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Multi-Annual *Work Programme* 2009-2012

European Chemicals Agency

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EUROPEAN CHEMICALS AGENCY
Muli-Annual Work Prorgamme 2009-2012

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Foreword by the Management Board

As the highest decision-making body of the European Chemicals Agency (ECHA), the Management Board was its first fully functioning body and, together with the Executive Director and the small number of initial staff, started work on setting up the Agency right from its foundation on 1 June 2007.

The REACH Regulation is the largest legislative project adopted by the European Union in recent years and the most ambitious chemicals legislation in the world. It aims to address a number of serious shortcomings of the former EU chemicals legislation, in particular the lack of information on risks to human health and the environment for the majority of chemical substances on the EU market and the slowness of the system for dealing with substances identified as hazardous.

Chemicals bring real benefits to our everyday life. Some chemicals can, however, also cause serious damage to human health and/or the environment. REACH will make those who place chemicals on the market responsible for understanding the potential adverse effects and managing the risks associated with the use of dangerous chemicals. REACH also aims to enhance the competitiveness of the EU chemicals industry by creating incentives for innovation and by removing distortions of the internal market inherent in the formerly fragmented legislative regime.

It was clear from the beginning that implementation of REACH would be a challenging undertaking; not only for the companies concerned but also for ECHA, which is the heart of the new system. The task of breathing real life into REACH operations will very much depend on the quality and effectiveness of the Agency's work, as regards both its own operating procedures, IT systems and the advice and assistance it provides to companies and to Member States. On the basis of the experience in the first one and half years since the Agency was set up, the Management Board trusts ECHA to meet these very high expectations. A successful implementation of REACH will clearly depend on strong links and close co-operation between ECHA and the competent authorities of the European Member States and the European institutions, above all the Commission and the European Parliament.

ECHA's work should be underpinned by sound scientific judgement and regulatory excellence and it will have to bring together the best scientific and technical expertise to make use of a steadily-growing amount of high-quality data on chemical substances. At the same time, it has to work completely independently. Only thus can it ensure that there is an objective basis for its opinions and decisions and that more innovative substances and technologies are generated that may replace substances or uses of substances which pose the highest risks to man or the environment.

Overview by the Executive Director

This document sets out the first Multi-Annual Work Programme of the European Chemicals Agency (ECHA) covering the years 2009-2012. By the end of October of each year ECHA's Management Board will revise this programme and at the same time adopt the Agency's next annual work programme, in which more details can be found on the year ahead.

The first Multi-Annual Work Programme is designed to set out ECHA's technical and scientific tasks and its objectives for the years to come. It also gives clear background explanations of the often very complex REACH procedures. We hope that this will make the programme more easily accessible for those who are not REACH experts and thus contribute to greater transparency. The first chapter covers ECHA's vision, mission and values, as developed in close cooperation with the Agency staff, as well as the overall objectives for the first phase of its operational activities. This is followed by an overview of the Agency's operational and administrative work in the coming years and its role in the REACH processes. The Annexes give an overview of ECHA resources and REACH milestones in 2009-2012.

ECHA has had to grow very fast and simultaneously take on many challenges since its creation in June 2007, in order to be able to cope with the many operational and administrative tasks it would be expected to deal with only 12 months later.

The Agency only started its operations about two months before the Management Board had to adopt this document. As a result, the descriptions of the tasks and assumptions made in the programme are subject to a number of uncertainties. They are therefore worded in quite general terms and may need correction in later editions.

As Executive Director of ECHA I have received a lot of positive feedback on the setting up of the Agency within such an unprecedentedly short time frame and on the start of REACH operations on 1 June 2008. But clearly the real challenges to make REACH work are still ahead of us. The years 2009-2012 will be crucial for ECHA as we have to complete and consolidate our working procedures and management to cope with the peak in workload expected in connection with the first registration deadline in 2010 and to make a credible start on the authorisation procedure for substances of very high concern. At the same time, ECHA needs to assist industry as much as possible in implementing REACH, in order to help achieve the expected benefits for the competitiveness of European-based companies.

Compared to the previous chemicals legislation, REACH does affect a much wider range of actors and requires a change of mindset for industry and the authorities. For the successful implementation of this new system, ECHA depends on cooperation based on trust with its institutional partners, the European Commission, the European Parliament and the Member State authorities, as well as with all stakeholders and interest groups. We would therefore very much appreciate your feedback on this Multi-Annual Work Programme that will be published on the Agency's website at www.echa.eu. We look forward to hearing your views.

I sincerely hope you will find the 1st ECHA Multi-Annual Work Programme interesting and useful.

Geert Dancet
Executive Director

1 Introduction

Established on 1 June 2007, the European Chemicals Agency (ECHA) is at the heart of the new regulatory system for chemicals in the European Union set out in Regulation 1907/2006 of the European Parliament and the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals[1]. By the end of 2008, REACH will be complemented by the recently agreed Regulation on Classification, Labelling and Packaging of substances and mixtures (CLP Regulation[2]). As European Regulations, these legislative acts are directly applicable in all Member States without the need for transposition into national law. The purpose of the REACH system is to ensure a high level of protection of human health and the environment, promote alternative methods to animal tests to assess the hazards of chemicals, facilitate the free circulation of substances within the single market and enhance competitiveness and innovation.

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

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

2 The European Chemicals Agency in 2009-2012

2.1 ECHA's Mission

ECHA's mission is to manage all REACH tasks by carrying out or co-ordinating the necessary activities, in order to ensure a consistent implementation at Community level and 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 decision-making process, using the best possible scientific, technical and regulatory capacities and by working independently in an efficient, transparent and consistent manner.

ECHA helps to achieve the aims of REACH and thus to ensure a high level of health and environmental protection, 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*

[1] Regulation (EC) No 1907/2006 (hereafter the "REACH Regulation" or "REACH")

[2] The CLP Regulation on classification, labelling and packaging of substances and mixtures, is expected to be adopted by the European Parliament and the Council in late 2008 and to be published by the end of 2008. It will implement in the EU the international criteria agreed by the United Nation Economic and Social Council (UN ECOSOC) for the classification and labelling of hazardous substances and mixtures and known as the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). The Regulation will repeal Directives 67/548/EEC and 1999/45/EC with effect from 1 June 2015.

vital to ensure its independence, high scientific, technical and regulatory capacities, as well as transparency and efficiency."[3]

The core purpose of ECHA is therefore to ensure a credible and sound decision-making process within REACH. 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.

One of the main REACH tasks is the management of the registration process for chemical substances; this will gather information on chemicals that is expected to be much more complete and of higher quality than the data previously available. ECHA plays a key role in ensuring consistency with regard to the evaluation of such information and decisions to require further information from registrants, and thus ensures the quality of the data collected. Moreover, ECHA manages the process of granting exemptions from registration for the purpose of Process and Product Orientated Research and Development (PPORD).

Through its Committees, ECHA provides opinions to the European Commission on authorisation applications for substances of very high concern and on proposals for restriction of the manufacturing, import and/or use of substances for which the risks are not otherwise addressed by the REACH processes.

ECHA will create an inventory for the classification and labelling of dangerous chemicals that are manufactured in the EU or placed on the EU market, and has duties relating to the harmonisation of such classifications. The Regulation of the European Parliament and the Council on Classification, Labelling and Packaging of Substances and Mixtures (CLP Regulation) gives ECHA certain additional responsibilities in this regard. ECHA is also to assist registrants, Member States and the European Commission in the implementation of REACH, and has important duties with regard to reducing the need for animal tests.

ECHA may be given additional tasks. However, any additional 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.

2.2 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. ECHA will be a trustworthy, efficient and transparent 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 an honest broker between all interested parties affected by the REACH Regulation. It will provide guidance to manufacturers, importers and users of chemicals in fulfilling their obligations, and will be an effective focal point for the European Commission, the European Parliament, the Member States, industry 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

[3] Recital 95 of the REACH Regulation.

