ANNEX 3

ARTICLE 117 REPORTS FROM ECHA

EXECUTIVE SUMMARY

1. REPORTING OBLIGATIONS OF ECHA

The EU Commission is to regularly report on the operation of REACH and the use and development of non-animal testing methods. It will use among others the respective reports by ECHA as information source to fulfil these obligations. ECHA's reporting obligations are also defined in REACH Article 117.

Article 117(2) of REACH states that:

Every five years, the Agency shall submit to the Commission a report on the operation of this Regulation. The Agency shall include in its report information on the joint submission of information in accordance with Article 11 and an overview of the explanations given for submitting information separately. The first report shall be submitted by 1 June 2011.

Article 117(3) of REACH states that:

Every three years the Agency, in accordance with the objective of promoting non-animal testing methods, shall submit to the Commission a report on the status of implementation and use of non-animal test methods and testing strategies used to generate information on intrinsic properties and for risk assessment to meet the requirements of this Regulation. The first report shall be submitted by 1 June 2011.

The following assessment is based in large part on the two reports to meet the requirements of Article 117 (2) and Article 117(3) that were published by ECHA on June 30th, 2011. These reports are viewed as complementing ECHA's annual reports, which are aimed at presenting the results of activities against the Annual Work Programmes adopted by ECHA's management board. Therefore, reference is made to the annual general reports by ECHA[1] and the Progress Report on Evaluation under REACH of 2010[2].

2. COMPOSITION AND ORGANISATION OF ECHA

ECHA reports that ECHA is set up, fully operational and fulfilling its tasks in time and to a good quality. Staff have been recruited and capacity been built in all relevant work areas. The Management Board, the committees and the Board of Appeal are working based on rules of procedure and fulfil their tasks within the legal deadlines.

ECHA further reports that the original planning did not consider all tasks and under-estimated the resource needs e.g. related to work on confidentiality, pre-registration, start-up of REACH processes, substance identification and the IT-infrastructure.

[1] Each 'General Report' is agreed by the Management Board of ECHA and published on the ECHA Internet site (http://echa.europa.eu/about/organisation/management_board/management_board_approved_documents_en.asp)..

[2] The Evaluation Reports are published on the publications section of the ECHA internet site (http://echa.europa.eu/publications_en.asp).

Furthermore, the unpredictability of the fee income is mentioned as a structural challenge.

ECHA identifies room for improvement with regard to the internal work efficiency and the efficiency of work within and between committees (including Forum). Workloads are expected to increase and in particular the resourcing of the committees is regarded as critical.

ECHA indicates a need for reviewing its funding, among other aspects to provide more flexibility to outsource work and secure a continuous income through the fees. However, ECHA does not specify the extent to which resources have been under-estimated, which resource needs are currently estimated for which activities, nor does it propose how the Fee Regulation could be changed.

3. CO-ORDINATION, CO-OPERATION AND INFORMATION EXCHANGE

ECHA report contains no specific section on co-ordination, co-operation and information exchange. ECHA implemented several horizontal activities to ensure coherency inside ECHA and across all its activities. Co-operation with the Member States, apart from the work in the committees, Forum and the helpdesk, is not specified with regard to the nature of the co-operation and its efficiency. The working relations with the Commission are also not described or qualified in detail.

ECHA reports co-operation with other scientific bodies of the EU. ECHA stresses that stakeholders are involved in all processes leading to an increase of transparency and credibility of decision making. Some activities, such as awareness raising campaigns, are conducted in co-operation with all stakeholders. Information dissemination is seen as successful, with most information from registration being published on the internet already.

Considering the relevance of understanding communication, co-operation and information exchange to understand reasons for good or less good functioning of the implementation of REACH, more and more detailed respective information could have been provided in the Article 117(2) report.

4. OPERATION OF REACH: REGISTRATION

The number of pre-registrations received exceeded the expected number by 15 times. This created some IT-problems and lead to a revision of ECHA's contingency planning for processing registration dossiers. To provide more certainty on the market and avoid large Substance Information Exchange Fora (SIEFs), ECHA now recommends that pre-registrations submitted by organisations that do not intend to proceed to registration should be removed by industry.

SIEFs suffered from difficulties in identifying lead registrants, abuse of the role of the SIEF formation facilitator and challenges in establishing substance identities and

sameness. Joint submission of data worked in the majority of cases and opt-outs are reported to be rare. Some registrants submitted separate dossiers or late registrations, the reasons for which are yet to be determined.

Data sharing is challenging to industry in particular where the relationships between companies are newly established in the SIEFs.

ECHA has processed a high number of inquiries of which some are believed to be submitted by companies hoping to remedy omitted pre-registrations. ECHA proposed that it would now provide information on what inquiries can and cannot achieve: In addition, it would collect fees for processing enquiries and request information on the intentions of enquirers to ensure that they have a legitimate reason for information requests and thus stop 'free-riding' and not justified data mining.

The processing of registration dossiers is regarded as generally successful and has proceeded without major technical or organisational difficulties. First compliance checks revealed that intermediate registrations are, in part, not sufficiently justified and that SME status (in order to obtain reduced fee rates) has been wrongly claimed in some instances. .

ECHA recommends several actions to improve the quality of registration dossiers, one of which is to consider whether ECHA should be empowered to initiate remedies for severe cases of incompleteness and noncompliance in registration dossiers.

The information provided on registration is comprehensive and provides a good overview of the activities of all stakeholders involved.

5. OPERATION OF REACH: INFORMATION IN THE SUPPLY CHAIN

ECHA provides little information on the functioning of communication in the supply chain beyond identifying a lack of harmonisation between exposure scenarios (ESs). ECHA hopes that the use of ES within CHESAR and IUCLID will increase harmonisation and intends to initiate an exposure scenario discussion platform for information exchange between registrants and downstream users.

6. OPERATION OF REACH: AUTHORISATION

ECHA has set-up infrastructure, capacity and competences, as well as work procedures, to process future authorisation applications. Up to now, ECHA has worked on the identification of Substances of Very High Concern (SVHC) for inclusion on the candidate list (preparation and management of dossiers) and on prioritisation proposals of Candidate Substances for inclusion in the authorisation list, including public consultations for both. In June 2011, 53 substances were listed on the candidate list and six substances on the authorisation list.

The development of SVHC dossiers is regarded as challenging and resource demanding. Improvements in dossier quality and content are regarded as necessary. Challenges in prioritisation proposals include, for example, the setting of sunset and application dates and the understanding of criteria for exemptions (intermediate uses, specific applications).

ECHA notes that a common understanding of risk management options under REACH is as yet missing. Member States don't have sufficient resources and sufficient information from the registration dossiers to prioritise substances for SVHC identification. In the public consultations, valuable information was obtained but third parties seem to lack an understanding of the aim and scope of this stage of the process.

The overall impression of the operation of the authorisation processes is that all actors struggle the understanding the procedure as such and its role in risk management under REACH, as well as the details of the provisions. Furthermore, ECHA and the Member States seem to suffer from a lack of (good quality) information with which to prioritise substances and prepare good quality dossiers.

7. OPERATION OF REACH: RESTRICTION

ECHA states it is well prepared to develop and process Annex XV dossiers on restriction proposals. It has built up related infrastructure, capacity and competences and gained experience, for example, by preparing a restriction dossier itself (mercury in measuring devices).

The efforts for the development of restriction proposals need to be proportionate to each case but still result in high quality of the dossiers. ECHA sees a conflict between the legal requirements and the practical needs for information in restriction dossiers, and recommends a review of the respective provisions in the REACH Annexes.

ECHA proposes to optimise the opinion forming work in the committees by shortening the consultation periods and aligning the procedures of the RAC to those of the SEAC. This includes introducing a public consultation on RAC opinions.

ECHA's improvement proposals are not well underpinned by argumentation; it is not clear why current guidance is not sufficient and the assumed consequences of shortening consultation periods with regard to the quality of third party inputs are not supported by evidence.

8. OPERATION OF REACH: EVALUATION

ECHA built up IT-infrastructure, work procedures and competences to carry out compliance checks of registration dossiers. The first dossier evaluations showed that many dossiers are non-compliant or that their quality should be improved. The core

improvement needs relate to the definition and description of the substance identity, the content of robust study summaries and justifications for data waiving.

The evaluation of intermediate registrations showed that the justification of intermediate status is often not sufficiently demonstrated and respective quality observation letters were sent to the registrants.
Testing proposals were assessed within the legal timeframes and involving stakeholder consultations. ECHA accepted most testing proposals unchanged or with modifications but found that the contributions from the stakeholder consultation should be more focussed on the substance in question in the future.

Challenges to dossier evaluation included, amongst other issues, the enforceability of decisions by the MS, finding the right balance between requesting information and related efforts and the level of regulatory output. Furthermore, ECHA highlights that evaluation decisions cannot address shortcomings in risk management and that the borderlines with other legislation should be discussed with all stakeholders.

Substance evaluations have not yet been performed but preparations have been made with regard to the procedures for setting up a Community Rolling Action Plan and agreeing criteria for substances to be evaluated.

In addition to the comprehensive overview of ECHA's evaluation activities, more details on the respective findings could be included in the reports, because the quality of registration dossiers is crucial for all REACH processes, even if this doubles information in the Evaluation Progress Reports.

9. NON-ANIMAL TESTING METHODS

ECHA concludes that registrants have made use of the mechanisms foreseen to avoid animal testing; i.e. data are shared, registrations are submitted jointly, existing data and alternative methods to provide information or waive requirements are used. ECHA considers that testing proposals have been submitted only as a last resort.

The analysis of registration dossiers showed that the use of existing data is the predominant approach to fulfilling registration requirements. Read-across, category approaches, waiving and weight-of-evidence approaches are also used quite often. The majority of the vertebrate animal studies since the beginning of 2009 reported in the dossiers have been conducted to close data gaps for Annex VII and VIII.

Improvement needs are identified in data sharing and joint submission in general, as deduced from the number of opt-outs and separate dossiers submitted. Furthermore, the evaluation of dossiers revealed that the avoidance of animal testing is not sufficiently justified, in all cases. Category approaches and read-across are, in part, not well documented or appear to be based on insufficient data, and waiving is not sufficiently justified based on the exposure scenarios etc.

Several research projects on-going within and outside the EU (without direct involvement of ECHA) are expected to deliver new non-animal test methods and strategies to combine information from different sources to avoid animal testing.
ECHA's reports don't include any targeted information on the use and implementation of non-animal testing methods (understood here as in-vitro testing) and the use of testing strategies, e.g. the justification for animal test proposals. Furthermore, no clear overview is given on the existence of (validated) in-vitro tests that could replace animal tests.

10. ENFORCEMENT

Enforcement of REACH is mainly the task of the Member States; ECHA is involved with regard to the Forum and referring cases of incompliance to the CAs. ECHA reports the Forum having work procedures in place and being fully operational. ECHA sees the Forum's growing workload as problematic and potential source of future problems. It also noted that there are challenges in enforcing the REACH requirements in a harmonised manner across all Member States.

ECHA requests that the Commission consider whether ECHA should be empowered to remedy severe cases of non-compliance where identified in registration dossiers.

Although ECHA has no direct enforcement tasks, in future reports a separate section would be helpful on ECHA's collaboration with the MS CAs and its ideas for becoming its own enforcement authority e.g. with regard to compliance of registration dossiers.

11. GUIDANCE AND SUPPORT

ECHA provides guidance and support to all stakeholders in the form of guidance documents, the helpdesk, IT-tools, ECHA website and training, webinars and workshops.

The co-operation with all stakeholders on the development of guidance is viewed positively, with consensus having been reached on many issues. Challenges are observed to still exist with regard to the translation of guidance documents, the timely provision of legal interpretations of REACH requirements and policy issues by the Commission as well as in the updating guidance in parallel to industry preparing for registration.

The ECHA helpdesk and the network of national helpdesks (HelpNet) which were established to agree on and ensure harmonised answers, are considered to provide resource efficient support for industry. FAQs have been published as one result of the common activities.

ECHA considers that the different IT-tools developed to process REACH information have been crucial for the success of the first registration deadline. Apart from a

system failure during pre-registration, the IT-system is reported as working well. The resources needed for the IT set-up and development were underestimated and sufficient funding should be provided to allow for future improvements and expansion of functions.

ECHA's website has steadily grown and it is planned that it will be revised to be more user-friendly in the future. Trainings, seminars, webinars and stakeholder days are named as additional guidance and support activities by ECHA. Their implementation is evaluated as successful as well.

The guidance and support activities appear to be well implemented and to be supporting all aspects of the operation of REACH.

12. REACH AIMS: PROTECTION OF HUMAN HEALTH

ECHA provides no specific information on human health benefits from the operation of REACH up to now.

13. REACH AIM: PROTECTION OF ENVIRONMENT

ECHA provides no specific information on environmental benefits from the operation of REACH up to now.

14. REACH AIM: ENHANCING COMPETITIVENESS, INNOVATION AND SINGLE MARKET

ECHA provides no specific information on enhancing competitiveness, innovation and single market from the operation of REACH up to now.

15. REVIEW OF ECHA REPORTS

A review of ECHA's reports against the legal requirements of Article 117(2) and 117(3), its tasks defined in the REACH text, its own work programs and general reporting standards show that ECHA generally has reported comprehensively with a high degree of quality. However, information on joint submissions (Article 117(2)) could be more consistent and reporting on how consistency at EU level is ensured (Article 75) appears to be missing from the reports. A structured overview of the operation of REACH is not provided and many recommendations are not transparently underpinned by argumentation in the report.

16. CONCLUSIONS AND RECOMMENDATIONS

ECHA's first reports according to Articles 117(2) and 117(3) provide a good basis for the EU Commission to prepare its report on the operation of REACH. Some identified shortcomings and general considerations regarding good reporting practice may be used to clarify the Commission's expectations towards ECHA's reports in the future, such as regarding the overall structure of the report, the (group of) addresses, the appropriate level of detail of different aspects of the operation of REACH, and the inclusion of budget information.

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A3.1. INTRODUCTION

A3.1.1 Overview

The objective of Task 3 is to provide a comprehensive overview of the information reported by the European Chemicals Agency (ECHA) on the implementation of REACH to support the European Commission in fulfilling its reporting obligations.

Information on the operation of REACH is presented in ECHA's report intended to meet the requirements of Article 117 (2). ECHA's conclusions on the use of non-animal testing are similarly provided in its report according to Article 117(3). The two reports were published on the ECHA website on June 30th, 2011.

ECHA is an independent Agency and works based on its objectives defined in REACH. The objectives are being further refined in its annual Work Programmes adopted by ECHA's Management Board. Guidelines exist for the compilation of Work Programmes by EU Executive Agencies as well as on how to compile Annual Activity Reports but they don't directly apply to the Article 117 reports.

ECHA's reporting on the operation of REACH according to Article 117(2) and 117(3) is regarded as targeted towards the operation of REACH and non-animal testing, and the annual reports are regarded as reporting against the work programme of the reporting year. It could be expected that information with high relevance for the operation of REACH would be repeated in the Article 117 reports, whereas information on implementation details of lesser importance would be only reported in the annual reports. The analysis of information in the annual reports was not in the scope of this study and could therefore be performed only in relation to a limited number of issues.

Facts, figures and qualitative information on procedures, cooperation, incompliance and improvement needs were mainly extracted from the Article 117(2) and 117(3) reports, processed and re-sorted under the different issues identified as relevant for the Commission report. In addition, ECHA's Progress Report on Evaluation under REACH[3] was analysed and the General Reports of the years 2008, 2009 and 2010[4] were screened for relevant information, and data was extracted where this was considered to amplify or clarify the information included in ECHA's Article 117 reports. In addition, clarification on a number of issues was requested from ECHA on 12.07.2011, 25.07.2011 and 03.08.2011. Such information provided by ECHA has been included in the report.

[3] European Chemicals Agency: Evaluation under REACH, Progress Report 2010, Helsinki 2010

[4] European Chemicals Agency: General report of the year 2010 – the year of registration, Helsinki 2011; European Chemicals Agency: General report of the year 2009 – the year of preparations, Helsinki 2010; and European Chemicals Agency: General report of the year 208 – the year of pre-registration, Helsinki 2009;

A3.1.2 REACH Implementation

In 2007, REACH came into force and ECHA was established. Pre-registration ended in 2008. During 2009 ECHA prepared for receiving registrations and in 2010 the first registration deadline expired. As of the current time, not all REACH provisions have come into full effect, e.g. no substance evaluation has been started and no application for authorisation has been submitted. Some of data from the first registration phase are published on ECHA's dissemination website.

The first years of REACH coming into effect were characterised by the set-up of infrastructure: in particular ECHA was set up as an entirely new agency; each Member States (MS) designated REACH competent authorities (CAs) and industry created "REACH units" or "REACH officers" within companies and formed Substance Information Exchange Fora (SIEFs).

Within ECHA, the Committees (including Forum) were established and helpdesks set up. Implementing guidance was developed and the REACH IT-system was set up.

The REACH aims of enhancing human health and environmental protection, while ensuring innovation and competitiveness of the European economy, are linked to several mechanisms of REACH such as the generation of new information (hazardous properties and risk management advice), shifting responsibilities, substitution of hazardous substances, etc. Assessing the extent to which the REACH aims are achieved requires information and data, among others on hazards, exposure levels and risks of single substances, as well as monitoring of the availability of substances on the markets. These data are hardly extractable from primary information but require analysis and assessment steps to derive suitable respective indicators.

At the current stage of REACH implementation, the market actors didn't have enough time to fully implement changes, for example in their selection of raw materials, their risk management and their communication behaviour. Hence, REACH effects on exposure levels or information availability are unlikely to be visible yet.

When formally considering the current State of Play, given standing practice in most reviews conducted on processes or institutions, it might be anticipated that ECHA's reports would discuss among others aspects the:

- efficiency and adequacy of the actually built-up institutional infrastructure to manage the required REACH tasks, including details of resourcing, workloads, competences etc.;
- division of labour and share of responsibilities between ECHA, MS and the Commission and possibly also with industry, including an analysis of overlaps, gaps and interlinks;
- process and outcome of establishing rules of procedure, working routines and co-operation agreements for the different committees and cooperation partners, including assessment of interlinks and friction points in cooperation, communication and information flow.

The extent to which the ECHA reports meet these expectations are described in Section 15.

A3.2. COMPOSITION AND ORGANISATION OF ECHA

A3.2.1 Introduction

ECHA was established on 1st June 2007 in accordance with REACH Article 75(1):

A European Chemicals Agency is established for the purposes of managing and in some cases carrying out the technical, scientific and administrative aspects of this Regulation and to ensure consistency at Community level in relation to these aspects.

ECHA became operational in 2008 and describes in its General Report 2010 that its mission is to manage all REACH tasks entrusted to it and to ensure a consistent implementation of REACH at Community level. Furthermore, ECHA seeks to provide Member States (MS) and EU institutions with scientific advice on chemicals. ECHA also has a key role in ensuring that 'the public at large as well as stakeholders in the chemicals industry have confidence that natural or legal persons are meeting the obligations placed upon them', as set out in Recital 65.

ECHA sees the establishment of a credible decision-making process and its independent contribution as crucial for the successful implementation of its mission. On its Internet site provides an organogramme of the roles and tasks of its departments and bodies which is summarised in Table 2.1.

Table 2.1: Information on the Bodies of ECHA
The European Chemicals Agency comprises: A **Management Board**, responsible for adopting the financial planning, work programme, annual reporting. An **Executive Director**, the legal representative of ECHA, responsible for the day to day management and administration of ECHA, including responsibility over its finances. The Executive Director reports to the Management Board. A **Secretariat** to support the Committees and Forum and undertake work on registration and evaluation processes as well as preparation of guidance, maintenance of databases and provision of information. A **Member State Committee** to resolve differences of opinion on draft decisions proposed by ECHA or Member States and make proposals for identification of substances of very high concern. A **Risk Assessment Committee** to prepare opinions on evaluation, on applications for authorisation, on proposals for restrictions and on classification and labelling. A **Committee for Socio-economic Analysis** to prepare opinions on applications for authorisation, on proposals for restrictions and on questions relating to the socio-economic impact of proposed legislative action. A **Forum** on enforcement matters to coordinate a network of Member States' competent authorities responsible for enforcement. A **Board of Appeal** to decide on appeals against decisions taken by ECHA
Source: ECHA Internet site (**http://echa.europa.eu/about/organisation_en.asp**)

Apart from the management of REACH, ECHA is or will be responsible for the implementation of the classification and labelling regulation, parts of biocides legislation and parts of the import and export (prior informed consent) regulation.

A3.2.2 Overall Management and Organisation of ECHA

Chapter 17 of the 117(2) report states that ECHA is successfully established, fully operational, including the Management Board[5] and the Board of Appeal, and fulfilling all tasks on time.

On ECHA's website it is stated that the Executive Director (ED) is the legal representative of ECHA who is responsible for the day-to-day management and all staff-related issues. Together with the senior management, he ensures that ECHA fulfils its objectives in a coherent, effective and efficient way.

ECHA's management is supported by the executive office (EO) which among others oversees the security and quality management and coordinates the strategic planning and monitoring.

The website also specifies that the senior scientific advisor ensures scientific quality, coherence and consistency of operational decision-making and advice provided. The internal auditor assesses specific processes in ECHA and coordinates related activities with other institutions[6].

The current structure of ECHA is illustrated in Figure 2.1.

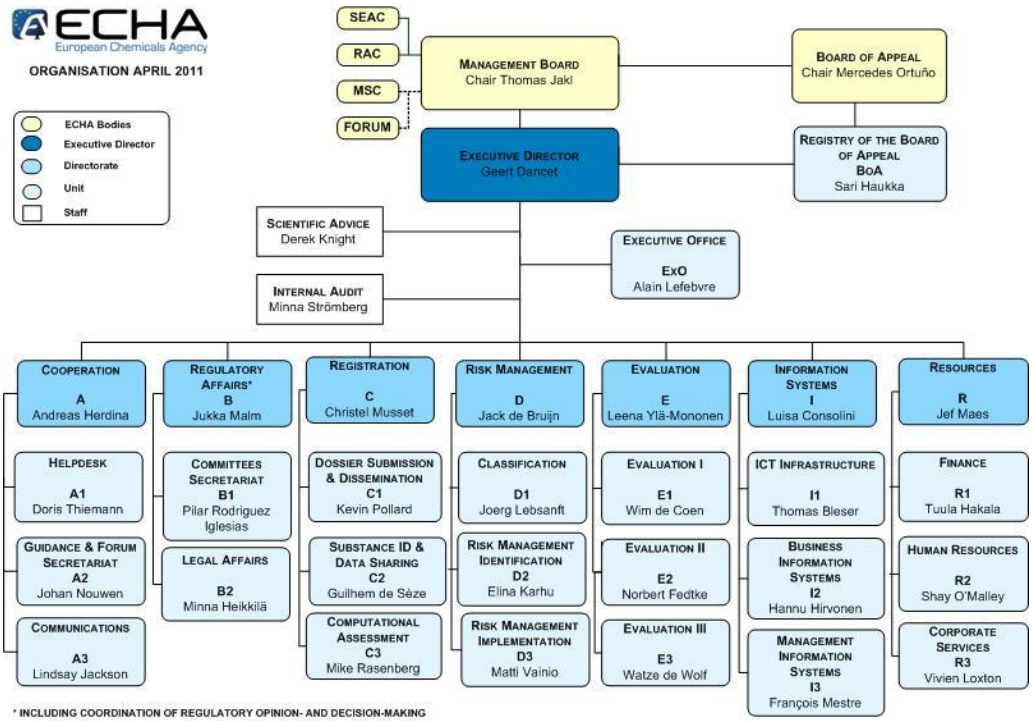

Figure 2.1: Organogramme of ECHA[7]

5 ECHA reports that its MB fulfilled its tasks within required deadlines and has met 22 times since 2007. It has had several working groups to prepare its discussions.

6 Information taken from the ECHA Internet site.

7 From the ECHA Internet site (http://echa.europa.eu/about/organisation/organigramme_en.asp).

According to the Article 117(2) report, the Management Board (MB) governs ECHA and provides strategic direction. It is composed of one representative nominated by each MS and appointment by the Council, (up to) six representatives appointed by the Commission and two independent persons appointed by the EU Parliament[8]. It is formally responsible for the adoption of strategic documents, such as the work programme and annual reports. The MB adopts the budget, provides opinions on the final accounts and appoints the ED, the Board of Appeal (BoA) and the committee members. The MB is fully involved in the budgetary cycles of ECHA since 2008.

ECHA has established several internal procedures including, amongst others, to implement quality assurance systems (Integrated Quality Management System established in 2009), to guarantee security of information (Security Plan, defined in 2008 and supported by the Security Officers Network), to manage ECHA's intellectual property and to maintain outside relations and deal with stakeholders.[9] This is part of an overall internal governance approach.

A3.2.2.1 Conclusions

A well-functioning ECHA is a core aspect for a well-functioning REACH implementation. Consequently, a description and analysis of the functioning of the overall management structure and control procedures, including mechanisms of quality control and internal and/or external review and audits would be useful information to provide when reporting on the operation/implementation of REACH.

The information is provided in more detail in the annual reports and on ECHA's website but has not been included in the Article 117 reports. Explicit mention of the main procedures and structures would be helpful for getting an overview of the operation of ECHA in the context of the operation of REACH.

A3.2.3 Board of Appeal

The Board of Appeal (BoA) is part of ECHA that reports to the MB but is independent from the ECHA secretariat and hence is able to take independent decisions on the appeals launched against ECHA's decisions[10]. It is composed of a full-time chairman and two full-time members as well as additional members. While the first appointment of board members in 2008 failed because the successful candidates declined appointment, the BoA became operational in 2009 (see Table 2.2)[11].

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8 Details on the composition of the Management Board from ECHA's website. Composition of the Management Board is dictated by dictated by REACH Article 79.

9 Details on the time and nature of procedures partly from the respective general reports.

10 According to REACH Article 91(1) appeals may be lodged against decisions pursuant to the Articles 9, 20, 27(6), 30(2), 30(3) and 51.

11 Details on composition and election of the BoA from the website and the general report of 2009.

The BoA developed and revised procedures, implemented quality assurance systems and established practical tools to facilitate communication and support parties in the appeal proceedings.

The BoA receives administrative support from the Registry (established in 2008) which among other roles developed and published procedural rules and managed proceedings and correspondence related to appeals.

The 117(2) report specifies that there is a high level of awareness by industry of the possibility to launch appeals but that little practical experience exists due to the low number of cases submitted to date. The procedure as such is evaluated as advantageous compared to court proceedings because of its suspending effects, the full authority BoA has to change ECHA decisions, its high speed and the availability of guidance and format templates.

The BoA is seen as an important element in the operation of REACH because it ensures high quality decision making by providing a point of legal redress. The fact that ECHA has implemented some of the appeals decisions is regarded as proof of sound administration.

Based on an argumentation founded on good governance and a comparison with appeal procedures in other agencies, ECHA recommends that (without describing related problems in the appeal procedures conducted to date):

- rectification and the appeal procedures should be separated; i.e. the appeal should not be subject to consultation with the Chairman of the BoA and the timelines for deciding on inadmissibility and rectification should be sequential;
- the time period for defence should start only after ECHA has passed a case to the BoA.

Table 2.2: Overview of BoA Activities and Member Appointments

	2007	**2008**	**2009**	**2010**	**2011 (Q1)**
Appeals finalised on the basis of rectification by ED	n.a.	-	1	-	2
Appeals concluded before consultation by ED (manifest inadmissibility)	n.a.	-	-	-	-
Written requests for information on appeals	-	-	5	1	6
Staffing # (regular / alternate member appointments)	-	0/3	3/8	3/11	2/11

Source: ECHA report on the operation of REACH, Table 18, p. 68.

A3.2.3.1 Conclusions

The information on the Board of Appeal illustrates the contribution of this body to the operation of REACH and points out well justified improvement options. However, it should be noted that the appeals procedure had not dealt with many cases, at the time of reporting.

A3.2.4 The Committees

The Member State Committee (MSC), the Committee for Risk Assessment (RAC) and the Committee for Socio-Economic Analysis (SEAC) are integral parts of ECHA. ECHA considers the Committees to be important in particular with regard to increasing the credibility of ECHA with respect to independence, scientific integrity and transparency of decision-making. Information relating to the operation of the Forum may be found in Section A3.10 (Enforcement).

All committees first met in 2008 and started work by developing a common understanding of their roles and tasks and by establishing respective rules of procedure and working procedures. Up to now the committees have processed all received dossiers within the legal timeframes. ECHA evaluates the committees' opinions and agreements to be of high quality and all were adopted either by consensus or unanimously.

ECHA regards MSC, RAC and SEAC as being fully operational and evaluates the range of expertise as well balanced and including the necessary skills to fulfil the required tasks. At present, the actual number of members in the committees is lower than legally foreseen (on average about 57% of possible members are actually participating), because some MS have not yet nominated all the possible candidates. The numbers of committee members are provided in Table 2.3.

Table 2.3: Number of Members of RAC, SEAC and MSC Committees

Committee	RAC	SEAC	MSC
Total possible	65	65	35
Members	36	30	29
% of Total Members not yet Nominated	45	54	17

Source: ECHA report on the operation of REACH, Figure 13, p. 64.

In their evaluation, ECHA considers the participation of eligible stakeholder organisations in the committees as observers to have been positive but notes that confidentiality needs to be balanced against transparency of decision-making, and that contributions need to be within the given timeframes.

The committees' workloads have increased continuously due to the high (and increasing) numbers and complexity of dossiers being brought forward (restrictions, harmonised classification and labelling, SVHC identification) and numbers of evaluation decisions received. The resources and time needed to process a dossier or evaluation decision are not specified in the report and it is unclear if such information has been gathered. The cumulative output of these Committees is shown in Figure A3.2.2.

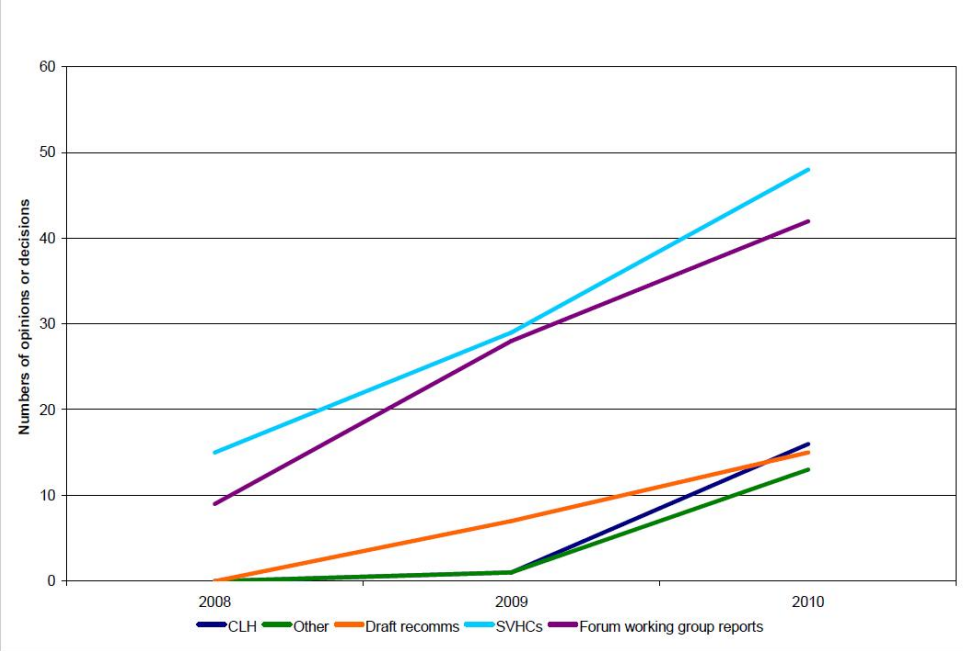

Figure A3.2.2: Cumulative Output of Committees & Forum (2008 – 2010)[12]

With a view to the increasingly high workload and the low number of participants in the committees, ECHA highlights a need for increased efficiency and use of resources. Current inefficiencies in the work of these Committees are not described in detail, except in relation to draft evaluation decisions in the MSC[13]. ECHA recommends an improvement of the rules of procedure in general but no details are provided.

