# TECHNICAL ASSISTANCE TO PREPARE THE COMMISSION REPORT ON THE OPERATION OF REACH
# 070307/2010/584820/SER/D3

# Final Report

**Prepared for**

## European Commission
## DG Environment

RPA

Ökopol

**March 2012**

# Technical Assistance to Prepare the Commission Report on the Operation of REACH:

# Final Report

## March 2012

prepared for

European Commission DG Environment

by

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# EXECUTIVE SUMMARY

## 1. BACKGROUND

REACH[1] was designed to address weaknesses identified in the chemicals policy, in the context of achieving *sustainable development in the chemicals industry within the framework of the Single Market*. The overall objectives that REACH was designed to address were:

- protection of human health and the environment;
- maintenance and enhancement of competiveness of the EU chemical industry;
- prevent fragmentation of the internal market;
- increased transparency (information on chemicals to consumers and across industry);
- integration with international efforts;
- promotion of non-animal testing; and
- conformity with EU international obligations under the WTO.

The four key elements in REACH are:

1. **Registration** (Title II) of substances manufactured or imported in amounts starting at 1 tonne per year (per manufacturer or importer);
1. **Evaluation** (Title VI) of which there are two types – dossier evaluation and substance evaluation;
2. **Authorisation** (Title VII) of substances of very high concern (SVHCs), aimed at ensure that risks from SVHCs are adequately controlled; and
3. **Restriction** (Title VIII) **a**imed at addressing risks not adequately controlled on a Community wide basis (including marketing and use restrictions applied under Directive 76/769).

## 2. STUDY CONTEXT

Article 117(4) of REACH states that:

*4. Every five years, the Commission shall publish a general report on:*
*a) The experiences acquired with the operation of this Regulation, including the information referred to in paragraph 1, 2 and 3; and*
*b) The amount and distribution of funding available by the Commission for the development and evaluation of alternative test methods.*

*The first report shall be published by 1 June 2012.*
This study was undertaken to support the Commission in meeting its reporting obligations under Article 117(4). The analysis undertaken was therefore based

[1] 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).

primarily upon the Article 117(1) reports provided to the Commission by Member States (MS) and the Article 117(2 & 3) reports provided to the Commission by the European Chemicals Agency (ECHA). Further information was provided by the Commission studies running in parallel to this study.

## 3. ORGANISATION

The **ECHA** was established on 1 June 2007 in accordance with REACH Article 75(1), became operational in 2008, and is structured as follows:

- **Management Board**: adopts and publishes ECHA rules, controls ECHA's budget. Also, appoints the Executive Director and ECHA Committee members;
- **Executive Director**: responsible for the overall management of ECHA;
- **Committee for Risk Assessment (RAC)**: provides opinions and evaluations on risks to human health or the environment;
- **Committee for Socio-economic Analysis (SEAC)**: provides opinions and evaluations on the socio-economic impact of possible legislative action on substances;
- **Member State Committee**: responsible for resolving divergences of opinion between ECHA and MS relating to Evaluation or SVHC identification;
- **Forum** for Exchange of Information on Enforcement (the Forum): Responsible for the co-ordination of MS REACH enforcement agencies;
- **Secretariat**: provides technical, scientific and administrative support; and
- **Board of Appeal**: decides appeals against ECHA's decisions.

All of the structures of ECHA have been established and would appear to be fulfilling their anticipated roles, overall, however not always on time. The ECHA committees RAC and SEAC are operating in a satisfactory manner. However, they do not as yet have their full complement of members, and there are concerns that they may not have the resources (i.e. members nominated by MS) needed for them to fulfil the future demands expected of them. Furthermore, ECHA believes that its resource needs were underestimated prior to its creation but recognises that it has been able to operate within agreed budgets, to date.

MS are each required to appoint at least one **Competent Authority** (CA) in accordance with Article 121 of REACH. These CAs are responsible for *performing the tasks allotted to competent authorities under this Regulation and for cooperating with the Commission and the Agency in the implementation of this Regulation.*

CAs are to cooperate and provide other CAs with *all the necessary and useful support to this end* and to inform the general public about risks associated with substances where this is necessary to protect to human health and the environment. CAs are also responsible for overseeing the enforcement of REACH, which is the responsibility of MS.
Each of the MS from the EU27 and the European Economic Area (EEA) (Norway, Iceland and Liechtenstein) have created at least one CA. However, the activities and

skill sets of different CAs vary greatly between MS, this includes the extent of the support offered by MS. Furthermore, it is not clear whether all MS are allocating adequate resources to their CA(s), as required under Article 85.

REACH places demands on **companies** throughout the chemical supply chain including substance manufacturers/importers, downstream users (including formulators of mixtures and articles manufacturers), distributors and retailers. Many companies, principally manufacturers and importers, have invested significant resources towards ensuring their compliance. In spite of the resources invested by companies they have not always submitted registration dossiers that fully comply with REACH. Furthermore, there are significant concerns regarding the current level of understanding of obligations under REACH, particularly by downstream users and SMEs.

**Box 1: Recommendations – Organisation**

- ECHA should clearly identify the costs of undertaking its activities (and expected future costs) and compare these with expectations and the current budget;
- the Commission should consider the findings of ECHA's review of its finances and make recommendations to ensure it has adequate funding for current and future activities;
- MS should review current resourcing for ECHA committees to ensure their adequate resourcing;
- MS should review current funding for CAs and ensure that funding is adequate for current and expected near-future activities;
- CAs should seek to share best practice and consider the sharing of expertise across MS boundaries; and
- renewed efforts should be made by ECHA and CAs to inform all actors of their obligations under REACH, especially downstream users and SMEs.

# 4. CO-ORDINATION, CO-OPERATION AND INFORMATION EXCHANGE

**ECHA** describes its internal organisation but details of internal co-ordination, co-operation and information exchange are not published; although measures have been taken to improve internal communication.