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 long term, ECHA aims to make the EU regulatory system for chemicals a benchmark 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 guarantor of the quality of the increasing amount of data it will hold on intrinsic and hazardous properties of chemicals and their uses, and it will make this information as easily accessible as possible whilst respecting the confidential nature some of the information. This communication process could, for example, include developing ways of disseminating information on chemicals that is understandable to the general public.
Within its legal framework, ECHA will also contribute broadly to the international commitments of the European Community.

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 REACH are properly communicated and that up-to-date information is received from the scientific community.

2.3 ECHA's Values

As a modern public administration, ECHA's values are transparency, impartiality, accountability and efficiency; it will manage the REACH operations in a secure, professional and science-based manner. This demonstrates the value that ECHA attaches 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 conduct*, the *ECHA communication strategy* and the *ECHA rules on transparency*. All actors concerned by the REACH Regulation should have equal access to information and assistance. The Agency pays particular attention to SMEs when communicating on REACH and supporting its 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 which cares about the wellbeing of its staff.

2.4 ECHA's overall objectives 2009-2012

ECHA has identified a set of overall objectives that will determine the success of its activities during the first years of its operational activities. These objectives are supplemented and refined by more detailed key targets outlined at the beginning of each of the subsequent sections.

These overall objectives have to be seen in the context of ECHA's legal remit. An overview of the milestones set out in the REACH Regulation for the period 2009-2012 is annexed to this Multi-Annual Work Programme (Annex 1).

Overall objectives 2009-2012:

- The most important objective will be **to make REACH work and to carry out the tasks assigned to ECHA** by implementing efficient and transparent procedures in a timely manner for all REACH processes and for tasks arising from the recently agreed CLP Regulation.
- A cross-cutting objective of ECHA will be **to win and retain the confidence of all stakeholders** in REACH and CLP operations, in particular by delivering consistent and high-quality science-based decisions and opinions and providing the best possible guidance, advice and assistance to all parties concerned.
- ECHA will make a **credible start on the evaluation and authorisation procedures**, including a regular update of the "candidate list" of substances of very high concern (SVHC).
- ECHA will **help promote alternative test methods and non-testing approaches** to assessing hazards of chemicals in implementing REACH. When taking decisions on testing and information needs, ECHA will focus on accepted methods which ensure the availability of appropriate hazard information whilst striving to minimise the use of animal testing.
- ECHA will ensure the timely availability and the further development of the **scientific IT tools required**, as well as and their international acceptance.
- ECHA will make efficient and proactive use of its steadily growing databases to **facilitate public access to information on chemicals throughout their lifecycle,** taking into account the legitimate confidentiality concerns of relevant parties.
- ECHA will **monitor its performance**, in order to be able constantly to improve and contribute to the reporting required by the REACH Regulation and evaluate possible synergies with related Community legislation.
- Through the Forum, ECHA will also **contribute to the effective enforcement of REACH.**
- ECHA will ensure the **availability of adequate human resources** to carry out its tasks through the timely recruitment of highly-qualified staff and comprehensive training.

3 Operational activities - Implementation of the REACH processes

3.1 Registration, pre-registration and data-sharing

Key targets 2009-2012
- Ensure that companies are able to fulfil their registration obligations as efficiently as possible in order to provide a basis for subsequent work, such as evaluation;
- Ensure the publication of the list of pre-registered substances on time by 1 January 2009;
- Tackle the expected peaks in workload resulting from the first registration deadline;
- Process down-stream user notifications for substances that have not been pre-registered.

Although registration, pre-registration and data-sharing are very much interlinked, they can be divided in two different parts, i.e. "pre-registration" and "data sharing" on the one hand and "registration" on the other. The first two processes are preparatory activities for the deferred registrations of phase-in substances. Registration started on 1 June 2008 for non-phase-in substances; registration for phase-in substances will come later.

3.1.1 Registration

An important change from the previous EU chemicals legislation is that, under REACH, responsibility for the management of the risks lies with the company that manufactures, imports, places on the market or uses a substance in the context of its professional activities. The registration provisions therefore require manufacturers and importers of substances in quantities of 1 tonne or more per year and per manufacturer or importer to implement on-site and recommend to their customers appropriate risk management measures based on a chemical safety assessment which are required to perform when the quantity manufactured or imported reaches 10 tonnes per year using the tonnage-related information on the intrinsic properties of their substances. This information must be compiled in a registration dossier and submitted to ECHA.

Under certain conditions, producers and importers of articles are also required to submit a registration dossier for the substances contained in those articles in quantities over 1 tonne per year and per manufacturer and importer. This obligation particularly applies for substances that are intended to be released. ECHA can also ask for a registration if the substance is present in articles in quantities over 1 tonne per year and per manufacturer or importer and it has grounds for suspecting that a substance is released from an article, and so presents a potential risk for human health or the environment[4]. In addition, ECHA has to process notifications for temporary exemptions from registration for substances that are used in product and process related research and development (PPORD).

The deadline for the submission of a registration depends on the status of the substance under previous chemical legislation. The REACH Regulation creates a transitional regime for substances which, under certain conditions, were already being manufactured, imported or placed on the market before the entry into force of the Regulation on 1 June 2007 and did not have to be notified under the previous legislation[5]. These substances are known as 'phase-in substances', and there are later deadlines for their registration (in 2010, 2013 and 2018). These deadlines depend on the tonnages being manufactured or imported and specific hazard characteristics.

In order to benefit from the transitional regime, phase-in substances must first be pre-registered. All substances which do not meet the legal definition of 'phase-in' are treated as new substances ('non-phase-in substances') and cannot be manufactured, imported or placed on the market without the successful submission of a registration dossier.

[4] 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.
[5] Directive 67/548/EEC

For non-phase-in substances, ECHA has established resources on the basis that approximately 200 – 400 registrations may be received annually during the first few years. Early registration of phase-in substances are initially expected to account for a relatively small number of dossiers and the rate of submission would be expected to accelerate considerably as the 2010 first phase-in deadline approaches. It is expected that approximately 20 000 registration dossiers will arrive at ECHA in 2010 (including dossiers submitted as part of a joint submission). A similar pattern is anticipated for the subsequent phase-in deadlines.

3.1.2 Preparing for registration and data sharing

Pre-registration, which takes place between 1 June and 1 December 2008, requires manufacturers and importers to provide a limited set of information on the phase-in substances they intend to register (no data, no market), in order to be entitled to take advantage of the transitional provisions for registration. Pre-registration is the starting point for the formation of Substance Information Exchange Fora (SIEF), where manufacturers and importers who pre-register can exchange information and jointly prepare the information to be submitted for registration.

Pre-registration is also an important step for ECHA. By 1 January 2009, one month after the pre-registration period has ended, ECHA has to publish on its website the list of all pre-registered substances. This list will comprise the names of the substances, including their EINECS and CAS numbers if available, the first envisaged registration deadline, and the names of similar substances for potential use in filling data gaps using methods such as read-across, grouping into chemical categories and quantitative structure-activity relationships (QSARs). This list, as an inventory of all existing substances manufactured, imported in the Community in quantities of 1 tonne or more per year and per manufacturer or importer, is therefore an important source of information, and also a valuable planning tool for the work related to registration and potential evaluation.

Substances which have not been pre-registered or registered cannot be manufactured, imported or placed on the market, and thus will be unavailable to downstream users (DUs). In order to avoid business interruptions, DUs may notify ECHA that a substance is not on the list. In such cases ECHA will publish on its website the name of the substance, and on request provide the contact details of the DU to a potential registrant. The workload associated with this activity is expected to occur mainly in 2009.

