three-year Forum Work Programme which is regularly updated and is available on the ECHA website. The core documents "Strategies of Enforcement of REACH and CLP" and the "Minimum Criteria for REACH and CLP Inspections" will continue to be regularly updated on the basis of harmonised enforcement projects supported by guidance and training material for local inspectors. ECHA will continue organising "train the trainers" events to promulgate best enforcement practice. The Forum's coordinated harmonised enforcement projects, e.g. on enforcing the "no data, no market" rule with regard to (pre-) registration, or on supply chain-related REACH obligations vis-à-vis substances in mixtures that are prepared by formulators or the appropriate classification and labelling of substances, and co-operation with customs services, will be of particular importance.

With the establishment of pilot projects, the Forum will improve the means of communication and elaborate the specific needs for inspectors, when checking specific processes. The RIPE tool will also be expanded with new features.

The Forum will continue to cooperate with the RAC and SEAC to give advice on the enforceability of proposed restrictions on substances, and to take measures to further improve the efficiency of this consultation process.

It will endeavour to make its work as transparent as the nature of its enforcement-related mandate allows. ECHA's new website introduced in December 2011 already provides an improved platform for publishing information on the Forum's activities. The Forum will continue to hold an open session with stakeholders once per year to discuss specific enforcement-related topics.

To increase the effectiveness of the harmonisation of enforcement, the ECHA Secretariat will, in close collaboration with the Forum, further develop information portals and exchange tools to facilitate communication amongst enforcement authorities. Activities regarding the coordination of the exchange of inspectors and study visits will stimulate and intensify information exchange. At the same time, the Forum will continue to develop and implement a harmonised methodology to allow, *inter alia*, effective measurement of the progress of its work.

4.2 Board of Appeal

Priorities 2013-2015

Embrace current and new legislative tasks efficiently and effectively by:

- Managing the highly volatile number of appeal cases deriving from complicated scientific and technical issues – not only from REACH and CLP, but also the Biocidal Products Regulation;
- Enhancing the procedural effectiveness and efficiency of the appeal system, including providing input, as appropriate, to the Commission for the purposes of amending the Rules of Procedure, *inter alia*, as a result of the entry into force of the Biocidal Products Regulation.

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 (AAMs) have been appointed and can be called upon, on a part-time basis, to cope with fluctuations in the volume of work, conflicts of interest situations, 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. An appeal may be lodged against certain Agency decisions concerning registrations, data sharing, testing proposals, compliance checks, substance evaluations, and PPORDs.

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. The number of appeals lodged before the Board of Appeal will depend upon the number of decisions taken by ECHA and the subsequent position taken by affected parties, i.e. as to whether or not to appeal against ECHA decisions. 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 2013–2015 are extrapolated from the predicted number of appealable decisions taken by ECHA.

It is expected that in the first months of 2013, prior to the second registration deadline, a higher share of registrations will be introduced by companies having less experience of, and expertise in, regulatory chemical issues, than was the case before the 2010 registration deadline. It is possible that this will result in a greater number of negative decisions from ECHA, reflecting the typical problems that these companies could have with the registration process.

It is foreseen that there will be an increasing number of dossier and substance evaluation decisions which could result in scientifically complex appeals. This will also require the targeted scientific training of BoA members and Registry staff.

The forthcoming Biocidal Products Regulation will require specific preparatory work, including review of the Rules of Procedure and the internal procedures of the Board, so that

it is able to handle appeals resulting from both the REACH Regulation and the Biocidal Products Regulation. The new duties placed on the Board of Appeal will also require capacity building in this new field of competence. Raising awareness among stakeholders of the scope of appeals under the new Biocidal Products Regulation will also need to be tackled.

During the 2013-15 period, the Board of Appeal will also need to analyse its structure and organisation systematically, on the basis of experience gained.

4.3 Communications

Priorities 2013-2015

Through external communication activities promoting the preparation of high quality dossiers, ECHA will:

- Reach out to industry and duty holders as a key audience providing not only regular news on developments, but also dedicated campaigns to guide the contribution of high quality data that is essential for the safe manufacture and use of chemicals;
- With ECHA's new website, launched in December 2011, designed to provide information and to contain multiple features making it more accessible in accordance with the needs of all audiences, this main communication tool of the Agency will – not least by disseminating information on registered chemicals in accordance with legal requirements – help all actors identify and address chemicals of concern.