The Competent Authorities for REACH and CLP[2] (CARACAL) has been established as the principle body that brings together all **CAs** to facilitate cooperation between CAs, and between CAs and the Commission and ECHA. CARACAL is working effectively but with some MS providing more resources than others, however this in some cases is simply a reflection of the resources available to MS for their CA(s). Further formal interaction between ECHA and MS occurs within the ECHA committees, especially the MS Committee. However, MS are also responsible for recommending members to RAC and SEAC. There are also a range of other bodies designed to facilitate the co-ordination, co-operation, and information exchange relating to specific functions of REACH (e.g. the Forum, and the helpdesk

[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.

information exchange tool, 'HelpEx') but these are considered under the relevant function of REACH, e.g. the Forum is considered as part of the discussions on Enforcement.

ECHA, CAs and the **Commission**, are positive about the quality of their interactions overall, both formal and informal. The work of the committees was considered by CAs to be above average however numerous recommendations were also made for their improvement. ECHA and CAs are largely positive regarding their communication, etc. with the Commission, however, again specific recommendations for improvement are also made (see Box 2).

Co-ordination, co-operation and information exchange also occurs with **other stakeholders**. Primarily, ECHA disseminates registration information and guidance. However, other stakeholders can provide information to ECHA as part of official consultation exercises and industry representatives have access to the Directors Contact Group (DCG) created by ECHA for this purpose. Stakeholders are also involved as observers in many ECHA committees. ECHA also describes relevant activities with organisations outside of the EU such as the Organisation for Economic Co-operation and Development (OECD) and non-EU Countries (which may also act as observers at CARACAL meetings).

**Box 2: Recommendations – Co-ordination, Co-operation and Information Exchange**

**Committees (these recommendation are described in more detail in main report)**
- more careful drafting of agendas, to ensure a reasonable workload, efficient fulfilment of objectives and avoiding overlaps between committees;
- agenda setting should have greater member involvement;
- earlier circulation of documents, other materials for meetings and earlier setting of meeting dates;
- contact details should be kept up-to-date and contacts outside of meetings better facilitated;
- translation provisions should be improved;
- committees should include more training, sharing of information/best practice; and
- committees should facilitate the dissemination of information generated under REACH to EU authorities tasked with the implementation or enforcement of other EU legislation.

**Between CAs**
- ECHA and CAs should keep contact details up-to-date; and
- ECHA, the Commission and MS should consider how to improve the provision of translation services for informal CA communication.

**CAs and the Commission**
- the Commission should work with MS as partners in drawing up the contents and agendas for the meetings;
- CAs and other relevant MS bodies should be more involved in the preparation of Commission proposals; and
- more of the key documents should be translated into a wider range of EU languages (may facilitate greater participation by some MS).

**Other Stakeholders**
- improve communication between DCG, CARACAL and Forum by greater circulation of documents amongst these groups;
- greater effort should be taken in selecting suitable observers for committees such as CARACAL;
- further effort should be focused on co-operation with other stakeholders, particularly with regard to the provision of REACH support; and

- information generated under REACH and collated by ECHA should be made available to EU authorities tasked with the implementation or enforcement of other EU legislation.

# 5. OPERATION OF REACH: REGISTRATION

All substances manufactured or imported in quantities of 1 tonne or more per year per registrant have to be registered. Registration involves the submission of hazard and risk information to demonstrate the safe use of a substance. Registration requirements increase at the following thresholds: 10 tonnes, 100 tonnes, and 1,000 tonnes. The registration requirements entered into force on 1 June 2007, however registration is being phased in until 1 June 2018 for substances already on the market in the EU (existing substances). To qualify for the phase-in provisions companies had to pre-register their substances by 1 December 2008.

ECHA received 2.7 million **pre-registrations** with respect to 146,000 phase-in substances, including 41,000 substances without an EC number (18%). Also, 14,500 substances were submitted as multi-constituent substances. The number of pre-registrations was 15-times higher than had been estimated. The reason for the large number of pre-registrations is not fully identified but many companies appear to have uncertain about their obligations and thus they pre-registered substances just in case. Inaccurate pre-registrations have hampered the formation of Substance Information Exchange Fora (SIEFs) and made it difficult for ECHA to predict future workloads.

The first phase-in deadline of 1 December 2008 has now passed and all substances manufactured/imported in quantities equal to or greater than 1,000 tonnes should have been registered, as should all potential Substances of Very High Concern (SVHCs) with CMR/PBT/vPvB properties and non-phase-in substances subject to **registration**. According to the ECHA's Evaluation Report 2011 (ECHA, 2012), a total of 25,378 complete registration dossiers had been received by the end of 2011. This figure is less than the 26,000 plus registration dossiers for almost 5,000 substances reported in ECHA (2011a), however there is no information to challenge the statement made in ECHA (2011a) that 75% of dossiers came from just seven countries. The reason for this discrepancy in the number of dossiers is not explained. Provisions for joint submission appear to be working well with 90% of dossiers being submitted in this way, however problems were encountered due to the late submission of lead registrations.

The **costs** of preparing a registration dossier are reported to have varied widely, between a few thousand Euros to over one million Euros. It has not as yet been possible to robustly estimate the **benefits** from registration to industry, trade, human health and the environment.

**Box 3: Recommendations – Registration (see also Box 10)**

- ECHA should encourage pre-registrants to voluntarily remove or amend unnecessary or inaccurate pre-registrations (already implemented by ECHA);
- ECHA should improve its system for collecting information from registrants on reasons for not registering pre-registered substances (already being attempted by ECHA);
- ECHA should introduce incentives to promote the timely submission of lead dossiers and to raise the awareness of member registrants on the timing of dossier submission; and
- ECHA, the Commission and industry should seek ways to allow non-lead registrants to provide registrant specific data on granulometry and other physicochemical endpoints while remaining within a joint registration (important for the registration of nanomaterials). This may include the addition of safeguards to ensure that any hazard or risk assessment undertaken by the lead registrant is updated, as appropriate.