ECHA will also have to deal with “late” pre-registrations from manufactures and importers manufacturing or importing a phase-in substance for the first time in quantities of 1 tonne or more per year and who can therefore pre-register even after 1 December 2008. ECHA will accept such “late” pre-registrations until one year before the final submission deadline (1 June 2017) and update the list of pre-registered substances accordingly.

The main purpose of the Substance Information Exchange For a (SIEF) is to share data, in order to minimise costs and prevent duplicate animal testing and to facilitate a common classification and labelling of substances. SIEF will be formed without ECHA involvement. To facilitate the process, however, ECHA has set up and will maintain an IT system where potential registrants and registrants of the same phase-in substance can find each others’ contact details on secure “pre-SIEF”, web pages. After publication of the list of pre-registered substances, 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. ECHA will also do all it can to ensure that the contact information held for active substances in biocidal products and plant protection products, which are authorised under other EU regulatory frameworks, are included in the corresponding pre-SIEF web pages. For non-phase-in substances and phase-in substances that have not been pre-registered an inquiry process prior to registration will allow ECHA to facilitate data sharing.

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 have been submitted, ECHA will take a decision on whether or not the test needs to be repeated by another potential registrant. It is expected that the number of such disagreements in a SIEF will peak in 2010, in the months before the first registration deadline.

3.2 Evaluation

Key targets 2009-2012

- Ensure efficiency and consistency of decisions and, where necessary, refine the operational procedures and technical-scientific criteria for performing evaluations and carrying out compliance checks;
- Perform as many compliance checks of registration dossiers as possible, in order to prepare for the first big wave of registration dossiers arriving in 2010. Close communication pathways will be established with industry to ensure that the correct information is provided in these dossiers.

The evaluation process includes two interlinked tasks: the evaluation of dossiers and the evaluation of substances.

3.2.1 Dossier evaluation

Dossier evaluation is one of ECHA's most demanding tasks due to the very high number of dossiers, the volume of information in each dossier and the considerable scientific and technical competence required. One of the main objectives of the next few years is to build up the necessary capacity for the work following the December 2010 deadline for registration of high-volume chemicals. High volume chemicals are generally the most complex substances to evaluate, on account of the large number of uses and diverse databases. During 2009 and 2010 the focus will therefore be on developing the capacities and scientific competences to take on the challenges of evaluation of these chemicals.

Moreover, in the period 2009-2010 it is expected that the procedures and tools for the implementation of REACH will still require further testing and refinement. The evaluation of dossiers is performed by ECHA, and includes examination of testing proposals and a compliance check.

Evaluation of testing proposals

The objective of the evaluation of testing proposals is to ensure that the proposals are sufficient to achieve compliance of the registration dossier with the relevant Annexes to the REACH Regulation (IX, X and XI). This helps prevent unnecessary animal testing and costs. ECHA has to evaluate any proposal for additional testing (this is obligatory for tests included in Annex IX and X of the Regulation) to ensure that the proposed tests will generate reliable and appropriate data and that all available information and options for alternative testing and non-testing methods to evaluate the hazardous properties have been properly considered.

Deadlines for the evaluation of testing proposals differ for phase-in and non-phase-in substances. Proposals for phase-in substances registered by December 2010 (the first registration deadline for those substances) will have to be evaluated by December 2012. Proposals for non-phase-in substances must be evaluated within 6 months of the date of registration.

The peak workload for the evaluation of testing proposals will occur between December 2010 and June 2016, after the bulk of the phase-in substances above 1000 and above 100 tonnes per year have been registered. Considerable uncertainty remains regarding the number of dossiers to be evaluated, as it is currently unknown how much data are already available for these substances. Current estimates will be refined after the first few years of operation on the basis of the general behaviour of registrants.

Compliance checks
The objective of compliance checks is to promote the quality of the registration dossiers. ECHA has to check a relevant quota of dossiers submitted (at least 5% per tonnage band) to verify whether the information in the technical dossier and in the Chemical Safety Report is adequate and corresponds to the legal requirements. In case of non-compliance, the registrant will be requested to submit the missing information.

Based on the number of expected registrations and in accordance with the minimum quota of 5% set by the Regulation, ECHA's minimum objective is to perform approximately 10, 40, 100 and 100 compliance checks in the years 2009, 2010, 2011 and 2012 respectively. However, intense compliance check work in the first few years could play a strategic role in improving the quality of registrations. ECHA therefore intends to allocate substantial resources to this activity in 2009 and 2010. The review will mainly concern dossiers for non-phase-in substances.

3.2.2 Substance evaluation

Substance evaluation is performed by Member State Competent Authorities (MSCAs) to clear up any initial concern about human health or the environment, and involves an assessment of all available information and, if necessary, requesting further information from industry. ECHA has a coordination role involving a multi-annual Community rolling action plan for the evaluation of substances; the Agency also ensures consistency of decisions on information requests.

The substance evaluation task has less immediate deadlines, except for certain substances notified under the previous legislation which are considered to be included in the Community rolling action plan. In order to submit the first Community rolling action plan by 1 December 2011, and in collaboration with Member States, ECHA will develop selection criteria for substances to be evaluated in order that the selection process can start at the beginning of 2011. In order to test the Agency and Committee procedures, ECHA may propose carrying out some early substance evaluations in 2009 and 2010 on non-phase-in substances.

3.3 Authorisation and Restrictions

Key targets 2009-2012
- Make a credible start on the authorisation procedure;
- Prepare new recommendation(s) for priority substances for authorisation, in order to develop the stock of candidate substances (2010-2012);
- Ensure the smooth continuation of the restriction procedures under the REACH Regulation.

Authorisations and restrictions can be used to address, at Community level, 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 single market. Restrictions may be imposed where there is an unacceptable risk that needs to be addressed on a Community-wide basis.

For both procedures, MSCAs (or the European Commission) have the right to initiate proposals for identification of substances as SVHCs. Furthermore, ECHA will carry out the preparatory work on prioritising substances for inclusion in the list of substances subject to authorisation; whilst the European Commission will ultimately take the final decisions.

3.3.1 Authorisation[6]

The authorisation procedure concerns SVHCs. These are substances which are a) Carcinogenic, Mutagenic or toxic to Reproduction (CMR), 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). This dossier should 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 will therefore create a platform to stimulate cooperation between Member States and provide training. Member States, ECHA and interested parties may comment on these dossiers. If no comments are received, the substance is considered to be identified as a SVHC and placed on the "candidate list" for possible future inclusion in the Annex to the Regulation listing substances subject to authorisation (Annex XIV, the "authorisation list"). If comments are received, the dossier is forwarded to the ECHA Member State Committee (MSC) for discussion and, as appropriate, approval.

An initial "candidate list" was published in the autumn of 2008. This list will be regularly updated by ECHA on the basis of a coordinated workflow for the input from Member States and requests from the European Commission to ECHA.

There have been 16 dossiers for the identification as SVHC handled by ECHA in 2008 for inclusions in the first "candidate list". In addition, the Commission has asked ECHA to prepare 5 dossiers for identification as SVHC in 2008. Despite the fact that there is no specific timeline indicated in the Regulation for Member States to submit their SVHC proposals, it is anticipated that the workload over the years 2009-2012 will increase.

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

At least every two years, substances from the "candidate list" will be prioritised by ECHA, taking into account the opinion of its Member State Committee, with the aim of recommending them to the European Commission for inclusion in the Annex to REACH listing substances subject to authorisation (Annex XIV, the "authorisation list"). Each substance included in this recommendation will be accompanied by a dossier specifying the details that apply in respect of the authorisation requirement (e.g. the date from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted, known as the "sunset date"). The number of substances included in the recommendation will also depend on ECHA's capacity to handle applications in the time provided for by the REACH Regulation.

Before ECHA sends its final recommendation to the European Commission, it will make its proposal publicly available and invite all interested parties to submit comments on the prioritised substances. The Agency will then review the comments received, and in due course update its proposal and send this to the Commission, which will decide on inclusion of the substances in the Annex.

