Readers should note that the Report presents the views of the consultant, which do not necessarily coincide with those of the Commission.

Final Report on the Review of the European Chemicals Agency

Main report

14 March 2012

pwc

Executive Summary

The Review of the European Chemicals Agency (ECHA) is a requirement of Article 75 (2) of Regulation (EC) N° 1907/2006, also known as the REACH Regulation. Hence, this report concerns the Review of ECHA as an organisation, but not of the REACH or CLP Regulations that are implemented by the Agency. The time period considered in the Review is 1 June 2007 – 31 December 2010.

The scope of the Review embodies the full range of ECHA's operations and processes, which has been divided in so-called work areas. For each work area, the report provides our assessment of the Agency's effectiveness[1], efficiency[2] and economy[3]. The reference points for assessing ECHA's performance have been derived from several documents, most prominent among which are the REACH and CLP Regulations, ECHA's own annual and multi-annual Work Programmes and the Revised Legislative Financial Statement for REACH as drawn up by the Commission.

Approach to the Review

The data collection for the Review took place through document analysis, interviews and a stakeholder survey in the period between 15 April and 17 August 2011. A total of 59 interviews were conducted, of which 27 with ECHA managers and 32 with stakeholders of the Agency. The stakeholder survey had a total of 132 respondents, i.e. a 64% response rate.

The data collection was followed by an analysis phase in which the data were used to gain insight in the relevant issues of the review period. Finally, the preliminary findings were presented to ECHA and the Commission to receive feedback and eliminate any factual errors. Stakeholders were invited to participate in a workshop in Brussels to validate the preliminary findings and provide their feedback.

Performance targets and objectives of the Agency

The text of the REACH regulation specifically establishes the European Chemicals Agency and defines its composition.[4] The REACH regulation, the CLP regulation and the Commission's Revised Legislative Financial Statement for REACH specify the Agency's tasks. The Agency has set operational objectives for the review period in its own annual Work Programmes.

Although we have been able to provide an assessment of the Agency's performance on most of its objectives, in some cases it was not possible to do so. Reasons for this are that some objectives were not specific or measurable in the years 2007-2009 and that for some work areas of the Agency the experiences during the review period were too limited to assess the Agency's performance.

[1] Effectiveness is defined as the extent to which ECHA has achieved its objectives.

[2] Efficiency is defined as the extent to which the desired effects are achieved at a reasonable cost (i.e. the best relationship between resources employed and results achieved).

[3] Economy is defined as the extent to which resources are available in due time, in appropriate quantity and quality at the best price.

[4] As per articles 75 and 76 of the REACH regulation.

Main findings from the Review

We have made the following findings about the work of the Agency.

The quality of ECHA's goal setting improved as the Agency developed

ECHA's targets became SMARTer during the review period. When starting in 2007, ECHA's annual Work Programme was relatively short and mentioned the main tasks in the form of bullet points. The 2008 Work Programme was almost twice the size of that of 2007 and went into more detail. The Work Programme for 2009 did include performance indicators for some of ECHA's operations, but none came with a norm for success. Another problem that we encountered was the absence of reported data for certain indicators. The Work Programme for 2010 presents a radical improvement in terms of the use of measurable indicators and clear norms for success. The same improvement logically influences its annual General Reports, as they mostly refer to the same objectives as the Work Programmes. Hence, the reports become more informative over time with regard to ECHA's performance.

ECHA has met most of its key objectives

Stakeholders are satisfied with the achievements of ECHA during the review period and the amount of work the Agency has been doing in a relatively short time. Limited time, uniqueness and scope of work the Agency had to cope with, however, led to several shortcomings which will be elaborated on further in this report. We should note here that the respondents were mostly positive and admitted that the majority of the imperfections of ECHA, such as delays and uneven distribution of workload could be considered as normal given the circumstances.

ECHA achieved most of the ***outputs*** planned in its Work Programmes, including:

- the set up of the new Agency;
- the pre-registration process, despite a much higher than expected number of pre-registrations;
- providing industry and other stakeholders with information about REACH and CLP and their implications in terms of rights, obligations and required activities;
- setting up an extensive IT infrastructure;
- facilitating the meetings and the development of working procedures of its various bodies (Management Board, Member State Committee, Risk Assessment Committee, Socio-Economic Assessment Committee, Forum and Board of Appeal);
- the registration process and the preparation of dossier evaluation.

However, there are some findings that suggest that ECHA could have improved its performance at the level of ***outcome*** during the review period. These findings are:

- Industry stakeholders found a number of processes, procedures and IT systems for (pre-)registration difficult or burdensome.
- The communication through the Agency's website, guidance and helpdesk was not always clear, consistent or complete, especially during the early years of the review period.
- The efficiency of ECHA's Management Board and Committees could be improved. In the case of the Committees this point relates to their output in terms of the number of opinions formulated annually on REACH and CLP dossiers, which will become more important in the future.
- The Commission was not fully satisfied with the support provided for international cooperation activities by the Agency.
- The performance in the area of dissemination was poor in comparison to other work areas of the Agency.
- The Agency was not always perceived by all stakeholders to be transparent and functioning independently.

ECHA's overall efficiency was reduced by complementary activities that often increased effectiveness

ECHA incurred several inefficiencies by performing activities not strictly required by REACH or CLP to guarantee effectiveness. Examples of these activities were the work done to prepare the "Plan B" system for registration, the fact that ECHA's Committees started meeting regularly before dossiers had come in for them to work on and the activities conducted additional to REACH and CLP to support industry's compliance during the review period.

Also, several activities were underestimated, with the result that other activities had to be cancelled or postponed due to the resources taken up by the underestimations. Examples of these were:

- The number of pre-registrations far exceeded expectations.
- ECHA's IT budget was underestimated.
- Recruiting the required staff took more time and effort than expected.
- Translations may have been more expensive than necessary in the early years.

Finally, some stakeholders perceive other inefficiencies, such as the correct proportion of the workload and available qualified staff. According to some members of ECHA's Management Board, the efficiency of the Board could be improved by implementing a number of suggestions for improvement.

ECHA's main type of costs is personnel costs. The Agency's directors decide how to allocate staff among the Agency's activities. As a result, prioritisation of one activity (more staff allocated than budgeted) results in fewer staff being available to other activities or staff having to spend more hours at work. As a result, inefficiencies have manifested themselves during the review period in the form of:

- a higher number of hours worked by staff than expected;
- delays in activities to which less resources were allocated.

ECHA has responded with flexibility to changing external circumstances

Budget planning and forecasting have shown to be adequate, given ECHA's uncertain environment. Also, budget implementation was effective, with variations in spending mainly being due to adjusted timing of activities. During the review period ECHA's Management and Financing Structure has functioned adequately, given a challenging organisational context.

ECHA's internal organisation proved flexible in the face of pre-registration and registration challenges and the Agency's IT infrastructure proved to be scalable during pre-registration. However, some resources were available later and in lower quantity/quality than originally estimated:

- ECHA's staff requirements for the first years were based on shorter recruitment periods and longer contracts than were realised in practice.
- The contract with the provider of REACH-IT was completed later than planned.

Conclusions on the Agency's performance

Our conclusions on ECHA's performance during the review period are presented below. We present first our conclusion on the various work areas of the Agency that were part of the scope of the review, followed by our more general and overarching conclusions.

The Agency performed well in most work areas during the review period, dissemination left room for improvement

The Review covered 16 work areas. Based on the assessment of our findings against the criteria of effectiveness, efficiency and economy we have assessed ECHA's performance during the review period to be good in most work areas.

In the area of dissemination however, the Agency did not achieve its own goals, or those set or implied by the REACH and CLP regulations. This is mainly due to the delay in the publication of the C&L Inventory and the availability of information on ECHA's dissemination website. Dissemination is of particular importance, as it is a key area in which ECHA can contribute to achieving the goals of REACH.

ECHA has had a good start-up as an organisation and implemented most of its REACH and CLP tasks effectively

ECHA has set up an effective organisational structure during the review period and has managed to implement the majority of its responsibilities under the new REACH and CLP regulations, despite a considerable workload that at times exceeded expectations. As a result, the Agency is in a good position to continue the implementation of REACH and CLP and other regulations such as Biocides and PIC. Based on our review findings and our own experiences with the Agency during the Review, we consider it capable of implementing the recommendations we have formulated in this report.

The Agency's overall efficiency has been reduced by unforeseeable circumstances and complementary activities

Regarding efficiency, we do not have sufficient information to assess the efficiency for each work area, as ECHA did not have a cost accounting system in place during the review period and therefore cost allocation to each work area was not possible for the Review. No budget overruns have been found for the Agency as a whole. Based on financial statements and interviews we conclude ECHA's overall efficiency was reduced: resources have in several cases been drawn away from planned activities to allow unforeseen and/or additional activities to be implemented.

ECHA's efficiency has been reduced during the review period due to several causes. Most prominent were unforeseeable circumstances over which the Agency had no control (such as the large number of pre-registrations submitted) and activities that can be seen as complementary to the implementation of REACH or CLP and are not required by either regulation (such as the campaign to promote SIEF formation, the provision of QOBLs to registrants and the numerous workshops organised by ECHA), but which ECHA judged to be necessary for the effective implementation of the Regulations. Clearly, ECHA is not to blame for unforeseeable circumstances and indeed has shown to be able to cope with them from the perspectives of effectiveness and economy and a reduction in overall efficiency due to re-allocation of resources from other activities could not have been avoided.

Regarding complementary activities, the situation is different. ECHA chose to implement complementary activities knowing that implementing those activities would require resources and therefore making an implicit or explicit cost-benefit analysis by weighing the estimated resource requirements against the expected benefits to the implementation of REACH and CLP. Many of these activities were aimed at facilitating industry

compliance with REACH and CLP. Our conclusion is that if the beneficiaries of these complementary activities indicate that they would rather not have them in the future, their contribution towards the effectiveness of the Agency should be considered as limited. Monitoring the satisfaction of the beneficiaries of complementary activities systematically would contribute to efficient resource allocation.

The Agency has demonstrated flexibility in the allocation of its resources

During the review period, ECHA has shown to be able to respond in a flexible and appropriate manner to unforeseen circumstances. This includes the re-allocation of resources when this was required, for example during the months leading up to the pre-registration deadline at the end of 2008 and in the preparations for the registration deadline during 2010, as well as reassigning staff back to their original roles after the unforeseen circumstances had been analysed and the appropriate level of resources required to manage the associated workload had been clearly established. The logical conclusion is that this flexibility and adaptiveness has allowed the Agency to limit the effects of these unforeseen circumstances on the overall efficiency of its organisation.

The Agency has successfully involved all stakeholders, but it could have done more to ensure its perceived independence

ECHA has implemented a number of activities to involve the various stakeholder groups in its work. A range of communication activities, including the Agency's comprehensive website, newsletters and press releases, helpdesk and stakeholder days, serve to inform a broad audience of stakeholders. ECHA has also organised workshops to involve various stakeholder groups, although workshops were mainly used to communicate and cooperate with industry stakeholders.

NGOs and MSCAs, as well as some Commission interviewees, have commented that ECHA appears to favour industry over other stakeholders. On the other hand, while industry stakeholders have indicated that the cooperation with ECHA could be more direct and that the Agency does not always follow their suggestions, they have not indicated that ECHA appears to favour other stakeholders over industry.

Another view has been that ECHA has two types of "clients": companies that it facilitates in complying with REACH as well as the Commission and MSCAs that it informs and supports through its analytical work and its various Committees. In the latter view, which is held by some industry representatives and some Commission interviewees, it is understandable that ECHA cooperates intensively with industry representatives, because they are responsible for supplying the information that ECHA needs to make REACH and CLP work. Hence, industry has significant duties under REACH and CLP, whereas NGOs have only rights. However, NGOs and MSCAs can also be understood in their wishes to avoid industry's interests outweighing those of other stakeholders in the decision-making of the Agency.

We conclude on two aspects of the intensive cooperation with industry stakeholders. First, ECHA rightfully recognises its independence as a key aspect of its mission statement, but has not been able to prevent the criticism of NGOs and MSCAs from arising. This means that the perceived independence of the Agency could be improved. Second, and as noted before, collaboration with industry is only to a certain extent required by the REACH and CLP regulations, but it does result in costs for the Agency. These costs cannot be justified when ECHA's activities go beyond what is required to ensure effective implementation of REACH and CLP and at the same time reduce its credibility as an independent agency.

Main recommendations to ECHA

We make the following recommendations to the Agency. Recommendations to the Commission will be addressed separately below.

Be more transparent about contribution to REACH and CLP objectives

ECHA does not explicitly report on its contribution to most of the objectives of REACH and CLP. It is clearly understood that ECHA cannot realise all of those objectives by itself. However, more specific goals on each of the objectives (or the aspects of those objectives that are within the scope of influence of the Agency), as well as a clarification on how ECHA contributes to the key objectives of REACH and CLP, may be expected from the Agency tasked with implementing these regulations. We recommend that this information be included in the Agency's annual Work Programmes and General Reports in future years, so that its stakeholders can read how ECHA contributes to the overall REACH objectives.

Capture the successes and learnings of the start-up period

The Agency has been able to celebrate many successes during the review period and has been able to learn from the first years of REACH and CLP implementation. The Agency has been transparent in its report about the progress made and targets achieved. The years 2007-2010 have also seen the groundwork for successful operations in the years to come.

We recommend the Agency capitalises on its achievements and lessons learned, because they can be expected to be very worthwhile not only to ECHA in its future operations but also to other regulatory agencies, the Commission and other public entities. Another reason for the Agency to harvest the learnings would be that part of its staff may leave over the coming years as a results of regular turnover and the logical reconsideration by its employees at the end of their five-year contracts. Thus, capturing lessons learned now will allow ECHA to protect its organisational knowledge base.

A good way to make the lessons learned available for future use would be to draft and continuously update factsheets or white papers on the Agency's successful approaches and interventions used in implementing REACH and CLP. Another way to do so is embedding lessons learned in ECHA's quality management systems.

Develop scenarios to ensure efficiency and economy in the future

During the review period, ECHA has been faced with unforeseen external circumstances that it could not influence and had to respond to by re-allocating resources. This affected its overall efficiency in comparison to the financial estimates of the Commission. As the Agency gained intimate knowledge of the scale and scope of the subject of its regulatory activities (the chemicals industry and the amount in which numerous substances are developed, produced and traded), it is in a position to develop scenarios for its activities in the years to come, addressing the resources required for its various activities more adequately than it could have done thus far. Therefore we recommend that the Executive Director develop scenarios calculating the amount of resources required given various *states of nature* affecting its tasks for the coming years. These scenarios would allow the Agency to strategically approach its new tasks, as well as prevent as much as possible reductions in efficiency as a result of external circumstances.

Broaden stakeholder management activities to prevent disengagement

During the review period, ECHA has implemented its stakeholder management activities along three main lines: broad communication and events aimed at all stakeholders (such as stakeholders days, website, newsletters and helpdesk), events and communication targeted at specific stakeholder groups (e.g. workshops

for industry and MSCAs) and specific roles and privileges for its 48 accredited stakeholders[5] (such as the right to attend Committee meetings).

We recommend that ECHA explicitly target SMEs subject to REACH as a separate stakeholder group, taking into account their need for more specific and concrete communication in their own language. Hence, translations are an important aspect of addressing this group.

Also, we strongly suggest to consider the criteria for accreditation of stakeholders, so that number of organisations allowed to attend Committee meetings increases. The reason for this is that currently, the attendance of Committee meetings is somewhat limited. Increasing the pool of potential attendants is likely to broaden the involvement of stakeholders in the implementation of REACH and CLP.

Share information and data when possible

As a final recommendation to the Agency, we encourage ECHA to share to the extent possible the information and data it manages, while respecting the essential role of protecting confidential information. This is the underlying requirement for achieving the goals of REACH and CLP regarding protection of human health and the environment as well as enhancing competitiveness and innovation, as well as a defining characteristic of a transparent and independent agency.

Main recommendations to the Commission

We make the following recommendations to the Commission.

Ensure future stakeholder-intensive agencies to get a more central location in Europe

ECHA requires numerous contributions from stakeholders to be able to effectively implement its regulatory tasks. The members of its bodies (MB, Committees and Forum) as well as its key stakeholders are often required to attend meetings at the Agency's premises. Stakeholders have cited several examples of the extent to which the Agency's location influences their contribution to its work, such as MSCAs not bringing a second person to Committee meetings because of the time investment required, NGOs not being able to attend Committee meetings, workshops or stakeholder days because of limited budgets and industry stakeholders selectively choosing which events to attend.

Therefore we recommend that in general, when new stakeholder-intensive agencies are to be established in the future, the Commission contribute to a decision (which is likely to be taken at the political level) to locate them in a more central location in Europe (defined in terms of the total travel times required for their expected key stakeholders).

Maintain the current role of ECHA under REACH and CLP

Although this report contains various suggestions of how the work of the Agency to implement REACH and CLP could be improved, we have also highlighted how ECHA performed many tasks well. In addition, we have not found any substantial problems with the tasks that have been assigned to the Agency under REACH and CLP. If anything, we have provided feedback on the manner in which those tasks were implemented.

[5] Any stakeholder that has presence in the majority of the 27 MS may request accreditation.

As a result, we recommend that ECHA's role under the REACH and CLP regulations stay the same in the coming period. Not only will this allow ECHA to make full use of the experiences from the start-up period of REACH and CLP in the future, it will also provide stakeholders with the consistency that is strongly beneficial in the implementation of complex regulations that require significant involvement from many organisations.

List of definitions and abbreviations

The following abbreviations are used in the report. Where appropriate a definition of the abbreviated term is also given.

- ABAC – Accountancy + Business Advice Centre (software), used throughout the European Commission and also by the European Chemicals Agency;
- BoA – the Board of Appeal of the European Chemicals Agency;
- CA –Competent Authority;
- CARACAL – Competent Authorities for REACH and CLP;
- CBI – confidential business information;
- C&L – classification and labelling;
- CLH – harmonised classification and labelling;
- CLP – the CLP regulation ((EC) No 1272/2008) sets the rules for classification, labelling and packaging of chemicals in the EU and entered into force on 20 January 2009;
- CSA – chemical safety assessment
- CSR – chemical safety report
- DCG – the Directors' Contact Group is a platform for the exchange of views between the European Commission, the European Chemicals Agency and In dustry Associations (CEFIC, Eurometaux, Concawe, REACH Alliance, FECC and UEAPME);
- ECHA – the European Chemicals Agency;
- HELPNET – REACH and CLP Helpdesk Network;
- IUCLID – International Uniform ChemicaL Information Database;
- IUPAC – International Union of Pure and Applied Chemistry;
- MB – Management Board of the European Chemicals Agency;
- MoU – Memorandum of Understanding between the European Chemicals Agency and another organisation
- MSC – the Member State Committee of the European Chemicals Agency;
- MSCA – Member State Competent Authority;
- NGO – non-governmental organisation;
- OECD – Organisation for Economic Cooperation and Development;
- OSOR – One Substance, One Registration (a leading principle of the REACH regulation);
- PPORD - Product and Process Orientated Research and Development allows a company to submit a PPORD notification to ECHA in order to be exempted from the obligation to register;
- RAC – the Risk Assessment Committee of the European Chemicals Agency;
- REACH –European Community Regulation on chemicals and their safe use ((EC) 1907/2006). It deals with the Registration, Evaluation, Authorisation and Restriction of Chemical substances. The regulation entered into force on 1 June 2007.
- SEA – socio-economic assessment;
- SEAC – the Socio-Economic Assessment Committee of the European Chemicals Agency;
- SIEF – Substance Information Exchange Forum;
- SFF – SIEF Formation Facilitator;
- SME – small or medium-sized enterprise
- SVHC – Substances of Very High Concern;
- QOBL – Quality Observation Letter;
- QSAR (modelling) – Quantitative structure-activity relationship modelling;
- WG – working group, for example of the Management Board of the European Chemicals Agency.

Table of contents

1. Introduction

01 The Review of the European Chemicals Agency (ECHA) is a requirement of Article 75 (2) of Regulation (EC) N° 1907/2006, also known as the REACH Regulation. PwC was commissioned by Directorate-General Enterprise and Industry of the European Commission to conduct the Review during the period of March 2011 - March 2012. Hence, this report concerns the Review of ECHA as an organisation, but not of the REACH or CLP Regulations that are implemented by the Agency. This also means that elements of REACH and CLP in which ECHA does not have a role, are not part of the scope of this Review.[6]

02 Our findings are included in the main report. Detailed findings per work area are included in Annex A. Annex C contains a detailed description of the research approach. The Review consists of the following activities, which are described in more detail in Annexes B through F:

- document analysis (Annex B contains a list of sources used);
- interviews (included in Annex C);
- a stakeholder survey (see Annex D for the raw survey results); and
- a stakeholder focus group (summarised stakeholder feedback is listed in Annex E);
- a comparison of actual costs against the budget is provided in Annex F.

03 Annex G contains the Tender Specifications for the Review.

04 A list of definitions and abbreviations used in this report is included on page 10.

1.1. Document analysis and interviews with ECHA staff

05 In the period 15 April – 18 May, both the Commission and ECHA supplied the Review Team with (references to) publicly available documentation, as well as confidential documents. The available documents were subsequently screened in order to select those documents for analysis that provide the best fit with the assessment questions. This resulted in an overview of the tasks and targets of the Agency.

06 A key part of the document analysis consisted of the confrontation of the tasks and targets from the overview of the tasks and targets of the Agency with ECHA's actual performance as it was documented in the Agency's reports. A second key aspect was the analysis of ECHA's finances through a comparison of its annual budgets with its annual accounts.

07 In the week of 23-27 May 2011, ECHA managers were interviewed by the Review Team at the ECHA premises in Helsinki. Together with the documents analysed these interviews yielded insight in the main issues the Agency was faced with during the review period.

08 During the Review, when there was cause to validate statements from interviews or survey results, the relevant documents were consulted. The result of the document analysis can be found in the body of the report, as well as Annexes A (results of the comparison between goals and performance) and G (results of the comparison between budgets and annual accounts).

1.2. Stakeholder survey

09 A key element of the data collection for this study has been a survey of over 200 stakeholders of ECHA, to which 132 replies were received. The target audience consisted of members of ECHA's various bodies, the Directors Contact Group and the CARACAL platform of Member State Competent Authorities, as well as a number of industry associations from the chemicals sector and relevant NGOs. We note here that no individual chemical companies have been surveyed. The response rate to the survey was 64%, and response was received from all types of stakeholders contacted. However, given the low numbers of response for some stakeholder types and for some specific survey questions, statistical analysis of the answers was not possible. Therefore we have

[6] Several other studies that contribute to an integral review of REACH have been conducted at the request of the Commission. An overview of all studies can be found at http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review2012/index_en.htm.

included the integral survey results in Annex D to this report, as well as included relevant examples of survey results in the text. For each result reported on, response is provided in both absolute numbers and percentages.

1.3. Stakeholder interviews and focus group

10 In addition to the desk research and survey results, the report contains various quotes of the 32 stakeholders who have been interviewed during the review process and the 34 stakeholders who have participated in a focus group to discuss the preliminary findings from the Review. These quotes do not necessarily provide a generic conclusion, but are considered by the Review Team to be relevant remarks expressing the view point of one stakeholder. The quotes are meant to be illustrative and provide valuable insights from the perspective of different stakeholders.

11 A crucial aspect of the outcome of this review, are the "lessons learned". We feel the review would not be sufficiently relevant if not all stakeholders could benefit from the "lessons learned" and the recommendations given. Therefore, special attention has been given to ECHA's capacity to learn in order to contribute to the Commission's review of the REACH Regulation by 1 June 2012.

12 We want to express our thanks to all who have participated in the Review and thus contributed to this report. First and foremost we thank the European Commission members of the Review's Steering Committee for their contributions and support. Just as prominently, we thank the management of ECHA without whose contributions the Review would not have been possible. Finally, we thank all members of ECHA bodies and stakeholder representatives who have generously donated their time to participate in the Review.

13 The PwC Review team consisted of:

- Hans Schoolderman (Responsible Partner, Netherlands);
- Bas Warmenhoven (Project Manager, Netherlands);
- Kari Storckovius (Finland);
- Geoffrey Schouten (Netherlands);
- Anna-Leena Teppo (Finland);
- Polina Frolova (Netherlands);
- Desirée Beeren (Netherlands).

14 The report is set out under the following headings:

- Chapter 2: ECHA is effective at the level of output, outcome could be improved;
- Chapter 3: ECHA's overall efficiency was reduced by complementary activities that often increased effectiveness;
- Chapter 4: ECHA has responded with flexibility to changing external circumstances;
- Chapter 5: Conclusions and recommendations.

2. *ECHA is effective at the level of output, outcome could be improved*

15 In this chapter we address the effectiveness of the Agency by comparing its performance to the key objectives that were set in Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and the Regulation on classification, labelling and packaging of substances and mixtures (CLP) as well as ECHA's Annual Work Programmes for the years 2007 through 2010. We consider the following main evaluation questions:[7]

- To what extent are the targets set by the Agency at an appropriate level to guarantee the contribution to the REACH objectives?
- To what extent has the Agency achieved the outputs which were planned in its work programmes?
- To what extent are the addressees of the Agency's outputs satisfied?
- To what extent has the Agency achieved the intended results of its activities?
- In which circumstances is the Agency achieving particularly good results, and why?
- To what extent has the Agency succeeded in setting up its Network(s) [e.g. OECD, Member States (MS), inspectorates, industry associations, REACH helpdesks] in accordance with its mandate? What has been the contribution of this/these Network(s) towards the attainment of the Agency's objectives?

16 We define the Agency's effectiveness as the extent to which it has achieved its objectives. Those objectives have been derived from the tasks of the Agency as specified in the REACH and CLP regulations, as well as the Commission's Revised Legislative Financial Statement for REACH and the Agency's own Work Programmes.

17 We recognise that during the first year after its inception (June 2007-June 2008), ECHA was occupied with the set-up of its systems & tools, procedures and governance structure. In addition, ECHA was trying to hire highly motivated and talented staff and simultaneously raising awareness across all stakeholders.

18 In the period June 2008 – to date, ECHA became fully operational and already faced important challenges as a result of some crucial deadlines stemming from the REACH and CLP Regulations. The uncertainty about the number of pre-registrations and registrations has had far-reaching consequences. ECHA had to prepare for (a potential lack of) performance of the IT-system, re-allocation of trained staff and other eventualities. In the timeframe 1 June – 1 December 2008, companies were allowed to file pre-registrations for phase-in substances in order to make use of the extended registration deadlines. Then on 30 November 2010 the first registration deadline resulted in 25,000 registrations for 4,300 substances.