## 6. OPERATION OF REACH: INFORMATION IN THE SUPPLY CHAIN

An important intended function of REACH was to facilitate flow of chemical safety information up and down the supply chain. This is happening and the quality of the information going down the supply chain would seem to have improved since REACH came into force. However, downstream users have encountered difficulties communicating their uses up the supply chain to registrants and the new extended Safety Data Sheets (eSDS) used to communicate information down the supply chain are often unwieldy and do not always facilitate the easy transfer of safety information to downstream users.

**Box 4: Recommendations – Information in the Supply Chain (see also Box 10)**

- ECHA should publish best practice guidance on the communication of uses; and
- ECHA and/or the Commission should, in collaboration with industry, consider whether current guidance provides sufficient clarification of the legal requirements of downstream users and based on this assessment consider amending current guidance.

## 7. OPERATION OF REACH: AUTHORISATION AND RESTRICTION

Authorisation procedure is intended to progressively reduce the risks posed by SVHCs by ensuring that they are properly controlled and progressively replaced by suitable alternatives where feasible. Restrictions may be applied where there are demonstrated risks to human health or the environment that can only be addressed through Community-wide action.

There are currently 73 substances on the candidate list, with 28 recommended for Annex XIV inclusion. However, it is considered too early to assess the practicality and effectiveness of the authorisation provisions under REACH, but it is noted that it is currently unclear whether or not provisions exist to remove a substance from the candidate list or from Annex XIV, should this be necessary. However, there is

concern caused by uncertainty about how authorisation will work in practice and about a perceived lack of transparency in the authorisation process.

In 2008, ECHA examined 26 non-finalised dossiers of substances prioritised under the Existing Substances Regulation but no recommendations for restrictions were reached. Looking forward, ECHA considers itself to be well-prepared to develop restriction proposals. Significantly, as addressed above, there are concerns about whether or not RAC and SEAC will have the capacity and resources to cope with future authorisation and restriction activities.

**Box 5: Recommendations – Authorisation and Restriction (see also Box 10)**

- ECHA, the Commission and MS should introduce greater transparency at all stages of the Annex XIV inclusion process;
- the Commission should examine and clarify whether the current legal framework enables the removal of substances from the candidate list and Annex XIV;
- the Commission should clarify and, together with ECHA and CAs, disseminate information on the legal role of the Candidate List under REACH and the role of actors in the supply chain;
- ECHA and MS should consider how they can ensure the adequate future performance of RAC and SEAC (this recommendation is described in more detail in main report);
- ECHA should set up an inventory of all substance restrictions/controls under REACH and other legislation. In this way any overlaps will be more evident; and
- the Commission should develop proposals to amend REACH or overlapping legislation to remove duplications.

# 8. OPERATION OF REACH: EVALUATION

There are three types of evaluation under REACH, Dossier Evaluation (including evaluation of testing proposals and compliance checks on registration dossiers), Substance Evaluation and the Evaluation of Intermediates. Evaluation has the potential to be a major driver of benefits from REACH.

Between 2008 and April 2011 ECHA initiated the compliance checks on 249 **dossiers**. In 2011 a total of 239 dossiers were under evaluation, of which 81 were initiated anew in 2011, 158 were carried over from 2010, and 146 dossier evaluations were completed in 2011. Shortcomings have been identified in a high proportion of these dossiers with respect to substance identity, justification for data waiving and read-across, the level of detail within robust study summaries and the quality of chemical safety assessments.

At least one CA commented on 29 of the 105 decisions (30%) and no referrals to the Commission comitology procedure were needed[3]. However, since ECHA (2011a) 5 decisions have been made by the Commission. According to ECHA (2012), one evaluation decision has been brought up to the Board of Appeal but this action not been decided at the time of writing.

[3] Due to the disagreement between the Member States on the use of the extended one generation reprotoxicity study some decisions have recently been passed to the Commission.

Looking to the future, ECHA has plans in place to ensure that it evaluates 1,000 dossiers (5%) by the end of 2013, as required, and, thereafter, to evaluate 600 dossiers annually.
The comparison of the number of processed dossiers and the evaluation targets indicates a need for ECHA to speed up the process of compliance checking significantly for these targets to be met. This may involve increasing work efficiency as well as total capacities.

The full provisions for **substance evaluation** have not yet been implemented and no substance evaluation had been started prior to the drafting of this report. However, the first Community Rolling Action Plan (CoRAP) was published on February 29 2012, with 90 substances planned for evaluation between 2012 and 2014. The currently foreseen number of substance evaluations falls short of the original target of 160 substances.

At this early stage industry is concerned about a lack of transparency in the substance evaluation process.

**Box 6: Recommendations - Evaluation**

- the Commission should consider whether provisions should be added to REACH to require registrants to amend Risk Management Measures (RMMs) where concerns are identified (this recommendation is described in more detail in main report);
- the Commission should consider whether the current provisions relating to the transfer of dossiers submitted under Directive 67/548/EEC into REACH are adequate (this recommendation is described in more detail in main report);
- ECHA and MS should continue ensuring a high level of involvement of stakeholders in the evaluation processes and transparency and understanding of the processes involved;
- ECHA should seek ways to increase the speed and efficiency of compliance checking in order to meet the targets for dossier evaluation;
- ECHA and MS should consider improving selection and targeting compliance checks to increase the regulatory impact of the evaluation process; and
- ECHA should monitor evaluation experience (ECHA, MS and stakeholders) and update its guidance, as appropriate.

# 9. ALTERNATIVE TESTING

REACH incorporates the principles of replacement, reduction and refinement (3R) for the use of tests involving vertebrate animals according to the requirements set out in Directive 2010/63/EU. REACH therefore includes provisions intended to minimise the use of such tests, principally the mandatory sharing of test data involving vertebrate animals for joint registration and the requirement to submit testing proposals before conducting new tests on vertebrate animals. Data sharing is facilitated by incentives to ensure that registrants submit one joint registration for each substance.

