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2011-2013

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EUROPEAN CHEMICALS AGENCY

Draft Multi-Annual Work Programme 2011-2013

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List of Acronyms

C & L	Classification and Labelling
CASPER	IT Characterisation Application for Selection, Prioritisation, Evaluation and Reporting
CHESAR	Chemical Safety Assessment and Reporting tool
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic or toxic to Reproduction
COM	European Commission
CSR	Chemical Safety Report
ECHA	European Chemicals Agency
ECVAM	European Centre for the Validation of Alternate Methods
eChemPortal	Global Portal to Information on Chemical substances
EEA	European Environment Agency
EEC	European Economic Community
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EMEA	European Medicines Agency
EU	European Union
EU-OSHA	European Agency for Safety and Health at Work
GHS	Globally Harmonised System of Classification and labelling of Chemical
HR	Human resources
ICT	Information and Communication Technology
IPA	Instrument for Pre-Accession
ISO	International Organization for Standardisation
IT	Information Technologies
IUCLID	International Uniform Chemical Information Database
JRC	Joint Research Centre of the European Commission
MB	Management Board
MS	Member State
MSC	Member State Committee
MSCA	Member State Competent Authority
ODYSSEY	Decision support system for evaluation activities
OECD	Organisation for Economic Cooperation and Development
PBT	Persistent, Bioaccumulative and Toxic
POPs	Persistent Organic Pollutants
PPORD	Product and Process Oriented Research and Development
(Q)SAR	(Quantitative) Structure-Activity Relationships
RAC	Risk Assessment Committee
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
REACH-IT	REACH-IT is the central IT system providing support for REACH
RIPs	REACH Implementation Projects
RIPE	REACH Information Portal for Enforcement
SAICM	Strategic Approach to International Chemical Management
SEAC	Socio-Economic Analysis Committee
SIEF	Data Sharing & Substance Information Exchange Forum
SME	Small and Medium Sized Enterprise
SVHC	Substance of Very High Concern
TA	Temporary Agent
TAIEX	Technical Assistance and Information Exchange instrument managed by the Directorate-General Enlargement of the European Commission
UN	United Nations
UN ECE	United Nations Economic Commission in Europe
vPvB	very Persistent and very Bioaccumulative

Foreword by the Management Board

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

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

At the time of writing this Multi-Annual Work Programme, the REACH Regulation has been in force for close to three years, and industry has been subject to specific obligations for almost two years. The European Chemicals Agency (ECHA) – established by REACH – has grown from a small number of core staff to nearly 400, and its bodies, the Board of Appeal, the three scientific Committees and the Forum for enforcement, are fulfilling their tasks under the two regulations. The networks for risk communication, for national helpdesks and for security officers also contribute to the implementation of REACH and CLP. The Management Board, the highest decision-making body of ECHA, steers the activities of ECHA and its other bodies.

The past years have confirmed the expectation that the implementation of the REACH and CLP Regulations are real challenges for all concerned – industry, the Member State Competent Authorities, the European Commission and ECHA, as the central co-ordinator for both regulations. ECHA has also learnt from the experience of pre-registration and has undertaken contingency planning in view of the high level of uncertainty concerning the number and timing of the registration dossiers and C&L notifications to be received by 30 November 2010 and 3 January 2011 respectively. Similar uncertainties also prevail for the 2013 registration deadline. However, the Management Board is confident that ECHA can manage these uncertainties in an efficient manner.

The precise number of registrations arriving within the November 2010 deadline will be decisive for ECHA's workload and finances during the years 2011 to 2013. Therefore, the underlying assumptions of the Multi-Annual Work Programme will need to be reviewed thoroughly in early 2011 and it is likely that the staff needs and resource allocation for the coming years will significantly alter. Moreover, it remains to be seen whether the revenue generated by dossier submissions by the first registration deadline will be sufficient – as forecasted by the Commission – to fund all Agency activities until 2014. The Management Board is ready to assist ECHA with this forthcoming re-assessment and the required changes needed to the 2011 Work Programme and its corresponding reflection in next Multi-annual Work Programme.

As was the case during the first years in ECHA's existence ECHA's work in the coming years must be underpinned by sound scientific judgement and regulatory excellence: this involves bringing together the best scientific and technical expertise with a view to making use of the steadily-growing high-quality data on chemical substances. At the same time, the Agency has to work completely independently. High-quality science and independence ensure objective and well-reasoned opinions and decisions, which will give the opportunity to ECHA to set its reputation as a world-class regulatory authority.

Overview by the Executive Director

The 2011-2013 Multi-Annual Work Programme of the European Chemicals Agency (ECHA) provides you with an overview of the Agency's activities during the three coming years. More detailed planning is presented in ECHA's annual Work Programme, which already exists for 2010. The Multi-Annual Work Programme is revised every year and its timespan moved forward by one year.

In the three years since the establishment of this Agency in 2007, ECHA has successfully managed the first steps in the implementation of the new EU chemicals legislation, and set important cornerstones for putting in place a comprehensive system for chemical risk assessment and management, which is unique in the world. This Multi-Annual Work Programme has been prepared at a time when the first registration deadline of 30 November 2010 was still many months ahead. At this point in time, ECHA is still confronted with a high degree of uncertainty, in particular with regard to the number of registration dossiers that companies will be submitting by the 2010 deadline (and by the subsequent 2013 deadline), which will be decisive for ECHA's workload and finances for the years 2011-2013. The programme is thus founded upon baseline figures for core operational processes (presented in Annex 3) which constitute a limited update of the European Commission's estimates made when the REACH Regulation was prepared. It should be noted that, should the number of 2010 registrations significantly increase above these estimates, ECHA will need to request additional staff to perform the scientific evaluation of the registration dossiers. A more certain planning will only be possible at the beginning of 2011, when the Multi-Annual Work Programme will undergo its next regular revision.

The European institutions are currently considering new tasks for ECHA which need to be considered in the preparation of this programme. The Commission's proposal for a new regulation on biocidal products¹, foresees that ECHA would take over the review of active biocidal substances and of applications for authorisation of biocidal products from 2013. In order to build up expertise and adjust the scientific IT tools in a timely way, ECHA has provided a plan to the Commission to start preparatory activities for the planned legislation from 2011 rather than 2012.

The Agency's scientific-technical activities in the field of evaluation, authorisation and restriction procedures will grow in importance in 2011-2013 and absorb most of the new scientific staff. The wealth of information generated per substance by the dossiers arriving at the first registration deadline and through dossier evaluation will put ECHA, Member States and the Commission in a much more solid position to propose or decide on the strong risk management instruments of REACH. ECHA will place emphasis on facilitating these efforts – not least through ensuring a credible start to substance evaluation in 2012 – and at the same time, provide the best possible advice to companies to ensure the safe use of their chemicals.

The successful implementation of REACH depends on cooperation based on trust between ECHA and its institutional partners, as well as with all stakeholders and interest groups. We would therefore very much appreciate your feedback on this Multi-Annual Work Programme, which will be published on the Agency's website at www.echa.europa.eu. We look forward to hearing your views.

I sincerely hope you will find the ECHA Multi-Annual Work Programme interesting and useful.

Geert Dancet
Executive Director

¹ COM(2009)267

Introduction

Established on 1 June 2007, the European Chemicals Agency (ECHA) is at the heart of the new regulatory system for chemicals in the European Union set out in the REACH Regulation². It has also been playing an important role in the new Regulation on the Classification, Labelling and Packaging of substances and mixtures (CLP³) since 2008. These legislative acts are directly applicable in all Member States without the need for their transposition into national law. Both regulations should contribute to fulfilment of the Strategic Approach to International Chemical Management (SAICM) adopted on 6 February 2006 in Dubai. The purpose of the REACH and CLP system is to ensure a high level of protection of human health and the environment and to facilitate the free circulation of substances within the single market. In addition, the REACH Regulation promotes alternative methods to animal tests to assess the hazards of chemicals, and enhances competitiveness and innovation. The REACH Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.

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

The successful implementation of the REACH and CLP Regulations requires a well-functioning Agency, capable of delivering independent and high-quality science-based opinions within strict legal deadlines, as well as ensuring that the operational aspects of the legislation function appropriately. However, the efficient operation of the REACH and CLP Regulations also depends on ECHA's institutional partners, in particular the Member States of the EU and the European Commission on the one hand, and on industry to properly implement the Regulations on the other. Indeed, from the very beginning, the credibility of the REACH and CLP systems will, for example, be determined by the allocation of sufficient resources at national level and an effective and fair enforcement policy. In addition, since ECHA is responsible for drafting scientific opinions for the European Commission, successful implementation will depend upon the initiation and appropriate follow-up of these processes by the European Commission and/or the Member States.

The planning in this Work Programme is founded upon the baseline figures presented in Annex 3, which are an update of the Commission estimates made when the REACH Regulation was prepared. It should be underlined that the baseline numbers are still subject to a high degree of uncertainty, meaning that a constant monitoring of the work volume is required, and potentially, a re-allocation of priorities and resources during the years to come. The biggest uncertainty concerns the volume of registration dossiers that companies will submit at the end of 2010, which will have a great impact upon the workload of ECHA in the years 2011-2013.

² Regulation (EC) No 1907/2006

³ The CLP Regulation (No. 1272/2008) on classification, labelling and packaging of substances and mixtures was adopted by the European Parliament and the Council in late 2008 and came into force on 20 January 2009. It implements in the EU the international criteria agreed by the United Nations Economic and Social Council (UN ECOSOC) for the classification and labelling of hazardous substances and mixtures - known as the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). The Regulation will gradually repeal Directives 67/548/EEC and 1999/45/EC with effect from 1 December 2010 regarding substances and 1 June 2015 regarding mixtures.

Alongside the existing REACH and CLP Regulations, the Commission has proposed a new Regulation concerning the placing on the market and use of biocidal products⁴. The proposed Regulation foresees additional tasks for ECHA – namely, proposing that the Agency would take over the review of active biocidal substances and the review of applications for authorisation of biocidal products from 2013. Provided that ECHA receives additional funding for this purpose, it would be able to begin recruiting staff, adjusting its IT tools and building up expertise in relation to the Regulation, from 2011.

The European Chemicals Agency in 2011-2013

ECHA's Mission

ECHA's mission is

- to manage all REACH and CLP tasks by carrying out or co-ordinating the necessary activities, in order to ensure a consistent implementation at Community level
- to provide Member States and the European institutions with the best possible scientific advice on questions related to the safety and the socio-economic aspects of the use of chemicals.

This is achieved by ensuring a credible and consistent decision-making process, using the best possible scientific, technical and regulatory capacities in order to achieve compliance with the REACH and CLP Regulations.