19 Besides the above-mentioned challenges on registration, during the review period ECHA has been preparing for facing the challenge of evaluating registered dossiers, the authorisation and restrictions processes, publishing the Classification and Labelling (C&L) Inventory, as well as providing sound scientific and technical advice to the Commission and MS, as well as guidance and tools to industry. In addition to these operational challenges, ECHA also planned a major reorganisation in the beginning of 2011, was expected to draw up several reports on (among other things) the status of implementation and use of non-animal testing methods and strategies and had to prepare for the Biocides regulation.

20 Therefore, we start this chapter by introducing the context of the applicable timeframe (paragraph 2.1) and describing ECHA's goal setting (paragraph 2.2). In paragraph 2.3 we analyse our findings on ECHA's effectiveness in the review period, using the results of our document analysis as well as the perspectives of the stakeholders who participated in the Review through the survey, interviews and focus group we conducted.

[7] For the full list of evaluation questions and the answers provided by the Review, please refer to Chapter 5 of this report.

2.1. The Review covers the years 2007-2010

21 This report and all findings and assessments in it concern the review period of 2007-2010. The Agency started its activities in 2007 and the first deadline for registration was specified by REACH art. 23 to fall on 1 December 2010. Hence, the review period covers the first three and a half years of the Agency's existence.

2.1.1. 2007 – Start-up of the new Agency

22 In fulfilment of the European Commission's duty to afford the necessary support towards the establishment of the Agency, it appointed the Interim Executive Director as of 1 June 2007. The Commission seconded 37 experienced officials to ensure the smooth setting-up of the Agency and it fully executed the Agency's 2007 budget to allow the Agency to build up its own financial systems, rules and resources before becoming fully financial independent.

23 On 1 January 2008 ECHA became fully independent from the Commission. The Agency became fully operational on 1 June 2008, when it was first allowed to take decisions with legal effect. By this time a lot of work had been performed in setting up the Agency. During the years 2007-2008 all bodies mentioned in Article 76 of REACH were established. Also, together with the contractor hired by the Commission, the IT backbone of the Agency was established.

24 An important aspect of the start-up period was that ECHA staff in 2007-2008 consisted in large part of employees seconded from the European Commission. This allowed the Agency to start several activities quickly, before becoming independent from the Commission on 1 January 2008.

2.1.2. 2008 – The year of pre-registration

25 Based on original estimates of the Commission when the REACH Regulation was prepared, approximately 170,000 pre-registrations were expected to be received. At closing date, 2.7 million pre-registrations were received. Despite the fact that over 15 times more pre-registrations were received than expected, pre-registration tools, ECHA's helpdesk and IT functions were able to cope (see also paragraph 2.3.1.2). As this higher number demanded more from REACH-IT and other systems, ECHA staff have reported to have had to spend much time to support the system, add servers and monitor the performance of the system on a 24/7 basis.

2.1.3. 2009 – Preparations for first registration deadline, increasing work for Committees

26 In 2009, the Agency spent quite some time on facilitating the start-up of Substance Information Exchange Fora (SIEFs), in which companies that had pre-registered the same substance in 2008 came together to prepare joint registrations. This involved in particular the task of improving the quality of the list of pre-registered substances which facilitated the SIEF creation process by companies that had pre-registered the same substance. The Agency was proactively supporting the process for establishing SIEFs between companies through a comprehensive awareness-raising campaign, a SIEF web section, dedicated helpdesk support as well as the organisation of conferences and workshops.

27 It was highlighted in interviews with members of the Management Board (MB) that enhanced technical assistance to companies in fulfilling the obligations related to the registration of chemicals was provided. This included the release of an IT tool to allow verifying the technical completeness of a registration dossier before submitting it to the Agency and the high number of REACH-IT manuals for industry.

28 In addition to supporting SIEFs and carrying out its day-to-day operations, ECHA worked towards building up capacities in relation to the evaluation and classification and labelling tasks; which meant implementing a set of new procedures, in particular by taking the first decision on a testing proposal following unanimous agreement in the Member State Committee (MSC) and adopting the first scientific opinion in the Risk Assessment Committee (RAC) on a harmonised classification and labelling for one substance of concern.

2.1.4. 2010 – The year of registration, some C&L tasks delayed

29 25,000 registrations for 9,200 substances were expected to be registered before the first registration deadline of 30 November 2010, with the submission rate peaking towards 30 September 2010 (especially for Lead dossiers[8]) and towards 30 November 2010 (predominantly for non-Lead dossiers). However, because of the high uncertainty on the number of registrations, ECHA had prepared contingency plans for handling up to 75,000 registrations.

30 By the deadline, ECHA had successfully received 25,000 comprehensive registration dossiers for 4,300 substances. Hence, the number of registrations ECHA was required to process equalled the expected number.

31 C&L notification tools were elaborated and technical advice was provided to industry on the notification of substances to the C&L Inventory. A public awareness raising campaign on the notification tools was implemented by the Agency. 3,114,835 notifications for 107,067 substances were received. The processes for the evaluation of requests for the use of alternative names were further developed.

32 In total, 30 CLH dossiers were processed by ECHA in 2010. Therefore, all proposals for harmonised C&L sent by the Member State Competent Authorities (MSCAs) and industry were processed within the legal timeframe. However, an intermediary C&L Inventory was postponed during the review period and was not available before February 2012. We will come back to this point in paragraph 2.3.7.1 below.

33 The international activities of ECHA in 2010 were detailed in the ECHA Work Plan for International Activities. This plan was prepared in consultation with the Commission and was then endorsed by the MB. Activities related to joint IT projects (eChem portal and IUCLID 5) with the OECD were completed also in this year.

34 Finally, ECHA also concluded its first cooperation agreements with third countries. A Memorandum of Understanding was signed with Environment Canada and Health Canada in May 2010 and a Statement of Intent late in the year with the US EPA Office of Pollution Prevention and Toxics.

2.2. The quality of ECHA's goal setting improved as the Agency developed

35 An important data source for this Review is constituted by ECHA's annual and multi-annual Work Programmes (which contain its objectives, often coupled to targets and indicators for performance with respect to a specific year) together with its annual General Reports (which report on its actual performance in a specific year). These documents, which are available on the Agency's website, have been used as one of the key sources for taking stock of its performance in the review period.

36 As we will show below, the quality of the objectives, targets and indicators improved over the years, thus allowing a better reference to assess the Agency's performance. As will become apparent later on in this chapter, the quality of ECHA's goal setting influences our ability to assess its performance. As a result, we were able to assess performance better for the year 2010 than for the previous years.

[8] I.e. the dossiers of lead registrants from a SIEF, as opposed to non-Lead dossiers submitted by other members of the same SIEF.

2.2.1. *Targets set by ECHA contribute to the majority of the REACH and CLP objectives, but have limited use as a benchmark for performance*

37 The text of the REACH regulation specifically establishes the European Chemicals Agency and defines its composition.[9] Further, the REACH regulation specifies the following objectives[10]:

1. ensuring a high level of protection of human health and the environment;
2. the promotion of alternative methods for the assessment of hazards of chemicals;
3. free circulation of substances on the internal market;
4. enhancing competitiveness and innovation.

38 In addition, the CLP regulation specifies the following objectives[11]:

5. ensuring a high level of protection of human health and the environment; and
6. ensuring the free movement of substances, mixtures and articles; by
7. harmonising the criteria for classification of substances and mixtures, and the rules on labelling and packaging.

39 Thus objectives 1 and 5, as well as 3 and 6, are the same. Objective 7 is clearly additional to the four objectives of REACH objectives.

2.2.1.1. Targets became SMARTer during the review period

40 When starting in 2007, ECHA's annual Work Programme was relatively short and mentioned the main tasks in the form of bullet points, without specifying or quantifying detailed outputs in the form of performance indicators. The 2008 Work Programme was almost twice the size of that of 2007 and went into more detail, although specific, measurable, attainable, relevant and time bound (SMART)[12] operational objectives and relevant, accepted, credible, easy to monitor and robust (RACER)[13] performance indicators were not yet included.

41 The Work Programme for 2009 did include performance indicators for ECHA's operations (the processes of (pre-)registration, evaluation, classification & labelling and restrictions & authorisations). Other activities described in the Work Programme did not include performance indicators yet. Some of the indicators for operations were quantitative in nature, but none came with a norm for success. As an example, one indicator mentioned is "the time needed to process registration dossiers", but it is not mentioned what the maximum or average process time for registration dossiers should be. Hence, it is not possible to assess the Agency's performance for these indicators, unless a norm can be inferred from the accompanying text in the Work Programme.

42 Another problem that we encountered was the absence of reported data for a certain indicator. In the example of processing time for registration dossiers, we do not have actual data on the increase or decrease of average processing time, as the processing time of registration dossiers is not available in the 2009 General Report. It is reported though that the Percentage of registrations processed within the legal timeframe was 100% in 2009.[14] However, the scope of the indicator used (Percentage of registrations processed within the legal timeframe) does not match that of the indicator in the 2009 Work Programme (the time needed to process registration

[9] As per articles 75 and 76 of the REACH regulation.

[10] As per article 1 of the REACH regulation.

[11] As per Article 1 (Purpose and scope) of the CLP regulation.

[12] As specified in EC (2009). Impact Assessment Guidelines, page 28, http://ec.europa.eu/governance/impact/commission_guidelines/docs/iag_2009_en.pdf

[13] As specified in EC (2009). Impact Assessment Guidelines, Annex 13. http://ec.europa.eu/governance/impact/commission_guidelines/docs/ia_guidelines_annexes_en.pdf

[14] General Report 2009, p12

dossiers).[15] As a result, it is not possible to assess specifically which operational goals were set by the Agency and whether they have been met. Although processing all registrations within the legal timeframe is clearly a good performance, it is conceivable that the Agency would aim to process registrations even faster than the legal requirement. Based on the indicator chosen and the absence of a performance target for this indicator, we cannot evaluate ECHA's performance against its operational objectives with certainty.

43 The Work Programme for 2010 presents a radical improvement in terms of the use of measurable indicators and clear norms for success. For all activities of the Agency, multiple indicators were introduced, including target values for 2010 as well as the administrative sources from which the relevant data would be retrieved (allowing for verification of the source data). As an example, the table with indicators for the support to the Committees and the Forum is provided below. It is evident from the table that both quantitative and qualitative indicators have been mixed as well as indicators describing both outputs as well as impacts and results, which contributes to the richness of the management information and the transparency to stakeholders. Interestingly, targets for the year 2010 as included in the Work Programme 2010 and the General Report 2010 are often consistent with the wording of results reported in the 2009 General Report, allowing for a comparison between performance in 2009 and 2010.

[15] This mismatch between indicators used in the Work Programme 2009 and the General Report 2009 actually occurs with most targets and indicators. The targets are set more in the spirit of quantitative measurements per se, whereas the performance is measured in terms of compliance with REACH and CLP requirements.

Performance Indicators & Targets

Indicators	Target in 2010	Means and frequency of verification
Percentage of opinions / agreements delivered in time.	Not less than 90 %	Annual internal report
Percentage of unanimous MSC agreements.	Not less than 80 %	Annual internal report
Percentage of Committee opinions adopted by consensus.	Not less than 70 %	Annual internal report
Degree of Committee opinions taken on board in the final decision of the European Commission.	High	Annual internal report
Feedback from the Member States enforcement authorities and ECHA stakeholders on the added value of the Forum activities.	Positive	Annual survey
Level of satisfaction of the Members and other participants with the support (including training and chairing) provided by ECHA to the Committees and the Forum.	High	Annual survey
Level of satisfaction of stakeholders, Competent Authorities and Members of the Committees with the overall transparency and publication of the outcomes of Committee processes and the Forum activities.	High	Annual survey

Source: ECHA Work Programme 2010, page 34

44 The improvement of the measurability of ECHA's annual targets is a clear sign of its becoming a fully developed public entity. Although the development is inherent to a young organisation, it also means that for the years 2007-2009 it is difficult to be very specific when assessing the Agency's performance.

2.2.1.2. ECHA set an ambitious target: to be fully operational on 1 June 2008

45 The 2007 Work Programme is clear about the main targets for the first year: the Agency must be set up and become fully functional. Important deadlines are 1 January 2008 (independence from the Commission) and 1 June 2008 (capability to take decisions with legal effect).

"The Agency must be operational, i.e. capable of taking decisions with legal effect as foreseen in the REACH Regulation from 1 June 2008, 12 months after entry into force of REACH. This requires that the Executive Director is in place and has the necessary means at his/her disposal to take these decisions."[16]

46 Working back from those deadlines, the management of the Agency-to be sets itself a number of ambitious targets, addressing the structure, systems and staff:

"The Work Programme of ECHA in 2007 focuses on the essential steps in setting-up the capacity of the Agency to take operational (REACH-related) decisions, including:

- ***Putting in place the Management Board***
- ***Selecting the Executive Director***
- ***Recruiting and training staff***
- ***Establishing systems, procedures and operational controls***
- ***Preparing the Agency's committees and the Forum***
- ***Installation of the IT systems and other facilities of the Agency***
- ***Creating the Agency's helpdesks and guidance tool."***[17]

47 It should be borne in mind that although ECHA consisted mainly of seconded Commission staff in 2007, the Agency had to be set up completely from scratch, making its goals for the first year (June 2007 – May 2008) very ambitious.

2.2.1.3. REACH and CLP objectives are not represented in operational objectives in ECHA's Work Programmes

48 The main objectives of REACH and CLP (as listed in paragraph 2.2.1) have not been represented in operational objectives in ECHA's Work Programmes, with the clear exception of objective 7 (harmonising C&L). For example, the Work Programmes do not specify which activities the Agency is conducting to promote alternative testing methods for the assessment of hazards of chemicals. However, just like the three other REACH objectives, it is mentioned as an overall objective in the 2010 Work Programme.

2.2.2. Use of targets and indicators in General Reports

49 As described above, ECHA has improved the goal setting in its annual Work Programmes during the review period. The same improvement logically influences its annual General Reports, as they mostly refer to the same objectives as the Work Programmes (even though targets and indicators vary or are not included in the 2007-2009 General Reports). Hence, the reports become more informative over time with regard to ECHA's performance.

2.3. ECHA has met most of its key objectives

50 Overall, both the survey respondents and the interviewees were satisfied with the achievements of ECHA so far and the amount of work the Agency has been doing in a relatively short time. Their general comments can be summarised with the following quote which was expressed virtually the same by all stakeholders:

"ECHA has done a great job"

[16] ECHA Work Programme for 2007, page 2.

[17] ECHA Work Programme for 2007, page 2.

51 Limited time, uniqueness and scope of work the Agency had to cope with, however, led to several shortcomings which will be elaborated on further in this report. We should note here that the respondents were mostly positive and admitted that the majority of the imperfections of ECHA, such as delays and uneven distribution of workload could be considered as normal given the circumstances.

2.3.1. ECHA achieved most of the outputs planned in its Work Programmes

52 The Agency set-up a Work Programme for each of the four years in the review period. The following paragraphs detail how ECHA has achieved most of the outputs it planned to achieve, with one major exception in the form of the C&L Inventory.

2.3.1.1. 2007 – Successful set up of the new Agency

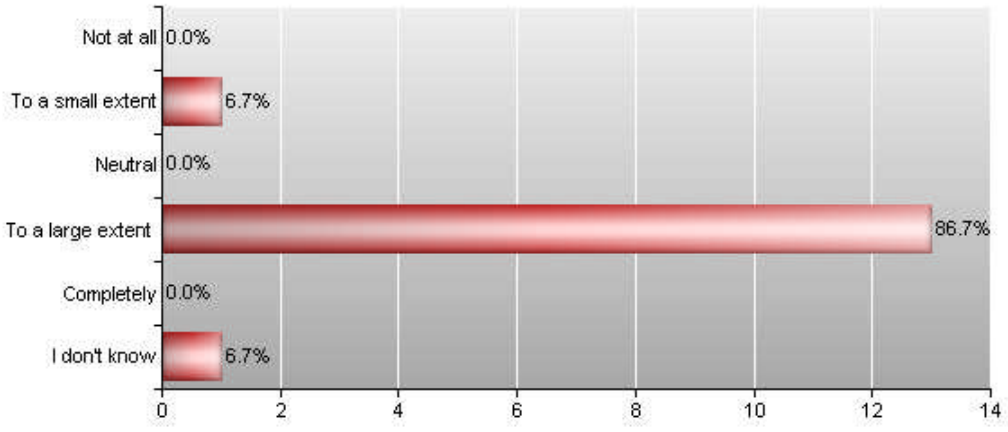
53 Stakeholders participating in the Review have acknowledged the high quality of the organisation set up in the short time available. They mentioned that ECHA has made remarkable achievements from both organisational as well as staff perspective, especially when taking into account the dynamic environment.

54 One of the challenges for ECHA's management team concerned recruiting staff of the appropriate quality at ECHA. Given a limited number of experienced candidates for positions, a member of the Commission's recruiting team for the initial ECHA staff of 2007 told us it was frustrating to see candidates withdraw after three successful interviews, due to an unwillingness to relocate to Helsinki, where the Agency is located. ECHA offered higher than average grades and compensation to their potential employees, however the location was viewed as a disadvantage by potential employees. The above-average pay grades and compensation for new employees have been reduced over the years 2009 and 2010 to be more in line with comparable positions in other agencies.

2.3.1.2. 2008 – Pre-registration successful against all odds

55 Overall, the survey respondents with an industry perspective were satisfied with the pre-registration process. It was considered to be carried out in an effective manner by most of the industry respondents.

To what extent did the overall pre-registration process coordinated by ECHA in the time period 2007-2010 work in an effective manner? (respondents: industry)



56 Survey response from industry suggests that companies could not easily identify (potential) other registrants of their substance through the pre-registration process: 7 out of 9 industry respondents disagreed that this could easily be done. Industry respondents were slightly more positive about the quality of the list of pre-registered substances as published by the Agency: although 35% of industry respondents answered "I don't know", the other responses varied from "Good" (28%) via "Average" (13%) to "Fair" (9%) and "Poor" (13%). No respondents selected the option "Outstanding" for this question. Hence – and because 35% of the industry respondents did not know what to answer to this question, we assess this area to represent points for improvement.

57 The following factors have been mentioned by interviewees as causes of the higher number of pre-registrations:

- A new activity as part of a new regulation, resulting in uncertainties for all actors, including:
  - difficulty for the Commission to correctly estimate the number of pre-registrations without any sort of benchmark;
  - uncertainty with companies on whether or not they should pre-register – according to interviewees from multiple stakeholder groups, many companies pre-registered "to be on the safe side", which is likely to be at least to a certain extent attributable to general communications coming from the Commission, the Agency and several industry associations that "scared companies into pre-registering".

- Absence of a barrier (such as a mandatory fee for pre-registration) or a data quality check on company identity (such as a requirement to prove the identity of the company and/or of the person submitting a pre-registration on behalf of that company) information and pre-registered data left room for opportunistic and pragmatic behaviour by companies.
- In order not to be caught unprepared, ECHA staff monitored the developments around pre-registration very closely and were at no point surprised by the high number of pre-registrations. The Agency did face resource challenges in both staff and IT systems, but the general judgement of the respondents is that ECHA managed the pre-registration process well. The only criticism made by stakeholders in this matter relates to the very frequent and sometimes inconsistent communication about the IT systems for pre-registration. One industry interviewee commented (and this impression was confirmed by ECHA as accurate):

"On one day they put a message on the website saying the system would work, only to counter it a few hours later with a message saying the system was down again. Sometimes there were also messages indicating that a tool would be fixed in two days, but then after two days it would be reported that more time was needed to fix it."

58 In addition to ECHA interviewees, most industry stakeholders have also commented that some (non-chemical) companies pre-registered purely to gain access to information on substances and to be able to subsequently offer consultancy services to SIEF members. A member of SEAC commented:

"Further to discussions in Council and Parliament, the pre-registration system was open to all companies which could pre-register all phase-in substances, leading to unnecessary pre-registrations, which created spam in the e-mailboxes of SIEF members."

59 An industry representative reported that ECHA has learned from this period and has implemented a lot of corrections to avoid a similar situation during the registration phase. The same representative commented, the *tsunami* of pre-registrations has led to a long-term problem for industry: on average 90% of SIEF members have no intention to be actively involved in the SIEF REACH registration processes whatsoever but from the perspective of the Lead Registrant they have to be kept informed of progress. This issue is to be solved separately for each SIEF and creates an administrative burden.

60 Comments from survey respondents on the IT systems for pre-registration are also mixed. The majority of industry interviewees reported that during the pre-registration period they faced many IT problems, but acknowledge that these were solved by ECHA in the end. Solving the problems however did take time (resulting in temporary unavailability and instability of systems) and at times required additional work from industry. One concern here was a misunderstanding on the design stage as the architects of the IT design were not sufficiently aware of the desires of end-users. Instead of freezing the IT development at an insufficient platform so that companies would not have to cope with several updates, ECHA would decide in favour of redesigning which caused some difficulties for industry (although it is uncertain what would have been the long-term result of freezing the IT work at an insufficient platform, with registrants having to "repair" the registration data later). One example of this is the absence of backwards compatibility with previous versions of tools such as IUCLID, causing companies to have to rebuild their (pre-) registration dossiers upon the availability of a new software version. Given these difficulties, most respondents agree that ECHA completed a very challenging job in spite of expectations of failure by some stakeholders.

61 Industry stakeholders are neutral about the statement that "The national helpdesks provide clear, adequate and legally sound advice". However, industry representatives indicated in interviews that complicated questions took a long time to be answered by the ECHA Helpdesk. There is also a concern of multinational companies who explained that they learned they could not always rely on the national helpdesks to provide the same answer in different Member States. This may also imply that national helpdesks do not provide the same answers when it comes to questions of SMEs.

62 The first stakeholders' day of ECHA took place on 10th of October 2008 in Helsinki. It was organised by the Agency in cooperation with the Commission and presentations were given by ECHA, the Commission, Cefic and several NGOs. This event has provided the opportunities for 600 stakeholders from 39 countries to:

- be informed about the latest developments in ECHA's activities and the forthcoming challenges in the implementation of REACH;
- share their views on REACH implementation and expectations regarding their involvement in ECHA's activities;
- ask questions and get answers on issues of interest from the ECHA management.[18]

63 When it comes to dissemination, especially non-industry stakeholders (including some Commission and Member States' representatives) were not satisfied with the dissemination website, which was reported by stakeholders to be poorly laid out and structured during the review period. Information was difficult to locate as the website has limited search facilities. In comparison, the eChem Portal of the OECD, which is partly supplied and co-financed by ECHA, provides better access to information, but to many respondents, this is still insufficient when compared to their expectations of what would be the results of REACH and CLP. Most stakeholders with an NGO perspective as well as some (but not all) Commission and MSCA representatives indicate that ECHA is too stringent when it comes to releasing company names in relation to dissemination information. One NGO commented:

"You want to know what the factory next to your house is doing."

64 Although the quote in itself is somewhat oversimplifying (no data about a specific chemical plant are made available as a result of REACH), one of the main ideas of REACH is that more information becomes public about the work of the chemical industry and the measures taken to ensure the safety of those operations.

2.3.1.3. 2009 – Preparations for first registration deadline, increasing work for Committees

65 Overall, we find that the Agency was quite successful in the operational work performed in 2009 as well as in supporting SIEFs. As described in paragraph 3.1.3, companies also benefited from other support that was proactively provided by ECHA, but not necessarily required by REACH or CLP (such as workshops to discuss the functionality of planned IT tools). Industry stakeholders clearly noted this as a positive point about ECHA's stakeholder management.

2.3.1.4. 2010 – Successful registration, some C&L tasks delayed

66 87% of Industry associations, NGOs and Commission representatives responding to the survey were somewhat satisfied with the registration process in general (art. 20), notably the registration of substances in articles and the PPORD notification process. However, the inquiry process (through which companies could submit inquiries prior to registration) was considered by industry respondents to be carried out rather poorly by ECHA (5 out of 6 respondents gave a below-average rating). We found that this can be explained by the fact that ECHA received almost 1,600 inquiries in 2010 – i.e. four times more than the number that was expected, of which more than 50% arrived in the last quarter of the year. The peak in the submission of inquiries, combined with problems in the quality of the substance identification information provided by inquirers, resulted in delays in processing the dossiers. Also, the overall user-friendliness of REACH-IT modules to prepare the inquiry dossiers was rated relatively poor (when compared to other ECHA software tools) by industry respondents to the survey.

[18] http://echa.europa.eu/news/events/1st_stakeholders_day_en.asp

67 In relation also to the comments on pre-registration, industry stakeholders advised to:

- issue less frequent updates to IUCLID or make REACH-IT backward compatible with earlier versions of IUCLID;
- ensure stable versions of the necessary tools well before the various REACH deadlines; and
- prevent compulsory updates to these IT support tools three months or less prior to deadlines, as these updates generate an additional need for technical support amounted to costs in the thousands of Euros per submitted dossier, per registrant.

68 All industry respondents surveyed stated that the quality observation letter (QOBL)[19] is a good measure to improve the efficiency of the dossier evaluation (compliance check) process. The respondents were mostly agreeing that the prioritisation process effectively identified the substances that will be first evaluated under testing proposals.

69 Another comment received concerns the selection of dossiers for dossier evaluation by the Agency. ECHA is tasked by REACH Article 41 to select at least 5% of all registration dossiers for dossier evaluation. Several NGOs have raised a point on the selection of registration dossiers for dossier evaluation (compliance check). They suggest to improve the evaluation processes by adjusting the approach used to select dossiers which would form the needed 5%. According to NGOs, more emphasis should be put on lead registrant dossiers (vis-à-vis the population), less on SIEF member dossiers and dossiers on intermediates. The reason for this suggestion is that lead registrant dossiers contain much more information than those submitted by SIEF members. These NGOs indicate that also dossiers on intermediates contain relatively little information, making them less valuable in terms of evaluation. According to them, ECHA should present clear arguments for the selection of dossiers, to prevent the impression that it selected dossiers with a relatively low workload to reach the 5% target as efficiently as possible.