So far, 90% of registration dossiers have been submitted jointly with registrants using data produced prior to the introduction of REACH as their main source of data. The second most used source of information came from the application of read-across,

especially for endpoints that would otherwise require longer-term animal studies. Overall, registrants have made extensive use of the provisions set out in Annex XI to REACH to provide data for registration.
To date no testing proposals have been rejected by ECHA directly as a result of information provided during consultation. However, it is unclear whether any testing proposals were withdrawn by the registrants as a direct result of consultation. Furthermore, in a number of cases the ambiguous description of the substance identity did not allow the assessment of testing proposals, which led to a prioritisation of those dossiers for substance evaluation (ECHA, 2012).

ECHA identified the quality of justifications for not conducting animal tests as an issue of concern. In addition, fewer testing proposals were submitted than originally anticipated, which ECHA considers to have been due to inappropriate adoption of alternative approaches. ECHA also reports that 107 higher tier animal tests seem to have been conducted without prior submission of a testing proposal. Furthermore, inconsistencies have been identified between the provisions in REACH and those in the Animal Test Directive 2012/63/EU, with respect to the control of tests involving cephalopods.

The Commission made available funding of about €240 million in the years 2007 to 2011 for the development of alternative methods as well as their evaluation and the promotion of their regulatory acceptance and use. In addition, a further €25 million was provided from industry through a public-private partnership initiative. However, it is not clear that funding is focused on the needs of legislation such as REACH. One outstanding issue relates to uncertainty about the applicability of standard test data for the risk assessment and registration of nanomaterials.

**Box 7: Recommendations – Animal Testing**

- ECHA should monitor the use of alternatives to ensure their effective use within REACH, and should update its guidance in line with information gathered (this recommendation is described in more detail in main report);
- the Commission should take action to ensure that REACH is brought into line with Directive 2010/63/EU and have equivalent provisions for cephalopods and vertebrate animals;
- the Commission should ensure that funding for the development of alternative methods is spent in a strategic manner with the aim of increasing the understanding of chemical toxicity, with a particular focus on the needs under legislation such as REACH; and
- the Commission should assess currently available test methods including alternative testing methods and, where necessary, update these for the assessment of nanomaterials.

# 10. ENFORCEMENT

The enforcement of REACH is primarily the responsibility of MS, as overseen by their national enforcement authority (frequently a CA), with the aim of verifying and ensuring the compliance of REACH. The White Paper (COM, 2001) expressed concerns about the levels of non-compliance with EU chemicals legislation and the uneven enforcement across MS. One expectation of REACH was therefore increased uniformity of enforcement throughout the EU/EEA to achieve the objectives of

REACH. Furthermore, proper enforcement is central to ensuring the realisation of the expected benefits of REACH from the increased protection of human health and environment, promotion of alternative methods, as well as the free circulation of substances on the internal market and enhancing competitiveness and innovation. The practical arrangements for enforcement vary between MS to allow MS to operate a system that best fits with their administrative structures or legal cultures and enforcement authorities typically have a mixture of administrative and criminal measures at their disposal. ECHA itself does not have enforcement powers but may request MS to undertake enforcement actions to ensure compliance with REACH.

The **Forum** has been established to coordinate the network of Member States authorities responsible for the enforcement of REACH, as required under this Regulation, and would appear to be functioning well. However, only 85% of possible Forum members (30 of 35 in 2010) have been appointed so far, and there are concerns regarding its ability to cope with future commitments (ECHA, 2011a and ECHA, 2012). The Forum has agreed a non-legally binding framework for MS enforcement of REACH so that enforcement may be as harmonised as possible while respecting the national differences in enforcement structure. However, it would appear that harmonised enforcement is proving very difficult in practice.

The **inspection** activities so far have covered manufacturers (37% of inspections), importers (23%), Only Representatives (3%) and downstream users (36%) with numerically move inspections focusing on SMEs than larger companies. The main focus of enforcement activities would also seem to be on SMEs.

A large proportion of companies have not as yet had any experience of REACH inspection or enforcement however companies are currently positive overall regarding their experience of such activities by regulators. Potential efficiencies in both inspection and enforcement were identified from synergies between the enforcement of REACH and other EU legislation.

**Box 8: Recommendations - Enforcement**

- ECHA should consult with MS and take steps to ensure that the Forum functions as effectively and efficiently as possible (this recommendation is described in more detail in main report);
- enforcement authorities should prioritise inspection/enforcement activities across EU to target limited resources where most benefit may be expected (this recommendation is described in more detail in main report);
- the Forum should consider how inspection and enforcement activities under REACH/CLP could be coordinated and/or combined with those for other EU legislation and act where practicable (this recommendation is described in more detail in main report);
- the Commission should use greater clarity in the wording of Article 117(1) information requests to CAs including clear definitions of duty holders, inspections and enforcement activities;
- CAs and the Commission should develop a more harmonised and systematic approach to the collection of information on the number and type of duty holders subject to inspections and enforcement, including for the assessment of outcomes from these activities; and
- the Forum should consider how it may facilitate greater harmonisation of inspection and enforcement of REACH across MS, including the level and use of sanctions.

# 11. GUIDANCE AND SUPPORT

Guidance and support on the operation of REACH is provided to varying degrees by ECHA, the Commission, MS and industry duty holders. **ECHA** is required to provide official technical and scientific guidance on the operation of REACH of relevance to industry, MS, the Commission and other stakeholders. ECHA guidance and support includes the provision of guidance documents (technical guidance, fact sheets, nutshell guidance, practical guides, Q&A documents and FAQs), IT tools, helpdesk and a supporting Internet site.