ECHA helps to achieve the aims of the REACH and CLP Regulations, and thus to ensure a high level of protection for human health and the environment, while at the same time fostering innovation and competitiveness. The Agency's founding Regulation stipulates that: *"The Agency should be central to ensuring that chemicals legislation and the decision-making process and scientific basis underlying it have credibility with all stakeholders and the public. The Agency should also play a pivotal role in coordinating communication around this Regulation and its implementation. The confidence in the Agency of the Community institutions, the Member States, the general public and interested parties is therefore essential. For this reason, it is vital to ensure its independence, high scientific, technical and regulatory capacities, as well as transparency and efficiency."*⁵ Moreover, the Agency *"should ensure that reduction of animal testing is a key consideration in the development and maintenance of guidance for stakeholders and in the Agency's own procedures"*⁶.

The core purpose of ECHA is therefore to ensure a credible and sound decision-making process within the REACH and CLP Regulations. Key prerequisites to enable ECHA to achieve this are that it:

- is independent;
- develops a high scientific capacity;
- develops a high technical capacity;
- develops a high regulatory capacity;
- works transparently;
- works efficiently.

⁴ COM(2009)267.

⁵ Recital 95 of the REACH Regulation.

⁶ Recital 47 of the REACH Regulation.

ECHA may be given additional tasks in addition to its current mission, such as those foreseen under the proposed Commission Regulation on biocidal products. These tasks would include the review of active biocidal substances and the review of applications for authorisation of biocidal products from 2013, and would require ECHA to begin dedicated recruitment and the building up of specific expertise from 2011 onwards. However, any additional Agency tasks would have to take into account the vast range of activities and strict deadlines for compliance set out in the REACH and CLP Regulations which ECHA has to meet in the first instance.

ECHA's Vision

ECHA's vision is to become *the* internationally recognised Agency on any question related to the safety of industrial chemicals and a source for reliable and high quality information on chemicals for the benefit of all citizens.

ECHA will be a benchmark regulatory authority and attract highly motivated and talented staff by applying the most modern administrative practices and staff policies. Industry should perceive ECHA as a reliable partner providing advice and assistance as needed.

In the short term, ECHA will function as a broker between all interested parties affected by the REACH and CLP Regulations. It will provide guidance to manufacturers, importers and users of chemicals to assist them in fulfilling their obligations, and will be an effective focal point for the European Commission, the European Parliament, the Member States, industry, other stakeholders and the general public, for knowledge concerning chemical substances. High priority will be given to developing effective communication and cooperation with the Member State Competent Authorities (MSCAs), so that use can be made of their highly-qualified scientific and technical resources. Another vital aspect will be to ensure close relations and regular dialogue with the European Parliament and the European Commission.

In the medium term, ECHA aims to continue making the EU regulatory system for chemicals a benchmark in Europe and for governments elsewhere. The Agency will be a key player internationally as its databases are expected to contain more information than any other comparable regulatory body worldwide. It will become a guardian of the increasing amount of data it will hold on properties of chemicals and their uses, and it will make this information as easily accessible as possible so that it can be of direct use to all interested parties whilst protecting confidential information in line with legislation.

Upon request and in co-ordination with the European Commission, ECHA will also contribute broadly to the international commitments of the European Union in the area of ECHA's activities.

Moreover, the Agency will, in particular, focus on making scientific information available for research, and establish well-functioning pathways with the scientific community, in order to ensure that the research needs arising from the REACH Regulation are properly communicated and that up-to-date information is received from the scientific community.

ECHA's Values

As a modern public administration, ECHA's values are transparency, impartiality, accountability and efficiency; it will manage the REACH and CLP operations in a secure, professional and science-based manner.

ECHA attaches importance to its independence from all external interests while at the same time closely cooperating with all stakeholders, the European institutions and Member States. The Agency pursues a strong policy of equal opportunities and environmental friendliness.

These principles are reflected in ECHA's internal rules and procedures, including the *Rules of Procedure of the Management Board, the Committees and the Forum*; the *ECHA Code of good administrative behavior*; the *ECHA communication strategy*; and the *ECHA rules on transparency*. All actors concerned by the REACH Regulation should have access to information and assistance. The Agency pays particular attention to SMEs when communicating on the REACH and CLP Regulations and supporting their implementation.

As a body of the European Union, ECHA sees itself as a high standard, modern public service agency. It wishes to be recognised as an attractive workplace and an excellent employer that cares about the wellbeing of its staff.

ECHA's key priorities 2011-2013

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

Key priorities 2011-2013:

- In early 2011, ECHA will finalise the processing of registrations under the REACH Regulation and CLP notifications submitted by the 2010/11 deadlines, after which the focus will shift to ensuring a successful receipt of registrations submitted by the second deadline in June 2013. Prior to this deadline, ECHA will optimise its guidance, IT tools and helpdesk functions in order to assist companies better in their registration and data-sharing tasks and to help them submit high quality registration dossiers.
- From 2011 onwards, ECHA will focus on evaluation activities in order to meet the deadline for evaluating testing proposals and on reaching the minimum compliance check target of 5% of registrations per tonnage band. Moreover, ECHA will support the successful initiation of substance evaluations to be undertaken by Member State Competent Authorities. These evaluations may lead to the need for further information to be provided by registrants and subsequently to the need for further risk management measures for particular substances of concern.
- ECHA will safeguard the smooth implementation of authorisation processes for which it will biannually update the candidate list of substances of very high concern and submit an annual recommendation to the European Commission for the authorisation list. ECHA will provide the Commission with a solid basis upon which to make decisions to grant or reject authorisations, by ensuring efficient handling of industry applications and through timely and high quality opinions from its scientific committees.
- ECHA will submit the first draft decisions on restrictions to the Commission and expects a steady increase in the number of new proposals after the registration deadline of November 2010. Furthermore, ECHA will develop a framework to facilitate the work of Member States in the identification of restriction needs.
- ECHA will significantly increase the availability on its website of information on the properties and uses of chemical substances provided via registrations, as well as

publish an inventory of CLP notifications, and will ensure proper scrutiny of confidentiality requests.

- ECHA will contribute, through facilitation of the activities of the Forum, to effective enforcement of the REACH and CLP Regulations by national enforcement authorities, so that chemicals circulating on the single European market comply with the requirements of REACH and CLP.
- ECHA will contribute to the review of the REACH Regulation which the Commission must carry out by 1 June 2012, and assist the Commission in any possible follow-up.
- Subject to funding provided by the Commission, ECHA will prepare itself, from 2011, for the implementation of the new Biocides Regulation which is currently in co-decision and which foresees the Agency beginning activities in this field in January 2013.

Implementation of the REACH and CLP processes

Activity 1 - Registration, Data-sharing and Dissemination

Priorities 2011-2013

- Ensure that companies are able to fulfil their registration and notification obligations as efficiently as possible and to stimulate the submission of high quality registration dossiers in order to provide a good basis for subsequent work, such as evaluation;
- Tackle the expected peaks in workload resulting from the registration and notification deadlines falling within this period;
- Ensure to the extent possible that the substance identity of the submitted dossiers is correct so that information and regulatory action on substances is targeted and well understood by industry and authorities;
- Continually update the database of information on the properties of chemicals and ensure that the information is made publicly available over the Internet.

Registration

The REACH Regulation is based upon the principle that responsibility for the identification and management of risks from a substance, lies with the company that manufactures, imports, places on the market, or uses the substance. Registration provisions therefore require manufacturers and importers of substances in quantities of 1 tonne or more per year and per company to collect or generate data per substance collectively, and to implement on-site and recommend to their customers, appropriate risk management measures. For substances manufactured or imported in quantities above 10 tonnes per year, the companies also have to complete a chemical safety report that includes exposure scenarios, leading to more precise estimates of risks and risk management measures. This information must be compiled in a registration dossier and submitted to ECHA; the Agency then verifies the completeness of the information provided and the payment of the corresponding fee, before assigning a registration number.

In addition to the registration obligations for substances as such and in mixtures, there is also a registration obligation for substances in articles, if the substance is intended to be released during normal and foreseeable conditions of use, or upon request from ECHA – if the Agency has grounds for suspecting that a substance is released from an article, and so presents a potential risk to human health or to the environment. From 2011, producers or importers of articles will also have to notify ECHA if an article contains a substance that appears on the candidate list of substances of very high concern that may be subject to authorisation, unless the producer or importer can exclude exposure⁷.

Moreover, ECHA has to process notifications for temporary exemptions from registration for substances that are used in product and process related research and development (PPORD), and may choose to request further information or impose conditions to ensure that a substance is handled in reasonably controlled conditions.

Registration under REACH began on 1 June 2008; however, the Regulation creates a transitional regime for substances which, under certain conditions, were already manufactured, imported or placed on the market before the entry into force of the Regulation on 1 June 2007, and which did not have to be notified under the previous legislation⁸. These substances are

⁷ Starting from 1 June 2011, any producer or importer of articles is obliged to notify ECHA if a SVHC included in the “candidate list” is present in those articles above certain thresholds.

⁸ Directive 67/548/EEC.

known as 'phase-in substances', and there are later deadlines for their registration (in 2010, 2013 and 2018) depending on the tonnages being manufactured or imported and upon specific hazard characteristics. In order to benefit from the transitional regime, phase-in substances had to be pre-registered between 1 June and 1 December 2008. Non-phase-in substances, and phase-in substances which were not pre-registered, cannot be manufactured, imported or placed on the market without the successful submission of a registration dossier.

ECHA will enter 2011 shortly after the first registration deadline of 30 November 2010 for high volume substances of 1000 tonnes per year or more, and for certain categories of substances of concern. At the time of writing, ECHA was anticipating, based upon analysis of pre-registration data, to receive registrations for approximately 9 200 substances by the 30 November 2010 deadline. As the number of registrations for these substances was subject to high uncertainty, ECHA developed this Work Programme based upon the Commission's original estimates of 25 000 registrations in 2010, but prepared contingency plans for handling up to 75 000 registrations. ECHA is expecting to receive up to 70% of the total volume of registrations after 1 October 2010, i.e. during the last two months before the deadline. These registrations must be processed by 28 February 2011.

Based upon its experience thus far, ECHA's planning took into account that a certain share of these registrations would be declared incomplete and would require a re-submission and a second round of completeness checks, before a registration number could be granted. Therefore, the completeness check work resulting from the first registration deadline is likely to continue well into 2011.

The high volume of technical completeness decisions around the first and second registration deadlines may result in a substantial number of appeals. Support from the submissions unit will be needed where the Legal Affairs Unit are required to prepare defence on behalf of ECHA.

ECHA will explore information from the first wave of registration dossiers useful for reporting purposes, such as the types of substances registered, the use of alternative methods to fulfil information requirements, and the availability of experimental information for endpoints. Such information will be part of the first report from ECHA to the Commission on the operation of REACH, due on 1 June 2011.

