ECHA
European Chemicals Agency

The Operation of REACH and CLP

2011

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Report on the Operation of REACH and CLP 2011

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Foreword by the Executive Director

This report gives the European Chemicals Agency's perspective on the first years of implementation of the REACH and CLP regulations - an extremely challenging but ultimately satisfying time for those of us involved. Industry and regulators have successfully met the demands placed by the legislators and the citizens – to gather and share comprehensive safety information on all high volume and most hazardous chemical substances for the benefit of human health and the environment.

Europe can be proud of REACH. It is the most ambitious piece of chemicals legislation in the world, improving safety for people and the environment at the same time as enhancing competitiveness and innovation. This report demonstrates that we are well on the way to realising those aims, thanks to a massive effort and support from many partners – industry, industrial associations, non-governmental organisations, Member States, the European Commission and Parliament.

Two of ECHA's abiding principles have been transparency and collaboration between regulatory authorities and stakeholder organisations. We have worked together to develop procedures, guidance and tools to enable companies to comply with the notification and registration requirements. We were also encouraged to ever greater transparency and disclosure in the wealth of information that we are now making available on line. The cooperation is also bearing fruit in the evaluation and risk management aspects of REACH and CLP.

Chemicals surround us, they are present in nearly all manufactured products that we buy and use every day. Thanks to REACH and CLP – and our collective efforts as highlighted in this report – we are making Europe a safer place where we can reap the undoubted benefits of chemicals without being harmed by them.

The Agency was helped to a flying start by the support of the European Commission, the Finnish State and Helsinki city. Without their support on practical issues at the start of our work, we could not have focussed so quickly on the job in hand. My personal thanks go to them. I must also thank my colleagues here in ECHA. It is my privilege to lead such a talented, committed and hardworking group of people.

Geert Dancet

Executive Director

Executive Summary

The REACH Regulation was adopted in December 2006, after seven years of preparation and extensive consultation on this complex piece of legislation. On 1 June 2007, the European Chemicals Agency (ECHA) was established and shortly after, at the beginning of 2009, the interlinked provisions for chemical classification and labelling were updated by the new CLP Regulation. This report is ECHA's view on the operation of these two Regulations so far.

The overarching message from ECHA is that the REACH and CLP Regulations are working well and the various actors responsible for the work, are responding as envisaged by the legislators. The success thus far of the legislation is to a large extent attributable to the effective collaboration between the key actors: industry, other stakeholder organisations, the Member States, the European Commission and the Agency. The efficient running of the Agency and the dedication of its staff have also played an important role.

Both Regulations have a series of deadlines that have been viewed as a test of the robustness of the Agency and the efficacy of the legislation. The first of these came in December 2008 with the deadline for pre-registrations, then in November 2010 the first registration deadline and more recently the January 2011 deadline for CLP notifications. Other regulatory deadlines will follow. At each milestone the Agency has ensured that it was ready for business and has coped well with the huge workloads.

Lessons have been learnt from the first three years of the operation of REACH and two years regarding CLP. Firstly, pre-registration resulted in a huge and unexpected number of pre-registrations for far more substances than will in practice be followed by registration. It has made the formation of SIEFs per substance by industry more complicated and slower. The consequent uncertainty over the estimates for the number of registrations for the first deadline meant that contingency planning was necessary as a precaution for scenarios that afterwards turned out to be significant over-estimates. More accurate estimates are needed to plan for the next registration deadlines and the subsequent evaluation work by ECHA.

Secondly the importance of working closely with industry and its role should not be underestimated. Industry needs certainty in REACH and CLP requirements, to plan its own activities and to fulfil its responsibilities. One example of how ECHA adapted its activities to assist industry in this respect was illustrated in the period leading up to the first registration deadline when ECHA stabilised the development of IT tools and guidance that were essential for registration. Legal clarity and timely legal advice from the Commission is also clearly essential in this respect.

A third general lesson learnt, is the interrelationship between the various aspects of REACH and CLP. For example, substance identification is the starting point for most REACH and CLP processes. Ambiguous substance identification leads to problems in the formation and functioning of SIEFs, difficulties in the evaluation of dossiers and subsequent difficulties with classification and labelling and risk management activities. This is an aspect we need to work further on in partnership with industry and the Commission in advance of the next deadline.

Looking to the near future, ECHA is giving a message to industry that registering high quality dossiers by May 2013 requires potential registrants to start as soon as possible because of the complex and time-consuming work ahead. For this purpose, industry needs stability and predictability of the registration-related parts of the legislation. Most of the issues raised in the report can be improved by more efficient implementation, without necessarily altering the legal text. Based on this, and as REACH is working well overall, ECHA is not arguing for changes to

the REACH or CLP Regulations in the short term, although some suggestions are made to the Commission to be considered in the context of any possible future changes to the legislation. Also ECHA does not foresee dramatic changes taking place in the guidance and IT tools. Instead limited updates of guidance and improvements to the IT tools are planned which convert previous experience into benefits for industry and regulators.

Experience points to three broad areas where the operation of REACH and CLP could be improved. Firstly at its core, REACH places the responsibility on industry; industry has to ensure safe use of chemical substances based upon assessing their properties, uses and resulting risks. This change of mindset, shifting responsibility from regulators to industry, has been challenging for regulators and industry and is not yet fully implemented. The properties of some substances and their effects on humans and the environment may in some circumstances be predicted adequately without conducting new animal studies, but industry has to make a robust scientific case and the quality of such arguments is generally not high enough. In addition, the quality of many of the chemical safety assessments is of concern. To overcome this, industry is invited to maintain full ownership of their registration dossiers, including after their submission to ECHA, and to proactively improve their quality while preparing dossiers for the next deadline.

A second fundamental element of REACH and CLP that needs further work is to provide information on substances and how to use them safely along the supply chain to downstream users, to consumers and to the public. The information provided by industry to ECHA has, or is being disseminated. Information essential for use, exposure scenarios with operating conditions and risk management measures, must be communicated down the supply chain in a form that is understandable and useful to the different parties. The means of achieving this effectively need to be strengthened and tools developed or improved to facilitate it.

Thirdly, to use resources effectively there is the issue of prioritising which chemical substances to select for further consideration in the REACH and CLP processes. REACH registration is resulting in a vast collection of information on substances which can be used in the selection of substances for further action where necessary by public authorities for the purposes of: dossier and substance evaluation, identification of SVHCs, restriction proposals and harmonised classification and labelling. ECHA is currently planning how to best facilitate the use of registration data to focus the resources of authorities optimally for promoting safe use of substances.

A number of more specific and cross cutting themes have emerged in this report:

- To ensure the success of the 2013 registration deadline industry, the Commission and ECHA need to benefit from the lessons learned in 2010. This may include a communication campaign; developing guidance on SIEF formation and functioning; and incentives for lead registrants to register well before the deadline;
- The principles that companies should follow when concluding on substance sameness should be clarified. The Commission is invited to consider issuing implementing legislation to REACH which would also ensure that substances of significantly different composition are not merged into single dossiers;
- The deadlines for some REACH processes could in due time be reviewed to ensure that the Committees and Forum can better manage their workload;
- ECHA will develop and carry out, in co-operation with the Commission and the MSCAs, actions to improve the preparation and the quality of proposals for substances for the candidate list, restrictions and harmonised classification and labelling (CLH);

- The Commission is invited to consider updating the fee regulation of REACH before the next registration deadline and many referrals are made for that purpose;

- There is a need to further clarify how REACH and CLP should be applied to chemical substances that are manufactured and used as nanomaterials;

- Sufficient resources are needed to ensure the continued success and coherence of the regulatory processes of REACH and CLP by the Agency but also to reinforce its scientific and regulatory capacity so as to respond better to pertinent questions and requests from other institutions.

Over the next years ECHA wishes to capitalise on its successful start-up period and continue to work in partnership with the European Commission, the Member State Competent Authorities and with its stakeholders to further strengthen the understanding and control of chemical substances in the EU. ECHA also wishes to see the increased internationalisation of the REACH and CLP principles. This could be achieved by making available ECHA's experience, tools and know-how to third countries, with the aim of sharing the regulatory burden of the assessment work with these countries.

Preface

This report is intended to meet the Agency's legal requirement according to Article 117(2) and recital 116 of the REACH Regulation. Article 117(2) states: *"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". Recital 116 states: "Regular reports by the Member States and the Agency on the operation of this Regulation will be an indispensable means of monitoring the implementation of this Regulation as well as trends in this field. Conclusions drawn from findings in the reports will be useful and practical tools for reviewing this Regulation and, where necessary, for formulating proposals for amendments."*

Hence, the main aim of this report is to help the legislator to review the implementation of the legislation. A number of follow up items are identified to assist the Commission with any future amendments or reviews of the legislation and to produce its own report on the working of the legislation according to Article 117(4) of the REACH Regulation.

In parallel, the Agency has also prepared its first report according to Article 117(3) of the REACH Regulation on the status of implementation and use of non animal test methods and testing strategies. The 117(3) report has been made available to the Commission at the same time as this report.

Whilst this report formally considers the REACH Regulation, ECHA will also cover in the report the first experiences of implementing the CLP Regulation. This approach is justified since the principle provisions relating to harmonised classification and labelling were originally present in the REACH Regulation and on account of the strong interface and interaction between REACH and CLP and therefore the corresponding ECHA activities. As the CLP Regulation does not contain any similar reporting requirement for ECHA as REACH does, no overlap will occur.

In several areas the full provisions of the legislation have yet to be implemented so a more comprehensive assessment will be made in the next five year report. Topics falling into this category include: substance evaluation (section 4), applications for authorisation (section 5), granting permission to use an alternative name for a substance in a mixture (section 7) or downstream user reports and chemical safety assessments. It should also be noted that no analysis could yet be made of the information on joint submissions or of the explanations given for submitting information separately when opting out from joint registration.

The structure of the report is based upon the principal activity areas of the Agency. The findings for each activity area are structured as set out below and, where available, data has been included to accompany the key messages. Unless otherwise stated, the data included in this report covers the period 2007 until and including the first quarter of 2011. The findings also take into account the regular formal and informal dialogue and feedback that ECHA has received from its stakeholders.

List of abbreviations

ACSHW	Advisory Committee on Safety and Health at Work
ATD	Access to Documents
BoA	Board of Appeal
C & L	Classification and Labelling
CASPER	Characterisation Application for Selection, Prioritisation, Evaluation and Reporting
CBI	Confidential Business Information
CEFIC	European Chemical Industry Council
CHESAR	Chemical Safety Assessment and Reporting tool
CLH	Harmonised Classification & Labelling
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic, Reprotoxic
COM	European Commission
CoRAP	Community Rolling Action Plan
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DCG	Directors' Contact Group
DG ENV	Directorate General for the Environment of the European Commission
DG ENTR	Directorate General for Enterprise and Industry of the European Commission
DG JRC	Directorate General Joint Research Centre
DNEL	Derived No-effect Level
ECHA	European Chemicals Agency
ECM	Enterprise Content Management
EC TAIEX	European Commission Technical Assistance and Information Exchange instrument for partner countries
ED	Executive Director
EEA	European Economic Area
EFSA	European Food Safety Authority
EINECS	European Inventory of Existing Commercial Chemical Substances
ENP	European Neighbourhood Policy
ENVI	European Parliament Committee for Environment, Food Safety and Public Health
EOGRTS	Extended One-Generation Reprotoxicity Studies
EP	European Parliament
ETUC	European Trade Union Confederation
EU	European Union
EU-OSHA	European Agency for Safety and Health at Work
FAQ	Frequently Asked Questions

HELPEX	HelpNet Exchange
HELPNET	REACH and CLP Helpdesk Network
HR	Human Resources
IPA	Instrument for Pre-Accession Assistance
IQMS	Integrated Quality Management System
ICT	Information and Communication Technologies
IT	Information Technologies
IUCLID	International Uniform Chemical Information Database
IUPAC	International Union of Pure and Applied Chemistry
MB	Management Board
MEP	Member of the European Parliament
MS	Member State
MSC	Member State Committee
MSCA	Member State Competent Authority
MoU	Memorandum of Understanding
NONS	Notified New Substances (substances already notified in accordance with Directive 67/548/EEC that are considered as registered according to Art. 24 of REACH)
OECD	Organisation for Economic Cooperation and Development
OR	Only Representative
PIC	Prior Informed Consent (Rotterdam Convention on Trade in Hazardous Chemicals)
PBT	Persistent, Bioaccumulative, Toxic
PNEC	Predicted No-effect Concentration
PPORD	Product and Process Oriented Research and Development
QSAR	Quantitative Structure-Activity Relationships
Q&A	Questions & Answers
R&D	Research and Development
RAC	Committee for Risk Assessment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
REACH-IT	REACH-IT is the central IT system providing support for REACH
REHCORN	REACH Helpdesk Correspondents' Network
RIPE	REACH Information Portal for Enforcement
RMO	Risk Management Option
RoI	Registry of Intentions
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SCOEL	Scientific Committee on Occupational Exposure Limits
SEAC	Committee for Socio-economic Analysis
SIDS	Screening Information Data Set
SFF	SIEF Formation Facilitator
SIEF	Data Sharing & Substance Information Exchange Forum
SME	Small and Medium-sized Enterprise

SVHC	Substance of Very High Concern
TCC	Technical Completeness Check
US EPA	United States Environmental Protection Agency
UVCB	Unknown, of Variable Composition, or of Biological Origin
vPvB	Very Persistent, very Bioaccumulative
WHO	World Health Organisation
WG	Working Group
W/W	Weight by Weight

List of legislation

DPD	Dangerous Preparations Directive; Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.
DSD	Dangerous Substances Directive; Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.
CLP Regulation	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.
Fee Regulation	Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
REACH Regulation	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.
RoHS	Directive 2002/95/EC on the Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment.
IED	Industrial Emissions Directive; Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control).

1 Registration

1.1 Objectives of the legislation

REACH aims to ensure that manufacturers and importers to generate data on the substances they manufacture or import, to use these data to assess the risks related to their substances and to develop and recommend appropriate risk management measures. Companies must submit a registration dossier to ECHA containing information to demonstrate that these obligations are met. Unless the REACH Regulation indicates otherwise, registration obligations apply to substances manufactured or imported in quantities of 1 tonne or more per year, and a chemical safety assessment is required for substances manufactured or imported in quantities of 10 tonne or more per year.

1.2 Key messages

Industry registered 4 300 substances in nearly 25 000 dossiers by the first registration deadline. These dossiers were successfully processed by ECHA within the relevant REACH deadlines.

By the first registration deadline industry registered nearly 25 000 dossiers covering 4300 distinct substances, of which 3400 were phase-in substances and 900 non-phase-in substances. These dossiers were successfully processed by ECHA within the relevant REACH deadlines. As such ECHA considers the process to have been a significant success.

The vast majority of the registrations were submitted by large companies (87%), for substances manufactured or imported in quantities over 1000 tonnes per year (90%). Only Representatives (ORs) submitted 19% of the registrations on behalf of non-EU manufacturers. Dossiers for substances used only as intermediates accounted for 25% of the submissions. Some additional registrations were submitted after the deadline, bringing the overall amount of registrations submitted in 2010 to just over 25 600 and by the end of the first quarter in 2011 to 26 337.

The successful submission of these dossiers illustrates that the process was understood by the majority of companies, including those in third countries, as shown by the high rate of registrations coming from ORs. Assistance from ECHA in various forms made a large contribution to this success.

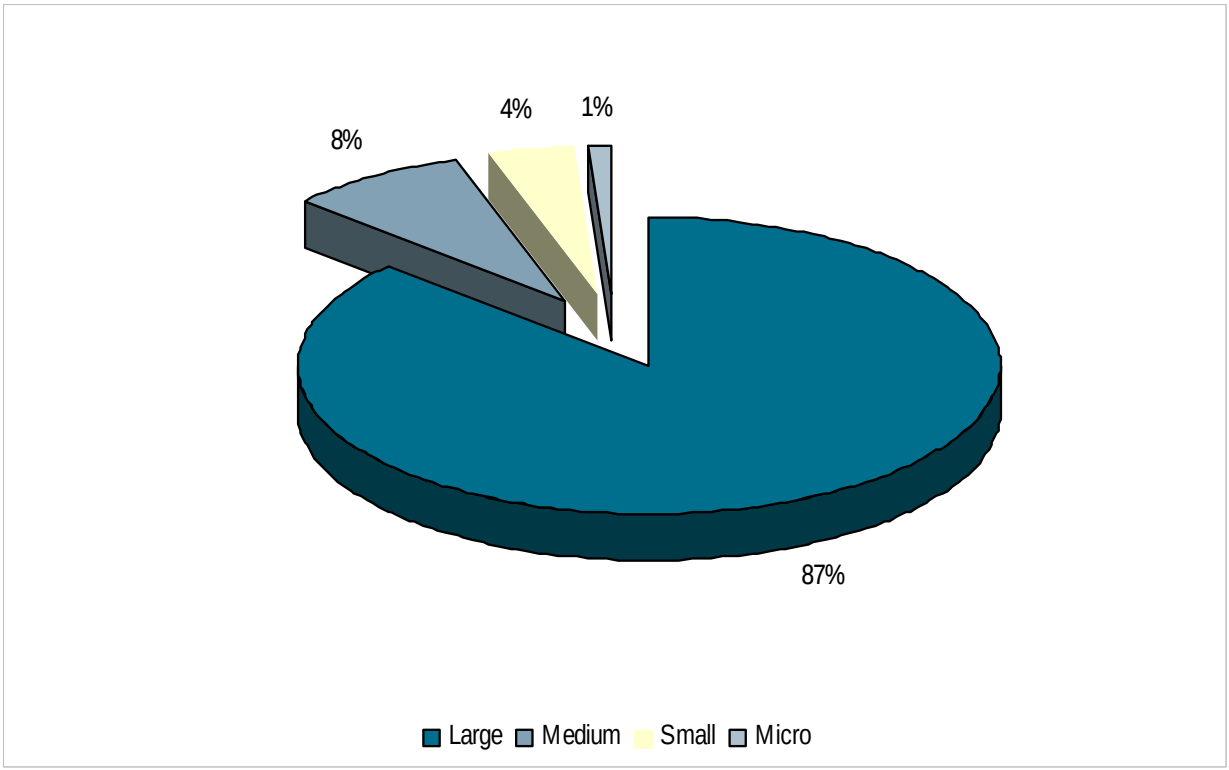

Figure 1: Company size of registrants in 2010

However, the process was not free from major challenges for all parties concerned, especially since the CLP notification deadline was only one month after the registration deadline of 30 November 2010; this required some companies to update their dossiers for the CLP regulation immediately after the REACH deadline. Additionally, the national enforcement authorities should investigate the cause of delays for the phase-in registrations that arrived after the 2010 deadline in order to prevent a recurrence of this for the 2013 deadline.

Table 1: Number of registration dossiers successfully completed by dossier type and year

Dossier type	2008	2009	2010	2011 (Q1)	Total to date
On-site isolated intermediates	12	85	1 373	70	1 540
Transported isolated intermediates	46	196	3 426	247	3 915
Full registration	10	217	18 969	1 686	20 882
Total	68	498	23 768	2 003	26 337

Successful collaboration between the Commission, ECHA and industry associations before the 2010 deadline proved to be important in achieving a successful result.

Throughout 2009, ECHA and the Commission received feedback through regular contacts with industry associations that registrants were concerned about meeting the 30 November 2010 registration deadline because they were facing a variety of practical problems and delays in setting up Substance Information Exchange Fora (SIEFs) and preparing their joint submissions. The Directors' Contact Group (DCG), bringing together Directors of the Commission, ECHA and of six industry associations, was established in January 2010 with the aim of monitoring the overall preparedness of companies to meet the 2010 deadline and to address situations that could hinder registration or which were not addressed in the legal text.

In particular, because the large volume of pre-registrations in 2008 resulted in a great deal of uncertainty of the real registration intentions for the first deadline, significant efforts were made to refine registration estimates through surveys performed by ECHA and industry associations. The results helped to provide reassurance that no major industry-wide problems were expected from companies seeking to register by the deadline. Furthermore, difficulties and solutions were identified and procedures put in place for all of the issues of concern raised by industry, within the legal framework of REACH and with the support of the Member States.

However, there remained a discrepancy between the numbers of phase-in substances that were indicated as intended to be registered in the surveys as compared to substances actually registered at the end of 2010. This difference resulted in concern for downstream users of possible market disruption in the supply chain. The DCG started a detailed analysis of the root causes of this towards the end of its first mandate in early 2011. However, no serious problems in the supply chains have been identified so far.

The DCG proved to be useful by establishing a constructive and effective dialogue between industry associations, ECHA and the Commission. It provided a route to channel concerns and for those concerns to be addressed in a timely manner.

The one substance one registration concept generally worked well but there were some difficulties for both lead registrants and joint submission members.

The joint submission of data worked well in general as shown by the proportion of registrations submitted jointly: nearly 90% of the total number, the remaining part also covering individual submissions of non phase-in substances. From approximately 3000 joint submissions containing almost 20 000 member dossiers, there were only 135 member dossiers with opt-outs for one or more end-points as described in Articles 11(3) and 19(2) of REACH. The main reasons for these opt-outs are, to a large extent, related to the disagreement over selection of registration information, for example the selection of key information used for classification and labelling of the substance. An overview of the opt-out reasons given per end-point type is shown in table 2.

Table 2: Justifications for opt-outs within joint submissions*

IUCLID section	No of dossiers	No of Opt-outs***	Breakdown of opt outs			
			Cost (%)	Disclosure (%)	Disagreement (%)	Other** (%)
Classification and labelling	97	190	0	0	77	23
Physico-chemical data	15	203	23	0	77	0
Environmental Fate	8	60	13	0	77	10
Ecotoxicology	35	304	7	0	88	5
Toxicology	31	668	16	0	70	14
General Information	5	11	25	0	75	0
Other	1	1	0	0	100	0
Total	135	1 437				

**Registration dossiers were screened for opt-out boxes ticked in IUCLID. In total, 135 dossiers had one or more opt-outs chosen for one or more end-point. Typically, one dossier contained two opt-outs but as there were a few dossiers with more than 50 opt-outs, the total number of opt-outs in these 135 dossiers is 1437. The opt-outs have been sorted per IUCLID section and per type of justification according to Article 11(3) of REACH ('cost' – joint submission would be disproportionately costly; 'disclosure' – joint submission would lead to disclosure of commercially sensitive information; 'disagreement' – disagreement with lead registrant on the selection of the information).*

***Other = not attributed to Article 11(3).*

****The number of opt outs refers to the number of endpoint study records for which members of joint submissions opt out and provide their own data instead of that of the lead registrant.*

However, a more detailed analysis reveals that in some cases the registrants, instead of opting out within the joint submission, instead submitted separate registration dossiers. For about 250 substances, ECHA received either multiple joint submissions or, in addition to the joint submissions, one or more individual submissions on the same substance. ECHA is currently examining the explanations for these situations. It appears that at least some of the registrants who submitted an individual registration considered this as an opt-out as 25% of the registrants who submitted individually explicitly mention opt-out in their dossier. The main justification given by these companies is the cost of the joint submission.

It would be useful to describe better in the Regulation the consequences of breaching the obligation of joint registration. In advance of any possible changes, it will be important to find effective means to encourage companies to consider and respect their obligations in relation to SIEF formation and joint registration in a timely manner.