70 All proposals for harmonised C&L sent by the Member State Competent Authorities (MSCAs) and industry were processed within the legal timeframe. However, an intermediary C&L Inventory has been postponed from December 2010 to February 2012. We will come back to this point in paragraph 2.3.2 and 2.3.7.1.

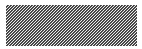
71 Outcomes of ECHA's Annual Survey indicate that the Level of satisfaction of the Commission with the support given by ECHA on international activities was "medium" and thus below the Agency's target of "high" (see the table on work area B4 in Annex A).

[19] The QOBL is a letter sent to registrants, to inform them in detail about the quality of their registration dossiers as reviewed by ECHA.

2.3.2. *Summarised results on effectiveness per work area of the Agency*

72 In this paragraph, we provide an overview of the main findings regarding effectiveness based on the data collected for each of ECHA's work areas. We provide an overview for each work area of the findings based on the three types of data collected: interviews, stakeholder survey and desk research. The summarised results from the various data sources are provided in the table below, which is followed by a discussion of the findings. The integral results of the desk research with main survey findings per work area are available in Annex A, the integral survey results are included in Annex D.

73 The centre column of each table contains the realised performance on each target. It is compared to the target and the indicator(s) where available. The result of this comparison is presented in the form of traffic light colours:

Performance	**Colour**
Target completely achieved	
Target partially achieved	
Target not achieved	
Target not SMART and/or indicator not present or not RACER and/or no realized performance reported, therefore no performance assessment possible	
Target does not concern the review period (2007-2010)	

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Work Area	Desk research	Stakeholder opinions (survey)	Illustrative Stakeholder opinions (interviews/focus group)
A1 – Registration, pre-registration and data sharing	Targets achieved, except for the timely processing of inquiries in 2010	Respondents are neutral to positive, except for more negative judgment about the inquiry process. About 20% of respondents criticise the quality of the list of pre-registered substances.	Registration and pre-registration were successful against all odds. (Industry interviewee) The whole SIEF process was not legally defined by the Regulation (this was not ECHA's fault!). (Industry interviewee)
A2 – Evaluation (excluding substance evaluation)	Most targets achieved, specifically the targets for numbers of compliance checks and evaluations of testing proposals	Respondents are neutral to positive on average, but there is a consistent minority that judges more negatively. This minority is largest (35%) with the criteria used for the selection of registration dossiers for dossier evaluation (compliance check).	The scientific level of decisions is not good at the moment. It is not clear how ECHA reached its decisions, but the outcome is very conservative. ECHA is saying companies are using alternative testing methods because less testing proposals are submitted than expected. This is turning the argument around. (NGO interviewee)
A3 – Authorisations and restrictions (excluding treatment of authorisation applications)	All performance targets met, except for the high satisfaction of MSCAs (i.e. not Committee members) with the quality of the scientific, technical and administrative support provided	More than 80% of respondents indicate that they consider the processes that were implemented in the review period to have taken place in an independent, transparent manner.	The technical quality of submitted dossiers is generally good. Only one Annex XV restriction proposal was also of good quality but evaluated to be non-conforming due to shortcomings regarding some Annex XV requirements. Now more strategic dossiers are arriving with less time available which improves efficiency. (SEAC member)

Work Area	Desk research	Stakeholder opinions (survey)	Illustrative Stakeholder opinions (interviews/focus group)
A4 – Classification and labelling	2 out of the 4 performance targets were fully met, the publication of the C&L Inventory has been significantly delayed and MSCAs (i.e. not Committee members) indicate satisfaction at the medium level with the quality of the scientific, technical and administrative support provided	Industry associations indicate they understand the delay in publication of the C&L Inventory, but find that the information provided by industry is not sufficiently taken into account in the Agency's C&L opinions.	The publication of the C&L Inventory has not happened yet and has been postponed to the autumn of 2011. In particular, SMEs would benefit from publication of the C&L Inventory as they have limited capacity to interpret the criteria for classification in the CLP Regulation and to determine the correct classification and labelling for their substances / mixtures. It is also not clear yet how ECHA will organise the process for bringing companies into contact that notified diverging C&L for the same substances. (Commission interviewee) The unit in charge of CLP in ECHA seems to be understaffed. (Commission interviewee)
A5 – Advice and assistance through guidance and helpdesks	All performance targets met, except for the high level of satisfaction expressed in feedback from guidance users	The guidance is well-used among respondents, but more than 25% of respondents disagree with the statement that the guidance was easy to find. Around 78% of respondents consider the guidance provided by the Agency appropriate and around 72% find the level of the guidance good or outstanding. Other respondents (22% and 28% respectively) give lower scores.	Member states complained about the speed of replies to questions. However, the questions are complex, all have to run through a system and there are needs to be arranged at the appropriate level (Helpnet, Commission services including sometimes Legal Service, CARACAL; depending on the type of question). Previously, discussions took place between Member states. Such intergovernmental aspects are less needed when having an Agency and for some Member states, this takes getting used to. (Commission interviewee) The HelpNet meetings have a consultative nature. ECHA sets the agenda. There is an electronic platform in place that facilitates commenting on various issues raised by ECHA or Member state helpdesks, the issues considered there are taken into account by ECHA when setting the agenda. (National Helpdesk interviewee)

Work Area	Desk research	Stakeholder opinions (survey)	Illustrative Stakeholder opinions (interviews/focus group)
A6 – IT support to operations	Delivery of several IT systems and functionalities was delayed in the years 2008-2010	In their recommendations for improvements, respondents refer mainly to planning and timing of software releases. In addition, there are several references to technical problems with the functionality of specific IT systems.	IT Systems needed upgrading although frequent changes does not amplify user friendliness. Newer versions are not backward compatible resulting in an increase of work load. (Industry interviewee) The ECHA website could increase user-friendliness as it lacks clarity in the routing and it is sometimes difficult to find documents fast. An example of this is the Registry of Intentions for harmonised C&L proposals, which cannot be found when starting from the "CLP" heading on the website. The same is true for opinions of RAC on proposals for harmonised C&L which can only be found via several intermediate search steps and not directly from the "CLP" heading. (Commission interviewee)
A7 – Scientific and practical advice for the further development of legislation	2 out of 3 targets achieved (the third target was not evaluated due to lack of data on the Agency's performance)	No comments on ECHA's performance.	Regarding nanomaterials, ECHA has devoted increasing numbers of highly qualified staff to the issue on which the Commission requested advice and that the Commission has benefited much from it. As effectiveness in this work area depends strongly on the "client's" perception of the added value of the advice, the effectiveness for nanomaterials is high. (Commission interviewee)

Work Area	Desk research	Stakeholder opinions (survey)	Illustrative Stakeholder opinions (interviews/focus group)
B1 – Committees and Forum	10 out of 16 targets achieved (for the other 6 targets, we lacked data on the Agency's performance)	10% of survey respondents do not agree that the RAC is performing its work independently. For the SEAC, MSC and Forum, this number is 3%, 5% and 0% respectively.	The workload of the MSC is high due to the diverse tasks, the need of learning about technical issues and detailed policy discussions. (MSC member) The workload within RAC is not evenly distributed among committee members. Some members hardly participate in meetings and do not volunteer for rapporteur work. (RAC member) The work between RAC and SEAC is overlapping and requires close cooperation. Important to remember the role of each committee as SEAC has to rely on answers given by RAC on specific issues and RAC has to submit relevant answers to be used in the impact assessment. (SEAC member) The agenda of the Forum is event-driven: issues for discussion are partly determined by the Forum members' experiences and partly by actual issues for enforcement. Members are mainly inspectors and their membership of the Forum is normally an additional task to their daily routine. Most of them had no experience with participating in EU coordination meetings prior to ECHA. They are active and keen to participate (the downside of not enforcing properly or in coordination with other Member states is having 'dirty' businesses in your country), but have limited time available next to their regular enforcement tasks. (Forum member)
B2 – Board of Appeal	No assessment. We lacked data on the Agency's performance for 7 out of 9 targets, results on the other 2 were mixed. This is partly due to the fact that the Board of Appeal only received a very small number of appeals during the review period.	No comments on ECHA's performance. Very few respondents indicate that they have had experience with the Board of Appeal, which stands to reason as the Board of Appeal only received a very small number of appeals during the review period.	The Board of Appeal has hardly had any cases thus far. This should not be interpreted as a positive judgment from industry, as not many appeal-able decisions have thus far been taken by the Agency. More cases should be expected once Evaluation, Restrictions and Authorisations have reached the decision-making stage. That said, the Board of Appeal is a very welcome institution, as it can save companies a lot of time when compared to a court case. The Board of Appeal is located at the Agency premises, but is operating completely independent from the Agency. (Industry interviewee)

Work Area	Desk research	Stakeholder opinions (survey)	Illustrative Stakeholder opinions (interviews/focus group)
B3 – Communications	5 out of 12 targets achieved, 1 clearly not achieved (timely publication of translations of guidance documents relevant to large numbers of SMEs) (for the other 6 targets (all with reference to the years 2007-2009), we lacked data on the Agency's performance)	21% of respondents indicate that they disagree that ECHA's communications are understandable to all stakeholders. However, the majority of stakeholders is positive about the effectiveness of ECHA's communications for their own organisations as well as contribution to the goals of REACH and CLP.	
B4 – Relations with EU institutions and international cooperation	2 out of 9 targets achieved, 1 (high satisfaction of the Commission with the Agency's support for international activities) clearly not achieved (for the other 6 targets (all with reference to the years 2007-2009), we lacked data on the Agency's performance)	No survey data collected	There has been frequent and good contact with different levels within ECHA (such as experts, directors, the Commission). ECHA is open for communication and that eagerness to learn from each other is characteristic for the international collaboration. (non-EU CA interviewee)
B5 – Dissemination	C&L Inventory not published in review period, dissemination website does not fully meet target	Between 18 and 38% (varying with the aspect concerned in specific questions) of survey respondents disagree that the dissemination website is effective.	There is no official deadline for making information available to stakeholders. The logical understanding would be to make it available as soon as the information is available. However, it (i.e. the publication of the C&L Inventory, *PwC*) has already taken more than a year which leads to stakeholders being deprived of the information they need for their learning processes and to contribute to the learning processes of ECHA as well as the Member states and other private actors. It is an example of how ECHA has not yet achieved the full transparency that may be expected. (NGO interviewee)

Work Area	Desk research	Stakeholder opinions (survey)	Illustrative Stakeholder opinions (interviews/focus group)
C1 – Management and Financing Structure	24 targets achieved, 5 partially achieved, 8 not achieved, for 9 no data were available	MB members are positive about the MB's effectiveness, stakeholder involvement, its mandate and the associated expertise represented by its members. Several MB members suggest that the MB could be more effective and efficient if it were: • smaller (10-12 members); • focusing on legal and financial matters rather than regulating chemicals; • implementing several practical suggestions.	ECHA's current financing structure is and remains a challenge: in the period 2007-2010 ECHA had to switch from subsidy funding to funding from fees paid by industry. In future, ECHA will get tasks from the Biocides Regulation as well and therefore a good and reliable accounting system to correctly allocate budget is key. Due to the current financing structure, there have been some budgeting and planning issues, mainly related to ECHA's budget dependency on registration fees, which remained uncertain till the end of 2010. Furthermore ECHA has a role as a public agency and is obliged to work under public subsidy and thus under public financial regulation of the EU. This is and remains challenging. (MB member)
D1 – The role of the Agency and its added value	1 target (recruitment of sufficient staff) partially achieved, for 1 no data were available in ECHA's General Reports	58% of respondents consider the Agency to be working transparently and autonomously to a large extent or completely	ECHA carefully listens to concerns and is open for dialogue. It is a matter of a supportive partnership. ECHA provides help when it is within its power as the Agency does not make law. Bi-weekly calls between ECHA and industry representatives take place to facilitate collaboration. (Industry interviewee)
D2 – The acceptability of the Agency	No assessment (no targets available)	84% of respondents are (somewhat) satisfied with the work of the Agency. 82% (strongly) agree that the Agency staff consists of competent professionals.	ECHA performed well taking into account the complexity of tasks. It is a professional agency with staff that has very good scientific and technical knowledge. ECHA has good understanding of its role; it is an independent organisation which gives advise but does not make policy. (Commission interviewee) ECHA should be more pragmatic and less rigid when it comes to preparing dossiers for the Committees. There is too much focus on implementing and analysing rather than finding solutions. (Commission interviewee)

Work Area	Desk research	Stakeholder opinions (survey)	Illustrative Stakeholder opinions (interviews/focus group)
D3 – The location of the Agency	1 target achieved (Agency operation by 1 June 2008), for 1 no data were available	No comments on ECHA's performance (the Agency was not able to influence the choice of its location). The information is provided for illustration only: • Around 40% of respondents indicate that the location presents difficulties for the Agency (recruitment, higher costs). • Around 32% of respondents indicate that they consider the distance to the Agency as an obstacle to their participation.	ECHA salaries are quite good (2 pay grades higher than normal, at least it was the case in 2007) and that approach has worked as many CVs came, and ECHA could choose highly qualified people. However, there is a signal that the families of the staff are not satisfied with Helsinki. Therefore, there is a concern that after several years there will be a challenge to keep the people. There are already a lot of Finns working in the Agency. (Commission interviewee) From some parts of Europe, travelling to Helsinki and back requires two full days. This may vary depending on the season, as flights are more frequent in summer. (MSCA interviewee) It does not seem to be convenient to travel to Finland for half a day. That creates a barrier to bringing an extra person for a specific issue. (MSCA interviewee)

2.3.3. *Some industry associations have specific suggestions for improvement of REACH and CLP implementation by the Agency*

74 Some industry respondents have mentioned examples of where ECHA could improve its implementation of REACH and CLP. We have included their main feedback (paraphrased by us in order to allow summary of feedback from multiple respondents) below:

- The inquiry process does not function properly.
- ECHA needs to have a pragmatic approach by focusing on new substances or/and companies with which ECHA has a genuine concern (e.g. over substance identity).
- Functionality of the IT system for pre-registration did not meet expectations.
- The registration itself turned out not to be the crucial step in the process. Because completeness checks are automated, subtle issues like whether requirements of legislation are truly met or not – can only be exposed via human intervention. Such issues are pushed forward to evaluation and are not raised during registration itself. (*Note PwC: This is largely an observation about REACH (specifically Articles 20 (2) and 41 (1)) and therefore not so much a point for improvement by ECHA.)*
- There does not appear to be a process for prioritising chemical substances for evaluation to ensure that the most hazardous are moved through the process ahead of less hazardous.

2.3.3.1. ECHA could have shared more of its workload in registration with industry

75 Several respondents and interviewees mentioned that the work of the Agency could be delegated and distributed better for instance over (more) working groups of ECHA's bodies. In addition it was mentioned by an industry representative that, where possible, the support of industry stakeholders could be called upon to propose, prepare and/or execute certain tasks, tools and/or procedures. An example of this is the pre-registration bulk-upload tool as developed by industry association CONCAWE. This tool has proven to be very useful, also for non-CONCAWE members. Similar solutions may be provided in preparation of future registration deadlines.

2.3.4. *ECHA's communications could be improved on several points*

76 Stakeholders have complained about many delays and technical problems at the early years. Even though it was considered to be normal for an Agency established in such a short time, some problems persist and are worth being elaborated on.

77 The ECHA website could increase user-friendliness as it lacks clarity in the routing and it is sometimes difficult to find documents fast. An example of this is the Registry of Intentions for harmonised C&L proposals, which cannot be found when starting from the "CLP" heading on the website. The same is true for opinions of RAC on proposals for harmonised C&L which can only be found via several intermediate search steps and not directly from the "CLP" heading. As a result, non-routinous users of the website (i.e. the majority of users) find it difficult to find the information they need.

78 This could result in an increased burden on national helpdesks, as they are the first point of contact for questions about REACH and CLP. Also, we consider that it might lead to users getting the impression that ECHA is not open or transparent, when in fact it is (because the information was made available through the website during the review period, but was difficult to find).

79 With regards to guidance documents, we have received and analysed much feedback from various stakeholders. The most prominent issues mentioned were:

- issuing guidance too late: some guidance arrived after the deadline users were supposed to submit or the guidance was significantly updated within a short timeframe of the critical deadline;
- guidance not being up-to-date: as the updating process can take quite some time, the guidance sometimes lags behind solutions or new knowledge available in the field;

- limited reflection of stakeholder feedback: several stakeholders feel that their feedback is not accounted for (sufficiently) in the guidance, industry representatives sometimes feel that they, as the real experts on their own chemicals, are not sufficiently heard;
- lack of availability of guidance in all 22 EU languages.

80 The concept of pre-SIEF was introduced by the Agency and the role of a SIEF Formation Facilitator (SFF) defined. REACH-IT allows Pre-Registrants to volunteer to be SFF by identifying this at pre-registration. The SFF initiates and conducts discussions after pre-registration, and facilitates the exchange of the information and data required to form a SIEF. This is also further supported through several publications, such as guidance and Q&A documents.

81 Furthermore, ECHA launched the campaign "the clock is ticking – form your SIEF now" and through tidying up the list of pre-registered substances the SIEF groupings were made more useful and accurate. The Agency assisted industry by organising workshops, webinars and other events, through direct contact with registrants and by focused support to Lead Registrants. Finally, by launching a Technical Completeness Check IT tool, ECHA supported registrants in improving the quality of their registration dossiers, thereby reducing the correction of errors afterwards.

82 We conclude that with regards to the facilitation of SIEFs, ECHA has been active and supportive to industry whereas this is not an explicit task of the Agency. However, according to industry stakeholders, ECHA did so only after strong suggestions by industry.

83 A last issue worth mentioning here is the lack of clarity perceived by stakeholders about who in ECHA is the proper contact person for a specific issue or question. Interviewees, especially representatives from the Commission and Member states have indicated that there is a need for clear focal points for each topic, who are able and authorised to answer questions on behalf of the Agency, in order to better facilitate policy-making and enforcement activities.

2.3.5. ECHA's bodies have functioned well thus far, efficiency may be improved

84 On the whole, ECHA's various bodies have functioned well during the review period. A minority of stakeholders have expressed concerns about the independence of the Committees, but no conflicts of interest have come to our attention during the Review.

85 We have found some inefficiencies in the functioning of ECHA's Committees. We will elaborate on these points in paragraph 3.1.2.

2.3.5.1. ECHA's Committees were well prepared for the first dossiers, some criticism on their functioning

86 ECHA has three Committees, consisting of members nominated by the Member states and appointed by ECHA's MB (RAC and SEAC) or appointed by the Member states (MSC). The Committees have various roles, but each has a role in some of ECHA's main processes (the 'pillars of REACH'). For the full description of the responsibilities of each committee, we refer to the ECHA website.[20] These are:

- the Member State Committee (MSC) – dossier and substance evaluation and authorisation;
- the Risk Assessment Committee (RAC) –classification and labelling, restriction and authorisation; and
- the Socio-Economic Assessment Committee (SEAC) – restriction and authorisation.

87 The members of the Committees are mostly employees of the Member state governments that nominated them and often part of the MSCA in their home country. Only a few Committee members are scientists that are independent from Member state governments. This is a direct result of the Member state nominations rather than ECHA's decision making. Although some smaller Member states do not have technical experts in their own

[20] http://www.echa.europa.eu/about/organisation/committees_en.asp

country, Member states such as Estonia and Slovenia have solved this problem by nominating German technical experts to be members of RAC on their behalf.

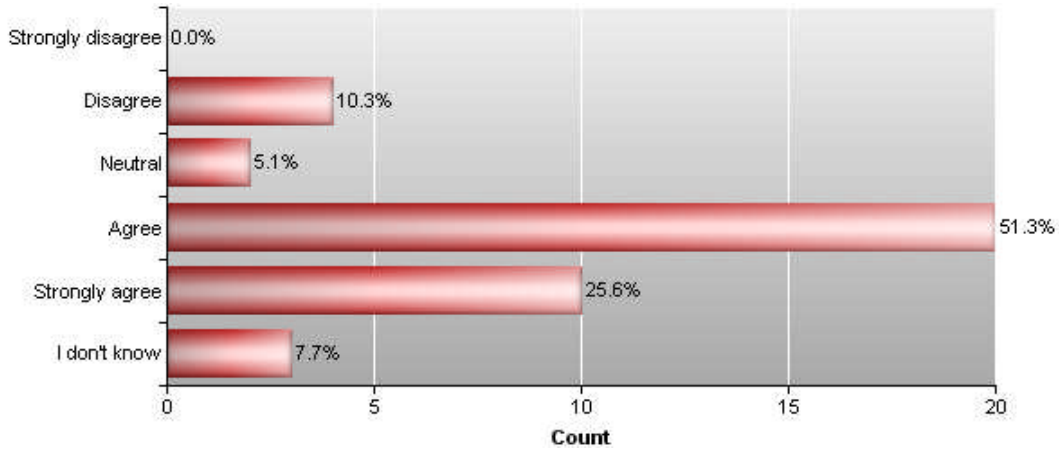
88 On 1 June 2009 ECHA submitted its first recommendation for inclusion of priority substances in Annex XIV to the Commission. Title VIII of the REACH Regulation, regarding restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles, and Annex XVII listing the adopted restrictions entered into force on the 1st of June 2009. The CLP Regulation, which came into force in the beginning of 2009, identifies a number of tasks for ECHA related to classification and labelling of substances. The RAC adopted its first opinion on one substance (Diantimony Trioxide) on 3 July 2009.[21]

89 This means that ECHA's Committees, which had been formally in place since 2007 and had started meeting at various dates in the first half of 2008, saw their workload increase as the first dossiers started to come in. This applies most strongly to the RAC. The uptake of the work continued in 2010, but still a very limited number of dossiers has been processed by the RAC and the SEAC when compared to the number of restriction and authorisation dossiers expected for the coming years.

90 By the beginning of 2009, all Committees had agreed on their rules of procedure and prepared the necessary groundwork to function adequately. Several Committee members have commented on this, indicating that the Committees have often met to discuss rule of procedure and theoretical approaches, without any dossiers on the table. This led to some examples of "overdesigning" procedures. This point will be addressed further in paragraph 3.1.2.

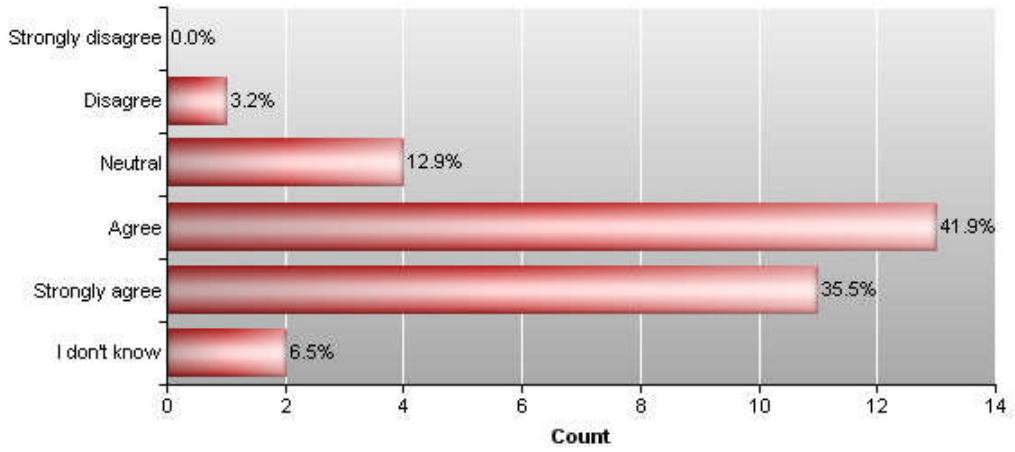
91 As the survey results presented below demonstrate, around 75% of the Committee and Forum members who participated in the survey indicate that the RAC, SEAC and MSC reach their decisions independently. However, for each committee there are also some respondents who are neutral to or disagree with the statements. Interestingly, no respondents have indicated that they strongly disagree.

All outcomes of RAC processes are the result of a fully independent decision making process. (respondents: Committee and Forum members who indicated that they have experience with the RAC)

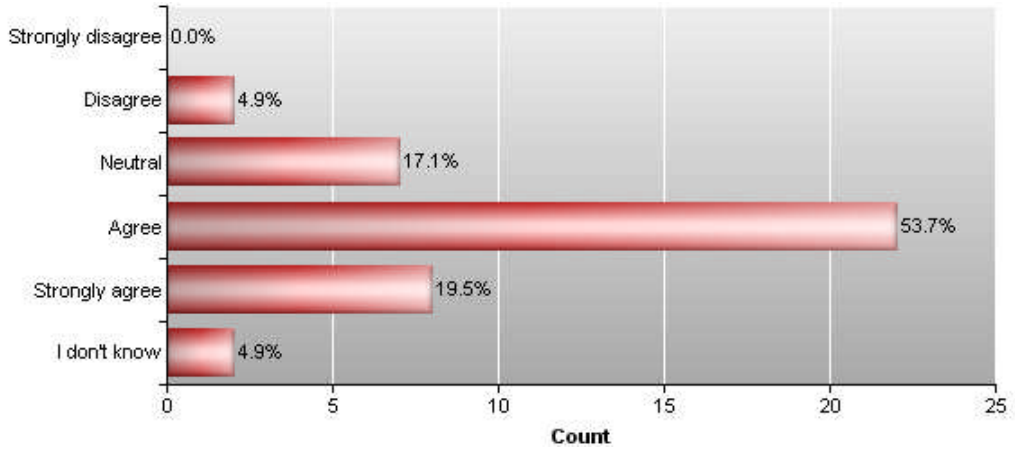


[21] The background document to the RAC opinion is available at http://www.echa.europa.eu/documents/10162/17090/background_document_diantimony_trixide_en.pdf

All outcomes of SEAC processes are the result of a fully independent decision making process. (respondents: Committee and Forum members who indicated they have experience with the SEAC)



All outcomes of MSC processes are the result of a fully independent decision making process. (respondents: Committee and Forum members who indicated they have experience with the MSC)



92 Almost all Committee members have commented that during meetings of RAC and SEAC policy considerations of Member states seem to have played a significant role at times, thus diluting the technical debate. While some of these interviewees have indicated that these problems have decreased over time as Committee members became more experienced in their roles, others do not share this view. A solution recommended by a SEAC member was that all RAC and SEAC members should be independent technical experts instead of government employees of the Member states.