Proactive and professional communication is fundamental to achieving the Agency's strategic goals. ECHA needs to be an intelligible spokesperson if there is to be the step change in the safer use of chemicals that the EU legislation requires. Without reaching out to its audiences, the Agency would neither be able to enable industry to provide higher-quality data to ensure the safe manufacture and use of chemicals, nor be able to consult effectively to address chemicals of concern. Internal communication is equally important to keep the Agency's staff abreast of developments in a fast-moving environment and to sustain the level of two-way dialogue that is essential to managing change in an environment of evolving responsibilities and finite resources.

ECHA has seven primary external audiences (industry; institutional partners; Accredited Stakeholder Organisations; third parties; the media; general interest audiences; and the focus groups of targeted communication efforts). ECHA's own staff is the eighth audience. The Agency has vehicles in place to reach all of these audiences, but they are under constant review – in response to regular feedback from users.

In addition to formal guidance documents and manuals, ECHA's current communication vehicles include: its website and intranet; 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, Work Programme, three-year rolling Multi-Annual Work Programme, regulatory reports and their layman's summaries.

In 2013-2015, ECHA will continue to provide multilingual products for the public as well as small and medium-sized companies. By 2013, it will also provide material translated into Croatian, in view of Croatia's accession to the EU by the middle of that year. ECHA will continuously add more terms, in multiple languages, to the ECHA terminology tool. The Agency will also have in place a new publication management tool that will facilitate the timely publication and revision of information provided in different language versions.

Cooperation with its Accredited Stakeholder Organisations will, even more so than in previous years, enable the Agency to gather their feedback and to count on their channels to multiply its outreach towards key industry audiences and the general public.

ECHA will run targeted campaigns in cooperation with stakeholders and institutional partners, for example: to raise awareness of new legal obligations (such as the need to classify and label mixtures in accordance with the CLP Regulation as from June 2015); applying for authorisations; and supporting companies with little experience in REACH and CLP that will join the number of companies submitting dossiers for the May 2013 REACH registration deadline.

Even before the outset of 2013, ECHA will start to communicate about the requirements under the new Biocidal Products and recast PIC Regulations, via awareness-raising activities and goal-oriented information campaigns.

Between 2013 and 2015, ECHA will continuously populate its website with news on developments in the EU's chemicals safety regime and its own activities. The information provided on the website, under the headings of "addressing chemicals of concern", "information on chemicals" and "chemicals in our life" – parts of which fulfil ECHA's legal role in disseminating information on registered chemicals on its website – contribute to the ability of all the Agency's audiences to use chemicals-related data intelligently and to take measures – in industry as well as in households – to address chemicals of concern.

Apart from further expanding the content and functionalities of ECHA's website, the years 2013 and beyond will see the Agency making use of social media, in accordance with its media strategy. By then, the Agency will also have intensified its contacts with media representatives, enabling it to better ensure a balanced media presence.

4.4 International Cooperation

Priorities 2013-2015

ECHA's cooperation with international organisations, particularly the OECD, and third countries, contributes to maximising the availability of high-quality data to enable the safe manufacture and use of chemicals and also addresses chemicals of concern, as it:

- includes instrumental work in advancing various tools and databases (IUCLID, QSAR, eChemPortal);
- includes presentations to relevant audiences outside the EU and the exchange of best practice with regulatory authorities in four OECD Member States; and
- helps ECHA staff to address scientific challenges.

The Agency's international cooperation and support for the European Commission's multilateral activities, as well its explanatory work to audiences outside the EU/EEA, contribute to the better quality of data submissions (via Only Representatives), as well as to ability of third country actors to identify and address chemicals of concern.

During 2013-2015, the Agency's work will again cover five main areas: OECD-related work; explanatory presentations on developments in the EU chemicals safety regime, as well as on the work of the Agency, to audiences in third countries (particularly OECD members and the EU's trading partners); presentations, particularly in EU candidate and potential candidate countries; cooperation with peer regulatory agencies in chosen OECD countries; and the provision of technical and scientific support to the European Commission in its multilateral work.