Despite the positive picture of joint registration described above, lead registrants and member registrants experienced a variety of difficulties. Feedback from industry associations indicated that some registrants were reluctant to take over the lead registrant responsibilities due to the amount of resources needed for administering the SIEF and preparing the joint submission as well as the lack of understanding of the legal obligations. The majority of lead registrants only submitted their dossiers in the three months preceding the deadline only. This resulted in equally last minute member registrations, since REACH sets the same registration deadline for lead and member registrants, whilst requesting that the members can only submit their registration after the lead dossier has been submitted.

Novel incentives are needed for lead registrants to submit their registration well before the next deadline. Assuming that the legal text of REACH will not be changed before the 2013 deadline, it is essential that the member registrants are made aware of the situation so that they can

foresee the need to protect their rights in SIEF agreements. The obligation to submit jointly needs to be emphasised through a communication campaign in 2013 (see section 2).

IT systems have played an enormously important role in receiving and processing the large volume of data required to comply with the REACH Regulation

The REACH regulation impacts a significant number of companies (more than 60 000 legal entities are registered in REACH-IT) and requires the submission and processing of enormous amounts of data in a very short timeframe between regulated (chemical companies) and regulators (ECHA and the Member States Competent Authorities (MSCAs)). Therefore ECHA has to be an IT-based Agency, and fully functional IT systems that are delivered in a timely way are the key to the Agency's success.

We believe that a significant positive role was played by the IT tools developed by ECHA and these resulted in a substantial increase in the number of dossiers passing the registration process. Of particular importance to registrants was the technical completeness check tool provided as a plug-in to the International Uniform Chemical Information Database (IUCLID) in late 2009, the freezing of the registration IT tools six months before the registration deadline and the release of user manuals translated into all EU languages (see sections 11 & 15).

Prior to the deadline, companies asked ECHA for training and other support to better understand the registration procedure. For example, companies struggled with the concept of business rules, i.e. format and administrative checks that ECHA's IT system performed on the dossiers before being able to accept them for processing and issuing an invoice. Accordingly, ECHA invested considerable resources to support the registrants, for example on webinars for registration-relevant issues, targeting lead registrants in 2009-2010.

After the first registration deadline ECHA and its stakeholders are now all in the position to streamline their respective processes and develop relevant tools and support for the registrants meeting the 2013 deadline. Specifically, the support expected from ECHA and by industry associations should be clarified. ECHA will ensure the timelines and any expected changes to its operations or IT tools are communicated well in advance to registrants.

An explicit reference to remedies for severe non compliance could be considered to be added to the REACH Regulation.

The registration system as set up by REACH may in certain specific circumstances give a competitive disadvantage to diligent companies. According to REACH, the technical completeness check (TCC) shall not include an assessment of the quality or the adequacy of any data or justifications submitted. Therefore in principle this could allow companies to obtain a registration number without making a serious effort to comply with the information requirements.

It would be useful to consider clarifying in the legislation how ECHA should deal with cases of incompleteness identified ex-post and cases of continued or severe non compliance e.g. if the dossier is not brought into compliance after a compliance check decision and/or enforcement action by a Member State. For example, the Commission could consider an explicit provision on withdrawal or revocation of registration numbers to deal with such clear cases of non-compliance and to rectify the situation.

Companies should ensure that they fulfil the conditions to register their substances as intermediates with reduced information requirements.

Under REACH, the information that companies need to provide for certain uses of substances as isolated intermediates may be reduced compared to requirements for non-intermediate uses of substances, provided that the use of the substance fulfils the following two conditions:

- The use of the substance meets the definition of an intermediate as described in REACH Article 3(15) and as further explained in the Guidance on intermediates; and
- The substance is manufactured and/or used under strictly controlled conditions.

ECHA's screening of over 400 registration dossiers for intermediates has indicated that 86% of them appear not to contain sufficient information to demonstrate that these conditions are fulfilled.

To ensure the safe use of chemicals and to demonstrate that they comply with the REACH Regulation, registration dossiers should provide sufficient information to show they satisfy the specific conditions to register the substance as an intermediate with reduced information requirements (Articles 17 and 18 of REACH). The ECHA Guidance on intermediates which was updated in December 2010 helps registrants to assess the intermediate status of their substance and lists information elements that they should provide in their registration dossiers. ECHA encourages registrants to proactively reassess and, where necessary, update their registration dossiers for intermediates declared to be manufactured and/or used under strictly controlled conditions.

Companies should ensure that the number of registrations to be made is not artificially reduced by expanding the definition of a substance or merging SIEFs for substances which have entirely different compositions

By comparing the list of substances registered by 2010 with the list of pre-registered substances with a registration deadline of 2010, it seems evident that at times industry has expanded the definition of the substance registered in 2010 in order to fit genuinely different substances within one dossier. This practice not only reduces the fee revenue of the Agency but also may undermine the control of risks if different substances are covered by the same hazard data, a sole chemical safety assessment and the same exposure scenarios. Clarifying the concept of the substance sameness, as suggested in chapter 2, would help avoiding these cases.

SMEs benefit from reduced fees under REACH, but it is important that this benefit is only provided to those companies fulfilling the requirements of SME status.

Small and medium-sized enterprises (SMEs) benefit from a fee reduction in both the REACH and CLP Regulations to help them comply with the regulations while maintaining their competitiveness. Companies are required to declare their SME status in the REACH-IT system and invoicing is automatically adjusted accordingly. ECHA does not verify the SME status at this stage. However, SME status has implications both for fair competition among companies and for ECHA's income.

ECHA verifies the size of the companies which are eligible for REACH and CLP rebates. In a pilot project of 66 companies checked in 2010, it was found that 58% of them had wrongly identified themselves as SMEs. Since 1 December 2010, ECHA started to collect administrative charges in line with the Fee Regulation from companies who wrongly claimed to be entitled to a reduced fee or a fee waiver. Of the companies contacted so far in 2011, 14% have claimed the

incorrect company size. ECHA will continue checking the SME status of the registrants and collecting the administrative charges where wrong claims have been made.

1.3 Follow up

- To ensure the success of the 2013 registration deadline, industry associations, the Commission and ECHA need to take on board the lessons learnt for the 2010 deadline and emphasise the need for starting the preparations without delay;
- The national enforcement authorities should investigate the cause for delays for the phase-in registrations that arrived after the 2010 deadline in order to prevent a recurrence of this for the 2013 deadline;
- Lead registrants should be encouraged to submit well before deadline. It is essential that the member registrants are made aware of the situation so that they can foresee the need to protect their rights in SIEF agreements;
- The Commission and MSCAs are invited to consider how to best ensure or enforce the requirement of joint registration, or if necessary, the Commission could consider altering the legal text to achieve this;
- The Commission is invited to consider legislation to clarify the notion of sameness of a substance to avoid companies from artificially placing together genuinely different substances into the same dossier;
- The Commission could consider a legal provision in REACH allowing ECHA to initiate remedies for severe non compliance;
- Industry should proactively reassess and, where necessary, update their registration dossiers for substances registered as intermediates while regulatory action should also be initiated where necessary to bring these dossiers into compliance with the legislation;
- ECHA will make industry aware that a significant administrative charge will be levied against those companies that wrongly claim to be eligible for the SME reductions.

1.4 Other facts & figures

Table 3: Overview on NONs and PPORDs by the 1st registration deadline

Percentage of NONS* registration numbers claimed	51
Number of NONS registrations updated	940
Number of PPORDs** successfully completed	679

***** *NONS: Substances that were notified under the Directive 67/548/EEC are considered as registered under REACH (Article 24). ECHA has assigned registration numbers to all these notifications and the owner of the notification can claim his registration number from ECHA via REACH-IT. ECHA will check the identity of the notifier and update his contact details (if necessary) before assigning the registration number. The notifiers have to claim their registration number before they can update their dossier, which may be necessary for example for tonnage band changes.*

*******PPORDs: If companies use a substance for product and process oriented research (PPORD) only, they can submit a notification to ECHA and be exempted from registration obligations for a limited time period (Art.9).*

2 Data sharing

2.1 Objectives of the legislation

REACH requires registrants of both non phase-in and phase-in substances to share data and to submit their registration dossier jointly to avoid unnecessary testing on vertebrate animals and reduce costs for industry.

Mechanisms in REACH are intended to bring registrants of a same substance together for data-sharing purposes. These include pre-registration of phase-in substances leading to the creation of substance information exchange fora (SIEFs) and the inquiry procedure for non phase-in substances, or phase-in substances which were not pre-registered.

2.2 Key messages

ECHA received many more pre-registrations than predicted and for many of these pre-registrations there was apparently no intention to proceed to full registration at a later stage. Despite the high numbers, ECHA managed the pre-registration process successfully.

Pre-registration was the first REACH process to be implemented in 2008. The objective was to gain knowledge on potential registrants of existing (phase-in) substances manufactured or imported to the EU market, to provide them with an extended registration deadline based on the intrinsic properties and tonnage of their substances, and to bring potential registrants to discuss the sameness of their substances with a view of data-sharing and joint registration. The Agency successfully managed the pre-registration process despite numbers that significantly exceeded expectations. ECHA received around 2.7 million pre-registrations, fifteen times more than initially estimated when the Agency was set up. Over 20,000 companies covering around 250 000 pre-registrations indicated in their pre-registration that they would register their substance by the 2010 deadline. In practice only 25 000 registration dossiers were received, hence 10 % of the potential registrants for 2010 actually proceeded with their registration.

In retrospect the pre-registration process had weaknesses which allowed many pre-registrations to be made for which there was no real intention to proceed to a subsequent registration. There was no barrier to enter the system: the process was fairly simple, requiring only a very limited set of information on the substances and in addition it was free of charge. Moreover, at the time of pre-registration there were still some uncertainties around the interpretation of possible exemptions such as substances covered by Annex IV and V of REACH, monomers in polymers, re-imports and recycled substances, leading many companies to pre-register their full portfolio of substances to be on the safe side.

As a result more than 140 000 phase-in substances, including all those listed on the European Inventory of Existing Commercial Chemical Substances (EINECS) were pre-registered, preventing the Agency and downstream users from having a clear picture of the intentions of substance suppliers in submitting registrations. It also invalidated the provisions foreseen in REACH for the downstream users of substances to ensure continued supply by inviting other companies to support a non pre-registered substance.

Table 4: Size distribution of SIEFs (based upon pre-registration information)

SIEF size (no of companies)	Substances	% total (of substances)
5000+	2	0.0
1000-4999	146	0.1
500-999	290	0.2
200-499	1 115	0.8
100-199	1 946	1.3
75-99	1 241	0.8
50-74	2 539	1.7
25-49	8 542	5.8
10-24	28 973	19.7
4-9	60 647	41.3
3	4 023	2.7
2	5 108	3.5
1	32 207	21.9
Total number	146 779	**100.0**

This led the Agency to make contingency plans for extensive resources to be available for processing dossiers in the final run-up to the registration deadline and as a safeguard measure to scale up REACH-IT for a much higher load than initially planned.

Although SIEF formation started late due to practical difficulties, in the end nearly 90% of the registrations submitted by the first deadline were done jointly.

The high number of pre-registrations resulted in significant challenges to SIEF formation and management. Pre-registrants with no registration intentions inflated the size of some pre-SIEFs and made it more cumbersome to manage communication among members causing delays in the formation of SIEFs. ECHA also received feedback that some pre-registrants abused the role of SIEF formation facilitator (SFF) in REACH-IT, by using the functionality available only to SFFs to advertise commercial services and by blocking genuine potential lead registrants from taking over the role. However, ECHA was able to collect only partial evidence from industry associations or pre-registrants about these reported abuses occurring in REACH-IT and consequently the Member State authorities to whom ECHA reported these abuses lacked the basis to intervene.

Moreover, SIEF formation proved to be a challenge for industry as it imposed novel communication obligations on companies which intended to register the same substance. Industry relied upon tools either put in place by industry associations (most optimal situation) or developed by commercial companies to exchange information and cooperate.

Even though ECHA has no formal role to support the SIEF process foreseen in REACH, ECHA provided resources to activate industry, to facilitate the functioning of SIEFs, as well as the nomination of lead registrants. In the end, for the first deadline, SIEF operations enabled nearly 90% of the registrations to be submitted as joint submissions.

Despite this success, lessons were learnt that should be applied in advance of the next registration deadline in 2013. Guidance to set out best practice SIEF functioning should be developed by industry, in consultation with ECHA, building on the solutions that have been

identified in the context of discussions in the Directors' Contact Group (DCG) before the first registration deadline (see section 1). In addition, to enable ECHA to identify lead registrants in a timely way and to assist in efficient SIEF formation, there should be a legal obligation for lead registrants to notify ECHA and for this information to be made public.

A communication campaign is needed to support these activities and to explain the obligations of lead registrants early enough to encourage one of the registrants to take up the role. Such a communication campaign would also need to highlight to existing lead registrants that their duties continue.

ECHA has processed almost 1500 inquiries of which about 50% have led to registration afterwards. It is possible that some companies believed an inquiry number is a remedy for missing the pre-registration deadline.

Article 26 of REACH requires the Agency to put potential registrants of substances that have not been pre-registered in contact with previous registrants for data sharing purposes. For this the potential registrant submits an inquiry to ECHA. In addition, data submitted more than twelve years ago can be used for registration by another manufacturer or importer and ECHA can provide this information on request. Altogether 1475 inquiries have been successfully processed by the Agency from approximately 3500 inquiries received so far.

Table 5: Inquiries accepted by the Agency

Inquiries accepted (substance ID confirmed) 1475	For substances registered at the time the inquiry was submitted	For substances NOT registered at the time the inquiry was submitted
	667	808
	Data available from ECHA	Data NOT available from ECHA
	566	909
	Followed by registration or registration update	NOT followed by registration or registration update
	751	724

ECHA observed that close to the first registration deadline, the number of inquiries related to phase-in substances suddenly peaked. At the same time, the quality in terms of substance identification dropped significantly leading to a high percentage of rejections. A possible explanation for this is that companies may have been acting under the false impression that a submitted inquiry would remedy the fact that their substances had not been pre-registered in due time. This possibility is supported by the observation that inquiries made for phase-in substances were more rapidly followed by a registration than for non phase-in substances (69% and 47%, respectively by the end of February 2011).

In order to limit inquiries to cases that industry really intends to register, inquirers could be required to confirm that they have the intention to manufacture or import the substance. It would also be useful to require written evidence in an inquiry of the appointment by a non-EU manufacturer of only representatives (ORs). A specific fee should be considered to avoid free-riding, according to the Fee Regulation to reflect the administrative work entailed in processing inquiries. Industry should be aware before the forthcoming registration deadlines that an inquiry after the deadline does not correct an illegal market situation when a company has failed to register a substance yet wishes to continue to market a substance.

Table 6: Data sharing

Number of *joint submissions* (successfully completed dossiers submitted by leads)	2 945
Number of successfully completed dossiers submitted by members	19 610
Member to Lead ratio	6.7
Number of requests for data > 12 years*	187
Number of requests for data <12 years*	117
Number of data-sharing decisions (when there is a dispute) made by ECHA	9

**ECHA provides data submitted more than twelve years ago to be used for registration by another manufacturer or importer on request. If study summaries or robust study summaries are less than 12 years old ECHA provides contact to previous registrant(s) in accordance with Articles 25(3) and 26(3).*

The data-sharing provisions of REACH are at its core and their implementation presented challenges to industry and ECHA.

The principle of 'one substance one registration' set by REACH requires that cooperation between potential registrants must be established and data must be shared. This mechanism seems to have worked relatively smoothly when formal cooperation was already in place between companies, e.g. the potential registrants were already members of a consortia or when contact between them was established through ECHA via the inquiry process.

However, ECHA and the Commission received frequent feedback that data-sharing was not so favourable to companies that were not part of existing consortia (e.g. importers, ORs or more broadly smaller companies), as they often do not have the expertise and manpower to successfully conduct their negotiations; hence they can be forced to accept the conditions offered by lead registrants and/or bigger companies or industry associations.

The concern that inexperienced companies are at a disadvantage is even clearer regarding data sharing disputes. For example, some registrations of phase-in substances were made very early by individual companies or consortia, i.e. before their SIEF was formed and discussions on sameness of substances and availability of data had started. It should be noted that for registrations submitted prior to the SIEF discussions and potential disputes, ECHA cannot make use of the Article 30(3) provision in REACH to block the registration of the company which is unwilling to share vertebrate data.

The data-sharing provisions in the REACH Regulation required extensive legal clarification before they could be implemented as practical procedures by ECHA. Careful consideration was given on how to incorporate substances notified under Directive 67/548/EEC (NONS), i.e. considered as registered according to Article 24 of REACH. In addition there are rare cases where the status of a substance is phase-in for a company and non-phase in for another. ECHA implemented a policy to encourage data sharing in these circumstances.

For data originating before REACH some practical problems were encountered. For instance ECHA had to develop specific rules to enable such registrants to pass the completeness check. In addition, ECHA does not yet hold data for substances used in plant protection and biocidal products and has not therefore been able to provide this to inquirers. For plant protection

products the provision of 'equivalent information' under Article 16 of REACH is problematic, as the up-to-date information is held by the MSCAs rather than the Commission, resulting in only limited information being available to ECHA in this context. For biocides, data are provided by the European Commission (DG JRC) in a format that prevents their inclusion into ECHA's databases.

ECHA received a relatively small number of formal data-sharing disputes for the phase-in substances preceding the first registration deadline. Procedures were put in place by ECHA for data-sharing and handling such disputes by the legal deadline. The existence of a dispute-solving mechanism has apparently encouraged companies to share data rather than end up in a dispute where ECHA may give a permission to refer to their data.

Finally, it should be noted that the practical implementation of Article 30(6) of REACH, which requires companies in breach of their data-sharing obligations in SIEFs to be penalised, has proved to be cumbersome. This is because the authorities of each Member State are organised differently and there is no one-size-fits-all solution to flag the companies to the relevant enforcement authorities.

In advance of the forthcoming registration deadlines, ECHA and the Commission, in dialogue with industry, should investigate how the data-sharing procedures can be made more transparent and how to promote best practice for data-sharing.

The complexity of substance identification for phase-in substances was problematic and has been underestimated in REACH.

The REACH registration and the inquiry processes are based upon unambiguous substance identification. REACH requires the identification of substances as they are manufactured and imported by individual legal entities. In practice this caused difficulties for some companies despite ECHA guidance to support industry on this issue.

Specifically, questions about substance sameness proved to be a major obstacle for the efficient working of SIEFs and industry frequently sought the views of ECHA and other authorities. For example, some pre-registrants decided to split a SIEF to better identify their substances covered by a generic entry in EINECS or took a decision to merge SIEFs for substances which were previously covered by several EINECS entries (e.g. several forms of a substance). ECHA has observed that, occasionally, substance identification agreed by the SIEFs went against the principles and conventions laid down in the guidance for identification and naming of substances in REACH, adding complexity to the task of data sharing. ECHA became aware of these discrepancies while trying to put potential and previous registrants in contact during the inquiry process. At this point it remains an open question to what extent the substances registered by more than one separate (joint) registrations are really the same substance or whether some registrations actually contain several substances.

In addition, failure to follow the rules for substance identification also creates difficulties in other REACH and CLP processes, e.g. dossier and substance evaluation, inclusion of substances in Annex XIV and harmonised classification and labelling.

Industry should pay specific attention to the adequacy, correctness and coherence of the substance identity information they submit in their dossiers in order to enhance efficient processing of their dossiers through all REACH processes. To support companies in the SIEF formation process, solutions need to be found to improve the understanding and application of substance sameness concepts. The Commission is invited to consider issuing implementing legislation outlining the principles that companies should follow when concluding on substance

identification and sameness because the REACH Regulation does not contain any detailed provisions on this aspect.

2.3 Follow up

- Companies who pre-registered but do not intend to register should be encouraged to deactivate themselves from REACH-IT or request deletion of unnecessary pre-registrations, so that genuine potential registrants can make most effective use of the pre-SIEF pages in REACH-IT;
- To allow future registrants to benefit from lessons learned in the run-up to the 2010 deadline, best practice SIEF guidance should be developed by industry. In addition, a communication campaign for the 2013 deadline should underline the importance of early and efficient communication within the SIEFs and promote best practice. Clearer communication is also needed on the obligations of lead registrants early enough to encourage lead registrants to emerge from SIEFs;
- To enable ECHA to identify lead registrants in a timely way and to assist SIEF formation, there should be a voluntary industry action or a legal obligation for lead registrants to notify themselves to ECHA and for this information to be made public;
- In order to limit the number of inquiries and process them in a timely manner, additional information could be requested from inquirers such as proof that they have a genuine intention to manufacture or import the substance and a specific fee should be considered to avoid free-riding;
- ECHA and the Commission should investigate how the data-sharing procedures can be made more transparent and how to promote best practice for data-sharing before the forthcoming registration deadlines;
- To support companies in the SIEF formation process, solutions need to be found to improve the understanding and application of substance sameness concepts. The Commission is invited to consider issuing implementing legislation outlining the principles that companies should follow when concluding on substance identification and sameness.

3 Dissemination of information on chemical substances

3.1 Objectives of the legislation

ECHA is required by REACH to provide free and easy access to basic data on substances collected in its databases, including information on their intrinsic properties, hazard profiles, classification and labelling, authorised uses and risk management measures associated with them.

The dissemination of information to the general public is balanced against right of companies to protect their confidential business information.

3.2 Key messages

Dissemination activities have accelerated after a slow start caused by the need to establish the criteria to assess confidentiality claims and to establish the boundaries between public and non-public information.

Dissemination of registration information started at the end of 2008 with the publication of the pre-registration list. Publication accelerated in December 2009 when non-confidential information from registration dossiers was first published on the ECHA website, after several issues had been resolved. Firstly, substantial time was needed to clarify the information that can be claimed confidential by registrants. This was mainly due to the need to define rules to decide which of the approximately 10,000 fields in an International Uniform Chemical Information Database (IUCLID) dossier could be made available on the Internet. Clarification was also needed on whether the names of the registrants and other information in the safety data sheet were to be disseminated. In addition, consultation with relevant stakeholders was required to ensure an open and transparent dissemination procedure. Finally, as the IT resources of ECHA were focused on the development of registration tools in advance of the first registration deadline, it was not possible to develop systems for automated dissemination of non-confidential information from the dossiers. As a consequence, publication started in 2009, requiring manual intervention, until automation was achieved in March 2011.

By 30 April 2011 ECHA had disseminated information for 3,411 substances (3079 phase-in substances, i.e. approximately 90% of the substances registered by the first registration deadline of 30 November 2010, and 332 non phase-in substances). This information came from dossiers submitted individually (e.g. for non phase-in substances) and by lead registrants in cases of joint submission. The remaining dossiers (i.e. those submitted by joint submission members) will be published by the end of 2011.

Table 7: User statistics for the dissemination website

	2010	2011 (until March)
Number of visits	100 000	40 000
Average number of visits per day	300	700

In parallel to making non-confidential information publicly available, the examination of the confidentiality claims according to Article 119(2) of REACH made by registrants will be initiated in 2011, with the aim of assessing all claims before the end of 2012. By March 2011, approximately 1 300 confidentiality claims had been made (see figure 2).

The full chemical name can be claimed as confidential by registrants in certain circumstances. A public name is used for dissemination purposes and the registrant devises the public name using the newly developed ECHA technical manual. The intention is to disclose the maximum information on the chemical structure, whilst keeping those aspects that are commercially sensitive, confidential.

In the future, if REACH and/or the CLP Regulations are amended, clearer wording of the information to be disseminated from registration dossiers would be helpful. In addition, the Fee Regulation could differentiate the payments for the different types of confidentiality claims.