93 The RAC and the SEAC are defined in the REACH regulation as the committees that "take over the role of the Scientific Committees attached to the Commission in issuing scientific opinions in its field of competence".[22] Thus, they clearly have a scientific role. What is more, REACH also clarifies the RAC and SEAC members' independence from their nominating Member state: "The Member states shall refrain from giving the members of the Committee for Risk Assessment or of the Committee for Socio-Economic Analysis, or their scientific and technical advisers and experts, any instruction which is incompatible with the individual tasks of those persons or with the tasks, responsibilities and independence of the Agency.".[23]

94 However, the REACH regulation also includes the following text: "It is necessary to ensure close cooperation between the Agency and the competent authorities working within the Member states so that the scientific

[22] REACH, preamble 102.

[23] REACH, Article 85 (7).

opinions of the Committee for Risk Assessment and the Committee for Socio-economic Analysis are based on the broadest possible scientific and technical expertise appropriate which is available within the Community.".[24] As described above, this cooperation currently takes place for most Member states by nominating representatives from the competent authority to serve on the Committees. As is evident from the current composition of the Committees, the MB has interpreted the REACH requirements to mean that these representatives meet the requirements for the Committees and has approved of nominees who are not independent scientific experts.

95 The issue of policy arguments being part of the discussion was seen by the Committee members interviewed as more serious when concerning the RAC members than when concerning the SEAC. Interviewees also noted that ECHA, in the person of the Chairs of each of the Committees, has at times intervened in discussions to prevent the discussion from deviating from the subject at hand. However, according to some Committee members, this has not been sufficient to guarantee a fully objective scientific opinion-forming.

96 We conclude that while REACH clearly refers to scientific and technical expertise as key to the composition of the Committee, in practice the Committee members are closely connected to the respective MSCAs. This may hamper the objective scientific opinion-forming of the Committees, as well as reduce the efficiency of their decision-making. We will return to the second point in paragraph 3.1.2.

2.3.5.2. The Forum contributes to consistent implementation at community level

97 The implementation of REACH and CLP through the activities of ECHA is consistent. We have not found any indications that REACH affects certain Member states differently than others. However, one main implementation aspect is enforcement of REACH requirements. For enforcement, ECHA has no implementation responsibility. This responsibility lies with the MSCAs on enforcement. ECHA facilitates coordination between Member states in the Forum.

98 As the graph below demonstrates, Forum members are satisfied with its composition and procedures, with the sole exception of the Forum's role in coordinating the exchange of inspectors. Also, Forum members responding to the survey all agreed (or strongly agreed) with the following statements:

- *The Forum has adequate procedures to ensure the independence of its chairman and members.*
- *The Forum has adequate procedures to ensure that all members are allowed to contribute to its decision-making processes in an equal manner.*

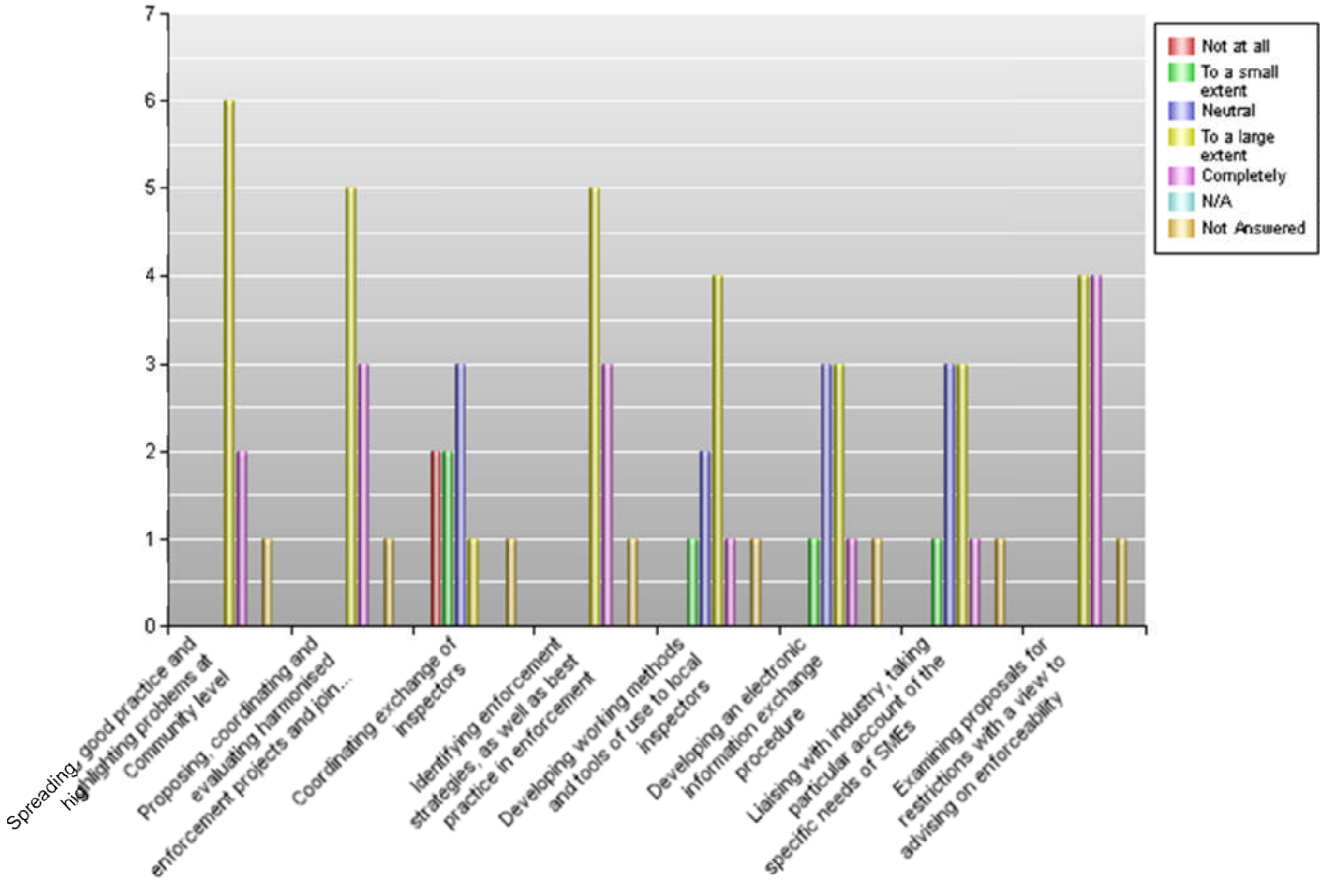
99 Finally, the following suggestions were made for the improvement of the functioning of the Forum by its members:

- *Better choice of Forum representatives at national level.*
- *It is important to distribute the workload with respect to the established working groups under Forum. However, this will of course be dependent on the national resources of the Member states.*
- *Forum may advise to ECHA to clarify if the necessary resources (time and expert support) are allotted to Forum members by the corresponding Member states for the due fulfilling of their duties.*

100 We therefore conclude that given the fact that the Forum is a new coordination mechanism, its composition and procedures are well-suited to its role and tasks, but that some points for improvement are evident from the feedback of Forum members.

[24] REACH, preamble 104.

The composition and procedures of the Forum ensure (Forum members)



2.3.5.3. The Board of Appeal is perceived to be well-organised

101 From both the Chair, members, additional and alternate members of the BoA, as well as other stakeholders (Industry, NGOs, Commission representatives), the consistent feedback through the survey (questions 10.1.1 through 10.3.3 in Annex D) and interviews is that sufficient guarantees are in place for the BoA to be a credible independent adjudicator. Industry stakeholders have indicated that they are satisfied with the existence of the BoA, as going to court (in the absence of an appeal procedure) would have led to higher costs and much more time spent on appeal procedures.

102 Although the conditions for an effective BoA are in place as described above, the actual effectiveness of the BoA is at this stage impossible to assess, as only two appeals have been lodged during the review period.[25] In addition, one appeal filed at the BoA resulted in a rectification[26] by the Executive Director (through which the decision subject to appeal was amended), thus not shedding light on the functioning of the BoA, and the other one was decided on by the BoA in 2011, thus outside the review period. It should be noted here that one industry representative suggested that the low number of appeals is due to the fact that during the review period, ECHA did not take a great number of decisions that are subject to appeal under Article 91 of the REACH regulation.

103 One clear suggestion for improvement has been provided by the alternate members of the BoA, who feel they are out of touch with the proceedings of the BoA and would like to receive more information about the way cases should be handled to be prepared when they themselves are called upon to serve on the BoA.[27]

[25] All BoA decisions can be found on http://www.echa.europa.eu/web/guest/about-us/who-we-are/board-of-appeal/decisions.

[26] In conformity with the procedure under Article 83(2), sub m of the REACH regulation.

[27] Cf. the answers to survey question 10.3.3 in Annex E.

104 A second point was raised during an interview with a BoA alternate and pertains to the procedure for declarations of possible conflicts of interest by members and alternates of the BoA. Currently, a member or alternate is required to inform the Chair of the BoA when they find themselves possibly conflicted, however the manner in which to inform the Chair is not specified for cases in which an alternate or additional member asks for the Chair's opinion on something the member plans to do that might create a conflict of interest. The recommendation was made to require the members and alternates to inform the Chair in writing, so that a record will be available and decision making is not dependent on the recollection and interpretation of both the member/alternate concerned and the Chair of the BoA. In order to protect the independence of BoA decision making beyond all doubt, we support this recommendation. ECHA has informed the Review Team that it supports this and that the recommendation has already been discussed by the MB and is likely to be included in the next revision of the BoA Code of Conduct.

2.3.6. *There are some barriers to effective international cooperation*

105 In the context of international cooperation, a Commission representative indicated it is important that ECHA sufficiently communicates with other international bodies or governmental agencies to prevent the duplication of work in areas such as assessment of chemicals or benefit from available knowledge on for example QSAR modelling. According to that same interviewee, sharing of data is prevented by the need for Memoranda including cumbersome procedures.

106 ECHA reports show that the Commission is not fully satisfied with the support provided for international cooperation activities by the Agency. According to a Commission interviewee, for ECHA to meet REACH requirements and deliver the necessary support to the Commission, it is important that they respect each other's roles. In this context, it is important that no bilateral memorandum of understanding (MoU) is considered/elaborated without the Commission's approval. Indeed, according to the interviewee, MoUs should only be drawn up by ECHA when requested by the Commission. This interviewee also considers it important that ECHA's discussions with third countries focus on supporting the implementation of REACH and efforts to develop international standards and stay clear of policy discussions.

2.3.7. *Dissemination of data is no success yet*

107 Dissemination was considered to be an issue by various types of respondents. In this paragraph we address the following aspects of dissemination:

- the C&L Inventory;
- dissemination of registration data through ECHA's dissemination website and the OECD eChem Portal;
- access to data for MSCAs and the Commission.

2.3.7.1. C&L Inventory

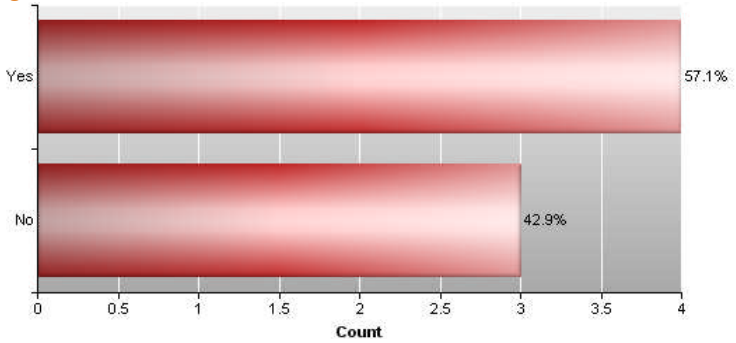
108 The C&L Inventory should have allowed access to data during the review period for industry, downstream users and non-industry stakeholders such as NGOs, based on the registrations and C&L notifications made by industry. However, an intermediary C&L Inventory has been postponed from December 2010 to May 2011, and again in June 2011 to the autumn of 2011, and in January 2012 to mid-February 2012[28] – despite having been announced in ECHA's 2010 Work Programme. The C&L Inventory was published in February 2012 at http://echa.europa.eu/web/guest/regulations/clp/cl-inventory.

109 This could possibly be explained by the fact that the C&L Inventory was originally planned to be available by the end of 2010, in line with the deadline for notifications which fell on 1 December 2010 under the original text of the REACH Regulation, before it was amended by CLP. However, when the C&L Inventory became part of CLP, it was planned to be delivered in 2011. By both counts, as well as ECHA's own planning in its annual Work Programmes, the Inventory has been delayed.

[28] On 18 January 2012, ECHA published the following news message: "The Public Classification & Labelling (C&L) Inventory is soon available: ECHA is close to launching the Classification and Labelling (C&L) Inventory on notified and registered substances that have, so far, been received from manufacturers and importers. The new portal on the ECHA website will be available to the public during the week commencing 13 February 2012." (http://echa.europa.eu, accessed on 20 January 2012)

110 Interestingly, industry representatives (57,1%) find it more or less acceptable that the public version of the C&L Inventory is not yet available.

It is acceptable that the public version of the C&L Inventory is not yet available. (respondents: industry)



111 As one industry representative remarked in the survey:

"Given the expected lack of harmonisation to be found in the C&L Inventory, publication of the Inventory will generate considerable confusion in the marketplace".

2.3.7.2. Dissemination of registration data

112 The dissemination of non-confidential (pre)registration data through ECHA's dissemination website has been criticised as insufficient by representatives of various stakeholder groups. That has to do not only with operational issues, but also with the confidentiality of registrants' information which ECHA has pushed too hard, according to the NGOs we have interviewed.

113 The dissemination website of ECHA is one outlet for dissemination. During the review period ECHA conducted its main dissemination activities through the OECD eChem Portal, which allows linking databases on chemicals throughout the world, based on formats and IT-standards that were agreed by the OECD MS, while further developing its own dissemination website. Various interviewees have recognised that the eChem Portal offers more possibilities to access ECHA's registration data than the ECHA website, but also indicate that some information is available through neither of the two outlets. ECHA plans to include searchable information on uses of substance and C&L on its own website in successive versions. This information cannot be disseminated through the eChem Portal as it is not part of the database used by the OECD and participating national authorities.

114 The following improvements were proposed by survey respondents and interviewees (Industry, NGOs, Commission, CARACAL members):

- *Disseminated data are mere IU5-Extracts, only useful for experts. For users in SMEs the displayed data need to be simplified and important information need to be highlighted. E.g. in section on C&L the actual classification of the substance needs to be highlighted, currently the actual classifications "disappear" between entries like "conclusive but not sufficient for classification" or "data lacking". Hazard pictograms should be visible.*
- *More reader-friendly subsections: E.g. the section "guidance on safe use" is only displayed in unformatted text*
- *Function to download/print all data of a substance e.g. as one pdf-file.*
- *Better search function to find alternative substances posing fewer risks: It should be possible to enter classification or use-descriptor as search parameter. Without that function it is difficult to find alternatives for a substance with a certain use. Also eChem Portal, for which a link is provided on the dissemination site does not include those search parameters*
- *The Data should be presented in an easy to go through format*
- *Dissemination of data in all EU languages would not be cost effective.*

- *All dissemination tools should be directly accessible from a box on the home page. Right now, they are difficult to find: you have to navigate in the left-side menu.*
- *The current publication process is good. Still some issues on ECHA decisions: the Agency has rejected suggestions for unclear reasons ("the suggestions were not acceptable to ECHA", without further details).*
- *Another issue is that we do not know who the lead registrant for a substance is. This is not part of the REACH regulation, but it has been assumed. As a result, we (NGO) cannot contact lead registrants to discuss a reduction of the use of animal testing.*

115 All of these comments, except for the last one, relate to the presentation of dissemination data on the website rather than the content of what is presented and are therefore within ECHA's capacity to solve. It is clear that some improvements – such as the first one mentioned above – will require more time and effort than others. Hence, we suggest that the Agency consider this feedback (and other suggestions about the dissemination website it has received directly from stakeholders and not through this report) and assess the possibilities to further improve the dissemination process.

116 We add to the above comments that the dissemination of information to European consumers and the general public has not been part of the scope of this Review. However, given the importance of the general public as a stakeholder, we suggest that this aspect be taken into account by the Commission and ECHA when considering the work of ECHA from 2012 onwards.

2.3.7.3. Access to information for MSCAs and the Commission

117 Another aspect of dissemination is criticised by representatives of MSCAs and the Commission, as they are expecting to have access to registration data for policy-making and enforcement purposes. In general, the Commission is not satisfied with the access to information. During the review period Commission employees did not have access.

2.3.8. Management Board

118 The MB consists of 27 members appointed by the Council (each Member state nominating one), a maximum of six representatives appointed by the Commission, including three individuals from interested parties without voting rights and two independent persons appointed by the European Parliament. The attendance of mandated representatives has been 83 % on average, but the absent members have mostly given a proxy to a colleague.

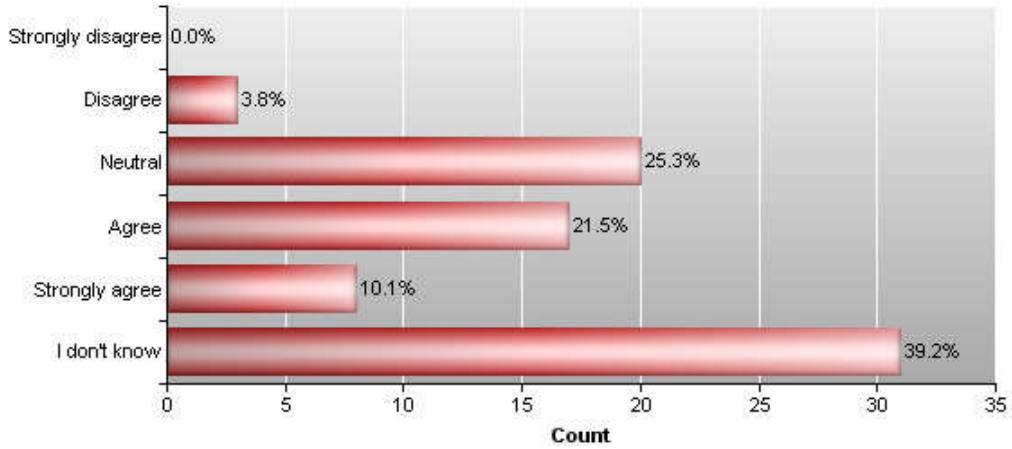
119 The tasks of the MB include the adoption of the work programmes, the annual report and other strategic documents as well as the adoption of the budget and the delivery of an opinion on the final accounts. The accounts are formally also reviewed by the European Court of Auditors (with a focus on the legality of the expenditure and the correct respect of procedures) and the European Parliament. In practice, DG Enterprise and Industry of the Commission (as ECHA's "parent DG") and DG Budget of the Commission (with a focus on the relevance of the expenditure vis-à-vis the Agency's formal tasks) also review the accounts.

120 During the review period, the MB has appointed the Executive Director, the BoA and the members of the Committee for Risk Assessment and the Committee for Socio-Economic Analysis, and has invited stakeholders to attend Committee meetings.

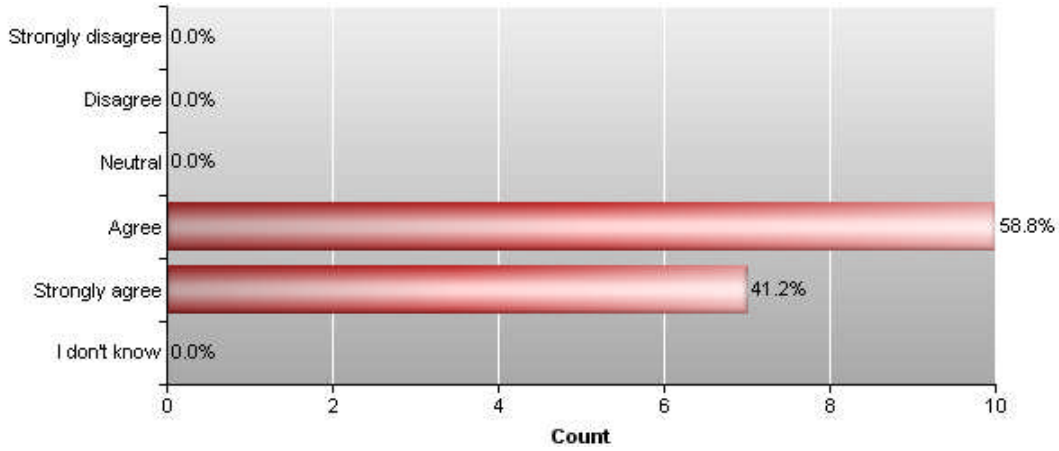
121 The meeting frequency used to be five per year, but now the MB is meeting quarterly. Much of preparation work is done in working groups (WGs). The members of the MB are mostly senior level representatives like Director Generals from different ministries in MS. Their backgrounds vary and can be for example environment, enterprise or labour. According to the feedback from members of the MB, the Committees, the Forum and the BoA, the MB is large but committed to the work. Competencies and experiences are considered appropriate by these respondents.

122 Most members of ECHA's various bodies are positive about the functioning of the MB, as demonstrated by the graphs below. [29]

The size and composition of the Management Board strike a reasonable balance between effective decision making and ensuring stakeholder representation, involvement and commitment. (respondents: members of ECHA bodies)

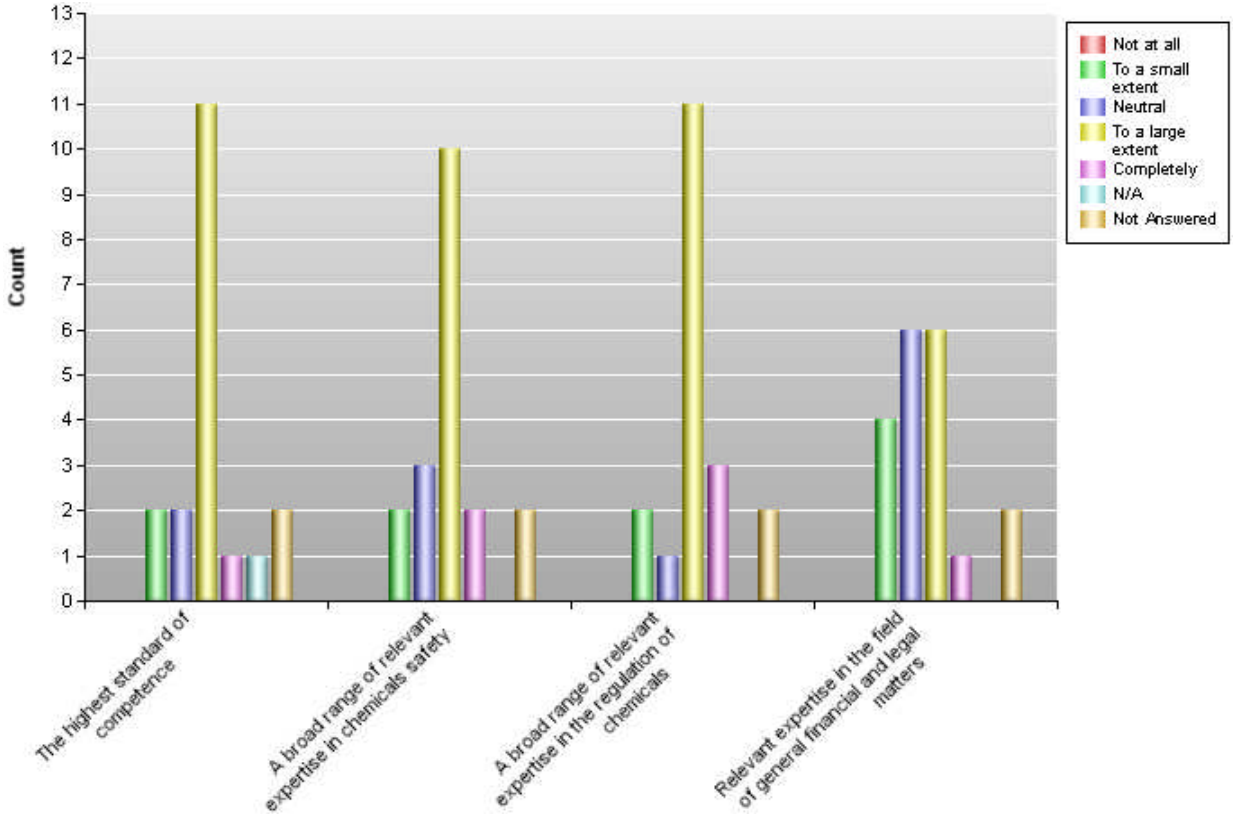


The Management Board has the proper mandate. (respondents: MB members)

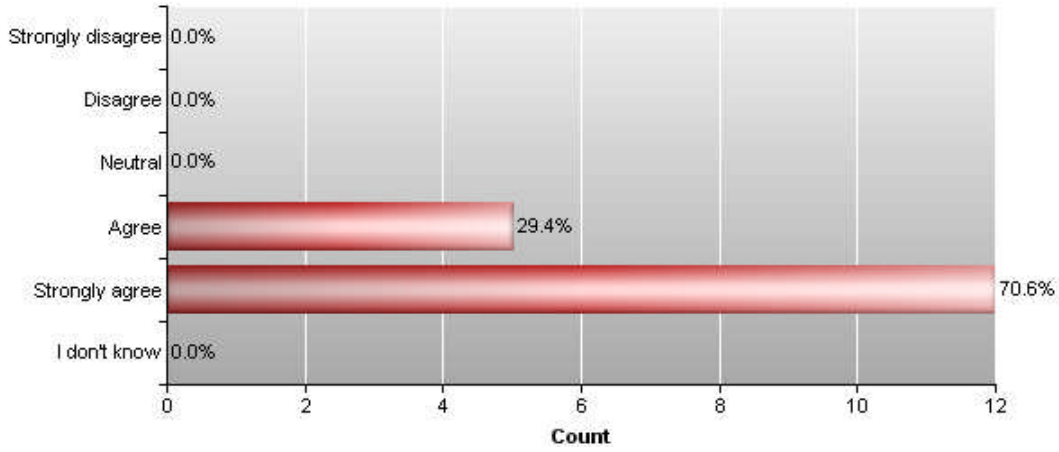


[29] See Annex D, questions 13.1 through 13.8 for all detailed survey answers.

The composition of the Management Board ensures: (respondents: MB members)



Decisions made by the Management Board are adequately implemented by ECHA. (respondents: MB members)



123 When asked for recommendations to improve the functioning of the MB, several MB members indicated that it could be more efficient if not all Member states would have to be represented. This would however require an amendment to the REACH regulation and cannot be achieved by ECHA alone.