ECHA has published 71 **guidance documents** that are freely available over the Internet which represent the consensus interpretation of the REACH legal text that is accepted by ECHA, CAs and national REACH enforcement authorities. Such guidance is essential for a company's efficient planning for and preparing of a registration dossier and is made available in a wide range of EU languages. MS refer to the agreed ECHA guidance documents and assist in the preparation of ECHA guidance. This guidance is welcomed by industry but there have been additional costs and confusion caused by changes to guidance.

The **ECHA helpdesk** has been established to deal with enquiries that could not be handled by MS helpdesks and has received more requests from SMEs than from larger companies. ECHA has also developed and made available **IT tools** to assist in the operation of REACH, particularly IUCLID 5, REACH-IT, and CHESAR, as required under REACH. There were difficulties with REACH-IT around the pre-registration deadline but these have not been repeated since. IUCLID and CHESAR have been positively received by industry but updates, while welcomed, have sometimes lead to additional costs. **ECHA's Internet site** has recently been updated and acts as primary host for the guidance and support offered. ECHA **disseminated** information on (pre-)registration via its Internet site, as required of it. However, limitations in the functionality of the relevant sections of the ECHA Internet site have limited the usefulness of this information.

All **MS** have helpdesks to provide advice on responsibilities and obligations under REACH which are functioning effectively particularly in assisting with registration, and are appreciated by industry. However, the effectiveness of functionality and effectiveness of helpdesks was observed to vary between MS. Helpdesks reported receiving a greater percentage of enquiries from SMEs compared to larger companies and SMEs were more reliant on the advice of helpdesks, overall.

**Box 9: Recommendations – Guidance and Support**

- ECHA, in consultation with Partner Expert Group (PEG) members should take steps to improve the effectiveness and efficiency of PEGs (this recommendation is described in more detail in main report);
- CAs, in consultation with helpdesk users, should take steps to ensure that their helpdesks avoid taking a legalistic approach to dealing with enquiries and offer support that is as practical as possible;
- more resources should be provided by MS to their helpdesks, especially in the run-up to phase-in deadlines;
- MS should seek to share best practice among themselves and offer more mutual assistance,

especially to those MS with fewer resources to dedicate to their helpdesks;
- ECHA should consult with MS and take steps to ensure that its support of MS helpdesks is as effective and efficient as possible (this recommendation is described in more detail in main report);
- ECHA should make every effort to make all IT tools and guidance on the use of these tools available in a wide range of EU languages, as soon as possible; and
- ECHA should take steps to improve the search and data collection functionality of information that it makes available.

# 12. REACH AIM: PROTECTION OF HUMAN HEALTH & ENVIRONMENT

REACH Article 1(1) states that, *The purpose of this Regulation is to ensure a high level of protection of human health and the environment*. The drivers of particular relevance to the generation of human health and environmental benefits were identified as registration, information through the supply chain, authorisation, and restriction. The key enhancers of the benefit drivers are the provision of guidance, evaluation, and inspections and enforcement activities.

**Registration**:

- improvements in the assessment of risks via Chemical Safety Assessment have produced benefits through the reduction in unsafe uses of chemicals;
- the generation or assessment of new hazard data is improving the reliability of classifications and thus there are improvements in safe use possible via other legislation;
- it is not yet clear that assessments for PBT/vPvB properties are resulting in benefits; and
- some SVHCs, especially CMRs, have been removed from the market place but some substance removals may be due to economic reasons only and the substances being removed may not always be more hazardous than their alternatives.

**Information through the supply chain:**

- additional information has been added to (e)SDS but benefits are being limited by important information being hidden among the volume of information sometimes being included in SDS, especially with respect to exposure scenario information; and
- the communication of information on SVHCs is producing benefits through the reduction in the use these substances by downstream users.

**Authorisation and Restriction:**

- at present it is not clear whether candidate listing and the possibility of a future authorisation requirement are acting as triggers for benefits and it is possible that these mechanisms are currently having a negative impact on health and the environment overall; and

- it is currently too soon to comment on whether or not the Registry of Intentions is acting as a signal to manufacturers and downstream users to consider developing or moving to alternatives.

**Box 10: Summary of Recommendations – Human Health and the Environment (these recommendations are described in more detail in main report)**

**Registration (other than those in Box 3)**

- ECHA and industry should increase their efforts to ensure the submission of high quality dossiers, especially with respect to PBT/vPvB assessment and the development of realistic exposure scenarios; and
- ECHA and the Commission may wish to consider increasing their efforts for supporting SME registrants in order to avoid unwanted withdrawal of substances with no additional benefits to human health and the environment.

**Information Through the Supply Chain (other than those in Box 4)**

- ECHA should continue its efforts to provide IT tools to facilitate communication, especially by registrants;
- industry should ensure that IT support tools developed by them to assist communication. These should integrate well with those produced by ECHA, especially CHESAR and industry should ensure adequate commitment from companies for this work;
- ECHA should review its guidance to ensure that it is sufficient to support communication by actors throughout the supply chain;
- consideration should be given to assessing and listing groups of substances on the candidate list to avoid formulators and downstream users shifting to unsuitable alternatives.

**Authorisation and Restriction (other than those in Box 5)**

- ECHA and MS should consider listing substance groups that include SVHCs, where substitution with a substance within the same group is likely;
- industry should develop guidance and training on alternatives assessment;
- industry, MA, and ECHA should compile information on possible alternatives to the use of the SVHC from commenting and other information sources , as well as to ensure the "exclusion" of substances known to be preferred alternatives but also having problematic properties; and
- the Commission and/or ECHA should undertake research to determine whether or not substitution takes place with less hazardous substances and the impact that candidate listing is having in this respect.

**Further Recommendations**

- the effectiveness of REACH for the protection of human health and the environment is best assessed at the level of the EU (the Commission and/or ECHA) rather than at a national level;
- data requests made to MS and/or industry should be harmonised at the EU level;
- the level of data gathering currently undertaken and the resources available to MS to undertake data gathering varied greatly between MS and this should be taken into consideration when drafting any information requests; and
- ECHA should consider how best to build on the success so far of the Risk Communication Network.