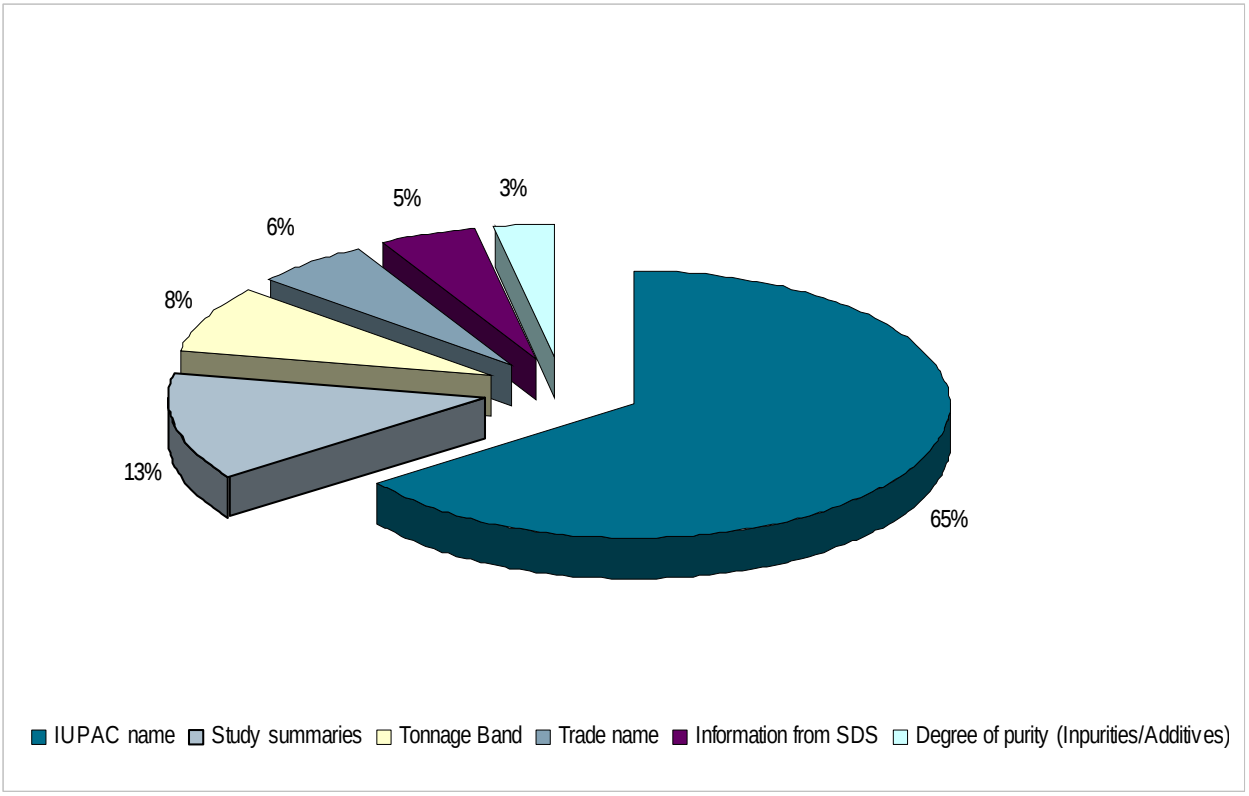

Figure 2: Confidentiality claims (Total number: 1 300 by March 2011)

The dissemination section of the ECHA website will be further improved in 2011.

ECHA intends to improve the dissemination of information by a number of means. The dissemination section of the ECHA website will be further developed in collaboration with stakeholders to ensure that it is transparent and accessible.

ECHA collaborates closely with the OECD on the global portal to information on chemical substances (eChemPortal) by funding the development and by taking over the hosting of the portal. One important step in this regard is the link established between ECHA's dissemination website and the eChemPortal, i.e. information on the ECHA dissemination website will also be available on the eChemPortal (also see section 16). The OECD Portal provides free public access to records on more than 600,000 chemical substances, from 22 data sources worldwide and for some of which there is an advanced search functionality of their intrinsic properties. Since its launch in December 2010, there have been over 20,000 visits to the Portal from 83 countries.

The classification and labelling (C&L) inventory is currently being constructed by ECHA. This will promote agreement between companies on an adequate classification of hazardous substances. The inventory was initiated at the beginning of 2011, after the deadline for C&L notifications. The notification process thus far has been successful and has resulted in the submission of over 3 million notifications. Non-confidential parts of the inventory are to be disseminated to the public in the second half of 2011 (see section 7).

It should be noted that the information to be published on the ECHA website will be of a scientific and technical nature, and will therefore require some expertise to understand it fully. In particular, from the perspective of the public and consumers, the dissemination website displays information on substances, not the marketed chemical mixtures, and there is no direct link between the information on substances and the marketed products.

ECHA disseminates information as it appears in registration dossiers but the responsibility for the quality of the disseminated information remains with the registrants.

ECHA disseminates the information on substances as it is reported in the registration dossiers by the registrants themselves. It is important that the readers of the dissemination website understand that the data has not been peer reviewed, that ECHA is not responsible for the quality of the data and that dissemination does not mean that ECHA has approved the published data. In the future, the quality of the information is expected to improve due to proactive updating of the dossiers by the registrants and also partly due to updates triggered by dossier evaluation carried out by ECHA.

3.3 Follow up

- If REACH and/or CLP Regulations are amended, clearer wording of the information to be disseminated from registration dossiers would be helpful;
- The Fee Regulation could require separate payments for different confidentiality claims.

4 Evaluation of registration dossiers

4.1 Objectives of the legislation

REACH provides for two dossier evaluation processes: compliance checks and the examination of testing proposals.

The purpose of the compliance check is to examine whether registration dossiers are in compliance with the information requirements of the REACH Regulation. ECHA may require the registrant to submit any information needed to bring the registration into compliance with the relevant information requirements. ECHA can decide which dossiers are checked for compliance and whether the examination covers all or part of a dossier. The REACH Regulation requires that ECHA carries out compliance checks on at least 5% of the total number of registration dossiers received for each tonnage band.

Registrants submit testing proposals and seek agreement from ECHA to conduct tests required by REACH Annexes IX and X, if they identify a data gap and cannot otherwise fulfil the REACH information requirements. In the examination of testing proposals ECHA evaluates all such proposals with the aim of ensuring that adequate and reliable data will be generated and unnecessary (animal) testing is avoided.

REACH also provides for a substance evaluation process. This process will start in 2012 and therefore there is no practical experience so far. Preparatory actions are currently being taken for this process, including the establishment of the first Community Rolling Action Plan (CoRAP). This process will therefore be covered more comprehensively in the next five year report.

4.2 Key messages

The scientific, legal and administrative capacity for evaluation tasks at ECHA has been increased to meet the regulatory objectives.

The REACH Regulation provides tight deadlines and requires high throughput numbers for the evaluation processes. All testing proposals received by 30 November 2010 have to be concluded with a draft decision by 1 December 2012. In addition, to meet the 5 % target for compliance checks for the dossiers submitted for the 2010 deadline, up to 1000 dossiers will be selected for compliance checks and ECHA plans to conclude them by the end of 2013 – for progress see table 8.

A systematic approach has been developed at ECHA to handle this high throughput process. It must ensure the scientific quality of the output is high and legally robust whilst being able to process complex dossiers of high tonnage chemicals from the first registration phase. To support the process, ECHA has established the necessary competency base and IT tools have been designed to assist the processing. Continuing process improvements have to be implemented to meet the challenging targets. The full capacity needed at ECHA has been estimated to be approximately 600 dossier evaluations per year.

Compliance checks confirm whether registrants have fulfilled their obligations with regard to REACH information requirements in many aspects of hazard and exposure information. So far, these initial checks have indicated that a significant proportion of dossiers have shortcomings and still need to be improved with further information.

Although many endpoint records and exposure scenarios are filled with valid information, registrants often did not provide dossiers in compliance with all the information requirements. In many cases information is missing or inadequate, and this problem has been addressed by requesting further information from the registrant. The results of the compliance checks conducted in 2008, 2009 and 2010 have been described in detail in the yearly evaluation reports published by ECHA according to Article 54 of REACH.

The content of the Article 54 reports should be viewed with the first ECHA report on the status of implementation and use of non-animal test methods and testing strategies (Article 117(3) of REACH) published at the same time as this 117(2) report. In the 117(3) report it is disclosed that many long term effects have not been covered by data for registered substances but by read-across and grouping approaches leading to predictions. Also justifications to omit the information completely have been used by the registrants. Such approaches are encouraged by the REACH Regulation to avoid unnecessary animal tests, but have to be justified. Over the next few years a focus will be to verify whether the predictions on the basis of read-across and the justifications for omitting the information that have been used are in line with the requirements of REACH and are adequate for the purposes of classification and labelling (C&L) and/or risk assessment.

Table 8: Information on compliance checks on registration dossiers (1 June 2008 – 30 April 2011)

	Phase-in	Non phase-in	Total
No of dossiers opened for compliance check*	111	138	249
Draft decisions sent to the registrant**	54	28	82
Final decisions	4	17	21
Quality observation letters***	10	34	44
Compliance checks concluded with no further action	5	31	36

**Dossiers opened for compliance check notwithstanding their current status, i.e. concluded (final decision, draft decision, quality observation letter (QOBL), concluded with no action) or currently under examination and not yet in one of the latter stages.*

*** Draft decisions which did not become final by 31 December 2010.*

***As part of a compliance check ECHA may identify shortcomings in the registration dossier which can not be addressed by requesting additional information. For example, the classification and labelling proposed by the registrant may be considered to not reflect the data in the dossier. In such cases, ECHA will inform the registrant through a QOBL which invites the registrant to revise and/or update the dossier by a target date. These letters do not constitute a formal decision requesting further information. Quality observation letters are notified to the Member States and the reaction of the registrant is monitored. Depending on the reaction of the registrant appropriate follow-up actions are determined.*

The scope of the compliance check process limits ECHA to requesting missing information. The borderline and links between compliance checks and risk management processes under REACH and CLP need to be better defined.

Careful consideration is needed to decide for which issues a draft decision is used to request further information. The draft decision has to be enforceable and the regulatory output has to be balanced with the administrative effort. This balance needs further development and has to be agreed with the Member States.

The outcome of a compliance check is a request for further information. On most cases the requested information concerns specific studies on properties of the substance, or information on uses and exposure. To certain extent missing information elements that are used for the derivation of the risk characterisation and risk management can be addressed in a draft decision, but the actual risk management measures applied or recommended by the registrants cannot be addressed or corrected by requesting further information. Instead, risk management tools under REACH, CLP, or other legislation should be applied. Nevertheless, there remain expectations that the compliance check will address such issues. The borderlines of compliance checks versus other risk management mechanisms under REACH and CLP needs further discussion with all stakeholders to be better defined.

Table 9: Compliance check decisions requesting further information (until 31 December 2010)*****

Type of information requested	No of decisions
Information regarding identification and verification of the composition of the substance (REACH, Annex VI, 2.)	5
Flammability (REACH, Annex VII, 7.10.)	1
Self-ignition temperature (REACH Annex VII, 7.12)	1
Granulometry (REACH Annex VII, 7.14.)	1
Dissociation constant (REACH Annex IX, 7.1.6)	1
Screening for adsorption/desorption (REACH Annex VIII, 9.3.1)	1
Growth inhibition study aquatic plants (REACH Annex VII, 9.1.2)	1
In vitro gene mutation study in mammalian cells (REACH Annex VIII, 8.4.3)	1
Screening for reproductive/developmental toxicity (REACH Annex VIII, 8.7.1)	3
DNELs as part of the human health hazard assessment (REACH Annex I, 1.4.1)	1
PNECs as part of the environmental hazard assessment (REACH Annex I, 3.3.1)	1
Exposure assessment and risk characterisation for the use of the substance in preparations (REACH, Annex I)	1
Full justification for adapting the standard testing regime for the two-generation reproductive toxicity study (REACH Annex X, 8.7.3) in accordance with Annex XI, 1.5, i.e. read-across	1
Improved robust study summaries (Annex 1, 1.1.4 and 3.1.5)	4

**In general, final decisions addressed more than one information item needed to bring the registration into compliance*

Testing proposals received so far indicate that registrants do not propose unnecessary animal studies.

The number of final decisions is still limited but some preliminary conclusions may be drawn taking into account draft decisions and third party consultations concluded thus far. Almost all testing proposals examined by the ECHA Secretariat have been either accepted unchanged or have been accepted with modifications. This demonstrates that registrants in general did not propose unnecessary testing. The evaluation reports published in February every year describe the results of the testing proposal the Agency examined the year before and the report on non-animal testing in REACH, the '117(3) report' also addresses this issue further.

It should also be noted that, in contrast to proposing unnecessary testing, in the limited number of compliance checks carried out by ECHA so far one of the most commonly observed non-compliance in the registration dossiers is that testing has been waived without sufficient and valid justification. In such cases, new tests have been requested in the evaluation decisions.

Table 10: Testing proposals* (1 June 2008 – 30 April 2011)

		Phase-in	Non phase-in	Total
No of registered dossiers	containing testing proposals	535	37	572
	containing testing proposals for vertebrate animals	404	26	430
No of endpoints	covered by registered testing proposals	1 087	76	1 163
	covered by registered testing proposals for vertebrate animals	664	43	707
No of third party Consultations	Closed	49	20	69
	Ongoing on 30 April 2011	52	1	53
	Planned	303	5	308
Dossiers with testing proposals opened for examination		145	31	176
Draft Decisions sent to the registrant		7	16	23
Final Decisions sent to the registrant		0	7	7
Terminated testing proposal examinations **		2	3	5

** Before embarking on testing to fulfil the data requirements specified in Annexes IX and X, registrants have to submit a testing proposal to ECHA. The testing proposal is submitted with the registration dossier, in which a justification for the test is offered. When a testing proposal concerns a study involving vertebrate animals, ECHA publishes the name of the substance and the hazard endpoints for which testing is proposed, inviting third parties to submit scientifically valid information and studies that address the relevant substance and hazard endpoint. ECHA has to decide on all testing proposals.*

***Terminated at the decision-making stage upon further information provided by the registrant (e.g. cease of manufacture, tonnage downgrade or withdrawal of a testing proposal).*

Table 11: Tests requested in the final decisions* (until 31 December 2010)

Tests requested under evaluation of testing proposals	Number of decisions**
Stability in organic solvents and identity of relevant degradation products (REACH Annex IX, 7.15)	1
Viscosity (REACH Annex IX, 7.17)	2
Sub-chronic toxicity study (90-day) in rats, oral route (REACH Annex IX, 8.6.2)	3
Developmental toxicity test in rats, oral route (REACH Annex IX, 8.7.2)	3
Two-generation reproductive toxicity test in rats, oral route (REACH Annex X, 8.7.3)	1
Long-term toxicity testing on invertebrates, (REACH Annex IX, 9.1.5)	1

** The outcome of a testing proposal evaluation is always a decision which may contain the acceptance or rejection of the testing proposal or it may define modified conditions for the test or suggest additional tests to be performed*

*** In some decisions, more than one test is requested*

Third party comments on testing proposals so far have not provided information that leads to the proposed animal test not being necessary. The assessment of and response to these comments is a major workload for ECHA and ECHA is providing advice to third parties to improve the contributions.

In relation to proposed vertebrate animal testing, third party (public) consultations have been conducted for 27 cases and responses have been provided by third parties in all of these cases. If the registrant claims the full chemical name is confidential, a meaningful public name (see section 3) can be used for the purposes of consultation with third parties.

The information provided by third parties included general proposals for read-across, (Q)SAR, recommendations for *in vitro* tests, and weight of evidence approaches. Specific information on registered substances has not been provided and little attention has been given by third parties to focus the alternative approaches on the specific substances according to the acceptance criteria for adaptations of standard information provided in the legal text. As a consequence, no testing proposals have so far been rejected due to new relevant information arising in a public consultation.

The processing of the third party contributions is a major workload driver in the examination of testing proposals. The assessments of the merits of the contributions and the related drafting of the legally binding decisions are case-by-case efforts, which add considerably to the total processing time for the ECHA Secretariat. Since January 2011, ECHA has published its responses to the third party consultations on testing proposals. This practice is intended to increase the transparency of the process and to encourage submission of relevant information. ECHA will continue to focus on communication and feedback to improve the content of the third party contributions.

Dossier evaluation has indicated that substance identity in registration dossiers is often not adequately described for phase-in substances.

The REACH Regulation does not provide for a quality check of substance identity of phase-in substances during registration. As a consequence, registration numbers have been allocated to dossiers with unclear substance identities (see section 2). In the dossier evaluation process the description of substances was found to be insufficient to establish and verify the identity of a number of registered substances.

Such shortcomings may hamper the evaluation process as follows: (1) testing proposal examinations rely on a clear identity of the registered substance for the third party consultation and for examining the merit of proposed tests with regard to the substance in question; (2) compliance checks also rely on a clear identity to verify that the information requirements are met by the information provided on the registered substance.

If such shortcomings are detected, decisions or other interaction processes with the registrant can be used to correct them. However, compliance checks will not be undertaken on all dossiers, so they cannot correct all registration dossiers with unclear or inadequate substance identity. As referred to in section 2, solutions need to be found to improve this situation for registration dossiers currently in the database and for those submitted for the next registration deadline. Clarifying the concept and application of substance sameness through implementing legislation would enhance ECHA evaluation activities.

Previously notified high production volume substances should be required to meet REACH information requirements.

The REACH Regulation contains transitional provisions for substances that were notified as new substances under the old EU chemicals legislation. These NONS are considered to be registered and have only to comply with REACH information requirements when they exceed the next REACH tonnage threshold which then triggers the obligation to submit a REACH compliant registration dossier for the substance. However, it was not foreseen that there would be cases of NONS that had triggered higher-tier testing but where the national competent authority had not finalised the testing requirements, the so-called 'unfinished NONS' cases. Hence ECHA had to develop legally sound procedures to deal with these cases. In addition, there is no provision in REACH to require NONS that were already notified above 1000 tonnes per annum to be compliant with REACH information requirements. To enable ECHA to evaluate, where appropriate, these NONS dossiers in a comparable manner to any other REACH dossier, it could be useful for the Commission to consider a deadline in REACH by which at least these dossiers have to comply with the REACH information requirements.

4.3 Follow up

- Continuing process improvements have to be implemented in dossier evaluation to meet the challenging targets;
- A focus for the compliance check over the next years will be to verify whether the read-across and grouping approaches for predicting properties of substances, and justifications for omitting the information, are in line with the requirements of REACH and are adequate for the purposes of classification and labelling and/or risk assessment;
- The borderlines of compliance checks in addressing insufficient risk management measures identified in the registration dossiers need to be further clarified;

- ECHA will continue to focus on communication and feedback to improve the content of the third party contributions for examination of testing proposals;
- As referred to in section 2, solutions need to be found to clarify the concept and application of substance sameness to support evaluation activities;
- The Commission is invited to consider a time limit in the REACH Regulation by which at least NONS above 1000 tonnes must comply with the REACH information requirements.

5 Authorisation

5.1 Objectives of the legislation

The authorisation process under REACH aims at ensuring that the risks from substances of very high concern (SVHCs) are properly controlled and that these substances are progressively replaced by suitable alternatives, if these are economically and technically viable; whilst at the same time assuring the good functioning of the internal market.

Inclusion in the Candidate List is a prerequisite for subjecting a substance to an authorisation requirement. In addition, inclusion in the Candidate List triggers obligations on article producers, importers and suppliers to generate and communicate information.

Substances on the Annex XIV ('Authorisation') List cannot be placed on the market or used after the so called 'sunset date' unless an authorisation is granted (or an authorisation application has been submitted before the application date and a decision on granting that authorisation has yet to be taken by the Commission). The final decision regarding the inclusion of substances in the Authorisation List, as well as decisions to grant or refuse authorisations, is taken by the Commission.

Preparations for applications for authorisation are well underway in ECHA, but there have been no applications for authorisation as yet and therefore there is no practical experience of the operation of REACH in this area. This will be covered in the next five year report.

5.2 Key messages

The identification of SVHCs and their inclusion in the Candidate List is proceeding.

This process is now proceeding relatively smoothly according to agreed procedures after a somewhat slow start. By the date of publication of this report 53 substances have been included in the Candidate List. Despite this, several actions have been brought in 2010 before the General Court challenging the identification by ECHA of seven SVHC substances and these cases are still pending. An action by a company for postponing the effect of ECHA's decision (interim measures) in one case has already been rejected by the General Court.

Although not foreseen in the current legal text, the process for removing substances from the Candidate List needs to be clarified and agreed. Practical issues requiring clarification are the processes that could be used to consider or include new relevant information appearing during the SVHC identification process or after inclusion of identified SVHCs in the Candidate List (e.g. the amendment of a classification).

Work on screening and selecting SVHCs is progressing but identifying substances for the Candidate and Authorisation List requires considerable effort.

The Member State Competent Authorities (MSCAs) have expressed their willingness to contribute to achieving the ambitious target expressed by Vice-President Tajani and Commissioner Potočnik in March 2010 for the inclusion of a total of 135 SVHC substances on the Candidate List by end of 2012. However, MSCAs appear to suffer from a lack of resources for their work and struggle with the identification of suitable substances for further work.

Registration dossiers in principle could provide valuable additional input, but the quality of the information in these dossiers, in particular descriptions of uses, conditions of uses and resulting exposures in chemical safety reports (CSRs), is not necessarily sufficient to support the identification. Furthermore, the data is not easy to screen in an automated manner.

On the basis of the work so far, in some cases it appeared questionable whether the uses covered by intermediate registration dossiers are in line with the definition of intermediates (Article 3(15)). Increasing the common understanding on what is considered an intermediate use is also relevant for the next step of authorisation (legal certainty for industry on when they need to apply for an authorisation and for the enforcement authorities to be able to enforce authorisation requirements).

The need to consider the regulatory effectiveness of different risk management instruments and the legal and practical consequences of including a substance in the Candidate List has been recognised. A framework for carrying out an analysis of the best risk management options (RMOs) analysis has been agreed to help Member States and the Commission in deciding whether to proceed with the SVHC identification process for a particular substance.

There are some cases where it is not legally possible to initiate a restriction procedure after the substance has been included on the Authorisation List. More importantly, depending on the case, there may be other reasons not to initiate these two procedures in parallel for the same substance, e.g. the effective use of resources in authorities and industry, legal clarity and predictability. Therefore, it is crucial to develop sufficient common understanding of the optimal timing of different actions, in particular if restrictions are needed to complement the authorisation requirement, to address risks related to the service-life or the waste stage of articles containing SVHCs.

There is wide agreement between MSCAs, the European Commission (COM) and ECHA on the need for improving the communication and coordination of the SVHC identification work and increasing a common understanding of the aims, possibilities and limitations of the different regulatory risk management instruments.