ECHA will continue its involvement in the international-level harmonisation process for the collection and exchange of structured information on chemical substances. This is key to facilitating the interoperability of IT platforms and the exchange of information between regulatory and industry actors; to avoiding the duplication of work by registrants; and to increasing synergies between regulatory actors. ECHA will continue its efforts to make IUCLID a standard for storing information on the properties and uses of substances at international level. To this end, ECHA will help coordinate new developments within the OECD community to safeguard IUCLID's maximum usability. ECHA will also identify new harmonisation needs at the international level – for example in the field of tests performed on nano-materials, *in vitro* test methods or non test methods – and contribute to the development of harmonised formats to be implemented in IT systems, in particular IUCLID.

In addition, ECHA will be engaged in the development of the OECD QSAR Toolbox to best serve the needs of 2018 registrants, and to promote its use for generating registration information and reducing testing on animals, whenever appropriate.

ECHA will also continue to develop and promote the *eChemPortal*. This portal is a major ECHA contribution to the EU's commitment to identify and make information on chemical properties publicly available.

With the years until 2015 seeing numerous milestones in the implementation of the EU's chemicals safety regime, ECHA's explanatory work to international audiences will remain important. Keeping these audiences up to date with developments satisfies their legitimate interest in obtaining information from the very EU agency mandated to implement the relevant regulations. The fact that 19% of dossiers submitted for the first REACH registration deadline were made by Only Representatives and that the ECHA Helpdesk receives a considerable proportion (17% in 2011) of its queries from outside the EU (mainly from the USA, China, India, Japan and Switzerland) – which also corresponds to the geographical spread of visitors to the ECHA website – indicates that there is a large audience for ECHA to address internationally: it is also in the Agency's own interest to reach out to them. Dossier submissions made via Only Representatives for the 2013 and 2018 registration deadlines may, as a result, provide improved data quality, and queries to the ECHA Helpdesk may be reduced in number if such audiences are better informed.

By 2015, ECHA will have further helped neighbouring countries make progress in their alignment with and understanding of the EU's chemicals safety requirements. The extent to which the Agency will, with financial support from the European Commission through funding from the Instrument for Pre-Accession Assistance (IPA) – managed outside the ECHA budget – continue to hold workshops, training and explanatory events in candidate countries and potential candidates, will depend on the Commission's decision, due in 2014, to further extend the respective IPA programme. The accession of Croatia to the European Union in mid-2013 will require special attention in the first half of that year, but will also change the picture regarding the Agency's involvement in the IPA programme beyond that date.

The Agency's cooperation with its peer regulatory authorities in Australia, Canada, Japan, and the United States of America – based on agreements concluded in 2010/11 - will by 2015, have become routine. Already in their initial stages, these contacts have been beneficial to the Agency, with a marginal investment in time and effort. This activity will continue to focus on exchanging information, best practice and scientific knowledge – thus also contributing to the capacity of ECHA staff to address scientific challenges. The Agency may review this cooperation against experience during the time period of this Multi-Annual Work Programme.

The European Commission is expected to continue to call on the Agency's scientific and technical capacity to support its multilateral agenda, in particular, when participating in bodies established by the UN and other international Conventions addressing the safe use of chemicals. The extent to which ECHA will engage in such activities between 2013 and 2015 will depend on respective requests from the Commission. The Conference of the Parties (COP) of the Stockholm Convention meets every second year; the next Conference of the Parties is scheduled for 2013. The following COP will take place during 2015. Meetings of the Conference of the Parties of the Rotterdam Convention will also be held in 2013 and 2015. As ECHA will by then have been assigned tasks under the PIC Regulation, which will implement the Rotterdam Convention in the EU, the Agency might be asked to support the European Commission at the annual meetings of this Convention's Chemicals Review Committee (CRC).

5 MANAGEMENT, ORGANISATION AND RESOURCES

5.1 Management

Priorities 2013-2015

To embrace current and new legislative tasks efficiently and effectively, while adapting to upcoming resource constraints, ECHA will:

- Continue building effective and flexible management structures and tools to maximise synergies between different processes;
- Use its planning tools to build well justified estimates and scenarios regarding future resource needs; to seek efficiencies in its processes in order to cope with the eventual EU savings strategy; and to take well informed decisions;
- Ensure quality by aspiring to acquire ISO 9001 and EMAS certification.

ECHA's highest decision-making body is the Management Board, consisting of 32 voting members representing each of the 27 EU Member States[13], as well as the Commission and Parliament. In addition, there are three non-voting members representing stakeholders, and three observers from the EEA-EFTA countries.