Importantly, ECHA expects available resources in the committees to be insufficient for predicted future work load and strongly requests the MS CAs to nominate the full permitted number of members. With regard to the RAC, ECHA proposes to split the committee; one part to work on harmonised C&L and the other on authorisation and restrictions.

A3.2.4.1 Conclusions

In the light of the important role of the Committees and the challenges experienced regarding cooperation, communication, resources and need of expertise, the information provided in the Article 117 reports could be more extensive and detailed.

Past difficulties and the nature of improvements of working practices are not described. Furthermore, the time and resources needed for future dossier processing

12 ECHA report on the operation of REACH, Figure 12, p. 63.

13 MS CA comments partly cause unnecessary work because they are not focused to the aim of dossier evaluation and could be prevented by better explanation of the draft decisions by ECHA. The MSCs work in general is regarded as efficient, because referral to the Comitology Procedure could be avoided by unanimous agreements in the MSC.

are neither specified nor related to the number of expected dossiers and the available resources. Hence, the extent and potential impacts of under capacity are not clear. Consequences of not meeting the deadlines are also not described in the report. Therefore, neither the urgency of taking action nor the consequences on the overall operation of REACH and meeting the goals of legislation are made clear.

A3.2.5 Staff and Skills Available to ECHA

ECHA reports that it started recruiting staff in 2007 and highlights the challenges encountered, including among other reasons, the required speed of recruitment and growth and the need for potential staff to relocate to Helsinki. ECHA stresses that renewed efforts will be needed to seek further suitably qualified staff and retain existing staff in the coming years. An overview of the number and contract types of the workforce over the first years of operation is given in Table 2.4.

Table 2.4: Number of Staff Working at ECHA

Year	Temporary Agents	Contract Agents	Seconded National Experts	Total
2008	210	9	5	224
2009	293	27	5	325
2010	381	43	6	430
2011	397	53	6	456

Source: ECHA report on the operation of REACH, Table 23, p. 80.

Mainly due to the fast growth of ECHA and the reorganisation of the internal structures, the coordination of staff is reported to be more challenging and resource demanding than anticipated. For example, the reorganisation of staff in preparation of the upcoming evaluation work proved challenging because staff needed to be integrated into interdisciplinary teams and, at the same time, internal scientific competency had to be increased. Since its establishment, ECHA has implemented internal training and coaching activities directed to capacity building among its staff. [14]

ECHA evaluated the initial staff model as a good basis for its work. However, a revision of the model for future staffing is considered necessary because some processes and tasks were not anticipated, under-estimated or missing. Also, the work load was unexpectedly high because of issues relating to data confidentiality, security modalities (access of MS CAs to REACH data) and the high number of pre-registrations received. Furthermore, resource needs were underestimated for the general start-up of ECHA, and for translation, substance identification aspects and IT-infrastructure.

A survey carried out by medical experts among ECHA's staff in 2010 is reported to have found that a significant number of staff are experiencing high stress levels due to high workloads. A comparison to "general" stress levels or those of other agency staff is not provided.

[14] Information on staff preparation for evaluation and training from general reports.

ECHA states however that it has improved its overall capacity to provide scientific and technical advice. For example, during 2010 ECHA improved its competency in relation to the safety of nanomaterials by closely following and commenting the RIPoNs and the scientific discussion on the definition of nanomaterials. It is not described to whom or how ECHA has provided scientific technical advice outside the REACH processes. ECHA also notes that it needs further resources not directly dedicated to specific REACH tasks for capacity building and answering science-related questions.

ECHA was restructured in January 2011 and a number of horizontal mechanisms were put in place such as a directors' coordination meeting and topic specific boards of directors, in order to take account of the growing staff numbers and to ensure consistent approaches are adopted across all activities.

A3.2.5.1 Conclusions

With regard to the operation of REACH it is important that sufficient and well qualified staff are available to ECHA to undertake all necessary tasks. The report suggests that respective resourcing is not adequate but fails to provide background information to justify this statement. In particular, the level of qualification and experience of personnel in relation to past and future tasks would be helpful.

A3.2.6 Resources and Funding

ECHA states that it needs sufficient and predictable funding to ensure tasks are fulfilled continuously and to a high standard. The fee incomes are seen as unpredictable (volume and timing), leading to contractual uncertainties, hampering of capacity building and structural challenges and difficulties in long-term planning. The number of staff allocated to the tasks discussed in the ECHA report during 2010 is presented in Figure 2.3.

ECHA also states that current provisions and possibilities for funding and financing its activities are not sufficient. According to the current provisions, ECHA can only pay MS experts in the context of public procurement but requires greater flexibility to achieve a higher level of co-operation, e.g. the possibility to provide grants. Furthermore ECHA requests that better account is taken of its resource and spending needs when considering a potential modification of the Fee Regulation and, among others, revenue arising from the appeal fees should be taken into account.

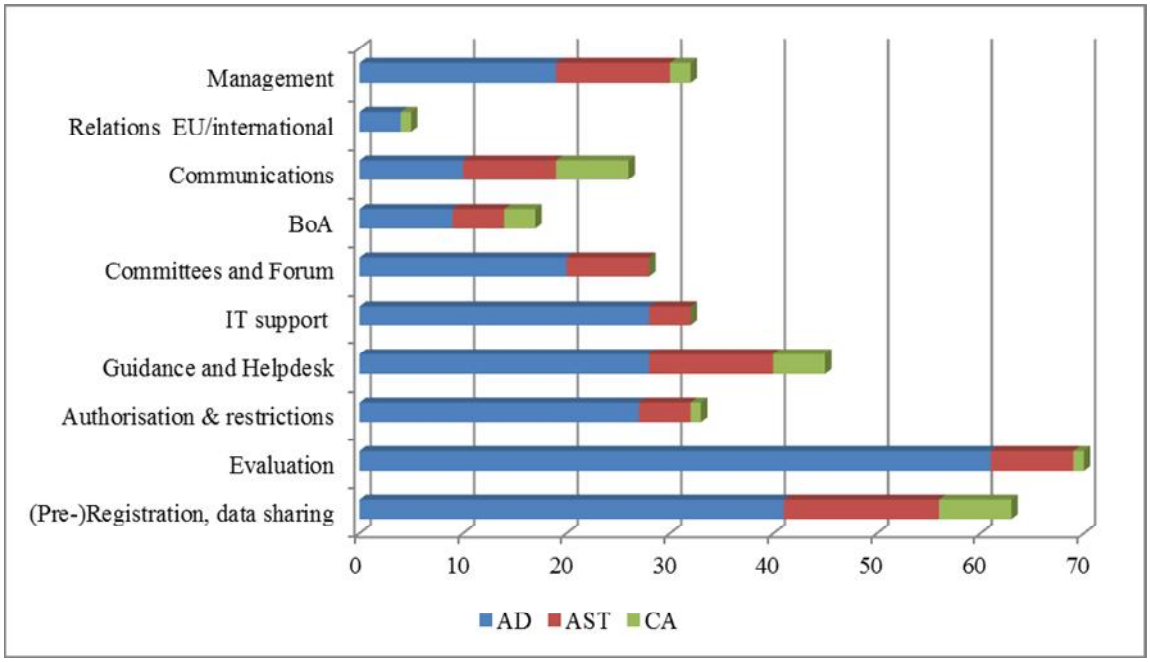

Figure 2.3: Number of ECHA's Staff according to Activities (2010)[15]

A3.2.6.1 Conclusions

ECHA's report does not link staff numbers with activity areas or tasks[16] and does not specify the qualifications and experience of staff Furthermore, no distinction is made between scientific/technical, IT- related and administrative personnel. The initial staff estimates are not compared to the current work-force and the extent to which additional personnel have been employed is not specified. It also remains unclear to what extent ECHA already uses its expertise to provide advice outside the formal REACH processes[17].

Due to these information gaps, ECHA's argumentation for increasing resources is not regarded as developed and presented well (although it may be factually correct). This is particularly underlined by the fact that – - despite ECHA's claim that resources had been originally under-estimated – all tasks were completed in time.

A comparison how other agencies that are to some extent funded by fee incomes tackle the funding problems would have been valuable information for developing improvement proposals.

15 ECHA General Report 2010, Annex 2, p. 9, available from the ECHA Internet site (http://echa.europa.eu/doc/about/organisation/mb/mb_03_2011_General_report_2010_final.pdf).

16 The above information / figure is NOT contained in the 117(2) report.

17 Information on international work is given in Section 10.6.

A3.2.7 Conclusions on Reporting Related to the Organisation of ECHA

Information provided on ECHA's internal structure is helpful to understanding whether ECHA can manage all tasks to ensure a smooth operation of REACH. However, data on the efficiency of ECHA's work is not so helpfully provided.

Based on the provided information, it is not possible to fully understand:

- which resources are available to ECHA (qualification, experience and numbers of staff per task/area);
- which resources are actually needed (no estimates on time per task and amount of task);
- how the stated resource needs of the past compare to the original planning; and
- the specific action that should be taken in the future.

A3.3. CO-ORDINATION, CO-OPERATION AND INFORMATION EXCHANGE

In its report, ECHA indicates that it co-operates and communicates with the Commission, MS and stakeholders on all relevant areas of its work so as to ensure transparency, credibility and acceptance of all decisions and procedures developed or implemented.

The efficiency and quality of communication and co-operation involving ECHA is generally assessed as "working well" but no particular evidence or performance specifications are provided.

A3.3.1 Inside ECHA

The 117(2) report mentions that ECHA was reorganised and horizontal procedures implemented to take account of the growing number of staff and the need to ensure credibility, transparency and independence. Difficulties in internal co-ordination, co-operation and information exchange are not specified[18].

No details are provided on whether internal reviews or audits were performed and, if they were conducted, which conclusions and recommendations they had and how they were implemented.

A3.3.1.1 Conclusions

ECHA's internal co-ordination, co-operation and information management is mainly the subject of the separate thematic study on reviewing efficiency of ECHA[19]. Nevertheless, a general overview and assessment of the efficiency of the processes and work relations inside ECHA's would have contributed to the overall picture on the operation of REACH.

A3.3.2 ECHA and the Member States

No details are reported by ECHA on the extent or level of co-operation, co-ordination and communication undertaken directly with the MS; this aspect is only addressed in the context of the committees, Forum and the helpdesk. For example, no description is provided of notifications from ECHA to the Member States (e.g. on the process of

[18] The general reports list several activities related to internal communication. In 2008, ECHA ensured internal information flow by establishing the intranet and the principle communication channels of regular staff assemblies and meetings of directors and at unit level. In 2009, based on a strategy and an action plan for improving internal communication, a number of communication tools (including a newly built intranet site (ECHAnet)) were established. These tools have been further developed in 2010.

[19] Review of the European Chemicals Agency (ECHA) based on Article 75 of Regulation (EC) N° 1907/2006.

dossier evaluations) nor on whether these are technically robust and regarded as useful. The level and nature of information Member States provide to ECHA is not described. It is also not clear if ECHA receives feedback from the MS CAs on how notifications of non-compliance are enforced[20].

In the annual general reports, ECHA states it has continuous contacts with MS (including visits to the CAs). In relation to more flexible instruments, ECHA describes that the intensification of co-operation with MS experts would be advantageous but would require the possibility to provide grants to make use of paid experts.

A3.3.2.1 Conclusions

Good co-operation, co-ordination and information flow are regarded as essential for the operation of REACH. Therefore, a more detailed analysis of challenges in this area (e.g. regarding resource needs, efficiency of communications, lack of feedback and procedures, misunderstanding etc.) would substantially facilitate understanding potential difficulties in enforcement and the processing of registration dossiers.

A3.3.3 ECHA and the European Commission

No details of co-ordination, co-operation and information exchange with the Commission are contained in ECHA's 117(2) report[21]. The quality and level of co-operation, co-ordination and communication achieved is not evaluated.

A3.3.3.1 Conclusions

A clear picture of the division of tasks and responsibilities between the Commission and ECHA and the related co-operation, co-ordination and communication needs are essential in order to understand how the development of opinions and decisions, as well as the legal interpretation of REACH, are functioning. For the evaluation of whether or not REACH is operating well, ECHA's view on the core challenges in this are essential and should be included in future reports.

A3.3.4 ECHA and other EU Bodies

In the general reports, ECHA states that it regularly liaises with the EU Parliament, the Council and the Commission. It regularly informs the Parliament's liaison person and the Members of special committees of the European Parliament.

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[20] It is only stated that enforcement is challenging due to the different approaches of the Member States.

[21] In the general reports, ECHA states that it has regular contacts with the Commission and that occasional, high-level meetings at Director General-level occur. At the working level, interactions occur with Commission officials from DG ENTR and DG ENV.

According to the 117 reports working procedures are being developed to facilitate co-operation with other EU scientific bodies (i.e. EFSA[22], SCOEL[23] and ACSHHPW[24]), where exchanges of information and methodologies are envisaged. ECHA also reports that it has co-operated with OSHA to reach companies and raise awareness on registration issues.

ECHA requests that reciprocal legal obligations should be placed on relevant EU bodies that it is to cooperate with, so as to ensure systematic information exchanges can occur and potential diverging opinions can be identified early and managed.

A3.3.4.1 Conclusions

Co-operation and co-ordination with other EU bodies is necessary in particular to ensure coherence and consistency of decisions and opinions across the EU. This aspect in ECHA's legal responsibility under REACH Article 75 is not specifically addressed (i.e. the questions of whether coherence is ensured and how this is achieved are missing).

The request for reciprocal legal obligations implies that ECHA's efforts to establish work relations with other EU scientific bodies were not adequately met; however the nature of difficulties are not stated and it cannot be decided if legal obligations are the best option.

A3.3.5 ECHA and Stakeholders

As described in the 117(2) report, ECHA involves stakeholders in many of its activities, in particular guidance and IT-tool development. The participation of stakeholders is considered of value as it is important for the credibility and transparency of decision-making, although consultation procedures are noted to slow down the processes. In total, over 50 EU-level stakeholder organisations work with ECHA.

ECHA reports that it has improved communication with third parties, amongst others by publishing the consultation results in the context of testing proposals. ECHA also organises Stakeholder Days, workshops and webinars for stakeholder involvement and transparency on different topics. An overview of stakeholder activities is provided in Table 3.1. Reaching and communicating with all relevant companies is stated as the greatest challenge facing ECHA.

Table 3.1: Overview of Stakeholder Activities (2007 – 2011)

Activity	2007	2008	2009	2010	2011
Stakeholder Days	0	1	2	2	1
Number of Participants (on site & web stream)	-	800	1,400	1,700	800*

[22] European Food Safety Agency.

[23] Scientific Committee on Occupational Exposure Limits.

[24] Advisory Committee on Safety, Hygiene and Health Protection at Work.

Table 3.1: Overview of Stakeholder Activities (2007 – 2011)					
Activity	**2007**	**2008**	**2009**	**2010**	**2011**
On-to-one Sessions	0	0	0	2	1
Number of Participants-	-	-	-	140	100*
Workshops in Brussels	0	1	1	0	1
Number of Participants	-	25	25	-	25-35*
Webinars	0	0	3	14	-
Number of Viewings	-	-	6,200	7,000	-
ECHA Speakers at External Events	20	100	90	90	80*
Note: * = expected. Source: ECHA report on the operation of REACH, Table 22, p. 73.					

A3.3.5.1 Conclusions

Information provided on ECHA's collaboration with stakeholders is sufficient to get an overview of what and how it contributed to the operation of REACH. However, an evaluation of the co-operation by the stakeholders, and potential feedback on ECHA's approach to involvement and transparency, would be of interest and could be usefully provided in future reports.

A3.3.6 Common Activities Involving ECHA, the Commission, MS and Stakeholders

ECHA co-operates and co-ordinates several common activities involving the Commission, Member States and Stakeholders (e.g. to raise awareness on pre-registering in time, SIEF formation, the need to notify in time, etc.).

The Directors Contact Group (DCG) was established in January 2010 and consisted of directors of the Commission, ECHA and six industry associations; MS representatives did not participate. The aim of the DCG was to monitor the preparedness of industry to meet registration deadlines and address difficulties. Its activities comprised the refining of registration estimates (since actual registration intentions were unclear due to the very high number of pre-registrations) and to develop solutions for issues of concern raised by industry. The contribution of the DCG is evaluated as being helpful by ECHA.

ECHA established a Risk Communication Network and together with that Network developed guidance relating to chemical risk communication.

A3.3.6.1 Conclusions

Information provided in the Article 117(2) report complements the information provided in the other sections. An assessment of the helpfulness of the DCG by other actors would be helpful to allow conclusions to be drawn on the relevance of this aspect to the operation of REACH.

A3.3.7 ECHA Interactions with Non-EU Actors and Organisations

ECHA's international activities are defined in the annual work plan adopted by the MB. ECHA reports activities in five fields:

- multilateral organisations and conventions;
- OECD work;
- contacts with regulatory counterparts;
- support to (potential) candidate countries; and
- dissemination of information on REACH implementation.

At the OECD level, ECHA co-operates in the development of IUCLID and the eChem Portal and contributes to the development of the QSAR Application Toolbox. It also supports the Commission in several OECD working groups[25] and in relation to work on the Stockholm Convention.

ECHA has participated in meetings and conferences in third countries relating to, amongst others, provision of information about REACH and to provide training to pre-accession countries. During 2010, ECHA signed the first co-operation agreements with "Environment Canada" and "Health Canada", as well as with the USE EPA Office of Pollution Prevention and Toxics.

A3.3.7.1 Conclusions

As the report deals with the operation of REACH, information on ECHA's collaboration with non-EU actors should clearly be pinpointed to highlight their contribution to the functioning of REACH; however, this is not the case in the current report. Other information would perhaps be better reported in the context of the general reports rather than in the context of Article 117(2).

A3.3.8 ECHA's General Information Dissemination Activities

Information channels for dissemination are reported to have developed as the REACH implementation progressed. The pre-registration list was published in 2008, non-confidential information in registration dossiers was published starting in December 2009 and the automatic publication of registration information started in March 2011. In April 2011, information from individual and lead registrants' dossiers was published for 3,079 phase-in (90% of all registered by Nov. 2011) and 332 non-phase-in substances (total 3,411). However, it should also be noted that there have been delays in the dissemination of information required under REACH. For example, an incomplete version of the classification and labelling inventory was not made available until 14 February 2012.

[25] For example, ECHA participates in task forces on chemicals, hazard assessment and exposure assessment, groups on the Globally Harmonised System for C&L, on nanomaterials and the test guidelines programme.

It is reported that there are approximately 700 visits to the dissemination website each day and until March 2011 a total of 40,000 visits had been counted. There are also 13,000 registered subscribers to the ECHA news service and the newsletter has been published every 2 months since July 2008. In addition, reports, guidance and leaflets are regularly published on the ECHA Internet site.

A3.3.8.1 Conclusions

The Article 117 reports give a good overview of how information on substances are made available to the general public, which is one important goal of REACH.

A3.3.9 Conclusions on Coordination, Communication and Information Flow

The Article 117(2) report lacks a structured overview of the co-operation, co-ordination and communication needs between the relevant actors within and outside the formalised processes of REACH. The actual implementation of respective mechanisms and an analysis of how well these approaches work, are also not provided.

Due to the lack of information on the nature of challenges encountered in the past and the consequences of unsuccessful co-operation, co-ordination and communication, the overall impression from the report is that there are no such problems. This is however questionable given the amount of (new) tasks and issues to work and communicate on and the (partly new) division of responsibilities and tasks.

The inclusion of a separate chapter on co-operation, co-ordination and communication in the next Article 117(2) report is recommended in order to provide an overview of these aspects of the operation of REACH and to highlight improvement needs. Furthermore, details of "informal" REACH procedures and implementation would be informative.

A3.4. OPERATION OF REACH: REGISTRATION

The presentation by ECHA of information on substance registration is split into a number of categories: pre-registration; SIEFs; joint submission; data sharing; inquiries; and data provision by ECHA; and registration.

A3.4.1 Pre-registration

ECHA reports that it received 2.7 million pre-registrations with respect to 140,000 phase-in substances). The number of pre-registrations was 15-times higher than had been estimated[26]. Approximately 50% of the pre-registrations were received two weeks ahead of the deadline. The list of pre-registered substances consisted of 146,014 substances, including 41,281 substances without an EC number[27] (18%). Also, 14,528 substances were submitted as multi-constituent substances.

It is noted that 82% of the pre-registering companies indicated they were SMEs and 20,000 companies indicated an intention to register before the first deadline (covering approximately 250,000 different substances). The highest numbers of sign-ups and pre-registrations came from Germany, the UK, France, Poland, the Netherlands and Italy.

The high number of pre-registrations led to a temporary overload of the IT-system and communication with industry on the system usability. In response, ECHA revised its contingency planning for the registration process and prepared to handle a maximum of 75,000 registration dossiers. The response included the training of 75 staff to be redeployed in case of submission peaks and the recruitment of interim staff. Additional staff was necessary for the first submission peak in September 2010 (lead registrants) but was not needed in the November (for member dossiers).

The reasons given by ECHA for the unexpectedly high number of pre-registrations are that the process was simple, required little information and was free of charge. Due to uncertainties regarding exemptions of substances from the scope of REACH companies tended to pre-register their entire portfolio to be on the safe side.

The large number of pre-registrations created confusion as to the actual registration intentions in the supply chain and triggered work by the Director's Contact Group (DCG) to estimate actual registration intentions by surveys of industry.

ECHA revised the list of pre-registered substances (March 2009) in particular regarding those substances without EC numbers, by clarifying substance identities with industry (General Report 2009).

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[26] Originally it was estimated that 130,000 pre-registrations for 70,000 substances and intermediates would be received. The source of this estimation is not specified in ECHA's report.

[27] This includes substances presumably manufactured in the EC but not placed on the market (phase-in status according to Article 3 (20)(b) and substances with an EC number, which was not used).

In order to clarify actual registration intentions and limit the size of the SIEFs, ECHA recommends that companies who pre-registered but don't then intend to register should (be encouraged to) deactivate themselves or request deletion of their pre-registrations.

A3.4.1.1 Conclusions

The information provided gives a good picture of the operation of the pre-registration process.

A3.4.2 Substance Information Exchange Fora

After pre-registration, industry was encouraged to form Substance Information Exchange Fora (SIEFs) and 2,176 lead registrants identified themselves voluntarily to ECHA.

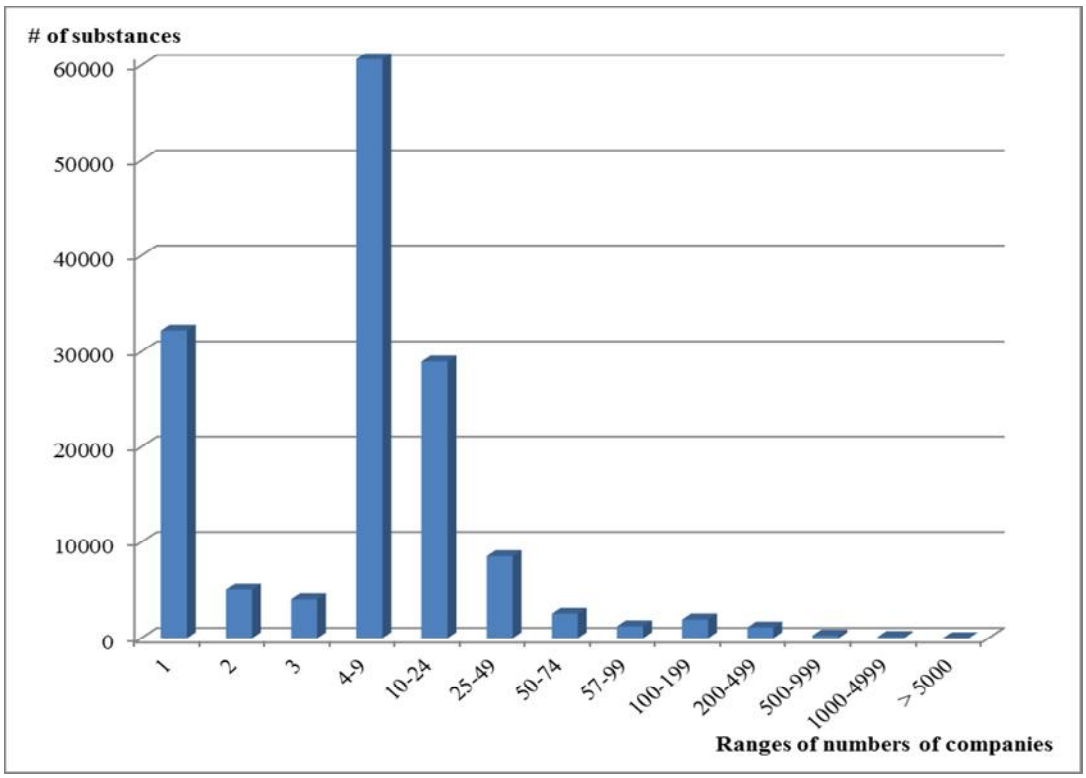

Figure 4.1: Size Distribution of SIEFs Related to Number of Substances[28]

Figure 4.1.1[29] shows the number of substances for which SIEFs were in a certain size range (number of participants). For example, approximately 32,000 substances have been pre-registered by just one company. The majority of substances (61,000) have

[28] ECHA report on the operation of REACH and CLP, Table 3, p. 15.

[29] Data relates to pre-registration information and does not reflect the actual status of SIEFs.

been pre-registered by between 4 and 9 companies. Hence, approximately 61,000 SIEFs had 4 to 9 participants.

According to ECHA's report, SIEFs appear to have struggled with several issues. Due to the high number of pre-registrants, many SIEFs that were established were large, making communication and co-operation complex, resource intensive and causing delays. The role of the SIEF formation facilitator also seems to have been abused in some cases by use of the role to advertise commercial services and by organisations blocking genuine potential lead registrants[30].

Given the communication and co-operation obligations that are placed on industry and, as follow-up to the lessons learnt, ECHA makes the recommendation that industry should be encouraged to develop guidance on 'best practice' for SIEFs and that this should be accompanied by an awareness raising campaign. In order to better support SIEFs, ECHA also recommends establishing an obligation on the lead registrants to notify ECHA and that ECHA should publish this information[31].

According to ECHA, a major challenge relates to establishing the identification and sameness of substances. This showed in relation to the number of pre-registrations made that did not include EC–numbers and became even more evident in relation to the different SIEF process.

With regard to this point, ECHA observes that the rules for substance identification and sameness are not yet fully clarified[32] and that, in any event, existing guidance on substance identification was not always followed. Unclear substance identifications may lead to issues such as the (undeserved) allocation of registration numbers, difficulties in SIEF formation (triggering for example splits and mergers of SIEFs), problems with data sharing and in the consultation of testing proposals. Therefore, ECHA request that the rules for substance identification be clarified by the Commission as a high priority and also asks the Commission to consider issuing implementing legislation.

A3.4.2.1 Conclusions

Information and recommendations related to SIEF formation provide a good overview of the implementation of respective obligations. ECHA's role is however not fully clarified and attention may be paid to which responsibilities should be/remain with industry (e.g. publication of information on lead registrants) and which should be taken by ECHA.

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30 The scale of the problem is not specified in ECHA's report and it is stated that only partial evidence could be collected on the issue. Due to this the Member States had lacked basis to intervene.

31 Although enhancing the implementation of REACH requirements SIEF formation and management are industry's responsibility and it may be discussed whether or not ECHA should invest (more) resources in supporting SIEFs.

32 Based on assumptions made by ECHA, difficulties in establishing substance identities and sameness could account for the difference seen in the numbers of registration dossiers and pre-registered substances. However, no evidence is provided by ECHA in support of this contention.

A3.4.3 Joint Submission

ECHA assessed the joint submission process to be generally working well. Nearly 90% of all dossiers were submitted jointly, resulting in a total of 2,945 lead dossiers and 19,610 joint dossiers; the average ratio of member to lead dossiers was 6.7.

ECHA states that industry reported difficulties in establishing lead registrants because of the high work load and a general lack of understanding of the obligations of this role. The late submission of lead dossiers also caused time pressure on other SIEF registrants. ECHA therefore recommends creating incentives to promote early submission of lead dossiers and to raise the awareness of member registrants on the timing of dossier submission.

Opt-outs for one or more endpoints were noted to have occurred in 135 cases. Of all dossiers in the range > 1000 tpa considered, 82 dossiers covering 60 substances included opt-outs. Opt-outs related to a total of 1,437 endpoints; typically, two opt-outs were included per dossier.

No opt-out was identified to be due to disclosure of confidential business information. The reasons for opt-outs are presented in Table 4.1 and Figure 4.2, differentiating between the various types of endpoint.

For 250 substances, ECHA received either multiple joint submissions (of lead and joint dossiers) or more than one individual (lead) dossier, in addition to a joint submission for the same substance. The reasons underlying industry's decision to make these separate submissions are not yet clear. However, a first assessment suggests that 25% of the registrants submitting separate dossiers understood this as an opt-out (IUCLID flag set in separate dossier).

A3.4.3.1 Conclusions

As ECHA should report on joint submission and reasons for separate submission (explicitly mentioned in the REACH text), the respective factual basis and its interpretation could be more extensive in ECHA's report and might even be compiled in a separate chapter rather than being included in the other issues reported. For a more detailed assessment see Section 15.1.

Table 4.1: Dossiers with Opt-outs

IUCLID section	Dossiers with opt-out	Total number of opt-outs
C&L	97	190
PC Properties	15	203
Env. Fate	8	60
Ecotoxicology	35	304
Toxicology	31	668
General Information	5	11
Other	1	1

Source: ECHA report on the operation of REACH, Table 2, p. 12.

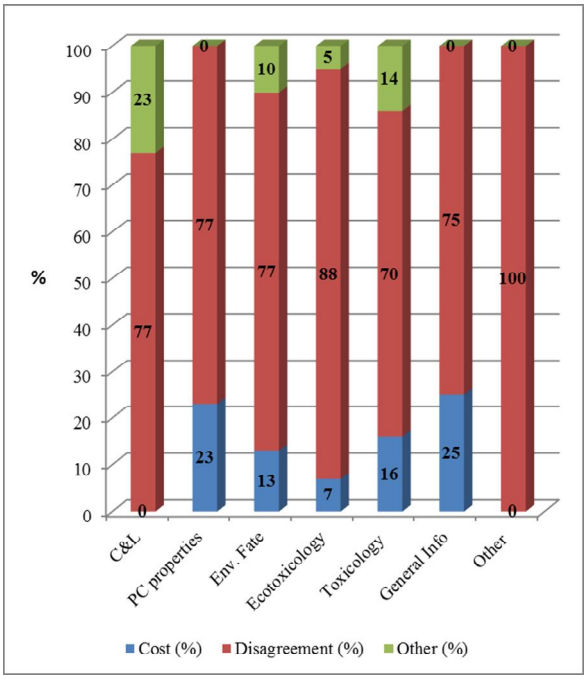

Figure 4.2: Opt-out Reasons[33]

A3.4.4 Data Sharing

ECHA has published information on data sharing on its website, including a guidance document.

ECHA reports that data sharing presented a number of challenges to industry. It is reported that data sharing works well in SIEFs where formal contacts existed before the formation of the SIEF. Companies which did not form part of existing consortia (in particular importers, ORs and SMEs) are noted to have lacked the expertise or man-power to carry out the necessary negotiations. ECHA states that inexperienced companies may even be more at a disadvantage in data sharing disputes but does not provide reason or evidence for this statement.

Only a small number of data sharing disputes have been forwarded to ECHA and all were resolved within the deadlines. ECHA believes the existence of the dispute settling mechanism had encouraged data sharing in the SIEFs.

The ECHA evaluation indicates that data sharing is working well with regard to avoiding vertebrate animal testing (c.f. Section 9.1).

It is reported that extensive legal clarification was needed on data sharing for NONS substances and in relation to (rare) cases where substances had phase-in status for one company but non-phase-in status for another.