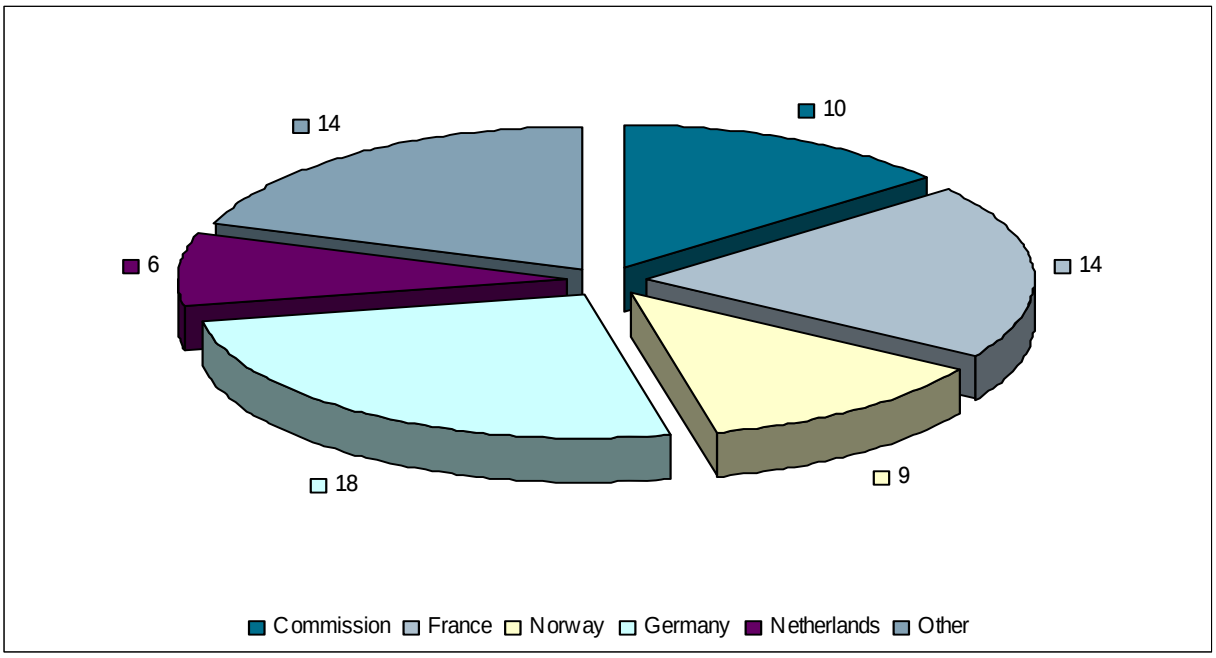

Figure 3: Intentions to submit dossiers on substances of very high concern (SVHC)

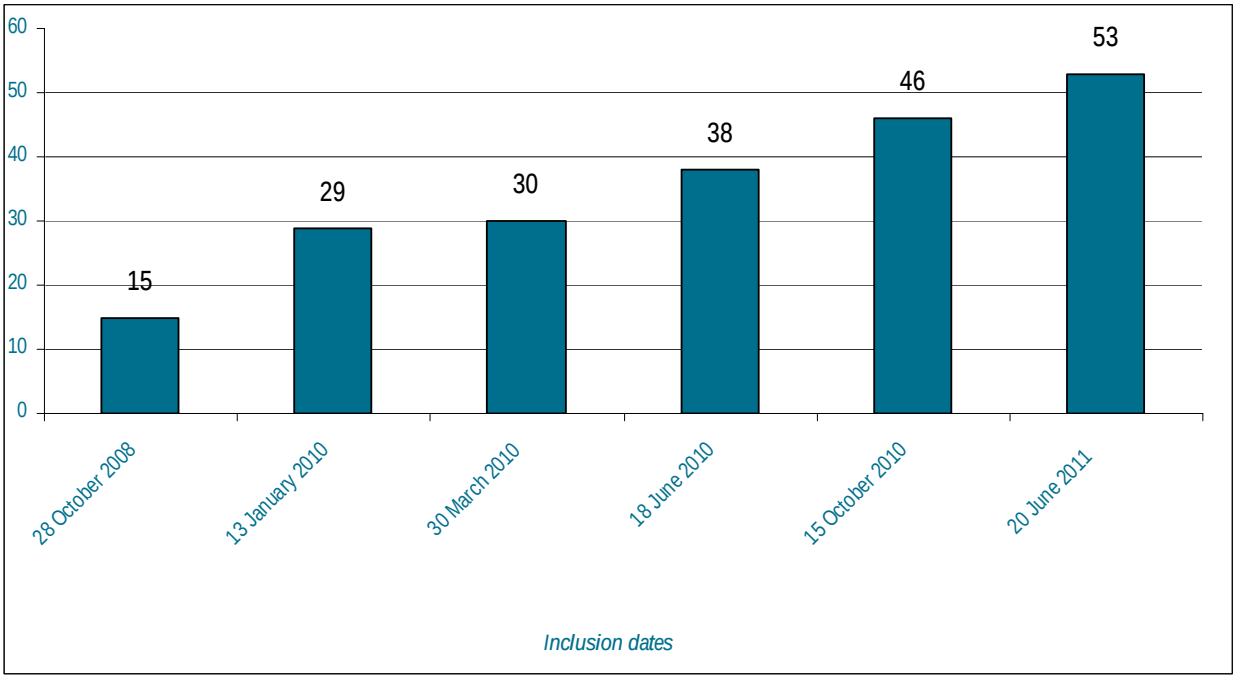

Figure 4: Cumulative number of substances on the Candidate List

The views on different roles and uses of the Candidate List have been clarified but in practice there continues to be challenges for the authorities and industry when carrying out their obligations.

The Candidate List is an obligatory step to subject substances to the authorisation requirement. The inclusion of a substance in the Candidate List triggers obligations on article producers and importers to notify ECHA and suppliers to communicate within the supply chain according to the conditions set out in Articles 7(2) and 33 of REACH.

The Candidate List is also the main mechanism to officially identify PBT/vPvB substances and substances of equivalent level of concern to CMR Cat. 1A/1B and to PBT/vPvBs. Finally, the Candidate List also has the effect of increasing awareness within industry and consumers. The extent to which these different roles are relevant varies between the different substances.

Maintaining and improving the quality of SVHC dossiers is crucial for effective management of the identification process and for the next priority-setting phase.

The identification of substances as an SVHC is fairly straight forward for a mono-constituent substance. However, for substances with several constituents (i.e. multi-constituent substances or substances of unknown, of variable composition, or of biological origin (UVCBs)) there is a need for a general approach on how to handle SVHC constituents, possibly in line with the provisions set out in the CLP Regulation for classified constituents.

Furthermore, discussion and increased common understanding is needed on how to best address substances of an equivalent level of concern as other SVHCs e.g. endocrine disrupting substances under Article 57(f). The further work in this area needs to be aligned with the development and decisions taken in the implementation of other relevant Community legislation.

In some dossiers for SVHC identification information on uses and exposure is not included. Although Annex XV only requires documentation of the available information, the low quality or absence of this information complicates and to some extent delays the passage of these substances to the next step in the authorisation process, i.e. prioritisation and possibly recommendation for inclusion in the Authorisation List. The provision of this information is therefore important for the efficient implementation of the second step in the authorisation process.

Two finalised prioritisation processes have resulted in an agreed approach to prioritisation and the clarification of important procedural and legal aspects.

Thus far ECHA has submitted two recommendations for including substances in the Authorisation List to the Commission, on 1 June 2009 and on 17 December 2010. As a result, an approach has been agreed on carrying out the prioritisation process and important procedural and legal aspects have been clarified.

The main elements that need further attention and clarification have been identified on the basis of work done so far. Issues are: how to best use the flexibility provided by the legal text when setting the application and sunset dates; to find agreement with industry on a consistent interpretation of which applications can be considered as uses of a substance as chemical intermediates in accordance with the clarification agreed between the Member States (MSs), the Commission and ECHA; as well as the 'scope' of the research and development (R&D) and product and process oriented research and development (PPORD) exemptions and the needs and limitations of using entry specific exemptions.

Public consultations on SVHC dossiers and on the draft recommendation on inclusion in Annex XIV have resulted in some useful additional information. However, the quality of contributions could be improved by continuously reminding interested parties on the roles of the public consultation at different phases of the authorisation process.

Providing the right information at the different commenting opportunities is still a challenge for all interested parties. For example, the issue of the appropriateness of the harmonised classification and labelling often arises during the public consultation, but this aspect cannot be considered further in the authorisation process as it is already decided in a separate regulatory process under CLP Regulation. It is also a challenge to explain that while the decision on the identification of a substance as an SVHC is solely based on its intrinsic properties, stakeholders are invited to provide information on the uses and alternatives to support the next phase in the process (prioritisation of substances for inclusion to Annex XIV).

5.3 Follow up

- ECHA will develop and carry out, in cooperation with the Commission and MSCAs, actions to facilitate the preparation and to improve the quality of Annex XV SVHC dossiers;
- ECHA together with MSCAs will develop a process for screening registrations and other information and the use of results of dossier and substance evaluation in order to identify potential cases for further risk management in general and for the authorisation process in particular;
- We invite the Commission to clarify the approach to be taken with SVHC constituents and ensure that the ways to address endocrine disrupting substances is coherent across different EU legislation. ECHA will use different means, including effective communication,

to promote a common understanding between industry, MSCAs and enforcement authorities on the uses that can be covered by intermediate registration dossiers;

- ECHA invites the Commission to clarify the process for removing substances from the candidate list when the legislation is changed.

Table 12: Authorisation – Overview (2008-2011)

Notifications in the Registry of Intentions*	
Number of intentions received	81
Number of intentions confirmed	64
SVHC dossiers*	
Number of dossiers received	57
Public consultations on SVHC reports	
Number of consultations opened for SVHC	58
Total number of comments received (SVHC)	1 432
Substances on the candidate list	
Number of substances put on the candidate list	53
Public consultations on draft recommendations for the Authorisation list	
Number of consultations opened	28
Total number of comments received	431
Substances recommended for the Authorisation list	
Number of substances recommended	15

** MSCAs or ECHA on request by the Commission, may prepare Annex XV dossiers for identification of substances of very high concern (SVHC), Annex VI dossiers proposing harmonised classification and labelling or Annex XV dossiers proposing restrictions.*

The aim of the public registry of intentions (RoI) is to allow interested parties to be aware of the substances for which the authorities intend to submit Annex XV or Annex VI dossiers and therefore facilitates the timely commenting by interested parties.

The RoI also serves to avoid duplication of work and encourage co-operation between Member States when preparing their dossiers. It should be noted that for the restrictions process there is a legal requirement for the Member State to notify the Agency its intention to prepare an Annex XV restriction dossier.

6 Restrictions

6.1 Objectives of the legislation

REACH foresees a restriction process to regulate the manufacture, placing on the market or use of certain substances if they pose an unacceptable risk to health or the environment. A restriction is designed as a "safety net" to manage risks that are not already adequately controlled by industry or addressed by the other REACH processes.

Any substance on its own, in a mixture, or in an article may be subject to a restriction if it is demonstrated that risks need to be addressed on an EU-wide basis. A restriction dossier needs to justify that the proposed restriction is the most appropriate risk management measure to address these risks.

6.2 Key messages

ECHA's opinion forming work on new restrictions is progressing well.

The first four new restrictions (see table 14) following the procedure set out under REACH have been initiated and will be concluded during the course of 2011. ECHA has established the necessary procedures and developed the scientific and technical capacity to manage the dossiers and support the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) in their opinion-making process. Whereas discussions on these first dossiers have been at times extensive, they have generated valuable experience and have provided a good basis for improving the quality of future dossiers and the efficiency of the working procedures. It is still too early to assess how successful the opinions have been in supporting the subsequent decision-making process in the Commission.

Table 13: Overview of restrictions

Notifications in the Registry of Intentions*	
Number of intentions received	14
Number of intentions confirmed	12**
Public consultations on proposals for restrictions	
Number of consultations opened for Restrictions proposals	4

**See description in section 5*

***In some cases intentions were sent separately for each substance. These were then grouped in a single dossier (i.e. 5 entries for phenyl mercury compounds in 1 dossier; 4 entries for phthalates in 1 dossier)*

ECHA has established a capability of developing restriction proposals.

ECHA has assembled expertise from different fields and has the capability to prepare restriction proposals if the Commission requests this. The experience gained from the work done so far, in particular, the proposal for mercury in measuring devices and the review work on the existing phthalates restrictions, can be used in planning and carrying out work on future restriction proposals.

Table 14: Number of comments received per restriction proposal

Substance	2010
Lead	40
Dimethylfumarate (DMFu)	9
Phenylmercury compounds	3
Mercury in measuring devices	17

The quality of restriction proposals and their effectiveness for the decision-making process require attention.

Restriction proposals and opinions on them need to provide a coherent and robust basis for decision-making by the Commission. The focus and details of restriction reports vary from case-to-case and it remains a challenge to prepare a high quality dossier which is proportionate to the case in question.

Restrictions are used as a safety net for cases where other measures, in particular registration obligations, do not result in a sufficiently high level of protection. Therefore, restrictions normally address concerns which are in one way or another exceptional. Consequently the requirements for the restriction proposals need to be flexible enough to allow the case specific characteristics to be taken into account whilst ensuring that the process produces a solid and coherent basis for decision-making.

The current structure and wording of Annex XV, Section 3 of the REACH Regulation (which covers the requirements of a restriction dossier) do not fully correspond to the needs of and support the preparation of clear and high quality proposals and background documentation, for a decision on whether to restrict the substance or not. In particular, the requirements related to the cost of a restriction and other socio-economic information would benefit from clarification. Annex XVI, which describes how socio-economic analysis may be conducted, is not considered helpful in developing a good quality analysis. This is partly because it merely indicates the different kinds of items that might be analysed, and so it would be beneficial if the most important issues relating to the (socio-economic or other) impacts were prioritised and included in Annex XV, Section 3. These comprise, in particular, the costs to the society as well as the health and environmental impacts of the restriction.

Experiences from the first dossiers can be used to improve the procedures and associated templates, develop further guidance and support the Member States in preparing Annex XV restriction proposals.

The timelines for developing opinions on restriction proposals are challenging in view of the need to ensure high quality work.

The timelines for different tasks in combination with the length of the public consultation periods (6 months plus 2 months) set out in Title VIII are very challenging. The procedures and timelines

of RAC and SEAC opinion forming differ with regard to the second public consultation without obvious benefits for the content or promptness of the restriction process.

RAC needs to give its final opinion, and in practice SEAC its draft opinion, in nine months while the length of the first public consultation is six months. ECHA's experience is that interested parties tend to provide their comments fairly late and this is likely to occur in future consultations. This means the Committees have difficulties in using the information provided by the interested parties in an optimal manner. It should be considered to shorten the public consultation period from six to three months. This would not compromise the quality of the comments but would facilitate an optimal use of them.

The time reserved for the second public consultation on the draft SEAC opinion is 60 days. In practice this means that SEAC has very little time to take into account the comments and adopt its final opinion. Thus, it would be beneficial to consider shortening the second consultation period to 30 days.

It would seem helpful to subject the draft RAC opinion to the same public consultation procedure as the SEAC opinion. This is not foreseen in Restriction Title of REACH. Extending the time of RAC's opinion making from nine to 12 months would make this consultation possible. Having RAC's draft opinion consulted at the same time as SEAC's draft opinion would not prolong the overall duration of the twelve month opinion-making process.

Information generated by other REACH processes can be used to identify concerns which can best be addressed by restrictions

To support the effective and proportionate use of restrictions, systematic use of available information is required to identify concerns and the best risk management instruments to address them. Registration, evaluation and authorisation processes will generate new information which can be used for this purpose.

Restrictions have proven to be an effective risk reduction instrument where the risks need to be addressed on an EU-wide basis. At the same time new restrictions are relatively heavy to introduce. Therefore, to be able to use restrictions in an effective and proportionate way and without undue delay, it is important to actively screen substances for which further risk management is needed and a restriction seems to be the most appropriate risk management option. Information generated by registration, evaluation and authorisation processes, including information on Candidate List substances in articles, can be used for this.

6.3 Follow up

- ECHA will develop and carry out, in cooperation with the Commission and Member States, a set of actions to facilitate the preparation of and to improve the quality of Annex XV restriction dossiers. These actions should ensure that the capability of the Member States and ECHA to prepare restriction proposals is used in a cost-effective and relevant manner;
- ECHA will, together with the Member States, develop an approach to screen registration and other information and to use the results of evaluation to identify potential cases for restrictions or other risk management measures;
- The Commission is invited to consider shortening the first public consultation period from six to three months and the second public consultation from 60 to 30 days to utilise comments from interested parties in an optimal manner;

- Consideration should be given to subjecting the draft RAC opinion of a proposed restriction to a similar public consultation requirement as that of SEAC by extending the opinion making time for RAC to 12 months;
- A revision of Section 3 of Annex XV and the restriction-related parts of Annex XVI could be considered to better integrate the experience and current thinking on how a restriction dossier should be prepared and presented. This would provide a better basis for opinion and decision making.

7 Classification & Labelling

7.1 Objectives of the legislation

Chemical substances to be placed on the market have to be classified if they have hazardous properties. For some substances legally binding (harmonised at EU level) classification exists. Substances with certain properties (classified as carcinogenic, mutagenic or reprotoxic (CMRs)), respiratory sensitisers and, if justified, substances classified for other hazards) are prioritised for harmonised classification and labelling (CLH). Self-classification by suppliers of substances is obligatory for those hazards where no harmonised classification exists and for mixtures. For active substances used in plant protection products or biocidal products, a fully harmonised classification and labelling is required.

The process for granting permission to use an alternative chemical name instead of the International Union of Pure and Applied Chemistry (IUPAC) name for a substance in a mixture under certain conditions allows for the confidentiality of the composition of the mixture to be maintained, while at the same time ensuring that the alternative names provide appropriate hazard information for ensuring the safe use.

The establishment and maintenance of a classification and labelling inventory of dangerous substances on the EU market will facilitate the agreement between companies on the classification and labelling of the same substance. In addition, it will provide information to the Member State Competent Authorities (MSCAs) and the public on how companies are classifying their substances.

7.2 Key messages

The CLH process at ECHA has been established.

Proposals for harmonised classification and labelling may come from MSCAs or in some circumstances from industry. By March 2011 over 150 dossiers have been submitted to ECHA, more than 40 have undergone public consultation, 18 opinions have been adopted by the Committee for Risk Assessment (RAC) and this work is gaining momentum. The process needs to be even faster in the future to cope with the foreseen 60 dossiers per year. The application of the legal provisions related to the classification criteria is generally clear. Following comments from stakeholders, consideration is being given on how to improve the process to ensure that there is an adequate public consultation for all relevant information, including information that is submitted late in the process, before drafting the final RAC opinions.

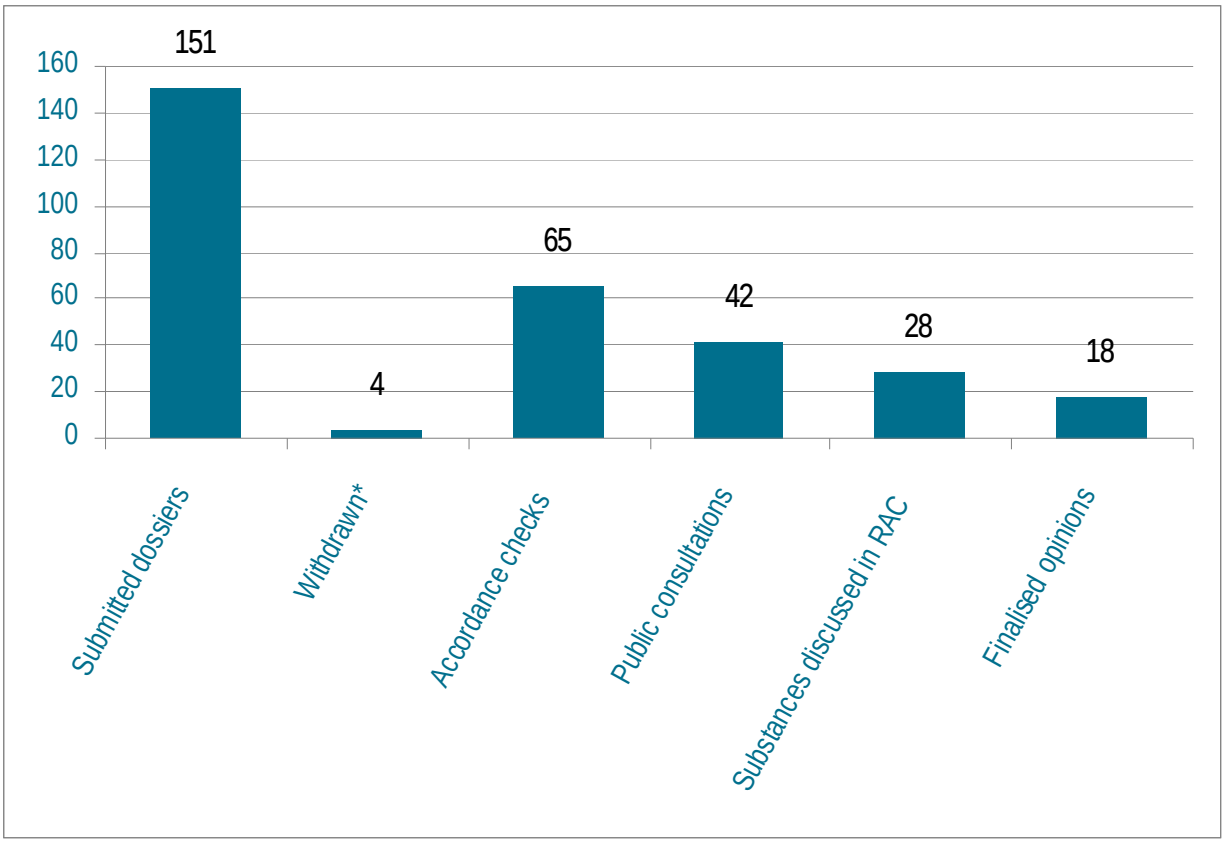

Figure 5: CLH Dossiers submitted for harmonised classification and labelling ***** (until March 2011)

* *Temporary withdrawal (awaiting new information) or permanent withdrawal.*

***Dossiers undergo an accordance check by ECHA and by the RAC rapporteurs. Dossiers that pass the accordance check are then subject to a public consultation before an opinion of RAC is adopted. All proposals are discussed in plenary sessions of RAC (usually during 1-4 meetings dependent on the need). The outcome can be agreement or disagreement with the proposed classification or a suggestion for an alternative classification. The opinion by RAC is forwarded to the Commission and where the Commission finds the proposed harmonised classification and labelling appropriate, it prepares a draft decision for inclusion of the harmonised classification and labelling in Annex VI of the CLP Regulation.*

The quality of CLH dossiers is important.

The rapid and efficient adoption of an RAC opinion requires high quality CLH dossiers. Some low quality dossiers from MSCAs have significantly reduced the throughput in RAC and the lack of involvement by some MSCAs to produce proposals is of concern. There is a need to re-consider the approach taken for low quality dossiers in order to allow RAC to cope generally with an increased number of dossiers in the near future (see section 13).

The additional workload caused by dossiers not fulfilling the highest standards has been a concern for RAC and in particular its rapporteurs. Lack of data has in some cases delayed the process because RAC rapporteurs invested a substantial amount of time to compile and assess the relevant missing data. In relation to the above points, the quality of dossiers should be improved. Following a workshop with RAC members, ECHA has proposed modifications to the accordance check procedure to ensure that only dossiers fulfilling the legal criteria are accepted for further processing. In cases of poor scientific quality RAC may consider the quality of the dossier to be insufficient to conclude on a classification.

The Classification and Labelling Inventory is being established.

The main objective of the Classification and Labelling Inventory is to promote agreement between companies on an adequate classification of substances. Notifiers and registrants are obliged to make every effort to agree on the classification of a given substance.

The notification process thus far has been successful and has resulted in the submission of over 3 million notifications. This success has in part been attributed to the successful functioning of the IT systems developed by ECHA.

Non-confidential parts of the inventory are to be disseminated to the public in the second half of 2011. The degree to which notifications for the same substance differ will now be assessed, however, spot-checks have shown that classifications do indeed differ, even for substances with a harmonised entry in the CLP Regulation.