## 13. REACH AIM: ENHANCING COMPETITIVENESS, INNOVATION AND THE SINGLE MARKET

The information was not available to clearly determine the enhancement of competitiveness, innovation and the single market resulting from the introduction of REACH. With respect to the **single market** there is no evidence of impacts on trade flows to date. With regards to **trade and competitiveness** some positive impacts are on intra-EU trade are being attributed to REACH by industry. On the subject of **innovation**, the evidence is mixed. Some companies have been able to benefit from an increased availability of information, but the majority of companies did not feel that this was the case for them and that registration was increasing the overall R&D costs for many companies with no net increase in innovation. The principle REACH mechanisms driving innovation were identified as:

- the submission of registration dossiers;
- Substance Information Exchange Fora (SEIFs)/Consortia;
- Safety Data Sheets (SDS) and extended SDS (eSDS),
- Chemical Safety Reports (CSRs); and
- the ECHA dissemination portal.

It has been possible to identify costs which industry claim are harming their competitiveness and innovation, but it is too early in the implementation of REACH for industry to see the anticipated benefits.

Estimates are available of the types and potential size of **costs** to industry with the principal costs resulting from:

1. **Human resources**: from REACH-related activities (inc. for pre-registration).
2. **Registration**: wide variation in reported costs so far and cost items but tor simple registrations ECHA fees could amount to 50% of total costs. SIEF/consortia costs have also been significant for many.
3. **Authorisation and restriction**: Industry expressed concerns about future costs but these provisions had not been sufficiently implemented for cost estimates to be developed at this stage.
4. **Information exchange in the supply chain**: Industry considered that REACH had increased these costs.
5. **Notification for articles**: No costs provided but comment was made regarding concern over differing interpretations by enforcement authorities.
6. **Downstream users' chemical safety reports**: from amending those provided; and
7. **Other costs**: costs for changes in production and relevant R&D activity, management of risk and other necessary investments.

**Benefits** may be occurring in the following areas, but these conclusions are currently very tentative:

1. **Increased consumer confidence**: a minority view by industry.
2. **Increased knowledge on the properties and uses of substances**: This benefit was felt to be occurring but that it had not as yet transferred into benefits to recognised by companies.
3. **Communication in the Supply Chain**: potential benefits were not recognised by companies which at this stage tended to be focused on the costs incurred.
4. **Improved risk management**: it was felt to be too early to be able to identify cost reductions related to the implementation of occupational health and safety obligations. However, there is evidence of improvements in risk assessment.
5. **Increased availability of information**: enhancing innovation for some companies.

**Box 11: Recommendations - Competitiveness, Innovation and the Single Market**

- impacts on competitiveness, innovation and the single market should be assessed at an EU level (MS, 2010);
- the Commission should monitor and gather data on the factors expected to bring business/trade impacts to the chemical industry in the EU/EFTA. With these data a more accurate assessment of impacts should be undertaken; and
- the Commission, ECHA and industry associations should work together to develop an action plan to find ways of enhancing the effectiveness of the key information driver to innovation benefits, including consideration of training and education, especially that focused on SMEs.

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# 1. INTRODUCTION

## 1.1 REACH Background

### 1.1.1 Commission White Paper

The legislation that became EC Regulation No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) was first officially described in the Commission White Paper of 2001 (COM, 2001). From COM (2001) it is clear that there were increasing concerns that the EU chemicals policy at that time was not providing sufficient protection to human health and the environment. In 2001, there was a distinction between 'existing substances' that had been on the market before September 1981 and 'new substances' that entered the market after that date. Previsions were in place, requiring the notification of new substances by any organisation wishing to place new substances on the market in quantities greater than 10kg per year, per company (Notification of New Substances (NONS) Directive 97/548/EC). The notification requirements for NONS increased when the quantity passed the following thresholds: 100kg, 1 tonne, 10 tonnes, 100 tonnes and 1,000 tonnes.

No Registration-like provisions were in place for existing substances (99% of substances). Consequently there was a general lack of knowledge about the properties and uses of these substances. Where concerns were identified regarding the harmful impacts to human health and/or the environment from the use of an existing substance, it was the responsibility of national and EU authorities to investigate these impacts and justify action, if needed. This was a time consuming and costly procedure and thus thorough risk assessments were undertaken on the use of very few existing substances. However, where unacceptable risks were identified then marketing and use restrictions could be imposed under Directive 76/769/EEC. Such restrictions have subsequently been included within REACH (Annex XVII).

REACH was therefore designed to address these weaknesses identified in the chemicals policy, within the context of achieving *sustainable development in the chemicals industry within the framework of the Single Market*. The objectives of REACH set out in COM (2001) were:

- Protection of human health and the environment;
- Maintenance and enhancement of competiveness of the EU chemical industry;
- Prevent fragmentation of the internal market;
- Increased transparency (information on chemicals to consumers and across industry);
- Integration with international efforts;
- Promotion of non-animal testing; and
- Conformity with EU international obligations under the WTO.

### 1.1.2 From the White Paper to REACH

Following the publication of the White Paper (COM, 2001), the new chemicals policy went through a series of stages leading to the adoption of REACH, as summarised below:

- 2001: Commission White Paper published;
- 2003: The European Commission's original legislative proposal on REACH;
- November 2005: First reading opinion adopted by the European Parliament;
- September 2006: Common Position adopted;
- July 2006 : Commission Communication on the Common Position was adopted; and
- December 2006: REACH adopted.

### 1.1.3 REACH Overview

EC Regulation No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) was adopted on 18 December 2006 and entered into force on 1 June 2007.

The overall aim of REACH is to achieve (Article 1(1&2)):

- a high level of protection of human health and environment;
- the promotion of alternative methods for assessment of hazards of substances;
- free movement of substances; while
- enhancing competitiveness and innovation.