REACH requires ECHA to make its first recommendation of priority substances by 1 June 2009. In the years 2010-2012 ECHA will prepare new recommendation(s), in order to take account of the growing stock of candidate substances and to apply as soon as possible the experience gained during the elaboration of the first recommendations.

[6] Future updates of this document will contain a list of SVHC on ECHA's work programme. The substances will also be indicated in the candidate list in accordance with Article 59.1 of the REACH Regulation

Authorisation decision procedure

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). The "authorisation list" will set a date by which the applicants have to submit their authorisation applications if they wish to continue using the substances in question after this "sunset date".

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 ECHA Risk Assessment Committee (RAC) and Socio-Economic Analysis Committee (SEAC) have to give their opinions on the application within 10 months from the date that ECHA receives the application. Third parties are given the opportunity to submit information as part of the process.

The work of the RAC and the SEAC starts with a check that the application received includes all the required information and, where necessary, a request to the applicant to rectify any deficiencies in the application. Furthermore, SEAC may require from the applicant or request from the third parties additional information on possible alternative substances and technologies. The Committees' opinions 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 to the European Commission, which takes the final decision to grant or refuse the authorisation.

The first applications are expected to be received by ECHA in late 2011 or 2012. The number of applications in a given year will depend on many factors, and will be refined after the first recommendation for inclusion in the above-mentioned Annex has been made. A preliminary estimate for the first few years would be in the order of 100 to 250 applications.

3.3.2 Restrictions

A restriction is any condition or prohibition imposed on the manufacture, import or placing on the market or use of a chemical. New restrictions can be introduced or existing ones amended where 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 socio-economic impacts of the restriction, including the availability of alternatives. New restrictions will be included in the relevant Annex to the REACH Regulation (Annex XVII) which will already include 'old' restrictions adopted under the Limitations Directive[7] that REACH replaces as of 1 June 2009.

The restriction 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 REACH is the most appropriate measure.

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 consultations processes. The opinions and supporting documentation delivered by ECHA to the European

[7] Directive 76/769/EEC

Commission will need to be comprehensive to allow the European Commission to draft, within 3 months of receiving the opinions, an amendment to the Annex containing restrictions.

The Restriction Title of REACH will enter into force on 1 June 2009. It is anticipated that the number of restriction dossiers will be limited in 2009 and will rise to an average of 10 per year afterwards.

Transitional restriction dossiers

There are around 25 substance dossiers prioritised under the former Existing Substance Regulation[8] for which the work on risk evaluation and on strategies for limiting identified risks could not be finalised before the entry into operation of REACH. REACH requires that Member States document the information on hazards and risks as well as the strategy for limiting risks from these substances and submit corresponding dossiers to ECHA by 1 December 2008. A few of these dossiers may contain a proposal for restriction.

These "transitional dossiers" which contain restriction proposals will be forwarded to the RAC and SEAC to be discussed as test cases mimicking the real restriction procedure. These discussions will be used to facilitate the development of workflows, including for cooperation between the two Committees, and the content of the conformity check and opinions. This work may also help ensure the efficient processing of these dossiers after 1 June 2009, when the Restriction Title of REACH will have entered into force.

3.4 Classification and Labelling

Key targets 2009-2012

- Establish a Classification and Labelling Inventory, making non confidential information available to the public and tackling the workload;
- Effectively deal with the procedure for proposals from MSCAs for a harmonised classification and labelling of certain dangerous substances;
- Transmit dossiers that have not been finalised under Directive 67/548/EEC to the Risk Assessment Committee for discussion and the adoption of opinions.

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

The REACH Regulation identifies two tasks for ECHA related to classification and labelling of dangerous substances: establishing a Classification and Labelling Inventory and dealing with the procedure for proposals from MSCAs for a harmonised classification and labelling of certain substances. Furthermore, the CLP Regulation allows suppliers of chemicals to submit proposals for harmonised classification and labelling.

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

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

- subject to registration (i.e. with a threshold of 1 tonne/year or more) or
- not subject to registration (i.e. are below the threshold of 1 tonne/year and/or outside the scope of the Registration Title of REACH) but which have to be classified as dangerous (either on their own or in preparations) pursuant to Directive 67/548/EEC or Directive 1999/45/EEC.

[8] Regulation (EC) No 793/93

The C&L information is either submitted as part of the registration dossiers or as a notification using REACH-IT and IUCLID 5. No fees are due for such notifications. ECHA will study the possibilities for simplifying the notification procedure for SMEs.

ECHA will store the information submitted by industry and will make the non-confidential part publicly available on its web page. In addition, all harmonised and legally-binding entries, either currently listed in Annex I to Directive 67/548/EEC or added in the future in accordance with the rules in REACH and the CLP Regulation respectively, 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, industry will be requested to make every effort to come to an agreed entry.

It is expected that up to 130 000 C&L notifications will arrive by the deadline of 1 December 2010, with the main peak being in 2010. After that date it is anticipated that around 17 000 dossiers will arrive each year until 2018. The whole process is intended to be mainly IT based, followed in certain cases by a manual validation by ECHA staff.

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. Under he CLP Regulation, for pesticidal or biocidal active substances a full harmonisation C&L is required. The procedure for submitting the proposals is comparable to the one described above for identifying SVHCs.

Under the CLP Regulation, manufacturers, importers or DUs may submit proposals for harmonised C&L for hazard classes for which no harmonised entry exists. They may also request the use of alternative “generic” chemical names for substances in mixtures, if a number of criteria are fulfilled.

The dossier from the MSCA or the manufacturer, importer or down-stream user provides the scientific basis determining how a substance fulfils the criteria mentioned above. This dossier is discussed within the RAC, which delivers an opinion on the proposed C&L after interested parties have been given the opportunity to comment on the dossier. The opinion of the RAC is forwarded to the European Commission, which to take the final decision resulting in harmonised C&L.

There are a number of substances pending for consideration for harmonised classification and labelling under the old chemicals legislation (Directive 67/548/EEC), and these are expected to be re-submitted to ECHA by the MSCAs for opinion from the Risk Assessment Committee (RAC).

3.5 Advice and Assistance through Guidance and Helpdesk

Key targets 2009-2012
- Complete and enhance the guidance framework and improve its accessibility;
- Reinforce the network with national helpdesks and adapt proactively to changed user requirements.

3.5.1 Guidance

Guidance describes commonly agreed ways on how to fulfil the obligations of the REACH Regulation for both industry and MSCAs, with the aim of facilitating its implementation. Guidance serves as an accurate reference framework, helping companies and industry associations to develop tailor-made and sector-specific solutions to fulfil their REACH requirements. The guidance documents were initially developed by the European Commission, together with relevant stakeholders in the REACH Implementation Projects (RIPs). As each RIP has been finalised, ECHA has taken over the documents.

The Agency is now responsible for guidance management, including publication, updating and the development of new guidance. Over time, guidance will become the documentation of generally agreed best practice.

ECHA systematically collects feedback and identifies areas for improvement resulting from the practical experience of guidance users. This feedback is sourced from ECHA's operational experiences, the ECHA helpdesk and guidance users from industry and national authorities. The relevant part of the guidance is then updated, including incorporation of experiences with good practice and new developments, such as the adoption of the CLP Regulation. In 2009-2012, ECHA will focus on completing the overall guidance, while keeping the guidance on registration up to date and further developing the guidance on exposure scenarios, chemical safety assessments and information requirements. In addition, guidance on risk communication and on the registration of substances in nana scale will be developed.

In 2008, in order to ensure the broadest possible acceptance, ECHA developed a consultation procedure to ensure close stakeholder involvement and access to high-level expertise for updating the guidance. For this purpose, ECHA maintains a comprehensive database of scientific experts and stakeholder organisations. Guidance updates include the development and possible translation of explanatory documents and guidance access tools, such as *Frequently Asked Questions*, *Summary Fact Sheets*, dedicated internet pages for specific REACH processes, the REACH Navigator, REACH terminology development or *Explanatory Notes*.