It should be noted that there may be valid reasons for different classifications, such as different impurities or different physical forms of the substance. In addition, for phase-in substances which are only used as chemical intermediates, in scientific research and development or in product and process oriented research and development, the full chemical name (IUPAC) can be claimed as confidential by a notifier and a public name is used for the Inventory. The notifier devises the public name using the alternative name criteria from the Dangerous Preparations Directive (DPD). Following the deadline of 3 January 2011, relatively few claims for confidentiality have been received. Nevertheless, to increase legal certainty, it could be useful for the Commission to consider clarification of the provisions in the CLP Regulation regarding the possibilities to claim confidentiality of the IUPAC name of the substance to be notified for the Classification and Labelling Inventory.

The legal text obliges notifiers and registrants of the same substance for which different entries appear in the Classification and Labelling Inventory to make every effort to come to an agreement on the entry. However, the CLP Regulation does not foresee that ECHA publishes the identity of notifiers. ECHA is currently investigating practical solutions to allow companies to get in contact with each other to agree on a classification. One option to be considered in this context could be a simple modification of the CLP Regulation that would make clear that the name of the notifying companies will be included in the public inventory.

Table 15: Number of notifications for the Classification and Labelling Inventory (2009 – 2011)*****

Item	Number
Number of C&L notifications received	3 204 462
Number of distinct substances	108 941
Number of submitting companies	7 250
Number of notified companies[1]	15 801

** Data does not include notifications received via registration dossiers*

The process for handling alternative name requests is under development

ECHA is currently setting up the process for handling requests for using alternative names for substances in mixtures. It is expected that this process will be ready for submissions by companies in September 2011. By organising a workshop with the MSCAs that have experience in handling the corresponding requests under the DPD, valuable input has been received for the

[1] Number of notified companies is an estimated number. Due to different parameters for calculation of companies notified on their own and in a group of manufacturers/importers, we cannot guarantee that the number of notified companies has not been double counted.

development of the ECHA process, as well as an insight into the future possible workload which may pose a challenge from a resource planning point of view if a substantially higher than expected number of requests arrive.

7.3 Follow up

- The CLH processes will be further developed by ECHA in collaboration with RAC, MSCAs and the Commission to increase the throughput of CLH opinions;
- The quality of dossiers submitted by MSCAs should be improved by taking into account the experience gained with the dossiers submitted thus far;
- ECHA is currently investigating what practical solutions can be implemented to bring companies into contact with each other to agree on the classification of substances for which different classifications have been notified to the Classification and Labelling Inventory.

8 Guidance

8.1 Objectives of the legislation

The objective of the ECHA guidance documents is to facilitate the implementation of REACH and CLP by describing good practice on how to fulfil the obligations of both Regulations.

The ECHA Secretariat is legally obliged to provide technical and scientific guidance and tools, where appropriate, in order to assist Member States and industry, including producers and importers of articles and especially SMEs.

8.2 Key messages

ECHA's guidance is a reference document and has contributed to the success of the first registration deadlines and the CLP notification deadline.

The ECHA guidance documents serve as a reference framework, helping companies and industry associations to develop tailor-made and sector-specific solutions to fulfil the obligations that both regulations place on them. The guidance documents are produced with the wide involvement of stakeholders and as such represent a broad-based agreement. This means guidance users have a high certainty that any action that is in line with the guidance will be acceptable to all other actors.

The majority of the guidance documents arising from the REACH Implementation Project Process managed by the Commission have now been published and ECHA has taken over responsibility for their management. These guidance documents were developed before the REACH Regulation was operational. Several of these have already been updated by ECHA before the first registration deadline and the CLP notification deadline. ECHA has prepared a plan to update a further set of guidance documents in advance of the next registration deadline in order to implement the lessons learnt from the first registration wave. However, only a few important changes are expected from this exercise as the main driver of the updates is to improve what exists and has worked already.

In certain cases in developing guidance there have been delays in clarifying policy issues and legal interpretations. ECHA invites the Commission wherever possible to provide advice to the Agency in a timely manner for the establishment of new or updated guidance.

New practical experience will also emerge over time and therefore updates of the guidance will be regularly needed to incorporate good practice.

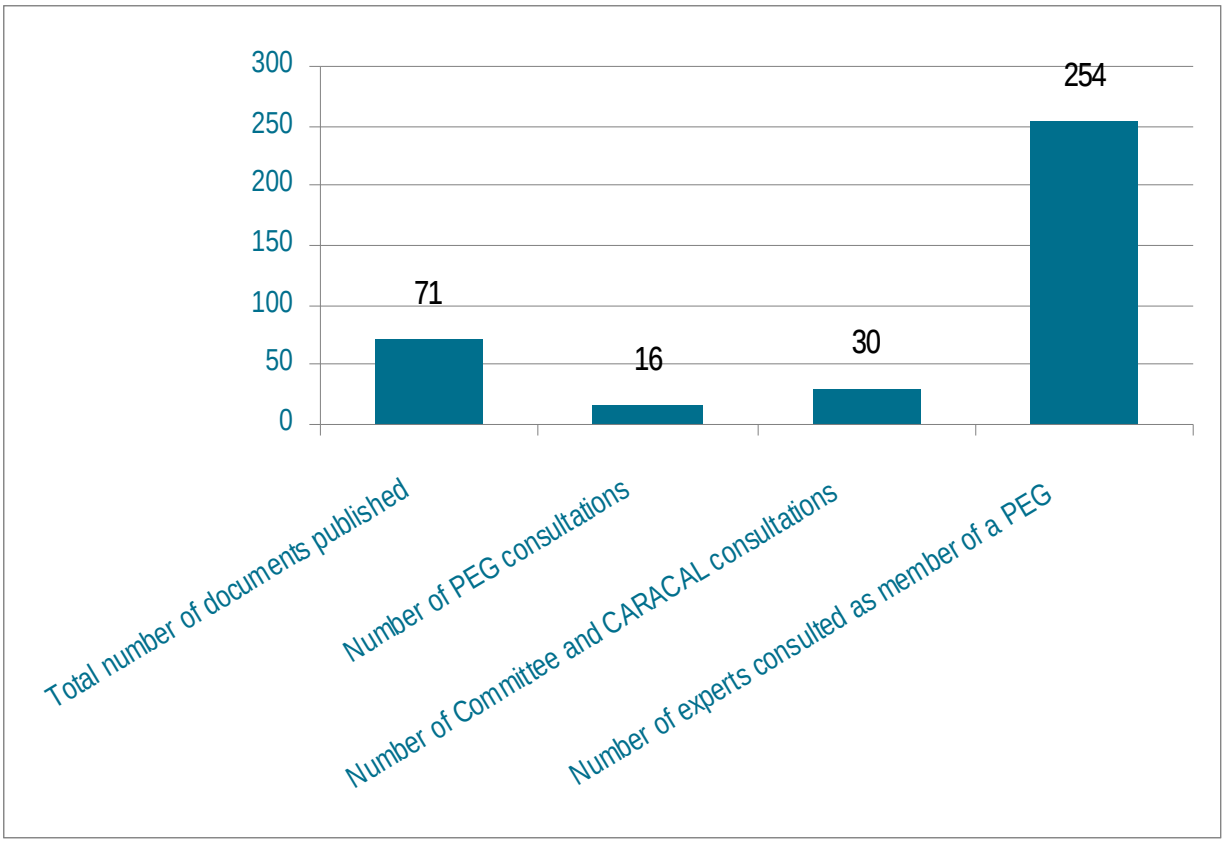

Figure 6: Statistics for ECHA Guidance (2007 - 2011)

The accessibility of guidance is continuously being improved to assist companies to comply with the REACH and CLP Regulations.

To improve the accessibility of the guidance for all stakeholders, ECHA has produced so-called 'quasi guidance' that includes fact sheets, guidance in a nutshell, practical guides, user manuals and the Navigator tool. The quasi guidance are available on the ECHA website and they explain the key messages of the guidance documents in simple terms and are particularly intended for small and medium size enterprises (SMEs). They also explain the use of IT tools that ECHA makes available to facilitate companies' submissions. Furthermore, many of these documents and several guidance documents are provided in 22 official languages[2] of the EU to further improve their accessibility. In the future, ECHA will also seek further ways to adapt guidance to continue to make it readily accessible, for example, by the re-design of the guidance website and by simplifying guidance where practical.

Registrants may need to update their registration dossier without undue delay after publication of new guidance.

Guidance reflects the 'state-of-the-art' in the practical implementation of the legislation, and therefore companies submitting registration dossiers should be aware that these will be evaluated against the latest version of the updated guidance.

[2] Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovakian, Slovenian, Spanish and Swedish

Article 22 of REACH requires registrants to update their registration "without undue delay". Publishing new guidance may lead a duty-holder under REACH to realise the insufficiency of a registration, for example due to increased knowledge of the risks of a substance to human health and/or environment. This may in some cases trigger the obligation to update the registration. The most realistic time for such an update will depend on individual circumstances and may involve minor issues such as basic information requirements or major efforts such as updating a registration dossier of an intermediate or a full registration dossier. Thus, a registration update without undue delay may vary from less than a month, to one year or even more. Companies acting diligently and updating their registrations without undue delay need to document this step including plausible justifications and factual explanations underpinning the scope and time of their efforts to carry out an update in their work.

Stakeholders are closely involved in the development of guidance to ensure a common understanding.

ECHA has put in place a guidance consultation procedure to update or revise guidance if shortcomings in the existing guidance are discovered or if new guidance is needed. This consultation procedure attempts to minimise the period that guidance with shortcomings is publicly available on the ECHA website, but at the same time ensures adequate buy-in of all relevant actors in the revision process. The guidance consultation procedure is open and transparent to participation by all relevant stakeholders, including the Commission, Member State Competent Authorities (MSCAs), industry and the enforcement authorities. All efforts are undertaken to reach consensus in order that guidance is acceptable to all involved parties.

Dissenting views concerning policy issues can cause delays to the guidance consultation process.

Guidance documents are produced with a wide involvement of stakeholders and as such represent a broad-based agreement. ECHA's stakeholder consultation process to update or consider new guidance has experienced some protracted discussions on scientific, technical or policy issues which have caused delays. Consequently, the ECHA Management Board adopted a revised guidance consultation process in March 2011. The new mechanism aims to provide a more predictable interpretation of sensitive policy issues and will enable ECHA to carry out the necessary updates of guidance linked to registration in good time ahead of the next registration deadline. This mechanism will also allow ECHA to finalise guidance on the basis of majority views if full consensus cannot be achieved.

So far, the most controversial issue related to ECHA guidance causing major delay in finalising the guidance has been the interpretation of the 0,1 % limit value for substances in articles (Articles 7(2) and 33 of REACH). Despite the recent confirmation by the Commission on the legal interpretation of this provision, certain Member States (MSs) still hold their dissenting view on this topic. This situation is causing uncertainty for the companies on how to implement REACH and therefore the Commission is invited to consider improving the clarity of the legal provisions in this regard.

Keeping dossiers under preparation aligned with on-going guidance updates in the run-up to a deadline is not ideal and is challenging for companies, particularly SMEs.

Industry associations have indicated to ECHA that work triggered by guidance updates and new guidance may entail significant resources which would be better deployed elsewhere, particularly when preparing for REACH or CLP deadlines. This is particularly the case for SMEs.

In order to allow industry to concentrate on preparing their dossiers in the period before REACH/CLP deadlines, ECHA envisages a moratorium of at least half a year ahead of the relevant REACH/CLP deadline for new and updated guidance documents. Additionally, ECHA intends to publish guidance documents at predictable dates spread over the year to enable industry to better prepare for changes.

8.3 Follow up

- ECHA will update several of its guidance documents that affect registration in order to take stock of the lessons learned from the first registration deadline and create more clarity, consistency and enforceability on registration in advance of the next registration deadline
- ECHA will seek new ways of adapting guidance to more closely meet the needs of its users. The 2018 registration deadline will particularly affect SMEs, and this group will be targeted to be a beneficiary of further adaptations to guidance;
- The Commission is invited wherever possible to clarify policy issues and legal interpretations in a timely manner in order to enable ECHA to review or update guidance before any relevant deadline;
- ECHA invites the Commission to consider clarifying, also in light of enforcement practice, the legal definition of an article in the REACH regulation to move beyond the continuing debate on the interpretation of the 0.1 % limit value regarding substances in articles.

9 The ECHA Helpdesk

9.1 Objectives of the legislation

The ECHA Secretariat is required to support Member State REACH and CLP helpdesks; provide advice and assistance to manufacturers and importers registering a substance; and to provide support and tools for the operation of REACH.

9.2 Key messages

ECHA supports a network of national helpdesks to foster cooperation among Member State REACH and CLP helpdesks and to harmonise replies they give to enquirers.

To support the Member State REACH helpdesks, REHCORN (REACH Helpdesk Correspondents' Network) was established in 2007 and then expanded in 2009 to include the national CLP helpdesks. This expanded network is called the 'HelpNet' (REACH and CLP Helpdesk Network).

Through the HelpNet, ECHA promotes a common understanding of REACH and CLP obligations and the harmonisation of answers given to companies across the EU/EEA. The capacity of the HelpNet has been strengthened by providing an IT exchange platform (HelpNet Exchange) for the exchange of information, face to face meetings (HelpNet Steering Group), hands-on training and webinars on different REACH and CLP processes as well as ECHA's IT tools.

The above is complemented by a programme of visits by the ECHA Helpdesk staff to national helpdesks to ensure a better understanding of their work, to promote best practice and to ensure targeted support for national helpdesks.

The HelpNet cooperation has proved to be very important to harmonise answers from the helpdesks. Specifically, a discussion of difficult questions takes place between national helpdesks, the European Commission and ECHA via the HelpNet Exchange. This is underpinned by the identification and approval of REACH and CLP frequently asked questions (FAQs) that are subsequently published on the ECHA website.

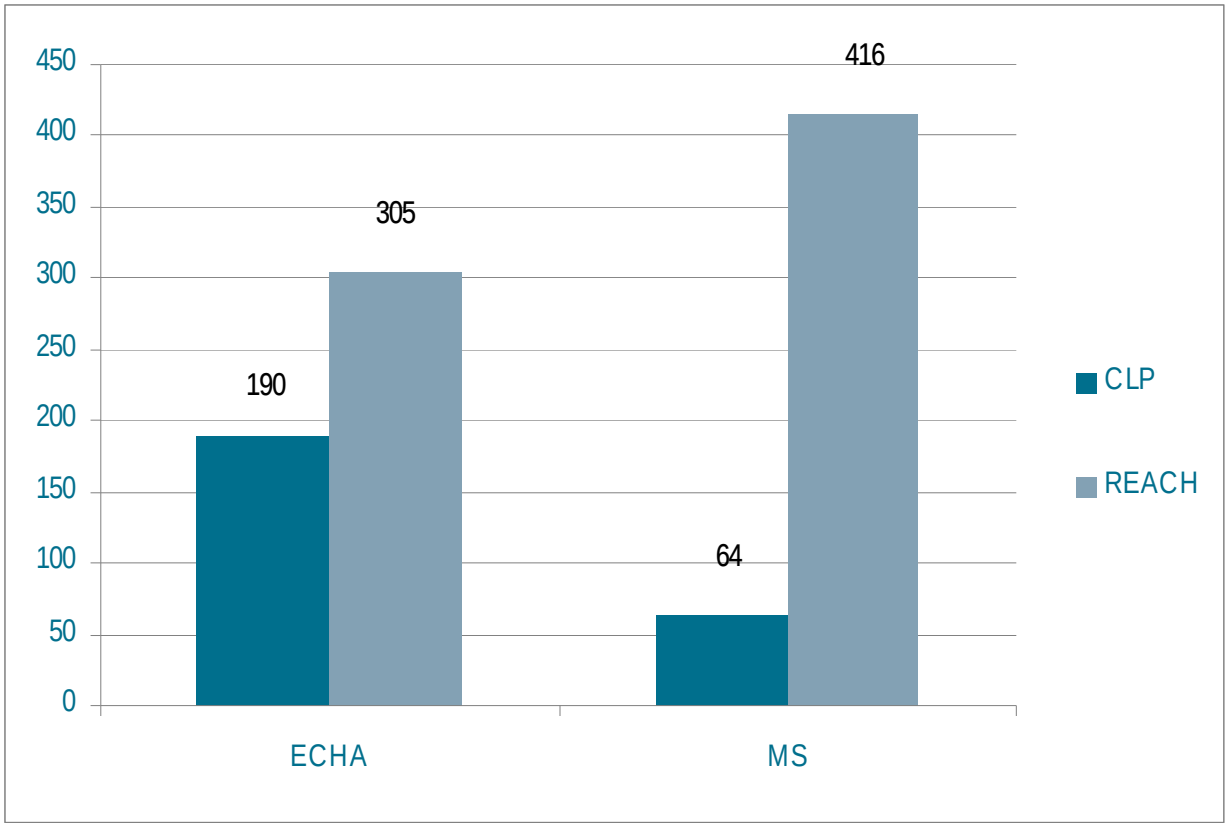

Figure 7: Number of questions opened/initiated in the HelpNet Exchange (2007 – March 2011)

The ECHA Helpdesk (together with HelpNet) provides a harmonised and resource-effective mechanism for supporting companies in the implementation of the REACH and CLP Regulations.

The ECHA Helpdesk and its activities within the HelpNet are essential elements in contributing to the consistent and harmonised implementation of the REACH and CLP Regulations at EU/EEA level.

The ECHA Helpdesk and the national REACH and CLP helpdesks are complementary in their respective tasks. National helpdesks are the first point of contact for companies including small and medium-sized enterprises (SMEs) established in their own country, they provide help in national languages and are well informed about the situation and needs of local companies. National helpdesks may invite companies to contact the ECHA Helpdesk if a question is not within their competence, or companies may contact the ECHA Helpdesk directly if they want to ensure the answer from a national helpdesk is shared by ECHA. If the ECHA Helpdesk is approached by companies, they are assisted to fulfil their respective REACH or CLP obligations. Companies established outside the European Economic Area (EEA) usually approach ECHA directly with their queries.

ECHA supports the national helpdesks to provide the best possible advice. In preparation for the first registration deadline in 2010, ECHA focused on supporting lead registrants, whilst the national helpdesks supported member registrants. As also highlighted in a video message by Vice-President Tajani posted via HelpNet to national helpdesks in May 2010 appropriate resources should be allocated to national helpdesks given the important role played by them

and to ensure they continue to be the first point of contact for companies established in their own territory.

The ECHA Helpdesk provides concise and understandable responses, mostly in a timely manner. However, the Commission is responsible for answering difficult questions that are unresolved and require legal interpretation. In the light of past experience, ECHA invites the European Commission to provide timely legal interpretations on REACH and CLP to ECHA and the HelpNet.

ECHA's helpdesk has a special focus on IT tools. As companies can only register or notify dossiers via IT, it has developed various IT tools to support the REACH and CLP processes (see section 11). These IT tools are available for users and are provided with release notes, manuals and user support. The ECHA Helpdesk supports users of ECHA's IT tools, particularly to install them and to get acquainted with their functionalities. The national helpdesks also provide tailored assistance on how to use the tools and to insert data to meet their legal obligations in particular focusing on SMEs and other companies taking part in SIEFs or group notifications.

The ECHA Helpdesk provides an enhanced service before key REACH and CLP deadlines.

The support to (pre-)registrants and notifiers close to the pre-registration deadline in 2008, the registration deadline in 2010, and the deadline for classification and labelling notifications in 2011 was a joint effort by the national helpdesks and ECHA. National helpdesks were trained on the pre-registration, registration and notification tools and processes. They were able to advise companies on how to fulfil their obligations in their national language. The ECHA Helpdesk established a phone service to address the needs of companies close to the deadlines. Even though this service was resource intensive and required contribution from many of ECHA's experts, it was much appreciated by industry.

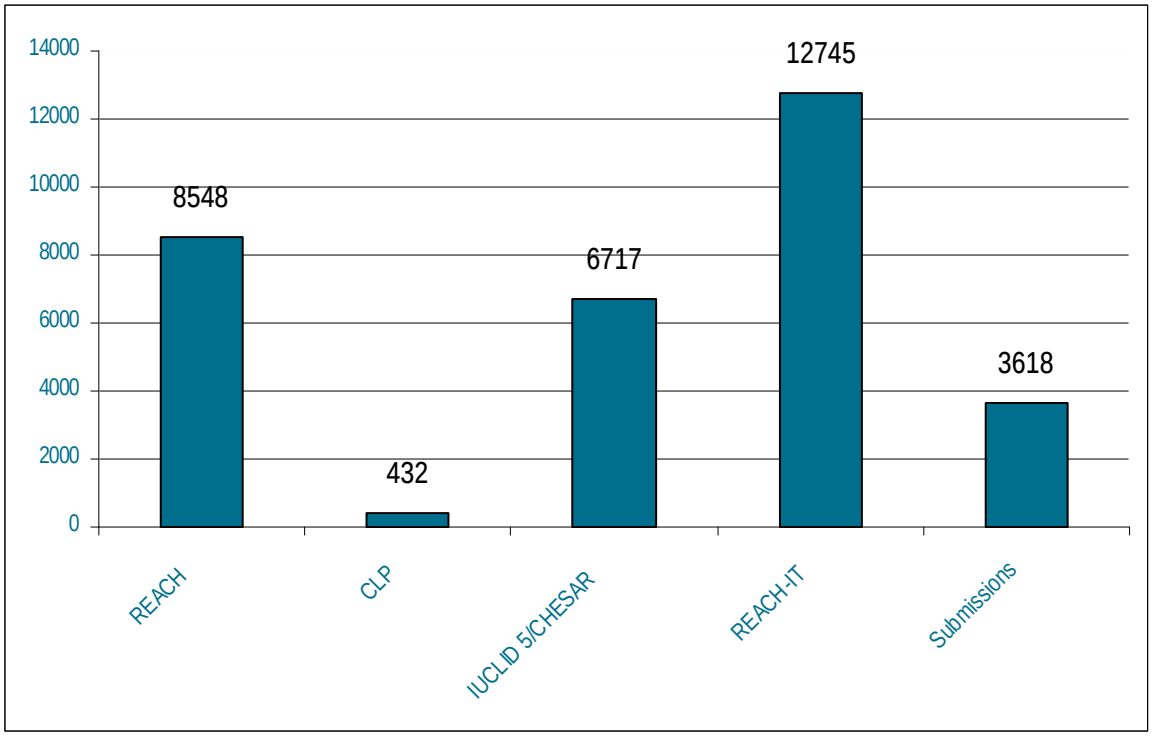

Figure 8: Questions received by the ECHA Helpdesk (until March 2011)

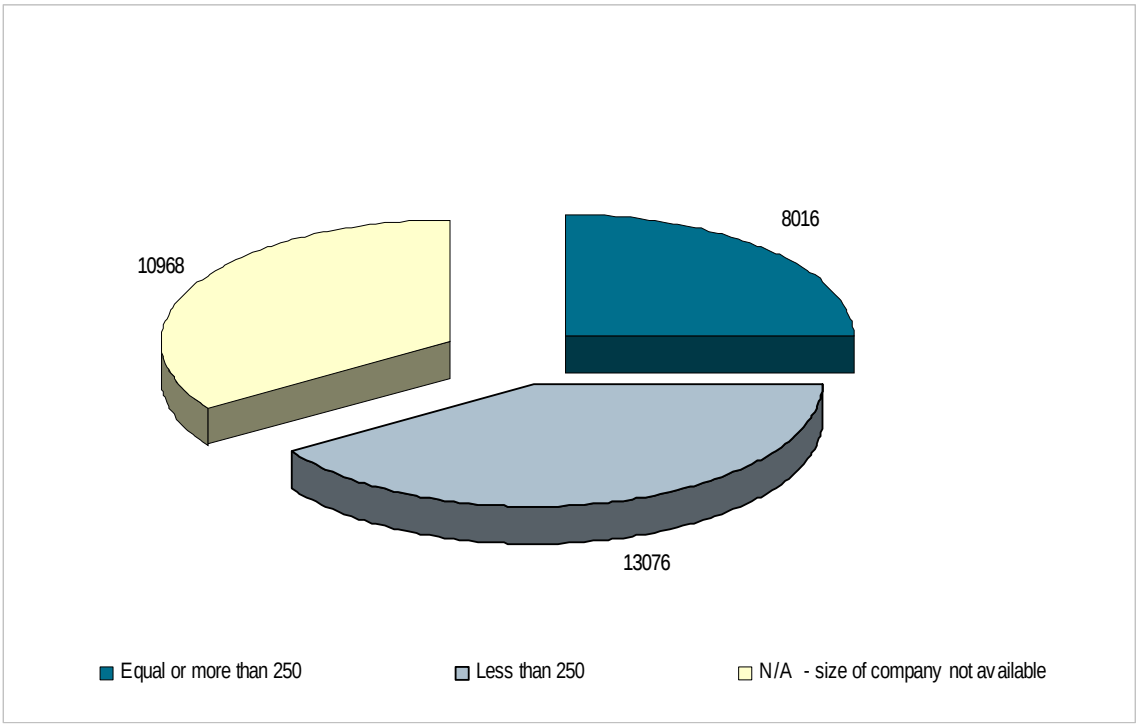

Figure 9: Number of Helpdesk questions received according to company size (until March 2011)

Table 16: Number of helpdesk questions received annually by ECHA according to company size

	2007	2008	2009	2010	2011	Total
Equal or more than 250	38	2 727	2 298	2 556	397	8 016
Less than 250	23	5 001	3 364	4 048	640	13 076
N/A - size of company not available	1 295	4 530	1 786	3 180	177	10 968
Total	1 356	12 258	7 448	9 784	1 214	32 060

9.3 Follow up

- The European Commission is invited to provide timely legal interpretations of the REACH and CLP Regulations to resolve difficult questions arising from the HelpNet;
- ECHA will continue to pay special attention to support companies in the use of its IT tools and will provide again a special service to lead registrants in advance of the next registration deadline;
- Appropriate resources need to be allocated to the national helpdesks as they are the first point of contact for companies and are best placed to provide tailored support for SMEs in their national language.