124 As evident from one of the other comments about improvements to the MB and also mentioned several times during interviews with MB members, the MB should limit its discussions to the management of the Agency and not dwell on chemicals policies. Doing so would focus the discussions and should be expected to increase the (already good) quality of decision making. We concur with this view, as the MB does not have a mandate to be involved in policy discussions.

2.3.9. *Stakeholders say ECHA could improve effectiveness and transparency*

125 We found ECHA has a good working relationship with the Commission. In the start-up phase the Agency was staffed with secondees from the Commission who supported strongly the establishment of different systems, quick knowledge transfer and getting all processes operational. The Agency has faced rapid growth in its start-up period and is now transferring from a fast growth organisation to a stable organisation.

126 ECHA interviewees have indicated that at various times (especially in 2007 and 2008) the Agency was dependent on opinions or legislative interpretations formed by the Commission. This concerned various aspects of the implementation of REACH, but most pressing were the inputs required to develop REACH IT and other tools during the years 2007-2008.

127 As commented by one of ECHA's staff members:

"In IT things are black and white. You cannot program for a process, unless you can clearly map every step of it."

128 As a result, ECHA's IT tools required multiple updates causing companies using ECHA's IT tools to do additional work or be confronted with downtime on systems that were upgraded. Another recent example was that the functionalities for submitting applications for authorisation in REACH-IT were delayed until after the discussions with the Commission would be finished in 2011.

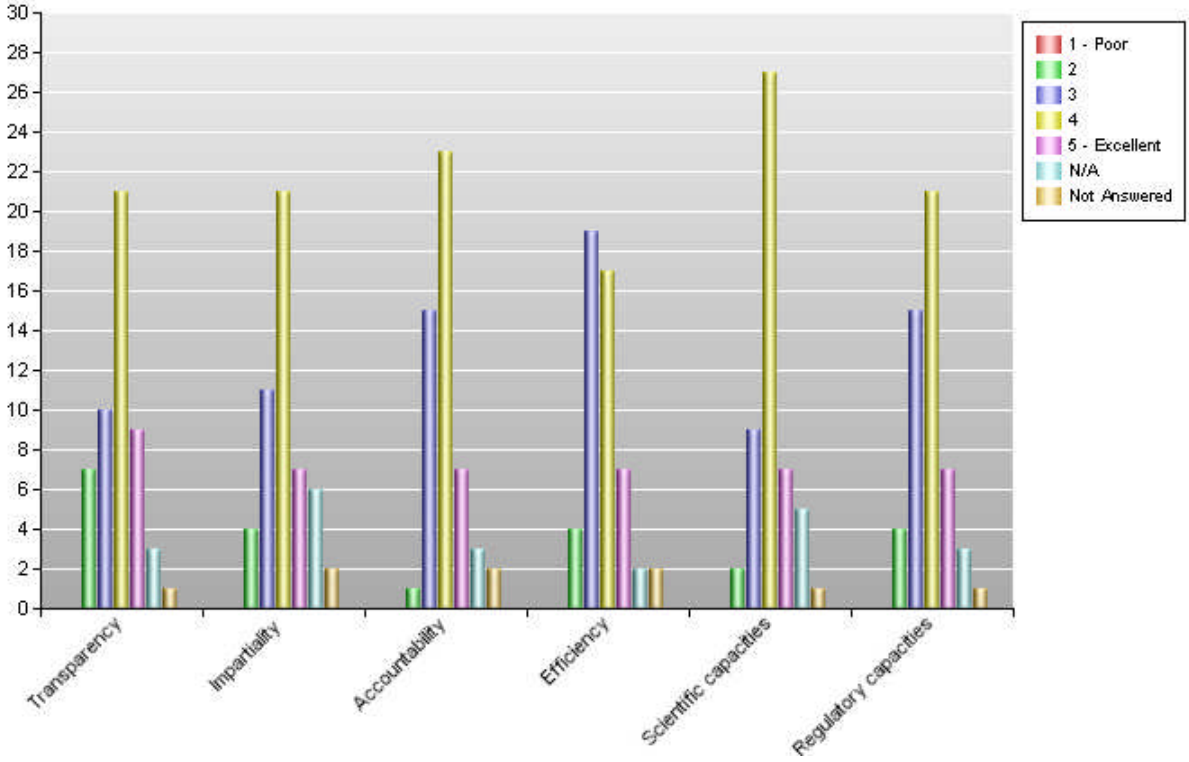
129 A suggestion made by industry and NGO interviewees was that ECHA could make more decisions itself. The general feedback from stakeholders on this point was that ECHA has developed a culture of risk-aversion and caution. According to interviewees, when facing uncertainties and difficulties in interpretations the Agency would generally turn to the Commission instead of taking a decision itself, leading to delays of up to 18 months. The stakeholders were generally unsatisfied with that and claimed ECHA to be not sufficiently self-confident, one of the possible explanations that were given was the unique role and young age of the Agency. Stakeholders therefore recommend that ECHA get more courage in decision making without being afraid of complaints and appeals. As one stakeholder added, overcoming the culture of caution will have the added advantage that multiple stakeholders can learn from the effect of decisions that lead to appeals:

"Cases lodged with the BoA or the European Court of Justice will provide clarity in legal interpretation. ECHA management should be open to use these opportunities and form clear opinions, thus allowing all stakeholders to learn about interpreting REACH."

2.3.9.1. Transparency can be improved

130 In general, ECHA performs well in the eyes of all stakeholders. The graph below shows that especially the Agency's scientific capabilities are considered good. Efficiency, impartiality and transparency – although still rated positively – show more room for improvement. Of these, efficiency will be addressed in more detail in the next chapter.

How would you rate the Agency as regulatory authority for the implementation of REACH and CLP on the following aspects in the sense of the aims of REACH? (respondents: all stakeholders)



131 The issue of transparency seems to be crucial for the Agency. We have received substantial feedback from various types of respondents on this issue. Generally, non-industry respondents claimed that while ECHA's formal reports are quite good, the Agency is too cautious when it comes to confidentiality of company data, thus reducing potential benefits to general public as well as to its non-industry stakeholders. Particularly NGOs have indicated they are not satisfied that ECHA does not seem to evaluate all confidentiality claims of companies due to lack of resources. They indicate that ECHA should make sure that all claims are evaluated and companies are not "automatically" granted confidentiality protection to save resources. ECHA has responded to this comment by indicating that almost 1,100 confidentiality claims were received in 2010 and most of those could not be assessed until the associated registration dossiers had been processed completely. Hence, ECHA planned to assess most of the claims during 2011. Hence, we have found no evidence that substantiates the NGOs' suggestion, but cannot give a definitive conclusion as the process was not yet completed at the time of the review.

132 Industry representatives have been critical on the way the input from the industry is taken into account by ECHA and the fact that discussions on Evaluation, Restriction and Authorisation are time-bound (which similar discussions were not under the regulatory framework preceding REACH). As a result, companies have complained about missing the opportunity to participate in meetings of the MSC, RAC and SEAC, because they were unaware of when they could attend and/or participate in meetings. They indicate that, together with industry associations, ECHA does have a responsibility to communicate the new procedures for stakeholder participation more clearly in order to ensure a good representation of industry interests in Committee meetings.

133 NGOs have a similar perspective but are not so much concerned with the timing of their attendance of Committee meetings, but rather with the fact that some discussions still take place behind "closed doors". They indicate that accredited stakeholders of the Agency are not permitted to attend Committee sessions where information classified as confidential is the subject of discussion. This relates to the NGOs' complaint that – in their view – more confidentiality requests are granted than necessary (as mentioned above), because it is precisely the granting of confidentiality requests that prevents them from attending Committee meetings in which the information declared confidential is discussed.

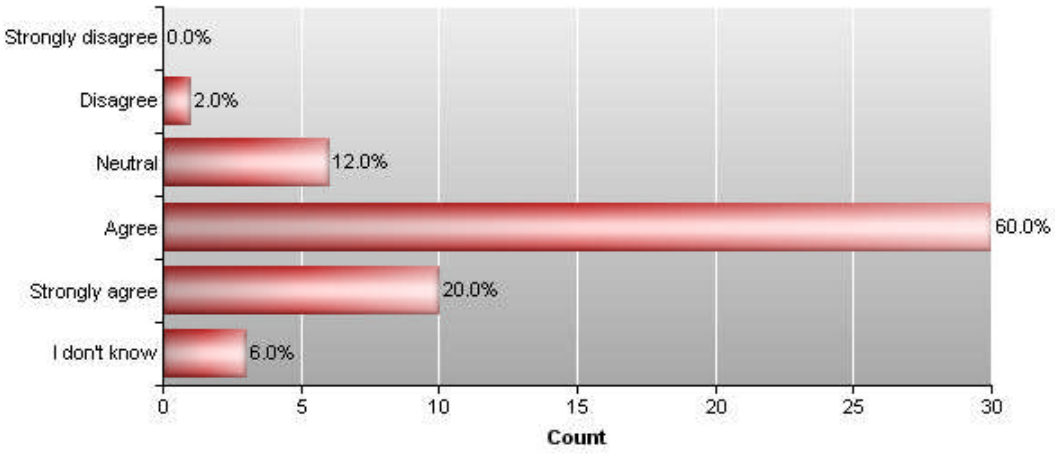
2.3.10. ECHA is generally seen as independent, but should prevent the impression of favouring industry over other stakeholders

134 ECHA states as part of its mission[30]:

"...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."

135 All stakeholders indicate that ECHA can be approached with comments and is responsive to feedback. Also, the Agency is generally seen as independent.

The Agency provided added value to the implementation of REACH and CLP as it operates independently from all stakeholders. (respondents: Industry, NGOs, DCG commission representatives, CARACAL representatives)



136 However, there is a general feeling among non-industry stakeholders that ECHA is more receptive to the needs and wishes of industry stakeholders than non-industry stakeholders. The following examples were mentioned in interviews:

- ***NGO and MSCA suggestion:*** ECHA has conducted several workshops with industry stakeholders only, for example concerning the development of IT tools for registration or the interpretation of various aspects of REACH and CLP. Non-industry stakeholders indicated that in such workshops, industry's interests are served tailoring ECHA's activities to their requirements when possible. NGOs were not asked for input in a similar manner and suggest that it happened more than once that ECHA asked them for input when implementation of industry suggestions was already underway and had to rework part of its solution because of valid points made by NGOs.
- ***NGO suggestion:*** ECHA is required under REACH to review confidentiality requests from companies and decide on whether or not confidentiality applies. However, many confidentiality requests have not been reviewed by the Agency and, as a result, automatically granted. This limits the access to information for other stakeholders. (see also paragraph 2.3.9.1 above) ***ECHA feedback*** is that this is not the case. All confidentiality claims received in the review period have been assessed or are expected to be assessed within the legal timeframe.
- ***NGO suggestion:*** Company names are not part of the dissemination of data through the ECHA website or the eChem Portal. NGOs have indicated this to be hampering their work.
- ***NGO suggestion:*** Even accredited stakeholders whose representatives signed a non-disclosure agreement are not allowed to be present during Committees' decision-making sessions.

[30] 2010 Work Programme, page 5.

137 Not all facts that these comments refer to have been assessed in the course of the Review. However, in light of ECHA's mission, even the impression of a bias towards one stakeholder group could be detrimental to the Agency's effectiveness. We will return to this point in paragraph 5.2.4.

3. ECHA's overall efficiency was reduced by complementary activities that often increased effectiveness

138 In this chapter we address the efficiency of the Agency by considering the resources used to achieve the performance as described in chapter 2. We consider the following main evaluation questions:[31]

- To what extent is the Agency's internal organisation contributing to a sound management of resources including the execution of the budgets?
- To what extent are the indicators used by the Agency appropriate and sufficiently extensive to measure the contribution to the REACH objectives?
- Is budgetary efficiency achieved without (through) transferring costs or other burdens to other public or private actors?

139 Efficiency is defined in the Review as: "The extent to which the desired effects are achieved at a reasonable cost (best relationship between resources employed and results achieved)"[32]. We have therefore operationalised efficiency as the ratio of effectiveness (results achieved for the required tasks under REACH and CLP) to realised costs (as compared to the original budget). As a result, inefficiencies identified in ECHA's operations may result from:

1. activities contributing to achieving desired results on which more resources were spent than originally planned or than necessary;
2. resources spent on activities that do not contribute to achieving desired results; or
3. complementary activities (i.e. activities not required under REACH or CLP) that contributed to achieving desired results but were not foreseen at the start of the Agency.

140 The limitation of this conceptual distinction is that it requires good insight in and appropriate benchmarks for both the activities performed and the costs incurred by the organisation under study. Otherwise, one cannot draw the conclusions that activities do not contribute to desired results or that more resources are spent than necessary. With ECHA, appropriate benchmarks are not always available, as many of its activities are new. Therefore, we make use of various alternatives to benchmarking for judging the efficiency of ECHA's operations. These are:

- the Revised Legislative Financial Statement and the underlying Staffing Model that was created by the Commission in 2006 to estimate resources required by ECHA;[33];
- ECHA's Annual Work Programmes and annual reports for the years 2007 through 2010;
- statements made in this Review's survey and interviews, which were validated by other sources.

141 This chapter addresses ECHA's organisational efficiency from an opportunity cost perspective: one euro spent on one activity is no longer available to be spent on another. As the management of ECHA can hardly influence the Agency's revenues (which in the review period were built up of registration fees and the contribution from the Commission), the focus should be on resource allocation and prioritisation of the Agency's staff's activities.

[31] For the full list of evaluation questions and the answers provided by the Review, please refer to Chapter 5 of this report.

[32] Tender specifications" Review of the European Chemicals Agency (ECHA) based on Article 75 (2) of Regulation (EC) N° 1907/2006", page 24.

[33] The latter as received in the form of a Microsoft Excel workbook "Copy of Required staffing total for European Chemicals Agency.xlsx" from the Commission on 20 May 2011.

142 We found that given the turbulent environment of the Agency in its first years, ECHA has done its best in making this prioritisation. However, unforeseen circumstances did result in a number of inefficiencies which are described in the paragraphs below. We stress that no evidence has been found of inadequate management leading to inefficiencies; the examples discussed are the result of choices made by ECHA's management for which arguments can be found in the focus on effectiveness.

143 We address the following aspects:

- ECHA's overall efficiency was reduced by some activities undertaken by the Agency outside the formal requirements under REACH and CLP, which were aimed at ensuring effectiveness of the Agency;
- for some of ECHA's activities, the resources required were underestimated – as a result, the Agency seems to be inefficient when compared to original assessments, but in fact could hardly have done better;
- the implementation of the budget did not result in any problems and we find that sufficient controls for prudent spending of resources are in place in the Agency;
- finally, given the context and structure of the Agency's finances, we find that ECHA has limited influence on efficiency.

3.1. ECHA incurred several inefficiencies by performing activities not strictly required by REACH or CLP to guarantee effectiveness

144 Contrary to the three examples described under 3.2, the examples described below are the result of decisions made by ECHA's management and approved by the MB. Although these decisions resulted in an overall less efficient implementation of tasks under REACH and CLP than was foreseen at the start of the Agency, they can be explained by a *risk management approach* to achieve effectiveness. All three decisions were aimed at preventing failure of the Agency to fulfil its tasks.

3.1.1. The "Plan B" system for registration required significant resources and preparations for registration were thorough

145 In October 2008 ECHA staff had sufficiently tested REACH-IT to feel confident it would keep working throughout pre-registration, even with the ±15-fold increase in the number of pre-registrations.

146 An external audit of REACH-IT performed in 2008:

- highlighted several necessary improvements to the system;
- recommended to not change the IT contractor before the 2010 deadline for registration;
- recommended to prepare a "Plan B" system to facilitate a back-up plan for registration, should REACH-IT not be able to cope with an increased number of registrations.

147 ECHA implemented these recommendations, incurring additional work in order to develop the Plan B system. As is evident from interviews with ECHA staff, this measure was considered as a guarantee that registration (the first important deadline under REACH and, according to all stakeholders, the first real test of the new regulatory framework) would not fail by offering an alternative option in the event REACH-IT would not be ready on time. The work on REACH-IT continued in parallel to the development of the Plan B system.

148 Therefore, although considered by the external auditor a valid measure to manage this operational risk, ECHA's IT department and the MB decided not to put the Plan B system to use as the risk that it was intended to mitigate did not materialise. With hindsight, we find that this has led to resources spent that have not resulted in concrete outputs, but at the time the Agency chose to minimise risk of failure by having a back-up plan ready, which has been of significant value to guaranteeing its performance.

3.1.2. *ECHA's Committees started meeting regularly before dossiers had come in for them to work on*

149 ECHA's bodies met for the first time on the following dates:

- MB: 27-29 June 2007;
- MSC: 26-27 February 2008;
- RAC: 29 - 31 January 2008;
- SEAC: 2 - 3 April 2008;
- Forum: 11 - 12 December 2007;
- The BoA has had annual meetings with its alternate members since 2009. However, it should be noted that the BoA's meetings are not comparable in nature to those of the MB, the Committees and the Forum. [34]

150 Of these bodies, the MB clearly had to start meeting earliest (as it did), because of its responsibility to guide and decide on multiple aspects of the ECHA organisation. As such, its tasks are more general and overarching in nature than those of the Committees, the Forum and the BoA, which have a functional role in the processes that resort under the auspices of the Agency.

151 Of these, the Forum again differs from the Committees and the BoA, whose primary activities are based on the submission and further preparation of dossiers and appeals. The agenda for the Forum's meetings is based on issues signalled by ECHA or the Forum members regarding the topic of enforcement in the MS.

Although being dossier and appeal-driven, it was decided by the Agency that the Committees and BoA should start meeting before the first dossiers and appeals were submitted, so that they would have sufficient time to decide on their rules of procedure, as stipulated by Article 85, sub 9 of the REACH regulation: "Each Committee shall draft a proposal for its own rules of procedure, to be approved by the Management Board, within six months of the Committees first being appointed." and Preamble 7 of Commission Regulation No 771/2008, laying down the rules of organisation and procedure of the BoAof the European Chemicals Agency: "For the same reasons, the BoA should be empowered to lay down rules for its own functioning and procedure."

152 It was during the following meetings that the Committees first adopted opinions on actual dossiers (types of dossiers are between brackets), with the time elapsed since the first meeting of the Committee:

- MSC: 4th meeting, 7-8 October 2008 (additions to the list of Substances of Very High Concern), 7 months and 10 days;
- RAC: 5th meeting, 10-11 February 2009, (CLH dossiers[35]), 1 year and 12 days;
- SEAC: 7th meeting, 2-3 June 2010, (Restriction dossiers[36]), 2 years and 2 months.

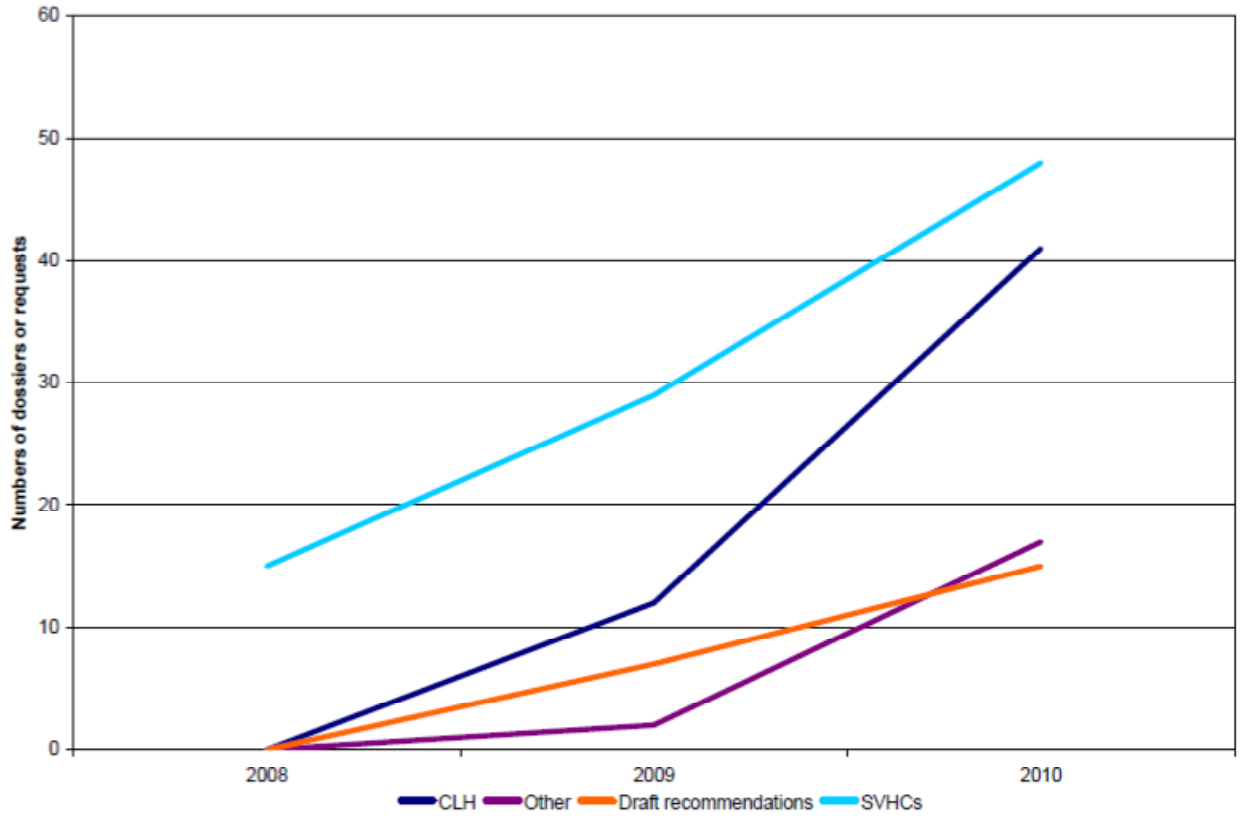
153 The qualitative information from the meetings agendas is corroborated by the statistics collected by ECHA about the review period, as shown by the numbers of dossiers or requests ("Committees and Forum cumulative input 2008-2010") in the graph below.[37]

[34] As published on the web pages for the various bodies that can be found at http://echa.europa.eu/about/organisation_en.asp.

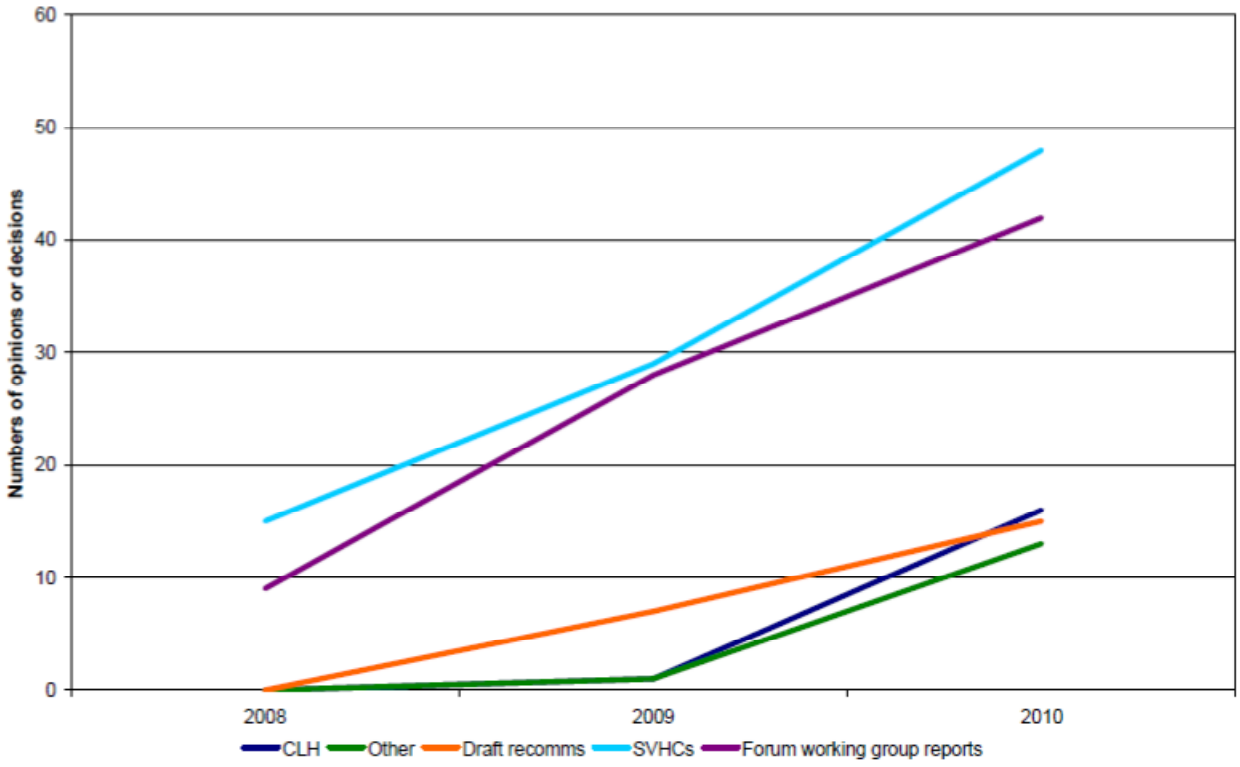
[35] The CLH dossiers were presented during this RAC meeting by the respective co-rapporteurs for information of the members. No dossiers were at this time ready for an integral plenary discussion. The first time such a discussion took place was during the 7th RAC meeting on 30 June - 3 July 2009.

[36] The Restriction dossiers were presented during this SEAC meeting by the respective co-rapporteurs for information of the members. No dossiers were at this time ready for an integral plenary discussion. The first time such a discussion took place was during the 9th SEAC meeting on 8-10 December 2010.

[37] Source: ECHA (2011). The Operation of REACH and CLP, figure 11 on page 65.



154 The next graph shows the "Committees and Forum cumulative output 2008-2010", in terms of the numbers of opinions or decisions. It shows that the output in terms of CLH dossiers, Draft recommendations and "Other" remained in the single digits until early 2009.[38]



[38] Source: ECHA (2011). The Operation of REACH and CLP, figure 12 on page 65.