[33] Based on data from ECHA report on the operation of REACH, Table 2, p. 12.

ECHA recommends that it investigates in collaboration with the Commission ways to make data-sharing procedures more transparent and to promote best practice by industry.

With regard to enforcing data sharing obligations, ECHA notes that penalising breaches of data sharing obligations is difficult due to the different organisation of enforcement authorities in the Member States.

A3.4.4.1 Conclusions

Data sharing is a task of industry and ECHA has limited influence on how this process is implemented. The information provided highlights some difficulties and indicates some options for improvement. An analysis of the extent of data sharing disputes related to vertebrate animal testing could usefully be provided, with reference to the Article 117(3) report.

The fact that ECHA sees inexperienced companies as being at a disadvantage in the formalised data sharing dispute settling according to Article 27(5) – (8) is of concern because that mechanism should not be biased. However, more explanation of why ECHA is concerned and how this could be solved, would be helpful.

A3.4.5 Inquiries and Data Provision by ECHA

Since REACH came into force, ECHA received 3,500 inquiries of which 1,475 were processed (remaining inquiries not accepted). Data sharing was possible for 566 substances. For 751 substances, a registration dosser was submitted or updated following inquiry. For phase-in substances, inquiries were followed by registration in 69% of cases while, for non-phase-in substances, this occurred in 47% of cases.

ECHA assumes that some inquirers felt that an inquiry could remedy the consequences of a missed pre-registration indicated by a significant increase in inquiries close to the registration deadline and the proportion of registrations following inquiries (c.f. above). Therefore, clear communication with industry is seen necessary by ECHA to make it clear that this is not the case. In order to limit abuse of the inquiry system, ECHA recommends requesting some information from inquirers such as, for example, proof of the intention to manufacture or import a substance. Furthermore, ECHA recommends that consideration should be given to levying a fee for inquiries to avoid free-riding. Evidence of the occurrence of abuse and free-riding is not provided.

ECHA notes that it cannot currently use some existing data, such as information on biocides, because the data format is not compatible with the ECHA IT-systems or in relation to, for example, data relating to pesticides legislation because in this case up-to-date information is held at the MS-level not by ECHA.

A3.4.5.1 Conclusions

The interpretation of information on inquiries may be questioned as, for example, the increase in inquiries before the registration deadline could also be due to late identification of registration needs. Also, the lower rate of registrations after inquiries could be due to economic considerations rather than the belief that no registration is necessary. Nevertheless, the implementation of fees for an inquiry and the increase of barriers for an inquiry to prevent abuse are not invalidated by this assessment, and may be particularly important given ECHA's resource constraints.

A3.4.6 Registration

Overall, ECHA evaluates the registration process to date to have been a success, attributed in part to the well-functioning IT-system. IT-tools developed for industry, such as the completeness check plug-in, are regarded as very efficient support for dossier processing. For the next deadline, ECHA intends to further streamline the IT-processes and to develop additional tools.

ECHA regards the registration obligations to now be well understood by industry, including by companies in third countries. Nevertheless, ECHA recommends that preparations for the next registration deadlines should be started now and appropriate awareness raising campaigns need to be implemented.

ECHA received about 25,000 registration dossiers for approximately 4,300 substances, of which approximately 3,400 are for phase-in substances and 900 are for non-phase-in substances (Table 4.3). All have been successfully processed.

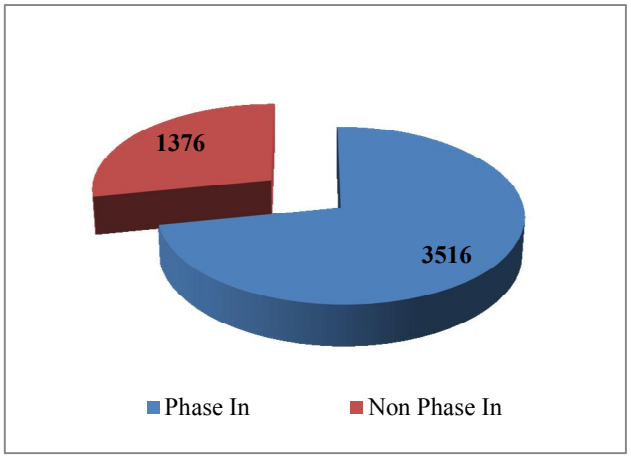

Figure 4.3: Number of Registered Substances (June 2008 – May 31, 2011)[34]

The following figures are derived from the notifications according to the classification and labelling regulation from by May 31, 2011.

[34] Additional information provided by ECHA on request.

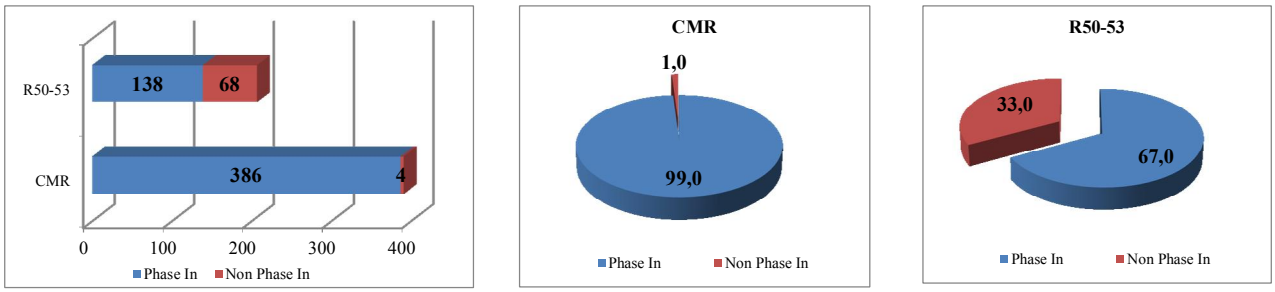

Figure 4.4: Total Number and Proportions of Phase-In and Non-Phase-In Substances in Notified Substances with a Classification as CMR or R50-53 (June 2008 – May 31, 2011)[35]

Table 4.2: Number of Registered Substances					
Completed dossiers	**2008**	**2009**	**2010**	**2011 (Q1)**	**Total**
Registration of on-site isolated intermediates	12	85	1,373	70	1,540
Registration of transported intermediates	46	196	3,426	247	3,915
Regular registration dossiers	10	217	18,969	1,686	20,882
Total registrations	***68***	***498***	***23,768***	***2,003***	***26,337***
Source: ECHA report on the operation of REACH, Table 1, p. 10.					

Approximately 10% of the pre-registering companies actually submitted a registration by the first deadline and a dossier has been submitted (including PPORD) for approximately 17% of all pre-registered substances. The size of companies registering in 2010 is shown in Figure 4.5.

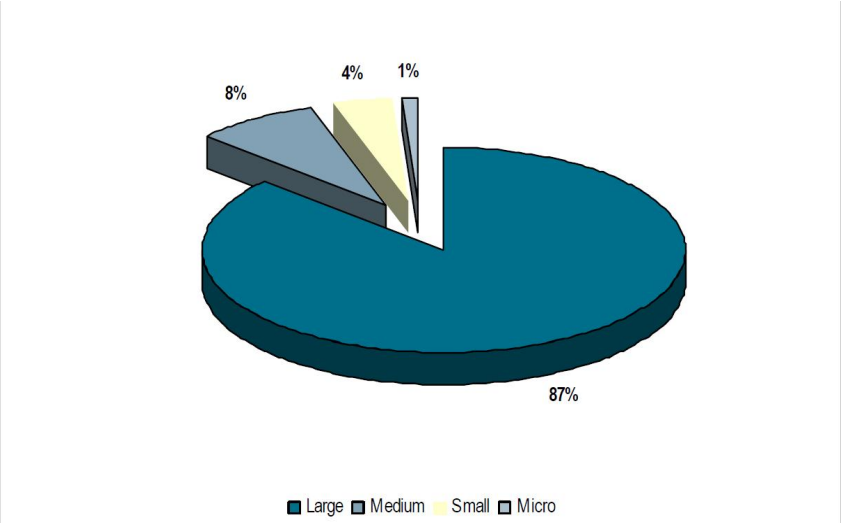

Figure 4.5: Company Size of Registrants in 2010[36]

35 Additional information provided by ECHA on request.

19% of all dossiers were submitted by only representatives (ORs). 940 NONS registrations were updated and, for 51% of NONS, a registration number was claimed. 679 PPORD notifications were completed. Figure 4.6 summarises the geographical origin of the submitted dossiers.

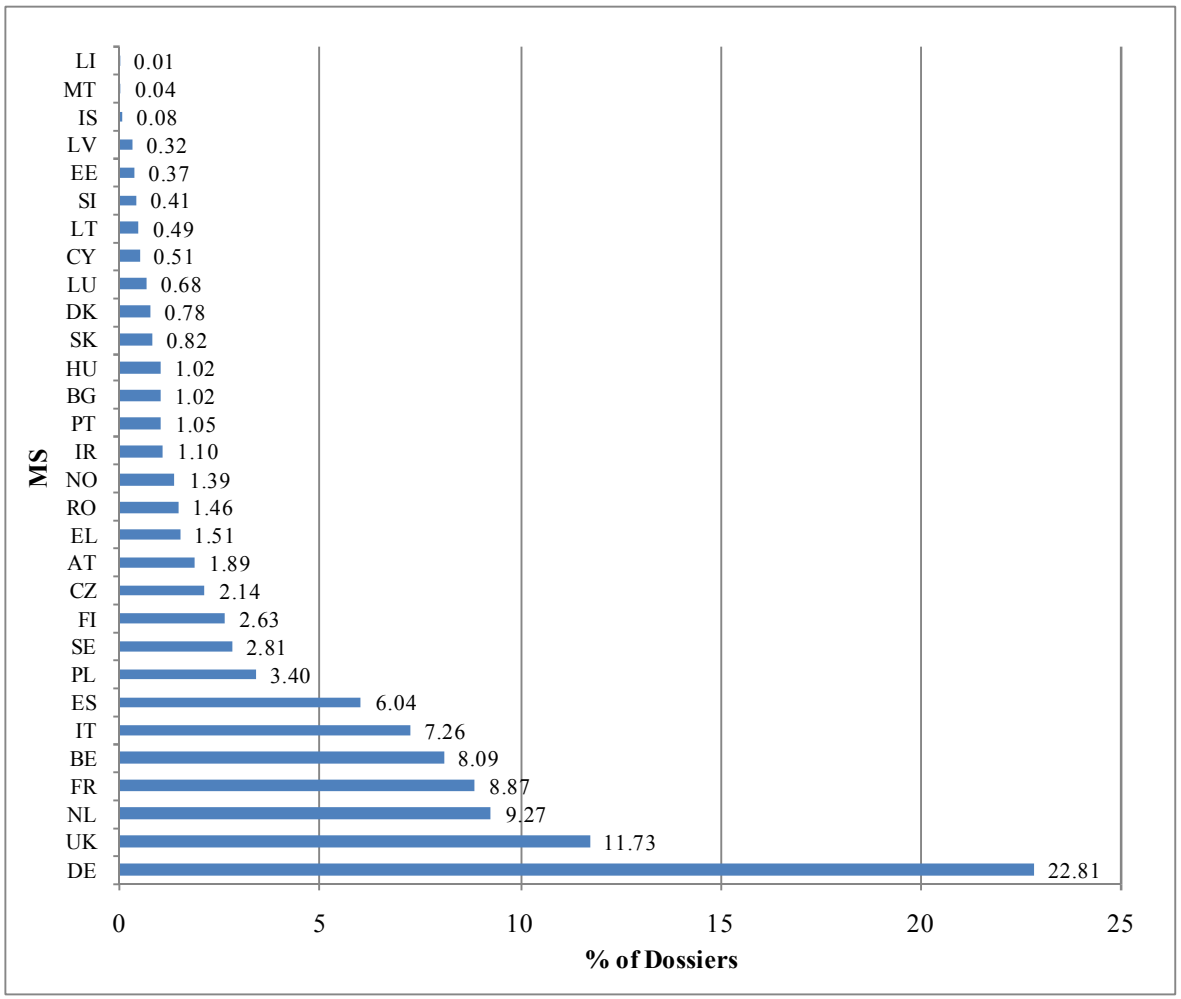

Figure 4.6: Proportion of Dossiers Accepted for Processing, by MS[37]

It is not yet possible to statistically evaluate the CSRs submitted with the registration dossiers because they are not provided in a standardized format that can be processed by ECHA and no respective information is provided. The only available figure cited is that 28% of the active lead registrants also provided a joint CSR[38].

Based on a comparison of pre-registered and registered substances, ECHA suspects that industry overstretched the interpretation of the sameness of substances in order to

36 ECHA report on the operation of REACH, Figure 1, p. 10.

37 Source: ECHA general report 2010, Annex 2, p. 11. Figures include dossiers received by 30th November 2010.

38 Additional information provided by ECHA on request. An active lead registrant is one who actually takes on the role of leading the joint submission.

reduce the number of registration dossiers. This contradicts a statement that it is an open question if registration dossiers contain more than one substance or different dossiers have been submitted for the same substances.

ECHA received a total of 1,300 confidentiality claims which are being checked in an on-going process started in March 2011. ECHA requests more respective differentiation of the Fee Regulation without specifying what should be differentiated, how and why. The reasons for information to be claimed as confidential are detailed according to the categories defined in the Fee Regulation are set out in Table 4.3.

Table 4.3: Types and Numbers of Confidentiality Claims

Type of Information	% of All Claims	Number of Claims
IUPAC Name	65%	845
Study Summaries	13%	169
Tonnage Band	8%	104
Trade Name	6%	78
SDS Information	5%	65
Degree of Purity	3%	39
Total	***100%***	***1,300***

Source: ECHA report on the operation of REACH, Figure 2, p. 23.

ECHA checked approximately 400 intermediate registrations and concluded that in 86% of the cases the conditions that allow claiming the provision of reduced information requirements had not been sufficiently demonstrated or justified. ECHA therefore highlights that there is a need for awareness raising of this issue across industry, including a need to provide motivation to update registration dossiers.

ECHA assessed the argumentation provided for reduced fees because of claimed SME status from 66 companies and found that 58% had wrongly identified themselves as SMEs. The difference in fees is being requested from such registrants plus an additional charge for wrongly claiming SME status.

According to ECHA, sanctions for incomplete and non-compliant registration dossiers are not in place. Therefore, the Commission should consider the need for legal provisions to allow ECHA to initiate appropriate remedies, for example to revoke a registration number in clear cases of non-compliance. It is considered important that industry reassess and, where necessary, update their registrations and bring any non-compliant dossiers into compliance.

It is also reported that approximately 600 dossiers were submitted after the registration deadlines, and it was suggested that the reasons for these late submissions should be clarified by the MS CAs.

A3.4.6.1 Conclusions

A comprehensive factual basis on the first registration phase is provided; however, the information was not analysed with regard to the hazards of substances and the

volumes registered. This information would have been helpful to inform a first impression of the potential benefits of information generation and dissemination.

The report shows that industry to some extent wrongly used the possibilities for cost reduction (SME fees, intermediates, extended substance definition). Hence, the request for legal clarification of how incomplete and incompliant dossiers should be sanctioned would appear well justified.

A3.4.7 Conclusions on Reporting Related to Registration

The Article 117(2) report provides a good overview of the facts related to the registration and pre-registration process of REACH, including data sharing mechanisms.

ECHA's opinion on its own role and the relevance of its support in relation to SIEFs and data sharing, which are primarily under industry's responsibility would be helpful to understand how well these legal provisions are implemented.

Information on joint submission and opt-outs could be analysed and interpreted in more detail, especially since there is a explicit reporting obligation in the legal text[39]. ECHA may consider providing respective information in either the Article 117(2) or the Article 117(3) report and providing cross-references to ensure consistency.

[39] There is also an inconsistency in the report: it is stated in the preface that NO analysis could be made of the reasons for separate submission; however at least for 25% it is stated that separate submission was understood as being due to registrants opting-out.

A3.5. OPERATION OF REACH: INFORMATION IN THE SUPPLY CHAIN

ECHA's 117(2) report contains a short section on supply chain communication which mainly consists of explanation on the respective objectives of REACH and the requirements for downstream users to check and implement exposure scenarios, use information from suppliers to provide information for their products (mixtures), notify ECHA on uses when DU CSRs are developed and on SVHC in articles.

ECHA states that a discussion platform for sharing and discussing experience on exposure scenarios among registrants and downstream users would be helpful and commits itself to initiate such platform in cooperation with industry.

ECHA describes a lack of harmonization of exposure scenarios regarding format and content and states that the development of CHESAR (including ES for communication) and IUCLID should contribute to standardization. ECHA wants to ensure that these tools are compatible with any instruments developed by industry.

The Article 117(2) report does not include any actual experience with supply chain communication or any description of specific activities by ECHA.

A3.6. OPERATION OF REACH: AUTHORISATION

ECHA's work has focused on generating and processing Annex XV dossiers for SVHC identification and the preparation of prioritisation proposals for inclusion of candidate substances on the authorisation list. In addition, a process for considering and discussing the regulatory effectiveness of different risk management instruments has been established in co-operation with the MS. The so-called risk management options analysis (RMO-analysis) is voluntary for MS CAs.

ECHA notes that a common understanding of the (interplay of) regulatory instruments, as well as their aims, possibilities and limitation, does not yet exist and that improvements in communication and co-ordination of activities and to establish optimal timing, are needed. This, in ECHA's opinion, should include avoiding the consideration of restrictions after the inclusion of substances in the authorisation list.

A3.6.1 SVHC Identification

In the report, ECHA states that the identification of SVHCs started slowly but has now reached the expected pace (Table 6.1). According to ECHA, the dossier preparation and consultation requires considerable effort (not specified or quantified) by MS and the MS CAs appear to be suffering from a lack of resources. However, MS CAs continue to express a willingness to contribute to reaching the target number of 136[40] SVHCs on the candidate list by the end of 2012.

Table 6.1: Authorisation Overview (2008 – 2011)	
Actions Related to Authorisation	**Number**
Notifications for SVHC identifications in registry of intentions received	81
Notifications in registry of intentions confirmed	64
SVHC dossiers received	57
Consultations opened for SVHC	58
Comments received in consultations	1432
Substances on the candidate list	53
Consultations opened on recommendations for the authorisation list	28
Comments received on recommendations for authorisation list	431
Substances recommended for authorisation list	15
Source: ECHA Report on Operation of REACH, Table 11, p. 34.	

MSs also appear to be struggling with the identification of substances as potential SVHCs for various reasons including because the CSR information from registrations are frequently of low quality and cannot be screened in an automated manner. The greatest intentions expressed regarding SVHC identifications for the future have been reported by Germany (18), France (14), the Commission / ECHA (10), Norway (9) and the Netherlands (6).

[40] The ECHA 117(2) gives a figure of 135 SVHCs.

According to ECHA, some of the SVHC dossiers did not contain information on uses and exposures[41] and ECHA has therefore blamed delays in the prioritisation step on these omissions. There are also difficulties in addressing multi-constituent substances or UVCBs (handling SVHC constituents). There appears to be no common understanding on how to address substances of equivalent concern under Article 57(f), e.g. endocrine disrupting substances, and it is noted that the further work in this area is to be consistent with the approaches under other legislation. Therefore, to ensure the adoption of a coherent approach ECHA asks the Commission for clarification on both issues. ECHA also plans to assess whether better use of the registration information (and information from the evaluation stage) could be made in the risk management processes under REACH and how this might be implemented.

In June 2011 the candidate list contained 53 substances (Figure 6.1). The reasons for inclusion of substances in the candidate list are summarised in Figure 6.2.

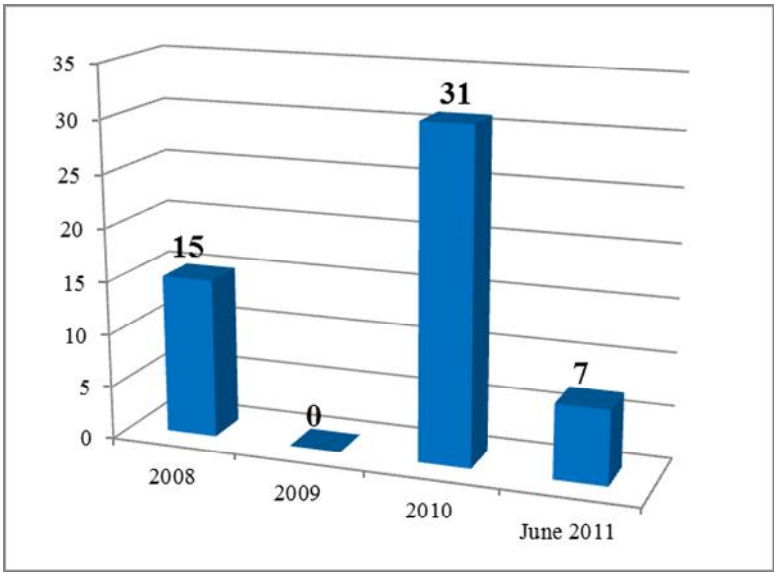

Figure 6.1: Number of Substances Included in the Candidate List (2008 to June 2011)[42]

[41] It is not legally required that Annex XV dossiers contain this information.

[42] Source: based on ECHA report on the operation of REACH, Figure 4, p. 34.

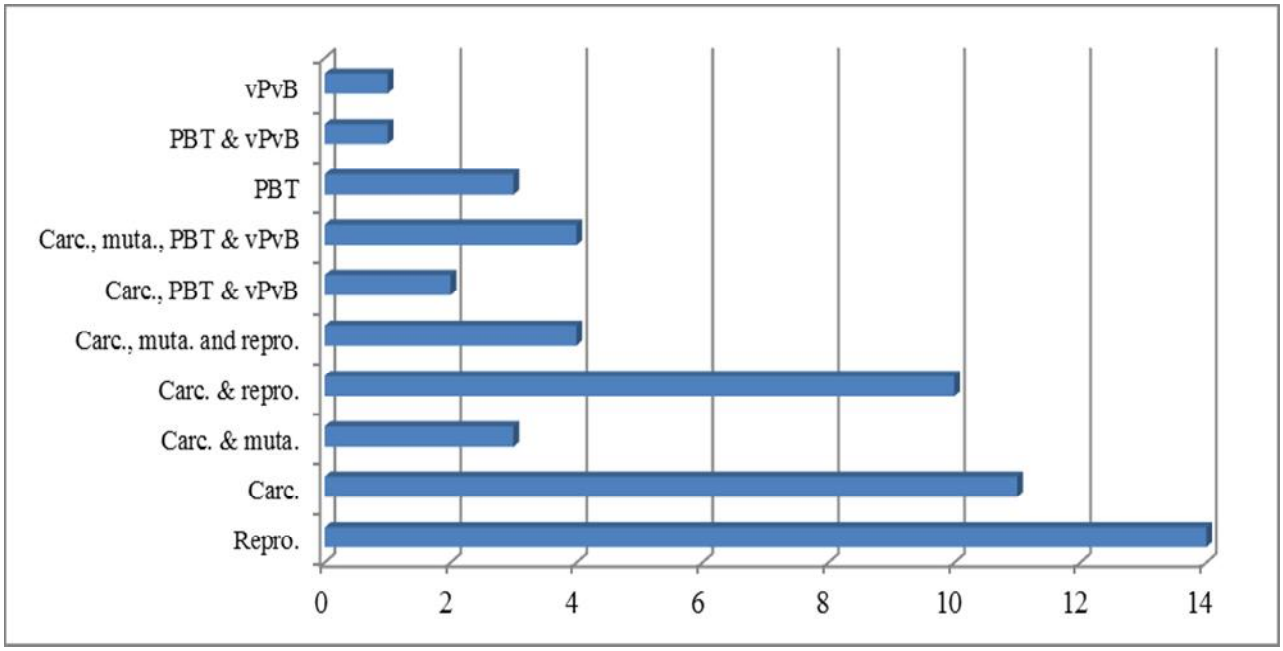

Figure 6.2: Reasons for SVHC Identification[43]

ECHA prepared five Annex XV SVHC dossiers and one dossier for updating the already existing Candidate List entry of Cobalt dichloride. The MSC decided unanimously that for four substances (Cyclodecane, 1,3,5 Trichlorobenzene; 1,2,3 Trichlorobenzene and 1,2,4 Trichlorobenzen) the available information was not sufficient to identify a substance as SVHC.

ECHA reports that the different requirements triggered by the inclusion of substances on the candidate list cause challenges to industry and authorities. For example, producers and importers of articles struggle with setting up systems to manage the notification and communication requirements under Article 7 and Article 33. The main challenges of authorities appear to be the prioritisation of substances for SVHC identification and providing support to article producers and importers, as well as enforcing the respective requirements for SVHCs on the candidate list contained in articles[44].

Seven cases relating to the identification of SVHCs by ECHA have been brought by industry to the General Court in 2010; final decisions are pending. In one of these cases a company asked for a postponement of the implementation of ECHA's decision but this was rejected.

ECHA draws attention to an issue regarding the current legislation since at present it is not possible to remove substances once they have been adopted onto the Candidate List. ECHA considers that this possibility should be allowed for and that appropriate

43 Source: own evaluation of candidate list.

44 Details on challenges were provided by ECHA in addition to the report, following a request by the contractors.

provision should be inserted into the legislation (e.g. through inclusion of a procedure for considering new information).

A3.6.1.1 Conclusions

The report gives a good overview of how identification of SVHCs has started and the difficulties that were faced. However, a more detailed description of difficulties and identification of quality issues with regard to the SVHC dossiers, as well as the resources needed for SVHC identification, would complement the picture provided. In particular, it would be valuable to understand why information missing from Annex XV dossiers caused delays in SVHC identification when SVHC identification can be based on a reference to the listing in Annex VI of CLP, if appropriate.

A3.6.2 Recommendations for Inclusion in the Authorisation List

An approach for the prioritisation has been agreed (it is not specified if only within ECHA or between ECHA and MS) and related legal and procedural aspects have been clarified as a result of the two prioritisation processes conducted thus far by ECHA. Of the two recommendations submitted to the Commission, one has already been implemented resulting in the inclusion of 6 substances on the authorisation list.

The prioritisation process is stated to be delayed by the frequent lack, or low quality, of information on uses and exposures in the Annex XV dossiers (c.f. above). Further challenges include the setting of appropriate application and sunset dates, the scope of R&D, PPORD and entry specific exemptions as well as a consistent and industry-shared interpretation of the definition of intermediate uses. ECHA does not specify any recommendations on how these issues may be resolved, except to promote clarification of "intermediate uses".

A3.6.2.1 Conclusions

The report gives a good overview of the challenges of prioritising substances for Annex XIV inclusion. However, a concrete proposal for resolving these problems is not given.

A3.6.3 Public Consultations

ECHA notes that the aim and scope of the different consultation processes related to the identification of SVHC and prioritisation for inclusion in the authorisation list, do not appear to be fully understood by third parties. The timing of information provided by third parties, as well as the content, shows a lack of understanding of the procedures. ECHA proposes that information on these aspects should be provided continuously, but concludes that valuable information was nonetheless obtained from third parties during the public consultations.

A3.6.3.1 Conclusions

The report provides sufficient information to get an impression of the operation of the public consultations on SVHC identification and Annex XIV inclusion.

A3.6.4 Authorisation

At present there is uncertainty about the coverage of the authorisation provisions in relation to registration of intermediates, and clarification is needed. ECHA expressed its intention to promote the development of a common understanding between industry, MS CAs and enforcement authorities.

Up to now no application for an authorisation has been received. However, ECHA expects that between 200 and 400 such applications will be submitted for the years 2013 and 2014, respectively. However, a basis for this estimate is not provided and preparations for processing these dossiers within ECHA are reported to be on-going.

A3.6.4.1 Conclusions

Since no authorisation applications were received within the reporting period, no information on implementation of related processes could be provided. However, it would have been interesting to know the basis upon which assumptions of the number of authorisation applications has been estimated. A process to get more precise information could have been outlined, in particular with a view to the consequences of the stated under-estimation of the pre-registration numbers.

A3.6.5 Conclusions on Reporting Related to Authorisation

The overall impression from ECHA's report is that the authorisation procedure is challenging with regard to:

- understanding the role of the candidate list and Annex XIV in the overall set-up of risk management instruments under REACH with regard to timing, interplay and triggered obligations, as well as regarding the tasks for industry and authorities;
- the identification of substances that could be identified as SVHCs on the candidate list, because the information base in registration dossiers is frequently not sufficient;
- the preparation of SVHC dossiers, because good quality information is frequently not available and because of the resource needs;
- the development of proposals for Annex XIV inclusion, due to the lack of use and exposure data for priority setting and the flexibility in setting conditions; and
- stakeholder involvement via consultations, because timeframe and content of comments appear to be not well understood.

A3.7. OPERATION OF REACH: RESTRICTION

ECHA states that it is well-prepared to develop restriction proposals. Procedural, scientific and technical capacity are in place to manage the dossiers and to support RAC and SEAC in their opinion making and initial experience in this area has been gained. ECHA considers its opinion forming on new restrictions to be progressing well.

A3.7.1 ECHA's Work on Restrictions

According to the general reports, in 2008 ECHA examined 26 non-finalised dossiers of substances prioritised under the Existing Substances Regulation. This led to no recommendations for a restrictions proposals being reached. In 2009 ECHA started a restriction proposal on mercury-containing measuring devices which was finished in 2010. During 2010 ECHA also conducted consultations on four restriction proposals and received a total of 59 comments[45]; the processes related to these will be concluded during 2011. ECHA also prepared review reports on restrictions for 6 phthalates following a request by the Commission.

ECHA received notification of 14 intentions from Member States to prepare a restriction proposal. Due to grouping, in some instances, of substances into single dossiers, the number of confirmed proposal intentions amounted to 12.

A3.7.1.1 Conclusions

The Article 117(2) report provides general information on ECHA's overall preparedness to work on restrictions but does not explain the nature of challenges and the type of experience gained from work on the first four new restriction proposals.

A3.7.2 Quality of Restriction Dossiers

ECHA stated that it is challenging to identify a proportionate level of dossier quality. This is due, amongst others, to standardised approaches often not being applicable to the specific and flexible approaches of restriction proposals.

ECHA acknowledges that the use of information from registrations, evaluation and other REACH sources is not optimal. In response, it plans to develop approaches to enable more efficient use of existing information.

With regard to the content of the dossiers, ECHA notes that the REACH requirements on restriction dossiers do not fully correspond to the need for clear and concise dossiers to support decision making. In particular, costs of a restriction and socio-economic information require clarification. The items to be considered in the socio-

[45] Lead 40; DMFu 9; phenyl-mercury compounds 3 and on mercury in measuring devices 17.

economic analysis (SEA) according to Annex XVI should be prioritised and the most important items should be included in Section 3 of Annex XV in order to take account of experience gained.

A3.7.2.1 Conclusions

Since the restriction process is not new under REACH, more information would be helpful on why the preparation of dossiers is particularly challenging (e.g. what are the challenges compared with the past approach with regard to the preparation of proposals). Furthermore, there is no discussion as to why the annexes need to be revised and why other options, i.e. guidance documents, are not sufficient. The latter could be assumed to be a good alternative because ECHA's proposals relate to clarification and prioritisation needs rather than changes in content.

A3.7.3 Committee Opinions

In the processes of consultation and opinion forming by the RAC and SEAC related to the restriction proposals, ECHA observed that the timelines are rather challenging with regard to the use of inputs from the consultation and notes that the differences in procedures between RAC and SEAC cannot be substantiated by any arguments or benefits (particularly where there is no consultation on the RAC opinion). Rather, ECHA regards the inclusion of a consultation phase on the RAC opinion as necessary for the transparency of the process. It is not clear if ECHA's assessment is based on a theoretical analysis of the REACH provisions, experience from the past restriction processes, or both.

The consultation processes for RAC and SEAC opinions are compared in the report and it is concluded that there are no obvious reasons for the differences. Furthermore, the benefits of aligning the two processes should not result in the overall consultation being prolonged.