10 Communication in the supply chain

10.1 Objectives of the legislation

REACH aims to make sure that downstream users ensure that they use substances in a way that does not adversely affect human health or the environment. They have the right to communicate their use upstream in the supply chain and will receive the relevant information for the safe use of the substance from their suppliers in safety data sheets and exposure scenarios attached to them. Downstream users are responsible for checking that that their uses are covered by the exposure scenarios provided by their suppliers, and if not, for assessing the risks related to the use of their substance, themselves. In both cases downstream users have to apply the necessary risk management measures to their own activities and, where relevant, to communicate the necessary risk management measures to their customers.

10.2 Key messages

Downstream users have a key role in the new risk management approach of REACH.

The REACH principle that industry is responsible for the safe use of substances extends also to downstream users. The first level downstream users, typically formulators of mixtures, will be the first ones dealing with extended safety data sheets with use specific exposure scenarios annexed to them. Their obligations are triggered by receiving extended safety data sheets with exposure scenarios from their suppliers for registered substances.

Downstream users need to check if their uses and conditions of use are covered by their suppliers' exposure scenarios. If they are not, either because they did not want to disclose their use to their supplier, or because their supplier failed to take it into account in their chemical safety report, they need to decide what action to take. They have options ranging from stopping their use, changing supplier or drawing up their own chemical safety report.

Reporting on uses and notifying substances in articles will complete the view on the use of hazardous substances over the forthcoming years

Downstream users need to report their uses to ECHA if they prepare their own chemical safety report so that the Agency and the national enforcement authorities can have the full picture on the uses of hazardous and PBT/vPvB substances. In addition, producers and importers of articles (of which the former are typically downstream users in the sense of REACH) have the obligation to notify ECHA if the substances of very high concern (SVHC) in their articles have not been registered for that use. This information will be further evaluated and may identify substances for which, in the longer term, Community-wide risk management measures could be initiated.

Many supply chain tasks and obligations are new under REACH, which means that best practice will only evolve in the course of several years.

The obligations for communication in the supply chain under REACH have, in part, stayed the same as under the previous legislation. Safety data sheets as a communication vehicle for information on substances are not new, but what is new is the inclusion of exposure scenarios. ECHA foresees that a discussion platform for registrants and downstream users to share experiences and solutions for developing and applying exposure scenarios in practice would be beneficial for all parties involved.

Due to the current lack of harmonisation in the format and content of exposure scenarios annexed to safety data sheets, downstream users receive exposure scenarios in many different formats and it will require a lot of time and resources to prepare good quality communication for their customers further down in the supply chain. The reporting of uses that are not covered by the exposure scenarios communicated in extended safety data sheets and the notification of substances in articles are also novel obligations, which often affect SMEs. The Agency needs to develop its support mechanisms bearing this in mind.

Harmonisation and standardisation within industry are the keys to successful supply chain communication. ECHA is committed to supporting industry in their challenging task.

REACH has multiplied the safety information that is supposed to travel within the supply chain. In order to fulfil this task it is essential that the information remains correct and understandable to those who need to apply the risk management measures. Currently downstream users are expressing some concerns on the unstructured and therefore sometimes lengthy safety data sheets that they receive from their suppliers. While ECHA has no direct role in the supply chain communication, it intends to support the harmonisation and standardisation efforts of industry in this regard. Chesar, the tool developed by ECHA for chemical safety reporting, will generate structured exposure scenarios for communication purposes. In future, this will support effective communication of information on safe use in the supply chain. The Agency will assist, to the maximum extent possible, in making tools developed by industry for communication in the supply chain compatible with the International Uniform Chemical Information Database (IUCLID) and Chesar. ECHA will also, where possible, clarify the fairly complex provisions regarding supply chain communication to the companies affected.

10.3 Follow up

- Subject to availability of resources, ECHA will continue to develop and publish support to downstream users to help them in fulfilling their tasks;
- ECHA will investigate whether Chesar could be further developed to support effective supply chain communication;
- ECHA will assist, to the maximum extent possible, to ensure that tools developed by industry for communication in the supply chain are compatible with IUCLID and Chesar;
- In cooperation with industry, ECHA will initiate a discussion platform for registrants and downstream users to share experiences and solutions for developing and applying exposure scenarios in practice.

11 Scientific IT tools

11.1 Objectives of the legislation

A key role of ECHA is to specify formats and software packages for the operation of REACH and CLP and make them available on its website. This includes tools to enable industry to prepare and submit the information required under the REACH and CLP Regulations. ECHA is also required to assist the development of chemical safety reports by industry, and especially SMEs, by means of IT tools.

Moreover, ECHA has a duty to establish and maintain databases with information on all registered substances and the classification and labelling inventory. This information is to be available to Member State Competent Authorities (MSCAs) and national enforcement authorities to carry out their work on other REACH & CLP activities.

ECHA must publish non-confidential information on registered substances on the Internet according to Article 119, information from the Classification and Labelling (C&L) Inventory, substances that are being or have been evaluated and on authorised uses and risk management measures.

11.2 Key messages

The REACH-IT system is the backbone of the implementation of the REACH and CLP Regulations and the system has been well developed in the three years after entry into operation of the Agency.

The REACH and CLP Regulations can only be successfully implemented if there are efficient IT systems to support the processes, due to the volume of data to process and the number of stakeholders involved. The REACH-IT system is an essential element for this implementation. In the initial phase, there were some system instability and performance problems related to the heavy load on the system created by the unexpectedly high number of users submitting pre-registrations in 2008. This forced ECHA to process registration dossiers manually. Nevertheless, after intensive development undertaken by ECHA, REACH-IT operated smoothly enabling ECHA to receive 25 000 registration dossiers by the first registration deadline in 2010 and over 3 million C&L notifications by the 3 January 2011 deadline. The majority of dossier processing steps are now automated, reducing manual intervention to exceptional cases only.

ECHA has recognised the need to be active in developing tools for industry to help them prepare and submit their dossiers, including the International Uniform Chemical Information Database (IUCLID) and the chemical safety assessment and reporting tool (Chesar). By contributing to the work of the OECD IUCLID User Group Expert Panel, ECHA ensured that specific requirements needed for the efficient implementation of REACH and the CLP Regulations were reflected in the development of IUCLID, whilst maintaining the harmonised format agreed at international level. ECHA has also produced several IUCLID plug-ins for registrants to ease their dossier preparation and submission. Of these, the technical completeness check (TCC) plug-in proved to be of significant practical value.

Table 17: Percentage of technical completeness check (TCC) failure

Dossier type	2009	2010	2011
On-site isolated intermediates	22	2	8
Transported isolated intermediates	29	3	10
Full registration	40	2	6
Process oriented research and development (PPORD)	4	2	0

Changes in the interpretation of the legislation that affected the registration process occurred relatively close to the 2010 registration deadline, requiring urgent changes to the IT systems which could have jeopardised the timely submission of the dossiers. Nevertheless at the request of industry, ECHA froze development of all IT systems needed for registration in advance of the first registration deadline, notably REACH-IT and IUCLID, to ensure that all users could be acquainted with the systems. The same approach is suggested for the next registration deadlines. It is also noteworthy, that the release of the IT systems for registration was accompanied by the simultaneous translation and publication of the related user manuals in 22 EU languages[3], increasing their accessibility.

ECHA will continue to invest in IT resources for the benefit of external and internal users and to ensure the efficiency of the Agency.

Considerably more resources than initially foreseen were necessary to ensure smooth registration in 2010. Consequently, work on other IT tools had to be reprioritised and postponed, and there is still substantial work to do. REACH-IT is currently being extended to cover all types of submission (e.g. applications for authorisation or reports and notifications from downstream users) as originally foreseen and will become the single point of entry or exit for incoming and outgoing data flow for REACH and CLP stakeholders. ECHA will continue to develop the registration tools and related user support mechanisms to be ready for registrants with a deadline in 2013 or 2018 (see sections 1 & 11).

In addition, an integrated view on all REACH and CLP processes and related data is needed to build coherent and consistent IT systems architecture. This will ensure the exchangeability of data between different processes and facilitate the access and extraction of relevant related data for supporting the tasks foreseen in the legislation such as substance evaluation by the Member States (MSs). ECHA is working on both short and medium term solutions to improve the accessibility of registration data for MS.

Generally, the development of bespoke IT applications and the key role that such applications play for the implementation of ECHA's processes has involved considerable effort in setting up

[3] *Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovakian, Slovenian, Spanish and Swedish*

suitable ICT infrastructure and operations that have to be maintained from the point of view of performance, security and business continuity. Human and budgetary resources allocated to IT will therefore remain high in the coming years to maintain and to further develop ECHA's information systems.

Databases have been established at ECHA for registered substances and CLP notifications. Measures are in place to enable MSCAs and enforcement authorities to access these data, but not all have been able to take advantage of this.

ECHA is handling confidential business information and it is therefore essential to ensure that proper security measures for access to data by national competent authorities and enforcement authorities were put in place and that the external actors commit to secure handling of the data. Whilst there has been an overall understanding and agreement on these aspects, the practical implementation of connecting MSCAs to REACH-IT has taken place at a pace somewhat slower than expected. Nevertheless by May 2011, 22 EU/EEA countries have access to REACH-IT.

A specific IT tool has been developed and is available to registrants to help prepare chemical safety reports.

In order to support the preparation of the chemical safety assessments (CSA) and reports (CSR) as required by REACH, ECHA took over the task of developing a tool designed for this specific purpose, Chesar. While the version containing the functionalities for full CSR production was published too late to benefit the 2010 registrants, it is believed, based on the positive feedback from industry, that the registrants of 2013 will extensively use the tool for their CSR preparation or for updating their existing registrations and CSRs. ECHA plans to create in advance of the next registration deadline a standard IT format for CSRs, to allow CSRs to have a database structure. This would greatly facilitate the analysis and utilisation of the CSR's in REACH implementation.

Table 18: Scientific IT Tools developed by ECHA for REACH and CLP

IT tools provided for industry to fulfil its obligations under REACH and CLP	REACH-IT for receiving submission for REACH and CLP and invoicing. IUCLID IUCLID plug-ins for Technical Completeness Check, fee calculation, dissemination, chemical safety report. CHESAR for preparing chemical safety reports. OECD QSAR Toolbox in support of alternative test methods. C&L notification tools: on-line notification tool embedded into REACH-IT, notification with IUCLID and a bulk XML tool for high volume submissions. SCBC system as backup in case REACH-IT would not be available.
IT Tools provided for the Agency to improve efficiency	REACH-IT for processing submissions and income management. IUCLID CASPER for prioritisation of dossiers for evaluation and reporting on substance, dossier and processes related information.

	ODYSSEY for supporting dossier evaluation. First phase of Enterprise Content Management system to manage the SVHC process and documents. QSAR Toolbox and other scientific applications for supporting computational methods in evaluation.
IT Tools for Member States	REACH-IT IUCLID Portal for enforcement authorities (RIPE) will be released in June 2011.
IT Tools for general public	Dissemination portal for publication of information on registered substances and C&L inventory. OECD eChemPortal for publication of information on substances from several publicly available databases outside the Agency.

11.3 Follow up

- Any instability in the interpretation of REACH is a challenge for IT development. Sufficient time and resources should be allocated to adapt or develop IT tools to any new or changed legal requirements. Furthermore, it is recommended that the registration IT tools are frozen at least six months before each deadline;
- Involvement of all relevant stakeholders in the development of IT tools is crucial, as it guarantees the best possible buy-in and maximises the usability of the tools;
- ECHA plans to create, in advance of the next registration deadline, a standard IT format for CSRs that allows CSRs and exposure scenarios to have a searchable database structure and will seek agreement from authorities and industry on this;
- ECHA needs to receive enough resources to further develop its IT tools so that they support all processes in the most efficient way, provide a secure access to data for competent authorities;
- An integrated view on all REACH and CLP processes and related data is needed to build a coherent and consistent IT systems architecture.

12 Scientific advice to EU institutions and bodies

12.1 Objectives of the legislation

The Agency shall provide the Member States and the institutions of the Community with the best possible scientific and technical advice on questions relating to chemicals.

Article 95 and 110 of REACH require the cooperation of the Agency with other relevant Community scientific bodies to ensure mutual support and to identify potential sources of conflict between scientific opinions.

12.2 Key messages

ECHA needs a stronger basis for preparatory work for new future activities.

ECHA is using all of its existing resources for the implementation of the REACH and CLP Regulations. However, concurrently the Commission has proposed new legislative tasks for ECHA, in particular related to biocides and the import and export of dangerous substances (Prior Informed Consent (PIC) procedure). While a new subsidy or new fee income may be applicable for the new tasks, there is currently not a sufficient basis for funding the necessary preparatory activities before the entry into force of the new legislation. These activities include the development of IT tools and work flows, guidance development and the recruitment of staff. For this purpose a specific subsidy should be granted to ECHA. Alternatively, a sufficiently long preparatory phase needs to be introduced into new legislative acts to allow preparations to be put in place after the finalisation of the legislation.

The role of ECHA in the area of development of test methods should be clarified.

In the REACH and CLP Regulations there is no specific role foreseen for ECHA for development and regulatory acceptance of test methods. The Commission has, however, asked ECHA to provide scientific and technical support in relation to the Organisation for Economic Cooperation and Development (OECD) Test Guidelines Programme. This is an important area that includes the development of alternatives to animal testing and is related to many other scientific and technical tasks of ECHA. ECHA therefore would appreciate a clear basis for using its resources for this work. In addition ECHA is following the work to develop alternatives to traditional animal studies with the focus on how such techniques can be used to provide adequate data for REACH and CLP.

ECHA is following the work of test method development at OECD level and in other areas, including the following:

- Endocrine disruptor definition, testing strategies and test methods;
- Nanomaterials definition, characterisation & modification of standard physico-chemical properties testing, toxicology studies, ecotoxicological & environmental fate studies as well as methods for assessing human and environmental exposure for nano materials;

- New OECD guidelines for hazard and risk assessment, notably extended one-generation reprotoxicity studies (EOGRTS) and the new *in vitro* eye irritation test which are relevant for harmonised classification according to the CLP Regulation.

The application of the REACH and CLP Regulations to substances that are nanomaterials should be clarified.

There are currently no specific provisions within the REACH and CLP Regulations for substances that are nanomaterials and, since they are not specifically exempted, the provisions of both implicitly apply to them. ECHA is currently analysing to what extent industry has included information about nanomaterials in their registration dossiers. While this work is ongoing, the preliminary understanding of ECHA is that it would be beneficial to more explicitly clarify how the registration and other obligations of REACH and CLP should be applied to substances in nanoform.

Cooperation with other EU risk assessment Committees and Panels is underway for the early identification and management of potential divergences of opinions of different Committees.

Article 95 and 110 of REACH require the cooperation of the Agency with other relevant Community scientific bodies to ensure mutual support and to identify potential sources of conflict between scientific opinions. Work is underway to put in place rules of procedure for cooperation between ECHA and the European Food Safety Authority (EFSA) and with the Advisory Committee on Safety, Hygiene and Health Protection at Work but this has been slow to be realised. The Commission is invited to consider legal clarification of the obligations of the bodies that ECHA has a legal obligation to cooperate with.

Once finalised, a mechanism will be put in place for the systematic exchange of information and methodologies between the EU bodies involved in risk assessment to ensure the early identification and management of potential divergences of opinions.

ECHA also follows the activities of other EU and worldwide scientific and regulatory bodies relevant to its work. This leads to in-house institutional knowledge and awareness and also professional development of its staff.

12.3 Follow up

- A mechanism needs to be developed that ensures additional specific resources are provided to ECHA when it needs to start preparatory activities related to new regulatory tasks. Alternatively, a sufficiently long preparatory phase needs to be introduced into new legislative acts to allow preparations to be put in place after the finalisation of the legislation;
- Resource allocation to ECHA should allow for a sufficient capacity of scientific knowledge to be built to enable advice to be given to questions and requests on science-related regulatory matters;
- The Commission is asked to consider clarifying the role of ECHA in relation to the development of test methods;
- There is a need to further clarify how REACH and CLP should be applied to chemical substances that are manufactured and used as nanomaterials;
- The Commission is invited to consider clarification of the obligations of the bodies that ECHA has a legal obligation to cooperate with to ensure a systematic exchange of

information and methodologies for the early identification and management of potential divergences of opinions.

13 The Committees and Forum

13.1 Objectives of the legislation

The Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) of the Agency should take over the previous role of certain scientific committees attached to the Commission in issuing scientific opinions in their field of competence.

RAC has the responsibility for considering proposals for harmonised classification and labelling (CLH); and both RAC and SEAC for considering proposals for restrictions, applications for authorisation and other questions relating to risks to human health or the environment. SEAC assesses the socio-economic impact of possible legislative actions on substances.

The Member State Committee (MSC) is required to reach agreement on specific issues including dossier and substance evaluation and the identification of substances to be included on the candidate list for eventual inclusion in Annex XIV.

The MSC should also give an opinion on the draft Community Rolling Action Plan (CoRAP) for substances which could constitute a risk to human health or the environment and on ECHA's draft recommendation of priority substances to be included in Annex XIV that would require authorisation.

REACH requires the Agency to provide a Forum for Member States to exchange information on enforcement and which coordinates a network of Member State Authorities which are responsible for the enforcement of chemicals legislation.

13.2 Key messages

The Committees and Forum have been successfully established and have become fully operational.

The Committees and the Forum are now fully operational with rules of procedure and working procedures for the REACH and CLP processes. Opinions and agreements to date have been adopted by consensus or unanimity. The range of expertise of Committee and Forum members is well balanced providing the necessary range of skills.

The Committees function in a transparent manner with the participation of stakeholder organisations.

Stakeholder organisations have played an active role in the work of the Committees. Currently each of the Committees has invited eligible stakeholder organisations representing different types of general interests (e.g. industry, trade unions, environmental and health non governmental organisations) to nominate a regular observer to follow and contribute to the work of the Committee. Their participation as observers has been positive and helps guarantee the credibility and transparency of the decision-making process. Nevertheless, the transparency of the Committees has to be balanced with the need to respect the confidential nature of some of their work and all stakeholders need to be encouraged to provide their contributions to the work of the Committees at the most appropriate time.

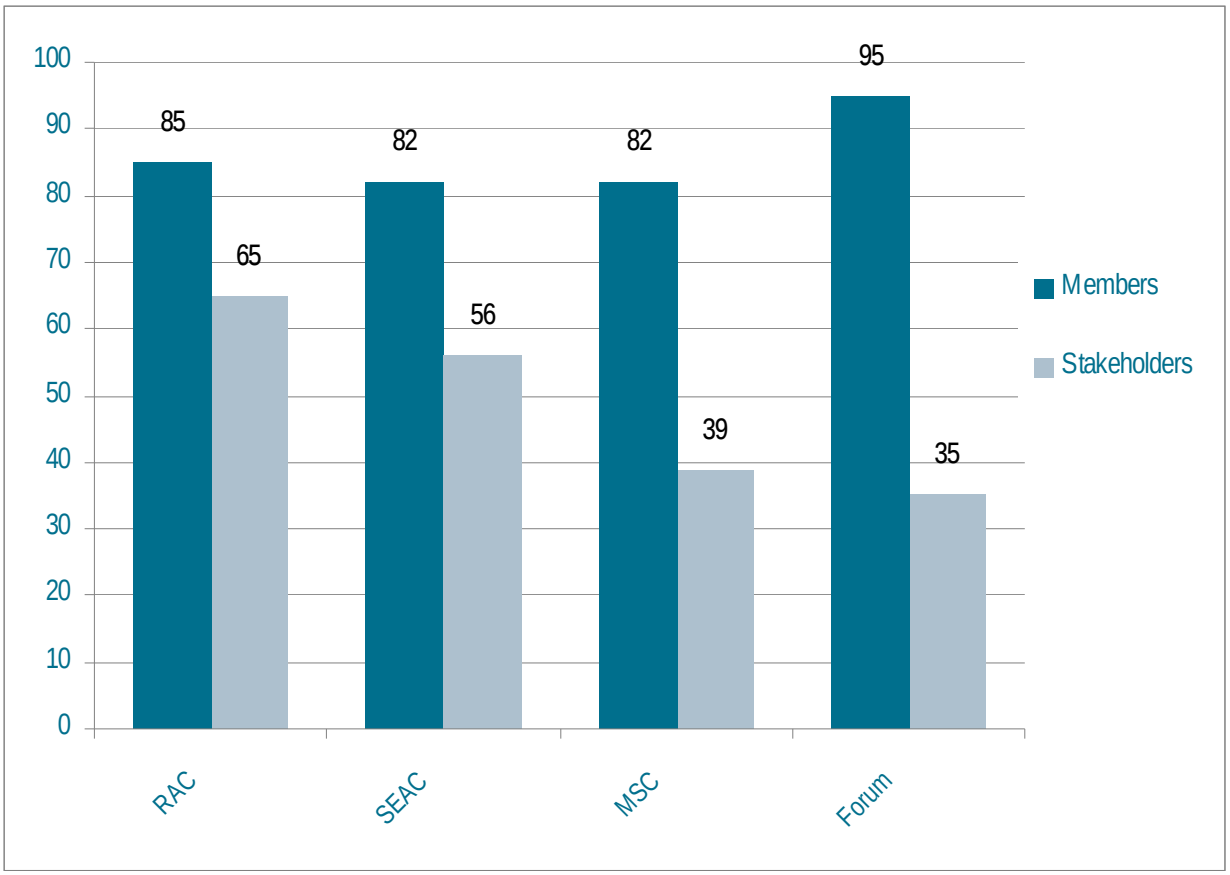

Figure 10: Participation rate in Committee and Forum meetings in 2010

The MSC has successfully taken up its role in achieving unanimous agreements in relation to evaluation and identifying SVHCs allowing ECHA to take final decisions efficiently.