ECHA will also compile in 2011, lessons learned from the first registration deadline, and review its support mechanisms to assist potential registrants concerned by the deadline of 31 May 2013, which is pertinent for the remaining substances manufactured or imported in quantities between 100 and 1000 tonnes per year and per company. During 2011 ECHA will also sample-wise review the self-declarations of companies which claimed and received SME rebates on their fees in the previous registration period.

According to the Commission's original estimates for the REACH proposal, ECHA will receive at least 20 000 registrations in the 2011-2013 period. This includes updates of existing registrations (about 10% per year) and several hundred registrations per year for non-phase-in substances. ECHA will review the estimates for the number of registrations that will be received in each of the years during this period; these may ultimately be considerably higher if many companies selling substances for which members of their Substance Information Exchange Forum (see below) have already registered dossiers by the 2010 deadline, decide to register faster in order to get registration numbers early, despite only being subject to a deadline in 2013 or 2018.

The notifications of substances in articles appearing on the "candidate" list and fulfilling the criteria set in the legislation will start in 2011. The Commission's original estimates were that ECHA would receive approximately 70 notifications of this type per year.

The work associated with PPORDs is expected to remain at the same level over the 2011-2013 period; with the processing of a few hundred notifications annually, and with a small proportion of them (expected to be ca. 10%) necessitating a legally binding decision to require additional information to the notifier and possibly the imposition of conditions. In 2013, notifiers may start requesting ECHA to extend their 2008 notifications, which will increase the total number of notifications on a yearly basis.

Data sharing

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

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

Pre-registration took place between 1 June and 1 December 2008, but it remains open for companies manufacturing or importing a phase-in substance for the first time in quantities of 1 tonne or more per year, up to one year before the relevant submission deadline. They then have the opportunity to join existing SIEFs in order to be part of a joint registration.

In the period 2011-2013, ECHA will continue to handle these "late" pre-registrations by updating the list of pre-registered substances accordingly, and by supporting (pre-)SIEF activities whenever appropriate. Consideration will also need to be given to whether SIEF formation can be enhanced following lessons learned during the 2008 pre-registration period and subsequent 2010 registration period.

For non-phase-in substances and for phase-in substances that were not pre-registered, an inquiry process prior to registration will allow ECHA to facilitate data sharing. ECHA expects to receive approximately 1500 inquiries per year.

Where agreement on the sharing of a study cannot be reached, ECHA will in certain cases either take a decision or will give permission to refer to the information already submitted. If no data has been submitted, ECHA will take a decision on whether or not the test needs to be repeated by another potential registrant. At the time of writing, ECHA assumed that the number of data sharing decisions would be small in 2011 and 2012, and increase to a fairly high number in 2013.

The high volume of data sharing decisions taken around the first and second registration deadlines of 2010 and 2013 may result in a substantial number of appeals. Support from the data sharing unit will be needed where the Legal Affairs Unit are required to prepare defence on behalf of ECHA.

The understanding of substance identity is an important function which applies largely in data sharing activities, but is also required in all types of registrations and notifications, including proposals for harmonised classification and labelling, and for authorisations and restrictions. Activity related to substance identification will remain high during the 2011-2013 period.

Dissemination

One of ECHA's tasks is to make a large part of the information on registered substances publicly available, free of charge, over the Internet – excluding, in particular, information for which a request for confidentiality was made by the registrant and is considered justified in accordance with Article 118(2).

Making information on chemicals publicly available is expected to have a positive impact on health and environmental protection in Europe and worldwide. Further to the first wave of registrations in 2010, ECHA will have collected in its databases information on substances which are present on the European market in large quantities, and on substances with specific hazardous properties – in particular, carcinogenicity, mutagenicity, toxicity for reproduction, or toxicity to aquatic organisms.

One core activity in 2011 will be to process the information submitted in 2010, assess whether requests for confidentiality provided by the registrants in their dossiers are justified and publish the information, including the classification and labelling inventory, in a user-friendly way on the ECHA website. As registration will peak again in early 2013, for the registration deadline of 31 May 2013, dissemination activity will be intensive in the latter part of the year. Dissemination of information submitted in the context of REACH processes other than registration, or deriving from previous legislation, such as risk assessment reports, will also take place over the entire period.

The information published will be linked to the OECD eChemPortal (Global Portal to Information on Chemical substances) which allows users to simultaneously search multiple databases prepared for government chemical review programs around the world. Participation in the eChemPortal is an important factor in establishing ECHA as the authoritative source of information on chemical substances in the EU.

Activity 2 - Evaluation

Priorities 2011-2013

- Initiate compliance checks for a high number of dossiers registered in 2010, in order to achieve the minimum compliance evaluation target of 5% of all dossiers, in the highest tonnage band, registered by the 2010 deadline; and prepare, where appropriate, scientifically sound and legally robust draft decisions to encourage companies to deliver good quality dossiers;
- Ensure that all testing proposals incorporated in the registration dossiers submitted in 2010 are handled within the legal deadlines and lead to scientifically solid decisions;
- Develop in cooperation with the Member States, criteria for the prioritisation of substances and ensure approval of the Community rolling action plan which will trigger substance evaluations by Member States, and facilitate the first decisions on this work;
- Use the established close communication pathways with industry to point out the main areas for improvement in the submission and update of registration dossiers.

The REACH Regulation distinguishes between dossier and substance evaluation. Dossier evaluation is further subdivided into the examination of testing proposals and the compliance check.

The general results of the evaluation processes (described below) will be contained in the annual progress report provided by ECHA in line with Article 54 of the REACH Regulation. This report will include general recommendations to potential registrants in order to improve the quality of future registrations, and it will also pay appropriate attention to 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 addition, the results will be communicated in stakeholder events, workshops, fact sheets and other communication tools to industry. This will contribute to the overall success of the REACH Regulation, and to the safe use of substances along the supply chain, by generating the necessary information while avoiding unnecessary animal testing.

Dossier evaluation

Dossier evaluation is one of ECHA's most demanding tasks due to the very high number of dossiers to be submitted, the volume of information in each dossier, and the considerable scientific and technical competence required. One of the main objectives of the years 2011 to 2013 is to use the capacity, which will have been built up in the preceding years, for the evaluation work on dossiers received by the November 2010 deadline.

With the resources currently planned for, and under current assumptions, ECHA expects to be able to conduct approximately 500 dossier evaluations per year between 2011 and 2013. As testing proposals have to be evaluated within certain deadlines, they will be given priority and the remaining capacity will be used for compliance checks.

In evaluating dossiers, the ECHA Secretariat produces scientific judgements. These judgments have to be based on sound science and require well-trained and experienced staff. A number of scientific disciplines, such as toxicology, chemistry, epidemiology, occupational hygiene environmental fate and effects, exposure assessment, as well as risk characterisation and management, are needed to come to scientifically robust evaluation results. As a second step, the scientific judgements on compliance of the registration dossiers, and the CSR with the information requirements, have to be transformed into legal documents requiring further information from the registrant. The robustness of these legally binding decisions depends upon the scientific evaluation in combination with the legal arguments.

High volume chemicals are generally the most complex substances to evaluate, on account of the higher information requirements and the large number of uses. In early 2011, registration dossiers will be prioritised for evaluation of testing proposals and for compliance checks. Following this prioritisation, the main tasks consist of organising the handling of hundreds of dossiers in an efficient manner. At the same time, scientific quality and legal robustness have to be ensured. This will be achieved by a strong focus on core tasks and by using the scientific capacity and the legal support available in the most efficient way. These efforts will be reviewed in the end of 2011 and will be improved, if necessary, as these tasks continue in 2012 and 2013.

Further scientific and administrative capacity building is necessary to manage the peak workload in the years 2011 to 2013. If a significantly greater number of registration dossiers arrive by the 2010 deadline than assumed in the Work Programme 2010, ECHA will have to recruit and train more staff to handle the higher evaluation workload. The high production volume phase-in substances will contain the highest level of information per dossier, and ECHA expects that a considerable part of this information will not have been generated using recent standard and quality assured testing methodology. This will inevitably complicate the evaluation of the dossiers and raise complex and scientifically challenging questions. ECHA will therefore continue to reinforce internal scientific competences and networks with external experts, and improve the strategies for effective and efficient evaluations.

The high volume of evaluation decisions may also result in a substantial number of appeals. Support from the evaluation units will be needed where the Legal Affairs Unit are required to prepare defence on behalf of ECHA.

Evaluation of testing proposals

Registrants submit testing proposals to ECHA as part of their registrations, if they identify a data gap and cannot otherwise fulfil the information requirements listed in Annexes IX and X of the REACH Regulation. ECHA evaluates all proposals for information requirements covered by these Annexes to the Regulation to ensure that the proposed tests will generate reliable and appropriate data, and that all available information has been considered. In this regard, the evaluation of testing proposals may be regarded as a specific case of compliance check.

When a testing proposal concerns a study involving vertebrate animals, ECHA submits the information on the substance, and on the hazard end-points covered by the testing proposal, for public consultation. ECHA's decision involves consultation with the registrants that submitted the testing proposal, the Member State Competent Authorities, and, if necessary ECHA's Member State Committee (MSC). If the MSC does not reach an agreement, ECHA refers the draft decision to the European Commission which takes the decision after further consultation with the Member States. This procedure was established to make sure that the best possible use is made of existing information, and that animal testing is required only when there is a broad consensus that such testing is indeed necessary.

Deadlines for the evaluation of testing proposals differ for phase-in and non-phase-in substances. Proposals for phase-in substances registered by 30 November 2010 (the first registration deadline for those substances) will have to be evaluated by 30 November 2012. Proposals for non-phase-in substances must be evaluated within six months of the date of registration.

The workload driver for the evaluation of testing proposals is the number of substances with a production or import volume above 100 tonnes per year, as these require the submission of testing proposals in accordance with Annexes IX and X of the REACH Regulation. The peak workload for the evaluation of testing proposals will start after December 2010, after the bulk of the phase-in substances above 1000 and certain substances of concern have been registered. Considerable uncertainty remains regarding the number of dossiers to be evaluated, as it is currently unknown how much data is already available for these substances. For the years 2011-2013, ECHA bases its planning on the assumption that 10% of the substances registered will contain a testing proposal. As the number of substances subject to dossier evaluation (thus excluding substances registered as intermediates) in the highest tonnage band is estimated to be about 3000, the expected number of testing proposals to be evaluated by the 2012 deadline is approximately 300.

Compliance checks

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

For the majority of the elements which may be verified under the compliance check, Annexes to the REACH Regulation set out the detailed information requirements. Identification of non-compliance issues will lead to a draft decision, requesting the missing information and setting a deadline for the submission of this information. The decision making process is the same as described for the evaluation of testing proposals.