3.5.2 Helpdesk

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

An important part of the work of the helpdesk is to provide support to the national helpdesks established by Member States, in particular through the REACH Helpdesk Correspondents Network (REHCORN) and the use of the RHEP tool, an internet-based exchange platform for harmonising answers to questions from industry. Workload peaks are expected before the first two transitional deadlines for registration in 2010 and 2013. Other peaks in workload may arise in the context of other REACH processes. The ECHA helpdesk will be proactive in adapting its activities to take account of such peaks.

ECHA will continue to support and coordinate the network of helpdesks at national and European level. Thee will be a special focus on making the REHCORN network more efficient and dynamic, in order to deliver the best possible service. Besides the harmonisation of answers to questions on REACH, an important aspect will therefore be the further development of common knowledge that is easily accessible for all relevant actors. This includes, *inter alia*, enhancing the internet platform RHEP and ensuring it is used more, and establishing a regular exchange of officers from national helpdesks.

3.6 IT operation support tools

Key target 2009-2012
- Complete development of functionalities for REACH-IT;
- Develop other IT tools needed for operations, especially tools supporting the assessment of substances.

The main IT tools used in the operational aspects of REACH are IUCLID 5 and REACH-IT. ECHA uses and administrates a number of additional specialised applications, such as the CSR tool that will be further developed after its first release in the autumn of 2009. ECHA is also developing IT tools and processes to assist in the prioritisation of registration dossiers for evaluation.

REACH-IT is an online system that manages the communication between industry, ECHA and Member States as well as ECHA's internal work-flows in relation to the REACH processes. After the completion of the initial functionalities for industry in 2008, ECHA will maintain and enhance the application over the next few years. A first priority will be the completion of the REACH-IT system for handling the evaluation and other workflows, and gradual replacement of "work-around" solutions. REACH-IT will need many further updates to become an instrument that can support industry, ECHA and other regulators, and the public in consulting databases and communicating on-line.

IUCLID 5 is viewed as the international standard tool for storage and exchange of data on the intrinsic and hazardous properties of chemicals. Dossiers on chemical substances have to be submitted to ECHA in the IUCLID 5 format. ECHA is providing end-user support and project management. New modules will be implemented in response to user requirements. Relations with IUCLID users will be formalised via the IUCLID Management Group (IMG), which will be in close contact with the OECD's IUCLID expert group.

In addition, ECHA will build a comprehensive IT tool that will facilitate the preparation of Exposure Scenarios and Chemical Safety Reports (CSR) that are required in some cases for registrations, and provide practical tools to companies for calculating the risks of chemical emissions. Finally, the Agency will focus on tools that will help to make better use of alternative computational approaches to animal testing through the (Q)SAR-toolbox and similar screening tools. Future work in the area of registration will include the provision of further refinements and functionalities in the registration process which were delayed during preparations for entry into operation, such as improving the content and format of automatically-generated communications.

ECHA is constantly developing manuals explaining the use of the IT tools and other practical aspects of how to fulfil REACH obligations.

3.7 Scientific and practical advice to the further development of legislation

ECHA will also provide appropriate advice to the Commission for the further development of REACH and CLP Regulation and any related legislation concerning chemicals as well as measures related to its 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 assist the Commission in preparing the first review of REACH scheduled for 2012.

4 ECHA's bodies and supporting activities

4.1 Secretariat

Key target 2009-2012

- Fulfil the tasks assigned by the REACH Regulation in the best possible manner while complying with the requirements of good governance and good regulatory practices.

The operational and administrative staffs work under the leadership of the Executive Director and are responsible for providing technical, scientific and administrative support to the Committees and the Forum and ensuring good coordination between them. The Secretariat also undertakes work pertaining to REACH operations and prepares guidance, maintains databases and provides information and support.

4.2 Committees and Forum

Key targets 2009-2012

- Deliver opinions on time, to allow the Executive Director or the European Commission to reach decisions on a scientifically-sound and well-argued basis;
- Ensure 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 updated frequently;
- Significantly improve the harmonisation of REACH enforcement, in particular through the coordination of harmonised enforcement projects.

4.2.1 RAC and SEAC

The Committees are an integral part of ECHA and play an essential role in carrying out its tasks. ECHA took over the role of certain Committees of the European Commission in issuing science-based opinions in its field of competence. The members of the Committees are experts appointed by ECHA's Management Board on the basis of proposals from the Member States.

The Risk Assessment Committee (RAC**)** is to deliver opinions on proposals for harmonised C&L of substances, on proposals for restrictions of substances and on applications for authorisation. The Socio-Economic Analysis Committee (SEAC) is to give opinions on the socio-economic factors related to applications for authorisation, on the availability and technical and economic feasibility of alternatives and on proposed restrictions and their socio-economic impact. The activities of the two Committees are to be conducted in parallel, and opinions will be delivered within 10 and 18 months of the date of receipt, and after public consultation. Both the RAC and the SEAC may also be asked by the Executive Director to deliver opinions on any other aspect within their field of expertise. The Committees are of paramount importance for the smooth and efficient functioning of REACH and the credibility of ECHA in ensuring its independence, scientific integrity and transparency.

The RAC delivers opinions on three different, but closely interrelated processes. As each of these processes may be concerned with different elements of hazard or risk assessment and risk management, a wide range of expertise is required. This includes expertise in judging the quality and adequacy of risk assessments and proposed risk management measures, and in assessing the quality and scientific robustness of the application of the criteria in proposals for harmonised C&L.

The SEAC delivers opinions that may cover a wide range of areas of competence, including the quality and scientific robustness of socio-economic assessments related to granting or refusing an authorisation or imposing a restriction, the assessment of the availability, suitability and technical feasibility of alternatives, and judging the quality and adequacy of proposed restrictions. As the SEAC does not have any directly comparable body under the previous chemical legislation, starting it up is particularly challenging.

ECHA is responsible for chairing and preparing the Committee meetings and ad-hoc working groups, which may include Members from both Committees to facilitate the coordination of workflows. If required, ECHA also provides support to the Committee members who have been appointed as rapporteurs for specific dossiers. The number of meetings depends on the incoming workload and, thus, also on the Member States and the European Commission, e.g. as initiators of restriction procedures. Committee meetings are planned to take place approximately every 2 to3 months.

The work of the two Committees and coordination of opinions on dossiers that have a potentially significant impact on industry will be highly challenging and demanding in terms of the time frame for adopting these opinions. The novelty of SEAC is an additional challenge which will require serious methodological work that should be completed before the first cases have to be examined towards the end of 2009. The workload of both Committees is expected to grow strongly from 2012 onwards.

4.2.2 MSC

The ECHA Member State Committee (MSC) consists of members appointed by and representing each Member State. Its purpose 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 the 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 SVHC for authorisation and on the Community Rolling Action Plan on substances to be evaluated.

The tasks of the MSC require detailed scientific deliberations on a broad range of scientific fields ranging from the best use of different test methods for obtaining information on the hazards of substances and the assessment of the environmental persistence of substances to agreeing on priorities for SVHCs to be included in the "authorisation list".

It is expected that between 2009 and 2012 the MSC will need to deal with a gradually increasing number of draft decisions from compliance checks on registration dossiers. In parallel, the "candidate list" of SVHC needs to be regularly updated. A correspondingly high number of meetings will be needed. The number of draft decisions on testing proposals reaching the MSC depends on the number of draft decisions that Member States comment on, but it is expected to be several hundred per year during the period 2010-2012, with a corresponding impact on the number of Committee meetings. From 2010 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.