Consequently, ECHA proposes that:

- consideration be given to shortening the first consultation period from 6 to 3 months and the second consultation period from 60 to 30 days, in order to give more time to the Committees to consider the third party input; and
- the Commission should consider aligning the consultation process of the RAC with that of SEAC.

ECHA states that shortening the consultation period *"would not compromise the quality of comments but would facilitate an optimal use of them"*.

There is no experience available yet on the usefulness of the committees' opinions for the subsequent decision making process in the Commission.

A3.7.3.1 Conclusions

ECHA's recommendations on opinion forming appear logical but it would be useful to have a comparison with experience gained. It can, for example, be questioned whether the quality (and quantity) of third party comments would not be compromised by shortening the consultation procedure. Furthermore, the compilation of comments requires time, in particular when groups of actors contribute together. ECHA seems to assume that third parties plan their contributions only in accordance with the deadline and don't also rely for example on the response of other actors, or that they may have to search for information.

A3.7.4 Conclusions on Reporting Related to Restrictions

It is not always clear whether the information in the report is based on experience or based only on an analysis of the legal text. As restrictions are not a new instrument and respective proposals have been developed in the past, a better description of the actual problems would have been helpful to understand this issue. The proposals for the revision of annexes (content of restriction dossier) and the legal text (number and duration of consultation on Committee opinions) are not underpinned by fully robust justifications.

A3.8. OPERATION OF REACH: EVALUATION

ECHA's 2010 Progress Report on Evaluation[46], published according to REACH Article 54 was used as an additional information source for this section, because the 117(2) report only briefly discusses evaluation and refers to that report[47].

A3.8.1 Activities on Dossier Evaluation

The Article 117(2) report states that ECHA has established the procedures, built up internal competences and capacities as well as an IT-infrastructure to evaluate registration dossiers. Consequently, ECHA states that it now feels capable of performing the evaluation of registration dossiers and testing proposals. Nevertheless, ECHA also recognises the need to improve the internal processes to meet the evaluation targets. Up to 1,000 dossiers (5%) submitted by the first registration deadline are to be checked for compliance by the end of 2013 and an on-going need for capacity to consider 600 dossier evaluations per year is projected by ECHA.

In parallel to the preparations for the expected peak of compliance checks starting in 2011, first dossier evaluations were performed during 2008 to 2011. An overview of the levels of activities is provided in Table 8.1.

Table 8.1: Overview of Compliance Checks on Registration Dossiers (01.06.2008 – 30.04.2011)

	Phase-in	Non-phase-in	Total
Number of Dossiers Opened	111	138	249
Draft Decisions Sent to Registrant	54	28	82
Final Decisions	4	17	21
Quality Observation Letters (QOBLs)	10	34	44
Compliance Check Concluded without Further Action	5	31	36

Source: ECHA report on operation of REACH, Table 8, p. 26.

The number of compliance checks started over time is illustrated in Figure 8.1.

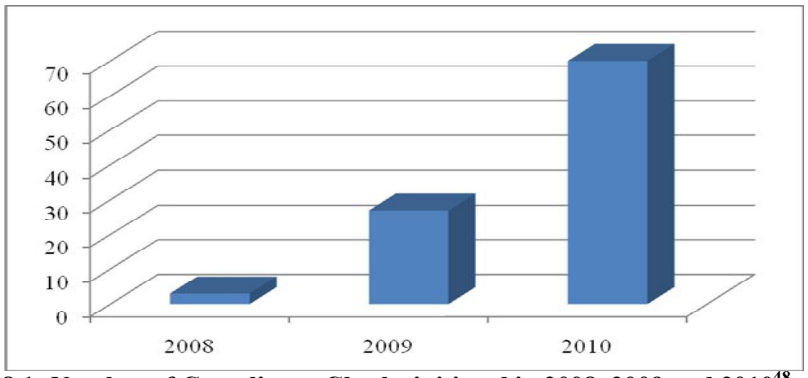

Figure 8.1: Number of Compliance Checks initiated in 2008, 2009 and 2010[48]

46 ECHA: Evaluation under REACH, progress report 2010; Helsinki 2010.

47 Reference is also made to the earlier evaluation reports but only the most recent one was analysed as it is assumed to integrate findings from earlier evaluation work.

Eight of the twelve draft evaluation decisions (75%) by ECHA were commented on by the MS CAs. These drafts were unanimously agreed in the MSC after discussion. ECHA regards some of the received comments as not focused to the scope and aim of the evaluation.

The discussion of draft decisions is a major determinant of the MSC's workload and ECHA therefore aims to provide better rationales for its draft decisions so as to avoid unnecessary comments and improve the efficiency of working. Nevertheless, ECHA acknowledge that the MSC agreements helped to take final decisions on evaluation efficiently because no referral to the Commission comitology procedure was needed.

According to the Evaluation Progress Report of 2010, in order to facilitate the evaluation process and create a better understanding of the evaluation outcomes and potential information requests, two actions were taken:

- the MSC rules of procedure were changed in 2010 allowing case owners and observers to attend meetings when draft decisions are presented and initially discussed, however not during actual decision making; and
- ECHA started providing oral explanation and scientific background information to registrants following draft decisions. ECHA stresses that such communication does not constitute advice and that these contacts within the commenting period don't replace the formal written procedures between ECHA and the registrants.

In the Article 117(2) report, ECHA describes challenges in relation to evaluation decisions were identified with respect to their enforceability and in finding the right balance between administrative effort and regulatory outcome. ECHA see a need to reach further agreement with the Member States on identifying solutions to these issues and to reach a common understanding on how evaluation decisions should be taken and with what focus.

Another difficulty highlighted in ECHA's report is the problem that for incompliant dossiers only hazard information can be requested but a modification or correction of risk management measures (RMMs) is not possible. Shortcomings in risk management are assumed to be covered by other legislation (e.g. based on the classification of substances). ECHA notes the scope of evaluation decisions as potential discussion points and that clarification should be sought with stakeholders.

Figure 8.2 shows a comparison of the outcomes of compliance checks in 2010 with the average of all compliance checks performed so far. The absence of any significant differences suggests that there has been no improvement of registration dossiers over time.

[48] Source: information from ECHA's General Reports of 2008, 2009 and 2010.

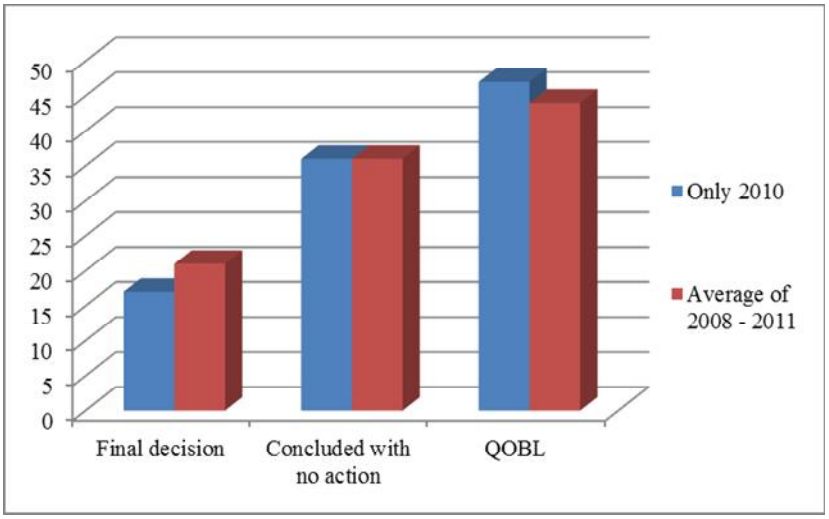

Figure 8.2: Outcome of Compliance Checks – Comparison of Data from 2010 and Averages from 2008 to 2011[49]

ECHA reports that it selected the dossiers considered for compliance checks based on either a) concern (54 dossiers in 2010 corresponding to 73%) or b) randomly (27 dossiers in 2010 corresponding to 23%). As expected, the percentage of quality observation letters (QOBLs) is higher and the percentage of final decisions is lower for the dossiers selected based on concern compared to the dossiers selected randomly. ECHA is currently developing an IT-tool that should support the prioritisation of registration dossiers for evaluation.

None of the evaluation decisions have resulted in an appeal so far and, as the time period to provide further information after dossier evaluation decisions has not yet elapsed, ECHA was unable to provide information on the reactions of registrants.

A3.8.1.1 Conclusions

The information provided gives a good overview of the operation of the dossier evaluation procedure.

A3.8.2 Findings and Consequences of Dossier Evaluation

ECHA observes that a significant proportion of registration dossiers is not compliant and it has been found that many registration dossiers are of insufficient quality: 47% of the dossiers checks concluded with a QOBL and 17% with a final decision in 2010. However, ECHA also cautions that the quality of these dossiers selected for evaluation should not be extrapolated to all dossiers, because they were submitted and selected early in the process.

[49] Sources: information from ECHA Evaluation Progress report 2010, Figure 3, p. 11 and ECHA report on the operation of REACH, Table 8, p. 26.

ECHA concludes that, in general, registrants fulfil their registration obligations. However various issues require improvement. The most frequent non-compliance and shortcomings[50] are:

- unclear substance identity;
- lack of proper justification for waiving; and
- insufficient level of detail in robust study summaries.

In the following sections, the various non-compliance and shortcomings observed and described in the Evaluation Progress Report of 2010 are compiled; naturally each of them only applies to some of the evaluated registration dossiers.

A3.8.2.1 Substance Identification

For some phase-in substances the identity is not adequately described and hence not verifiable because spectra are either missing, insufficient or inconsistent (related to the substance composition), analytical data are missing or information on the production process - in the case of UVCBs - is insufficient.

Insufficient substance identification may result in the illegitimate allocation of registration numbers and since not all substances undergo a compliance check, these cases may remain undetected.

ECHA sees a need to clarify the rules for substance identification and sameness (c.f. also Section A3.4.6 on Registration).

A3.8.2.2 Performance of Tests

Observed shortcomings relate to the level of detail in robust study summaries submitted, which frequently doesn't allow judgment on whether or not the test was conducted according to the guidelines. Furthermore, the purity of test materials sometimes appeared to differ from the registered substance and there were cases where the justification for testing only considered a small share of the constituents of a UVCB. ECHA also noted cases where preliminary test results were used instead of definitive studies and where the test concentrations were outside the maximum or minimum concentrations specified in the guidelines.

A3.8.2.3 Adaptation of Information Requirements

ECHA noticed that the adaptations of information requirements were frequently either poorly justified or not justified at all. Related shortcomings include the lack of legal reference for omission of data, the lack of sound scientific arguments, as well as the incorrect use of the adaptation rules (incompliance with conditions set out in Annex

[50] ECHA provides an extensive list of incompliances and shortcomings observed as well as recommendations on how to provide (improved) information in the dossiers in its Evaluation Progress Report of 2010. Only the overarching core aspects have been included in this report. For further detail the original source should be consulted.

XI and column 2 of Annexes VII – X). The justification on the most appropriate adaptation is often not clearly developed and documented in the technical dossier. Exposure-based waiving is not based on well documented exposure scenarios, risk characterisation ratios or on strictly controlled conditions.

A3.8.2.4 Use of Data to fulfill Information Requirements

Registrants were noted to have applied different approaches to fulfilling their obligations. Shortcomings related to the different options observed by ECHA can be summarised as follows:

- weight of evidence (WoE) argumentation is often insufficient, e.g. because several secondary sources all make reference to the same primary source, robust study summaries are missing and the endpoint is not flagged for WoE in IUCLID;
- (Q)SARs) used are in some instances not sufficient to predict the absence or presence of the substance property being considered;
- where non-validated in-vitro methods are used, the information provided is frequently insufficient to judge the validity of information for the particular endpoint;
- the read-across hypothesis and category approaches are often not clearly identified, described or justified in the registration dossier. The underlying data are often not checked with regard to whether the data are robust enough to allow for classification and risk assessment; and
- robust study summaries lack detail and are sometimes inconsistent with the information presented in the CSR.

A3.8.2.5 Classification and Labelling

Self-classification is not always performed correctly. That is hazard data and the classification and labelling conclusions are inconsistent or the harmonised C&L is not implemented without justification.

A3.8.2.6 Chemical Safety Assessment

Several types of inconsistencies were found within the CSRs and between the information in CSRs and the IUCLID data: In addition, the justification for omitting information or for using non-standard defaults is missing in some cases. The documentation of the exposure assessment is often not transparent and the RMM advice are not sufficiently detailed.

As a consequence of the compliance checks conducted so far, ECHA note that it will focus future work on the verification of read-across and waiving justifications for long-term effects and on the adequacy of surrogate information for classification and risk assessment.

ECHA sent decisions and quality observation letters (QOBLs) on the evaluation results to the registrants. The type of information requested in final decisions or mentioned in QOBLs for the period until December 2010 is provided in Table 8.2; it

should be noted that a decision or QOBL can address more than just one endpoint or type of information.

Table 8.2: Number of Requests for Information or for Improvement in Final Decisions or Quality Observation Letters		
	Number Requested in Decisions	**Number Noted in QOBL**
Identification and Verification Of Substance Composition	5	6
Flammability	1	
Self-ignition Temperature	1	
Granulometry	1	
Dissociation Constant	1	
Screening for Adsorption / Desorption	1	
Growth Inhibition Study Aquatic Plants	1	
In Vitro Gene Mutation Study in Mammalian Cells	1	
Screening for Reproductive / Development Toxicity	3	
DNELs as part of Human Health Hazard Assessment	1	8
PNECs as part of the Environmental Hazard Assessment	1	
Expo. Assessment & Risk Characterisation For Substance Use In Mixtures	1	
Adaptation Justification for 2-Generation Reprotox Study (read-across)	1	
Improved Robust Study Summaries	4	5
Classification and Labelling		18
Guidance on safe use(e.g. sufficient advice on prevention of exposure)		6
Purity of Test Material		1
Identified Uses, Strictly Controlled Conditions, Status as Intermediate		11
Data Sharing		3
Inconsistent Information Regarding Tonnage Band		2
Source: ECHA report on the operation of REACH, Table 9, p. 27 and Progress Report on Evaluation under REACH 2010; Table 4, p. 13.		

A3.8.2.7 Conclusions

The Article 117(2) report contains rather little information on the nature of non-compliant registration dossiers. With a view to the fact that registration and the quality of information submitted is the basis of all REACH processes, the report should provide more details on the outcome of dossier evaluations (even if this results in the duplication of information provided in the Evaluation Progress report and the annual reports).

ECHA also does not give an opinion on whether or not the quality of registration dossiers is "within the expectations", on the possible consequences for the operation of REACH, nor with respect to achieving the goals of legislation.

A3.8.3 Evaluation of NONS Dossiers

According to the Evaluation Progress Report of 2010, ECHA has assessed dossiers relating to NONS in amounts above 1,000 t/a. 53 letters were sent requesting registrants to update their dossiers. 19 dossier updates were received of which four contained testing proposals. Following further checking, 27 assessments were

dropped because manufacture ceased (3), the substances had intermediate status (6) or due to other reasons (18). For the remaining 26 NONS dossiers, a compliance check was initiated resulting in 13 draft decisions, one final decision and three conclusions without action. Nine evaluations are still on-going.

ECHA outlines that NONS notifications are not adequately covered by the REACH provisions. For example, it was during the implementation of REACH that it was agreed that NONS dossiers that were not yet finalised by the MS CAs would phased into the system. For NONS notified in amounts exceeding 1,000 t/a no obligation existed to update information according to REACH. ECHA states that there is a need to consider imposing a deadline by which at least NONS dossiers above 1,000 tpa should be fully compliant with the requirements of other REACH dossiers.

A3.8.3.1 Conclusions

The Article 117(2) report lacks figures on the number of NONS applications concerned and the outcomes of work on these compared to work on other substance dossiers. The legal gaps identified and related improvement proposals are understandable and relevant for the operation of REACH (level playing field for all substances).

A3.8.4 Intermediates

ECHA screened 303 dossiers of on-site and transported, isolated intermediates registered in 2009 to check if reduced registration according to Articles 17 or 18 was justified. ECHA observed that in many cases registrants had provided insufficient information to verify the claimed intermediate status. However, since the guidance on intermediates was published only in December 2010, QOBLs were only sent for the obviously doubtful cases concerning intermediate status.

ECHA observed that the requirement to submit "any available information" according to Article 17(2)d and 18(2)d is frequently not met, e.g. the information used to support classification and labelling is often not included. Furthermore, information on RMMs and strictly controlled conditions (SCC) are often found to be missing or contradictory.

ECHA initiated 11 compliance checks on submitted intermediate dossiers which were all concluded with QOBLs requesting amongst other information verification of intermediate status or data on RMMs / SCCs.

A3.8.4.1 Conclusions

The information provided is sufficient to understand the operation of REACH related to the reduced registration requirements for intermediates. It is yet unclear how ECHA will proceed with the intermediate registrations, i.e. if no update is submitted by the respective registrants following the guidance update.

A3.8.5 Evaluation of Testing Proposals

Up to now, all testing proposals have been processed within the legal deadlines. An overview of the proposals received until 31 December 2010 is given in Figure 8.3.

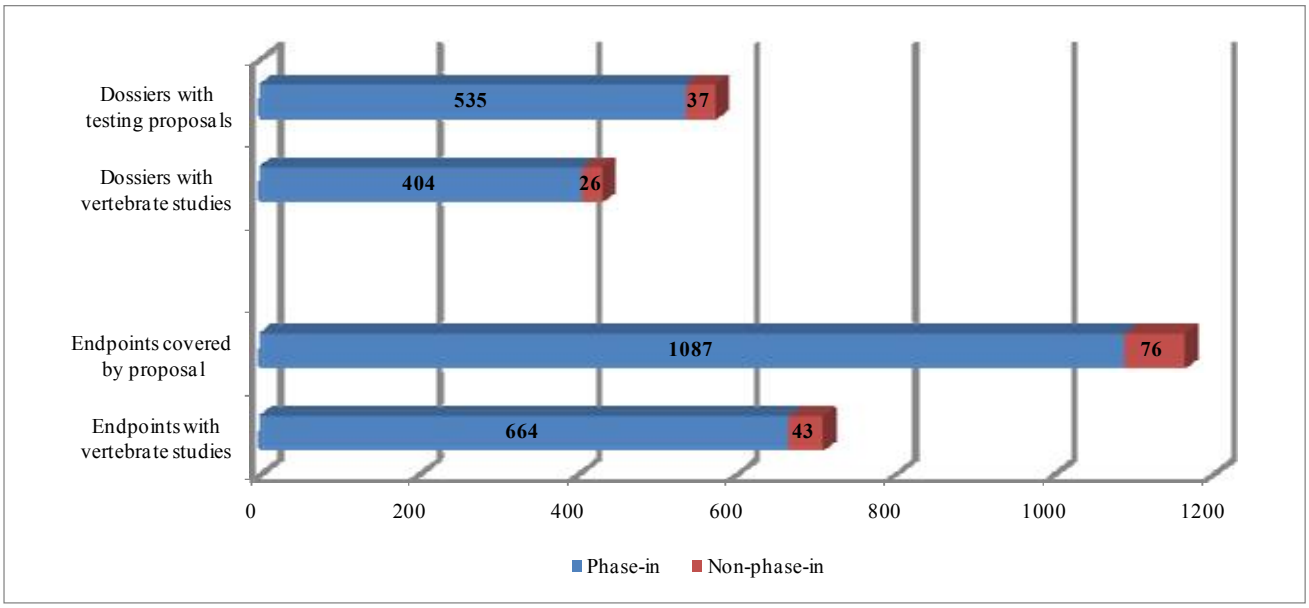

Figure 8.3: Overview of Testing Proposals Received by December 31, 2010[51]

In some cases, studies were proposed for the same substance and same endpoint by several registrants, indicating that joint submission and data sharing had not been achieved in all cases. In a few cases (less than 5% of the total), proposals were submitted for tests of Annex VII or VIII instead of carrying out the study. Some testing proposals contained insufficient justification. The status of evaluating testing proposals is summarised in Table 8.3.

Table 8.3: Status of Testing Proposal Evaluation (until 31 December 2011)

	Phase-in	Non-phase in
Dossiers with Testing Proposal Opened	145	31
Draft Decision Sent to Registrant	7	16
Final Decision Sent to Registrant	0	7
Terminated and Info Provided	2	3
On-going	136	5
Source: ECHA report on the operation of REACH, Table 10, p. 28		

In almost all cases, ECHA accepted the registrants' testing proposals either unchanged or with some modification. In some cases, further tests were requested, of which the majority concerned long-term vertebrate animal studies.

[51] Source: ECHA report on the operation of REACH, Table 10, p. 28.

In 2010, four decisions on testing proposals were adopted. In three of these, the MSC was involved.

27 third party consultations on the testing proposals were carried out and comments were received in all cases. Altogether 105 comments from third parties were received, of which 100 were submitted by NGOs, 3 by individuals and 2 by a REACH consortium[52]. However, ECHA states that none of the submitted information modified any of the testing proposals and evaluates the inputs received as not substance specific and not very focused in many cases. ECHA started publishing its assessment of information from third parties on its Internet site in 2010.

ECHA states that the assessment of third party input to testing proposals is a major driver of its workload. In order to ensure more efficient work ECHA plans to promote the improvement of content of third party contributions to testing proposals.

Difficulties encountered with regard to the testing proposals are cases where the registrant claims the substance ID as confidential. Here, a public consultation is not possible.

ECHA conducted two workshops related to:

- testing proposals with representatives of ECHA, MSCA, MSC and the Commission to create a common understanding about examination of testing proposals (April 2010); and
- non-test methods with representatives of MS, Commission, industry, NGOs and other organisations and institutions in order to identify scientific challenges in the regulatory acceptance of non-test data (September 2010).

A3.8.5.1 Conclusions

The information provided on the evaluation of testing proposals is sufficient to get an impression of the operation of this aspect of REACH. However, it would be assist further evaluation if ECHA was to provide its opinion on whether or not the provisions for testing proposals has been effective in its aim of avoiding unnecessary testing.

A3.8.6 Substance Evaluation

The full provisions of legislation have not yet been implemented and no substance evaluation has been started yet. In preparation of the future tasks required, ECHA organised a workshop with the Member States on the criteria for prioritising substances for evaluation and to agree on timelines and processes to develop a first Community Rolling Action Plan (CoRAP). The first CoRAP is to be established in February 2012 and should cover a three year period: The plan will be revised annually.

[52] Figures on numbers of comments were provided by ECHA on request of the project team.

A3.8.6.1 Conclusions

Information provided on substance evaluation is sufficient to get an impression of the (future) operation of this procedure.

A3.8.7 Conclusions on Reporting Related to Evaluation

ECHA provides a comprehensive factual overview of the activities performed in the context of substance evaluation. However, more information could be provided on the outcome of compliance checks of registration dossiers, as the level of compliance is an important pre-condition of achieving the goals of legislation. Referring to the Evaluation Reports is not regarded as sufficient, as no consistent picture can be obtained based on the Article 117 reports alone.

An interpretation of the evaluation results with regard to the implementation of REACH is not available and it is not clear if the quality level of dossiers is significantly higher or lower than expected.

A3.9. USE OF NON-ANIMAL TESTING METHODS

A3.9.1 ECHA's Overall Messages on the Use of Non-Animal Testing

In their first report on the functioning of REACH with regard to the objective of promoting non-animal testing, ECHA is of the opinion that in general the data sharing mechanisms of REACH are working and registrants are making use of these processes. This opinion is supported by the fact that nearly 90% of all registration dossiers[53] were submitted jointly. From nearly 3,000 joint submissions covering almost 20,000 member dossiers, there were about 135 member dossiers with opt-outs[54] (< 0.6%). Of the 14,875 dossiers for phase-in substances (excluding category dossiers) registered in amounts exceeding 1,000 tpa, 82 dossiers covering 60 substances have been flagged for opt-out of which 19 opt-outs concerned endpoints requiring animal testing.

Also of relevance here, are the observations discussed in Section A3.4.3 that ECHA had found separate submissions had been made for approximately 250 substances.

For non-phase-in and not pre-registered phase-in substances, ECHA had processed 1,500 inquiries for data sharing with 50% of these inquiries being followed by a registration. Thus, while there is some room for improvement, some aspects of data sharing and avoiding of new animal testing, are considered to be working.

ECHA has analysed the endpoint summary records of all the substances registered in amounts exceeding 100 tpa between 2008 and February 2011 (excluded data for: non-isolated intermediates, PPORD notifications, NONS substances and category dossiers)[55]. In total, 16,494 dossiers are covered by the analysis and 1,862 individual dossiers were analysed (see Figure 9.1).

The analysis provides a cumulative overview of all submitted information but doesn't allow the identification of key data and information redundancy for single substances. Importantly, whether or not the information fulfils the REACH requirements was not ascertained. However, ECHA concludes from the analysis that, in general, registrants don't carry out unnecessary animal testing and make good use of existing information and alternative approaches.

53 The remaining 10% include individual submissions of non-phase in substances.

54 The number of opt-outs related to animal studies is not specified.

55 Intermediate registrations, PPORD notifications and NONS dossiers were excluded because of limited or different information requirements. Category dossiers were excluded because of the complex interrelationships between endpoints which made a reliable data analysis impossible.

This is supported by the following findings:

- approximately 50% of all endpoint summary records are filled with existing experimental data;
- registrants applied alternative approaches, such as read-across (app. 23% of all ESRs), waiving / omission[56] of data requirements (app. 12% of all ESRs) as well as weight of evidence approaches (app. 10% of all ESRs); and
- testing proposals were used as the last resort with, of all registered substances[57], 574 dossiers containing testing proposals.

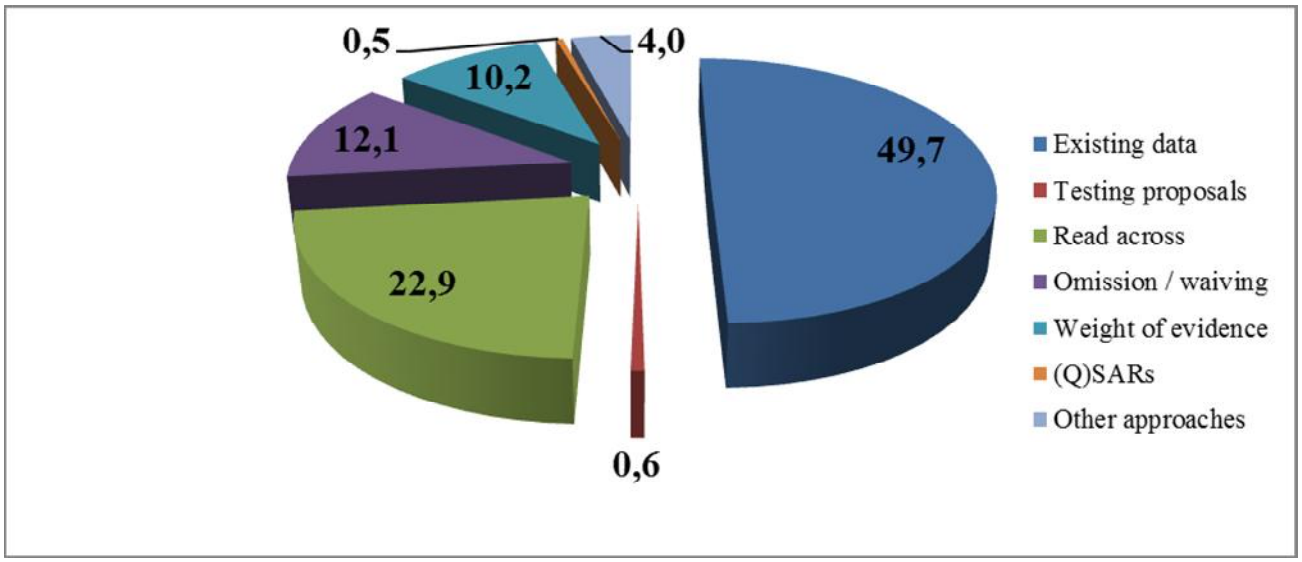

Figure 9.1: Information Types in ESRs of Analysed Dossiers (%)[58]

It is however of some concern that ECHA highlights in its report that the information quality and the quality of justifications for not conducting (animal) tests in the registration dossiers are frequently insufficient. As reported in detail in the Evaluation Progress Report of 2010[59], shortcomings in the registration dossiers[60] include:

- reported experimental data in some cases don't meet the requirements of REACH;
- the justification for read-across is frequently not sufficient, i.e. base data and argumentation are either not provided, not detailed enough or incorrect;

56 Adaptation according to column 2 (Annex VII to X) and/or waiving according to Annex XI.

57 3,308 phase-in and 1,347 non-phase-in between 2008 and February 2011.

58 Information taken from ECHA report on the use of alternatives to testing on Animals, averages of information provided for each endpoint in the ESR analysis.

59 European Chemicals Agency: Evaluation under REACH – Progress Report 2010, Helsinki 2011. Available at: http://echa.europa.eu/doc/evaluation_under_reach_progress_report_2010_en.pdf

60 For details on the quality of registration dossiers see the chapter on evaluation.

- the justification of waiving information requirements is frequently not sufficient, i.e. argumentation lacks reference to the legal basis, is missing or not detailed enough, is incorrect or, when based on exposure does not appropriately refer to detailed exposure scenarios and risk characterisations; and
- registrants partly used screening studies to fulfil higher tier test requirements - this is clearly non-compliant.

ECHA considers the fact that a lower number of testing proposals was received than expected partly to be due to the (inappropriate) use of alternative approaches and as a result of waiving. As a consequence of dossier evaluations, ECHA therefore expects further tests to be requested in the future: No indication of the quantity of such testing that might be anticipated is given.

In total, 574 testing proposals were received covering 1,175 tests of which 711 related to in vivo vertebrate animal studies. Among the totals are 78 substances registered in category dossiers (17 different categories) for which 104 studies were proposed. Proposals for studies on developmental toxicity and toxicity to reproduction were most frequently proposed. The types of proposed studies are listed in Table 9.1 and Figure 9.2.

Table 9.1: Study Types included in the Testing Proposals	
Type of Test	**Number of Proposals**
Developmental Toxicity	239
Toxicity to Reproduction	231
Repeated Dose Toxicity (oral)	121
Long-term Toxicity to Fish	38
Repeated Dose Toxicity (inhalation)	27
Genetic Toxicity (in vivo)	25
Bioaccumulation: Aquatic / Sediment	17
Repeated Dose Toxicity (dermal)	6
Long-term Toxicity to Birds	4
Carcinogenicity	3
Total	***711***
Source: ECHA report on alternatives to animal testing, Table 3, p. 52.	

In the 27 public consultations on test proposals conducted by the time ECHA published its report, no information was obtained from third parties that could be used to fulfil the respective data requirements[61]. ECHA regards this as evidence that registrants make full use of existing information and alternative approaches before proposing new tests.

ECHA reports that 107 higher tier studies seem to have been conducted without prior submission of a testing proposal. Justifications for these tests include that testing was triggered from non-EU legislation or requested by MS CAs (e.g. NONS). Studies on vertebrate animals required for Annex IX and X were conducted for bioaccumulation in fish, repeated dose toxicity (sub-chronic and chronic duration, all routes), pre-natal

[61] As of July 15th, 2011 5 reports are published on the outcome of consultations of testing proposals on ECHA's website. In average, 4.4 institutions commented on a testing proposal.

developmental toxicity, and reproductive toxicity (one- and two-generation studies). They make up less than 1% of all endpoint summary records.