ECHA is obliged to carry out compliance checks on at least 5% of the submitted registrations per tonnage band. The workload driver for compliance checks is therefore the number of dossiers received per tonnage band. However, due to the large variation in the number of dossiers registered per year, with a bulk of registration dossiers expected in the years 2010, 2013 and 2018, the legislator has not defined a timeframe within which the 5% target should be met. In addition, there is still uncertainty over the number of dossiers that will be submitted by industry. Knowing that the annual capacity for dossier evaluations is 500, and assuming that 10% of the highest tonnage band substances registered in 2010 contain a testing proposal, it is ECHA's target that the 5% target for compliance checks should be reached by 2013 for these dossiers. If the number of incoming testing proposals is different from what is anticipated, ECHA will have to re-evaluate the situation..

Substance evaluation

Substance evaluation aims at verifying whether a substance constitutes a risk for human health or the environment. Substance evaluations are performed by Member State Competent Authorities (MSCAs) and involve an assessment of all available information and requests for further information from registrants, if appropriate.

The first draft Community rolling action plan for substances subject to substance evaluation has to be submitted by the ECHA Secretariat to the Member States by 1 December 2011, and will be updated annually. According to the REACH Regulation, ECHA will develop criteria for prioritising substances for substance evaluation in cooperation with the Member States, and the ECHA Secretariat will continue dialogue with the Member States in this regard. The MSCAs will select substances from this list and start their evaluations. ECHA has a coordination role in establishing and updating the Community rolling action; the Agency also ensures the consistency of decisions on information requests. ECHA expects, in line with original Commission estimates, that the number of substances on the Community Rolling Action Plan will gradually increase to 100, resulting in about 10 and 30 decisions in 2012 and 2013 respectively, requesting further information from registrants.

Activity 3 - Authorisation and Restrictions

Priorities 2011-2013

- Prepare Annex XV dossiers for identification of SVHCs and for restrictions on request of the Commission;
- Support the further development of the list of candidate substances and prepare new recommendation(s) for priority substances for authorisation;
- Set up and implement an efficient and effective procedure for handling the authorisation applications and ensure that all authorisation applications are handled with a high degree of scientific and technical quality;
- Ensure that all dossiers in the restrictions process are handled with a high degree of scientific and technical quality.

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

Regulation to ensure a high level of protection of human health and the environment, while enhancing competitiveness and innovation, is achieved.

Authorisation

The authorisation procedure concerns Substances of Very High Concern (SVHCs). These are substances which are: a) Carcinogenic, Mutagenic or toxic to Reproduction (CMR), categories 1 or 2; b) Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) according to the criteria set out in the REACH Regulation; and c) substances of an equivalent level of concern identified on a case-by-case basis.

Identification of substances of very high concern (SVHC)

The identification procedure for SVHCs starts with the preparation of a dossier by an MSCA or ECHA (at the request of the European Commission). These dossiers provide the grounds justifying the identification of the substance as a SVHC in accordance with the criteria mentioned above. The preparation of such dossiers is a challenging task. ECHA has created a platform to stimulate discussion and cooperation between Member States and will continue providing support to the Member States, for instance through further improvement of formats and guidance and, if needed, training.

On request of the Commission, ECHA has started the development of the first SVHC dossiers of which one dossier has been finalised and submitted. It is expected that ECHA will continue to receive requests for the development of dossiers for other potential SVHCs in the coming years. Once finalised, these dossiers will be submitted in accordance with the fixed submission dates for new Annex XV dossiers that have been agreed in collaboration with the Member State Competent Authorities and the Commission.

As a result of the informal collaboration between the Member States, on identifying and grouping potential SVHCs, stimulated by ECHA, it can be anticipated that a substantial number of SVHC dossiers will enter the process in the coming years – leading to an increased workload in this area. The candidate list, which contained 29 substances in early 2010, is expected to grow faster in the period 2011-2013. The Member States and the Commission should base their selection of SVHCs on the agreed framework for documenting the analysis of the best Risk Management Option when choosing the most appropriate risk management instrument for specific substances for which regulatory action is needed.

Inclusion of substances in the list of substances subject to authorisation (Annex XIV)

On 1 June 2009, ECHA submitted its first recommendations for the list of substances subject to authorisation to the Commission, and it is assumed that the respective Annex XIV will be adopted by the Commission in the course of 2010. The experience gained during the elaboration of the first recommendations will be used to develop future recommendations on an annual basis. Working closely together with the Member State Committee, ECHA will further shape its priority setting approach for selecting substances from the “candidate list”. ECHA will continue to develop, for each substance included in its recommendations, a dossier specifying the details that apply in respect of the authorisation requirement (e.g. the application dates, “sunset dates”, and proposed exemptions, if applicable) and the justifications for these entries.

Applications for authorisation

Substances subject to the authorisation requirement may only be placed on the market and used if an authorisation has been granted (unless the use is exempted from the authorisation requirement). Applications for authorisation can be made by manufacturer(s), importer(s) and/or downstream user(s) and can be submitted separately or jointly. An application can

cover the applicants' and/or their downstream users' uses. The content of an application may vary but certain minimum requirements apply, such as a chemical safety report (unless already submitted as part of a registration) and an analysis of alternatives.

The Risk Assessment Committee (RAC) and Socio-Economic Analysis Committee (SEAC) have to give their opinions on the application within ten months from the date that ECHA receives the application that is considered by the Committees to conform with the requirements laid down in the legislation. Third parties are given the opportunity, within this timeframe, to submit information as part of the process. ECHA supports the rapporteurs of the Committees and coordinates the process through which comments can be submitted. It also assists the rapporteurs in developing opinions that address the risks and socio-economic factors associated with the uses applied for and the availability, risks and technical and economic feasibility of alternatives. The compiled opinions are forwarded by ECHA to the European Commission, which takes the final decision to grant or refuse the authorisation.

Anticipating that based on the ECHA recommendation, the Commission will include in 2010 the first substances into the authorisation list, the first applications to authorise the use of any of these substances are expected to arrive in 2011. In line with the original estimates of the Commission, ECHA is expecting the number of authorisation applications per year to grow from 100 to 400 in the first years. This estimate will have to be reassessed in late 2010. The number of applications in a given year will depend on many factors, and will be refined on the basis of the experience obtained with the first substances that will be included in the list requiring authorisation. Furthermore, close contacts with relevant industry organisations are being established in order to better assess and plan the upcoming workload for the Secretariat and the Committees.

Restrictions

A restriction is any condition for, or prohibition of, the manufacture, import, placing on the market or use of a chemical. New restrictions can be introduced, or existing restrictions can be amended, when there is an unacceptable risk to health or the environment which needs to be addressed on a Community-wide basis. Any such decision has to take into account the socio-economic impacts of the restriction, including the availability of alternatives. New restrictions will be included in Annex XVII to the REACH Regulation, which already includes 'old' restrictions adopted under the Limitations Directive⁹ that the REACH Regulation replaced on 1 June 2009.

The restrictions process is initiated by a notification of intent to prepare a scientific dossier. Restriction dossiers can be prepared by a Member State or by ECHA (at the request of the European Commission). The dossiers have to include, among other things, information on the hazards and risks which give rise to concern; available information on alternatives; and justifications that action is needed on a Community-wide basis and that a restriction under the REACH Regulation is the most appropriate measure following the criteria outlined in Annex XV of REACH.

The ECHA Risk Assessment Committee (RAC) and Socio-economic Analysis Committee (SEAC) check the conformity of the dossiers and, where necessary, ask the Member State or ECHA to remedy any deficiencies. The Committees then have to give their opinions on the suggested restrictions within 9 and 12 months respectively. During that period, interested parties have the opportunity to comment on the dossier and the draft opinion of the SEAC. ECHA will coordinate these consultation processes. The opinions and supporting documentation delivered by ECHA to the European Commission will need to be scientifically

⁹ Directive 76/769/EEC.

sound and comprehensive to allow the European Commission, if appropriate, to draft an amendment to the Annex containing restrictions, within three months of receiving the opinions.

The Restrictions Title of the REACH Regulation entered into force on 1 June 2009. ECHA has prepared itself and the Committees well to receive the incoming dossiers that are under preparation by the Member States, or indeed by the Agency upon request by the Commission, and to handle these dossiers in the restriction process to a high degree of scientific and technical quality, and within the legal timeframe.

The original Commission estimate was that ECHA would process a growing number of restriction dossiers per year in 2011-2013. Apart from preparing restriction proposals at the request of the Commission, ECHA supported the Commission in 2009/2010 in the review of the available evidence to re-examine some of the current restrictions (e.g. on phthalates and on mercury in measuring instruments). This, in turn, may also lead to the development of one or more restriction proposals by ECHA in the period 2011-2013.

ECHA plans to develop a framework for the identification of restriction needs (e.g. on CMR substances in consumer articles or Annex XIV substances in articles) and, based upon that, agree with Member States and the Commission on a work plan for the development of Annex XV restriction dossiers for substances for which concerns have been identified (e.g. as a result of reviewing incoming registration dossiers). Furthermore, ECHA will start evaluating the notifications of substances in articles with a view to identifying when a full registration will be requested to promote effective risk management.

Activity 4 - Classification and Labelling

Priorities 2011-2013

- Maintain a Classification and Labelling Inventory, making non-confidential information available to the public and tackling the workload;
- Deal effectively with proposals from MSCAs and industry for harmonised classification and labelling of certain hazardous substances;
- Deal effectively with requests from industry for the use of alternative chemical names of substances in mixtures.

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

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

Establishment of a Classification and Labelling Inventory (C&L Inventory)

By 3 January 2011 at the latest, industry has to notify ECHA of the classification and labelling (C&L) of substances which are on the market on 1 December 2010 and are either:

- subject to registration under the REACH Regulation (i.e. with a manufacturing or import threshold of 1 tonne/year or more), or
- meet the criteria for classification as hazardous (either on their own or in mixtures) according to the CLP Regulation or Directive 1999/45/EEC, regardless of the quantities in which they are placed on the market.

ECHA will store the information submitted by industry in its C&L inventory and will make the non-confidential part publicly available on its website. In addition, all legally binding harmonised classifications contained in Annex VI to the CLP Regulation will be stored in the C&L Inventory. ECHA will compare the individual entries submitted by industry with other entries in the Inventory for the same substance (either harmonised or from other notifiers). In cases where there are differences in entries from different registrants or notifiers for the same substance, it is the obligation of industry to make every effort to come to an agreed entry.

It is expected that more than one million C&L notifications will arrive shortly before the deadline of 3 January 2011, with the main peak being during the last quarter of 2010. After that date, it is anticipated that several thousand new notifications will arrive each year. The whole submission process will be IT based, followed, in certain cases, by a manual validation by ECHA of the substance identity. Based on ECHA's experiences with pre-registration under the REACH Regulation, it is expected that the first versions of the public C&L Inventory, the very first of which will be published by the end of 2010, might contain a large number of entries with insufficient information on substance identities and differences in classifications. It is anticipated that major 'cleaning up' of the Inventory will be completed within the Work Programme period. The more C&L notifications that arrive by the 2011 deadline, the longer the process of 'cleaning up' the Inventory.