The recurring tasks of the Management Board include the adoption of strategic documents, such as annual and multi-annual 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.

Based on analysis in 2012, the methods of work of the Management Board will be discussed in order to determine possible improvements, for the period 2013-2015, in the organisation of the meetings of the Board and its working groups.

Relations with the European institutions, Member States, other EU Agencies and other stakeholders will continue to be ensured by the Agency, with a special emphasis on relations with Member State Competent Authorities, in order to mobilise and support them, as they become more involved in REACH activities.

The day-to-day management of ECHA is a task of the Executive Director. Efforts to strengthen strategic management methods and simplify and streamline the daily functioning of the Agency will continue during the 2013-2015 period. Another internal management challenge to be addressed will be the integration of new activities under the biocides and PIC regulations, when they become part of ECHA's mandate. This will be done by reviewing the organisation of the Agency's work to find synergies between old and new processes – in particular, in the field of biocides. The foreseen reductions in REACH and CLP resources will require additional management effort to ensure flexibility in terms of

[13] In addition, Croatia is planned to join the EU on 1 July 2013.

staff allocation between Work Programme Activities. In order to ensure the effective functioning of the Agency, ECHA will continue the development and implementation of tools to manage and, when necessary, to integrate, planning, resource allocation, performance monitoring, and risk management. By 2014, the management systems should have reached a mature state and their automation achieved.

In 2013-2015, ECHA will continue the implementation of its Integrated Quality Management System (IQMS) - an important tool to guarantee efficiency and efficacy. The Agency will also implement a roadmap (to be defined in 2012) for ISO 9001 certification, with the aim of obtaining certification for key processes by the end of 2015. The implementation of the Eco-Management and Audit Scheme (EMAS) will be sufficiently advanced to prepare for certification in 2015 or 2016.

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

ECHA will comply with all its statutory obligations to protect individuals with regard to the processing of their personal data with the support of its Data Protection Officer. The process of notifying existing, sensitive processing operations within the Agency to the European Data Protection Supervisor will be finalised in 2013, after which relevant work will involve updates and notifications of new processes.

The development of knowledge management will continue during the period, in order to facilitate decision-making and support ECHA's mission to provide information on chemicals.

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

5.2 Finance, Procurement and Accounting

Priorities 2013-2015

To embrace current and new legislative tasks efficiently and effectively, while adapting to upcoming resource constraints, ECHA will:

- Maintain financial self sustainability as long as possible, through the prudent management and investment of income and the tight control of expenditure;
- ensure that its financial systems are set-up to accommodate a full separation of the related funding sources, in view of its new tasks under the biocides and PIC regulations. Activity-based cost accounting is to be implemented on a full-scale basis.

ECHA's means of financing consist of (1) income generated from fees and charges, (2) a balancing subsidy granted by the budgetary authority from the EU budget, and (3) any voluntary contributions from the Member States and EEA-EFTA countries. ECHA may also

receive funding from the EU's external assistance Instrument for Pre-Accession Assistance (IPA).

ECHA will start the multiannual period 2013-2015 with budgets that can be covered by income reserves from the previous period. The second REACH registration deadline, in May 2013, is expected to yield considerably less income compared to the first, and it is therefore anticipated that towards the end of the referred period, a subsidy will be required in order to balance the Agency budget. From that time onwards, and for the following years, it is expected that ECHA will enter into a mixed funding regime for REACH/CLP, in which part of the expenditure will be covered by fee income and the rest balanced by an EU subsidy. In each of the years 2013-2015, a subsidy is foreseen for PIC and biocides tasks, and is included in the budget outline.

The overall objective of ECHA's financial management will continue to be assuring the best use of available financial resources in line with the principles of economy, efficiency and effectiveness. As regards procurement and contracting, ECHA will continue to outsource part of its operational activities to ensure the efficient implementation of the regulations under which it holds tasks. Establishing the contractual basis for ICT development, logistics and other services, will continue to impose demands for efficient procurement and contracting in the period 2013-2015. Emphasis will be given, as in the past, to prudent financial management that complies with relevant EU rules and regulations. Managing and safeguarding the Agency's cash reserves will continue to be a key objective.
A review of ECHA's financial regulation, which is expected to include a mechanism for managing the surplus from our revenue, is due in this period.