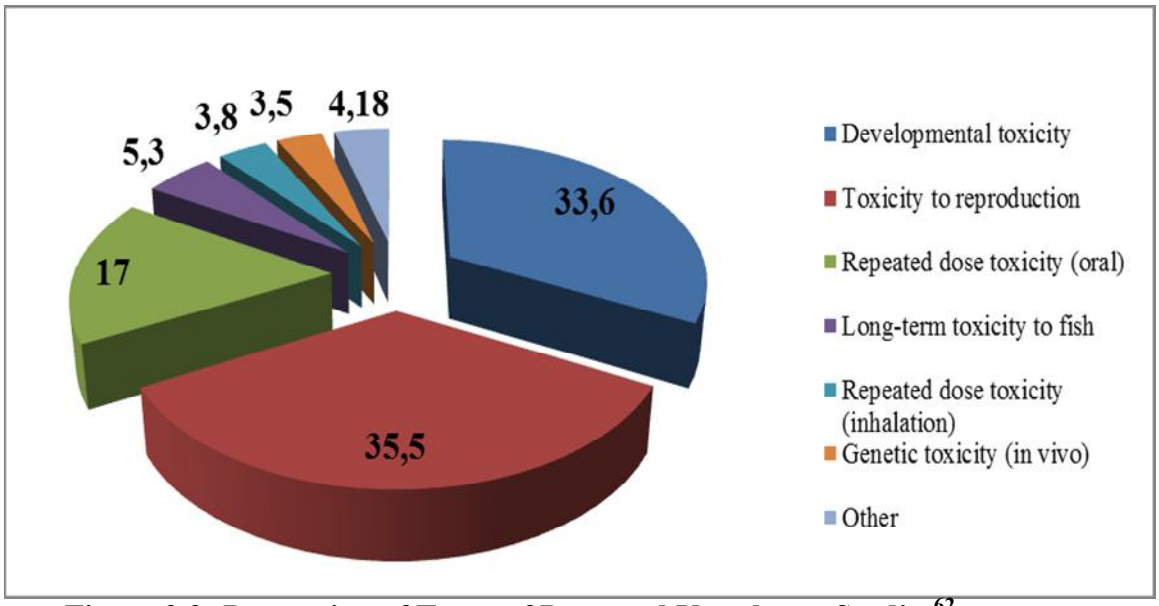

Figure 9.2: Proportion of Types of Proposed Vertebrate Studies[62]

ECHA assessed which type of information was used to actually fulfil the information requirements under REACH in a substance-specific approach. Here, not all endpoints were considered and only the key data for the endpoint were extracted. The analysis provides an overview of the relative share of the different information types to fulfil the registration obligations. This analysis was done only for phase-in substances above 1000 tpa, except those registered as intermediate only and except category dossiers. In total 14,875 dossiers are covered and 1,504 dossiers were used to extract information (lead dossiers and separate submissions).

The percentage with which endpoints were filled with information from experimental studies (ES), testing proposals (TP) or by use of alternative methods (AM) is provided in Table 9.2 and Figure 9.3. The column "no data" (ND) applies when information is not required (e.g. because no positive test results trigger the need to conduct further tests).

The ECHA report mentions that no quality check of information was performed and draws the attention to the fact that in particular the results for repeated dose toxicity or reproductive toxicity may be misleading because registrants frequently entered data from screening studies into the respective IUCLID fields.

Table 9.2: Share of Information Types used to fulfil Obligations for the Different Endpoints				
Endpoint	**% ES**	**% TP**	**% AM**	**% ND**
Acute Toxicity	85		15	
Skin Irritation	78		22	

62 Source: based on data in Table 8.1 of this report.

Table 9.2: Share of Information Types used to fulfil Obligations for the Different Endpoints				
Endpoint	**% ES**	**% TP**	**% AM**	**% ND**
Eye Irritation	75		25	
Skin Sensitisation	63		37	
Repeated Dose Toxicity	67	7	26	
Genetic Toxicity In Vitro	77		23	
Genetic Toxicity In Vivo	41		32	26
Toxicity To Reproduction	42	10	48	
Developmental Toxicity	47	10	43	
Bioaccumulation Fish	15		85[63]	
Toxicity to Fish	75		25	
Long-term Toxicity to Fish	16		82[64]	
Long-term Toxicity to birds	7		92[64]	
Long-term Toxicity to Mammals	1.8		7	91
Toxicity to Other Terrestrial Organisms	4		4	92
Source: based on information contained in Section 3.3 of ECHA's report on the use of alternatives to animal testing methods, p. 45 – 47.				

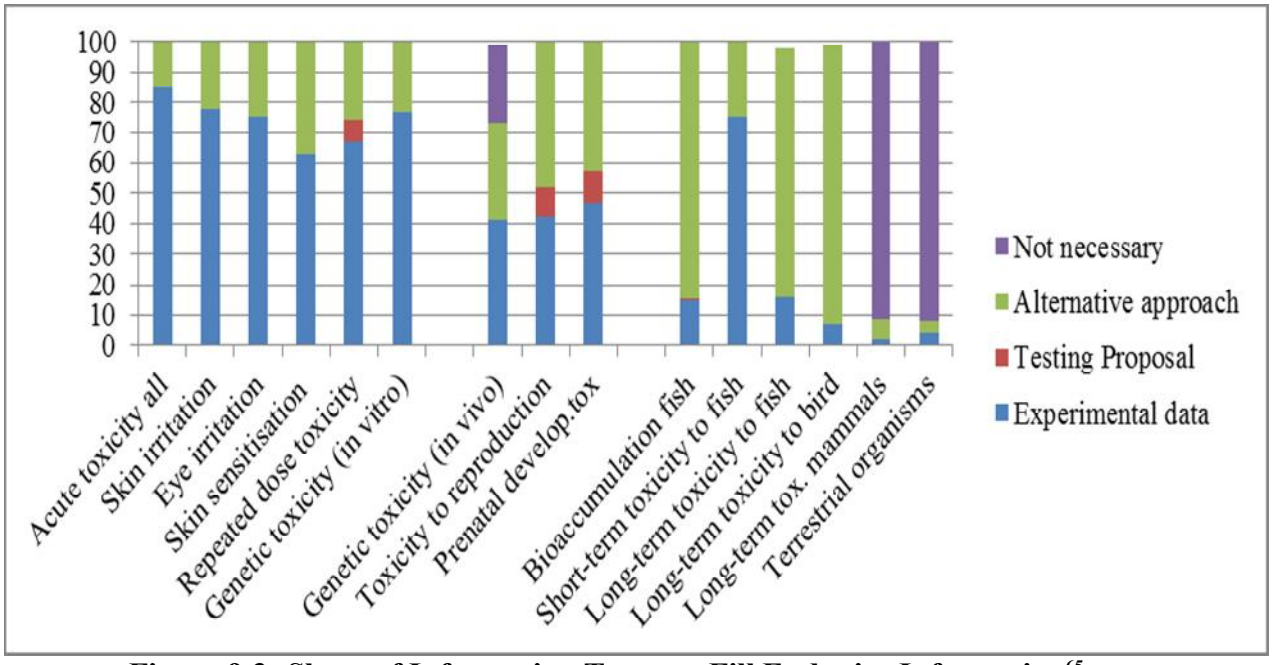

Figure 9.3: Share of Information Types to Fill Endpoint Information[65]

The information requirements of Annex VII and Annex VIII include animal testing for several endpoints[66]. According to ECHA's analysis, the majority of tests carried out since 2009 (96.8% of all new experimental studies and 94% of all experimental in vivo studies) were done to close data gaps for these endpoints.

63 Experimental data on invertebrates were counted as alternative method.

64 Justification for omission.

65 Source: based on information in Table 9.2.

66 Acute toxicity, eye and skin irritation, skin sensitisation, sub-acute repeated dose toxicity, repeated dose / reproductive toxicity screening study, shot-term toxicity on fish.

Table 9.1: New* Experimental Studies conducted to fulfil REACH Requirements			
	Total # of studies	% of all studies	% of the in vivo studies (1849)
In vitro VII and VIII	1,491	44.64	
In vivo VII and VIII	1,742	52.16	94.21
In vivo IX and XX	107	3.20	5.79
Total	3,349	100	100
*All studies with references dated 2009 or later were considered as "new". Source: calculated based on ECHA report on the use of alternatives to animal testing, Table 2, p. 50.			

ECHA states that it will continue to promote a better quality of registration dossiers by, for example, educating registrants in the compliant use of adaptation possibilities, communicating on voluntary efforts and compliance checks including asking for missing information.

A3.9.1.1 Conclusions

ECHA provides a comprehensive overview of the information types in registration dossiers. This includes information on the numbers of separate dossiers and opt-outs, the use of existing data, waiving, category approaches etc. Furthermore, testing proposals are analysed.

For a better understanding of the reporting requirement, a clarification of ECHA's view what the term "non-animal testing methods" comprises (e.g. only in-vitro tests or any way of fulfilling data requirements) and "testing strategies" would have been helpful.

With respect to non-animal test methods (understood as in-vitro testing) the report does not present details on their use and the extent to which they have replaced animal studies, apart from those required in Annex VII and VIII. Furthermore, the total number of avoided animal tests, differentiated by vertebrate and non-vertebrate studies, is not provided.

With regard to testing strategies the report provides information on which type of data is used the most frequently to fulfil the REACH requirements. The actual strategy behind data waiving (types of arguments) or behind proposing a specific test are not described in detail. For example, no assessed is provided regarding the extent to which the guidance on information requirements seems to have been applied in this respect. It is however noted that it may be too early in the registration process of useful, relevant information to be available for analysis and that this could be an output of the dossier evaluation work to be included in the next Article 117(3) report.

A3.9.2 General Information on Non-animal Testing Methods and Testing Strategies

According to the ECHA report, several research projects on the development and optimisation of alternative methods are on-going. Some examples of projects on-going within the EU include:

- Re-Pro-Tec; 2004 – 2009, reproductive toxicology;
- A-Cute-Tox; 2004 – 2009; acute toxicity tests;
- Sens-it-iv; 2005 – 2010; skin and respiratory sensitisation;
- Carcinogenomics; 2006 – 2011; carcinogenicity;
- Predict-iv; 2008 – 2010; chronic toxicity; and
- COLIPA-DG RTD joint research initiative; 2009: repeated dose toxicity.

These and other research programs are expected to deliver new approaches to combine different tests in an optimal way to receive information on certain endpoints (testing strategies). However, before alternative methods and approaches can be used for regulatory purposes, they need to be fully validated. The European Centre for the Validation of Alternative Methods (ECVAM) is currently validating in vitro tests for skin sensitisation, severe ocular irritation and non-irritation. Further in vitro methods[67] have already been adopted and included in the Test Methods Regulation.

ECHA is active in the field of developing alternative methods by contributing and funding of the OECD QSAR toolbox[68] and cooperation with the JRC Computational Toxicology Group to promote computer-based prediction method. Further relevant activities of ECHA relate to capacity building, the organisation of specific workshops and participation in international meetings[69].

The ECHA experts on QSARs and non-testing methods contribute to work on substance identification, substance and dossier evaluation (advice on the use of QSARs, read across and category approaches by the registrants) and the development of the CoRAP list[70].

ECHA also disseminates information from the endpoint summary records in its data base in order to enable future registrants to (better) predict the properties of their substances by read-across from analogous substances.

In September 2010, ECHA organised a workshop in order to clarify concepts, possibilities and restrictions of non-test methods and develop a common

67 More information can be found on ECVAM's website http://ecvam.jrc.ec.europa.eu/.

68 Currently the share of information provided by (Q)SARs is only 0.5% of all ESRs.

69 According to additional information provided by ECHA, the expenditures for the 4-year project on developing the QSAR toolbox was 1.6 million Euros.

70 Information provided by ECHA in addition to the reports and following direct requests from the consultants.

understanding on the use of these methods in the regulatory context. A report on the workshop results is however not available.

In the context of the last registration deadline, ECHA informed via a press release that dossiers for substances > 100 tpa may be considered to be complete if, instead of a 28 d study on repeated dose toxicity, a testing proposal for a 90 d study is submitted AND adequate risk management (RMM) is in place. The same decision was communicated to apply to substances > 1000 tpa if no screening study for reproductive / developmental toxicity is submitted but a testing proposal is contained for a higher tier test AND adequate RMMs are in place. These opportunities were reported to have been used in 55 dossiers (in relation to repeated dose tests) and 61 dossiers (for screening study reproductive/developmental toxicity tests).

Apart from the above information, ECHA's report doesn't include detailed information on which specific activities were launched since REACH came into force to promote the use of non-animal testing.

A3.9.2.1 Conclusions

The Article 117(3) report does not provide an overview of the availability of non-animal testing methods or guidance on testing strategies in general but does mention on-going work without specifying the value or time horizon in relation to REACH. Furthermore, ECHA's involvement in the development of non-animal testing methods is unclear.

A3.9.3 Conclusions on Reporting on Non-Animal Testing Methods and Testing Strategies

The Article 117(3) report and parts of the registration information in the Article 117(2) report provide a good overview of the information submitted to fulfil REACH registration requirements. It documents that in general available information is used and new testing is avoided. However, ECHA draws the attention to the fact that justification for alternative approaches may be insufficient in some cases.

With regard to the reporting requirements, the reports do not provide details of the use and implementation of non-animal testing methods and testing strategies. This information is most likely not yet available and should therefore be one output of the dossier evaluation work. It would be helpful to have an evaluation of whether the goals of minimising animal testing and generating good hazard information can be brought into a balance, for example, by the use of in-vitro testing and the use of testing strategies, in addition to the use of alternative approaches.

A3.10. ENFORCEMENT

A3.10.1 Enforcement-Related Information in the Report

Enforcement of REACH is primarily the task of the Member States.

ECHA hosts and supports the Forum and states that procedural rules and work procedures for the committee are in place. Apart from the delegated members from the MS, stakeholders participate in (the public parts of) the meetings. The Forum meets in plenary and has set up several topic-specific working groups. 15% of the possible members of the Forum appear not to be nominated yet.

The Forum established a work program, set minimum inspection requirements for MS and carried out two joint enforcement projects. ECHA states that the Forum promotes the dialogue between MS CAs, ECHA and the Commission to facilitate a common understanding of implementation and enforcement of REACH.

ECHA reports that the Forum's workload is increasing and stresses that its members should receive full scientific, technical and administrative support from the MS. In addition, ECHA recommends assessing whether the legal powers of the delegated persons should be reviewed to enable their effective functioning. Furthermore, ECHA mentions in its report that the work efficiency should be improved.

ECHA provides the MSCAs with rights to access the REACH-IT system. In May 2011, 22 EU/EEA countries had respective access and could use that data for their enforcement activities.

ECHA observes that a harmonised enforcement of REACH in the Member States with their sovereign national implementing legislation is very difficult. ECHA therefore also suggests that it should be empowered to impose measures to remedy incompliant registration dossiers.

A3.10.2 Conclusions on Reporting on Enforcement

The Article 117(2) report contains only scattered information on ECHA's role and activities related to enforcement. A comprehensive overview could consist of an outline of co-operation and communication work with the MS CAs on enforcement. Furthermore, a discussion of whether or not ECHA wishes to have enforcement obligations and authority (e.g. in relation to evaluation and dossier compliance issues) would seem to deserve a more prominent place.

A3.11. GUIDANCE AND SUPPORT

A3.11.1 Guidance Documents

Most REACH Implementation Project (RIP) guidance documents are published on the internet and ECHA has taken over full responsibility for them. Some have already been updated and an updating plan exists for the "older" guidance. ECHA highlights that the guidance documents contributed to the successful management of the first registration deadline. An overview of available guidance materials is given in Table 11.1.

Table 11.1: Overview of Guidance Documents Available on ECHA's Internet site (July 2011)

Guidance Description	Guidance Document	Guidance fact sheet	Nutshell guidance
Registration	x	x	x
Annex V	x		
Waste and Recovered Substances	x	x	
Pre-registration	x		
Data Sharing	x	x	
Intermediates	x		
Monomers and Polymers	x		
Scientific Research and Development and PPORD	x		
Labelling and Packaging Regulation (EC) 1272/2008	x		
Classification and Labelling Notification	x		
Requirements for Substances in Articles	x	x	x
Downstream Users	x	x	
Application for Authorisation	x		
Socio-Economic Analysis – Authorisation	x		
Dossier and Substance Evaluation	x		
Dossiers for Harmonised Classification and Labelling	x		
Annex XV Dossier on the Identification of SVHC	x		
Annex XV Dossier for Restrictions	x		
Socio-Economic Analysis - Restrictions	x	x	
Communication on Risks and Safe Use of Chemicals	x		
Identification and Naming of Substances	x	x	
Compliance with CLP of Substances and Mixtures	x		
Information Requirements / Chemical Safety Assessment			
Concise Guidance	7	CSA, use descriptors	CSA
In-depth Guidance	20	Introduction	
Priority Setting for Evaluation	1		
IUCLID (several manuals)	Several		

Source: Analysis of information on ECHA's Internet Site.

In addition to the above, there are practical guides, Q&A documents and FAQs are also published by ECHA.

A guidance consultation procedure has been established in order to allow the involvement and participation of stakeholders, so as to ensure transparency. ECHA states that due to the consultation procedure the guidance is well accepted and widely

used. Feedback from stakeholders on their involvement and the functioning of the consultation procedure is not provided. Furthermore, ECHA states that due to delays in the former processes, the consultation procedure had been revised but does not specify what exactly has been changed.

It is intended that guidance should be developed through reaching a consensus between stakeholders but ECHA retains the right to finalise guidance on the basis of majority views where this is not possible. Nonetheless, in many cases, consensus was actually reached. An example where consensus could not be reached is the interpretation of REACH requirements for substances in articles (0.1% threshold) which was discussed and proved controversial. This led to a delay in the finalisation and publication of the guidance.

ECHA reports that 71 guidance documents are published on the internet. From 2007 to 2011, 16 PEG consultations were carried out involving a total of 254 experts. In addition, 30 consultations were conducted in CARACAL. Almost 6,000 pages of guidance documents are translated into 22 languages while the glossary contains approximately 1,000 terms and definitions in all 23 languages.

Past and future challenges identified by ECHA relate to the validation of translations of the guidance. Causes of difficulties are the terminology which was partly developed during the legislative process, time pressure and the high quality demands on the guidance. Availability of personnel with adequate competency and time available for validation of the documents is scarce: currently the work is partly performed by agency staff and partly by MS CAs.

The need to obtain legal interpretations of REACH and related policy issues is reported to have also delayed guidance development. Therefore, ECHA requests the Commission to provide the necessary information in a timely manner. With regard to the interpretation of the article definition and of the 0.1%-threshold for substance in articles, ECHA requests clarification and also that consideration is given by the Commission to enforcement practices.

ECHA intends to include the lessons learnt from registrations to date during the guidance updating process. In addition, ECHA notes that potential revisions should take better account of the needs of SMEs, with view to the significance of the deadline in 2018.

Updating of guidance may also result in the need for urgent updating of registration dossiers by industry. This could be particularly problematic if this were to be performed close to registration deadlines, and ECHA therefore proposes to freeze guidance development half-a-year ahead of the registration deadlines.

A3.11.1.1 Conclusions

The information on guidance documents provides a good overview of the operation of REACH with regard to support of companies in implementing the legal provisions.

A3.11.2 Helpdesk

The ECHA helpdesk focussed on support for lead registrants and on the installation and functioning of IT-tools, whereas the national helpdesks focussed on support for member registrants. ECHA also processed referrals from national helpdesks and requests from non-EU companies. The number of questions to the ECHA helpdesk is illustrated in Figure 11.1 with reference to company size ranges, where possible.

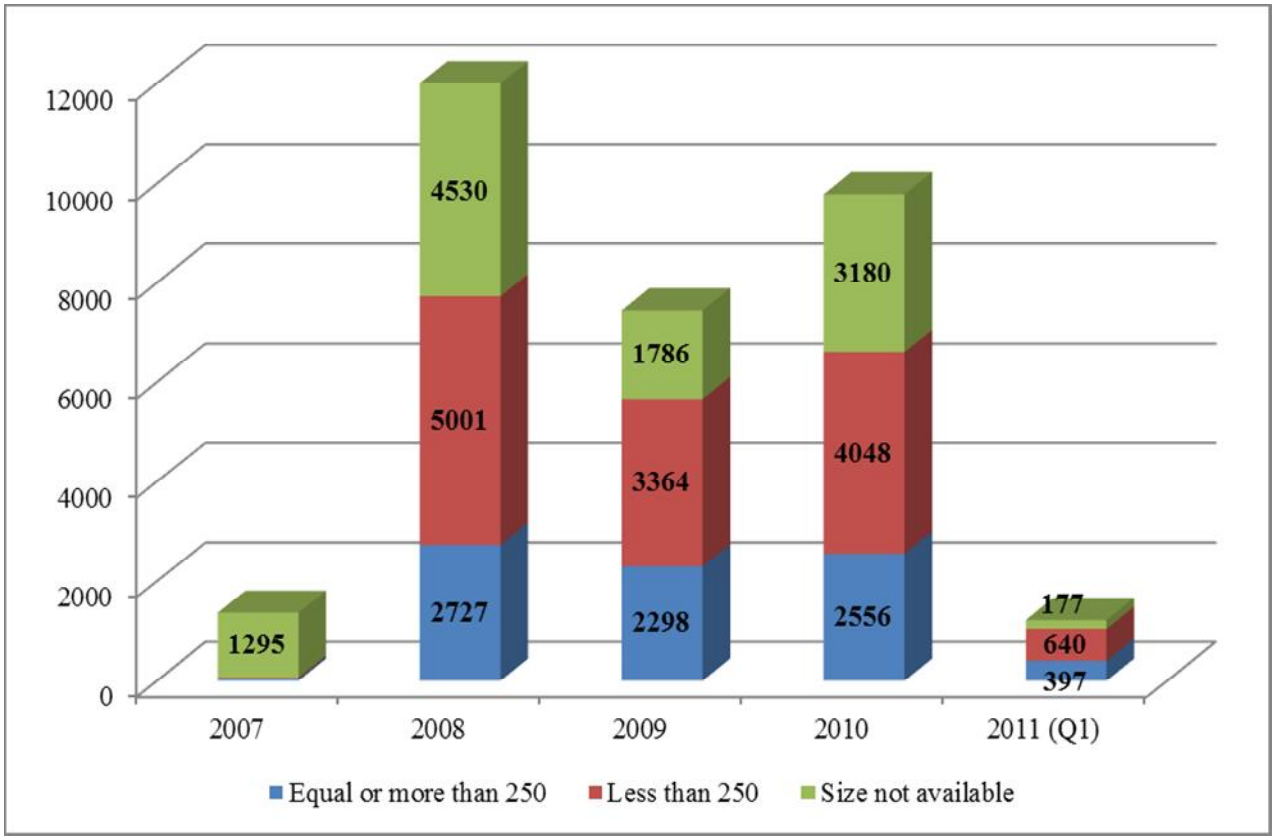

Figure 11.1: Overview of Helpdesk Questions according to Company Size (2007 – 2011 (Q1))[71]

On average, approximately 25% of the questions were posed by companies with more than 250 employees, approximately 40% by SMEs; for 35% of the questions, the company size is not known.

Figure 11.2 gives an overview of the topics for questions to the helpdesk. REACH-IT triggered the most questions, followed by general information on REACH and IUCLID / CHESAR.

[71] Source: ECHA report on the operation of REACH, Table 16, p. 51.

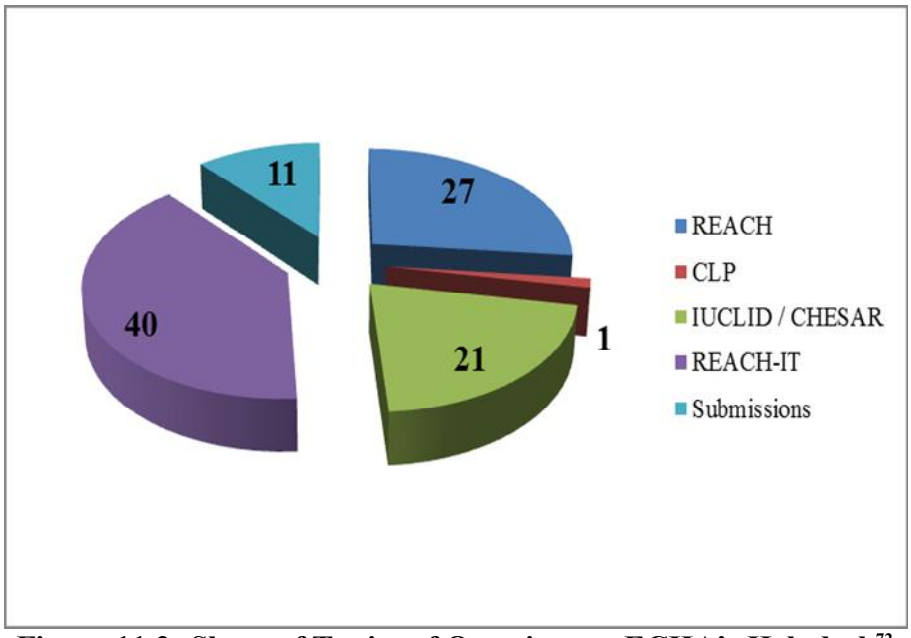

Figure 11.2: Share of Topics of Questions to ECHA's Helpdesk[72]

The capacities of the helpdesk were increased before the deadlines for pre-registration and registration; ECHA states that this was appreciated by industry.

A3.11.2.1 Conclusions

The information on ECHA's helpdesk provides a good overview of this operation of REACH with regard to direct support to companies.

A3.11.3 ECHA Support for National Helpdesks

ECHA supported the network of national helpdesks (REHCORN). This was established in 2007 and expanded in 2009 by including the CLP helpdesks. In the context of the expansion, the network was renamed HelpNet. The aim of HelpNet remains to create a common understanding of the REACH requirements and to ensure that national helpdesks provide harmonised answers.

ECHA established an IT-platform in support of HelpNet called HelpNet Exchange. In addition, it organised face-to-face meetings (HelpNet Steering group) and training and webinars for the helpdesk staff. ECHA also visited national helpdesks to understand them better. FAQs from HelpNet discussions were agreed and published. ECHA states that it opened 305 issues for discussion in HelpNet Exchange while 416 were launched by MSCAs.

The ECHA evaluation concludes that HelpNet and HelpNet Exchange provide good, harmonised and resource efficient support to companies. HelpNet Exchange is valued

[72] Source: ECHA report on the operation of REACH, Figure 7, p. 50.

as good discussion platform and provides the possibility of agreeing and approving FAQs.

ECHA requests that the Commission should provide legal interpretations to questions which are difficult and as yet unresolved, in a timely manner to the ECHA helpdesk and HelpNet.

A3.11.3.1 Conclusions

The information on ECHA's support to national helpdesks provides a good overview of this operation of REACH, informing on both (indirect) support to companies and the level of co-operation between ECHA and the MS.

A3.11.4 IT-tools

ECHA was responsible for the set up of the IT-infrastructure to manage information from REACH. The main IT-tools for REACH implementation are: the REACH-IT and IUCLID (now version 5).

ECHA described the REACH-IT system as the "backbone of the implementation of the REACH and CLP Regulations" and considers this system to have been well developed during its first three years of operation. It is via REACH-IT that (pre-)registrations are received by ECHA and it provides a means of communication between registrants and ECHA, as well as between different registrants for the formation of SIEFs.

Some initial instability was reported due to the unexpectedly high number of organisations submitting pre-registrations in 2008. However, after "intense development" ECHA reports that REACH-IT functioned well during the period of the first REACH phase-in deadline during which it received 25,000 registration dossiers and during the period for classification and labelling notifications under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) during which it received three million notifications. The registration submission via REACH-IT is now reported to have become mostly automated, requiring manual intervention by ECHA only in exceptional circumstances. Further references to REACH-IT was provided by ECHA when describing the REACH activities which it facilitated but only very limited information was provided on the actual functions of this system.

To support industry ECHA developed several IUCLID plug-ins, including tools to perform a technical completeness check, calculate fees etc. CHESAR is another IT-tool to support the preparation of a chemical safety report. Furthermore, C&L notification tools were developed that are embedded into REACH–IT.

For its own use, ECHA has developed a prioritisation tool for dossier evaluation (CASPER) and a tool to support dossier evaluation (ODYSSEY). A portal for

enforcement authorities, called RIPE, was established specifically for the Member States. The dissemination portal is open to the general public.

ECHA reports that the high number of pre-registrations submitted overloaded the IT-system leading to a temporary system failure (followed by a need to manually process dossiers). After further development work, the IT-system is now running and stable; no major problems were reported at the first registration deadline.

The tool CHESAR supports the preparation of CSRs and the generation of ESs for supply chain communication. Further developments to CHESAR are envisaged and the system will be fully operational before the registration deadline in 2013. ECHA also plans to assist industry in the development of IT-tools that are compatible with CHESAR and IUCLID.

ECHA highlights in its report that the set-up of IT-infrastructure demanded considerably more resources than had been foreseen. Furthermore, the IT-tools required updating due to changes in the REACH interpretation, expansion to enable all types of submissions, and improvement to provide better functionalities for the users. The access of MS CAs to the REACH-IT also requires extensive programming activity to ensure the protection of confidential business information. ECHA therefore stresses that there is a need for sufficient time and resources to further develop the IT-infrastructure. ECHA also recommends that stakeholders be involved in any further IT-development.

A3.11.4.1 Conclusions

The information on IT-tools is comprehensive and shows ECHA's related activities. However, detailed information on the resource needs and the key drivers of workload related to the IT-development, as well as the up-coming challenges for the next registration deadline and the inclusion of further functionalities, are not sufficiently detailed to enable a judgement on the resourcing of past and future work. Due to the high relevance of the IT-system further justification would have been expected.

A3.11.5 Internet site

ECHA makes little direct mention of its Internet site in its Article 117 reports but, by inference from other information provided, it is clear that this Internet site is perhaps the host of the most comprehensive and authoritative collection of guidance and support for applicable across the EU. ECHA does however note that its website has grown from initially 40 to approximately 500 webpages, most of which are available in the 23 official languages of the EU. ECHA counts 270,000 visits per month from 200 different countries. ECHA also states that it plans to make its Internet site more user-friendly in the future.

A3.11.5.1 Conclusions

The information on ECHA's internet site is sufficient to inform on this aspect of the operation of REACH.

A3.11.6 Other Activities

ECHA also documents its other activities, describing the provision of guidance and support to industry and Member States in form of:

- webinars (e.g. on registration);
- facilitation of SIEF formation/functioning and identification of lead registrants;
- training of national helpdesk staff ; and
- training to pre-accession countries.

A3.11.7 Conclusions on Reporting on Guidance and Support

The Article 117(2) report contains comprehensive facts and figures of the activities of ECHA with regard to guidance development and publication, helpdesks, IT-tool development and the website (see Section 11.5). However, some information on the past and future resource investments, in particular in the development of the REACH-IT could have been expected given ECHA's expressed concern about the adequate resourcing of its activities.

A3.12. REACH AIMS: PROTECTION OF HUMAN HEALTH

In the Article 117 reports, ECHA provides no specific information on human health impacts from the operation of REACH.

A3.13. REACH AIM: PROTECTION OF ENVIRONMENT

In the Article 117 reports, ECHA provides no specific information on environmental benefits from the operation of REACH.

A3.14. REACH AIM: ENHANCING COMPETITIVENESS, INNOVATION AND SINGLE MARKET

In the Article 117 reports, ECHA provides no specific information on enhancing competitiveness, innovation and single market from the operation of REACH.

A3.15. REVIEW OF ECHA ARTICLE 117 REPORTS

A3.15.1 Introduction

In the following section, ECHA's reports relating to REACH Articles 117(2) and 117(3) are discussed in relation to benchmarks derived from:

a) the legal reporting obligations set out in REACH Article 117(2) and 117(3);
b) ECHA's roles and tasks as defined in REACH;
c) the objectives and indicators defined in ECHA's work programmes; and
d) recognised standards for governmental and corporate reporting, and examples of reports from other EC agencies.

The detailed analyses of ECHA's reports against these benchmarks are contained in Appendix A3.17 (legal obligations), Appendix 2 (roles and tasks defined in REACH) and Appendix 3 (objectives and indicators of the work programmes). The following sections summarise the findings and provide overall conclusions.

A3.15.2 ECHA Reporting Obligations defined under REACH

A3.15.2.1 Reporting on the Operation of REACH

ECHA's reporting obligations on the operation of REACH are defined within Article 117(2):

Every five years, the Agency shall submit to the Commission a report on the operation of this Regulation. The Agency shall include in its report information on the joint submission of information in accordance with Article 11 and an overview of the explanations given for submitting information separately.