Handling proposals for harmonised Classification and Labelling (C&L)

MSCAs can submit proposals for harmonised C&L for substances that are CMRs, for respiratory sensitisers, and, on a case-by-case basis, for substances that have other hazardous effects with a justification for action on a Community-wide basis. For pesticidal and biocidal active substances, a full harmonisation of the C&L is required. The procedure for submitting the proposals is comparable to that described above for identifying SVHCs.

Additionally, manufacturers, importers and downstream users may submit proposals for harmonised C&L for hazard classes of substances for which no harmonised entry exists.

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

ECHA expects about 90 proposals to arrive each year in this reporting period. There are also a number of substances that were already discussed, but not finalised, under previous chemicals legislation (Directive 67/548/EEC), and some of these are expected to be re-submitted to ECHA by the MSCAs for opinion from the RAC in this reporting period.

Evaluating requests for the use of alternative chemical names

Manufacturers, importers and downstream users of substances in mixtures may submit a request to ECHA for the use of alternative "generic" chemical names in cases where it can be demonstrated that the disclosure of the identity of the substance puts the confidential nature of the business at risk. For each request, ECHA will evaluate within six weeks whether the criteria for use of the alternative name are fulfilled. ECHA expects to receive an increasing number of requests each year (up to 150 requests in 2013) during the reporting period.

Activity 5 - Advice and Assistance through Guidance and the Helpdesk

Priorities 2011-2013

- Delivery of high-quality guidance documents while ensuring buy-in by stakeholders;
- Publish guidance on authorisations and restrictions;
- Review of the registration guidance, integrating experience from the 2010 registration deadline, in advance of the 2013 registration deadline, and further improve accessibility to these guidance documents;
- Provision of advice and assistance to industry as well as harmonised answers across the EU, via the network of national helpdesks, on the REACH and CLP Regulations, as well as other new legislation in which ECHA may be given such a role.

Advice and assistance during the period 2011 to 2013 will continue to provide support to stakeholders, while adapting to priority needs as they evolve.

Guidance

Guidance describes commonly agreed ways for industry and MSCAs to fulfil their obligations under the REACH and CLP Regulations, with the aim of facilitating the implementation of these Regulations. Guidance serves as an accurate reference framework, helping companies and industry associations to develop tailor-made and sector-specific solutions to fulfil obligations that both pieces of legislation place on them. With regard to information requirements, ECHA guidance follows the balance in the legislation which aims at generating reliable and high quality information to ensure the safe use of substances while minimising the need for additional animal testing. The guidance documents were initially developed by the European Commission, together with relevant stakeholders in the REACH Implementation Projects (RIPs). In 2007, ECHA took over responsibility for providing scientific/technical guidance from the European Commission, and since then, the Agency has been responsible for guidance management including publication, updating and the development of new guidance.

ECHA systematically collects feedback and identifies areas for guidance updates or development resulting from the practical experience of guidance users. This feedback is sourced from ECHA's operational experiences, the ECHA helpdesk, and guidance users in industry and national authorities. The relevant part of the guidance is then updated, including incorporation of best practice and new developments. This iterative further development of guidance will determine ECHA's work during 2011 to 2013. Moreover, ECHA is planning to carry out an assessment of experiences from the first registrations related to relevant existing guidance and advice, and draw up a plan for improving them to support industry to prepare for the second registration dead-line. This review shall be done also with a view of better promoting the use of intelligent testing strategies that will generate reliable information for the safety assessment of substances while avoiding animal testing, when not necessary.

Furthermore, in 2011, ECHA will focus on the guidance on authorisations and restrictions. Due account will be taken of the operational experiences gained during the first wave of registrations and notifications, while keeping the existing guidance on registration up to date. ECHA will also complete the work initiated in previous years, by further developing advice on exposure scenarios related to the guidance on information requirements, and chemical safety assessment. However, ECHA aims at freezing the development of registration guidance before the end of 2012 in order to ensure that registrants are fully aware of the requirements for the next registration deadline.

Throughout 2011-2012, ECHA will provide guidance on authorisations and restrictions as well as on substance evaluation. Existing guidance will also be kept aligned with new developments on nano-materials, and where appropriate, new guidance will be developed throughout 2012 and 2013.

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

Benefiting from ECHA's new website in 2011, which will include more user-friendly functionalities and a totally revised "touch and feel", the accessibility of guidance will improve. This guidance includes explanatory documents and guidance access tools, such as [Frequently Asked Questions](#), [Fact Sheets](#), [Guidance in a nutshell](#), and new dedicated internet pages for specific REACH and CLP processes, the REACH Navigator, and for REACH terminology development.

Helpdesk

The helpdesk started to operate with the opening of ECHA on 1 June 2007 and was therefore ECHA's first regular external activity. It gives advice to registrants (and other REACH actors submitting data to ECHA), and to non-EU companies, on REACH obligations as well as on the use of the software applications IUCLID 5 and REACH-IT. The ECHA helpdesk has, since the start of 2009, also had responsibilities related to the implementation of the CLP Regulation.

In addition, during 2011-2013, an important part of the work of the helpdesk will be to coordinate and provide support to the network of national helpdesks on REACH and CLP Regulations established by Member States (HelpNet), with a view to providing harmonised answers to industry by means of the use of an internet-based exchange platform (HelpNet Exchange).

In its own interaction with customers (industry), workload peaks are, in particular, foreseen during the first half of 2011, due to the need for support to registrants failing in their submission of dossiers, and more difficult questions related to the CLP Regulation. From mid-2011 towards 2012, it is foreseen that the number of questions will progressively decrease, although their complexity may increase, and may cover a wider range of topics, such as authorisation and restrictions.

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

ECHA will continue strengthening its cooperation with the national helpdesks with a special focus on making the HelpNet activities more proactive in delivering the best possible service in a timely manner. Besides the harmonisation of answers to questions on REACH and CLP Regulations, further training events will ensure capacity building at the national and European level, and the further development of common knowledge that is easily accessible for all relevant actors.

Activity 6 - Scientific IT tools

Priorities 2011-2013

- Further develop REACH-IT, IUCLID 5 and CHESAR to enable other types of dossier submission necessary under the REACH and CLP legislation;
- Develop IT systems to make the information stored in ECHA databases available to the right audiences: enforcement authorities, stakeholders, and the general public;
- Develop other IT tools needed for operations, in particular for supporting work processes, evaluation and risk management activities;
- Automate processes as far as possible to decrease manual work, improve efficiency, and to enable ECHA personnel to focus on regulatory and scientific aspects of the work.

ECHA is developing a wide range of IT systems to support the REACH operations. A very challenging area of development is related to the automated processing of the large volumes of data electronically submitted by industry in very short periods of time. At the time of writing, the main existing systems in this domain are REACH-IT (an online system managing communication between industry, ECHA, Member States and the European Commission, and the dissemination of information over the Internet), complemented by a case and document management system supporting the work of the ECHA Secretariat and its Committees, and IUCLID 5 (the main system developed for industry to prepare registrations and notifications).

In early 2011, ECHA will provide the enforcement authorities with access to information on registered substances via the RIPE system (REACH Information Portal for Enforcement).

ECHA will also continue to develop or enhance a number of additional specialised applications, such as the Chemical Safety Assessment and Reporting tool (CHESAR), decision support systems for priority setting and reporting (CASPER), and for evaluation (Odyssey). Another area of development covers screening and predictive systems (e.g. the (Q)SAR toolbox) to help make better use of alternative computational approaches to animal testing.

Having passed two critical milestones for the REACH-IT system at the end of 2010 and early 2011, with the handling of the first wave of registrations and of probably several millions of C&L notifications, ECHA will go into the 2011-2013 period with the experience gained from that work and will be in a position to efficiently prepare its IT landscape so that the next challenges (e.g. the second registration deadline in 2013) can be met. REACH-IT will be upgraded and/or redesigned, as appropriate, further to the business and application architecture planning carried out in 2010 and the knowledge gained in 2010. Additional development will cover increasing the automation level and building interfaces with other systems, e.g. the document and record management system, to ensure seamless interoperability and to utilise fully the potential of each system. Further areas of work will be related to adapt the application to changing and possibly new legal requirements.

Significant effort is expected to be put on further development of REACH-IT and the Document Management System in this period, to reinforce support in areas other than registration, in particular evaluation, authorisation and restriction activities, and the public dissemination of information. In addition, existing database systems, such as REACH-IT; the global eChemPortal and RIPE will also need further updates to become instruments that can support industry, ECHA, Member State competent and enforcement authorities, and the public in consulting databases and communicating online.

ECHA also publishes manuals to help registrants understand the main IT systems they will need to use for the preparation of their registrations (IUCLID and Chesar) and subsequent submission to ECHA (REACH-IT). In light of experience gained in 2010, these data submission manuals and REACH-IT user manuals will be updated in 2012 to reflect interpretations of REACH and developments in the IT systems. However, ECHA aims at freezing the development of registration guidance before the end of 2012 in order to ensure that registrants

are fully aware of the requirements for the next registration deadline. The manuals help to ensure that registrants can minimise the risk of failure at registration. They are made available in the 22 EU languages.

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

Activity 7 - Scientific and technical advice to EU Institutions and bodies

Priorities 2011-2013

- Maintain good relations and maintain the network for collaboration with EU institutions and relevant bodies within the EU that are internationally active on chemicals;
- Develop further ECHA's capacity to provide scientific and technical advice in the areas of testing methods (including alternative test methods) and nanomaterials;
- Start building up ECHA capacities from 2011 to deal with new responsibilities under the future Biocides Regulation, subject to the Commission providing the necessary resources.

In 2011-2013, ECHA will further enhance its co-operation with the EU institutions, in particular the European Parliament and the Commission. The scientific capacity of ECHA and its scientific committees will, by 2011, have achieved a degree of maturity allowing the latter institution to send relevant questions of a scientific nature to ECHA for which policy-makers need an answer.

ECHA will in particular provide appropriate advice to the Commission for the further development of the REACH and CLP Regulations, and any related legislation concerning chemicals, as well as measures related to their implementation. This will also include active contributions to addressing new and emerging issues such as addressing the specificities of nanomaterials. ECHA will undertake activities related to reporting, contribute to evaluating the efficiency and effectiveness of REACH, and provide scientific and technical assistance to the Commission in preparing the first review of REACH scheduled for 2012.