4.2.3 Forum

The REACH Regulation requires each Member State to set up a system of official controls and other activities as appropriate to the circumstances. Effective, harmonised and equal enforcement throughout the Community is of crucial importance for the credibility and success of REACH. The Forum functions as a platform for Member States 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.

The impact of conclusions or initiatives of the Forum will depend on the involvement of the members and their ability to mobilise resources of national authorities responsible for enforcement. For this reason it is difficult to estimate precisely the workload for the Forum. However, ECHA will emphasise enforcement and support the active involvement of Member States in harmonised enforcement activities wherever possible.

The Forum will undertake activities included in a regularly updated work programme; the first work programme has been established for 2008–2010 and can be found on the ECHA website. In this initial phase the Forum is focusing its activities on the clarification of the tasks of REACH enforcement officers and elaboration of best practices. The involvement of the Forum in a number of "coordinated projects", e.g. on enforcing the "no data, no market" rule with regards to pre(registration), will be of particular importance.

The Forum will develop enforcement strategies and 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.

4.3 Board of Appeal

Key targets 2009-2012
- Take high quality decisions without delay, in order to build up the stakeholders' confidence in the appeal procedure;
- Tackle the expected peak in workload resulting from the first registration deadline in 2010;
- Provide input to the Commission to adjust and enhance the Rules of Procedure after the first few years of experience, in order to ensure procedural efficiency.

The Board of Appeal is an integral part of ECHA, but takes its decisions independently. It consists of a Chair and two members, who may not perform any other duties in ECHA. Additional members may be appointed if appeals need to be processed at a more satisfactory rate. 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, examination of testing proposals, compliance check of registrations, substance evaluation or exemptions from the general obligation to register for product and process orientated research and development, as well as , possibly under the future CLP Regulation, decisions on the use of alternative names for substances in mixtures. The decisions of the Board of Appeal can be contested by bringing an action before the Community Courts.

The number of appeals lodged before the Board of Appeal will depend on the number of decisions taken by ECHA. The resources of the Board of Appeal and its Registry have been established on the assumption that approximately 200 appeals will be lodged every year, except in 2010 when the number is expected to be double that. These estimates will be refined on the basis of experience acquired after 2009.

The main challenge for the Board of Appeal is to demonstrate that it can take high quality decisions quickly and to build up a consistent body of case-law. A comprehensive and user-friendly database of relevant case-law is to be established to enable potential appellants to make confident and informed decisions about whether and to what extent to appeal. The Board of Appeal will also develop appropriate guidance on the appeal procedure, in order to minimise delays or rejections caused by procedural errors.

4.4 Communication

Key targets 2009-2012
- Promote the image of the Agency as reliable partner;
- Raise awareness and improve knowledge of REACH, in order to assist its implementation;
- Develop REACH competence, e.g. through the training of trainers.

ECHA's communication policy is set out in the *ECHA communication strategy*. The activities cover the internal information exchange with the different actors within ECHA, including the Committees and the Forum, as well as external communication with the broader public.

Communication with the general public plays a pivotal role for ECHA by supporting its overall quest for openness and transparency while still fulfilling the requirements for data protection and data security. The aim of ECHA's external communication strategy is to ensure that the Agency's role, values and work are well known, and that communication activities support ECHA's overall operational objectives. Complementary to ECHA's guidance and helpdesk activities, external communication improves the level of knowledge about REACH in companies and at Member State level. Information needs thus have to be actively monitored, in order to improve communication. To

this end ECHA will further develop its cooperation with stakeholders, in order to provide tailor-made opportunities for exchange of information and so obtain feedback and expertise. ECHA's annual stakeholder workshops will be a key forum for this type of exchange.

Through coordination and advice, ECHA will contribute to the development of effective communication of information on chemical risks management at the European level. To this end, the work of the Risk Communication Network established in 2008 with Member States and EU institutions will be further developed in 2009-2012.

The main communication tool will continue to be ECHA's website, while annual stakeholder workshops and other events, an effective press service, and e-news will play an increasing role as ECHA's operations mature. Depending on the target audience and the type of document, translations are to be provided.

To enhance common understanding and to provide up-to-date information on the implementation of REACH, ECHA provides REACH training for trainers from the Member States. ECHA will redefine and further develop its REACH training programmes on REACH for ECHA staff and Member State experts who need to keep up with the latest technical and scientific developments in the field.

In the period leading up to the first registration deadline, ECHA's main communication messages will revolve around the list of pre-registered substances, SVHC, registration and data sharing, as well as classification and labelling. From 2011 onwards, the focus will shift more towards the substitution of SVHC, consultations, and information on chemicals for the general public.

4.5 Relations with EU institutions and international cooperation

Key targets 2009-2012
- Establish good relations and a network for collaboration with EU institutions and similar bodies in the EU;
- Contribute to REACH-related work of the OECD.

4.5.1 Working relations with EU institutions and bodies

In 2009-2012 ECHA will further enhance its co-operation with the EU institutions, in particular the European Parliament and the Commission.

The REACH Regulation provides for a horizontal framework which applies to most of the chemical substances manufactured or placed on the European market. On many occasions, therefore, ECHA's work affects Community bodies involved in sector-specific legislation on the assessment and management of the risks from chemicals. For this reason, ECHA is required to cooperate with these bodies, 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. There is also some cooperation with the European Medicines Agency (EMEA) and the European Commission's non-food Scientific Committees.

Regular working relations are also expected to be established with the European Environment Agency (EEA), the European Commission's Joint Research Centre (JRC) and the European Agency for Safety and Health at Work (EU-OSHA). In addition, contacts will be set up with research policy and funding bodies, including the European Commission's Directorate-General for Research, with the aim of communicating the scientific needs arising from the REACH Regulation. ECHA will structure these partnerships, e.g. by creating a network for collaboration with similar bodies in the EU or developing Memoranda of Understanding.

4.5.2 Working relations with international research bodies

ECHA will focus on making scientific information on chemicals available and accessible for research needs. At the same time, the Agency will establish good and well-functioning contacts with the scientific community, academia and national agencies to ensure that research needs arising from REACH are properly communicated and up-to date information received from the scientific community.

4.5.3 Working relations with third countries and international organisations

Cooperation with third countries and 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 for the implementation of REACH, in particular the project management of the Global Portal to Hazard Data and the further development of the QSAR-Toolbox. The Agency was also requested to contribute to the work of the Task Force on Existing Substances and its subgroups. Other OECD related activities in which ECHA is involved include contributing to the work of the Task Force on Exposure Assessment, the Harmonised Templates Project and the work on the health and environmental aspects of nano-materials.

In addition to OECD-related activities, ECHA will support the European Commission's work on the Stockholm Convention on Persistent Organic Pollutants (POPs). The Agency may also hold joint conferences with the OECD on specific topics. In addition, ECHA has been requested by the European Commission to organise or attend meetings and conferences with third countries on the requirements of REACH and to provide adequate training. Furthermore, it has been charged with helping to improve co-operation between the Community and third countries by participating in the exchange of best practices in fields covered by its remit.

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.

ECHA may invite representatives of third countries to participate in the work of the Agency either as "active members" (third countries) or as observers (international organisations). This is of particular relevance for EEA countries, accession and candidate countries and the OECD.

5 Management, Organisation and Resources

5.1 Management and Organisation

Key targets 2009-2012
- Improve Internal Control Standards, in particular by setting-up an Agency-wide risk management system;
- Develop performance indicators to assist ECHA management.

ECHA's highest decision-making body is the 35-member strong Management Board consisting representatives from each of the 27 EU Member States, three members representing the European Commission, two independent members appointed by the European Parliament and three representatives of interested parties appointed by the Commission (the latter without voting rights)[9].

[9] In future, the EEA-EFTA States will fully participate in the Management Board, the Committees and the Forum, and will within these have the same rights and obligations as the Member States, except for the right to vote.