The first report shall be submitted by 1 June 2011.

Table 15.1 sets out the requirements and provides comments on their interpretation.

Table 15.1: Legal Requirements for ECHA Reporting on the Operation of REACH

Required to Report on	Note
Joint submission according to Article 11	Article 11 sets out which information shall be submitted jointly, which shall be submitted separately and which may be submitted jointly on a voluntary basis
Reasons for separate submission	Reasons for submitting information separately specified in Article 11 are a) costs, b) disclosure of confidential business information and c) disagreement with the lead registrant.
Operation of REACH	c.f. Section 15.3

The statistics provided by ECHA relating to joint submissions, separate submissions and opt-outs are not fully clear, in part due to the inconsistent use of references in

support of the inclusion of, for example, numbers of substances, dossiers, end-points and percentages throughout the Article 117(2) and the Article 117(3) report.

SIEF formation and agreement on joint submissions are clearly the responsibility of the registrants. ECHA has supported SIEF formation, e.g. through problem solving related to substance identification. However, an explanation of how ECHA sees its role and of how this fits with the shared responsibilities between industry and authorities, is not provided. Indeed, ECHA's overall role in facilitating joint submissions and the activities performed to promote joint submissions are not made entirely clear.

On page four of its Article 117(2) report ECHA states that no analysis of reasons for separate submissions and opt-outs could be provided. However, some information is included that would have allowed for the identification of general trends.

ECHA concludes that it would be helpful to clarify the consequences of breaching the obligation for joint submissions within the legal text itself. However, this conclusion is not substantiated by provision of any evidence that registrants submitted separate dossiers because they were unaware of the consequences. Furthermore, no proposals are made on how to facilitate the resolution of disagreements in SIEFs on the selection of studies (indicated as the main reason for opt-outs).

Consideration of ECHA's reporting on the operation of REACH more generally is set out in Section 15.3.

Table A1.1 in Appendix 1 to this Annex sets out the details of our analysis of the ECHA Article 117(2) report against these requirements.

A3.15.2.2 Reporting on Non-Animal Testing

The reporting obligations placed on ECHA under REACH regarding non-animal testing are defined within Article 117(3):

Every three years the Agency, in accordance with the objective of promoting non-animal testing methods, shall submit to the Commission a report on the status of implementation and use of non-animal test methods and testing strategies used to generate information on intrinsic properties and for risk assessment to meet the requirements of this Regulation.

The first report shall be submitted by 1 June 2011.

Table 15.3 sets out the requirements from Article 117(3) and provides comments on their interpretation.

Table 15.3: Legal Requirements from REACH for ECHA Reporting on Non-Animal Testing	
Required to Report on	**Note**
Implementation and use of non-animal test methods	No differentiation between vertebrate and non-vertebrate tests required
Implementation and use of testing strategies	Not defined what is understood as "testing strategy"

ECHA provides an extensive analysis of the type of information submitted in registration dossiers and used to fulfil the REACH obligations. Following this analysis, ECHA concludes that carrying out new tests is generally avoided by using existing data or alternative methods, such as category approaches, waiving or weight of evidence. This appears to reflect well the status quo after the first registration deadline.

No in-depth assessment was provided as to whether or not the quality of submitted data was sufficient nor of whether the use of waiving, read-across and non-validated alternative test methods was sufficiently justified. This was explained as being due to too few dossier evaluations having been finalised prior to the preparation of the ECHA report. However, a general trend was identified, indicating that some of the alternatives proposed may not be sufficient to meet relevant information requirements. This may potentially trigger future needs for testing to complete some dossiers.

It is also mentioned in the report that in some cases non-validated non-animal tests have been used but that discussion of validity of these methods by registrants is not always sufficiently robust. With the exception of test data specifically provided in REACH Annex VII and VIII, the number of non-animal tests conducted in place of potential animal tests is not provided. Also information is missing regarding the justifications given when developing testing strategies and on the evaluation by registrants used to identify gaps in necessary study end-points. The report also does not give an overview of the current situation regarding the existence and validation of non-animal tests as possible alternatives to animal test methods. Finally, the report does not give an overall picture of ECHA's involvement in promoting non-animal test methods, including the level of resources expended.

In conclusion, although providing much information of value, there is an absence of focused information on the implementation and use of non-animal test methods within the REACH process and of ECHA's contribution.

Table A1.2 in Appendix 1 to this Annex sets out our analysis of the ECHA report against these requirements in more detail.

A3.15.3 ECHA's Roles and Tasks, As Set Out in REACH

The comparison of roles and tasks within the content of the Article 117 reports is limited to the assessment of whether or not information has been provided while assessment of the quality of such information is not considered here[73].

Article 75(1) of REACH states that ECHA *"[…] is established for the purposes of managing and in some cases carrying out the technical, scientific and administrative aspects of this Regulation and to ensure consistency at Community level in relation to these aspects."* Consequently, the level of success achieved in the operation of ECHA is an essential determinant and indicator for the operation of REACH as a whole. According to Article 117(2), ECHA is to report on the operation of REACH and, being a part of REACH, also on its own operation.

Several of ECHA's tasks have not yet been performed because the respective legal provisions have not yet come into effect, including the processing of applications for authorisation, substance evaluations or DU notifications of substances in articles. Consequently, ECHA could only report on its preparations to date towards fulfilling these obligations.

The Article 117(2) report does not explicitly relate to the legal definition of ECHA's role and tasks (no concise overview is provided). However, the report structure does reflect the main activity areas and organisation.

A focused description of which activities are undertaken to ensure consistency at Community level, is not provided. Furthermore, details of how and what scientific advice has been provided to the Member States and other EU institutions are also not addressed.

ECHA's reports lack any specific information on its budget (no figures are provided at all). To illustrate this issue, no details are given regarding how far revenue and expenditure are in balance nor of how revenue and expenditure have been estimated and integrated into the Community budget as a whole. The only budget-relevant figure provided in the report is in relation to the number of staff.

For all REACH processes (registration, authorisation, evaluation and restriction) ECHA provides statistics and overviews of the work performed. Experience and challenges observed from most of the main tasks are also reported. However, information is not provided on several minor tasks or actions, such as the publication of the list of those interested in non-pre-registered substances or on the receipt of information on substances from the Commission. It is also not clear whether ECHA has obtained relevant information but following evaluation did not consider it to be worth reporting or if no information was available and, consequently, no such evaluation was attempted.

[73] The information on quality is evaluated partly in the first sections of this report (Conclusionss) and partly in Section 14.5 of this report.

It is noted that little information is provided on the formal communications between ECHA, the Commission and the Member States.

ECHA also has roles and tasks set out in REACH that relate to the minimisation of animal testing. These are set out in Table 15.3, accompanied by a brief assessment of reporting against these roles and tasks.

Table 15.3: Roles and Tasks of ECHA according to REACH – Animal Testing

Tasks and roles	Article	117 Reports
Determine the appropriateness of test methods	13	Application of role reported
Provide non-phase in registrants with details of previous animal testing	26	Information on processing of inquiries reported in Article 117(2) report. No details on types of tests and success with regard to data sharing. More information could be expected in future reports
Facilitate data sharing to avoid in SIEFs to avoid duplicate testing	30	Reporting on the operation of data sharing to avoid duplicate testing. Testing avoided but no estimate of numbers of tests involved. See Section 15.2.2 and Appendix 1, for assessment
Evaluation of testing proposals	40	Analysis of content of testing proposals in Article 117(3) report. Conclusions from evaluation and consultations in Article 117(2) report. See Section 15.2.2 and Appendix 1, for assessment
Report to Commission on status of implementation and use of non-animal test methods and testing strategies	117(3)	Report provided to Commission

Information on the minimisation of animal testing is primarily provided in ECHA's Article 117(3) report. This report is assessed in Section 15.2.2 and therefore is not considered further here. Evaluation of the information provided on alternative approaches and testing proposals are primarily part of the Evaluation Progress Report and the Article 118(2) report.

The summary of ECHA's roles and tasks as defined by REACH and the detailed comparison these against the information reported by ECHA, is provided in Appendix 2.

A3.15.4 ECHA Work Programme 2009 – 2012

A3.15.4.1 Introduction

ECHA's objectives are defined directly within the REACH regulation. Based on these, ECHA's Management Board adopts annual work programmes to plan the actual activities necessary in order to achieve the objectives. The annual reports published since 2007 provide some information on the performance of ECHA in comparison to these established work programmes. As for all executive agencies of the Commission, the work programmes are centrally supervised and guidelines exist for how they should appear. Guidelines are also available for annual activity reports. It

should be noted, however, that these guidelines do not apply to the Article 117 reports. Rather, the Article 117 reports refer to the operation of REACH and, more specifically, to non-animal testing. Hence, these are essentially different in nature than ECHA's annual reports. However, as ECHA plays a core role in the REACH implementation, the reports are clearly interrelated. It might therefore be expected that the core objectives of ECHA, defined as "targets" in the first multi-annual work programme covering the time period of 2009 – 2012, would be addressed and discussed either directly or indirectly within the Article 117 reports.

The Multi-annual Work Programme sets out ECHA's overall work plan, structured according to the following headings:

- operational activities – implementation of the REACH processes;
- ECHA bodies and supporting activities; and
- management, organisation and resources.

Given the implicit importance of ECHA to the functioning of REACH, it is considered not unreasonable to expect that some assessment of ECHA's performance against this work programme would be provided within ECHA's Article 117 reports. The details of the work programme have, therefore, been summarised here and an assessment has been undertaken of the extent to which ECHA's Article 117 reports provide information on progress made against this work programme.

A3.15.4.2 Assessment of Work Programme and Reporting

The multi-annual work programme does not incorporate any indicators but does specify "targets". For these targets, the annual work programmes (WP) of 2009 and 2010[74] set out "indicators" of performance. However, while the established indicators do not cover all of the targets, they also sometimes go beyond the scope of the stated targets. Furthermore, the indicators in the annual WPs do not appear to necessarily directly link to the targets of the multi-annual work programme.

It should be noted that the Article 117(2) report is intended to discuss the operation of REACH and not the performance of ECHA per se. Hence, our analysis against ECHA's work programme should to be viewed solely within the context of an attempt to evaluate how far ECHA's reporting on its performance is relevant to the overall operation of REACH. The same argument applies to considerations of those issues related to non-animal testing and testing strategies in the Article 117(3) report.

A detailed table summarising the targets and indicators in the WPs, and giving an assessment of availability of information on these indicators in ECHA's report, is provided in Appendix 3. The findings of this evaluation are summarized and conclusions drawn below.

[74] The WPs of 2007 and 2008 do not contain any indicators; the WP of 2011 was not analysed as it is not included in the reporting period of the Article 117(2) report.

The indicators as set out in the annual WPs and the targets of the multi-annual WP are not mentioned in ECHA's Article 117 reports. For many quantified indicators, no matching information is available in the reports[75]. This appears to be due to several reasons:

- the reporting periods do not match;
- a consistent reporting scheme has not yet been established by ECHA;
- indicators have lost relevance or have proved to be unhelpful for the assessment of performance; and/or
- indicators relate to ECHA's internal organisation and/or efficiency, rather than to the operation of REACH (However, as explained above, efficient working of ECHA should be regarded as integral to the efficient implementation of REACH).

Nevertheless, some qualitative information is provided in ECHA's Article 117(2) report that matches some indicators. However, no quantitative information is provided that would inform on any of the indicators of ECHA's internal organisation, including its budget and the spending of resources, staff management, control procedures or quality standards. This omission should be seen within the context of a general lack of information on ECHA's budget, internal procedures or management practices. In this respect, the Article 117(2) report briefly mentioned that an internal governance approach has been adopted including policies on quality assurance, data security and management, transparency etc. but the report fails to provide any detail on these policies. It should be noted that a separate study has been commissioned to assess ECHA's efficiency, effectiveness and economy in building up its capacities and in managing its operations ,as well as assessing ECHA's role/added value, acceptability and location.

ECHA's 117(2) report includes statements regarding the successful processing of dossiers or requests "within the legal time frame" and these statements do inform a number of indictors of success. However, apart from the qualitative statement that timelines were met, no quantification of actual processing time is provided for any of the indicators. "Timely" is specified but it is not clear if the process was "just in time" or if the established timelines were, for example, 'easily met'; this may be due to a lack of data. However, if the report is to contribute meaningfully to improving the operation of REACH, a more detail account of the actual processing times (resources and physical time) and resource drivers might have been considered helpful.

Several indicators refer to feedback from stakeholders, the Committees and/or the Commission on the quality of work undertaken by ECHA, i.e. on the level of satisfaction. In this respect, ECHA states for several REACH procedures that it values the involvement of stakeholders. However, no feedback is quoted on the level of satisfaction of stakeholders with ECHA's performance or their involvement in the

[75] It is not always clear if quantitative information is available but not provided or is not available, e.g. because it has not been collected (yet) or there is no intention (any more) to collect it.

processes. Also, little or no information is provided on any differences in views that may exist on the quality of cooperation with Member States and the Commission.

Quantified and qualitative information is lacking in relation to several other indicators, such as those relating to the provision of training. Details on how ECHA's input is processed by the Commission or by other EU-bodies is also missing, as are details of cooperation (e.g. proposals of solutions for differences in views in Committees) with other bodies.

The Article 117(2) report does, however, contain quantified information matching several indicators including those that refer to IT-tools, awareness raising events, guidance documents, the helpdesk, processing of registration and SVHC dossiers. Qualitative information is also provided on the procedures with the Committees.

In conclusion, the Article 117 reports do not directly refer to ECHA's work programmes but the information provided touches upon many of the aspects for which indicators exist. Furthermore, the level of detail and quantification provided is often limited. In this respect, it may be of value for the Commission and ECHA to clarify the relationship between the operation of ECHA and the operation of REACH, as well as to give consideration to which of the established indicators of ECHA's work programmes should be addressed in future Article 117 reports. However, defining such considerations is beyond the scope of this study.

A3.15.5 Reporting Benchmarks

To gain a wider perspective on the robustness of ECHA's Article 117 reporting, consideration has been given to current practice with regard to reporting outside of the specific context of REACH and ECHA. Specifically, a range of national and international reporting standards have been reviewed in order to identify principles and standards from current practice that could form a benchmark against which the content of the Article 117(2) and Article 117(3) reports may be assessed. The documents and their analysis are set out in detail in Appendix 4.

Importantly, the reporting by ECHA should enable the Commission (and the general public) to decide on the extent to which ECHA has fulfilled its tasks and obligations with respect to the effective and efficient operation of REACH.

Based on our analysis of reporting principles and standards, the following generic principles were identified as being relevant benchmarks with regard to (public) performance reporting by ECHA:

1. The basis for and the purpose of reporting should be stated.
2. The tasks and roles of ECHA, should be described, in particular in the first report as a newly established agency.
3. The division of tasks and responsibilities between ECHA and the European Commission (and the Member States) should be described including an evaluation of how this works and making proposals for improvements.

4. The report should relate to the plans established by the organisation, its work programme or any contract agreements made.
5. The report should be focussed on a few, critical aspects of performance[76], highlighting core challenges, e.g. relating to capacities and original planning.
6. Information should relate to the past and the future, as appropriate.
7. Financial and non-financial information should be integrated, resources linked to results, plans and priorities.
8. Comparative information should be provided (e.g. trends from other agencies).
9. Procurement policy, contracts and services provided, should be made transparent.
10. Information on the management and resourcing of larger IT-projects, should be included.
11. Methods of reporting should be stated, especially if benchmarks and scores are used, including clear indications on the limitations of data.
12. The information should be provided in a straightforward way, flowing logically through the report (e.g. strategy, programme activity, results, evaluation – progress against goals, future).
13. Information should be credible, fairly interpreted, reliable and balanced, information sources should be stated.
14. A short, non-technical summary should be provided.

It should be noted that the above principles and topic areas have been developed from various reporting practice rules that reflect "best practice in reporting" and, hence, insistence on meeting all of these would be to request much more than an "average" level of reporting of ECHA.

Furthermore, rules from corporate reporting may be more focused on linking activities and outcomes (of companies) with the resources and budget than appears to be necessarily the case for a public body. Furthermore, a comparison between this benchmark and the 2010 annual reports published by the European Food Safety Authority (EFSA) and European Agency for Safety and Health at Work (OSHA) demonstrates that these other reports did not fully comply with all 15 principles set out above. In particular, there were several items not addressed, such as the description of roles and responsibilities as well as detailed explanation of the budget and potential changes to the original plan. Also, no indicators were provided to measure work or compare indicators against the organisations' targets and work programmes.

The following sections aim to assess the extent to which ECHA's report on the operation of REACH fulfils all the benchmarks derived in Appendix 4. However, it is important bear in mind that ECHA is required under Article 117 to report on the operation of REACH and not on its own performance *per se*[77].

[76] This principle relates to public reporting and appears not to be applicable to reporting to the Commission. The project team have interpreted this principle to mean that more information should be provided on those aspects of performance considered to be **critical** in the supporting text or as a summary, e.g. to illustrate the overall performance assessment.

[77] This aspect is the topic of the annual general reports.

It is not within the scope of the present study to evaluate whether or not ECHA is performing well. Rather, the focus here is on the performance of ECHA as this relates to its reporting of the operation of REACH. As stated in Section 15.4, in this respect, it may be of value for the Commission and ECHA to clarify the relationship between the operation of ECHA and the operation of REACH prior to the publication of further Article 117(2) or Article 117(3) reports.

In each subsection, the benchmarks are briefly interpreted. In line with the statement above, each benchmark has been related to how the implementation of REACH has been reported, as far as possible. In some cases, the benchmarks are not appropriate to measuring REACH implementation but relate solely to ECHA's work. In these cases, the benchmarks have been used to assess how the operation of ECHA may contribute to the implementation of REACH and how well this has been reported.

It is the Article 117(2) report that primarily reports on the implementation and operation of REACH and this is therefore the primary focus for the analysis provided here. However, consideration is given to the Article 117(3) report where considered of relevance.

A3.15.5.1 Purpose of Report

The purpose of the Article 117(2) report is stated in the preface (p.4) which quotes the legal basis of the report. It is further explained that the main aim of the report is to support the Commission in reviewing the implementation of legislation. The purpose of the Article 117(3) report is clearly stated in its Introduction. Consequently, the benchmark is regarded as being fulfilled for both ECHA reports.

A3.15.5.2 Description of Tasks and Roles

With regard to the operation of REACH as a whole, this benchmark would require a description of the relationship of the legal provisions of REACH to each of the issues described in the report. The summary of the "objectives in legislation" in each Chapter of the Article 117(2) report comprise this description and the Introduction to the Article 117(3) report sets out the legal objectives relevant to this report.

In relation to ECHA's performance, this benchmark would require a description of ECHA's legal tasks and roles in relation to its actual work. A structured compilation of tasks and roles is not part of the Article 117(2) report, however, some related information is provided in the various chapters. However, relevant details are provided throughout the Article 117(3) report and most specifically in Chapter 1.5.2.

As the Commission is the main addressee of the 117(2) report, it might be argued that neither a description of REACH nor that of ECHA is actually needed. Therefore, on this basis, the contained information is regarded as sufficient and the benchmark is understood as being met for both reports. However, additional information on how ECHA is perceiving is role in the implementation of REACH would have made a valuable addition to the ECHA report.

A3.15.5.3 Division of Tasks and Responsibilities; Improvement Proposals

In the context of the operation of REACH, the benchmark would require a description of roles and responsibilities of all actors and an analysis of whether their implementation of REACH is progressing well. ECHA's 117(2) report contains relevant information in various parts but highlights the incomplete shift of responsibilities as a core area for improvement.

In relation to the performance of ECHA, the division of tasks and responsibilities with the MS CAs and the Commission are core determinants of the smooth implementation of REACH and, therefore, should be described. However, in the Article 117(2) report, no clear description of the division of tasks and responsibilities is provided; this omission applies in particular to aspects relating to the Commission. In several of the Chapters, the formal cooperation procedures are described (ECHA support to Committees, Helpdesk etc.) but an overview of inter-linkages and divided / shared responsibilities is missing. Correspondingly, an evaluation of challenges related to the shared / divided responsibilities and tasks, structural difficulties (or the non-existence of them) and problems (e.g. in cooperation and communication) are essentially absent apart from a few limited examples[78].

With regards to the Article 117(3) report, the emphasis is rightly placed on ECHA's role in the reduction of animal testing. However, additional information is provided throughout regarding the interplay between different stakeholders, including those from industry.

This benchmark is regarded as not being fulfilled for the Article 117(2) report but as being fulfilled for the Article 117(3) report.

A3.15.5.4 Reference to Plans, Work Programme or Contract Agreements

References to Plans, Work Programmes etc. in relation to the operation of REACH is interpreted here as being limited to consideration of whether or not the legal deadlines for implementation have been met on the one hand and in relation to the institutional context of ECHA on the other hand.

The plans for implementation of REACH are mainly defined by the legal deadlines in REACH. The core milestones of the legal implementation are quoted in both reports and an assessment of whether or not, and how well, they were implemented and met is included in all cases (e.g. with respect to pre-registration, registration, SVHC candidate list and working of SIEFs with respect to the limiting of animal testing). Legal provisions which are not yet in operation are also mentioned.

The institutional status of ECHA and details of its formal relationship with the Commission are currently not fully agreed or formalised, e.g. by contractual

[78] For example, it is stated that the MS CAs created (unnecessary) work by commenting on Agency decisions regarding dossier evaluation.

agreements between ECHA and the Commission. Rather, these may only be defined from the provisions in the REACH legal text and the self-defined work programmes produced by ECHA. The latter are not explicitly discussed in the Article 117(2) report. (An evaluation of information contained in ECHA's Article 117(2) report and ECHA's work programmes is provided in Section A3.15.4). Furthermore, the extent to which ECHA's expectations and plans have been fulfilled are often described, including the expected number of pre-registrations and the implementation of IT-tool development.

Details of where ECHA has adapted its plans to better implement REACH are also provided in relation to the fulfilment of legal obligations (e.g. duration of consultation periods for Committee opinions, Fee Regulation, implementing legislation on substance identity) and in relation to ECHA's internal activities (e.g. related to the contingency planning after the pre-registration phase, the programming of IT-tools that had to be delayed due to the slower progress with the development of registration software and the slower than anticipated start to the identification of SVHCs).

This benchmark is of only limited relevance to the Article 117(3) report. However, reference to the overall work of ECHA, relevant to this report, is given throughout.

The benchmark is regarded as being fulfilled for both reports.

A3.15.5.5 Focus on a Few, Most Critical Aspects of Performance

In relation to the operation of REACH, the benchmark would require the highlighting of those determinants that most influence the successful implementation of REACH. In the context of this study, this benchmark is understood as requiring that a few critical aspects of performance (i.e. smooth implementation of REACH) should be particularly highlighted among the information provided in the main body of the Article 117 reports.

In the executive summary, three paragraphs list the core lessons learnt[79] which are related consequences[80]. However, these do provide focus on critical aspects for the REACH implementation since they relate to the core difficulties that ECHA experienced in the first years of operation of REACH. This again highlights the uncertainty as to the extent to which the Article 117(2) report should include information on, and analysis of, the internal operation of ECHA *per se*, or whether such information should be limited solely to consideration of the importance of the internal operation of ECHA to the efficient implementation of REACH.

[79] Contingency planning based on pre-registration numbers went wrong; industry needs legal clarity and timely support by ECHA and COM; substance identification is crucial for all subsequent processes.

[80] Better estimates are needed for the next registration deadline; little changes in legislation if possible and updates of registration related guidance should be frozen at least half a year before the registration deadline; clarification of rules for substance identification.

The three main improvement areas identified by ECHA relate to the:

1. Shifting of responsibilities from MS authorities to industry, which has not been completed. A potentially high level of non-compliant registration dossiers is cited as evidence of this failing, in particular the insufficiently robust justifications provided for data omissions and estimations of substance properties are highlighted, as is the low overall quality of CSRs.
2. Communication of information throughout the supply chain should be improved by strengthening mechanisms for such communication and developing/ improving the communication tools.
3. Use of data from registration to prioritise substances for further REACH processes such as substance evaluation, SVHC identification, restrictions etc.

The first area for improvement is discussed in several places throughout the report.

For the second area for improvement, there is only one short section addressing communication in the supply chain and key aspects of communication related to the supply of safety data sheets (SDS) had only just begun at the time of reporting. Relevant concerns that were identified include: the non-standardised safety information provided by SDS; the excessive length of some SDS; and ECHA's plans to further develop CHESAR. However, further discussion of the lack of IT tools and mechanisms for effective supply chain communication are not apparent in the main report.

The third area for improvement identified in ECHA's report is discussed in several sections of the report. However, in the context of the entire Article 117(2) report and the various issues highlighted, it is not given the prominence that would justify its identification as one of only three main areas for improvement.

At the end, a list is provided of additional, more specific, and cross-cutting issues.

It is noted that the shortage of MS CA resources, the expected challenges related to ECHA's income and the well-functioning IT-systems are not mentioned as key factors determining the successful implementation REACH.

In total, the executive summary provides a focus on the challenges of the past and related lessons learnt, from ECHA's perspective. It outlines ECHA's opinion on the key determinants of a successful REACH implementation. However, the focus in the executive summary does not fully correspond with the core factors influencing the operation of REACH and neither is it fully consistent with the content of the report itself.

Each section of ECHA's report contains a description of the legal objectives and sometimes an explanation of obligations, followed by a series of key messages and a section on follow-up activities by ECHA (and sometimes other actors, mainly the Commission and sometimes industry or the MS). Whereas the description of legal

objectives and requirements may be useful for the general public and some other stakeholders, it appears of questionable value to the Commission.

The key messages which form the chapter structure relate to:

1. Facts and figures: "Industry registered 4,300 substances... (p. 8).
2. Progress evaluations: "The identification of SVHCs and their inclusion in the Candidate List is proceeding" (p. 30).
3. Recommendations: "An explicit reference to remedies for severe non-compliance should be added to the REACH Regulation" (p. 11).
4. Identified problems: "The complexity of substance identification for phase-in substances was problematic and has been underestimated in REACH" (p 18).
5. Future plans: "The dissemination section of the ECHA website will be further improved in 2011" (p. 21).

These key messages focus attention on implementation highlights or lessons learnt but make it difficult to get a coherent picture of the implementation of REACH. Furthermore, the lack of coherence may present challenges to the Commission in fully understanding the basis of some suggestions made.

The Article 117(3) report focuses on the key REACH mechanisms of relevance to this report, namely:

- data sharing through the joint submission of registration dossiers[81];
- measures to avoid the need for unnecessary tests (read-across etc.);
- the use of non-animal testing; and
- the development of alternatives to animal testing.

The benchmark is regarded as being partially fulfilled for the Article 117(2) report and as being fulfilled for the Article 117(3) report.

A3.15.5.6 Information Should Relate to the Past and the Future

The benchmark is understood as requiring a good balance between reporting of past events (experience gaining during the reporting period) and forecasting/ planning for the future.

In most parts of the 117(2) report, information on the implementation of REACH are summarised under the key messages of each section. Sometimes information is extrapolated, e.g. predictions on the workloads of the Committees. Each issue subsumed under a key message concludes with either a recommendation or a statement on ECHA's plans for the future.

[81] This aspect is mentioned in the introductory parts and summaries but more detail is provided in the Article 117(2) report, in particular with regard to the types of studies opted out and the reasons for separate submissions.

Consideration of past activities is the focus of the Article 117(3) report but sufficient emphasis is also given to predictions and planning for the future.

The benchmark of providing information on the past and future considered to have been met for both reports.

A3.15.5.7 Financial and Non-Financial Information Should Be Integrated

This reporting benchmark anticipates the inclusion and clear linking of resources used to activities and outcomes. With regard to the future, the resource planning and allocation of tasks should follow justified priorities.

For ECHA's 117(2) report, this benchmark would require the provision of information linking the use of resources to the implementation, and operation, of REACH. The information provided would naturally focus on the use of resources by ECHA but could also extend to consideration of how resources used by the Commission, Member States, Industry and other actors have been used to support the implementation of REACH. However, ECHA was only able to report on its own resources. Nonetheless, the benchmark may be applied to ECHA's resources in relation to its successful management of all of its tasks.

In ECHA's Article 117 reports, no information is provided on the budget, hence no evaluation of work efficiency is possible. The report details the number of staff but without linking staff allocation with performance of specific tasks and neither is this information linked to the original planning.

No quantitative correlation is made between ECHA's work and its resource use. Rather only general qualitative statements are made that resources were 'overspent' for several areas and 'less than expected' for others, without specifying the extent of over- or under spending nor are such statements linked to considerations of possible future budgetary consequences.

This benchmark is considered not to have been met by either report.

A3.15.5.8 Comparative Information Which Should be Provided

This reporting benchmark aims to enable readers to compare the performance or development of an institution with others and to identify trends.

In relation to the operation of REACH as a whole, a comparison with other legislation does not seem reasonable[82]. However, some comparative information on the success of REACH implementation could have been included for tasks where these existed before REACH; examples would be the development of restrictions or preparation of dossiers for new substances. A detailed analysis of trends does not, however, seem a

[82] This is due to the complexity of REACH resulting from the variety of tasks, the involvement of all industry sectors and the complete supply chains which does not match that of other, newly implemented legislation to which REACH could be compared.

reasonable expectation for these first reports given the short time that has elapsed since the implementation of REACH.

In relation to the establishment, and work, of ECHA comparative information on the set-up of other agencies could have been included in the report (e.g. regarding management structures, speed of growth, management of tasks and staff). In Chapter 17 of ECHA's report, it is stated that *"the setup of ECHA has been pointed to as a model for other EU Agencies and bodies*" but no further reference is made in relation to similar institutions. Some trend information is provided on staff development. Importantly, apart from the provision of the number of NONS applications processed, there is no comparison with the regulation of chemicals pre-REACH.

Reference is made to relevant activities undertaken by other organisations within the EU and worldwide (e.g. OECD activities). However, again no comparisons are provided between REACH-related work and work undertaken under other EU legislation (e.g. cosmetics) or under other legislative frameworks nationally within the EU or across the world.

The benchmark is regarded as not fulfilled for either report, to the extent applicable at this point in time.

A3.15.5.9 Procurement Policy, Contracts and Services Should be Transparent

This benchmark appears only relevant to ECHA's contracting and procurement policies and then only to the extent to which these aspects of the operation of ECHA would be important to the successful operation of REACH. In this respect, details of cleaning contracts for ECHA's offices, for example, would be of no relevance. However, some consideration of the extent to which use has been made of external contractors to help ECHA fulfil its obligations under REACH would be relevant (e.g. the use of external IT staff and the use of consultants to help ECHA prioritise SVHCs).

It is noted also that staff numbers are differentiated between "Temporary Agents", "Contract Agents" and "Seconded National Experts" but, apart from this, no data are provided that could be considered to address this benchmark.

No mention is made of such aspects in the Article 117(3) report.

This benchmark is regarded as not fulfilled for either report, to the extent applicable at this point in time.

A3.15.5.10 Information on Large IT-Projects

IT-systems may be regarded as an integral part of REACH implementation since these form the basis for all information exchange and for the use of the submitted information.

The Article 117(2) report contains a separate chapter on IT-tools and also makes reference to and gives explanation of the IT-side of the REACH implementation. From the information provided, it is obvious which elements of the IT infrastructure are in place and that, apart from one failure during the pre-registration phase, these appear (on the basis of ECHA's description(to have worked well. However, no detailed overview of the operation of ECHA's IT systems is provided. For example, details might have been included on the functionalities which are still missing, data security systems that are implemented and of how future developments will be managed. In addition, while there is mention that (more) resources are needed to support IT needs in the future, neither the scope of the projected resource needs or predicted expenditure requirements are specified.