The implementation of REACH, and in particular the development of manufacturers' and importers' registration dossiers, will require new testing of chemical substances with vertebrate animals in order to fill the data gaps in knowledge on the hazards of these substances. At the same time, it is also an aim of REACH to promote alternative methods for assessing the hazards of substances. The development of new and existing standardised test methods that may replace or reduce the need for animal tests is an activity that is carried out in national and European research programmes, in the ECVAM programme for the scientific validation of alternative methods, as well as at international level under the auspices of the OECD. In the EU, the Commission is responsible for the regulatory acceptance of new methods and their adoption and inclusion in the Test Methods Regulation, as well as the eventual related revision of the information requirements specified in REACH, Annexes VII-X. ECHA is providing scientific and technical support to these activities.

Based on the priorities set out in the Work Plan developed in 2009, ECHA will further extend its internal capacities in the area of the characterisation, hazard and safety assessment and risk management of nanomaterials. ECHA will participate in various scientific and regulatory activities at EU and OECD level with the ultimate aim to develop appropriate guidance to industry, as well as to be able to evaluate registration dossiers that contain information on the hazards, risks and risk management of nanomaterials. ECHA will also contribute to the Commission's report on types and uses of nanomaterials, including safety aspects, to be submitted to the European Parliament in 2011.

The new biocides legislation proposed by the Commission, in which ECHA is foreseen to be responsible for a number of tasks, is intended to enter into operation in 2013. It can be anticipated that the Commission will request ECHA to complement, where necessary, the work carried out by Joint Research Centre of the Commission in providing scientific and technical support throughout the ongoing negotiations of the proposed legislation with the Council and Parliament.

ECHA will also start its first specific reporting activities to the Commission as required by REACH during the 2011-13 period. This will include the first five-year report for the Commission on the operation of the REACH Regulation; in this context ECHA will also make suggestions for improving the workability of the Regulation. ECHA will also draw up the first three-year report 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, with a view to promoting the use of alternative methods by registrants for the second registration deadline. Furthermore, ECHA will contribute to the first review of the Agency, which is due by June 2012.

The REACH Regulation provides for a horizontal framework which applies to most of the chemical substances manufactured in or placed on the European market. On many occasions, therefore, ECHA's work affects European Union bodies involved in sector-specific legislation on the assessment and management of the risks from chemicals. For this reason, the REACH Regulation requires ECHA to cooperate with these entities, in order to avoid duplication of work and conflicting scientific opinions, and in particular with the European Food Safety Authority (EFSA), and with the European Commission's Advisory Committee on Safety, Hygiene and Health Protection at Work – where worker protection issues are concerned. To this end, Rules of Procedure and Memoranda of Understanding were put in place as from 2009 and 2010. Through this work the Agency contributes to creating synergies with other EU legislations and will continue to do so.

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

ECHA's bodies and cross-cutting activities

Activity 8 - Committees and Forum

Priorities 2011-2013

- Deliver opinions on time, to allow the European Commission or the Executive Director of ECHA to reach regulatory decisions on a scientifically-sound and well-argued basis;
- Provide a solid basis for decision making ensuring a maximum number of unanimous agreements in the Member State Committee (MSC), in particular, to ensure that the "candidate list" of substances of very high concern can be frequently updated and that ECHA's draft decisions on testing proposals and compliance checks are addressed with high scientific quality and in a timely manner;
- Produce scientific opinions on specific *ad-hoc* questions, in particular on those of an urgent nature;
- Significantly promote the harmonisation of REACH and CLP enforcement, in the Member States, in particular through the Forum and the coordination of its harmonised enforcement projects.

The Committees 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 Regulation and the credibility of ECHA in ensuring its independence, scientific integrity and transparency.

Chapters 4.1.1 and 4.1.2 describe the activities of the three ECHA Committees in a general manner. The type and number of throughputs to be handled by the Committees is directly determined by the various REACH and CLP processes and driven by the expected amount of dossiers described under Activities 2, 3 and 4. Thus during 2011–2013, the dossiers will mainly represent the drivers of the Committees' activities.

RAC and SEAC

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

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

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

The activities of the two Committees will be conducted in parallel when dealing with restriction proposals and authorisation applications. For instance, in the case of restriction proposals, opinions will be delivered within nine (RAC) and twelve (SEAC) months of the date of receipt, and after public consultation. The legal timelines pose a challenge for the Committees and the

Secretariat, and thus efficient working procedures have to be in place in order to cope with the challenges.

During 2011-2013, the ECHA Secretariat will continue to chair and to prepare Committee meetings and *ad hoc* working groups – which may include members from both Committees to facilitate the coordination of workflows. As required, the Secretariat will provide support to the Committee members who have been appointed as (co-)rapporteurs for specific dossiers. Moreover, the Committee members need full scientific and technical support from the Member State Competent Authorities, especially when serving as (co-)rapporteurs.

The number of plenary meetings is estimated to be six per year in the case of the RAC, and four to five in the case of the SEAC. It is already discernable that more than six plenary meetings a year will not be feasible for the Committee members or for the Secretariat. In the years 2011–2013, both Committees are expected to hold an increasing number of working group meetings to support the rapporteurs and to prepare the conclusions of the Committee. The Committees will therefore need to adapt their work to a potentially unmanageable workload.

Coordination with other EU scientific committees, dealing with the same or similar substances under different regulatory frames, will represent an additional challenge; with early identification of potential divergences in the opinions being a critical issue.

MSC

The ECHA 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 proposed by ECHA on the evaluation of testing proposals or compliance checks as part of dossier evaluation, on draft decisions proposed by the Member States on substance evaluation, and on proposals for identification of substances of very high concern (SVHC). Where the MSC fails to find a unanimous agreement, its opinion will be forwarded to the European 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 in a broad range of scientific fields – ranging from the best use of different test methods for obtaining information on the hazards of substances and the assessment of the environmental persistence of substances, to agreeing on priorities for SVHCs to be included in the “authorisation list”. That is why the members are assisted in each meeting by experts from their competent authorities.

It is expected that between 2011 and 2013, the MSC will be informed of a high number of draft decisions regarding compliance checks on registration dossiers and testing proposals and will potentially seek unanimous agreement on them, once at least one Member State submits respective comments. It is currently estimated that 10-20% of the draft decisions would require agreement to be sought in the MSC.

From 2011 to 2012, dossier evaluation will form a major part of the workload for the MSC. The Committee is expected to start work on substance evaluation in 2012.

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

Forum

The REACH Regulation requires each Member State to set up a system of official controls and other activities as appropriate to the circumstances. Effective, harmonised and equal enforcement throughout the Community is of crucial importance for the credibility and success of REACH. The Forum functions as a platform for Member States to meet to exchange information and to coordinate their enforcement activities, including the enforcement of the CLP Regulation. It is chaired and driven by Member State representatives but supported by a secretariat of ECHA staff.

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

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

The Forum will undertake activities included in a regularly updated work programme which can be found on the ECHA website. The Forum is focusing its activities on the clarification of the tasks of REACH enforcement officers, and the elaboration of best practice. The involvement of the Forum in a number of “coordinated projects”, e.g. on enforcing the “no data, no market” rule with regard to (pre-)registration, will be of particular importance.

The Forum has developed enforcement strategies and will develop minimum criteria for REACH enforcement, undertaking harmonised projects and preparing guidance materials and training materials for inspectors. In addition, it will cooperate with the RAC and the SEAC to give advice on the enforceability of proposed restrictions on substances.

Activity 9 - Board of Appeal

Priorities 2011-2013

- Take high quality decisions without undue delay while further building stakeholders' confidence in the appeal procedure;
- Tackle the evolving workload from appeals against Agency decisions and in particular any major fluctuations therein;
- Provide input to the Commission to adjust and enhance the Rules of Procedure after the first few years of experience, in order to further improve the procedural efficiency and the effectiveness of the appeal system. This may also imply making recommendations about improvements in the organisational structure of the Board.

The Board of Appeal is an integral part of ECHA, but takes its decisions independently. It currently consists of a full-time Chair and two full-time members, who may not perform any other duties in ECHA. Additional and alternate members have been appointed and can be called upon, on a part-time basis, to cope with fluctuations in the volume of work. 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 European 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. Decisions against which an appeal may be lodged include rejections of

registrations, data sharing, examinations of testing proposals, compliance checks of registration dossiers, substance evaluations, or exemptions from the general obligation to register for product and process orientated research and development (PPORD).

The number of appeals lodged before the Board of Appeal will depend upon the number of decisions taken by ECHA, and the decisions of affected parties whether or not to contest possible adverse decisions. Consequently, the Board of Appeal cannot itself define its own workload but must address all the appeals brought before it.

For the 2011-13 period, the main challenge for the Board of Appeal will be to take high quality decisions in a timely manner without developing major backlogs, as well as to build up a consistent body of case-law. It can be anticipated that, in the aftermath of the 2010 registration deadline, the workload of the Board of Appeal may fluctuate substantially. However, the estimated baseline figures for appeals have been kept stable for the period 2011-2013 for resource planning purposes.

Another characteristic of the period will probably be a change in the types of appeals lodged: it is foreseen that towards 2013, appeals will be focused more on dossier and substance evaluations than in 2011, when emphasis will most likely be on issues concerning data sharing and registrations. This gradual shift will necessitate the focus on knowledge management by the Board of Appeal changing accordingly.

At the end of the 2011-13 period, the Board of Appeal will also need to analyse systematically, on the basis of the experience gained, whether there are needs to modify the adopted ways of working or the procedures in place – including during the organisational review foreseen in the REACH Regulation for 2012. This is also the time when the first judgements of the Court of First Instance on possible appeals against the Board of Appeal's decisions could be expected, which may lead to refinements in the Board of Appeal's decision-making practices.

Activity 10 - Communications

Priorities 2011-2013

- Continue to improve communications to better support the achievement of ECHA's objectives
- Enhance communications, in particular, with the general public and with small and medium sized enterprises (SMEs) also by providing translations;
- Further develop and deepen the involvement of stakeholders in ECHA's work;
- Understand the public's perception of the safe use of chemical substances (Article 34 of the CLP regulation).

Over the 2011-13 period, ECHA's communication activities will continue to focus on four areas:

1. Media relations: where ECHA's relationship with the press will be managed both proactively and reactively – seeking to explain ECHA's work to the media as well as responding in a helpful, timely and efficient way to enquiries and media reports;
2. External communications: where ECHA will seek to further develop its relationships with its stakeholders – both the ones who already play an active role and those who, as yet, do not. ECHA will also seek continually to improve communications in particular for the general public as well as for small and medium-sized enterprises. The Agency will continue its practice of providing those publications and web-pages that are important for the general public and SMEs in 22 official EU languages;

3. Internal communications: as ECHA becomes larger, internal communications become ever more important. The policy set in 2009 will be reviewed and further developed to ensure that internal communications are as effective as they need to be;
4. Digital communications: ECHA's internet site will be rebuilt during 2011, and its intranet site that was relaunched in late 2009 will be further developed and improved.