155 The agenda and minutes of the various Committee meetings show that in meetings, prior to discussing actual dossiers, time was spent on relevant points, such as deciding on rules of procedure, developing formats for delivering written advice on dossiers, coordinating with other ECHA bodies and external stakeholders, developing guidance for industry and Member states etc. However, it was commented by various interviewees (including Committee members) that specifically the RAC and SEAC could have been more efficient if they would have spent less time working on these topics before the actual dossiers. Interviewees also indicated that, when the first dossiers did come in, the Committees were able to spend much time on discussing the dossiers, which led to discussions sometimes deviating from the matter of fact of the dossier at hand. As one industry representative phrased it:

"ECHA appears to have used some "gold plated" approaches in the period 2007-2010 – in other words, examined dossiers or queries extremely thoroughly as part of a learning process and because there was time (due to limited numbers of dossiers/queries)."

156 The quote above indicates two reasons why the first dossiers took much time: addressing them was part of the Agency's learning process, but also there was a natural tendency to spend much time on each dossier simply because that time was available. The latter effect could have been reduced by ECHA management and the chairmen of the three Committees, while the former is – at least to a certain extent – crucial to the development of a young organisation.

157 Reflecting on the number of dossiers that currently take up most of the meetings of the Committees, some survey respondents have also cast doubt on whether the Committees would be able to cope with a large workload which is expected to come in the near future – especially in RAC and SEAC due to increasing numbers of CLH, restriction and authorisation dossiers. As one Committee member phrased it in his comments:

"The workload for Committees' members is too high. It is necessary to reconsider the time table for some of the works."

158 To overcome this problem it was suggested to streamline the discussions and provide more information to MSCA to reduce number of proposals for amendment as well as to use the bureaucratic structure of the Committees in a pragmatic and flexible way.

159 We conclude that the operation of the RAC and the SEAC could have been more efficient, given the actual number of dossiers that were received by these Committees during the review period. As ECHA's secretariat could see the development of the workload before the actual meetings took place, it could have taken the initiative to cancel some of the meetings or, as several interviewees have recommended, make use of tele- or videoconferencing to replace physical meetings. A more pro-active role of the ECHA secretariat and/or the Committee chairs (who are employees of ECHA) could have reduced the time and resources spent by the RAC and SEAC.

160 Similar comments have been provided by interviewees about the preparatory meetings of the BoA. As the first appeals were submitted only in 2009, and the BoA members were first selected in mid-2008, over half a year elapsed before the BoA could work on actual appeal cases. Like the RAC and SEAC, the BoA could have been more efficient, given the actual number of cases it received during the review period. However, for the BoA, there is a much shorter lead time before an appeal should be discussed (because of the shorter time available to decide on an appeal) when compared to the dossiers of the RAC and SEAC. Also, the number of members of the BoA is much smaller and its alternate members are not compensated unless they actually work on an appeal procedure. Hence, the reduction in efficiency (in terms of costs incurred by ECHA) on the BoA is deemed much smaller than that on the RAC and SEAC, although it is not possible to exactly quantify either.

3.1.3. ECHA conducted several activities additional to REACH and CLP to support industry's compliance during the review period

161 ECHA took several initiatives not required by the REACH and CLP regulations to engage the industry in the pre-registration and registration processes. Examples of these initiatives are:

- The Agency actively sought input from industry users to improve the specifications of various IT systems and tools.
- During the registration period, the Agency's employees actively assisted companies without requiring that they first go through the Helpdesk.
- ECHA organised a campaign aimed at industry to provide support in the formation and organisation of SIEFs.
- In the beginning of 2010, the Directors Contact Group (DCG) met for the first time. The DCG is a joint initiative of the Commission, ECHA and industry associations. As stated on ECHA's website, its "objectives are to monitor the overall preparedness of companies and to identify and resolve the priority issues of concern in meeting obligations relevant to the registration of chemical substances. Special attention is also paid to priority issues of concern for a secured supply of high volume substances to downstream users.".[39]

162 In implementing these activities, the Agency again aimed to increase its effectiveness, considering that during the pre-registration and registration much of its success depended on gaining industry commitment. In doing so, it knowingly allocated resources to these activities, which could have been directed otherwise. The final result (a number of registrations almost exactly equal to original expectations) suggests that the Agency has been effective in supporting industry's compliance with REACH. However, it is difficult to conclude what would have happened if the Agency had not undertaken these additional activities.

3.2. Several activities were underestimated, as a result other activities had to be cancelled or postponed

163 The experience of the first 3.5 years of the Agency has shown that some of the estimates that laid at the basis of calculating the resources required were caught up by reality. Contrary to the topics addressed in paragraph 3.1, the reductions in efficiency addressed here are therefore not the result of ECHA management decisions. Three examples are addressed below.

164 As a result of the *opportunity cost* of spending more time of ECHA staff on the activities described in the paragraphs below, these examples resulted at least partly in fewer human resources being available to other activities, thus contributing to the reduction of the Agency's effectiveness in the work areas A6 (IT support to internal operations), B3 (translations) and B5 (C&L Inventory and other dissemination activities) as described in chapter 2.

3.2.1. The number of pre-registrations far exceeded expectations

165 As mentioned earlier, the actual number of 2.7 million pre-registrations exceeded the expectations on which ECHA's budget was based by a factor of 15. The causes leading to this situation (as discussed in paragraphs 2.1.2 and 2.3.1.2) can be largely attributed to the fact that pre-registration or anything like it simply occurred for the first time. However, the fact remains that ECHA's staff incurred a substantially larger workload as a result. Additional manual work had to be done given the postponed automation of tasks.

166 As became evident from interviews with the ECHA staff members who were responsible at the time, this particularly affected the amount of hours spent on improving and monitoring the performance of the IT systems, as well on replying to questions and clarification requests received by the ECHA Helpdesk. Also, additional costs were incurred by adding more hardware to support the IT system. The analysis of budget variations for the year 2008 in Annex G shows that (next to the opportunity cost of additional staff time awarded to IT) ECHA spent € 300,000 less than planned on translations as a result of resources shifted towards the additional work on REACH-IT.

167 In addition to the above, ECHA carried out additional activities to ensure the systems' contributions to its effectiveness, which are described in paragraph 3.3.2 below.

[39] http://echa.europa.eu/stakeholders/dcg_en.asp

3.2.2. ECHA's IT budget was underestimated

168 According to ECHA interviewees, REACH-IT took more resources than anticipated due to various, mainly external, reasons. ECHA interviewees have indicated that the contract cost twice as much in the end as the contractor did not deliver the functionalities required by the Agency and because rework was necessary to implement legal changes in REACH-IT. Examples of these changes given by ECHA are the CLP legislation and the OSOR principle for pre-registration. The exact budget overrun on the IT contract is not evident from the Agency's annual General Reports (see also the analysis of budget variations in Annex F).

169 It was commented that REACH-IT started as an "intellectual exercise", putting a theoretical model into an IT system while some aspects (final decisions on CLP, the fee regulation, the OSOR principle, differences in the interpretation of re-import of substances) were still subject to decision making. This resulted in a sizeable amount of "rework" on the system, which was unforeseen in the original resource estimates.

170 Another aspect that ECHA interviewees have commented on is that no budget was foreseen for IT maintenance, which is a significant part of the operational costs of a fully IT-based agency. However, the Commission's Legislative Financial Statement does includes a reference to "IT hard-and software costs including costs related to the maintenance and running of REACH IT"[40], which suggests that at least for REACH IT maintenance costs were estimated as part of the financial preparation for ECHA.

171 The pressure on the IT budget caused by the above-mentioned aspects affected resources available for other IT applications, resulting in delays in the development of ECHA's internal systems. The effect of this in the review period is that internal processes, such as the preparation of evaluation decisions, were conducted more slowly and with fewer internal controls than there could have been when sufficient budget would have been available. The result of this is that tracing back decision-making steps in for example the evaluation process will be more labour-intensive and more prone to errors than when a workflow system would already have been available during the review period.

3.2.3. Recruiting the required staff took more time and effort than expected

172 One very important task of the Commission and ECHA has been to recruit the appropriate staff for the Agency. As commented by numerous interviewees, this has been a big challenge , as is reflected by the fact that in the years 2008, 2009 and 2010, the recruitment targets were not achieved (see table below). As voiced by two interviewees (Commission representative and industry representative):

"The location is a disadvantage. It is relatively hard for partners of ECHA staff to find a suitable job in Helsinki."

"It's already difficult to hire scientific experts therefore retaining is crucial."

ECHA total staff	2007	2008	2009	2010
Commission staff model estimates (end of year)	101	248	355	437
Realised total staff (end of year)[41]	101	224	325	430
Departures (annual total)	n.d.	n.d.	27	10

Sources: Commission Staff Model, ECHA's Multi-Annual Staff Policy Plans 2007-2010, ECHA (2011). The Operation of REACH and CLP

173 The reasons for the lower-than-planned numbers in recruitment as evident from our findings are provided in paragraph 4.3.1. The effect of the recruitment challenges has been that ECHA had to complete its human resources by hiring interim staff and contract agents. Both the additional recruitment efforts as well as the efforts required for hiring these additional human resources resulted in more work for the Agency. An as yet

[40] REACH revised legislative financial statement, Commission staff working document. SEC(2006)924, 12.7.2006.Brussels, page 34.

[41] Including contract agents and seconded national experts.

intangible cost of hiring interim staff and contract agents instead of "regular" temporary staff (employees of contracts of up to five years in duration, which may however be renewed multiple times) will be the reduced knowledge created within ECHA as an entity as a result of the expected shorter duration of these flexible employments and the less stronger connection between contract agents and the Agency. Quantifying these various costs has not been possible based on the information available to the Review Team, but may be conducted by ECHA itself in the future.

3.2.4. Translations may have been more expensive than necessary in the early years

174 According to ECHA interviewees, the European Translation Centre (CdT) had limited or no expertise in the area of the complex scientific translations required by ECHA, but the Agency was not allowed to procure the required translation capacity on the market.[42] Hence, building up the required expertise in the CdT took time and caused additional work for ECHA staff, who had to spend time proofreading the technical translations. Some of the proofreading was outsourced to Member state contacts of the Agency and this resulted in additional costs. We find that the requirement for ECHA to procure translations from the CdT during the review period has reduced the Agency's economy and efficiency in this work area when compared to procurement of translations from the market. However, at the end of the review period, the CdT had increased its capabilities to supply the type of translations required by ECHA. Thus the burden on the Agency's resources has been reduced.

3.3. Some stakeholders perceive other inefficiencies

175 When we asked in the online survey to suggest top challenges ECHA faced in the period 2007-2010, the efficiency issue was mentioned by four respondents with different backgrounds. While some of them generally advised ECHA to become more efficient, others elaborated on the topic. Workload was named to be one of the reasons of decreased efficiency. These four stakeholders seem to doubt the correct proportion of the workload and available qualified staff.

176 According to MB members, the efficiency of the MB could be also improved by shortening the meetings and making sure that the presentations do not contain repetitions of the documents sent to MB members in preparation of the meetings. It was also suggested to use of videoconferencing for some meetings.

177 Moreover, the size of the MB was doubted. According to one MB member, who referred to other agencies such as EFSA, a smaller MB but with a more predominant role of the Commission is more efficient. Others suggested that not every Member state should necessarily be represented in the MB. We note here that the composition of the MB is prescribed by REACH and therefore not for ECHA to change.

3.4. ECHA's staffing model limits flexibility to influence efficiency

178 A noteworthy aspect of efficiency is that ECHA's main type of costs is personnel costs: these increased from 42% to 59% of ECHA's annual budget in the years 2007 through 2010. The Agency's directors decide how to allocate staff among the Agency's activities. As a result, prioritisation of one activity (more staff allocated than budgeted) results in fewer staff being available to other activities[43] or staff having to spend more hours at work than required by their contracts. As a result, inefficiencies manifest themselves not so much in the form of budget overruns, but in other forms such as:

- higher number of hours worked by staff than expected (possibly resulting in burned-out employees);
- delays in activities to which less resources are allocated.

[42] REACH article 104(2) specifies: "The translation services required for the functioning of the Agency shall be provided by the Translation Centre of the bodies of the European Union."

[43] As consistent with the economic theory of opportunity cost, that stipulates that the cost of any activity may be measured in terms of the value of the best alternative that is not chosen (i.e., that is foregone). The theory was first introduced by F. von Wieser (1914). *Theorie der gesellschaftlichen Wirtschaft* (translated into English in 1927 by A. Ford Hinrichs under the title "Social Economics") and has been refined and applied by economists ever since.

179 Both of these have been shown above to take place in the review period.

4. ECHA has responded with flexibility to changing external circumstances

180 In this chapter we address the economy of the Agency by assessing its resources planning in relation to the activities actually carried-out, i.e. "The extent to which resources are available in due time, in appropriate quantity and quality at the best price.". [44] We consider the following main evaluation questions:[45]

- To what extent have the forecasting and budget planning activities of the Agency been effective for resource planning and design and operationalisation of supportive tools (e.g. IT solutions)?
- To what extent is the Agency's internal organisation capable and flexible to rapidly respond to resource needs due to uncertainties related to volumes of work?
- To what extent is the Agency's IT infrastructure flexible to respond to uncertainties related to volumes of work?

181 We address the following aspects of economy:

- ECHA has adequate budget planning and forecasting systems, as is evidenced by effective budget implementation and an appropriate management and financing structure.
- The Agency has demonstrated the required operational flexibility on several occasions during the review period.
- Despite the above, there are elements of the Agency's external environment that it cannot control. These external influences affect ECHA's resource planning.

4.1. Budget planning and forecasting have shown to be adequate, given ECHA's uncertain environment

182 The Agency's budgetary and management procedures and systems perform adequately, but as is evident from several examples provided in chapters 2 and 3, the Agency was also dealing with an uncertain environment. The result was that not all resources requirements could have been predicted fully, which is reflected by some variations in the implementation of the budget. ECHA has taken a pro-active approach to (financial) risk management in the review period, thus not allowing external circumstances to significantly thwart its efforts in implementing REACH and CLP.

4.1.1. Budget implementation was effective, variations in spending were mainly due to adjusted timing and volume of activities

183 Budget implementation at ECHA has been effective during the review period. The amended budgets have been justified and MB has approved them without excessive discussions. When comparing budgets against the realised amounts for each year in the review period, we have found that there were relatively small variations in spending but significant variations in invoicing. The variations in invoicing are those that have caused discussion and need for major decisions. An overview of the budget variations for each of the years in the review period is provided in Annex F.

184 The variation was due to differences between predicted and actual volumes of registration dossiers. This is an uncertainty, which will continue in the future and this should be addressed through ECHA's financial management, as well as possibly the financial regulation and the budgeting processes. ECHA works as an EU

[44] Tender specifications" Review of the European Chemicals Agency (ECHA) based on Article 75 (2) of Regulation (EC) N° 1907/2006", page 24.
[45] For the full list of evaluation questions and the answers provided by the Review, please refer to Chapter 5 of this report.

agency, but in some extent could be characterised also working like a very "output driven" organisation. It has certain core processes which have inputs, throughputs and outputs and the monetary process is based on the cash flow invoiced from customers. On the other hand, it still has the role as a public agency and is obliged to work under public financial regulation of the EU. Currently, ECHA cannot use a bank loan for example or invest any redundant funds in interest-bearing (low-risk) assets, and thus has very limited possibilities to manage its finances effectively.

185 There were some particular cases during our review period, which characterise the challenge. First of all, several re-allocations of funds were necessary due to changes in workload for some activities during the review period, which were introduced in chapter 2. The second example concerned a budget transfer of under-spending by balancing renovation cost of the Agency premises. The third case addresses cash management generally, which was solved in 2010 by an arrangement with the Bank of Finland. Finally, we discuss the Agency's entitlement to use Commission services, i.e. the Internal Audit Service.

4.1.1.1. Example 1: Shifting costs due to external circumstances

186 In IT, several activities have been carried out in a different way than originally was intended. In 2009, the year of preparations for first registration deadline, the majority of the expenditure of IT costs were due to major IT development projects and the related hardware, software and licenses. Other activities included the support and technical guidance given to industry and the MS, as well as translation activities. Due to the above-mentioned reasons, total actual commitments were 12% less than the planned spending.

187 In 2010, more complicated dossiers than originally expected, were registered. The postponement of the redesign of the Agency's website to 2011 (due to significant IT work in other areas such as registration and dissemination) created considerable reductions in the 2010 expenses as well. Moreover, the BoA's budget needs for the review period were calculated on the basis of 100 appeals (most of them expected in 2010) while only two were lodged.

188 The major part of the budget thus freed up was used for the development and the further maintenance of IT tools in support of the implementation of the REACH and CLP regulations. Savings that resulted from the more economic offers that were submitted for several IT and other projects were also used here.

4.1.1.2. Example 2: The budget transfer of 2008 under-spending by balancing renovation costs

189 In its June 2008 meeting, the MB was provided with a report on the use of the budget 2008 and was informed of the risk of considerable under-spending in 2008, which would result in partial repayment of the Community subsidy budgeted by the Commission if the subsidy was not fully spent.[46] A solution was presented to the problem, i.e. the potential payment of renovation cost in the form of a lump sum, instead of spreading the cost over the next 11 years and paying it off in a form of advanced rent which would reduce the rental cost in future years.

190 Several MB Members had expressed the wish to receive more detailed background information. At the same time, it was acknowledged that there was considerable time pressure if ECHA were to implement the proposal in 2008. It was noted that there is a written MB procedure on the budget transfer necessary for allowing ECHA to fund its share of the construction work on the Agency's conference centre. With reference to the discussions at the meeting of the MB of September 2008, it was concluded that there would to be no urgent need to revise these provisions.

191 The MB was informed that there was an agreement which was based on the following observations:[47]

- the lump-sum payment of the renovation costs of the conference would not negatively affect the implementation of the work program 2008;
- the transfers would be made within the available budget appropriations for 2008;
- according to the background document the proposal was in line with the Agency's Financial Regulation;

[46] ECHA (2008). Minutes of the Meeting of ECHA's Management Board 18/19 June 2008, page 10.

[47] ECHA (2008). Minutes of the Meeting of ECHA's Management Board 17/18 December 2008, page 7.

- an early termination of the rental contract would not have negative implications for the Agency; and
- the conditions proposed by the building owner for the calculation of the lump sum payment appeared to be financially acceptable.

192 It was stressed in the MB that similar situations should be avoided in the future and attention was drawn to the need for keeping the budgetary authority informed in an appropriate manner. As a result, the MB endorsed the proposal made for addressing the under-spending of the budget in 2008.

4.1.1.3. Example 3: On cash-management 2009 and 2010

193 There was some discussion in the MB in 2009 that the Financial Rules would not address the aspect of how to make efficient use of the fee income and how to manage the cash over different budget cut-offs. In MB meeting two options were identified to overcome this problem. The first one would have consisted of an amendment to the REACH Regulation aimed at defining fee income as so-called 'assigned revenue'. The second option would have been the creation of a reserve fund. This meant that derogation from the Framework Financial Regulation would have been required. It was seen that an amendment to the REACH Regulation was not a realistic option and therefore only the reserve fund was seen as appropriate.

194 The MB was later debriefed on the Commission's view regarding the establishment of a reserve fund for fee revenues. In the absence of a legal base, derogation from the General Framework Financial Regulations would not be a viable option. However, ECHA was confident that a solution would be found for carrying over unused fee revenues into the following financial year. Given the amount of fee income expected towards the closing of the registration deadlines, the Commission had seen an obligation to support ECHA in the sound financial management of the fee income and had proposed that the Agency present to the MB a set of draft rules on this aspect at the next meeting.

195 In 2010 the management of the Agency's cash reserve deriving from fees and charges was discussed. The MB members were reminded that ECHA had negotiated a contract with the Central Bank of Finland aimed at short-term cash management which entered into force on 1 December 2010. For the mid-term management, ECHA was in negotiation with the European Investment Bank (EIB) in view of possible co-operation. The arrangement with the EIB could serve the Agency's investment and risk diversification needs with regard to longer maturities covering up to two years.

196 Hence, at the end of the review period the Agency was investigating the possibilities of cash management more thoroughly. This can be expected to be beneficial to its cash management during the coming years.

4.1.1.4. Example 4: Self-financing Agency using Commission services

197 The MB Working Group on Audit matters had informed the other MB members that as the Agency would be self-financing in 2011-2013, the mandate of the IAS to continue internal audits at the Agency deserved clarification. To this end, the Agency was asked to write to the IAS in order to agree on the continuation of the IAS work at ECHA during the self-financed period. Although the result of this request falls outside the review period, the example shows that the institutional framework linked to the financial structure has required clarification for both the MB and the Agency's management.

4.1.2. ECHA's Management and Financing Structure functions adequately, given a challenging organisational context

198 The following paragraphs outline the issues that we addressed for ECHA's management and financing structure. Our main finding is that the current working of the management and financing structure is hindered by a contradiction between the nature of work of ECHA and the way of EU public funding structure: ECHA functions very much like a private entity, whereas the financing structure limits its possibilities to make the most effective and efficient decisions. Also the annual planning cycle is too short for an agency which operates and needs to respond adequately to a changing environment. The challenge has been solved by ECHA management and the MB, but it requires resources which could be used more efficiently for developing the work of the Agency itself.

4.1.2.1. ECHA's funding structure has several inherent risks

199 The finance structure, based on both subsidy and industry fees, is supportive in a situation of up-scaling. Downscaling due to decrease in registration, economic downturn etc. would be challenging as the personnel cost is not flexible downwards. There is not any mechanism available for extra funding (such as a bank loan , or additional fees for additional services, etc.).

200 The Agency is tied to an annual planning of funding, which, in a starting and growing agency, seems to be a very short period. If the funding had been allocated for more than one year at the time during the review period, this would have allowed ECHA to respond with more flexibility to changing circumstances. Although the functions of the Agency are already stabilising, there are still significant uncertainties, which may wake needs for quick decisions in budget. Fee income is depending on the registration scheme. As a result of the young age of the Agency and the newness of the regulation, there are uncertainties with work load and the fee invoicing that have led to fluctuations vis-à-vis the original budget.

201 Future income is uncertain, as it depends heavily on application fees for authorisations. A finance risk is caused by the uncertain lead time after listing of substance on the Candidate List as the industry may substitute the substance concerned before authorisation is required. Also, other chemical risk management approaches (e.g. restrictions) may turn out to be used. This will have an immediate (negative) impact on the revenue streams for ECHA.

4.1.2.2. Systems supporting the finance have worked without problems, a cost accounting system is under development

202 The ABAC budgeting software is designed for Commission accounting based on expense budgeting and does not provide for fee invoicing which has been added to the functionality of REACH-IT. The Agency uses the SAP accounting system for its own accounting.

203 The institutional context in budgeting is heavy. However, there is certain flexibility within budget lines and titles. During the review period the system has been seen flexible enough as the operational risks (such as a significant volume increase in pre-registrations – realised – and registrations – not realised) have been foreseen and mitigated early enough.

204 There has not been a management accounting system in place during the review period. A cost accounting system is currently being developed for which ECHA as an EU agency is pioneering. We find this to be a key aspect of a further maturing agency, as it allows for more precisely allocating resources and monitoring efficiency in the various work areas.

4.1.2.3. ECHA has identified its main (financial and operational) risks

205 Risk management is based on the Agency's annual planning and reporting cycle, so it goes hand in hand with budgeting and other routines. The Agency organised specific risk management training for Directors, Heads of Unit and Team leaders in the spring of 2010. Then the risk identification and assessment was updated and the impact and vulnerability were collectively assessed in a specific workshop. Once the main financial and operational risks had been identified, mitigating measures were defined, and the identified risks, their assessment and the mitigating measures were integrated into ECHA's Risk Register.

206 ECHA's main financial risks result from the uncertainty of the baseline figures, i.e. the estimated number of different types of dossiers to be processed, based on which the workload as well as the revenues from industry can be predicted. The main risks identified in 2010 are related to the number of registration dossiers, their distribution and possible peaks over the registration period and the functioning of the IT system.

207 The financial risk assessment is the responsibility of both ECHA management and MB members and connected to the operations of the agency. ECHA's Internal Audit Capability and the Commission's Internal Audit Service perform their own risk assessments, but are also utilising the management's risk assessment results.

4.1.2.4. Integrated Quality Management System is under development

208 The IQMS is planned to cover the entire organisation and is designed with an integrated approach. ECHA has its own quality statement. One of the main objectives in the policy is to emphasise the will of treating industry and other stakeholders (including the general public) equally. Quality in ECHA is seen as assurance for its stakeholders, fair and equal treatment as well as documenting and demonstrating the equal treatment to all stakeholders.

209 "Integrated" in ECHA means that all functions in the Agency will be covered by the quality management system. HR and finance are not yet in the system but according to our interviews with ECHA staff they will be. They have quality documents but not formally covered yet by the system.

210 As reported by ECHA interviewees, 50% of the processes are ready for ISO certification. The remaining processes are not functioning yet, hence they have not been certified thus far. There are plans for the remaining processes to be certified in 2012.

4.1.2.5. Security measures are in place to protect confidential information, a security policy is to be developed

211 According to ECHA interviewees, ECHA is in a special position as they receive confidential information from the industry; the information collected by ECHA can interest various third parties and this puts a specific emphasis on security management. The Agency's management says that leaking information would set suspicion on the Agency and in worst case even the REACH regulation and the EU policies can be questioned.

212 When asking whether ECHA has faced any security breaches or leaks, interviewees told us none have been identified so far. The Agency has done attack screening using an external company for testing the system's defences. This screening has resulted in the identification of multiple attempts to hack into the system, thus demonstrating a clear need for the Agency's efforts in IT security.

213 Physical security risks have been assessed and the human factor has been identified as one of the major risks. In addition to intentional security breaks (i.e. burglary and/or data theft), there are also unintentional behaviours associated to the human factor that present a security risk. A computer virus intruding the Agency via a USB stick, or a laptop having visited outside the office, are examples of this. There are however safety measures in place to prevent these risks, but as of yet no overarching policy. A procurement process has been initiated to develop such a policy and implement the necessary measures to mitigate all security risks identified.