In the start-up phase, the Board's activities were dominated by the need to put in place quickly a general framework allowing the Agency to become fully operational. As from 2009, the Management Board will be able to concentrate on key areas, including the review of certain core policies. At the same time, the Board will continue to scrutinise and adopt the annual reports, the budget and the annual and multi-annual work programmes of ECHA.

The day-to-day management of ECHA is 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. ECHA was initially divided into three directorates but the rapid growth of the Agency led to the creation of a fourth directorate in late 2008. Further adjustments to the organisational structure may be necessary in future. Amongst the major challenges for management in 2009-2012 will be to ensure that decisions are taken in line with the ECHA standard operating procedures and within the legal deadlines; that sufficient, appropriate staff are available in time and that IT tools are developed and function as planned. Other important aspects are the complex and critical management of revenue, including reimbursement for tasks performed by the Member States, and ensuring consistent external communications.

In 2009-2012, the requirements for the implementation of ECHA's Management, Quality (ISO 9000:2000) and Internal Control Standards will be refined, 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. In view of the rapid growth of ECHA, the progressive expansion of its core areas of operation, and its changing control environment, it is expected that the overall risk assessment and the resulting audit plan will be updated annually on a three-year rolling basis.

Further developing ECHA's security policy and implementing related action plans, as regards both IT and physical security has been identified as a priority for the next few years. This includes reinforcing ECHA's structures in those areas (IT, facility management, and overall organisation), formalising key procedures, setting up a business continuity plan, and developing awareness-raising measures.

Finally, management will have to ensure that ECHA fulfils its reporting duties, in particular with regard to the first three-year report on non-animal test methods and strategies, the first five-year report to the European Commission on the functioning of REACH, and the report on the safe use of chemicals, which are due in 2011. The latter will be ECHA's contribution to the review of its operations and the first Commission report on REACH in 2012.

5.2 Budget, finance and procurement

Key targets 2009-2012
- Continue to provide reliable budgetary and activity planning;
- Cope efficiently with expected fluctuations in fee revenue.

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
2) Income generated from fees and charges which ECHA levies for performing the tasks with which it is charged under REACH and the CLP Regulation. In addition, a small portion of ECHA's budget is funded from the EEA contribution; this is calculated as a percentage of the Community contribution; and
3) Any voluntary contribution from the Member States and EEA countries.

2009 is the last year under the current Financial Perspectives period in which ECHA features in the Commission's planning as receiving a Community contribution. No Community contribution is thus planned for the years 2010-2013; 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 Regulation during this period[10].

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, with the first main peak expected around the 1 December 2010 deadline and involving an estimated 20 000 registrations, efficient budgetary planning and cash management will be of 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. To meet the challenges imposed by the revenue uncertainties, financial processes will need to be reviewed in 2009 in the light of new data generated as a result of the publication of the list of pre-registered substances.

ECHA's current Financial Regulation also needs to be amended so that the Agency can be allowed to retain reasonable levels of reserves from its fees and charges income from any given year, to be used to offset lower levels of fee income in future years. The arrangements for the use of such reserves will have to be defined and put into practice in the course of 2009.

As regards procurement and contracting, ECHA will continue to outsource part of its operational activities, to ensure the efficient implementation of the REACH Regulation. The major framework contract "for services on technical, scientific, health, environmental and socio-economic questions concerning the implementation of the REACH Regulation" launched in early 2008 will expire in 2012 and therefore new tendering procedure will be launched well in advance of that date, if the experience gained is evaluated as positive. Meeting ICT development challenges and ECHA's administrative needs will also continue to impose a considerable demand for efficient procurement and contracting processes during the period 2009-2012.

In anticipation of having the necessary human resources in place from 2009 onwards, an important overall objective for ECHA's financial management is to make the best use of available financial resources in line with the principles of economy, efficiency and effectiveness.

5.3 Human resources and infrastructure

Key targets 2009-2012

- Ensure availability of sufficient high-quality human resources to meet ECHA's objectives, by means of timely recruitment and on-going development of existing staff;
- Ensure a sound framework for the management and administration of ECHA's staff including appropriate staff representation;
- Ensure a high-quality working environment for ECHA staff and Committees in line with the highest health, safety and environmental standards;
- Ensure a high level of IT support for administrative processes, in order to optimise efficiency.

Human resources

ECHA's human resources policy for the 2009-2011 period is set out in the Multi-Annual Staff Policy Plan 2009-2011. The plan anticipates that the number of statutory staff will more than double.

During the reporting period, considerable effort will also be devoted to optimising HR administration and management procedures, in particular through the adoption of appropriate ICT solutions, to reduce the administrative overheads of managing the growing staff numbers. Priority will be given to

[10] European Commission Regulation (EC) 340/2008

developing/sourcing and implementing an on-line application procedure to streamline personnel selection.

2009 will see the finalisation of the regulatory framework for the management of Agency staff, with the adoption by the Management Board of the implementing rules of the Staff Regulations, as well as the establishment of the formal organs of social dialogue within the Agency, with the establishment of the Staff Committee. All temporary agents recruited on an initial 5-year contract will have to undergo written tests by the end of the third year.

The presence of a Staff Committee will facilitate the development of staff welfare actions to promote the wellbeing and integration of members of staff and their families in their new place of employment/residence. The first staff of the Agency recruited in 2007 will become eligible for promotion in 2009 and ECHA will establish an annual reclassification exercise from 2009 enabling promotion on a merit basis.

A comprehensive training programme covering general core skills such as information technology tools, management and control, and languages will be further developed, in order to ensure ongoing career development for a full complement of staff of around 500 by end of 2012.
Due to the complexity of scientific tasks to be performed, high priority will be given to on-the-job training, to effectively use the expertise of the staff that has essentially constructed ECHA. Following general induction training for all new staff, job-related training schedules will be developed and put in place. This will enable ECHA to use resources efficiently and provide long-term planning for training needs.

Infrastructure
Infrastructure tasks include the management of the Agency's premises; ECHA is now the sole tenant since the owner moved out in September 2008. The new long-term lease provides long-term stability for the location of ECHA and also holds out the prospect of a purchase option.

The owner's move will trigger a lot of infrastructure measures and the procurement of renovation works, goods and services that need to be properly planned and implemented. The renovation works will be carried out in several stages, in line with the need for additional space as ECHA grows.

The conference centre on ECHA's premises is scheduled to be operational as of January 2009. The conference centre facility needs specialised technicians to operate and maintain both the centre itself and the modern audio visual equipment which has been installed.

Long-term security needs to be ensured for ECHA. The Agency will be carrying out security assessments in accordance with ISO 27001, and occupational health checks

5.4 Informatics and Communication Technology

Key targets 2009-2012:
- Establish, implement and maintain Agency-wide architectural guidelines with regards to the technical infrastructure, applications, data structures, business processes and workflows;
- Enforce, promote and refine governance best practice in the execution of IT projects;
- Maximize and ensure continuity, efficiency and a high level of security in all IT supported business operations.

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 growing need for IT tools described in the previous chapters, the ICT services are organized in key functional clusters: the management of the technical infrastructure; oversight of operations; the execution (or support for the execution) of large projects; the management of core and administrative

applications, including the document management system; the delivery of project management services and quality assurance in project management practices; the monitoring and enforcement of security policies.

As from 2009, the ICT function is expected to focus on the integration and harmonization of the technical solutions deployed in support of the REACH legislation. These include the REACH-IT system itself, all interim applications deployed as part of the contingency plan and additional existing core systems (e.g. IUCLID5, CSA/CSR, etc.). As the core of the integration process, a review and consolidation of the overall REACH-IT architecture will be carried out in 2009 together with the reinforcement and consolidation of the underlying technical infrastructure and resources (e.g. data centre; disaster recovery; procedures; staff). Secure network connections with Member State Competent Authorities (MSCAs) will be expanded, maintained and monitored in line with the established security policy and procedures. The latter will be further reviewed and fine-tuned in accordance with the ISO 27001 standards.