In 2011, after the first registration deadline in 2010 and the wealth of information that it will bring, ECHA will be able to start to promote the availability of information on chemical substances to the general public. For the first time, the Agency will undertake activities to raise awareness of the impact of its work, as well as of the information that all citizens can access through its dissemination database and inventory. This work will be done in partnership with ECHA's stakeholders.

ECHA will finalise an extensive study into the public's perception of the safe use of substances – the final report is due to be delivered in January 2012. This will, *inter alia*, build on the results of a *Eurobarometer* survey conducted in all 27 EU Member States during 2010. It will conclude with a report to the European Commission in accordance with Article 34/1 of the CLP Regulation, on the basis of which the Commission will report to the European Council and Parliament on the potential need for amendments to the legislation on classification, labelling and packaging.

Currently, ECHA is investing an annual €3-4 million in translating its documents. During 2011 and beyond, ECHA will maintain its practice of translating documents of relevance particularly to the general public and to companies, in particular SMEs, for publication on its website. ECHA will ensure that user manuals for IT tools are available in all EU languages to facilitate their use. ECHA will also endeavour to make translations gradually available in Croatian, Icelandic and Norwegian.

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

ECHA's main communication tools will continue to be its website, intranet and extranet; bi-annual Stakeholder Days, targeted stakeholder workshops, and other tailor-made events; press releases, news alerts, articles, interviews and press briefings; external newsletters; e-newsletters; and its annual General Report, Work Programme and audience specific publications.

In 2012, the new website will allow ECHA to publish a larger scope of documents in all official EU languages more easily and swiftly, as well as to translate deeper layers of its website for access in languages other than English.

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

Activity 11 - International cooperation

Priorities 2011-2013

- Contribute to the REACH and CLP related work of the OECD and the UN;

- | |
|---|
| <ul style="list-style-type: none">- Establish bilateral cooperation or working agreements with agencies similar to ECHA in major third countries. |
|---|

Respective provisions in ECHA's establishing Regulation entrust the Management Board to decide on the participation of third countries and international organisations in the work of ECHA (Articles 106 and 107), while in other cases the initiative has to come from the European Commission (Article 77(2)(l)). Moreover, Article 120 of the REACH Regulation stipulates that for any exchange of confidential information with third countries or international organisations, a specific agreement between the EU and the third party has to be laid down.

It is foreseen that after the first registration deadline in 2010, ECHA will start receiving requests from third countries or international organisations for confidential data. Therefore ECHA plans, in cooperation with the Commission, to assess the need for and remit of possible confidentiality agreements, in 2011.

Multilateral activities

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

ECHA has been asked to participate in a number of OECD activities which are of relevance to the implementation of the REACH and CLP Regulations: in particular the project management of the Global Portal to Information on Chemical Substances (eChemPortal), for which ECHA will ensure hosting from 2011, and the further development of the QSAR Application Toolbox, which will be rolled-out in 2012. The Agency also participates in the further planning on OECD cooperation on the assessment of chemicals after 2010 – including the implementation of the related OECD work plan in the interim phase. ECHA will, in cooperation with the Commission and the Member States, develop procedures ensuring adequate coordination between REACH implementation and contributions from the EU to the refocused OECD programme.

Other OECD related activities in which ECHA will be involved during the period 2011-2013, include contributing to the work of the Task Force on Exposure Assessment; to the Harmonised Templates Project; to the work on the health and environmental aspects of nanomaterials; to the Test Guidelines Programme; and to the work of the Task Force on Harmonisation of Classification and Labelling, and its subgroups, if appropriate.

In addition to OECD related activities, ECHA will continue supporting the European Commission's work on the Stockholm Convention on Persistent Organic Pollutants (POPs). Another international activity for which the Commission is likely to continue requesting support from ECHA relates to the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). Considering the role and various tasks that the CLP Regulation gives to ECHA, the Agency expects to take part in the work of the UN ECE Sub-Committee of Experts on the GHS and its correspondence groups, whenever their work is of a scientific and technical nature. In addition, ECHA will be monitoring other international chemical management instruments, such as the implementation of the Rotterdam Convention, and negotiations on the legally binding instrument for mercury. The Agency will remain prepared, on request and resources allowing, to provide scientific and technical support to the Commission.

Working relations with third countries and international organisations

In consultation with and on request from the European Commission, ECHA organises or attends meetings and conferences with third countries on the requirements of the REACH Regulation, and supports the provision of adequate training in this regard (for instance, within the framework of TAIEX seminars). ECHA has been regularly charged with helping to improve cooperation between the Community and third countries, by participating in the exchange of

best practice in fields covered by its remit. In line with the decision of the Management Board on a general approach to cooperation with third countries taken in December 2008, ECHA focuses particularly on EU candidate countries and potential candidates for EU accession. Overall, ECHA will intensify its relations with these countries in a manner commensurate with their alignment with the REACH Regulation.

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

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

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

Management, Organisation and Resources

Activity 12 - Management

Priorities 2011-2013

- Ensure that ECHA's organisation is adapted to the growing workload and increasing size of staff;
- Further strengthen the security policy implementation;
- Prepare for ISO 9001;
- Ensure efficient management of the Agency.

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

In the start-up phase (2007-2010), the Board's activities were dominated by the need to put a general framework swiftly into place allowing the Agency to become fully operational. From 2011 onwards, the Management Board will be able to concentrate on its permanent regulatory tasks. The tasks of the Management Board include the adoption of the work programme, the annual report and other strategic documents, as well as the adoption of the budget and the delivery of an opinion on the final accounts. The Board also appoints the Executive Director, the Board of Appeal and the members of the Committee for Risk Assessment and the Committee for Socio-economic Analysis, and may accept stakeholder organisations that can be invited by the Committees, the Forum or other Agency networks as observers.

The day-to-day management of ECHA is a task of the Executive Director. He carries out his duties independently, without prejudice to the respective competences of the European Commission and the Management Board.

In 2011, the organisational structure of ECHA will become more fixed, as the Agency will no longer be growing dramatically each year. The number of directorates will increase to seven and each will have a coherent set of responsibilities. However, cooperation across directorates will remain essential for the Agency's success.

In 2011-2013, ECHA will continue the implementation of the Quality Management System and documentation of the process system and related procedures, so that they fit into the new structures of a fast developing Agency and are adapted to the level of risk associated with the effective running of operations. The focus will shift towards the system assessment and evaluation with a view on optimisation and improvement. The preparation for certification according to ISO 9001 will continue.

In view of the rapid growth of ECHA, the progressive expansion of its core areas of operation, and its changing control environment, it is important that the corporate risk management system is further enhanced.

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

ECHA's security policy has been identified as a priority for the next few years in order to ensure that the Agency's personnel, information assets (in particular registration data), the buildings and equipment are adequately protected. This includes formalising key procedures, reinforcing relevant structures and setting up a full-scale business continuity plan.

Finally, ECHA will fulfil its reporting duties, in particular by submitting a report on the functioning of the REACH Regulation to the European Commission in 2011, in accordance with Article 117(2) of the Regulation.

Activity 13 - Finance, procurement and accounting

Priorities 2011-2013

- Provide reliable budgetary planning and ensure a tightly managed execution;
- Manage adequately the cash reserves expected from the first registration deadline of 2010.

On account of the rapid growth of ECHA's operations and the need to ensure that financial management complies with the relevant rules and Regulations of the European Community, the finance function is a key support process.

In order to finance its activities, ECHA relies on following sources of funding:

1. Community contribution granted by the Budgetary Authority of the EU (i.e. the European Parliament and the Council); and a proportional small fraction as EEA-EFTA contribution;
2. Income generated from fees and charges which ECHA levies for performing the tasks with which it is charged under the REACH and the CLP Regulations; and
3. Any voluntary contribution from the Member States and EEA-EFTA countries.

The initial years of functioning of ECHA were financed through a Community contribution. The year 2010, with the first main income peak expected around the November deadline and

involving a large number of registrations, was therefore a transition year and funded through income from fees and charges; while a refundable bridging subsidy was foreseen to assure liquidity during the year 2010. No Community contribution is thus planned for the years 2011-2013; that is to say that it is anticipated that ECHA will fully cover its expenditure from fees and charges levied in accordance with the Fee Regulation¹⁰ during this period.

As the registration deadlines imposed by the REACH Regulation are expected to cause significant fluctuations in the levels of ECHA's revenue from year to year, efficient budgetary planning and cash management will be of the utmost importance. This is all the more crucial because the Fee Regulation provides for a proportion of the fees and charges collected to be transferred to the competent authorities of the Member States as remuneration for specific tasks entrusted to them, while ensuring that sufficient financial resources remain for ECHA.

The overall objective of ECHA's financial management is to make the best use of available financial resources in line with principles of economy, efficiency and effectiveness. As regards procurement and contracting, ECHA will continue to outsource a small part of its operational activities, to ensure the efficient implementation of the REACH Regulation. Establishing the contractual basis for ICT developments, logistics and other services will continue to impose a considerable demand for efficient procurement and contracting in the period 2011-2013.

Activity 14 - Human resources and corporate services

Priorities 2011-2013

- Provide reliable human resource (HR) planning and continue to ensure the availability of highly qualified human resources to meet ECHA's objectives;
- Ensure a sound framework for the management and administration of ECHA's staff;
- Ensure a high quality working environment for ECHA staff and its Committees, in line with the highest health, safety and environmental standards.

Human resources

ECHA's human resources policy for the 2011-2013 period is set out in the Multi-Annual Staff Policy Plan for the same period.

The first years in the establishment of the Agency were characterised by a very fast growth in staffing, with a total of 426 Temporary Agent posts foreseen in the Establishment Table for the year 2010. A further, more modest growth is foreseen for the period 2011-2013, the size of which depends on the volume of dossiers that arrive in the registration and C&L notification deadlines of 2010 and early 2011. The main focus of the HR strategy will be a shift to the further developing of the competency and skills base of the staff of the Agency as well as their effectiveness. The training and development programme will therefore be modified to reflect this change in focus.

During the reporting period, considerable effort will continue to be devoted to optimising human resource administration and management procedures, in particular through the further development of integrated ICT solutions, to reduce the administrative overheads of managing human resources and for developing a consistent reporting and management framework.

The Human Resources unit of ECHA will, in close partnership with the Staff Committee, foster and promote the wellbeing of staff and their families.

¹⁰ Commission Regulation (EC) 340/2008.

Corporate services

The Agency's infrastructure tasks include the management of its premises, for which the Agency has established a long term lease agreement; providing stability for the location of ECHA. The agreement also holds out the prospect of a purchase option which may be considered following the registration deadline of 2010.