ECHA will continue to give weight to its control function and will, in particular, carry on checking the correct application of fee reductions to SMEs, granted upon the basis of the self-declared size of companies, and hence the correctness of the fees paid to ECHA.

5.3 Human Resources and Corporate Services

Priorities 2013-2015

To embrace current and new legislative tasks efficiently and effectively, while adapting to upcoming resource constraints, ECHA will:

- Put emphasis on consolidating the organisational and management development of the Agency. Human Resource-specific attention will evolve from an initial focus on growth and recruitment towards the retention and competence development of Agency staff; the matching of the Agency's human resources to its strategic and operational requirements; and towards ensuring the optimum utilisation of those resources;
- Make the most efficient use of its conference facilities and audio-visual equipment in order to limit excessive travelling by members of ECHA bodies and its staff.

To ensure that ECHA acts as a hub for scientific and regulatory knowledge building, it will:

- Orient the training programme of its scientists towards abilities that support the regulatory and scientific capacity of the Agency.

Human Resources

ECHA recognises that the knowledge, experience and motivation of its staff are key enabling factors in achieving its strategic aims. ECHA's strategic priorities for 2013-2015 take account of external factors and pressures (such as budgetary pressures, the integration of new tasks, and the requirement for greater administrative efficiency) and are aligned with ECHA's Multi-annual Staff Policy Plan for the same period.

ECHA's human resources policy for the period 2013-2015 is focussed on four areas. Firstly, ECHA will continue to build a sustainable, high-performing work environment that will facilitate a culture of teamwork, integration and the adaptability of people. In the context of the changing external environment, ECHA must become more flexible and agile to enable it to deliver on its mandate; hence, there is a requirement for informed priority-setting and flexible resource allocation, whereby posts are re-assigned to priority areas.

ECHA's biocides and PIC activities will formally commence in 2012 and will continue during the period 2013-2015. This will necessitate additional staff recruitment and integration, and internal redeployment and reorganisation in order to optimise the newly required expertise and capabilities, without adversely affecting REACH and CLP activities.

Secondly, learning and development activities will be realigned to optimise organisational and individual performance and reinforce the scientific and regulatory know-how of Agency scientists. ECHA aims to develop a focused, systematic approach to enhance its scientific and regulatory capability, while ensuring a balance between organisational and individual requirements.

Thirdly, ECHA needs to develop current and future managers and leaders, to proactively influence, motivate and empower staff in the achievement of its objectives. Lastly, a continuing priority will be the enhancement of staff engagement and well-being at all levels of the organisation.

Corporate Services

The Agency's infrastructure tasks include the management of its premises, for which the Agency has established a long-term lease agreement.

Following an overall assessment of the possible adaptation and refurbishing requirements of ECHA's premises – which will be conducted in 2012 - a multi-annual programme for further fitting out of the premises will be concluded. The focus in the 2013-2015 period will be to implement this programme, to the extent possible. Further improvements in some of the technical infrastructure will also be necessary in order to ensure the operability of the premises.

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

In line with its EMAS aspirations ECHA will make the most efficient use of its conference facilities and audio-visual equipment in order to limit the number of physical meetings, the number of participants to such meetings, and the travelling needs of its own staff.

5.4 Information and Communication Technology

Priorities 2013-2015

- Implement Management Information Systems to enable ECHA's administration to reach the higher level of efficiency required by the expected (increasing and in some respect, peak) workload levels, while at the same time facing stringent resource constraints;
- Manage the ICT infrastructure capacity to sustain ECHA's business and administrative Information Systems at an appropriate level of performance, operability, security and availability, and to ensure business continuity.

In 2013 and 2014, a foreseeable peak in registration and post-registration tasks will put ICT infrastructure under pressure with regard to performance and high availability: the ICT infrastructure will have to scale its capacity and performance to meet these challenges. ECHA will duly leverage, in the programme period, the ICT infrastructure upgrade implemented in 2012, and the outsourcing contract established at the end of 2011, to enhance the High Availability configurations, the efficiency of operations and the performance required by ECHA's information systems evolution – particularly for the peak conditions created in 2013 by a new registration deadline. A challenge will be to enhance IT support to Business Continuity Plans in a continuous manner, to address the needs stemming from the joint operation of three legislations and the increasing expectations of the extended availability of services.