The Article 117(3) report mentions the development of an IT tool to enable ECHA to identify the different approaches taken to fulfil dossier information requirements by registrants, including the identification of animal tests and the use of alternatives. However, no reference is made to the role played by IT in the avoidance of animal testing (e.g. in relation to the role of REACH-IT in SIEF formation). This information may not have been considered to be central to the Article 117(3) report but, given the importance and relevance of IT tools (including REACH-IT), reference could have been provided to other sources of information such as the Article 117(2) report.

Consequently this benchmark is evaluated as being partly fulfilled for the Article 117(2) report but as not being fulfilled for the Article 117(3) report.

A3.15.5.11 Reporting Methods, Benchmarks and Limitations of Data Should be Stated

In the preface to the Article 117(2) report, the structure of the report is introduced as following ECHA's main activity areas and the time period to which data relate is specified. However, no further reference is given to reporting methods or standards, whether or not the indicators of their own work programmes have been used, etc. When registration information is quoted, it is explained that no evaluation of the quality of that information has taken place yet.

The presentation, analysis and justification of data use are clearly included in the Article 117(3) report.

This benchmark is regarded as not being fulfilled for the Article 117(2) report because only limited information on the reporting method and underlying benchmarks is provided. However, this benchmark is considered to have been fulfilled for the Article 117(3) report.

A3.15.5.12 Information Should be Provided in a Straightforward Way

This reporting benchmark applies to the way a report is written and consequently to some extent will be determined by the intended audience. One example of an

appropriate "logical flow" is a sequence of presenting strategy, programme activity, results, evaluation and progress against goals, future.
Article 117 states that these reports are to be addressed to the Commission and this requirement, therefore, provides a basis for evaluation.

ECHA's report is structured in-line with its general reports but no clear overall structure can be discerned for the Article 117(2) report. In this respect, the first chapters could be considered to have been grouped together (REACH processes, CLP and support infrastructure) but, from Chapter 10 onwards, no internal logic is evident. Within the chapters, the core structuring elements are the key messages ECHA wants to give on the operation of REACH but no reasoned explanation for the choice of these key messages is provided. Within each chapter, the key messages generally relate to issues relevant to the chapter heading but they do not seem to follow an overall logic structure.

The text, however, is generally easy to read and understand and within the context of each key message, a flow is maintained from presenting facts or past experience, reaching conclusions, to making recommendations. This is a positive attribute of both of ECHA's Article 117 reports. However, it would appear that the Article 117(2) report in particular is primarily formatted so as to be accessible to the general public rather than having been intended to provide the Commission with a detailed report on the operation of REACH. Indeed, the format used would appear to be primarily designed to draw attention to those issues regarded as important by ECHA.

The Article 117(3) report is more obviously written to inform the Commission, with information presented in a well structured and readily comprehensible manner, suitable for its intended audience.

If the general public were the required audience for the 117(2) report then it might be argued that (with the exception of providing a clear picture of the basis/need for REACH) this benchmark would be met. However, as the Article 117(2) report is clearly intended to be addressed to the Commission, the benchmark is considered to have been not met for that report. In contrast, this benchmark can be considered to have been fulfilled for the Article 117(3) report.

A3.15.5.13 Information Should be Credible, Fairly Interpreted, Reliable and Balanced

With respect to the Article 117(2) report, facts and figures are well presented stating information sources and pointing out the limitations of data provided. Where data are provided, ECHA's interpretation of that data is transparent and enables the reader to challenge it; this does not apply to budget and staff information.

For several aspects, in particular the "soft" aspects of communication and co-operation with the Member States and the Commission, ECHA provides no details on the nature or the source of any problems or challenges identified (e.g. in relation to the efficiency of work of the Committees).

Some recommendations for improvement are made without full analysis of the issue. For example, legal clarification is requested on the consequences of separate dossier submissions in breach of legislation without providing details of (or links to) any analysis of the underlying reasons for separate submissions. Furthermore, requests for more resources and changes of the fee regulation are not substantiated by argumentation on past expenditure or precise definition of future additional needs.
With regard to the factual information presented, the report is regarded as very credible and reliable. However, in terms of interpretation of procedures and justification of recommendations, the report is not sufficiently detailed and does not fully substantiated by good argumentation as so can't be regarded as presenting credible and reliable information.

Little consideration is given to feedback received by ECHA from the Commission, MS or other stakeholders. Therefore, it is difficult to assess, on the basis of the ECHA reports, whether or not the information reported represents a balanced presentation of the implementation of REACH or of the performance of ECHA in this respect.

The use of data within the Article 117(3) report would appear to be robust throughout, fairly interpreted, reliable (within the parameters stated) and their interpretation would appear to be balanced.

This benchmark can only be considered to have been partly fulfilled for the Article 117(2) report. However, this benchmark is considered to have been fulfilled for the Article 117(3) report.

A3.15.5.14 A Short and Non-Technical Summary Should be Provided

Both ECHA reports contain an executive summary that is short and easily understandable. Due to the nature of the topics covered, both summaries are necessarily technical in part. However, the summary of the Article 117(2) report published separate from the report itself differs from the summary provided inside the Article 117(2) report, which in turn does not fully correspond to the information provided in the full report.

This benchmark is regarded as being only partially fulfilled for the Article 117(2) report. However, this benchmark is considered to have been fulfilled for the Article 117(3) report.

A3.15.6 Overall Conclusions of the Contractor from the Benchmark Analysis

A summary of the extent to which ECHA's Article 117 reports meet the benchmarks is set out in Table 14.4.

The Article 117(2) report fulfils most of the benchmarks related to the report fully or in part. The only benchmark missed is the description of the reporting method. This

may be potentially due to the lack of specific Commission reporting guidelines or reflect a failure to develop adequate internal guidance. Improvement needs can be identified with regard to provision of a more straightforward overview and logical flow of sub-sections. Furthermore, some recommendations and interpretations require more substantiation by evidence.

Some core information on the operation of REACH that would be expected in the Article 117(2) report is largely absent. For example, this report is missing a suitable discussion on the division of tasks and responsibilities, on co-operation and communication issues, on the linking of input and output resources to tasks, on the overview of the management; while specific development of the REACH IT-system as provided and only partially meets the benchmark criteria.

The Article 117(3) fulfils the benchmark criteria to a greater extent than the Article 117(2) report. This is noteworthy given that the benchmarks applied were primarily derived for more general organisation reporting and therefore would have been anticipated to be more likely suited to an assessment of the Article 117(2) report.

Like the Article 117(2) report, the Article 117(3) report is limited with respect to provision of information on financial matters, procurement and that necessary to allow for comparative assessment. The one area where the Article 117(3) report does not perform well against the benchmarks is with respect to the provision of IT information.

Table 15.4: Summary of Benchmark Analysis of ECHA's Article 117 Reports

No.	Benchmark	Fulfilled[1]		
		Yes	Partly	No
1	Purpose of report	X		
2	Description of tasks and roles	X		
3	Division of tasks and responsibilities	117(3)		117(2)
4	Reference to plans	X		
5	Focus on critical aspects performance	117(3)	117(2)	
6	Information related to past and future.	X		
7	Integration of Financial and Non-Financial Information			X
8	Provision of Comparative Information			X
9	Transparency on Procurement			X
10	Information on IT-system		117(2)	117(3)
11	Methods of Reporting	117(3)		117(2)
12	Straightforward information	117(3)		117(2)
13	Information should be credible	117(3)	117(2)	
14	Summary should be provided.	117(3)	117(2)	

Note 1. X indicates a conclusion for both Article 117(2) and Article 117(3) reports.

A3.16. RECOMMENDATIONS

A3.16.1 Summary of Findings

The Article 117(2) report provides a comprehensive picture on the operation of REACH from ECHA's perspective. The factual information provided and related explanation cover all REACH processes and activity areas of ECHA, including preparatory work for provisions which have not yet been started (e.g. substance evaluation).

ECHA's 117(2) report is not fully consistent with regard to the figures on joint submission, the reasons for joint submissions and the proposal to change the related legal provisions. Furthermore, ECHA's role in joint submission and data sharing is not clearly described.

The Article 117(2) report does not provide a structured overview of the overall operation of REACH and the key successes and critical issues are not easily identified from the report. Furthermore, details on how ECHA ensures consistency at EU level, which is one of its main objectives according to Article 75 of REACH, is not provided. More detailed information on the communication and information flows (formal and informal) between ECHA, the EU Commission and the Member States could also be added to facilitate a better understanding of the operation of REACH.

The Article 117(3) report contains a comprehensive analysis of the information submitted with the registration dossiers, including a note that data quality is the responsibility of the registrants and could not be subjected to evaluation. However, information is missing on the number of animal tests replaced by non-animal tests, details on justification for testing strategies and a simple overview of existing (and validated) non-animal tests. Furthermore, ECHA's involvement in developing non-animal test methods could be usefully elaborated in more detail.

ECHA's Article 117 reports do not match the indicators set in its annual and multi-annual work programs, partly because reporting periods don't match, a consistent reporting scheme is not yet fully developed, the reports have different purposes and some indicators may have lost relevance.

Compared with general reporting standards derived from different international guidelines on (public) performance reporting, both ECHA reports are regarded as of high quality. The main aspect not met is with regard to the matching of inputs and outputs, namely the budget of ECHA with its achievements and/or activities.

A3.16.2 Recommendations

Currently, both reports are addressed to the EU Commission and the general public. In particular the current Article 117(2) report shows that this may lead to having:

- too much unnecessary information in the reports for the Commission, e.g. the description of legal obligations;
- a lack of information that may be of great interest to the Commission (e.g. on on challenges to optimal communication and co-operation)

It is recommended that if future reports are written for the general public then a separate version of the report should be prepared for the EU Commission, to better target its information needs.

The Commission and ECHA should agree on the focus of reporting on the operation of REACH, i.e. put into operation the second part of the Article 117(2) provisions. Reporting could either provide a broad overview (information is provided on each REACH building block and activity area of ECHA) or be focused to the critical aspects. It may be also useful to provide a very brief overview of what is working well plus a more elaborated description of the key issues.

The Commission and ECHA may want to discuss and clarify the relationship between the "operation of ECHA" and the "operation of REACH" in order to better distinguish between ECHA's performance reporting in its annual reports and ECHA's reporting on the operation of REACH in the Article 117(2) report. This may not always be unambiguously possible, but a general understanding could help avoid misunderstandings.

Another issue that could be discussed and clarified between ECHA and the Commission is with regard to how far the opinions and perspectives of other stakeholders should be reported by ECHA. With respect to the focus on the operation of REACH it would appear helpful to have such information integrated in ECHA's reports to obtain a full picture.

A core aspect to clarify is whether or not the linkage of expenditures to outcomes should be part of ECHA's Article 117 reports. This could relate to ECHA's expenditure alone (although this is more regarded as performance reporting) or could include consideration of the costs and benefits to other stakeholders. Currently, the contractor expects this type of analysis and information to be included as part of impact assessment work and therefore understands that ECHA could be responsible for reporting on this.

Finally, ECHA may consider how to better integrate information from their annual reports into the Article 117 reports. This may relate to the linking of indicators from work programs, more precise references to, or copying information from, the annual or evaluation reports.

APPENDIX 1
(TO DRAFT FINAL REPORT ANNEX 3)

ANALYSIS OF LEGAL REPORTING OBLIGATIONS

A3.17. APPENDIX 1 TO DFR ANNEX 3: ANALYSIS OF LEGAL REPORTING OBLIGATIONS

Table A1.1: Initial Analysis of ECHA Report against Requirements to Report on Joint Submissions and Reasons for Separate Submission	
Contents	***Joint submission:*** statistics on dossier numbers (joint and separate), reasons for separate submission for 25% of separate submissions; ***Opt-outs:*** Statistics (number of dossiers containing opt-outs and number of end-points; differentiated according to IUCLID sections) and proportion of reasons differentiated into cost, confidentiality, disagreement with lead registrant and "other". ***General:*** Difficulties related to finding lead registrants and timing of submissions of lead registrants and member registrants. ***ECHA's conclusions***: ECHAs evaluation: joint submission works well, reasons for separate dossiers need further investigation. ***ECHA's recommendations***: Consequences of breaching obligations to be made clearer *in the regulation;* companies need to be encouraged to fulfil obligations of SIEF formation and joint submission in a timely manner.
Omissions	***Joint submission:*** total number of dossiers submitted separately not given (only number of substances); 25% of separate dossiers (number of substances unclear) partly explained as misunderstanding (opt-out ticked); share of individual dossiers of non-phase-in substances not specified; total number of substances with separate dossiers unclear. ***Opt-outs:*** Analysis of what information that *could* be submitted jointly (safe use and CSR) was actually submitted jointly is missing; no proposal on solving disagreements in SIEFs (main reason for opt-outs); no proportion given for opt-outs per intermediate and "regular" substance; no specification if several members opted out within one SIEF (several disagreements with 1 lead registrant), "other reasons" not specified. ***General:*** No information on the role of and actions taken by ECHA to encourage joint registration, justification why clarifying consequences of breaching obligations in the legal text would lead to more joint submissions.

Table A1.2: Initial Analysis of ECHA Report against Requirements on Non-Animal Testing	
Contents	Analysis of information submitted in registration dossiers of substances > 100 t/a and > 1000t/a, tables and diagrams presenting information types submitted for all end-points (endpoint summary records → overview of ALL information; substance specific analysis providing key information used per end-point), testing proposals differentiating between vertebrate and non-vertebrate tests and different annexes. Statement that no quality check of information was done. Conclusion: animal testing was avoided. General information: non-animal test methods are partly in place and partly in development or under validation
Omissions	Description of what is understood under "test strategies" and clear answer to legal obligation to report on their use and implementation (e.g. reference to IR/CSA guidance); linking data omission/waiving and category approaches etc. to test strategy is not given. Little information how testing proposals are developed (testing strategy reference) compared to information on data omission, references to how CSR is used in developing proposals are missing [general report: most testing proposals were accepted without or with modifications; hence seem to be OK]. No conclusions on the use and implementation of testing strategies with regard to feedback / revision of guidance documents; no discussion of the balance between avoiding animal testing and providing too little data (overstretching applicability of data omission / read across etc.). The report was not submitted by 1 June 2011.

Table A1.2: Initial Analysis of ECHA Report against Requirements on Non-Animal Testing	
Comments	(Positive): Assumptions are transparent, presentation of information understandable and well structured, uncertainties and non-validation of submitted information stressed; some in-depth analysis on screening studies. (Negative) no overview is given of which methods for which endpoints are validated, available but not yet validated, under development or still missing; ECHA only enumerates research projects without specification of progress and expected results (types / time)

APPENDIX 2
(TO DRAFT FINAL REPORT ANNEX 3)

COMPOSITION AND ORGANISATION OF ECHA

A3.18. APPENDIX 2 TO DFR ANNEX 3: COMPOSITION AND ORGANISATION OF ECHA

A3.18.1 Introduction

In the tables that follow red text is used to show where the 117 Reports do not match the tasks and roles set out and green text is used to show where these reports do match these tasks and roles. Black text is used to show where information would not be expected at this time.

The overall tasks and roles of ECHA are summarised and compared with the information given in ECHA's Article 117 reports.

A3.18.2 General Composition and Organisation

The details of the composition and organisation of ECHA are reviewed in the thematic study on the ECHA review and therefore not discussed in detail in relation to the tasks and obligations defined for ECHA and its bodies in legislation.

A3.18.2.1 Tasks and Responsibilities

Table A2.1 includes tasks and roles that could equally be included under other headings of this Appendix. However, as these tasks form an integral part of the operation of ECHA it has been decided not to separate these out here.

Table A2.1: Roles and Tasks of ECHA According to REACH – Overall Tasks and Responsibilities

Tasks and Roles	Article	117 Reports
ECHA "… is established for the purposes of managing and in some cases carrying out the technical, scientific and administrative aspects of this Regulation and to ensure consistency at Community level in relation to these aspects."	75	Purpose of ECHA not explicitly mentioned in the report
ECHA supports Committees and contributes to forming of opinions on evaluations, authorisation applications, restriction proposals and proposals for classification and labelling as well as other issues arising from the operation of REACH related to human health or the environment.	76	Support activities of ECHA described e.g. development of rules of procedure, set-up of Committees, contribution to opinion making etc.
Provide MS and the EU institutions with scientific and technical advice on chemicals issues falling within its remit and which are referred to it.	77	Not specifically reported, except in the context of the helpdesk (HelpNet)
ECHA supports work promoting cooperation in chemical safety at international level	77	Separate chapter on ECHA's involvement in work at international level
Coordination of Forum	77	Mentioned in report
Process pre-registrations, registrations and conduct evaluation	77	Statistics and evaluation of processes provided
Preparation of guidance.	77	Separate section on guidance in the report
Database maintenance and information provision	77	Details and statistics on information provided in different forms on ECHAs website.

Table A2.1: Roles and Tasks of ECHA According to REACH – Overall Tasks and Responsibilities		
Tasks and Roles	**Article**	**117 Reports**
BoA to decide on appeals	75	Separate Section on Board of Appeal
Publish list of nominees for committees	85	Not reported
Keep an up-to-date list of experts	87(2)	Not reported
Remunerate expert work	87(3)	Remuneration mentioned in general
Maintain register of declarations of commitment and interest of members of the MB, the ED and members of Committees and the Forum	88(2)	Policy on conflicts of interest described
Handling of appeals by BoA	93	Separate Section on Board of Appeal
Receive appeals against decisions on PPORD, evaluation, completeness checks, data sharing…	9(10); 20(5); 27(7), 30(5)	Separate Section on Board of Appeal, including details on appeals processed
Avoiding and resolving conflicts with other bodies: Identification of issues, pro-active coordination, common resolution if possible	95	Progress in agreeing with other scientific bodies described
Balancing of budget: Revenue and expenditure shall be in balance	96(4)	No figures part of the report. Several mentions of that it needs to be ensured that the fee income covers ECHA costs and that more resources were needed than expected for several tasks
Estimation of revenues and expenditure submission to COM for integration in Community budget and allocation of subsidies, if necessary	96(5) ff	Only general statements related to the Community budget and estimates of revenues and expenditures
Implementation of budget, provision of provisional accounts, auditing (Detailed provisions on how the budget should be implemented, the accounting officer should report etc.)	97	No figures provided Number of staff provided
Publication of transparency rules for information on safety of chemicals	109	Not reported
Cooperation with other Community bodies	110	General statements provided
Provide formats and software for submission of information	111	Separate section on IT-tools and mentioning of formats and software in several contexts

A3.18.2.2 Fees and Charges

Table A2.2: Roles and Tasks of ECHA according to REACH – Fees and Charges		
Tasks and Roles	**Article**	**117 Reports**
Collection of charges for services ECHA provides and which are additional to those set in REACH	74(5)	Not reported, if specific fees were collected in addition to those set out in the Fee regulation

A3.18.2.3 Competent Authorities

Table A2.3: Roles and Tasks of ECHA according to REACH – Competent Authorities		
Tasks and Roles	**Article**	**117 Reports**
Provide guidance on communicating chemical risks to the public	123	Information on Risk Communication Network and guidance provided
Receive information from authorities on incomplete or non-compliant registration dossiers	129	Not reported

A3.18.2.4 Transitional Provisions

Table A2.4: Roles and Tasks of ECHA according to REACH – Transitional Provisions		
Tasks and Roles	**Article**	**117 Reports**
State reasons for all decisions taken	130	Not explicitly reported, but part of the supporting documents provided with decisions
Handle information provision and request of substances under ESR	136	Not reported

A3.18.3 Co-ordination, Co-operation and Information Exchange

A3.18.3.1 Data Sharing

Table A2.5: Roles and Tasks of ECHA according to REACH – Data Sharing		
Tasks and Roles	**Article**	**117 Reports**
Process inquiries prior to registration: Agency to inform inquirer if substance has not been registered or provide details on registrants and submitted information, if registered within 12 year before inquiry. Information to former registrants on inquiry and information to several inquirers on the same substance	26	Detailed section in inquiries including consequence's for registration No information on communication with registrants
Adopt guidance on cost-sharing in accordance with Article 77(2)	27(2)	Cost-sharing guidance mentioned
Handling of difficulties in data sharing: Receiving information from potential registrants on non-agreement, permitting access to information based on cost sharing proof; similar procedures for individual registrants and SIEFs	27(5), (6); and 30(2), (3)	Included; only few cases brought to ECHA
Receive pre-registrations and late pre-registrations	28(1); 28(6)	Numbers provided
Publish list of pre-registered substances	28(4)	Number of pre-registered substances included and list mentioned
Publish interests in non-pre-registered substances	28(5)	Not reported
Receive information on substances from non-registrants	28(7)	Not reported

A3.18.3.2 Information Provision

Table A2.6: Roles and Tasks of ECHA according to REACH - Information		
Tasks and Roles	**Article**	**117 Reports**
Make information publicly available over the internet if non-confidential, free of charge	119	Section on information dissemination with detailed information on which information is provided since when and how
Make information available to third countries and international organisations if cooperation is agreed with EU, if for the purpose of chemical safety and if confidentiality is ensured by the partner	120	Not reported, if information was made available to third countries. Information on cooperation agreements provided

A3.18.3.3 Downstream Users

Table A2.7: Roles and Tasks of ECHA according to REACH – Downstream Users		
Tasks and Roles	**Article**	**117 Reports**
Receive justification why use is not identified	37(3)	Not reported
Receive DU notifications: Information that a use is continued and a DU CSR must be carried out or exemptions are relied on	38(1)	Not reported Requirement probably not relevant at the time of reporting
Receive DU C&L notification if his classification differs from that of the registrant	38(4)	Not reported

A3.18.4 Operation of REACH: Registration

Table A2.8: Roles and Tasks of ECHA according to REACH - Registration		
Tasks and Roles	**Article**	**117 Reports**
Receive registration dossiers on substances as such and in mixtures, including monomers	6	Numbers of registration dossiers and processing No information on number of monomer registrations, no information on substances registered in mixtures.
Receive registration dossiers on substances in articles intended to be releases [...]	7(1)	No information provided
Receive notifications of SVHC in articles [...]	7(2)	Not yet in force by time of reporting
Request registration of substances in articles [...]	7(5)	Depends on notification, which is not yet in force by the time of reporting
PPORD: Completeness check, draft decision, potentially information request, imposing conditions, prolongation; information to MS	9(3)(4)(7)	Number of PPORD notifications received and outcome of TCC No information on evaluation of PPORD notifications and communication with MS
Process updates of registration dossiers, if due to changes in tonnage: completeness check; update information to be forwarded to the MS.	12(2); 22	No specific information on updates of registration dossiers; some information scattered e.g. on NONS updates, updates after inquiries etc.
Receive information on registered substances from the COM and include in data base	16(1)	No information provided
Receive registration dossiers on isolated intermediates On-site & transported: reduced data, if manufacture and use under strictly controlled conditions (joint submission according to Article 19)	17; 18	Numbers of registration dossiers and processing
Assign a submission number	20 (1)	Not specifically mentioned
Completeness check Within 3 weeks; within 3 months, if phase-in dossier is submitted 2 months before deadline; also for updates due to higher tonnage band. Not including the adequacy or quality check of submitted data	20 (2)	General statement that completeness check is automated and in time.
Inform registrants of incomplete dossiers Specification of missing information and deadline for providing data; confirmation of receipt of additional information and renewed completeness check.	20(2)	General statement that incomplete dossiers do not pass the completeness check and registrants are informed

Table A2.8: Roles and Tasks of ECHA according to REACH - Registration		
Tasks and Roles	**Article**	**117 Reports**
Reject incomplete dossiers, if additional information is not provided in time.	20(2)	Incomplete dossiers are not accepted No information on updating of incomplete dossiers and number of incomplete and not updated dossiers rejected
Assign a registration number, and registration date, communicate to registrant	20(3)	Assigning registration numbers reported in different contexts
Notification of MS on registration: initial information on the status of submission, completeness check and information requested to concerned CA and provision of information on the further processes	20(4)	No information on communication with MS
Inform registrants of additional information, which is submitted by later registrants and made available in the database	20(6)	No information provided
Assign registration numbers to notified substances	24	Assigning registration numbers reported in different contexts

A3.18.5 Operation of REACH: Authorisation

Table A2.9: Roles and Tasks of ECHA according to REACH - Authorisation		
Tasks and Roles	**Article**	**117 Reports**
Recommend substances for Annex XIV inclusion. First recommendation by June 1, 2009, then at least every second year	58(3)	2 prioritisation processes reported
Publication and consultation of prioritisation proposal; updating of recommendations according to the comments received	58(4)	Information on consultations and their outcomes provided
Prepare Annex XV dossier for SVHC identification, if the COM requests.	59(2)	Details provided in the report Unclear how many and which dossiers were prepared by ECHA
Circulate MS dossiers for SVHC identification	59(3)	Not specifically mentioned, but implicitly reported
Consultation of SVHC dossiers	59(4)	Information on consultations and their outcomes provided
Include substance or refer dossier to MSC, depending on receipt of comments.	59(6) or (7)	Details provided in the report
Publication of candidate list after inclusion of new identified SVHC	59(10)	Statistics on candidate list provided
Receipt of authorisation applications	62(1)	No applications have been received yet
Acknowledge receipt of authorisation application	64(1)	No applications have been received yet
Consultation of authorisations: Publication of information on uses for which applications are received and for reviews of authorisations; collection of third party comments	64(2)	No applications have been received yet
Processing of applications for authorisation: Referral of application and committee opinions to the COM and MS with or without applicants' comments. If comments are received: forwarding to Committees to enable revision of draft opinions	64(5)	No applications have been received yet
Publication of (parts of) opinions	64(6)	No applications have been received yet
Publication of authorisation decisions in data base	64(9)	No authorisations have been granted yet

Table A2.9: Roles and Tasks of ECHA according to REACH - Authorisation		
Tasks and Roles	**Article**	**117 Reports**
Receipt of DU notifications of using a substance with granted authorisation	66(1)	No authorisations have been granted yet
Develop and maintain register of authorised uses	66(2)	No authorisations have been granted yet

A3.18.6 Operation of REACH: Restriction

Table A2.10: Roles and task Tasks s of ECHA according to REACH - Restriction		
Tasks and Roles	**Article**	**117 Reports**
Prepare Annex XV dossier if the COM requests and suspects a risk	69(1)	Review of phthalates and work on mercury reported
Prepare restriction proposal for substances in articles (if a substance is included in Annex IVX, ECHA is to consider if risks are not adequately controlled in articles. If so, a dossier shall be prepared)	69(2)	Not reported
Prepare a restriction proposal if the Annex XV Dossier shows that measures in place are not sufficient to control the risks	69(3)	Mercury restriction reported
Receive intentions for restrictions from MS	69(4)	Statistics on intentions reported
Handle restriction dossiers: Communication with Committees, circulation of drafts	69(4)	Reported, that capacity to handle dossiers and support Committees is established
Inform of intentions for restrictions: Publication, information of registrants	69(4)	Registry of intention mentioned
Maintenance of a list of substances, for which restriction proposal is intended	69(5)	Registry of intention mentioned
Consultation of restriction proposals	69(6)	Number of consultations reported
Consultation of SEAC opinion	71(1)	Not reported[83]
Submit restriction proposal to COM	72(1)	No new restriction proposal finalised
Publication of Committee opinions on restrictions	72(2)	Publication reported as part of consultation
Provision of documents on restrictions	72(3)	No new restriction proposal submitted to COM by time of reporting

A3.18.7 Operation of REACH: Evaluation

Table A2.11: Roles and Tasks of ECHA according to REACH - Evaluation		
Tasks and Roles	**Article**	**117 Reports**
Examination of testing proposals, including prioritising proposals	40(1)	Statistics on evaluation of testing proposals and details on content and challenges No reporting on prioritisation of proposals
Conduct consultation of testing proposals: Publication of substance and proposed test, invitation of comments, consideration of information received	40(2)	Details on past consultations, including commenting provided in the reports
Draft decisions on testing proposals Procedures and timelines defined in Article 43	40(3)	Status, nature and type of decisions provided

[83] The first consultation on a SEAC Opinion on DMFU started in March 2011.

Table A2.11: Roles and Tasks of ECHA according to REACH - Evaluation		
Tasks and Roles	**Article**	**117 Reports**
Checking compliance of registration dossiers (> 5% per each tonnage band); prioritise dossiers	41(1) 41(5)	Statistics on state of compliance checking provided. No information on prioritisation of dossiers
Provide list of checked dossiers to MS	41(2)	No information on communication with MS
Draft decisions on registration dossier, considering information from third parties including that submitted in the context of pre-registration	41(3), 41(6)	Details provided in the reports
Evaluation of information submitted by the registrants following an agency's decision on compliance	42(1)	Timelines not yet expired for providing additional information
Notification on completed compliance checks to COM and MS	42(2)	No information on communication with MS
Use of information from compliance check in substance evaluation	42(2)	General statement, that the use of information between procedures should be enhanced. Substance evaluation has not yet started
Development of prioritisation criteria for substance evaluation together with the MS	44(1)	Conduction of workshop with MS and reference to criteria documents provided in the report
Development of community rolling action plan (CoRAP) for substance evaluation. First plan to be submitted Dec. 2011; annual updates Feb 28 each year	44(2)	Conduction of workshop with MS and references to documents in the report
Adoption and publication of CoRAP including identification of MS making the evaluation	44(2)	No CoRAP prepared yet
Coordination of activities of MS on substance evaluation	45(1)	Substance evaluation has not yet started
Ensuring substance evaluation according to planning (make decision or forward for conflict management to MSC/COM)	45(2)	Substance evaluation has not yet started
Receive information on substances to include on CoRAP and decide if it should be included.	45(5)	Not reported; information on registry of intentions contained but not in the context of substance evaluation
Publish information requests and receive information (in addition to Annex IX and X regarded necessary by the rapporteurs and requested from registrants)	46(1)(2)	Substance evaluation has not yet started
Ensure coherence in information requests by monitoring requests for information and developing criteria for prioritization	47(2)	Substance evaluation has not yet started
Inform COM, MS and registrants of follow-up from substance evaluation	48	Substance evaluation has not yet started
Inform COM and MS of intermediate evaluation if performed by a single CA for on-site isolated intermediates.	49	Not reported
Processing of comments on dossier evaluation decisions: Information of registrants / DU that they may comment on draft decisions, information of evaluating CA and consideration of information in the draft decision.	50(1)	Processing of comments and communication with registrants described. No details on communication with CAs and DUs
Receive notification of ceasing production or use	50(2)	Not reported
Adopting evaluation decisions: involves notification of decisions, adoption if no comments or referral to MSC if comments are received	51	Details on decision making (with and without MSC) provided in the report
Decision on testing: in case registrants or DUs don't inform ECHA of an agreed decision among themselves	53	Not reported

Table A2.11: Roles and Tasks of ECHA according to REACH - Evaluation		
Tasks and Roles	**Article**	**117 Reports**
Reporting on evaluation by 28th of February every year on progress on evaluation	54	Substance evaluation has not yet started

A3.18.8 Animal Testing

Table A2.12: Roles and Tasks of ECHA according to REACH – Animal Testing		
Tasks and Roles	**Article**	**117 Reports**
Determine the appropriateness of test methods	13	Application of role reported
Provide non-phase in registrants with details of previous animal testing	26	Not reported however not particularly relevant to reporting period. Information could be expected in future reports
Facilitate data sharing to avoid in SIEFs to avoid duplicate testing	30	Reporting on the operation of data sharing to avoid duplicate testing. Testing avoided but no estimate of numbers of tests involved. See Section 15.2.2 and Appendix 1, for assessment
Evaluation of testing proposals	40	Partial reporting. See Section 14.2.2 and Appendix 1, for assessment
Report to Commission on status of implementation and use of non-animal test methods and testing strategies	117(3)	Report provided to Commission

APPENDIX 3
(TO DRAFT FINAL REPORT ANNEX 3)

INDICATORS FROM ECHA'S WORK PROGRAMME

A3.19. APPENDIX 3 TO DFR ANNEX 3: INDICATORS FROM ECHA'S WORK PROGRAMME

The following table lists the key targets set out in the multi-annual work programme. The indicators matching the key targets which are contained in any of the work programmes of the years 2009 and 2010 are compiled in the middle column and the type of data provided in the 117 reports for measuring the indicators is provided in the last column. The allocation of indicators to targets is based on the interpretation of indicators by the project team.