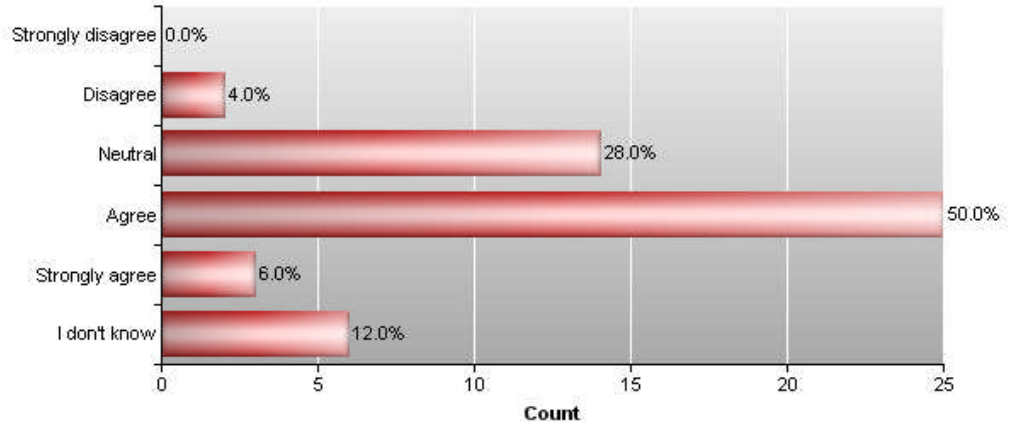
214 One important challenge for ECHA is in the fact that for some companies a piece of information can be public, for others extremely confidential. ECHA puts a significant workload into assessing which data are confidential and which are not, which requires a lot of case-by-case analysis. On the other hand the IT infrastructure for dissemination of data has been increasing during the review period, thus requiring the Agency to safeguard more systems. This presents an increased risk for security management, confidentiality screening and for IT systems which are used for dissemination.

4.2. The Agency proved its operational flexibility in the early years of its existence

215 ECHA's operational flexibility was called upon as early as the fifth semester of its existence, when the Agency faced pre-registration numbers much higher than expected. Again with the registration deadline at the end of the review period, circumstances demanded operational responsiveness.

216 The web-survey respondents were positive about the ability of ECHA to adapt to new situations and (legal) interpretations of REACH and CLP, although NGOs showed less satisfaction than other respondents (industry, Committee members and national helpdesk representatives).

The Agency has proven to be able to adapt to new situations and (legal) interpretations of REACH and CLP. (all respondents)



217 In the paragraphs below we highlight two aspects of the Agency's operational flexibility.

4.2.1. *ECHA's internal organisation proved flexible in the face of pre-registration and registration challenges*

218 During the review period, ECHA's internal organisation demonstrated its flexibility when the Agency prepared for the pre-registration and registration deadlines. In the following paragraphs, we address both these stages in more detail.

4.2.1.1. Pre-registration challenges were met by a risk management approach and impressive staff motivation

219 In the period before the pre-registration in 2008, it became clear that the number of pre-registrations would far exceed expectations, which was dealt with by the Agency as described in paragraphs 2.1.2, 2.3.1.2 and 3.2.1.

220 ECHA management responded to this challenge by both re-allocating internal ECHA resources and attracting IT resources. As a result, even though some stakeholders told us that they expected REACH to end with a failed pre-registration, the Agency succeeded in supporting pre-registration. This was made possible to a large extent by much additional work done by ECHA staff, which leads to the question of whether a similar success will be replicable in the future. Given the fact that ECHA was in 2008 in the start-up phase of the organisation, the motivation and energy displayed by staff may not be at the same impressive levels in future years.

221 Another aspect that contributed to the flexibility of the internal organisation resulted from the Agency's risk management activities, such as the external audit of REACH-IT that identified areas where urgent improvement was needed and the subsequent activities undertaken to prepare adequately for registration as described below. Risk management is a strong capability of the Agency, that will be an asset in the years to come, as it already was in the years leading up to registration.

4.2.1.2. Lessons learned from pre-registration helped to address the challenge of registration

222 At the end of 2009 the Agency created an internal working group named "Taskforce 2010". It also hired a Contingency Manager to help plan for the 2010 registration deadline. Other complementary measures that were taken in preparation of registration included the analysis of nine scenarios, which led to training and temporary redeployment of 80 staff. Also, external human resources were attracted to manage the workload.

223 These measures prepared the Agency for accepting as many as 75,000 registrations. When the actual number turned out lower, the redeployed employees could return to their regular duties as early as October 2010.

Hence, although the planning for registration took time and resources, the impact as a result of redeployment was kept to a minimum. As described in the previous paragraph, ECHA's planning and risk assessment capabilities proved helpful to support registration.

4.2.2. The Agency's IT infrastructure proved to be scalable during pre-registration

224 Another aspect that was clearly demonstrated during the pre-registration phase was the scalability of REACH-IT. Although ECHA staff was very busy monitoring the system, it did prove possible to increase its capacity by adding hardware in the form of additional servers and thus support the numerous pre-registrations. Given this experience, we expect the core of the Agency's IT infrastructure to be flexible to increasing volumes of work in the future.

4.3. Some resources were available later and in lower quantity/quality than originally estimated

225 Even though ECHA's organisational flexibility and planning capabilities are adequate, external circumstances remained beyond its control. Below, we describe two significant resource challenges faced by the Agency in the review period.

4.3.1. ECHA's staff requirements for the first years were based on shorter recruitment periods and longer contracts than were realised in practice

226 The staff model designed by the Commission was based on the assumption that 40 staff seconded from the Commission would start their work in Helsinki mid-2007 and stay on until end of 2008 (in addition to staff that was to be recruited from other sources than the Commission). Instead:

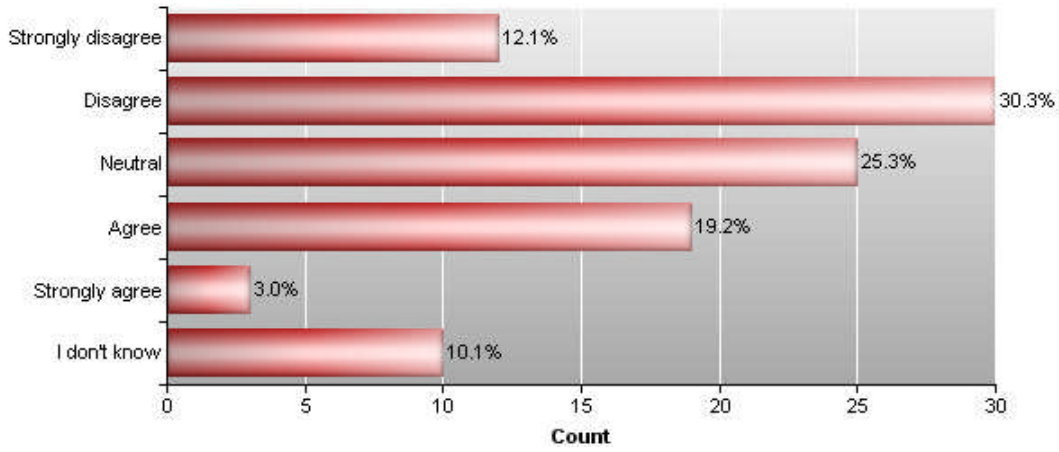
- the date of adoption of REACH resulted in a delay of recruitment, hence the recruitment stage was completed later than foreseen in the Commission Staff Model;
- many secondees did not start work in Helsinki until September 2007;
- many secondees did not stay for the full 18 months.

227 Recruitment of temporary agents from other sources than the Commission also fell short of expectations. Several reasons have been indicated by interviewees for the lower number of total recruited staff (Commission secondees and other):

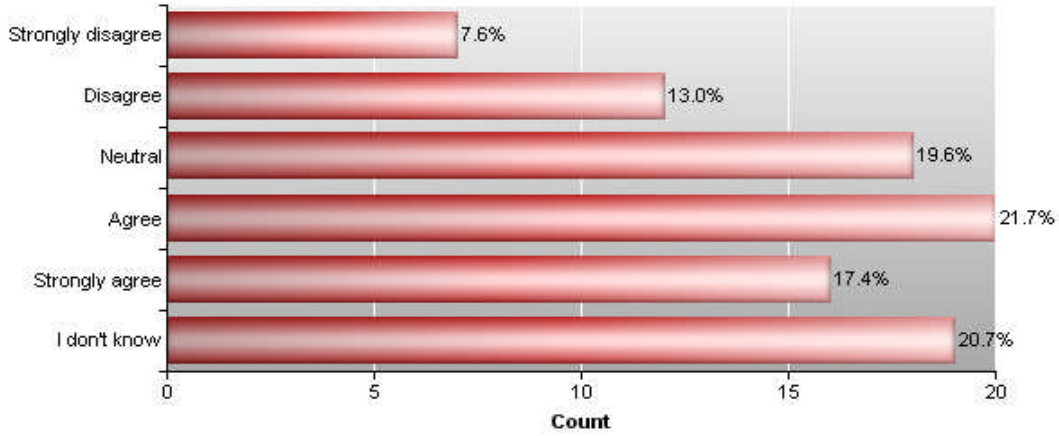
a. good candidates were difficult to find because standards were set high and the markets for chemical specialists and other specialists needed for working at the Agency were already tight before the Agency existed;
b. many candidates were enthusiastic, but refrained from taking a job in Helsinki because their spouses could not easily get jobs there or their families had other reasons not to want to move to Finland (such as the climate or the relative distance to other European countries), see also the illustrative answers to the survey questions included below;
c. of the candidates that did join ECHA, many came in later than expected due to longer-than-expected relocation processes (with aspects such as finding housing taking more time than estimated) and a significant group left earlier than planned.

228 This resulted in fewer man-months available to the Agency in the first years, as is evident from ECHA's annual reports (see also the table in paragraph 3.2.3). The seconded and recruited staff were supplemented by interim staff and contract agents to make up for the difference. However, some of these additional staff agents did not have experience with previous regulatory frameworks on chemicals. We suspect these to be some of the main causes for the substantial overtime put in by many staff and the burn-out problems that resulted from this.

I consider the location of the Agency as no obstacle to attract the right staff. (respondents: all stakeholders)



I would consider working for the Agency if it was not located in Helsinki. (respondents: all respondents to the survey)



229 As a result of the above, both the timely availability and the average quality (at least in terms of the benefits of previous experience with chemicals regulation) of the staff were lower than was estimated in 2006. It certainly is not a development for which ECHA could be held responsible, as the Agency did not choose its own location but was located in Helsinki as a result of decision making by the Council and the Parliament. Given ECHA's ambitious staffing targets (hiring highly-educated specialists in a field of expertise where industry already faces a problem to recruit sufficient staff), it is our view that this may have been expected by the Commission when calculating the staff model. The lower staff numbers might have been prevented if recruitment activities and resources had been increased accordingly. However, this cannot be said with certainty as there may not have been many more candidates even if recruitment activities would have been increased.

4.3.2. *The contract with the provider of REACH-IT was completed later than planned*

230 The contract took more time and funds than originally planned to deliver the functionality required by ECHA (see paragraphs 3.1.1, 3.2.1 and 3.2.2). The management of the contract also required additional effort from ECHA's IT department, thus consuming more resources. This was part of the cause for the difficulties with REACH-IT in 2008 as described in Chapter 2.

5. Conclusions and recommendations

231 This final chapter contains PwC's conclusions and recommendations. In order to provide an integral response to the evaluation questions posed by the Commission, we start by answering each of the evaluation questions explicitly in paragraph 5.1. Paragraph 5.2 contains our overall conclusions on ECHA's performance in the review period. Our recommendations to ECHA and the Commission are provided in paragraph 5.3.

5.1. Answers to the questions posed by the Commission

232 The table below provides an overview of our answers to the questions posed in the Tender Specifications for the "Review of the European Chemicals Agency (ECHA) based on Article 75 (2) of Regulation (EC) N° 1907/2006". These Specifications are included as Annex G to this report.

Questions per work area (as posed in Tender Specifications)	Our answers	Paragraph reference in this report
Registration, pre-registration and data-sharing (A1)		
1. Have the main obligations from REACH been implemented in an effective, efficient and economic manner?	Activities under work area A1 have been implemented by ECHA in accordance with REACH. Deadlines have been met. However, due mainly to the high number of pre-registrations and ECHA's complementary activities to actively support industry in the processes of registration and SIEF formation (see under question 3 below), more resources were required to achieve effectiveness. ECHA demonstrated flexibility in re-allocating resources when necessary. As a result, the activities were implemented in an effective and economic manner, but at higher costs than was foreseen, thus resulting in lower overall efficiency.	2.3.2, 2.3.3, 3.1.1, 3.2.1, 4.2.1, 4.2.2, Annex A
2. What are the main shortcomings that have been detected (if any)?	The quality of the list of pre-registered substances did not meet the expectations of the Commission, but this was not ECHA's fault (as virtually all known substances were registered, which reduced the value of the list). The role of ECHA in the process of data sharing was limited to stimulating SIEF formation and deciding disputes, whereas industry stakeholders had expected a more active role of the Agency in the process of data sharing.	2.3.2, 2.3.3, 3.2.1, 4.2.1, 4.2.2, Annex A
3. Has the Agency undertaken activities in this work area which can be seen as complementary (but not strictly required by REACH) and which either had positive or negative impacts on the operations of REACH?	ECHA pro-actively strived for effectiveness and thereby accepted lower overall efficiency, leading to less resources being available for e.g. development of IT support to internal processes and translations. ECHA organised events and targeted webinars to inform and prepare industry for their obligations on (pre-) registration and data sharing. Although the activities that received less resources may have had less influence on ECHA's overall effectiveness, stakeholders are divided on whether this was a good choice: industry and MSCAs tend to be in favour, NGOs against. As we cannot tell whether REACH and CLP compliance would have been lower if	2.3.2, 2.3.3, 3.2.1, 4.2.1, 4.2.2, Annex A

	these complementary activities had not taken place, we cannot give a definitive opinion on this matter.	
4. What recommendations (if any) does the contractor have to improve the operations of the Agency in this area of work to contribute more effectively to the objectives?	We recommend that the ECHA Secretariat discuss any future significant re-allocation of resources with the MB by presenting a cost-benefit analysis on how they are expected to influence the effectiveness of all its tasks, including those that have to make do with less resources. The MB should in its decisions refer to the reasons why a re-allocation was approved or rejected, again referring to effectiveness of ECHA's tasks.	2.3.2, 2.3.3, 3.2.1, 4.2.1, 4.2.2, Annex A
Evaluation (A2) ***(substance evaluation is excluded from the scope of this interim-evaluation)***		
1. Have the main obligations from REACH been implemented in an effective, efficient and economic manner?	We find that ECHA has implemented most tasks under REACH for this work area. For some tasks, no performance data were available. We have not been able to establish the efficiency and economy of the work done in this work area.	2.3.2, 2.3.3, Annex A
2. What are the main shortcomings that have been detected (if any)?	In stakeholder interviews NGOs were critical of ECHA's performance. Several NGOs find that ECHA motivations (both scientific arguments and motivations for decisions not to take on suggestions from NGOs) are insufficient. We conclude that NGOs are critical of the evaluation process as it is implemented by ECHA. They are however the only type of stakeholders who voice this concern.	2.3.2, 2.3.3, Annex A
3. Has the Agency undertaken activities in this work area which can be seen as complementary (but not strictly required by REACH) and which either had positive or negative impacts on the operations of REACH?	Complementary activities were undertaken in the form of issuing so-called Quality Observation Letters (QOBLs) to registrants, to inform them in detail about the quality of their registration dossiers as reviewed by ECHA. Industry respondents to the survey gave positive feedback about the use of QOBLs. On the other hand, the use of QOBLs claimed resources that were originally budgeted for other ECHA operations. NGOs argued that these efforts would have been better spent on additional dossiers to be evaluated. It is not possible to assess the impact on the REACH operation, as the amount of resources consumed by producing QOBLs is unknown.	2.3.2, 2.3.3, Annex A
4. What recommendations (if any) does the contractor have to improve the operations of the Agency in this area of work to contribute more effectively to the objectives?	ECHA should clearly motivate any and all of its decisions in order to document the scientific soundness of its draft decisions it has aimed to achieve.[48] Another recommendation would be for ECHA to prepare a cost-benefit analysis if it intends to continue the use of QOBLs during the remaining dossier evaluations (both for the 2010 registration round and those of 2013 and 2018). The MB should decide whether the benefit of providing registrants with detailed feedback (especially in the case of SMEs) is worth the investment required. We suggest that if the Agency intends to continue the use of QOBLs, it should consider thoroughly	2.3.2, 2.3.3, Annex A

[48] I.e. the indicator specified in its Work Programme for 2009, page 13.

	whether the QOBL instrument can be targeted to specific groups of registrants (e.g. SMEs or first-time registrants), who benefit more from detailed feedback than others in terms of the resulting learning curve. It should be noted here that QOBLs do in no way create additional requirements for the companies that receive them, but instead should be understood as another form of guidance to registrants. Finally, more performance data should be collected for this work area, so that the Agency's effectiveness in this area may be established more clearly in the future.	
Authorisations and restrictions (A3) ***(the treatment of authorisation applications is excluded from the scope)***		
1. Have the main obligations from REACH been implemented in an effective, efficient and economic manner?	There is insufficient experience with restriction and authorisation to fully judge the effectiveness in this area. However, we found that ECHA has fulfilled its obligations under REACH and that stakeholders and Committee members are positive about the procedures ECHA has put in place. There are no indications that authorisation or restriction tasks were not conducted in an efficient or economic manner.	2.3.2, 2.3.3, Annex A
2. What are the main shortcomings that have been detected (if any)?	No shortcomings have been detected due to limited experience with both processes. One challenge that has been identified relates to a possibly very steep increase in the number of authorisation and restriction dossiers. The number of dossiers is as yet unknown, but will strongly affect ECHA's workload and, as a result, its resource requirements and efficiency.	2.3.2, 2.3.3, Annex A
3. Has the Agency undertaken activities in this work area which can be seen as complementary (but not strictly required by REACH) and which either had positive or negative impacts on the operations of REACH?	No complementary activities have been identified.	2.3.2, 2.3.3, Annex A
4. What recommendations (if any) does the contractor have to improve the operations of the Agency in this area of work to contribute more effectively to the objectives?	We recommend that the Agency develop scenarios on the number of restriction and authorisation dossiers that are expected for the coming period and consider whether current working procedures are still feasible when facing a very high number of dossiers.	2.3.2, 2.3.3, Annex A

Classification and Labelling (A4) ***(the assessment of confidentiality requests is excluded from the scope)***		
1. Have the main obligations from the CLP Regulation been implemented in an effective, efficient and economic manner?	ECHA has processed C&L dossiers effectively. However, the final result in terms of C&L data being published through the C&L Inventory has not been achieved (see also below and under Dissemination (B5)). There are no indications that CLP tasks were conducted in an inefficient or uneconomic manner.	2.3.2, 2.3.3, Annex A
2. What are the main shortcomings that have been detected (if any)?	The C&L Inventory, a main visible outcome that was planned by the Agency for December 2010, was delivered in February 2012. Stakeholders in the Commission and MSCAs have indicated this inhibits their functioning as policymakers, as they did not have access to the C&L information until recently.	2.3.2, 2.3.3, Annex A
3. Has the Agency undertaken activities in this work area which can be seen as complementary (but not strictly required by CLP) and which either had positive or negative impacts on the operations of the CLP Regulation?	No complementary activities have been identified.	2.3.2, 2.3.3, Annex A
4. What recommendations (if any) does the contractor have to improve the operations of the Agency in this area of work to contribute more effectively to the objectives?	To make it a key priority to eliminate any remaining obstacles to publishing the C&L Inventory.	2.3.2, 2.3.3, Annex A
Advice and assistance through guidance and helpdesks (A5)		
1. Have the main obligations from the REACH and CLP Regulation been implemented in an effective, efficient and economic manner?	ECHA has provided extensive guidance to stakeholders and organised a three-tier helpdesk system, involving National Helpdesks and the Commission. Stakeholders are positive about the quality of the guidance and helpdesk functions. However, stakeholders also indicate that it can take a long time for the ECHA Helpdesk to respond. This is to be expected, as the ECHA Helpdesk only addresses questions that cannot be answered by the National Helpdesks and that sometimes require input from the Commission.[49] Resources for translations have been reduced by € 0.3 million as a result of re-allocating resources to IT-work in 2008. Another aspect of this was the fact that the limited expertise of the European	2.3.2, 2.3.4, 4.2.3, Annex A

[49] This limitation applies to questions that originate from EU Member States. The ECHA helpdesk does address questions "in first instance" if they originate from non-EU countries.

	Translation Centre (CdT) in the area of complex scientific translations led to additional costs.	
2. What are the main shortcomings that have been detected (if any)?	Some guidance documents have not been translated into all EU languages. We also found that translations of guidance have often been available at a late stage when compared to the deadlines for complying with REACH and CLP requirements. This especially affects importers, downstream users and SMEs, i.e. not the "inner circle" of industry. Higher costs due to required used of the CdT due to the requirement to build up technical expertise as described above.	2.3.2, 2.3.4, 4.2.3, Annex A
3. Has the Agency undertaken activities in this work area which can be seen as complementary (but not strictly required by REACH or CLP) and which either had positive or negative impacts on the operations of REACH and the CLP Regulation?	ECHA organised HelpNet to support the National Helpdesks in their tasks and ensure consistency. This positively affected the implementation of REACH and CLP, as is also provides National Helpdesks with their own helpdesk for difficult REACH- and CLP-related questions. ECHA proofread CdT translations to ensure technical adequacy. This has positive effects, because the quality of guidance was better as a result.	2.3.2, 2.3.4, 4.2.3, Annex A
4. What recommendations (if any) does the contractor have to improve the operations of the Agency in this area of work to contribute more effectively to the objectives?	We recommend that ECHA's Management Board discuss and agree on a procedure for planning the timely publishing of guidance in the appropriate languages to ensure the required level of compliance with REACH and CLP by SMEs in the period 2012-2018 and beyond.	2.3.2, 2.3.4, 4.2.3, Annex A
IT support to operations (A6)		
1. Have the main obligations from the REACH and CLP Regulation been implemented in an effective, efficient and economic manner?	ECHA has fulfilled the tasks set by REACH and CLP, notably the further development of IUCLID as the international standard for information on substances and the effectiveness and security of REACH IT. However, the Agency was not fully effective with regard to developing the IT systems aimed at supporting its internal working processes. Development of these systems was delayed due to the higher than estimated resource requirements of REACH IT. The delay resulted in lower efficiency of several of the Agencies internal processes than would have been possible with fully developed IT support, such as the preparation of C&L dossiers for the RAC and SEAC. ECHA has conducted significant efforts to establish and monitor the security of its IT systems. Although the security systems have thus far not been breached, ECHA did find that there have been attempts to do so on a regular basis during the review period. Hence, the need for security efforts is clear and fulfilling that need contributes to	2.3.2, 2.3.3, 3.2.2, Annex A

	effectiveness. The development and maintenance of REACH IT became more expensive than originally estimated by the Commission, resulting in an apparent reduction of overall efficiency of the Agency and demanding re-allocation of resources.	
2. What are the main shortcomings that have been detected (if any)?	REACH IT has often been unstable or inaccessible during the pre-registration period. Also, there have been the numerous updates of various software tools and formats that increased the burden for registration on chemical companies. Access to data from REACH-IT was non-existent for the Commission and MSCAs by the end of the review period, which has hampered their policy-making and enforcement tasks.	2.3.2, 2.3.3, 3.2.2, Annex A
3. Has the Agency undertaken activities in this work area which can be seen as complementary (but not strictly required by REACH and CLP) and which either had positive or negative impacts on the operations of REACH and the CLP Regulation?	No complementary activities have been identified.	2.3.2, 2.3.3, 3.2.2, Annex A
4. What recommendations (if any) does the contractor have to improve the operations of the Agency in this area of work to contribute more effectively to the objectives?	We recommend that ECHA urgently supply the Commission and those MSCAs who do not have it yet with the access to registration information required for policy-making and regulatory purposes as well as complete the IT support of internal processes. During the busy period expected for the coming years, it will be challenging to complete these tasks. We also recommend that ECHA continue its policy on IT security it has completed during the review period. With more and more data, data security and compartmentalisation of data and user groups will remain a strategic issue for the Agency.	2.3.2, 2.3.3, 3.2.2, Annex A
Scientific and practical advice for the further development of legislation (A7)		
1. Have the main obligations from the REACH Regulation been implemented in an effective, efficient and economic manner?	This work area concerns the advice provided by ECHA to the Commission at the Commission's request in the areas of biocides of nanomaterials.[50] A Commission interviewee indicated high satisfaction with the work done on nanomaterials. From ECHA's General Report it becomes clear that the advice regarding biocides also resulted in high satisfaction on the part of the Commission. We conclude that ECHA was effective in providing advice, as the satisfaction of the Commission as its "client" is key to effectiveness in this work area. No information is available however or about the efficiency or economy of the development of the advice.	2.3.2, Annex A

[50] The Tender Specifications (p. 28) describe the scope of this work area as follows: "Support provided to the Commission in the context of the debate on nanomaterials; Support provided to the Commission in the context of the co-decision procedure for the new Biocides Regulation."