REACH is based on the principle that manufacturers, importers and downstream users of substances and mixtures are responsible for ensuring that in placing these on the market they do not adversely affect human health or the environment (Article 1(3)).

The regulation applies to all substances manufactured, placed on the market and used in the EU either on their own, in mixtures or in articles (Article 1(3).

The four key elements in REACH are:

1. **Registration** (Title II)**:** of substances manufactured or imported in amounts starting at 1 tonne per year (per manufacturer or importer);

2. **Evaluation** (Title VI): of which there are two types – dossier evaluation and substance evaluation;

3. **Authorisation** (Title VII)**:** of substances of very high concern (SVHCs), aimed at ensuring that risks from SVHCs are adequately controlled. Authorisation may also be granted where the use can be justified for socio-economic reasons and no suitable alternatives are available, which are economically and technically viable

(Recital 22). Authorisation is also intended to ensure the good functioning of the internal market and that SVHCs are progressively replaced by alternative substances or technologies, where viable (Article 55); and

4. **Restriction** (Title VIII)**:** aimed at addressing risks not adequately controlled on a Community wide basis (including marketing and use restrictions applied under Directive 76/769).

The provisions of REACH apply to the vast majority of substances manufactured, imported or used in the EU, and apply throughout the supply chain for those substances. These provisions are intended to be applied without prejudice to other EU workplace and environment legislation (Recital 5). However, a Commission study has identified areas of (COM, 2012h):

- **double regulation**: where controls put in place under REACH which are repeated under other legislation. For example, the requirement to register co-formulants, safeners and synergists used in the production of plant protection products even though substances used in this way are covered by the provisions of the Plant Protection Products Regulation (EC) No 1107/2009;

- **inconsistencies and gaps**: where controls put in place under REACH are inconsistent with those under other legislation or where there are gaps between these controls. For example, restrictions on the use of benzene, creosote and azodyes in toys set out in REACH Annex XVII differ from those set out in the Toy Safety Directive 2009/48/EC. Also, substances used as active ingredients within biocidal products are considered registered under REACH while according to the Biocidal Products Directive 98/8/EC the manufacture of these substances is not assessed; as well as

- **synergies and complementarities**: where the provisions of REACH complement those of other legislation or *vice versa*. For example, the provisions of REACH and CLP complement one another by design, and the information gathered under REACH is valuable to the operation of legislation such as the General Product Safety Directive 2001/95/EC. Furthermore, REACH includes provisions for the dissemination of safety information of use under other legislation, primarily in the form of Safety Data Sheets (Title IV).

## 1.2 Impact Assessments

Prior to the adoption of REACH a number of impact assessments were undertaken by national and EU bodies, and since the adoption of REACH a project by European Commission-Eurostat has sought to establish a robust baseline against which the impacts of REACH can be compared in future.

The Commission and some Member States undertook impact assessments of REACH prior to its implementation. This study is interested in establishing what were the

predicted impacts on the EU and EEA as a whole but national and regional variations are also of importance. Therefore, EU wide studies have been considered in the first instance with national studies considered where necessary to inform on regional variations or where such studies contain assessments more recent than the corresponding EU studies.

It should be noted that the studies considered here refer to the understanding of REACH during its development. Most of the studies assessed were based on the Commission Proposal of October 2003 (COM, 2003b). The studies are of varying scope, quality, level of uncertainty and depth of assessment. There are also significant differences in the 'REACH versions' being assessed with regards to information requirements for the registration of substances and requirements for chemical safety assessments (CSAs) (e.g. many do not include reduced information and CSA requirements for 1 to 10 tonne substances). Furthermore, the provisions for Authorisation regarding the development of the candidate list and the requirements for applications vary significantly.

It is beyond the scope of this study to undertake a synthesis of all the previously generated impact assessment information, updated in line with current knowledge. Rather the purpose here is to set out the sorts of expectations of the implementation of REACH established by these studies.

The European study that forms the basis of the analysis undertaken here is the study published in 2004 that sought to combine the expectations set out in thirty six EU and national studies prior to that date (Ecorys, 2004):

Reference is also made to the following EU wide studies:

- RPA (2003): Assessment of the Business Impacts of New Regulations in the Chemicals Sector Phase 2: Combined Costs of REACH and Entity Fees;
- COM-EIA (2003): Commission Staff Working Paper - Extended Impact Assessment;
- DHI (2005): The impact of REACH on the environment and human health;
- RPA (2003): Impact of the New Chemicals Policy on Health and the Environment; and
- Ökopol (2007): Analysis of Studies Discussing Benefits of REACH.

There were significant variations in the predicted impacts of REACH produced by different MS authorities. However, these appear to be largely due to differing assumptions made regarding the nature of the impacts of REACH. EU-wide impact assessments therefore generally assumed that impacts would apply in a uniform manner across the EU, approximately in proportion to the size and structure of the chemical industry across the EU. This assumption was also made with regard to MS added to the EU-15 after many of the studies were completed and has been assumed here to also extend to the EEA countries considered as part of this study.

### 1.2.1 Eurostat Study

In 2009, the European Commission/Eurostat published a baseline study establishing a set of indicators that will be used to monitor the effectiveness of REACH and providing the baseline data against which the performance of REACH can be judged[4]. An update of this study began in January 2011, with a completion dated in December 2012[5]. The baseline study together with its update is designed to provide data on the impact of a range of key elements of REACH implementation, as set out in Table 1.1, and findings to date are summarised in the relevant sections of this report.