In the tables that follow red text is used to show where the 117 Reports do not match the targets set out and green text is used to show where these reports do match these targets.

Table A3.1: Indicators and "Targets" in Work Programmes

Targets of multi-annual work programme	Indicators (paraphrased) from work programmes of 2009 and 2010	Data in 117 Reports
Ensure that Companies are Able to Register Efficiently	Development of IT-updates and upgrades and timely delivery of new functionalities to REACH IT according to planning and budget	Detailed description of IT-tools provided and their functioning and update in separate section of the report. In addition, information on IT-performance in registration and future plans outlined.
Ensure that Companies are Able to Register Efficiently	Proportion of IT-system "up-time", response time of ICT helpdesk	Failure of IT in pre-registration described and remedies. No detailed and quantification of "up-time" or "down-time" of IT but general conclusion that IT worked well and. ECHA helpdesk is stated to provide answers "mostly in a timely manner" (p. 50)
Ensure that Companies are Able to Register Efficiently	Number of training sessions on IT and number of IUCLID user manuals provided	General statement that training was provided and assistance given e.g. by webinars prior to registration. Number of IT-manuals published
Ensure that Companies are Able to Register Efficiently	Volume and quality of guidance and translations	Statistics on guidance provided Statements on quality of guidance and translation to all languages included.
Ensure that Companies are Able to Register Efficiently	Timely delivery of the CSR-tool	Timely not defined, CHESAR not completed in time for first registration deadline.
Ensure that Companies are Able to Register Efficiently	Proportion of enquiries to the helpdesk resolved within adequate response time	Statistics on enquiries provided, adequate response time not specified.
Ensure Publication of List of Pre-Registered Substances on Time	Good quality list of pre-registered substances published by 31st December 2008	List and revised list published to improve quality
Tackle Workload from First Registration Deadline	Proportion of inquiries, registration dossiers and PPORD notifications processed in the legal timeframe	Statistics provided, all dossiers processed in time.
Process DU Notifications for Non-Preregistered Substances	No indicators identified	No information provided

Table A3.1: Indicators and "Targets" in Work Programmes		
Targets of multi-annual work programme	**Indicators (paraphrased) from work programmes of 2009 and 2010**	**Data in 117 Reports**
Perform as many Compliance Checks as possible	Proportion of testing proposals and compliance checks performed within the legal timeframe	Statistics provided, all processed in time
Ensure Efficient and Consistent Evaluation Decisions	Scientifically sound draft evaluation decisions are prepared within the deadline	Statistics and qualitative information on decision making included
Make a credible start on authorisation	Proportion of SVHC Identification dossiers processed in the legal timeframe and percentage of solutions to differences of views suggested (SVHC identification)	Statistics on dossiers provided, no breaching of timeframe reported. No information on suggestions of solutions for differences in views
Prepare Recommendations for Priority Substances for Authorisation	No indicators identified	2 recommendations prepared
Ensure Smooth Continuation of Restrictions	Average time for dossier processing (restrictions) and percentage of solutions to differences of views suggested (restrictions)	No information on dossier processing time given. No information on (solutions to) differences of views
Complete Guidance Framework and Improve Accessibility	Endorsement, update and publication of (new) guidance; volume and quality of guidance and translations; feedback of users on quality of guidance	Statistics on guidance provided, including volume and translation Feedback on guidance stated as positive
Complete Guidance Framework and Improve Accessibility	Level of satisfaction of visitors to website	No information on level of satisfaction; Number of visitors given, statement to improve the user friendliness of the website
Reinforce network of national helpdesks	Number of harmonised answers at level of REHCORN and proportion of answers provided in time set by the originator of question	Statistics on harmonised answers, FAQs generated et. No information on timelines for providing answers
Complete functionalities of REACH-IT	Delivery of IT-projects against plan and budget and level of user satisfaction with internal IT services	No comparison of planning and budgeting of IT-projects against actual execution and spending. No information on user satisfaction with internal IT-services
Develop IT-tools for operation (ECHA)	IT business continuity & disaster recovery plan operational in August 2010	No information on such plan
Fulfil Tasks in Best Manner	Level of satisfaction on support to the Committees and Forum as well as with transparency of information	No information on satisfaction of Committees and Forum on support and transparency Statement of improvement needs in procedures and cooperation at several places
Fulfil Tasks in Best Manner	Number of quality policies adopted	No information reported Adoption of an internal governance approach including quality assurance scheme mentioned
Fulfil Tasks in Best Manner	Satisfaction with support provided to the Commission, number and quality of contributions to Commission papers (including take-up) and legislation development	No feedback from the COM on contributions provided or inclusion of work in legislation development

Table A3.1: Indicators and "Targets" in Work Programmes		
Targets of multi-annual work programme	**Indicators (paraphrased) from work programmes of 2009 and 2010**	**Data in 117 Reports**
Committees and Forum: deliver opinions on time	Proportion of Committee opinions and agreements delivered in the legal timeframe and in consensus, quality of opinions	Not explicitly stated, but also no breaching of timeframes stated. Decision making in consensus mentioned. Quality of opinions stated to need improvement.
Committees and Forum: deliver opinions on time	Degree of Committee opinions taken on board in the final decision of the EU COM	Not reported
MSC: Ensure Unanimous Agreements	Proportion of draft decisions accepted unanimously in MSC	Unanimous agreements reached
Forum: Improve Harmonized Enforcement	Feedback from MS and stakeholders on added value of Forum	Feedback not reported
BoA: Take Timely and High Quality Decisions; Build Stakeholder Confidence	Confidence of stakeholders in appeal decisions, number of appeals lost, quality and legal soundness of appeal decisions	Statistics on appeals provided, not very many cases conducted yet. Quality of decisions stated as high, but no reasoning Awareness of stakeholders on appeal procedure mentioned but no information on their confidence
BoA: Tackle Workload from Registration Deadline	Number and duration of appeal processing against registration and PPORD decisions	Statistics provided
BoA: Provide Input to Commission on Rules of Procedure	No indicators identified	Not reported
Promote the Image of ECHA as Reliable Partner	Level of stakeholder satisfaction with their involvement and with ECHA publications	No overall feedback included
Raise Awareness and Improve Knowledge of REACH	Number of training sessions organised, number of participants to events, number of meetings in new conference centre, satisfaction with training events	No information on number of training and feedback Overview of conferences, seminars etc. including number of participants
Raise Awareness and Improve Knowledge of REACH	Number of events, ECHA contributes to and feedback on ECHA participation in international meetings, number of third country stakeholders reached by ECHA events	Overall number of international events provided, general information on third country stakeholders given
Develop REACH Competence through Training of Trainers	Number of trainers trained	No information reported
Contribute to REACH-related OECD Work	Number and quality of contacts with institutions in third countries.	No details provided, however general information on international cooperation included
Establish Good Work Relations with EU bodies	Number of joint activities with EU institutions; occurrence of conflicts of opinions with EU institutions	General information provided. No details or specific conflicts mentioned.
Improve Internal Control Standards	Percentage of implementation of establishment plan, level of implementation of risk mitigation plan	No information provided on internal control. Adoption of internal governance approach including control procedures mentioned

Table A3.1: Indicators and "Targets" in Work Programmes		
Targets of multi-annual work programme	**Indicators (paraphrased) from work programmes of 2009 and 2010**	**Data in 117 Reports**
Improve Internal Control Standards	Endorsement and execution of audit rolling plan, number of "critical" findings by auditors relating to the internal control system, percentage of audit recommendations implemented within the deadline, number of reservations in the annual report of the European Court of Auditors	No information on internal audits included in the report
Improve Internal Control Standards	Percentage of statutory documents submitted to the Management Board within legal deadlines	No statistics provided but general statement that the Management Board fulfilled all its statutory tasks in time.
Improve Internal Control Standards	Number of SOPs approved and time taken for processing new SOPs	No information on SOPs contained
Develop Performance indicators	No indicators identified	No statement on that indicators are available in the work programmes
Provide Reliable Budgetary and Activity Planning;	Commitment rate, payment rate, cashed fee income, percentage of budget execution	No details on the budget provided
Cope Efficiently with Expected Fluctuations in Fee Revenue	Surplus necessary for the reimbursement of the Community subsidy	No details on the budget provided
Ensure Availability of Qualified Staff	Percentage of selection procedures for the new posts for the year completed, turnover of the Temporary Agents	No statistics of qualifications Overview of total staff number provided
Ensure Sound Staff Management and Administration	Average number of training days per staff member	No details on staff training
Ensure IT-support to Staff	Level of user satisfaction with internal IT services,	No information provided
Ensure High Quality of Work Environment	Level of satisfaction of staff	No information provided
Implement Guidelines on Technical Infrastructure (incl. Applications, Data Structures, Business Processes and Workflows)	No indicators identified	No information provided
Ensure Best Governance Practice in IT-Projects	No indicators identified	No details provided Adoption of an internal governance approach mentioned
Organise Smooth Running and Security of all IT-supported operations	Number of security incidents where leak of confidential information was identified	No information provided Adoption of an internal governance approach including guarantee for data security
Indicator not Linked to Target	Number of complaints on procurement procedures	No information provided
Indicator not Linked to Target	Level of satisfaction with the conference centre	No information provided
Indicator not Linked to Target	Level of satisfaction on support of the Commission in international activities	No information provided
Indicator not Linked to Target	Joint international IT-projects	No information provided

APPENDIX 4
(TO DRAFT FINAL REPORT ANNEX 3)

ANALYSIS OF DOCUMENTS ON REPORTING

A3.20. APPENDIX 4 TO DFR ANNEX 3: ANALYSIS OF DOCUMENTS ON REPORTING

A3.20.1 Introduction

In order to derive benchmarks for ECHA's report regarding the content and the type of presentation, different documents available on the internet were screened and analysed to identify current best practice with regard to reporting by governmental and private organisations.

The documents analysed include guidance for reporting by EU Agencies, the Commission, business and non-EU governments. Together these documents provide an overview of current principles and practice with regard to public reporting. No Commission document on reporting standards has been made available to the project team and none could be identified by internet research.

The current reporting practice identified is summarised for comparison with the Article 117(2) and Article 117(3) reports published by ECHA. Finally, in order to place any assessment of the ECHA reports into the context of reporting by EU agencies, the 2010 annual reports published by two EU agencies are briefly compared to the summarised current practice.

A3.20.2 Report on Best Practice in Governance of Agencies

A3.20.2.1 Key Recommendations

The authors of the report "Best practice in governance of agencies" analysed and identified best practice for governing agencies carrying out activities on behalf of the European Union (Jan et al, 2008). They compared practices of national and EU agencies and derived several recommendations. Some recommendations relate to the performance reporting of agencies.

The recommendations are related to "performance agreements" between ECHA and the parent EU Institution. As the roles and tasks of ECHA are defined directly in the legislation, no such additional agreement exists. For the purpose of this report, the recommendations regarding the performance agreements are related to ECHA's Article 117(2) and Article 117(3) reports. However, consideration of is also given to the extent to which its annual work programmes provide information that might have been presented in these reports.

Recommendation 11 specifies that:

"Each EU agency should be governed by a yearly performance agreement which is formulated between the Agency and the responsible DG. It should contain:

- *main objectives for the next year*
- *financial framework*
- *indicators to measure performance*

- *special tasks of."*

ECHA formulates annual and a multi-annual work programmes containing descriptions of tasks, objectives and indicators. The work programmes should thus be a reference for reporting. Work programmes and annual reports are made available via the Internet.

The authors further specify that, in particular for newly established EU agencies, a clear description of the particular tasks should be included [in the performance agreements]. Hence, it should also be part of the work programme and at least the first report according to Article 117(2) in order to provide transparency on the full range of tasks.

Recommendation 12:

"These 'performance agreements' should be linked to the budget cycle. They should only contain a limited number of objectives and indicators and be based upon regular negotiations between agency and DG. They should also entail regular reports, which are public."
"By this strong linkage between the budgetary cycle and the performance system, the financial steering and the performance orientation of the agencies are interlinked and by this are supposed to direct the steering orientation towards the agencies' outputs."

This is interpreted with regard to ECHA's reporting obligation as recommendation to interlink performance outcomes with the annual budget and provide relevant information in the report.

Recommendation 15

"EU agency performance should be as widely as possible scrutinized by the general public. This necessitates the following steps:
- *all agency performance agreements and reports have to be published and should be available in the Internet*
- *all reports should have a short and non-technical summary*
- *all reports should be easily linked with the appropriate budget items"*

Recommendation 16
"EU agency performance should be regularly (and ad hoc) audited by the European Court of Auditors. This should:
- *not be limited to traditional elements of financial management and the proper use of public money*
- *also consider administrative efficiency and effectiveness*
- *include a rating of the financial management of agencies"*

A3.20.2.2 Conclusions for ECHA Report

The recommendations on best practice in governance by agencies underline the importance of linking inputs (resources) to outputs (results of activities) and providing sufficient, understandable information to be able to scrutinise an agency's work.

A3.20.3 Commission Report on Internal Audits in 2009

A3.20.3.1 Key Recommendations

The report from the Commission is based on findings of the Internal Audit Service (IAS) from audits carried out in Commission departments and executive agencies in 2009 and related consultation reports. It does not discuss reporting obligations and standards in particular, but summarises information "on significant risk exposures and control and corporate governance issues" in the work of the Commission and its Agencies. Nevertheless, conclusions can be derived regarding the interpretation of how and what should be included in agency reports.

According to the IAS report, **business continuity planning** should be an integral part of EU institution's management. "There must be an overview at institutional level of the services' business continuity planning. To ensure this overview, a complete list of critical activities must be established." This could be interpreted as that reports should provide information whether or not it major influences on ECHA's work have been identified and which (see also next paragraph).

According to the IAS report, **risk management** should be an integrated tool in the overall management. This could be interpreted as encouragement to clearly set out in the report which risks exist in the operation of ECHA and explain how they are managed.

IAS recommends that a **procurement and grant management policy** should exist (planning, documentation, controls of procurement (contracts), procurement rules, evaluation of obtained services) in an agency. Fraud prevention and the application of sanctions in case of non-fulfilment of contracts should be in place and used. This could be interpreted as requirement to present the rules and procedure for procurement as well as to make transparent which types of services were commissioned.

Clear **handover of tasks** from DGs to Executive Agencies should be ensured as well as a clear **division of responsibilities**, as recommended by the IAS report. This could be interpreted as recommendation to present the division of responsibilities between ECHA and the EU Commission in the report, including an evaluation of how this is working and what could be improved. In case of ECHA, this recommendation could be extended also to the division of tasks and responsibilities with the Member States.

With regard to **IT-projects,** the IAS report states that they should be managed in a systematic way by implementing a formalized project management, including risk management, ensuring confidentiality and data protection, monitoring of external service providers, procurement planning and sourcing strategy etc. With regard to the ECHA report, this could be interpreted as recommendation to present details on the IT-projects carried out, including the overall planning, risk management and finances involved.

A3.20.3.2 Conclusion for ECHA Reporting

From the IAS report, important issues in the governance of agencies are identified. It can be assumed that these should also be addressed in the reporting of agencies and hence would be relevant also for ECHA. The issues are business continuity planning and risk management, procurement and grants, (division of) tasks and responsibilities and IT-projects.

A3.20.4 OECD Good Governance Principles

A3.20.4.1 Key Recommendations

The OCED good governance principles relate primarily to private sector organisations and cover a range of different areas. Item V on "disclosure of information and transparency" states:

"The corporate governance framework should ensure that timely and accurate disclosure is made on all material matters regarding the corporation, including the financial situation, performance, ownership, and governance of the company."

This is further specified as follows (only the main headings are listed):

***"A.** Disclosure should include, but not be limited to, material information on:*
1. The financial and operating results of the company[84].
2. Company objectives.
3. Major share ownership and voting rights.
4. Remuneration policy for members of the board and key executives, and information about board members, including their qualifications, the selection process, other company directorships and whether they are regarded as independent by the board.
5. Related party transactions.
6. Foreseeable risk factors
7. Issues regarding employees and other stakeholders.
8. Governance structures and policies, in particular, the content of any corporate governance code or policy and the process by which it is implemented."

With regard to ECHA reporting, in particular items 1, 2, 6, 7 and 8 are relevant; issues 3 and 5 are not applicable to public institutions; item 4 may be applied in part (e.g. information on board members).

The OECD governance principles on disclosure of information also address how information should be prepared and disseminated:

[84] In the explanations to this point it is specifically mentioned that "The management's discussion and analysis of operations is typically included in annual reports. This discussion is most useful when read in conjunction with the accompanying financial statements."

"B. Information should be prepared and disclosed in accordance with high quality standards of accounting and financial and non-financial disclosure.
[...]
E. Channels for disseminating information should provide for equal, timely and cost efficient access to relevant information by users."

A3.20.4.2 Conclusions for ECHA Report

The OECD good governance principles on disclosure of information and transparency can be considered as relevant for ECHA reporting. They underline the relevance of issues identified in the former sections.

A3.20.5 Accounting Standards Board

A3.20.5.1 Key Recommendations

The Accounting Standards Board (ASB) has developed a Reporting Statement providing best practice guidance on how companies should prepare the Operating and Finance Review (or OFR) required by UK legislation. The statement sets out general principles for reporting and a disclosure framework, listing items and headings of an OFR. In addition, guidance is provided with examples on how the items could be reported.

According to the ASB, the OFR should be formulated by the directors to allow stakeholders to assess the organisation's strategies and its potential for success in meeting the challenges it faces. It is a narrative explanation of the main trends and factors underlying the development and performance of an enterprise.

The principles of the statement can be summarized as follows:

- set out an analysis of the business through the Board of Directors' eyes;
- focus on relevant issues which are of core interest for the target group;
- be forward-looking and describe how the long-term objectives should be reached;
- complement and supplement the financial statements with the OFR;
- be comprehensive and understandable, provide evidence and make references to information sources; too much information may obscure the judgement;
- be balanced and neutral, handle good and bad aspects evenly; and
- be comparable over time.

The disclosure framework could be organized according to the following headings:

- nature, objectives and strategies of the business;
- current and future development and performance;
- resources;
- overall risks and uncertainties;
- relationships with other actors;
- financial position;

- cash flows and liquidity; and
- key performance indicators.

A3.20.5.2 Conclusions for ECHA Report

The ASB principles on the operating and financial review can be understood as relevant for ECHA reporting. They underline the relevance of issues identified in the former sections. The proposed headings of the disclosure framework could guide the structure of an Agency report.

A3.20.6 International Corporate Governance Network

A3.20.6.1 Key Recommendations

The International Corporate Governance Network (ICGN) makes recommendations on how companies should provide public reports in order to enable responsible investment decision making. It stresses that:

"a proper understanding of the company's strategic objectives, as well as the financial and non-financial risks and opportunities which may affect its ability to meet those objectives." are the essential information to include in reports. It is furthermore specified that *"Non-financial issues that may be material include: the impact of environmental risk, such as climate change; matters affecting employees, customers, suppliers and host communities; the development and protection of intellectual property and other intangible assets which are crucial to success; ethics, and governance arrangements. Other non-financial matters which are relevant may be company or sector-specific."*

With regard to the nature of non-financial business reporting the IGCN specifies that reports should:

- be informative and, where helpful, include forward-looking elements;
- be material, relevant and timely;
- describe the company's strategy opportunities and risk management including the respective roles and influences of the management board;
- be accessible and enable to obtain a whole picture of the company;
- use key performance indicators linked to strategy;
- facilitate comparisons;
- use objective metrics and/or evidence-based estimates; and
- be strengthened where possible by independent assurance.

A3.20.6.2 Conclusions for ECHA Report

The recommendations by IGCN match and underline the relevance of the items identified in the former sections.

A3.20.7 CCAF Reporting Principles

A3.20.7.1 Key Recommendations

The Canadian Comprehensive Auditing Foundation carried out a project on public performance reporting and provided a final report and reporting principles, an update of which has been published by the Canadian Ministry of Finances. The core of the report is principles for public performance reporting that aim to guide governments and government agencies in compiling their reports.

The CCAF reporting principles are:

1. Focus on the few, critical aspects of performance
2. Look forward as well as back
3. Explain key risk considerations
4. Explain key capacity considerations
5. Explain other factors critical to performance
6. Integrate financial and non-financial information
7. Provide comparative information
8. Present credible information, fairly interpreted
9. Disclose the basis for reporting

A3.20.7.2 Conclusion for ECHA Report

These principles are designed for reporting by agencies to the general public, which does not necessarily fully correspond to the requirements for reporting to the "contractors of agencies". Nevertheless, the principles are also regarded as valid for the reporting of ECHA, particularly in the light of the public presentation of the ECHA reports.

A3.20.8 Public Performance Reporting - Good Practice Handbook Canada

A3.20.8.1 Key Recommendations

The handbook on public performance reporting outlines the manner of reporting of the Canadian government. The Canadian government applies a result-focused reporting system with a clear structured reporting format focusing on content and has four overall reporting principles. In addition, as part of a management accountability framework, clear management expectations for high organisational performance are formulated (10 statements on modern public service management) to identify strengths and weaknesses of organisations.

The four principles (bullet lists detail the principles in the context of reporting to the Parliament) are quoted below.

Principle 1. Focus on the benefits for the public, explain the critical aspects of planning and performance, and set them in context:

- clearly present the program activity architecture;
- discuss priorities within the context of the management strategy;
- link to the whole-of-government framework;
- demonstrate links to broader government priorities;
- discuss challenges, risks, opportunities, and their impact on plans and performance;
- discuss horizontal links;
- describe delivery mechanisms; and
- include responses to official comments, reports and audits.

Principle 2. Present credible, concise, reliable, and balanced information (e.g. provide factual, independently verifiable, evidence-based performance information):

- use the management strategy as the basis of reporting;
- report positive and negative aspects of performance;
- provide factual, independently verifiable, evidence-based performance information;
- provide informative financial tables;
- use comparisons and trends; and
- provide links to further information.

Principle 3. Associate performance with plans, priorities, and expected results, explain changes, and apply lessons learned:

- link performance to plans; and
- discuss lessons learned and corrective actions.

Principle 4. Link resources to results (e.g. discuss changes to plans):

- link resources to results
- discuss changes in resources

In addition, the following overall considerations are listed as relevant for any reporting:

- information reported should be straightforward. It should flow logically across key reporting elements (i.e., strategic outcomes, program activities, and their expected and actual results) and across reports ;
- reports should focus on outcomes, i.e. expected and actual results at the program activity level and progress made toward the strategic outcomes.
- reports should clearly communicate the strategic outcomes and the program activities and their expected results, discussing how the department plans to make progress toward the strategic outcomes through its program activities;
- reports should report back against those plans and expected results. Performance at the program activity level and the contribution of program activities to the strategic

outcomes should be clearly described and well substantiated with credible and reliable evidence;
- reports should present information concisely and with limited use of jargon so they are clear and easy to understand for official agencies and the public; and
- reports should tell a balanced performance story, addressing both the positive and the negative aspects of performance, including lessons learned.

A3.20.8.2 Conclusion for ECHA Report

The reporting principles are interpreted also with regard to reports to the Canadian Parliament, which would correspond to the relationship between ECHA and the Commission as well as to that between ECHA and the European Parliament. Hence, these principles are regarded as relevant for defining benchmarks for analysing ECHA's report.

A3.20.9 British Columbia's Reporting Principles

A3.20.9.1 Key Recommendations

The reporting principles of British Columbia are based on the CCAF reporting principles outlined above. Their reporting handbook provides some explanation on how they understand the reporting principles including the eight core areas of information set out here.

1. Explain the public purpose served: Public performance reporting should explain why an organisation exists and how it conducts its business, both in terms of its operations and in the fundamental values that guide it. This is important to interpreting the meaning and significance of the performance information being reported.

2. Link goals and results: Public performance reporting should identify and explain the organization's goals, objectives and strategies and how the results relate to them.

3. Focus on the few, critical aspects of performance.

4. Relate results to risk and capacity: Good performance reporting should report results in the context of an organization's risks and its capacity to deliver on its programs, products and services.

5. Link resources, strategies and results: Public performance reporting should link financial and performance information to show how resources and strategies influence results. Related to this is how efficiently the organization achieves its results.

6. Provide comparative information: Public performance reporting should provide comparative information about past and expected future performance and about the performance of similar organizations when it would significantly enhance a reader's ability to use the information being reported.

7. Present credible information, fairly interpreted: Public performance reporting should be credible—that is, based on quantitative and qualitative information that is fairly interpreted and presented, based on the best judgement of those reporting:

- consistency: means measuring and presenting information consistently from one period to the next, and clearly explaining any breaks in the consistency of reported information;
- fairness: means the information is honestly reported and is neutral or free from bias, with checks and balances against subjectivity;
- relevance: means that information relates to the organization's objectives and the extent to which results are achieved. Results should deal with effectiveness, efficiency and costs;
- reliable: means the information is, in all significant respects, complete or free from significant omissions. Reliable also means the information is reasonably accurate or free from material error. "Reasonably accurate" refers to the cost-benefit of producing reliable information;
- verifiable – means the information can be reproduced or traced and independently verified;
- understandable – means the reporting avoids jargon and vagueness, and is succinct. The information is presented in a format and using language that helps the reader appreciate its significance; and
- timely: means received in sufficient time to inform decision making. Timeliness for management means information is available for management decision-making on a routine basis. Timeliness for legislators and the public means meeting legislated public reporting timeframe commitments that are designed to inform future policy decisions.

8. Disclose the basis for key reporting judgements: Public performance reporting should disclose the basis on which information has been prepared and the limitations that should apply to its use.

A3.20.9.2 Conclusion for ECHA report

The principles are the same as the overall Canadian reporting principles. However, the application of these principles is explained in more detail. There are no additional issues with regard to the ECHA report but these issues are better understood.

A3.20.10 California Cooperative Healthcare Reporting Initiative

A3.20.10.1 Key Recommendations

The California Cooperative Healthcare Reporting Initiative (CCHRI) has amongst others published the principles for their reporting on the Internet[85].

[85] Point 6, as published on the California Cooperative Healthcare Reporting Initiative Internet site (http://www.cchri.org/about/about_report_princ.html).

The reports themselves should adhere to the following requirements:

- the purpose of the report should be to provide health care performance information to stakeholders;
- the report should be timely (i.e., the interval between data collection and report should be as short as possible without compromising the quality of the report);
- the report should list its authors and sponsors;
- all measures and reporting methodologies should be stated explicitly, especially if benchmarks or composite scores are used;
- reporting of performance measures should follow nationally accepted guidelines, where available, unless there is a strong reason to deviate from these guidelines;
- the report should disclose the limitations of the data and any cautions in interpreting the analyses provided;
- reports should, where possible, contain the results of trending analyses (i.e., assessment of statistically reliable changes over time on a comparable measure);
- text should reflect fair and appropriate treatment of all health plans, physician organisations, and physicians;
- language explaining missing data should fairly represent the reason a plan, physician organisation or physician rate is not displayed; and
- elements of performance displays should have consistent meaning across all presentations (e.g., interpretation of three stars as "good").

A3.20.10.2 Conclusions for ECHA Report

These principles stress transparency issues and list several aspects that should be included, such as trends and comparisons, sources of information etc. The CCHRI principles underline the appropriateness of the Canadian principles identified earlier as benchmarks for assessing ECHA's reports.

A3.20.11 Conclusions on Benchmarks for ECHA's Report

The report by ECHA should enable the Commission (and the general public) to decide whether ECHA has fulfilled its tasks and obligations effectively and efficiently. Based on the analysis of reporting principles and standards, the following benchmarks could be used to assess ECHA's Article 117 reports:

1. The basis for and the purpose of reporting should be stated.
2. The tasks and roles of ECHA, should be described, in particular in the first report as a newly established agency.
3. The division of tasks and responsibilities between ECHA and the European Commission (and the Member States) should be described, including an evaluation of how this works and making proposals for improvements.
4. The report should relate to the plans established by the organisation, its work programme or any contract agreements made.

5. The report should be focussed on a few, critical aspects of performance[86], highlighting core challenges, e.g. relating to capacities and original planning.
6. Information should relate to the past and the future, as appropriate.
7. Financial and non-financial information should be integrated, resources linked to results, plans and priorities.
8. Comparative information should be provided (e.g. trends from other agencies).
9. Procurement policy, contracts and services provided, should be made transparent.
10. Information on the management and resourcing of larger IT-projects, should be included.
11. Methods of reporting should be stated, especially if benchmarks and scores are used, including clear indications on the limitations of data.
12. The information should be provided in a straightforward way, flowing logically through the report (e.g. strategy, programme activity, results, evaluation – progress against goals, future).
13. Information should be credible, fairly interpreted, reliable and balanced, information sources should be stated.
14. A short and non-technical summary should be provided.

It should be noted however that the above principles and items have been selected from different best practice reporting rules and hence would be requesting more than "the average" from ECHA. Furthermore, rules from corporate reporting may be more focused on linking activities and outcomes (of companies) with the resources and budget, as would be the case for a public agency.

A3.20.12 Reports for Comparison with the ECHA Article 117 Reports

A3.20.12.1 Introduction

In order to get an initial impression of reporting by other agencies or public institutions, annual reports were screened. At EU level, the reports of EFSA and OSHA were looked at and at national level, the report by the Medical Research Council and Defra (both UK) were considered, as well as the report by the German Occupational Health and Safety Authority. The tables of contents are provided and the Chapters briefly described below.

A3.20.12.2 Annual Report of the European Food Safety Authority 2010

The European Food Safety Authority (EFSA) was set up in 2002 and has a mandate to support EU risk managers with scientific advice. The content provided in its report has been screened in order to compare it with the ECHA report.

[86] This principle relates to public reporting and appears not to be applicable to reporting to the Commission. The project team have interpreted this principle to mean that more information should be provided on the critical aspects of performance in the supporting text or as a summary, e.g. to illustrate the overall performance assessment.

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The introduction of the report provides brief information on the Authority itself; however, no details of its legal basis, who delegates work to it or the nature of specific tasks are provided. It is stated in the introduction that EFSA has developed a method to measure its performance and started an organisational review with view to a planned restructuring in 2011.

Chapter II with four sub-sections on the key activities of EFSA highlights the main achievements of the year 2010 and provides examples of the outputs generated and the work done. Achievements are not related to a work programme and indicators are not provided to allow a comparison between the objectives / goals and the actual outcome.

Chapter III provides an outlook of the work and activities in 2011. The organisational chart is not further explained and does not explain the relationship to the EU COM and / or the Member States. Annex III describes the scientific outcomes in detail. The financial report provide a very general overview of the Authorities expenditures.

A3.20.12.3 Annual Report of the European Agency for Safety and Health at Work 2010

The European Agency for Safety and Health at Work (OSHA) was created in 1996 to be the main EU reference point for safety and health at work.

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7. Topic centre
8. Website usage and media coverage
9. Publications 2010
10. Finance 2009/10
11. Board assessment
12. Outlook for 2011

The summary sets out the main content of the work conducted by the OSHA in 2010. In chapters 1 to 3 the activities of OSHA are described with regard to data compilation and evaluation, publications, campaigns, publications etc. Chapter 3 outlines the various topics and methods of OSHA's cooperation with Member States, the Commission and Stakeholders. In Chapter 4 on administrative activities basic information on OSHA's budget, staffing, IT projects, documentation and "other issues" are provided.

The Annexes contain various lists and overviews, amongst others an organizational chart of ECHA. The financial information in Annex 10 contains a comparison of budget and actual expenditures according to the main budget positions. The outlook for 2011 describes the issues that will be worked on in the future.

A3.20.12.4 Conclusions for the ECHA Report

The reports by EFSA and ECHA do not fully accord to the principles of reporting identified here. There are several items missing, such as the description of roles and responsibilities as well as a detailed explanation of the budget and potential changes to the original planning. Furthermore, no indicators are provided to measure work or compare them against the organisations' targets and work programmes.

A3.20.13 References

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