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

Activity 15 - Information and Communication Technology

Priorities 2011-2013

- Operate the technical ICT infrastructure of the Agency at a high service level and maximise continuity, efficiency and security for all supported business operations;
- Assure a consistent and common corporate architectural approach as well as foster best practice in governance of IT projects.

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

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

The expansion and further optimisation of network, communications, technical infrastructure and user support will continue, in order to accommodate the increased and evolving needs of ECHA and its stakeholders. Secure network connections with Member State competent and enforcement authorities and with the Commission will be further expanded. During the 2011-13 period, the ICT infrastructure will also play a major role in the Business Continuity and security plans.

Architectural reviews and experiences from the current registration process point to a need for further ICT developments and an extended support requirement to business needs in the period following the 2010 registration deadline. The need for re-factoring existing applications and to integrate them in an overall enterprise resource management approach becomes more and more apparent: the period 2011-2013 would be the logical window for this. The initial estimates for ICT resources for the period in question did not foresee these requirements, however, benchmarking against other Agencies and organisations similar to ECHA, also suggests that the initially foreseen budget and resource level for operational ICT systems was underestimated.

ANNEXES

Annex 1: Overview of the milestones from REACH and the CLP Regulations, 2010-2013

	Milestones from the Regulation
2010	<ul style="list-style-type: none"> Progress report on evaluation by 28 February 2010 (Art. 54) First 5 year MS-COM report on the operation of REACH by <u>1 June</u> (Art. 117.1): this first 5 year report to include enforcement aspects (Art. 127) Transitional measures regarding restrictions end on <u>1 June</u> (Art. 137) First registration deadline for phase-in substances >1000 t/y, R50/53 >100 t/y and CMR cat.1+2, by <u>30 November</u> (Art. 23.1¹¹)
2011	<ul style="list-style-type: none"> Classification & Labelling notifications in accordance with CLP Regulation, Art. 40 by <u>3 January</u> Progress report on evaluation by 28 February 2011 (Art. 54) Notifications for SVHCs in articles start from <u>1 June</u>, six months after a substance is put on the “candidate list” (Art. 7.2) First 5 year ECHA-COM report on the operation of REACH by <u>1 June</u> (Art. 117.2) First 3 year ECHA-COM report on non-animal test methods and strategies by <u>1 June</u> (Art. 117.3) First draft Community Rolling Action Plan for substance evaluation to be submitted to MS by <u>1 December</u> (Art. 44.2)
2012	<ul style="list-style-type: none"> 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 <u>20 January</u> Progress report on evaluation by 28 February 2012 (Art. 54) First 5 year COM general report on the operation of REACH and funding for development and evaluation of alternative test methods to be published by <u>1 June</u> (Art. 117.4): this report to include COM review of registration requirement 1-10t/y as basis for possible legislative proposals (Art. 138.3) COM review of scope of the REACH Regulation, as basis for possible legislative proposals by <u>1 June</u> (Art. 138.6) Review of ECHA by <u>1 June</u> (Art. 75.2) Deadline for ECHA’s draft decisions on testing proposals for registrations received by 1 December 2010, on <u>1 December</u> (Art. 43.2.a)
2013	<ul style="list-style-type: none"> Progress report on evaluation by 28 February 2013 (Art. 54) Registration deadline for phase-in substances ≥ 100 t/y by <u>1 June</u>

¹¹ Unless otherwise indicated, legal references are made to the REACH Regulation.

Annex 2: Estimated ECHA Revenue and expenditure 2011-2013 (including staffing plan)¹²

Estimated resources for 2011

Activities (Title III of the Budget)	Human Resources			Draft budget	Revenues
The numbering below refers to the Activity numbers in this Work Programme, not to the numbering in the budget	AD	AST	CA		
Implementation of the REACH and CLP Processes					
Activity 1: Registration, data-sharing and dissemination	39	13	6	700.000	224.300.000
Activity 2: Evaluation	82	11	5	700.000	
Activity 3: Authorisation and restrictions	26	5	2	1.800.000	11.700.000
Activity 4: Classification and labelling	14	3	0	200.000	60.000
Activity 5: Advice and assistance through guidance and helpdesk	26	12	5	1.500.000	
Activity 6: Scientific IT tools	24	3	0	13.600.000	
Activity 7: Scientific and technical advice to EU institutions and bodies	8	3	0	500.000	
ECHA's bodies and cross-cutting activities					
Activity 8: Committees and Forum	17	8	4	3.800.000	
Activity 9: Board of Appeal	12	5	3	900.000	
Activity 10: Communications	10	8	7	6.500.000	
Activity 11: International cooperation	6	1	0	1.000.000	
Management, organisation and resources					
Activity 12: Management	21	20	3	800.000	
Total	285	92	35	32.000.000	
Activities 13-15: Organisation and resources (Title II: Infrastructure)	26	53	26	14.000.000	3.000.000*
Title I (staff expenditure)				61.800.000	
Total (REACH and CLP)	311	145	61	107.800.000	239.060.000
In Establishment plan:	456				
New activity: Biocides	3	1	2	1.000.000	

¹² The estimates for biocides are based on ECHA's estimates for resource needs and any resources are subject to the adoption of the relevant legislation (COM(2009)267).

Subsidies for biocides				1.000.000	
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* bank interest

Estimated resources for 2012

Activities (Title III of the Budget)	Human Resources		CA	Draft budget	Revenue
	AD	AST			
<i>Implementation of the REACH and CLP Processes</i>					
Activity 1: Registration, data-sharing and dissemination	39	13	6	400.000	24.100.000
Activity 2: Evaluation	84	11	6	900.000	
Activity 3: Authorisation and restrictions	32	8	3	2.400.000	1.900.000
Activity 4: Classification and labelling	16	3	1	400.000	150.000
Activity 5: Advice and assistance through guidance and helpdesk	26	12	5	1.500.000	
Activity 6: Scientific IT tools	24	3	2	12.150.000	
Activity 7: Scientific and technical advice to EU institutions and bodies	8	3	0	700.000	
<i>ECHA's bodies and cross-cutting activities</i>					
Activity 8: Committees and Forum	19	8	4	4.600.000	
Activity 9: Board of Appeal	12	5	3	700.000	
Activity 10: Communications	10	8	7	6.500.000	
Activity 11: International cooperation	6	1	0	1.000.000	
<i>Management, organisation and resources</i>					
Activity 12: Management	24	22	4	800.000	
Total	300	97	41	31.050.000	
Activities 13-15: Organisation and resources (Title II: Infrastructure)	26	53	30	14.200.000	1.500.000*
Title I (staff expenditure)				60.000.000	
Total (REACH and CLP)	326	150	71	106.250.000	27.650.000
In Establishment plan:	476				
New activity: Biocides	4	1	6	1.000.000	
Subsidies for biocides				1.000.000	

* bank interest

Estimated resources for 2013

Activities (Title III of the Budget)	Human Resources		CA	Draft budget	Revenues
	AD	AST			
<i>Implementation of the REACH and CLP Processes</i>					
Activity 1: Registration, data-sharing and dissemination	39	13	9	700.000	30.600.000
Activity 2: Evaluation	84	11	6	900.000	
Activity 3: Authorisations and restrictions	32	8	3	2.500.000	36.400.000
Activity 4: Classification and labelling	16	3	1	500.000	450.000
Activity 5: Advice and assistance through guidance and helpdesk	26	12	6	1.000.000	
Activity 6: Scientific IT tools	24	3	2	10.500.000	
Activity 7: Scientific and technical advice to EU institutions and bodies	8	3	0	500.000	
<i>ECHA's bodies and cross-cutting activities</i>					
Activity 8: Committees and Forum	19	8	4	7.000.000	
Activity 9: Board of Appeal	12	5	3	1.000.000	
Activity 10: Communications	10	8	5	6.000.000	
Activity 11: International cooperation	6	1	0	1.300.000	
<i>Management, organisation and resources</i>					
Activity 12: Management	24	22	4	1.000.000	
Total	300	97	43	32.900.000	
Activities 13-15: Organisation and resources (Title II: Infrastructure)	26	53	28	14.700.000	1.100.000*
Title I (staff expenditure)				61.800.000	
Total (REACH and CLP)	326	150	71	109.400.000	68.550.000
In Establishment plan:	476				
New activity: Biocides	11	7	6	6.3120.000	4.120.000
Subsidies for biocides				2.192.000	

* bank interest

Annex 3: Baseline figures for 2011-2013

ECHA's main activity drivers	Estimate for 2011	Estimate for 2012	Estimate for 2013
Dossiers arriving¹³			
Registration dossiers (including updates)	8100	5100	12400
Confidentiality requests	450	560	1300
Access to data older than 12 years	100	120	120
Requests for registration information from third parties	500	50	200
PPORD notifications	150	200	450 ¹⁴
Inquiries	1500	1500	2000
Number of notifications under REACH Art. 7(4)	40	70	70
Number of reports under REACH Art. 37(4)	45 000	45 000	300
Restriction proposals (REACH Annex XV)	10	12	15
Proposals for harmonised classification and labelling (REACH Annex XV)	90	90	90
Proposals for identification as SVHC (REACH Annex XV)	40	30	30
Authorisation applications	130 ¹⁵	240 ¹⁶	400 ¹⁷
Alternative name requests	20	50	150

¹³ These figures do not include the carry over deriving from the previous year and processed in the year in question.

¹⁴ 50% are extensions of 2008.

¹⁵ Based on the original Commission estimate of 8 new substances added on Annex XIV list.

¹⁶ Based on the original Commission estimate of 15 new substances added on Annex XIV list..

¹⁷ Based on the original Commission estimate of 25 new substances added on Annex XIV list.

ECHA decisions			
Decisions on dossier evaluation			
- No of dossier evaluations initiated	500	500	500
- No of dossier evaluation decisions	350	350	350
- No of substance evaluation decisions		10	30
Decisions on data sharing	50	50	400
Decisions on completeness check (negative)	660	90	160
Decisions on completeness check (positive, i.e. with registration numbers or update confirmation)	20 350	4600	12000
Decisions on releasing information requested by third parties	280	25	100
Decisions on confidentiality requests (negative)	150	30	65
Decisions on requests for alternative names	20	50	150
Appeals	100	100	100

Others			
Updates of the draft Community rolling action plan for substances subject to substance evaluation	1	1	1
Recommendations to the European Commission for the authorisation list	1	1	1
Questions to be answered/harmonised answers (REACH Advice, REACH-IT, IUCLID 5, others)	7 000	7 000	10 000
Management Board meetings	4	4	4
MSC meetings	6	6	6
RAC meetings	6	6	6
SEAC meetings	4	4	5
Forum meetings	3	6	3
New TA posts to be filled	30+4 ¹⁸	20+0 ¹⁹	0+14 ²⁰

¹⁸ Biocides.

¹⁹ Biocides.

²⁰ Biocides.