Most of ECHA's processes will involve more collaboration with external regulatory partners (MSCAs, the COM) and with outsourcing service providers. This calls for rethinking ECHA's systems and processes as well as secure data access policies and solutions. In the context of the implementation of more distributed processes spanning beyond the organisational borders of ECHA to involve "partner" authorities, ECHA will continue to enhance remote access solutions to facilitate and secure access to ECHA's information systems by external users.

In 2013-2015, in order to sustain the evolution of its Information Systems at the enhanced levels of efficiency required by the incumbent resources constraints, ECHA will explore the deployment of flexible and efficient infrastructure service provisioning, to make the best use of the "infrastructure as a service" solutions that are becoming mainstream in the IT sector.

The growth and the increased complexity of managing the Agency, demands a more comprehensive planning and reporting system to complement the Agency's current budget an accounts management systems – with further functionalities to cover budgeting, procurement and contract management, and integrated reporting.

The further implementation of an integrated Human Resources Management System (HRMS), which began in 2012, is expected to improve the daily work of HR staff and help the Agency to adapt better to its new needs in terms of recruitment; individual rights; financial HR management; training and development; time tracking; and management.

6 ANNEXES

6.1 Annex 1: Overview of the Milestones from REACH and the CLP Regulations, 2012-2015[14]

	Milestones from the Regulations
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. ▪ Entry into force of the Biocidal Products Regulation (expected) July 2012. ▪ Possible submission of the draft annual update of the Community Rolling Action Plan by 28 February 2012 (Art. 44(2)). ▪ First five-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 the scope of the REACH Regulation, as the 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 (Art. 23(2)). ▪ Application date of the provisions of the Biocidal Products Regulation, 1 September 2013.
2014	▪ The Agency is responsible for the Review Programme of existing biocidal active substances, 1 January 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 three-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).
2015	▪ Transitional period to allow a gradual migration from the existing CLP system to the new regime ends. C&L of mixtures placed on the market will have to comply with the CLP Regulation (1 June).

[14] The table will be updated for PIC.

6.2 Annex 2 : Estimated ECHA Revenue and Expenditure 2013-2015 (including staffing plan)

Estimated resources for 2013

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	33	11	12	1 450 000	40 000 000
Activity 2: Evaluation	85	13	7	2 500 000	
Activity 3: Risk management	43	8	7	1 150 000	2 700 000
Activity 4: Classification and labelling	14	3	3	230 000	
Activity 5: Advice and assistance through guidance and helpdesk	22	10	5	400 000	500 000
Activity 6: Scientific IT tools	26	9	2	11 500 000	
Activity 7: Scientific activities and technical advice to EU institutions and bodies	8	0	3	320 000	
ECHA's bodies and cross-cutting activities					
Activity 8: Committees and Forum	23	8	7	2 400 000	
Activity 9: Board of Appeal	6	4	4	100 000	
Activity 10: Communications	9	8	7	6 500 000	
Activity 11: International cooperation	4	0	0	1 358 000	
Management, organisation and resources					
Activity 12: Management	24	15	4	1 855 000	
Total (REACH and CLP)	297	91	72		
Activities 13-15: Organisation and resources (Title II: Infrastructure)	24	51	33	15 000 000	5 500 000
Title I (REACH and CLP) (staff expenditure)				62 529 000	
Total (REACH and CLP)	**321**	**140**	**94**	107 292 000	**48 700 000**
In Establishment plan:	**461**				
Activity 16: Biocides *(total budget)*	38	9	12	9 582 500	n.a.
Activity 17: PIC *(total budget)*	1	4	1	1 632 000	n.a.
TOTAL ECHA	**360**	**153**	**107**	**118 506 500**	