So far the MSC has reached unanimous agreement in relation to evaluation draft decisions, compliance checks and identifying Substances of Very High Concern (SVHCs). As a consequence, there has not been a need to refer the decision making process to the Commission's comitology procedure which has allowed an efficient management of the process overall. At the same time evaluation decisions are becoming the main workload driver for the Member State Committee (MSC). In the evaluation process the draft decision prepared by ECHA is referred to the MSC for agreement if one or more Member State Competent Authority (MSCA) proposes amendments to the draft decision; this currently occurs in more than 75 % of cases.

While a considerable proportion of the proposed amendments are justified in the view of ECHA and may lead to improving the quality of the final decisions, there is also scope for increasing efficiency of the process. ECHA is already undertaking a series of measures e.g. to improve the communication with the MSCA regarding the rationale of the draft decision. At the same time MSCAs should focus their interventions to be in line with the scope and aim of the evaluation process and refrain from proposing amendments that for example address policy level questions, or aim to achieve perfect dossiers.

Efficient enforcement of REACH and CLP requires a common view and close cooperation between authorities

The Forum has established its work programmes for harmonising enforcement activities, set minimum requirements for inspections and Member States have carried out the first two jointly planned enforcement projects designed by the Forum. The Forum is carrying forward its work through a multitude of working groups which elaborate practical approaches to enforcement tasks in implementing the REACH and CLP Regulations, for example involving customs authorities etc. in the enforcement or detailed mapping of all interactions needed between ECHA, MSCAs and national enforcement authorities. In addition, the Forum is promoting a dialogue between MSCAs, the ECHA Secretariat and the Commission to facilitate common understanding on how to implement and enforce the REACH and CLP provisions in the most efficient way. Harmonising enforcement in the 30 countries applying REACH and CLP, against the background of divergent sovereign national implementing legislation and administrative practices, requires the Forum to identify topics of common benefit and constitutes a long-term task of this ECHA body.

The growing workload of the Committees and Forum is a cause for concern and the support for the members should be strengthened.

The workload of the Committees and Forum is constantly growing with the REACH and CLP processes running in parallel and feeding into the Committees and Forum. This is exacerbated by tight deadlines in some REACH processes. The deadlines for some REACH processes should be reviewed to ensure that sufficient time is allowed for Committees to function efficiently and produce high quality outputs (also see section 6).

The number of RAC and SEAC members remains significantly less than what is provided for as a maximum in the legislation and this is likely to remain in focus as the workload of the Committees increases. MSCAs are urged to nominate additional experts to allow the Management Board to appoint two members per nominating Member State for RAC and SEAC.

Given the increasing workload of Committee and Forum members it is imperative that members should have the full support of Member States to function effectively (Article 85(6) & Article 86(3)). This means members should be allowed sufficient time and provided with adequate scientific, technical and financial resources to carry out their work for the ECHA Committees and the Forum. Where necessary the legal powers provided to Forum members should also be reviewed to enable them to function effectively.

To further assist members, the efficiency of the Committees and Forum will continue to be strengthened by improving working practices, where possible.

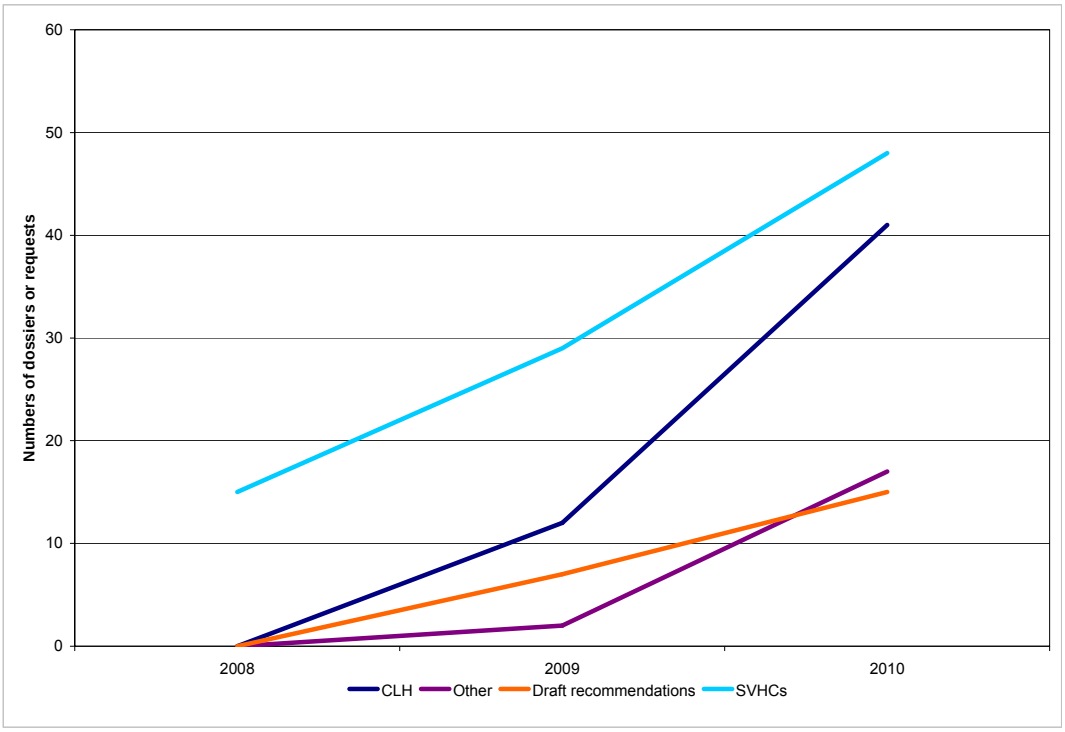

Figure 11: Committees and Forum cumulative input 2008-2010

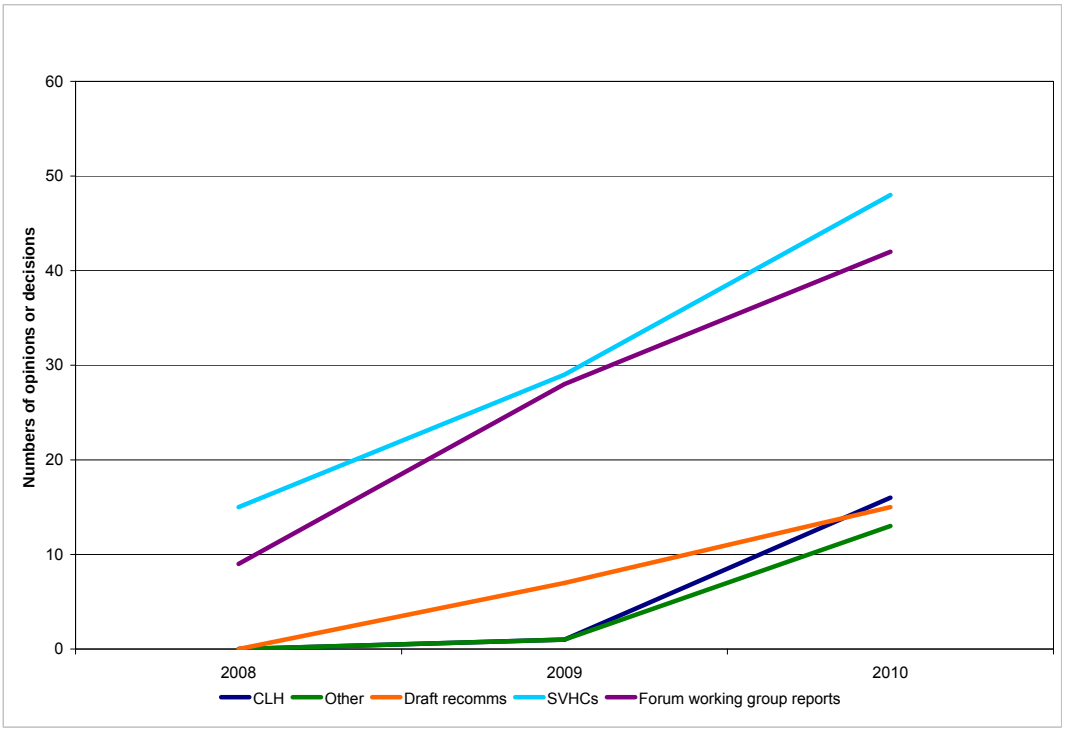

Figure 12: Committees and Forum cumulative output 2008 – 2010

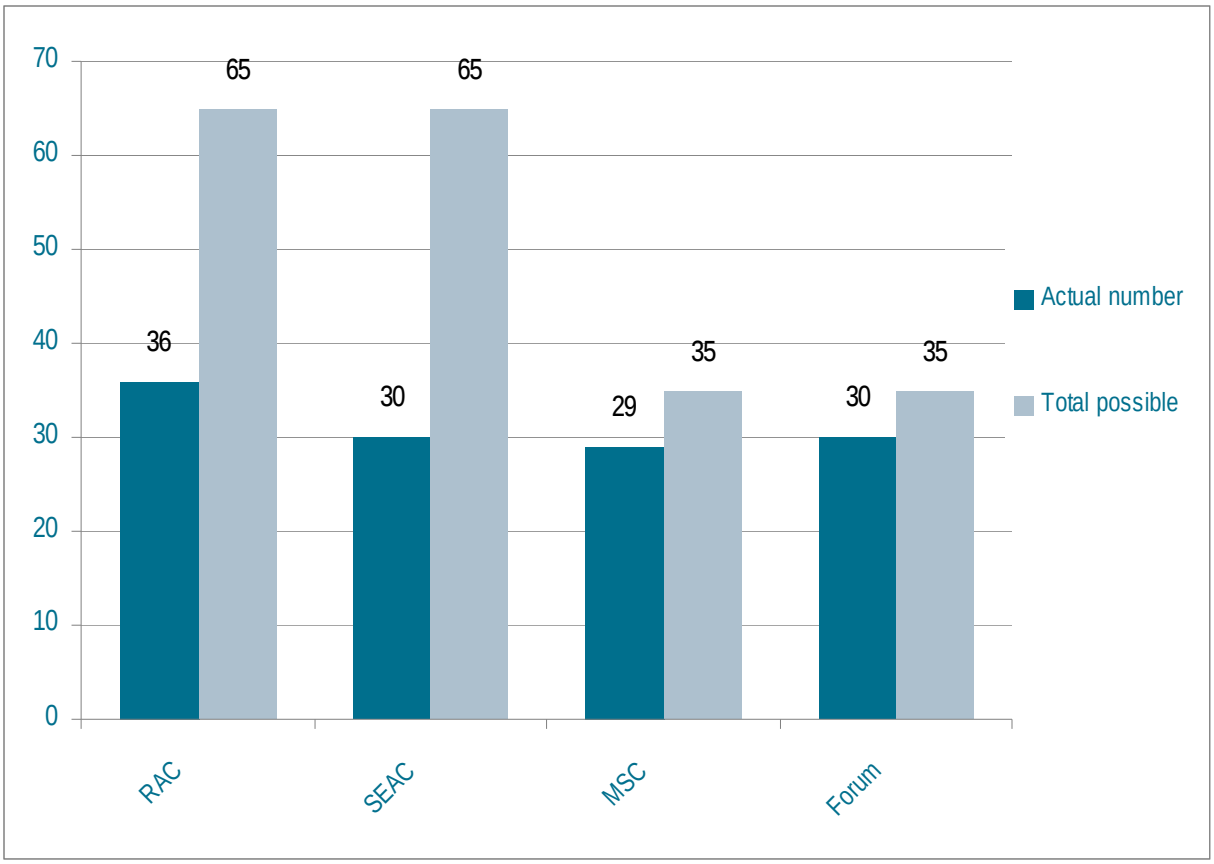

Figure 13: Committee and Forum members in 2010 compared to the total members allowed.

The quality of dossiers submitted by Member States could be further improved taking into account the experience thus far.

The quality of dossiers submitted by MSCAs could be further enhanced to facilitate the work of Committees to form high quality opinions or to find well justified agreements. This could be achieved by further dialogue between MSCAs and ECHA to improve the quality of dossiers in the light of experience. In turn this will assist members in their tasks for the Committees and Forum (see sections 5 & 7).

Appropriate measures should be introduced to enable RAC to cope with its future workload.

Despite the practical efforts described above to increase the efficiency of the work of the Committees, it is very likely that, particularly the Committee for Risk Assessment will face an unmanageable workload in the coming years. The magnitude of the workload will depend especially upon the number of authorisation applications which are foreseen to reach a level of 200-400 annually in 2013-2014. As there is still considerable uncertainty about these figures the best approach would be to enable ECHA, through a Management Board decision, to split the current RAC into two parallel committees. One of these could deal with proposals for harmonised classification and labelling (CLH), and the other with authorisation applications and restriction proposals (the same approach of enabling the split of a Committee is followed in the proposal for Biocides Regulation). In parallel, ECHA will explore all avenues to increase the efficiency of the Committee work through improved working practices within the current structure.

Another important change, requiring revision of the CLP and Fee Regulations, would be to enable remuneration for the work of the RAC rapporteurs of CLH proposals including CLH work on active substances of biocides and plant protection products. This would help to ensure appropriate support is provided for these numerous dossiers going through RAC and will help to maintain a sufficiently high level of interest for RAC members to act as rapporteurs for CLH proposals. This arrangement should distinguish between CLH proposals originating from REACH dossiers and those that cover active substances for biocides or plant protection products. The Regulations on pesticides and biocides should also foresee enough fee revenue to pay for RAC rapporteurships.

13.3 Follow up

- The deadlines for some REACH processes and the efficiency of the operation of the Committees and Forum should in due course be reviewed to ensure the Committees and Forum function effectively. MSCAs should nominate the permitted number of potential members that are allowed under REACH and ways to improve the support to Committee and Forum members should be explored by ECHA, MSCAs and the Commission;
- The quality of dossiers submitted by MSCAs should be improved by taking into account the experience gained with the dossiers submitted thus far;
- ECHA will, together with the MSCAs and the Committees look for ways to maximise the efficiency of the Committee procedures, and calls upon the MSCAs to increase their support for the Committee work to cope with the increasing workload;
- Structural changes to RAC should be considered, enabling it to respond to its increasing workload if other practical measures prove to be insufficient. This would include enabling the splitting of RAC when the workload so requires, and a change to the CLP and Fee Regulations to ensure the remuneration for the work of rapporteurs for CLH proposals that are based on registration dossiers. The regulations on pesticides and biocides should also foresee enough fee revenue to pay for RAC rapporteurships.

14 Board of Appeal

14.1 Objectives of the legislation

The Board of Appeal (BoA) is responsible for deciding on appeals lodged against certain decisions taken by ECHA. Decisions against which an appeal may be lodged include rejections of registrations, data sharing, examinations of testing proposals, compliance checks of registration dossiers, substance evaluations and exemptions from the general obligation to register for product and process orientated research and development (PPORD). BoA is an integral part of ECHA, but takes its decisions independently.

14.2 Key messages

BoA currently consists of a full-time Chair and two full-time members, who are not permitted to perform any duties in ECHA other than for BoA. Alternate and additional members have been appointed and can be called upon, on a part-time basis, to assist in BoA's decision-making (for instance, where a member would have a conflict of interest and/or where the number of cases so requires). The members of BoA are appointed by ECHA's Management Board on the basis of a list of candidates proposed by the European Commission. BoA is assisted in its functions by the Registry.

The number of appeals lodged before BoA depends upon the number of decisions taken by ECHA, and the subsequent decisions of affected parties to contest possible adverse ECHA decisions before BoA. Consequently, BoA cannot define its own workload but must address all the appeals brought before it.

The introduction of an internal appeal procedure serving as an additional source of legal redress has been well received by stakeholders.

Surveys undertaken by ECHA during its contact with stakeholders have shown that there is a high awareness of the possibility to submit an appeal and the related procedure. Industry appreciates the existence of a specialised forum for legal redress, given the high significance ECHA decisions have for business on the one hand and the complexity of REACH on the other. However, it should be noted that due to the relatively low number of appeals received to date the appeal procedure has not yet realised its full potential.

The procedural rules succeed in reflecting BoA's special role as a forum for legal redress while, at the same time, still being part of the Agency that initially adopted the disputed decision.

The appeal procedure entails clear advantages for applicants compared to recourse to the court proceedings, including the suspensive effect of appeals and BoA's full authority to review and reform ECHA's initial decision. Moreover, there are further features that contribute to the user-friendliness of the procedure, such as quicker procedure than using the courts. In addition, extensive supporting guidance and formats etc. have been made available for appellants to use.

Experience is still limited, but the general workability of the procedure and its importance for the industry regulated by REACH has been demonstrated.

To date, procedural activities related to submitted appeals have been processed efficiently and within the specified time limits. Moreover, the important role that the BoA appeal procedure has in ensuring high quality decisions and the exercise of a good and sound administration was underlined by the first appeal cases, which led ECHA to rectify some of the appealed registration decisions. Appeals can also provide ECHA with valuable feedback on the clarity of its processes and communications.

Certain aspects of the appeal procedure should be improved in order to enhance its legal clarity and workability.

The possible rectification of a contested decision by the Executive Director (ED) should not be made subject to prior consultations with the Chairman of BoA.

There appears to be no added value in the current consultation process for the following reasons:

- Firstly, it is not clear whether the consultation covers solely the question on admissibility of the appeal or also the Chairman's preliminary opinion on whether the appeal is well-founded (for the majority of cases a careful judgement on the latter is unrealistic within the set time limits). The Chairman should not give any opinion on any of these questions before BoA has adopted its decision on the appeal. In fact, a preliminary opinion on these questions could be seen as prejudging BoA's final decisions and thus interfering with the collegial and independent decision-making procedure of the BoA;
- Secondly, the timelines for the Chairman of BoA to decide on manifest inadmissibility and for the ED to decide on possible rectification of a decision by ECHA are in both cases 30 days after the filing of the appeal, although the processes are partially sequential. This potentially impedes the practicability of the consultation process.

Moreover, the two month timeline for defence runs from the date of service of the appeal, i.e. also in parallel with the deadline for checking admissibility and assessing the possibility of rectification. This is not the case with appeals in other Agencies. Reference is made to Articles 67 *et seq*. of Regulation (EC) 2100/94 on Community Plant Variety Rights, Article 61 of Council Regulation (EC) 207/2009 on the Community trade mark and Article 38 of Council Regulation (EC) 1592/2002 (EASA), where an appeal is only remitted to BoA if no prior rectification occurred.

It is therefore proposed that the provisions governing ECHA's rectification should be similar to those granted to other Agencies. In particular, the Agency should be provided with one month to decide whether or not to rectify the decision or to remit the case to the BoA. The two month period to submit a defence would only start once the case has been remitted to the BoA.

Table 19: Overview of BoA activities and Member appointments (2007-2011)

	2007	2008	2009	2010	2011 (Q1)
Number of appeals finalised on basis of rectification of ECHA decision by ECHA Executive Director	n.a.*	0	1	0	2
Number of appeals concluded before consultation by ECHA Executive Director because of manifest inadmissibility	n.a.*	0	0	0	0
Number of written requests for information on appeals	0	0	5	1	6
Staffing (Numbers of regular / alternate and additional BoA members)	0	0/3	3/8	3/11	2/11

**The REACH Titles subject to appeal did not enter into force before 1 June 2008; therefore it was legally impossible to file an appeal in 2007*

14.3 Follow up

- The Executive Director's right to rectify a decision should not be made subject to any consultations with the Chairman of BoA;
- The procedures of rectification and appeal should be clearly separated;
- The time period for defence should only start running after the Agency has, within 30 days, assessed the possibility to rectify the decision and thereafter remitted the case to the Board of Appeal;
- If the Fee Regulation is modified, account should be taken of the revenue from appeal fees compared to the cost of the Board of Appeal so that a desired degree of self-financing is achieved.

15 Communications

15.1 Objectives of the legislation

Communicating to stakeholders and the general public on the activities of the Agency is an inherent element of managing the legislation under the mandate of Article 75 of REACH as well as the various provisions that assign CLP-related tasks to the Agency. This communication spreads information on ECHA's implementation of the Regulations and also serves to enhance the reputation of the Agency.

More specifically, one of the key tasks of the Agency is to ensure that the decision-making processes in implementing REACH and the CLP legislation and the scientific basis underlying it are credible for all stakeholders and the public.

Various articles in the regulations require the Agency to publish guidance, tools, opinions, decisions, public consultations and information on chemicals and its ongoing work on the website. The Agency follows a translation practice of making a large part of these publications available in 22 official EU languages[4]. In this regard, the legislation determines that ECHA shall use the Translation Centre of the bodies of the European Union for its translation needs.

The Agency is required to provide guidance and coordination to stakeholders including Member State Competent Authorities (MSCAs) on communication to the public on the risks and safe use of chemicals (Article 77(2)(g),(h) and (i) of REACH). The legislation also foresees a role for stakeholders in working with the Agency to promote transparency and understanding of the rigour with which decisions about substances are taken and guidance and other tools are developed.

15.2 Key messages

For REACH to be a success, communication is essential

The REACH regulation fundamentally changed the way the safe use of chemicals is managed in Europe. All these changes have greatly increased the number of companies that need to know, understand and comply with the regulation compared to the pre-REACH era. Many of them are companies far beyond the chemicals sector, including small and medium-sized enterprises.

The greatest challenge for ECHA has been to reach all those companies who need to know. The Agency has been addressing this challenge by publishing information promptly and distributing it via the Internet, organising awareness raising campaigns and regular events and having a proactive relationship with the media.

The Agency publishes a series of publications to meet the needs of different audiences.

[4] Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovakian, Slovenian, Spanish and Swedish

Table 20: The number of publications (2007 – 2011)

Publications	2007	2008	2009	2010	2011 Q1
Administrative	2	3	3	3	1
Guidance	9	39	6	14	6
IT manuals	1	10	3	15	4
Practical guides	0	1	-	10	1
Fact sheets	0	8	10	5	3
Q&A / FAQ	1	4	4	9	1
Reports	0	0	3	5	2
Leaflets	2**	10	7**	9*	2
Total	15	75	36	70	19

** One in cooperation with the Commission. ** Two in cooperation with the Commission.*

The number of publications has increased from 15 in 2007 to 70 in 2010 and this trend is set to continue in 2011. Ten percent of the publications are updates of previously published guidance documents or IT manuals.

To address the needs of companies, the Agency has also organised awareness raising in cooperation with the Commission, stakeholders and Member States: highlighting the importance of pre-registering on time; SIEF formation; and the need to register and notify in time.

Reaching hundreds of thousands of companies requires the best use of modern technology and imaginative, collaborative communication

The ECHA website is a one-stop-shop for all the information the Agency publishes. The site is regularly updated and it has grown from an initial 40 pages to 500. Most of them are available in 22 languages.

Since the early months of its creation in 2007, traffic to the Agency's website has increased from around 35,000 visits a month to 270,000 a month. The highest number of visits, just below half a million, was recorded during the last weeks before the pre-registration deadline in 2008.