As from 2009, all IT projects, applications and major systems will be managed in accordance with standard Agency governance processes and so comply with the supportability and maintainability capacity of the ICT unit on one hand and ECHA's architectural guidelines on the other. The expansion and further optimization of network, communications, technical infrastructure and user support will continue, in order to accommodate the increased number of staff.

6 ANNEXES

Annex 1: Overview of the milestones from REACH and the CLP Regulation, 2009-2012

	Milestones from the Regulation
2009	▪ List of pre-registered substances to be published by 1 January (Art. 28.4)
	▪ First ECHA recommendations on inclusion of substances in the list of substances subject to authorisation (Annex XIV) by 1 June (Art. 58.3)
	▪ Title VIII "Restrictions" and Annex XVII apply from 1 June (Art. 141.4) (Commission to compile inventory of Annex XVII by 1 June (Art. 67.3) and incorporate any amendments to the Limitations Directive since EIF. From 1 June 2009 until 1 June 2013 MS may maintain existing and more stringent restrictions)
	▪ Directive 76/769/EEC (Limitations Directive) repealed by 1 June
2010	▪ First registration deadline for phase-in substances >1000 t/y, R50/53 > 100 t/y and CMR cat.1+2 by 1 December 2010 (Art. 23.1)
	▪ First 5y-report MS–COM on operation of REACH by 1 June 2010 (Art. 117.1) – this first 5y-report to include enforcement aspects (Art. 127)
	▪ Transitional measures regarding restrictions end on 1 June (Art. 137)
	▪ Classification & Labelling notifications in accordance with Art. 113 by 1 December (Art. 116)[11] (Title XI "C&L" will become part of the GHS Regulation once adopted (Art. 41-43, 56.11 COM(2007)355 final))
2011	▪ Notifications for SVHC in articles start from 1 June, six months after a substance is put on the '"candidate list"' (Art. 7.2)
	▪ First 5y-report ECHA-COM on operation of REACH by 1 June (Art. 117.2)
	▪ First 3y-report ECHA-COM on non-animal test methods and strategies by 1 June (Art. 117.3)
	▪ First draft CRAP to MS by 1 December (Art. 44.2)
	▪ Report on the safe use of chemicals (Art. 36a of the CLP Regulation) by [three years after the date of publication in the Official Journal]
2012	▪ First 5y general report by the European Commission on operation of REACH and funding for development and evaluation of alternative test methods to be published by 1 June (Art. 117.4) – this report to include COM review of registration requirement 1-10t/y as basis for possible legislative proposals (Art. 138.3)
	▪ COM review on scope of the Regulation as basis for possible legislative proposals by 1 June (Art. 138.6)
	▪ Review of ECHA by 1 June (Art. 75.2)
	▪ Deadline for ECHA's draft decisions on testing proposals for registrations received by 1 December 2010 on 1 December (Art. 43.2.a)

[11] Art. 41 of the CLP Regulation after entry into force of this Regulation

Annex 2: ECHA Revenue and expenditure 2009-2012 (including staffing plan)[12]

Activities	2009						2010					
	Staff			Expenditure (€ '000)			Staff			Expenditure (€ '000)		
	AD + AST	Other staff	TOT	Title I	Title II	Title III	AD + AST	Other staff	TOT	Title I	Title II	Title III
3.0 Operational activities												
(Management, coordination and support)	26	3	29	3 387			32	3	35	3 922		
3.1 Registration and Pre-registration	22	2	24	2 803		75	30	2	32	3 586		75
3.2 Evaluation	45	2	47	5 489		550	67	2	69	7 733		600
3.3 Authorisation and Restriction	8	1	9	1 051		800	15	1	16	1 793		800
3.4 Classification and Labelling, SVHC	18	1	19	2 219		800	18	1	19	2 129		800
3.5 Advice and Assistance	34	6	40	4 672		1 172	44	7	51	5 716		1 250
3.6 IT-Tools for operations	21	1	22	2 569		6 300	25	1	26	2 914		5 700
4.0 ECHA's bodies and supporting activities												
4.1 The Secretariat												
4.2 Committees and Forum	18	2	20	2 336		3 500	28	3	31	3 474		4 000
4.3 Board of Appeal	16		16	1 869		400	23		23	2 578		2 500
4.4 Communication (incl. translations)	13	4	17	1 985		4 500	18	4	22	2 466		3 350
4.5 Relations with EU and intern. Relations	13		13	1 518		710	24	1	25	2 802		600
5.0 Management, Organisation and Resources						1 910						2 240
5.1. Managing ECHA (incl. MB + Legal Advice)	22	1	23	2 686			26	2	28	3 138		
5.2 Budget, Finance and Procurement	20	3	23	2 686			23	5	28	3 138		
5.3 Human resources and infrastruture	23	4	27	3 153	7 910		25	4	29	3 250	8 283	
5.4 ICT	25	4	29	3 387	2 330		28	2	30	3 362	2 850	
TOTAL	324	34	358	41 812	10 240	20 717	426	38	464	52 001	11 133	21 915

Revenues	2009 Revenues (€ '000)	2010 Revenues (€ '000)
Fees and Charges	3 593	333 701
EC contributions	70 908	0
Third countries (EFTA)	1 511	0
Other (bank interests etc.)	160	700
TOTAL	76 172	334 401

[12] Explanatory overview. Note that the budget estimates 2009 are lower than notified to Commission and the budgetary authority with the PDB for 2009

Activities	2011						2012					
	Staff			Expenditure (€ '000)			Staff			Expenditure (€ '000)		
	AD + AST	Other staff	TOT	Title I	Title II	Title III	AD + AST	Other staff	TOT	Title I	Title II	Title III
3.0 Operational activities												
(Management, coordination and support)	32	3	35	3 764			32	3	35	3 974		
3.1 Registration and Pre-registration	31	2	33	3 549		75	31	2	33	3 747		75
3.2 Evaluation	69	2	71	7 636		700	69	2	71	8 062		1 100
3.3 Authorisation and Restriction	17	1	18	1 936		800	17	1	18	2 044		800
3.4 Classification and Labelling, SVHC	18	1	19	2 043		800	18	1	19	2 157		800
3.5 Advice and Assistance	53	8	61	6 560		1 210	53	6	59	6 699		1 160
3.6 IT-Tools for operations	25	1	26	2 796		4 250	25	1	26	2 952		3 500
4.0 ECHA's bodies and supporting activities												
4.1 The Secretariat												
4.2 Committees and Forum	35	4	39	4 194		6 045	35	3	38	4 315		8 305
4.3 Board of Appeal	27		27	2 904		500	27		27	3 066		600
4.4 Communication (incl. translations)	25	1	26	2 796		2 600	25	2	27	3 066		2 400
4.5 Relations with EU and intern. Relations	25	4	29	3 119		643	25	4	29	3 293		690
5.0 Management, Organisation and Resources						2 188						2 349
5.1. Managing ECHA (incl. MB+Legal Advice)	28	3	31	3 334			28	2	30	3 407		
5.2 Budget, Finance and Procurement	24	5	29	3 119			24	3	27	3 066		
5.3 Human resources and infrastruture	25	4	29	3 119	8 579		25	4	29	3 293	8 956	
5.4 ICT	30	2	32	3 442	2 850		30	2	32	3 634	2 850	
TOTAL	464	41	505	54 311	11 429	19 811	464	36	500	56 775	11 806	21 779

Revenues	2011 Revenues (€ '000)	2012 Revenues (€ '000)
Fees and Charges	13 546	26 648
EC contributions	0	0
Third countries (EFTA)	0	0
Other (bank interests etc.)	5 300	3 800
TOTAL	18 846	30 448