2. What are the main shortcomings that have been detected (if any)?	No shortcomings have been identified.	2.3.2, Annex A
3. Has the Agency undertaken activities in this work area which can be seen as complementary (but not strictly required by REACH) and which either had positive or negative impacts on the operations of REACH?	No complementary activities have been identified.	2.3.2, Annex A
4. What recommendations (if any) does the contractor have to improve the operations of the Agency in this area of work to contribute more effectively to the objectives?	We have no recommendations to improve the operations of the Agency in this area, as it has been effective during the review period.	2.3.2, Annex A
Committees and Forum (B1)		
1. Are the Scientific Committees and the Member States Committee working in an effective, efficient and economic manner?	In general, we find that the Committees are considered effective by stakeholders and the members of the Committees themselves. Stakeholders perceive the Committees as independent and the quality of output as good. Also, we have established that all deadlines for Committee output have been met in the review period. Hence, we conclude that the Committees are effective. The efficiency of the Committees could be improved, as working procedures could facilitate the efficiency of meetings and the decision-making on Committee opinions. Based on the analysis of ECHA's tasks and performance as described in its Work Programmes and General Reports, we have found that the resources required for the work of the Committees were available in time and in the proper quality and quantity. Hence, the Committees were supported in an economic manner.	2.3.2, 2.3.5.1, 3.1.2, Annex A
2. Is the Forum working in an effective, efficient and economic manner?	In general, the Forum is considered effective by stakeholders and members of the Forum. The Forum is clearly new to its members, who were not used to international cooperation on enforcement before 2009. During the review period, this has limited the effectiveness of the Forum, but this is clearly not something ECHA could have prevented. As a result however, the effects of the Forum's activities on national enforcement practices vary between Member States during the review period. For the efficiency of the Forum, it is difficult to develop a benchmark, as it did not have concrete performance targets during the review	2.3.2, 2.3.5.2, 3.1.2, Annex A

	period or a specific resource and/or cost allocation. This is related to the fact that the activities of the Forum (coordination between Member states on national enforcement practices) is completely new and did not exist under the previous regulatory framework. Hence, we have no assessment of the Forum's efficiency. Based on the analysis of ECHA's tasks and performance as described in its Work Programmes and General Reports, we have found that the resources required for the work of the Forum were available in time and in the proper quality and quantity. Hence, the Forum was supported in an economic manner.	
3. What are the main shortcomings that have been detected (if any)?	The relatively high workload for especially the RAC and MSC, combined with several concrete opportunities for making meetings and decision-making procedures more efficient, signals an urgent need to improve procedures. This need becomes more urgent with the expected increase in the workload due to the uptake of the authorisations and restrictions processes and possibly the new Biocides and PIC regulation.	2.3.2, 2.3.5.1, 2.3.5.2, 3.1.2, Annex A
4. Has the Agency undertaken activities in this work area which can be seen as complementary (but not strictly required by REACH) and which either had positive or negative impacts on the operations of REACH?	No complementary activities have been identified.	2.3.2, 2.3.5.1, 2.3.5.2, 3.1.2, Annex A
5. What recommendations (if any) does the contractor have to improve the operations of the Agency in this area of work to contribute more effectively to the objectives?	To urgently improve efficiency of the meetings of the Committees with the highest workload, for example by facilitating tracked changes in decision-making documents to be made available to Committee members, increasing the use of working groups and tele- and videoconferencing support. Especially in the most overburdened Committee, the RAC, the members and the Chairman should consider carefully which aspects of their discussions to date are explicitly part of the RAC's responsibility ("need to haves"), which aspects are additions to its responsibility that are not required by REACH or CLP but have been included thus far in its working practices ("nice to haves"), and which aspects border on its responsibility but are also covered by other ECHA processes or Committees. The latter two groups of topics should as much as possible be avoided. We recommend that the RAC (as well as other ECHA bodies that find themselves confronted with too much work, now or in the future) reconsider its rules and procedures to avoid drifting away from the "need to haves". Finally, we recommend that ECHA develop indicators based on the tasks and objectives of the Forum and monitor and evaluate the performance of the Forum together with the Forum members, to ensure its influence on the coherence of national enforcement practices.	2.3.2, 2.3.5.1, 2.3.5.2, 3.1.2, Annex A

Board of Appeal (B2)		
1. Have the main obligations from the REACH Regulation been implemented in an effective, efficient and economic manner?	Based on the low amount of only two appeals lodged in the review period – of which only one subject to the integral appeal process because in the other case the ECHA decision was amended, both outside the review period – we cannot judge the effectiveness, efficiency or economy of the work of the Board of Appeal (BoA). However, stakeholders recognise the way the BoA is organised as a sufficient guarantee for an independent appeal procedure and appreciate the reduction in the administrative burden due to not having to go to European Court of Justice as a first instance of legal redress. Hence, there are no indications that the BoA is not effective. ECHA has taken precautions to reduce the costs of the BoA in the event of a low caseload, by having alternate members that are not paid if they do not work on actual BoA cases and by allowing ECHA staff supporting the BoA to work on other ECHA processes (without involvement in (the preparation of) appeal-able decision-making). Hence, we find that the efficiency of the BoA could not be further improved without damaging (the good perception of) its independence.	2.3.2, 2.3.5.3, Annex A
2. What are the main shortcomings that have been detected (if any)?	About the setting-up of the BoA, we have the following comments: • Alternate members who report that they have a possible conflict of interest currently do not have to do this in writing to the Chairman of the Board of Appeal in all situations. The Management Board has proposed to make it mandatory for potential conflicts of interest to be reported in writing, in order to make sure that a clear and verifiable statement is always available for reference if required. • Alternate members have indicated that they would like to be better informed about the procedures and processes of the BoA in order to stay motivated.	2.3.2, 2.3.5.3, Annex A
3. Has the Board of Appeal undertaken activities in this work area which can be seen as complementary (but not strictly required by REACH) and which either had positive or negative impacts on the operations of REACH?	We have not found indications of complementary activities.	2.3.2, 2.3.5.3, Annex A
4. What recommendations (if any) does the contractor have to improve the operations of the Agency in this area of work to contribute more effectively to	In order to maximise the utility of the preparatory work done, a low-cost and pragmatic approach could be taken to inform alternate members about the processes and procedures of the BoA, such as a summary by e-mail. We do not recommend to involve alternate members in the preparation of appeals dossiers when this is not required for capacity reasons, as their work will result in costs for the Agency.	2.3.2, 2.3.5.3, Annex A

the objectives?		
Communications (B3)		
1. Have the main obligations from the REACH and CLP Regulation been implemented in an effective, efficient and economic manner?	ECHA has met most of its communication targets, but survey results indicate that not all stakeholders can easily understand ECHA's communications. There are no indications that communications were not implemented in an efficient and economic manner.	2.3.2, 2.3.4, Annex A
2. What are the main shortcomings that have been detected (if any)?	The one performance target that was not met concerns the timely translation of guidance documents aimed at SMEs.	2.3.2, 2.3.4, Annex A
3. Has the Agency undertaken activities in this work area which can be seen as complementary (but not strictly required by CLP and REACH) and which either had positive or negative impacts on the operations of REACH and the CLP Regulation?	The Agency has organised workshops and webinars directed at industry stakeholders in order to facilitate compliance with REACH and CLP. It is difficult to assess to what extent compliance would have been lower (if at all different) in case these workshops and webinars would not have taken place. Industry stakeholders indicate that they have benefited from these communications by the Agency, but we cannot provide a definitive assessment of their impact on the operations of REACH and CLP.	2.3.2, 2.3.4, Annex A
4. What recommendations (if any) does the contractor have to improve the operations of the Agency in this area of work to contribute more effectively to the objectives?	We recommend that the Agency consider its communication approach to facilitate understanding by the large audience of SMEs, as this stakeholder group will become more and more important in the coming years. Also non-industry stakeholder groups could benefit from a targeted communication approach.	2.3.2, 2.3.4, Annex A
(Relations with EU institutions and) international cooperation (B4)		
1. Have the main obligations from the REACH Regulation been implemented in an effective, efficient and economic manner?	Relations with non-EU CAs are good and important results have been achieved in cooperation with the OECD. We therefore consider that ECHA has performed effectively in this work area. Relations with EU institutions are addressed in other work areas where relevant. There are no indications that ECHA's tasks were not implemented in an efficient and economic manner.	2.3.2, 2.3.6, Annex A
2. What are the main shortcomings that have been detected (if any)?	The Commission has indicated that it is not fully satisfied with the support provided for international cooperation activities by the Agency. This concerns mainly the distribution of roles and tasks between ECHA and the Commission. Commission representatives indicated that they are happy with the work done together with the OECD, but that ECHA is allocating too many resources when it comes to relationships with non-EU countries, to the detriment of other	2.3.2, 2.3.6, Annex A

	tasks.	
3. Has the Agency undertaken activities in this work area which can be seen as complementary (but not strictly required by REACH) and which either had positive or negative impacts on the operations of REACH?	We have not found indications of complementary activities.	2.3.2, 2.3.6, Annex A
4. What recommendations (if any) does the contractor have to improve the operations of the Agency in this area of work to contribute more effectively to the objectives?	We recommend that ECHA and the Commission agree on a clear set of goals and distribution of tasks and associated resources for international cooperation.	2.3.2, 2.3.6, Annex A
Dissemination (B5)		
1. Have the main obligations from the REACH Regulation been implemented in an effective, efficient and economic manner?	Two main targets have not been (fully) achieved (see the shortcomings described below. There are no indications that dissemination tasks were not implemented in an efficient and economic manner.	2.3.2, 2.3.7.1, 2.3.7.2, 2.3.7.3, Annex A
2. What are the main shortcomings that have been detected (if any)?	The C&L Inventory has been delayed multiple times, resulting in a delay of more than one year in comparison to the deadline of December 2010 set by the Agency itself. The Commission, MSCAs and NGOs have indicated that this hampers them in their work to various extents. The dissemination website of the Agency did not provide sufficient information during the review period, according MSCAs and NGOs. Query possibilities are also rated insufficient.	2.3.2, 2.3.7.1, 2.3.7.2, 2.3.7.3, Annex A
3. Has the Agency undertaken activities in this work area which can be seen as complementary (but not strictly required by REACH) and which either had positive or negative impacts on the operations of REACH?	ECHA has chosen to invest time and resources in working with the OECD on its eChem Portal. This has resulted in a comprehensive dissemination structure, but the Portal suffered from the same criticism of providing insufficient information as the Agency's dissemination website during the review period. As the structure allows for effective dissemination once more data are available, we judge the impact of this additional activity to be slightly positive.	2.3.2, 2.3.7.1, 2.3.7.2, 2.3.7.3, Annex A
4. What	We recommend that ECHA address the information needs of industry	2.3.2, 2.3.7.1,

recommendations (if any) does the contractor have to improve the operations of the Agency in this area of work to contribute more effectively to the objectives?	as laid down in the REACH and CLP regulations and the expectations of NGOs more adequately in the coming period, by improving the quality of data provided. The means of presentation of the information is an improvement opportunity as well. Preliminary findings[51] from an ongoing study on the contribution of REACH to innovation suggest that innovation will be increased if more data are disseminated. Hence, dissemination is the main contribution of ECHA to achieving the benefits of REACH and should be an important priority for the Agency.	2.3.7.2, 2.3.7.3, Annex A
ECHA's management and financing structure (C1)		
1. Does the size, composition and context of the Board strike a reasonable balance between the need to retain an effective decision making body and the need to ensure stakeholder representation, involvement and commitment?	Over 50% of the survey respondents agree to this statement (only 6% disagree, the remainder are neutral). However, several members of the MB refer to examples of other agencies that have fewer MB members and are more effective and efficient in their decision-making. They consider that the MB is more of an administrative body than the Committees and Forum and therefore has a lesser need to ensure continuous representation of all Member States. We agree with the latter assessment, as another study found that "the standard approach (i.e. with all Member States represented) is unnecessary, costly, and ineffective. There are interesting exceptions to the dominant model of agency governance, for instance in the case of EFSA having a 15 member board mainly composed of professionals and experts.".[52]	2.3.2, 2.3.8, Chapter 4, Annex A
2. To what extent do the Agency's management systems and processes contribute to the effectiveness and efficiency of its operations?	The management systems in place function adequately and address most aspects of the Agency's organisation. The quality of target setting and evaluation has improved during the review period, but could be broadened further to incorporate more stakeholders' assessments of the Agency's performance.	2.3.2, 2.3.8, Chapter 4, Annex A
3. Has the funding structure limited the effective, efficient and economic implementation of the Agency's operations?	Budget implementation and budget execution are good, especially given the turbulent environment of the review period. The funding structure provides several challenges to the planning and accounting functions of the Agency, as the income from industry fees was and remains to a large extent unpredictable.	2.3.2, 2.3.8, Chapter 4, Annex A
4. What are the main shortcomings that have been detected (if any)?	During the review period, no cost accounting system was used that allowed to allocate resources to specific tasks and processes (e.g. at the level of the Agency's work areas). Hence, it has not been possible to fully assess the efficiency of the work in each work area.	2.3.2, 2.3.8, Chapter 4, Annex A
5. What recommendations (if any) does the contractor have to change the financing	We recommend that the financing structure remain largely the same. For the tasks of the Agency under the Biocides and PIC regulations, we recommend that a subsidy be granted similar to that for setting up the Agency and starting the implementation of REACH and CLP, but excluding the costs of practical matters of organisational set-up (i.e.	2.3.2, 2.3.8, Chapter 4, Annex A

[51] Available at http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/docs/events/ci-smit_en.pdf.

[52] Ramboll, Euréval and Matrix (2009). Evaluation of the EU decentralised agencies in 2009. Page 3.

structure of the Agency in order to ensure a smooth implementation of operations?	the costs of acquiring and redesigning the building or setting up the accounting system). The cost of recruiting and training people however should be recognised in the start-up phase of Biocides and PIC.	
The role of the Agency and its added value (D1)		
1. Does outsourcing to the Agency provide added value compared to possible alternative options of implementing the Community policy in question (e.g. through the Commission Services themselves, an Executive Agency, the contracting out of individual tasks, etc.)?	The current situation of ECHA as an independent agency in Helsinki shows (in comparison to the feasibility study report[53] published before the Agency was founded) that: • The costs for the implementation of REACH and CLP are in line with what was predicted by the feasibility study, and therefore the first consideration can be expected not to have changed. • ECHA clearly requires the ability to pay staff out of its fee income. • Due to the use of seconded Commission staff during the start-up phase of the Agency, the disadvantages vis-a-vis the "enhance ECB option" have been reduced. The transition has been seen as effective and efficient by all stakeholders. • As is shown by various findings, the Agency's independence and transparency are key to its current and future effectiveness and credibility in a broad stakeholder context. In conclusion, the current experience with ECHA unequivocally supports the decision to form an independent agency and gives no indication whatsoever to reconsider that decision.	2.3.2, 2.3.9, 2.3.9.1, Annex A
Acceptability of the Agency (D2)		
1. Does ECHA fulfil its obligations in a manner acceptable to all stakeholders involved?	As becomes clear from interview results, criticism can be voiced on several aspects of ECHA's work. However, as with any other policy field, it is simply not possible to satisfy all stakeholders when taking decisions that are the subject of conflicting interests. This pertains to many topics about which stakeholders have voiced their concerns to us. On the other hand, ECHA has proven to be able to engage and communicate to all stakeholders in one way or another and, by doing so, has achieved active stakeholder participation. Some members of ECHA's bodies have indicated that they sometimes find it difficult to work in an environment where English is the working language and no translations are provided. Although introducing translations in the Agency's numerous bodies would lead to significant costs, ECHA management and the chairmen of its bodies should take into account the effect the language barrier might have on the participation of its bodies' members in meetings and written communication. A clear challenge that remains to be met by the Agency is the dissemination of data and information it has acquired during the review period. Doing so successfully will be crucial to its credibility as	2.3.2, 2.3.10, Annex A

[53] Feasibility study on the resource requirements for a Central Entity. Final report. (June 2002). Deloitte & Touche. Ref. B4-3040/2001/329289/MAR/C3.

	an independent and transparent Agency. Failure to do so could lead to disengagement from stakeholder groups.	
Location of the Agency (D3)		
1. Does the current location (Helsinki, Finland) pose any challenges to the effective and efficient implementation of the REACH Regulation?	The current location affects the implementation of REACH in three main ways, when compared to more central locations in Europe:[54] 1. It increases long-term costs of human resources, as finding, hiring and retaining staff is more expensive. Retention is made more difficult by the fact that the spouses of Agency employees often do not find a job at their level in Helsinki and prefer to return to more central locations in Europe to further pursue their careers. 2. It increases travel costs reimbursed by ECHA to members of its bodies. 3. It creates a barrier for the Agency's stakeholders to attend meetings, in terms of both time and costs. The costs incurred by ECHA (points 1 and 2) have thus far not led to challenges to the implementation of REACH. However, they could be reduced through tele- and video-conferencing, teleworking (for example working from home on Mondays and Fridays) – or even offshoring some Agency tasks to branches in other countries – and other solutions that limit the costs due to physical distances. These solutions will contribute to the Agency's efficiency. The use of tele- and video-conferencing may also be useful to address the third point, but it cannot change the fact that the majority of ECHA's stakeholders representatives are based in Brussels.	2.3.2, 4.3.1, Annex A

5.2. Main conclusions from the Review

233 We have provided conclusions for each work area in the table in the previous paragraph. Therefore, we will provide below our more general and overarching conclusions only. The conclusions in paragraph 5.1 and the paragraphs below should accordingly be read together.

5.2.1. ECHA has had a good start-up as an organisation and implemented most of its REACH and CLP tasks effectively

234 As is evident from several findings and conclusions in this report, ECHA has set up an effective organisational structure during the review period and has managed to implement the majority of its responsibilities under the new REACH and CLP regulations, despite a considerable workload that at times exceeded expectations. As a result, the Agency is in a good position to continue the implementation of REACH and CLP and other regulations such as Biocides and PIC. Based on our review findings and our own experiences with the Agency during the Review, we consider it capable of implementing the recommendations we have formulated below.

[54] There are also advantages to the location in Helsinki, such as good housing, a school for the children of ECHA employees etc. However, these do not directly affect the Agency's cost base.

5.2.2. The Agency's overall efficiency has been reduced by unforeseeable circumstances and complementary activities

235 As discussed mainly in chapter 3, ECHA's efficiency has been reduced during the review period due to several causes. Most prominent were unforeseeable circumstances over which the Agency had no control (such as the large number of pre-registrations submitted) and activities that can be seen as complementary to the implementation of REACH or CLP, but are not strictly required by either regulation (such as the campaign to promote SIEF formation, the provision of QOBLs to registrants and the numerous workshops organised by ECHA). Clearly, ECHA is not to blame for unforeseeable circumstances and indeed has shown to be able to cope with them from the perspectives of effectiveness and economy, but a reduction in overall efficiency due to re-allocation of resources from other activities could not have been avoided.

236 Regarding complementary activities, the situation is different. ECHA chose to implement complementary activities knowing that implementing those activities would require resources and therefore making an implicit or explicit cost-benefit analysis by weighing the estimated resource requirements against the expected benefits to the implementation of REACH and CLP. Many of these activities were aimed at facilitating industry compliance with REACH and CLP. Our conclusion is that if the beneficiaries of these complementary activities indicate that they would rather not have them in the future, their contribution towards the effectiveness of the Agency should be considered as limited. Monitoring the satisfaction of the beneficiaries of complementary activities systematically would contribute to efficient resource allocation.

5.2.3. The Agency has demonstrated flexibility in the allocation of its resources

237 During the review period, ECHA has shown to be able to respond in a flexible and appropriate manner to unforeseen circumstances. This includes the re-allocation of resources when this was required, for example during the months leading up to the pre-registration deadline at the end of 2008 and in the preparations for the registration deadline during 2010, as well as reassigning staff back to their original roles after the unforeseen circumstances had been analysed and the appropriate level of resources required to manage the associated workload had been clearly established. The logical conclusion is that this flexibility and adaptiveness has allowed the Agency to limit the effects of these unforeseen circumstances on the overall efficiency of its organisation.

5.2.4. The Agency has successfully involved all stakeholders, but it could have done more to ensure its perceived independence

238 ECHA has implemented a number of activities to involve the various stakeholder groups in its work. A range of communication activities, including the Agency's comprehensive website, newsletters and press releases, helpdesk and stakeholder days, serve to inform a broad audience of stakeholders. ECHA has also organised workshops to involve various stakeholder groups, although workshops were mainly used to communicate and cooperate with industry stakeholders.

239 NGOs and MSCAs, as well as some Commission interviewees, have commented that ECHA appears to favour industry over other stakeholders. On the other hand, while industry stakeholders have indicated that the cooperation with ECHA could be more direct and that the Agency does not always follow their suggestions, they have not indicated that ECHA appears to favour other stakeholders over industry.

240 Another view has been that ECHA has two types of "clients": companies that it facilitates in complying with REACH as well as the Commission and MSCAs that it informs and supports through its analytical work and its various Committees. In the latter view, which is held by some industry representatives and some Commission interviewees, it is understandable that ECHA cooperates intensively with industry representatives, because they are responsible for supplying the information that ECHA needs to make REACH and CLP work. Hence, industry has significant duties under REACH and CLP, whereas NGOs have only rights. However, NGOs and MSCAs can also be understood in their wishes to avoid industry's interests outweighing those of other stakeholders in the decision-making of the Agency.

241 We conclude on two aspects of the intensive cooperation with industry stakeholders. First, ECHA rightfully recognises its independence as a key aspect of its mission statement, but has not been able to prevent the criticism of NGOs and MSCAs from arising. This means that the perceived independence of the Agency could be improved. Second, and as noted before, collaboration with industry is only to a certain extent required by the REACH and CLP regulations, but it does result in costs for the Agency. These costs cannot be justified when ECHA's activities go beyond what is required to ensure effective implementation of REACH and CLP and at the same time reduce its credibility as an independent agency.

5.3. Main recommendations to ECHA and the Commission

242 We have provided recommendations for each work area in the table at the beginning of this chapter. Therefore, we will provide below our general and overarching recommendations only. The recommendations have been formulated by PwC, based upon our findings from the Review and the recommendations made by stakeholders during a stakeholder focus group meeting. We have used our professional experience to weigh the findings and stakeholder recommendations. In order to be fully transparent, we have included the recommendations made by stakeholders in Annex E to this report.

5.3.1. Main recommendations to ECHA

243 We make the following recommendations to the Agency. Recommendations to the Commission will be addressed separately in paragraph 5.3.2.

5.3.1.1. Be more transparent about contribution to REACH and CLP objectives

244 As addressed in chapter 2 ECHA does not explicitly report on its contribution to most of the objectives of REACH and CLP. It is clearly understood that ECHA cannot realise all of those objectives by itself. However, more specific goals on each of the objectives (or the aspects of those objectives that are within the scope of influence of the Agency), as well as an clarification on how ECHA contributes to the key objectives of REACH and CLP, may be expected from the Agency tasked with implementing these regulations. We recommend that this information be included in the Agency's annual Work Programmes and General Reports in future years, so that its stakeholders can read how it contributes to the overall REACH objectives.

5.3.1.2. Capture the successes and learnings of the start-up period

245 The Agency has been able to celebrate many successes during the review period and has been able to learn from the first years of REACH and CLP implementation. The Agency has been transparent in its report about the progress made and targets achieved. The years 2007-2010 have also seen the groundwork for successful operations in the years to come.

246 We recommend the Agency capitalises on its achievements and lessons learned, because they can be expected to be very worthwhile not only to ECHA in its future operations but also to other regulatory agencies, the Commission and other public entities. Another reason for the Agency to harvest the learnings would be that part of its staff may leave over the coming years as a results of regular turnover and the logical reconsideration by its employees at the end of their five-year contracts. Thus, capturing lessons learned now will allow ECHA to protect its organisational knowledge base.

247 A good way to make the lessons learned available for future use would be to draft and continuously update factsheets or white papers on the Agency's successful approaches and interventions used in implementing REACH and CLP. Another way to do so is embedding lessons learned in ECHA's quality management systems.

5.3.1.3. Develop scenarios to ensure efficiency and economy in the future

248 During the review period, ECHA has been faced with unforeseen external circumstances that it could not influence and had to respond to by re-allocating resources. This affected its overall efficiency in comparison to the financial estimates of the Commission. As the Agency gained intimate knowledge of the scale and scope of the subject of its regulatory activities (the chemicals industry and the amount in which numerous substances

are developed, produced and traded), it is in a position to develop scenarios for its activities in the years to come, addressing the resources required for its various activities more adequately than it could have done thus far. Therefore we recommend that the Executive Director develop scenarios calculating the amount of resources required given various *states of nature* affecting its tasks for the coming years. These scenarios would allow the Agency to strategically approach its new tasks, as well as prevent as much as possible reductions in efficiency as a result of external circumstances.

5.3.1.4. Broaden stakeholder management activities to prevent disengagement

249 During the review period, ECHA has implemented its stakeholder management activities along three main lines: broad communication and events aimed at all stakeholders (such as stakeholders days, website, newsletters and helpdesk), events and communication targeted at specific stakeholder groups (e.g. workshops for industry and MSCAs) and specific roles and privileges for its 48 accredited stakeholders[55] (such as the right to attend Committee meetings).

250 We recommend that ECHA explicitly target SMEs subject to REACH as a separate stakeholder group, taking into account their need for more specific and concrete communication in their own language. Hence, translations are an important aspect of addressing this group.

251 Also, we strongly suggest to consider the criteria for accreditation of stakeholders, so that number of organisations allowed to attend Committee meetings increases. The reason for this is that currently, the attendance of Committee meetings is somewhat limited. Increasing the pool of potential attendants is likely to broaden the involvement of stakeholders in the implementation of REACH and CLP.

5.3.1.5. Share information and data when possible

252 As a final recommendation to the Agency, we encourage ECHA to share to the extent possible the information and data it manages, while respecting the essential role of protecting confidential information. This is the underlying requirement for achieving the goals of REACH and CLP regarding protection of human health and the environment as well as enhancing competitiveness and innovation, as well as a defining characteristic of a transparent and independent agency.

5.3.2. Main recommendations to the Commission

253 We make the following recommendations to the Commission.

5.3.2.1. Ensure future stakeholder-intensive agencies to get a more central location in Europe

254 ECHA requires numerous contributions from stakeholders to be able to effectively implement its regulatory tasks. The members of its bodies (MB, Committees and Forum) as well as its key stakeholders are often required to attend meetings at the Agency's premises. Stakeholders have cited several examples of the extent to which the Agency's location influences their contribution to its work, such as MSCAs not bringing a second person to Committee meetings because of the time investment required, NGOs not being able to attend Committee meetings, workshops or stakeholder days because of limited budgets and industry stakeholders selectively choosing which events to attend.

255 Therefore we recommend that in general, when new stakeholder-intensive agencies are to be established in the future, the Commission contribute to a decision (which is likely to be taken at the political level) to locate them in a more central location in Europe (defined in terms of the total travel times required for their expected key stakeholders).

[55] Any stakeholder that has presence in the majority of the 27 MS may request accreditation.

5.3.2.2. Maintain the current role of ECHA under REACH and CLP

256 Although this report contains various suggestions of how the work of the Agency to implement REACH and CLP could be improved, we have also highlighted how ECHA performed many tasks well. In addition, we have not found any substantial problems with the tasks that have been assigned to the Agency under REACH and CLP. If anything, we have provided feedback on the manner in which those tasks were implemented.

As a result, we recommend that ECHA's role under the REACH and CLP regulations stay the same in the coming period. Not only will this allow ECHA to make full use of the experiences from the start-up period of REACH and CLP in the future, it will also provide stakeholders with the consistency that is strongly beneficial in the implementation of complex regulations that require significant involvement from many organisations.