People visiting the ECHA website are located in more than 200 countries around the world. The ten most active countries (Germany, France, UK, Japan, USA, Italy, Belgium, Finland, China and Spain) each generate around 100,000 visits a year. The ten most visited pages include the Candidate list of Substances of Very High Concern (SVHCs), the list of pre-registered substances and information on registered substances.

Making information available in 22 languages is a demanding task

Since ECHA's establishment in 2007, the Agency has translated a great deal of material. In total almost 6,000 pages of technical/regulatory content is available in 22 languages to ensure that language barriers do not prevent companies from complying with the new requirements. This work involves two types of challenge. Firstly, the terminology of the new chemicals legislation, in addition to being highly technical, has been partly created during the legislative process and thus is difficult to translate. Secondly, it has been difficult to produce 22 language versions of the required material in line with the very ambitious timelines the new regulation has introduced.

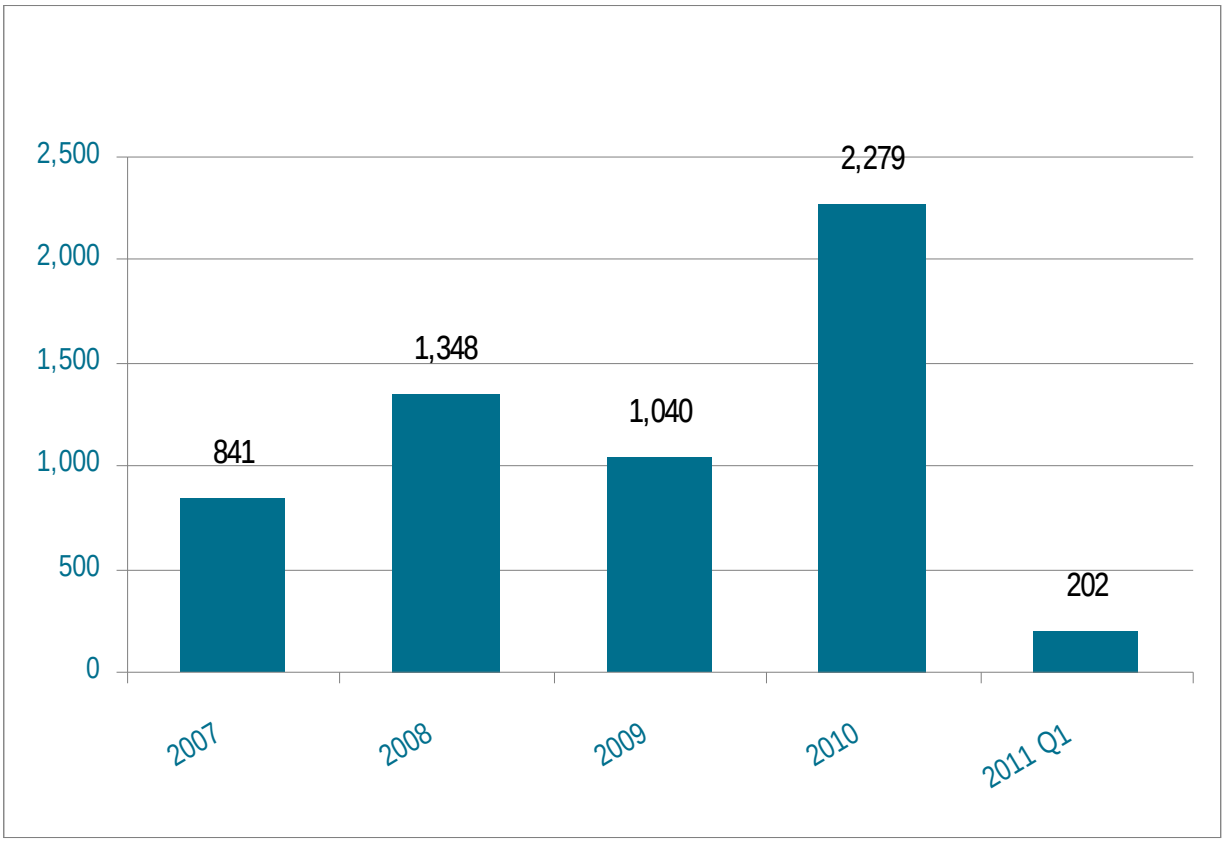

Figure 14: The number of pages translated

The most considerable challenge to ECHA in making translations available has been to ensure their quality – in terms of completeness and correctness. To this end, general and/or short texts undergo in-house validation within the Agency. For more demanding guidance documents, this has not proved feasible as knowledgeable in-house personnel - native speakers of the 21 additional EU languages - have limited time to engage in the proofreading and validation of long documents. Therefore, ECHA has outsourced the validation of guidance documents to MSCAs. Twelve countries[5] have volunteered to do this work on selected documents.

In addition to the validation of translations, ECHA has conducted a terminology project to enhance consistency in the use of REACH and CLP terminology by translators. The terminology database that is the outcome of the project was launched to the public in April 2011. It consists of almost 1,000 terms and definitions in 22 languages and is expected not only to facilitate the work of translators but also help any stakeholder who needs the terminology in more than one EU language.

Building strong proactive relationships with the key media facilitates balanced and accurate coverage of the REACH and CLP implementation.

The Agency works with the media to actively promote information on updates of guidance and tools that are critical to industry as well as information that is of importance to help them to comply with the legislation (see table below). It has been publishing press releases and accepting interview requests since its early days and has progressively added other media

[5] Bulgaria, Cyprus, Estonia, Finland, France, Hungary, Italy, Latvia, Lithuania, Poland, Slovenia and Spain

services. The number and location of news subscribers clearly shows the worldwide interest in EU chemicals legislation. The current 13,000 readers of ECHA's news are located in over 100 countries and we know from our use of statistics that many of the recipients of our e-News distribute it further to their colleagues, making the number of readers much larger than the mailing list.

The bimonthly ECHA Newsletter has been published since July 2008. It aims to support the strategy and objectives of the Agency, by informing companies about their responsibilities and the services and tools that are available to support them. The Newsletter is written in an easy to understand language and thus serves also the media and general audiences in their search for information on REACH and CLP implementation.

Table 21: The number of general enquiries and media services provided (2007 – 2011)

Activity	2007	2008	2009	2010	2011 Q1
General enquiries	388	1 620	1 821	2 600	462
Press enquiries	195	1 401	1 251	2 979	622
Interviews	20	50	70	67	20
Press Events	2	0	0	5	0
Press Releases	6	59	17	29	7
News Alerts	0	0	37	82	12
Newsletters	0	6	6	6	1
e-News	0	0	0	38	13
Subscribers of news	0	4 713	8 851	12 000	13 000

Cooperation with stakeholders improves transparency and ensures that all salient views are considered in decision making.

Stakeholders are important to ECHA. Our work is closely followed by our key stakeholders. Over 100 organisations have indicated their interest in working closely with ECHA. Over 50 EU level organisations fulfilling ECHA's eligibility criteria have been accepted as Accredited Stakeholder Organisations and can be invited to participate in ECHA's work. The Agency involves many of these organisations in its Committee work and in the work of the Forum, HelpNet, Risk Communication Network and Project Expert Groups. In addition, ECHA welcomes all stakeholders to Stakeholder Days, workshops and webinars in order for them to be informed about upcoming issues. These events form the most visible stakeholder activity, and the one with the highest number of participants.

Table 22: An 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)	0	800	1 400	1 700	800*
One-to-one sessions	0	0	0	2	1
Number of participants	0	0	0	140	100*
Workshops in Brussels	0	1	1	0	1
Number of participants	0	25	25	0	25 - 35*
Webinars	0	0	3	14	0
Number of viewings	0	0	6 200	7 000	0
ECHA speakers in external events	20	100	90	90	80*

** Expected*

In addition to providing a forum for dialogue and finding synergies through joint initiatives, the Agency has worked together with some of the Official Stakeholder Organisations and EU Agencies in reaching out to larger difficult-to-reach audiences. For example, in 2010, the Agency worked together with European Trade Union Confederation (ETUC) and the European Agency for Safety and Health at work (EU-OSHA) to raise awareness of the first registration deadline and the classification and labelling (CLP) deadline. Through this partnership the Agency was able to reach tens of thousands of companies.

Consistent communication about the risks and safe use of substances across Europe is essential if consumers are to believe the advice that they receive

The main role for the Agency in the communication of risks and the safe use of chemicals at national level is to provide guidance to individual member states so that different approaches and unilateral statements about the risks posed by individual substances can be minimised.

The Agency established in 2008 a voluntary Risk Communication Network. The first task for the network was to assist the Agency in the development of the risk communication guidance, in particular with a view to ensuring its workability. The guidance was published in 2010 and since then the network has been following and contributing to the communication study required by the CLP regulation. The study, which will be submitted to the EU Commission early in 2012, will provide recommendations to further improve the CLP Regulation regarding the communication of hazardous chemicals to the general public. In addition, the document will provide tools and methodologies for MSCAs and other stakeholders on how to enhance the comprehension of pictograms, hazard communication elements and of labels to the general public.

15.3 Follow up

- ECHA will continue to support companies by providing them with information and tools (often in 22 languages), to help them to comply with their legal requirements;
- ECHA will continue to make best use of modern technology – launching a new and more user friendly website, providing more webinar style learning opportunities and starting to make use of the possibilities of social media where appropriate;
- Member States are encouraged to work with ECHA to help companies by validating and ensuring the accuracy of REACH and CLP documents that ECHA makes available in 22 EU languages;
- ECHA will further develop its proactive media work, reaching out to sectors of the media that speak to downstream users of chemicals for example;
- Stakeholders are encouraged to work with ECHA – by becoming accredited stakeholders, participating in pubic consultations and attending webinars, workshops and Stakeholders' Days;
- Member States are encouraged to work with ECHA in the Risk Communication Network. The coordination of communication on the risks of chemicals is essential in terms of the trust that consumers will have in REACH, CLP and the Authorities that implement them.

16 International co-operation

16.1 Objectives of the legislation

As an EU regulatory Agency, ECHA has a public profile in a globalised world which makes communication with third-country counterparts and audiences an inherent part of its mandate of managing the implementation of REACH and CLP (Article 75 of REACH). Partly, such activities are also covered by the EU's external relations and supported through respective financial instruments (in the case of ECHA, the Instrument for Pre-Accession, (IPA)) under relevant external policy provisions.

More specifically, the Agency's establishing Regulation stipulates that ECHA shall support the Commission by providing technical and scientific support in international cooperation (Article 77(2)(l) of REACH) whilst Articles 106 and 107 regulate the potential for third countries and international organisations to participate in the work of the Agency, and Article 120 opens avenues for the Agency to cooperate with them and share workload in assessment of dossiers submitted to different authorities around the globe.

16.2 Key messages

ECHA also handles international activities, by establishing bilateral contacts with stakeholders and peers, cooperation in OECD activities, as well as in supporting the Commission in its cooperation with multilateral organisations and conventions.

As an EU Agency, ECHA is currently developing its external relations with the objective of continuing to raise its international reputation as well as the global standing of the REACH and CLP Regulations.

ECHA has started its international activities, mainly in five fields: supporting the Commission in its cooperation with multilateral organisations and conventions; participating in OECD activities; establishing peer contacts with selected regulatory counterparts; supporting candidate and potential candidate countries; and disseminating information on the implementation of REACH and CLP as well as the work of ECHA by attending events in third countries, particularly in non-EU OECD countries and the EU's main trading partners.

ECHA's international cooperation is outlined by the Management Board which adopts annual work plans for international activities after agreement with the Commission. The annual work plans allow the Commission to formally ask for ECHA's support, particularly in multilateral fora established by international chemical safety conventions whenever ECHA's scientific expertise is needed.

Within the limits of its available resources, this basis has enabled ECHA to create an international identity which needs to be further strengthened to support the global outreach of the REACH and CLP Regulations.

ECHA has been expanding its bilateral technical working relations with selected peer regulators to exchange experience and knowledge in the area of chemicals management. During 2010, ECHA concluded a memorandum of understanding (MoU) with Environment and Health Canada

as well as a statement of intent with two parts of the US Environmental Protection Agency (EPA). Such bilateral working arrangements are also being pursued with other OECD countries, namely Australia and Japan. ECHA's maintenance of peer contacts with regulatory authorities of selected third countries is of importance for future ECHA work to avoid duplicating technical regulatory work as much as possible and thus improving the efficiency of the evaluation of chemicals worldwide.

Further reaching agreements for the exchange of non-public confidential business information (CBI) may be needed in the future with selected third countries, but this falls within the Commission's remit. The Commission is invited to consider initiating negotiations to conclude agreements on the exchange of confidential information on chemical substances subject to REACH processes with selected third countries in accordance with Article 120 of REACH. This would ultimately permit ECHA to partly or fully rely on assessment work done by others and thus share the regulatory burden.

ECHA has coordinated the further development of the International Uniform Chemical Information Database (IUCLID) with OECD to ensure maximum harmonisation and re-use of data across regulatory programmes worldwide as well as promoted its use by industry, MSCAs and other international authorities.

Moreover, ECHA collaborates closely with the OECD on two large projects: the eChemPortal (global portal to information on chemical substances) and the QSAR Application Toolbox by funding their development and by taking over the hosting of eChemPortal. The Portal now provides free public access to information on chemical substances, including those published on the ECHA website (see section 3). This is a significant contribution to the EU Community long-standing commitment to identify and make information on chemical properties available to the citizens. Other OECD-related activities in which ECHA is involved include contributing to the work of the Task Force on Hazard Assessment, including the SIDS-programme (screening information data set), the Test Guidelines Programme, the Working Party on Manufactured Nanomaterials, and the Task Force on Exposure Assessment.

Given the increasingly tangible global outreach of REACH and of other EU chemicals legislation, ECHA's collaboration with third countries will figure ever-more importantly.

ECHA also receives financial resources from the EU Instrument for Pre-accession Assistance (IPA) for training candidate and potential candidate countries in how they may work with the ECHA Committees and Forum. The success of this programme in the future will depend on the resources that can be set aside for its organisation and implementation.

The Management Board has adopted a general approach regarding the participation of third countries in the work of the Agency.

The Management Board has adopted a general approach that relations with third countries on a path towards aligning with the EU chemicals acquis, should be gradually intensified, according to their progress in actual alignment. So far, no third country has reached such a state of alignment to the chemicals acquis that their participation has been in line with this general approach. However, after concluding its respective Accession negotiations, Croatia will become increasingly involved in ECHA's work, depending on respective transitional arrangements.

16.3 Follow up

- Through the annual work plan on international activities, the Commission should support the Management Board in further empowering ECHA's autonomy to undertake technical collaboration with third country peer organisations and to disseminate information on REACH and CLP;
- The Commission is invited to consider initiating negotiations to conclude agreements on the exchange of confidential information on chemical substances subject to REACH processes with selected third countries in accordance with Article 120 of REACH. This would ultimately permit ECHA to partly or fully rely on assessment work done by others and thus share the regulatory burden;
- It should be recognised that the know-how and IT tools developed by ECHA contribute to spreading the "REACH" standard to the rest of the world. Helping third countries to apply this know-how and tools requires resources.

17 The operation of the Agency

17.1 Objectives of the legislation

The structure of the Agency should be suitable for its required tasks and the Agency should have the means to perform all the tasks required to carry out its role.

17.2 Key messages

The Agency has been successfully established and is fully operational.

The Agency was successfully established in 2007 and within one year became operational. The set up of ECHA has been pointed to as a model for other EU Agencies and bodies. This success has been founded upon the prior planning and provision of expert seconded staff by the Commission.

In addition, the support provided by the Finnish Authorities and the City of Helsinki has been exemplary and has underpinned the successful start up of the Agency and the comfortable relocation and integration of staff in Helsinki.

The Management Board has been successfully established and is functioning well.

The Management Board (MB) has been successfully established and is functioning well. Since its first meeting in 2007, the Board has fulfilled all its statutory obligations in a timely manner, including the establishment of a Board of Appeal (BoA). Moreover, the Board has provided strategic direction to the Agency on important matters, such as the security requirements for the access of Member State Competent Authorities (MSCAs) to the REACH databases, the modalities for fee transfers to Member States, the management of the Agency's cash reserve and in relation to contingency planning for the first registration deadline. Since its first meeting in 2007, the Management Board has met 22 times. Several standing working groups have been established to prepare and follow-up important decisions, including audit matters, planning and reporting and fee transfer.

The composition of the MB with representatives from all Member States (MSs) is important for the implementation of REACH. The appointment process for these members involves the Council and Parliament and this makes the process fairly slow, but at the same time brings significant stability and commitment from the members of the MB.

A higher than expected workload has been experienced or higher resources needed due to unforeseen issues.

During the design of the Agency, the Commission carried out thorough and valuable planning work for the different operational tasks of the Agency. In many respects this planning has proven to be accurate and facilitated the resource programming for the Agency. However, certain tasks could not be anticipated or were under-estimated in terms of resource needs. Some examples are highlighted below.

Issues relating to confidentiality of data and access to information held by the Agency have caused an unexpectedly heavy work load. This has been exacerbated due to the complexity of

decision-making for some requests according to the Access to Documents Regulation, especially requests regarding the technical dossiers submitted by registrants to ECHA. Establishing the security modalities for the access of MSCAs to REACH data has been an equally resource-intensive process to establish and administer.

The pre-registration of much higher than expected numbers of substances in 2008 led to a correspondingly larger work load than anticipated and had the knock on effect that contingency plans were put in place for significantly larger numbers of registrations at the first deadline than were actually needed. In addition, in several areas the original planning underestimated the actual resource needs, including the resources needed for planning and starting up of new REACH and CLP processes; the complexity and time needed for substance identification aspects; and the financial resources needed for IT infrastructure.

It is also noteworthy that as well as sufficient resources for the Agency, concurrently it is also important that Member States provide sufficient resources to the MSCAs for REACH and CLP purposes. In the absence of such resources the MSCA's will not be able to contribute to the implementation of the legislation in an appropriate way, and this will have a knock on effect for ECHA to carry out its functions. This is especially critical in areas where the Member States have the right of initiative (restriction proposals, SVHC identification, CLH proposals), conduct the main part of the work (substance evaluation) and provide a contribution to the work of ECHA Committees.

ECHA needs to be guaranteed financing for its operations.

It is essential that sufficient and predictable financial resources are available for ECHA to carry out its operations. The initial years of functioning of the Agency were mainly funded through a subsidy from the Union budget. 2010 was a transition year and substantial income was expected to come from registration fees. In practice however, this income was actually received towards the end of the budgetary year. Both the timing of the fee income as well as uncertainty of the total volume, constituted a challenge in the resource management of the Agency. The operations of ECHA could only be assured through an exceptional and reimbursable subsidy granted to ECHA by the Budgetary Authority.

The unpredictability of the fee income in terms of volume and timing represent a significant structural challenge to an Agency such as ECHA. For example there is a high uncertainty around the revenue that can be predicted from authorisation applications for substances that may be phased out by early substitution following their inclusion in the Candidate or Authorisation Lists. The annual institutional budgetary cycle only allows ECHA a short term financial prospect. This is compounded by the financial mechanisms (e.g. balancing subsidy) offering little flexibility for fee earning agencies. This results in possible contractual uncertainties, hampers capacity building and results in limitations to longer term activity planning. In this context it could be relevant to review the Fee Regulation to better align the fee income with the actual dossier processing costs and thus more closely accommodate the budgetary requirements of the Agency.

ECHA has been working closely with MSCAs as well as with other capacities in the field of chemicals. Over the years several circumstances have been observed and situations identified where cooperation and joint works with Member States capacities could be more extensively fostered. Further it is recognised that ECHA could rely more on Member States capacities for the implementation of its work Programme. Given that public procurement is the main instrument that ECHA currently possesses, it has been used in some cases to establish a contract of cooperation between ECHA and the Member States. If ECHA were equipped with

the instrument to establish grants, more extensive cooperation with and contributions to ECHA's work could be established.

These issues could be considered in the context of the revision of financial instruments and in the interinstitutional discussion on Agencies that is currently taking place.

The recruitment of adequate numbers of qualified technical and scientific staff has been a specific challenge to the Agency.

The set up of ECHA has been a success largely as a result of the dedicated and hard work of ECHA staff. Nevertheless it should be noted that the Agency has been particularly challenged in recruiting suitably qualified staff to relocate to Helsinki as well as with the speed of recruitment that was required.

As a result, and given the (pre-) registration and other demanding deadlines in the REACH regulation, the staff of the Agency has been under exceptionally high pressure of work in the start up phase. In 2010 a survey was carried out by medical experts on the stress levels of ECHA staff and a significant number of staff had levels of stress that were a cause of concern.

The initial staff model envisaged for ECHA has given a good basis and orientation for the building up of the staffing capacities for ECHA. However, it turned out that several processes and activities stemming from the legal requirements, were not foreseen in the model. It is therefore envisaged to revisit the initial model and the assumptions made at the start up phase and to reassess the human resources needs in a longer term perspective. It is hoped that these requirements are taken up by the institutions in the context of the development of the financial framework 2014-2020.

Table 23: Number of staff working at the Agency

	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

ECHA is strengthening its procedures for avoiding conflicts of interest

Since the start-up of the Agency, ECHA has had a system in place for identifying any interests that could potentially present a conflict for its staff, the members of its Management Board, the members of the Committees as well as their advisers and invited experts. For instance, the first decision signed by the Interim Executive Director in 2007 concerned guidance and templates for declaring potential conflict if interests for the incoming Agency staff. In view of experiences gained by other agencies, ECHA started in 2011 to give a higher visibility to these efforts and is now revising and where necessary improving the existing practices.

Co-ordination of staff and horizontal activities within the Agency was more challenging than originally anticipated.

As the Agency has grown in size a number of horizontal activities have been necessary to ensure it is a credible, transparent and independent Agency. These have included putting in place an internal governance approach that includes a quality assurance scheme; guaranteeing the security of the information ECHA handles in large quantities; managing and protecting ECHA's intellectual property; maintaining effective relations with other institutions and the

Member States (MSs); and maintaining a transparent approach in dealing with stakeholders. This aspect was underestimated in the original resource planning for the Agency.

To ensure these horizontal activities are carried out in a coherent manner an Executive Office has been established to co-ordinate the corporate activities of the Agency and activities related to the Executive Director (ED). In addition, several staff have been recruited or re-deployed to horizontal, co-ordinating activities. Nevertheless this aspect needs further enhancing to ensure the continued success and coherence of the work of the Agency.

The Agency was restructured in January 2011 to enable effective management of the higher staff numbers. The organisational structure reflects the REACH & CLP processes in terms of the business operations but also facilitates horizontal activities. To complement this several horizontal mechanisms have been put in place to ensure a consistent approach is taken across the growing organisation: these include the 'Director's Coordination Meeting' and several topic-specific Boards of Directors, such as the 'Business Programme Board' and the 'Directors IT Board'.

17.3 Follow up

- The predicted workload at ECHA will continue to increase and therefore renewed efforts will be made to seek suitably qualified staff and to ensure the existing staff have a rewarding career at ECHA;
- ECHA will continue to closely monitor and, where necessary, revise the staff and resource estimates for its activities;
- Sufficient resources are needed to ensure the continued success and coherence of the work of the Agency, including staff in a horizontal function;
- When reviewing the Fee Regulation or establishing a new one, the Commission should cooperate with ECHA and the Member States so that sufficient coverage of all regulatory resources needed to undertake all processes for which no subsidy is assumed to arrive will be available.

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