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	33	10	13	1 000 000	9 300 000
Activity 2: Evaluation	85	12	8	2 600 000	
Activity 3: Risk management	43	7	7	1 200 000	4 500 000
Activity 4: Classification and labelling	14	3	4	250 000	600 000
Activity 5: Advice and assistance through guidance and helpdesk	22	10	5	500 000	
Activity 6: Scientific IT tools	26	9	4	11 800 000	
Activity 7: Scientific activities and technical advice to EU institutions and bodies	8	0	3	700 000	
ECHA's bodies and cross-cutting activities					
Activity 8: Committees and Forum	23	8	8	2 800 000	
Activity 9: Board of Appeal	6	4	4	150 000	
Activity 10: Communications	9	7	8	5 100 000	
Activity 11: International cooperation	4	0	0	250 000	
Management, organisation and resources					
Activity 12: Management	24	15	4	1 900 000	
Total	297	85	68		
Activities 13-15: Organisation and resources (Title II: Infrastructure)	24	50	33	15 000 000	5 000 000
Title I (staff expenditure)				62 700 000	
Total (REACH and CLP)	**321**	**135**	**101**	105 950 000	**19 400 000**
In Establishment plan:	**456**				
Activity 16: Biocides *(total budget)*	36	14	9	11 815 300	n.a.
Activity 17: PIC *(total budget)*	1	5	1	1 281 300	n.a.
TOTAL ECHA	**358**	**154**	**111**	**119 046 600**	

Estimated resources for 2015

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	33	10	13	800 000	7 000 000
Activity 2: Evaluation	84	11	8	2 600 000	
Activity 3: Risk management	44	7	7	1 200 000	9 000 000
Activity 4: Classification and labelling	14	2	4	250 000	600 000
Activity 5: Advice and assistance through guidance and helpdesk	22	9	5	500 000	
Activity 6: Scientific IT tools	24	8	4	12 100 000	
Activity 7: Scientific activities and technical advice to EU institutions and bodies	8	0	3	750 000	
ECHA's bodies and cross-cutting activities					
Activity 8: Committees and Forum	25	8	8	4 100 000	
Activity 9: Board of Appeal	6	4	4	150 000	
Activity 10: Communications	9	7	8	3 600 000	
Activity 11: International cooperation	4	0	0	800 000	
Management, organisation and resources				850 000	
Activity 12: Management	24	14	4	15 300 000	4 500 000
Total	297	80	68		
Activities 13-15: Organisation and resources (Title II: Infrastructure)	24	50	33	58 000 000	
Title I (staff expenditure)					
Total (REACH and CLP)	**321**	**130**	**101**	**101 000 000**	**21 100 000**
In Establishment plan:	**451**				
Activity 16: Biocides *(total budget)*	38	12	9	12 167 100	n.a.
Activity 17: PIC *(total budget)*	1	5	1	1 206 600	n.a.
TOTAL ECHA	**360**	**147**	**111**	**114 373 700**	

6.3 Annex 3: Baseline Figures for 2013-2015

ECHA's main activity drivers	Estimate for 2013	Estimate for 2014	Estimate for 2015
Dossiers arriving[15]			
Registration dossiers (including updates)	15 200	5800	5700
Testing proposals	410	20	20
Confidentiality requests	770	250	240
Access to data older than 12 years	240	270	290
PPORD notifications (incl. requests for prolongation)	400	400	400
Inquiries	2400	2000	2000
Data sharing disputes	33	7	7
Number of notifications under REACH Art. 7(2)	70	70	70
Number of reports/notifications under Article 38	400	4400	270
Restriction proposals (REACH Annex XV)	8	8	9
Restriction proposals developed by ECHA	3	3	3
Proposals for harmonised classification and labelling (CLP Annex VI)	70	70	70
Proposals for identification as SVHC (REACH Annex XV)	30	30	30
SVHC dossiers developed by ECHA	5	5	5
Authorisation applications	30	50	100
Alternative name requests	150	200	200
Substances on the CoRAP to be evaluated by MSs	50	50	50
ECHA decisions			
Evaluation			
- No. of decisions on TP	20	130	130
- No. CCH concluded	560	290	290
- Out of which CCH decisions	350	180	180
- No of substance evaluation decisions	30	45	45
Decisions on data sharing	3	-	-
Decisions on completeness check (negative)	470	190	180
Decisions on confidentiality	80	50	30

requests (negative)			
Decisions on access to documents requests	400	500	600
Appeals	36	20	20
Others			
Updates of the 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)	8 500	6 200	6 200
SME checks	300	350	400
Management Board meetings	4	4	4
MSC meetings	6	6	6
RAC meetings	6	6	6
SEAC meetings	4	5	6
Forum meetings	3	3	3
New TA posts to be filled REACH/CLP	10	0	0
Recruitment due to turnover	25	25	25
New TA posts to be filled for Biocides	36	3	0
New TA posts to be filled for PIC	2	1	0