**Table 1.1: Key Elements and Indicators Considered by the Eurostat Baseline Study[1]**

| Key Elements of REACH | Baseline Study Indicator System | | |
|---|---|---|---|
| | Administrative Indicators | Risk & Quality Indicator System | Supplemental Indicators |
| Registration of Chemicals | ✓ | | |
| Substance Evaluation | ✓ | | |
| Authorisation and Restriction | ✓ | | |
| Establishment of a Central Agency | (indirect) | | |
| Protection of Human Health and the Environment | | ✓ | ✓ |
| Improvement of Knowledge on Properties and Safe Uses of Chemicals | | ✓ | ✓ |
| Assessment of Existing and New Chemicals in a Single, Coherent System | | | ✓ |
| Increased Transparency and Consumer Awareness | | | (✓) |
| Promotion of Alternative Methods for Assessment of Hazards of Chemicals | | | ✓ |
| Maintenance and Enhancement of the Competitiveness of the EU Chemical Industry | Not within the scope of the Baseline Study | | |
| Prevention of Fragmentation in the Internal Market | Not within the scope of the Baseline Study | | |
| Conformity with EU's International Obligations under WTO | Not within the scope of the Baseline Study | | |

Note 1: A reproduction of information from Table 1.3 of the Baseline Study Report.

## 1.3 Reporting Obligations

Incorporated within REACH are various reporting obligations and deadlines that apply to the Member States (MS), European Chemicals Agency (ECHA) and the Commission, and these are the focus of this project. The Member State reporting obligations apply equally to the twenty-seven Member States of the European Union

[4] The REACH Baseline Study – A tool to monitor the new EU Chemicals Policy on Chemicals, Statistics in Focus 48/2009, European Communities, available from European Commission Internet site (http://epp.eurostat.ec.europa.eu/portal/page/portal/product_details/publication?p_product_code=KS-RA-09-003).

[5] The supply of statistical services in the field of Environment Statistics: REACH baseline study – 5 years update – (REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals), being undertaken by the Ökoinstitut for DG Eurostat (Unit E3: Environmental Statistics and Accounts).

and the three European Free Trade Association (EFTA) Member States that also fall within the European Economic Area (EEA), namely Norway, Liechtenstein and Iceland.

**Note:** ***"MS" in this report therefore refers to the EU Member States and the three EFTA States Members of the EEA (Iceland, Liechtenstein and Norway).***

In particular, the obligations to report are defined within Article 117 (Reporting), Article 125 (Appropriate Controls), Article 126 (Penalties) and Article 127 (Enforcement) of the REACH Regulation as set out in Table 1.1.

**Table 1.1: Reporting Obligations under REACH**

***Article 117***

1. *Every five years, Member States shall submit to the Commission a report on the operation of this Regulation in their respective territories, including sections on evaluation and enforcement as described in Article 127. The first report shall be submitted by 1 June 2010.*

2. *Every five years, the Agency shall submit to the Commission a report on the operation of this Regulation. The Agency shall include in its report information on the joint submission of information in accordance with Article 11[6] and an overview of the explanations given for submitting information separately. The first report shall be submitted by 1 June 2011.*

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

4. *Every five years, the Commission shall publish a general report on:*
   a) *The experiences acquired with the operation of this Regulation, including the information referred to in paragraph 1, 2 and 3 and*
   b) *The amount and distribution of funding available by the Commission for the development and evaluation of alterative test methods.*

   *The first report shall be published by 1 June 2012*

***Article 125***

*Member States shall maintain a system of official controls and other activities as appropriate to the circumstances*

***Article 126***

*Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission no later than 1 December 2008 and shall notify it without delay of any subsequent amendment affecting them*

[6] Article 11 refers to the responsibilities of registrants of chemicals to submit certain information.

| **Table 1.1: Reporting Obligations under REACH** |
|---|
| ***Article 127***<br>*The report referred to in Article 117(1) shall, in relation to enforcement, include the results of the official inspections, the monitoring carried out, the penalties provided for and the other measures taken pursuant to Articles 125 and 126 during the previous reporting period. The common issues to be covered in the reports shall be agreed by the Forum* |

## 1.4 Information Sources for the Study

The analysis that follows is based primarily upon the Article 117(1) reports provided to the Commission by Member States (MS, 2010) and the Article 117(2 & 3) reports provided to the Commission by ECHA (ECHA, 2011a and ECHA, 2011b, respectively).

The Article 117 information provided by ECHA was supplemented by information from annual general reports, annual work programmes, and the Progress Report on Evaluation under REACH of 2010 published on ECHA's Internet site[7].

Further information was provided by the following Commission studies into specific aspects of the implementation of REACH conducted in parallel to this study (it is understood that these reports will be published by the Commission, in due course)[8]:

1. COM (2012a): REACH Baseline Study: 5 Years Update;
2. COM (2012b): Review of the European Chemicals Agency (ECHA) based on Article 75 of Regulation (EC) N° 1907/2006;
3. COM (2012c): Scientific Technical Support on Assessment of Nanomaterials in REACH Registration Dossiers and Adequacy of Available Information;
4. COM (2012d): Technical Assistance related to the Review of REACH with regard to the Registration Requirements for Substances Manufactured or Imported between 1 and 10 Tonnes and the Registration Requirements on Polymers;
5. COM (2012e): The REACH contribution to the development, commercialisation and uptake of products of emerging technologies;
6. COM (2012f): Impact of REACH on Innovation;
7. COM (2012g): Impact of REACH on Single Market and Competitiveness;
8. COM (2012h): Technical assistance related to the scope of REACH and other relevant EU legislation to assess overlaps;
9. COM (2012i): Inspections requirements for REACH and CLP;

[7] This information is published on the publications section of ECHA's Internet site (http://echa.europa.eu/publications_en.asp).

[8] These studies were not completed at the time of analysis and therefore the information drawn from them for this study may change slightly by the time of the publication of the individual final study reports.

10. COM (2012j): Implementation and enforcement of restrictions in Member States; and
11. COM (2012k): Assessment of health and environmental benefits of REACH.

## 1.5 Study Objective

The Specifications state that (See Annex 1):

> *The objective of the contract is to provide scientific and technical support to the first general report of the Commission due by 1 June 2012. The Commission's report will include the information received from reporting of MS and of ECHA and inputs from the Commission on experience acquired with the operation of REACH.*

***The provision of support to the Commission for the drafting of its first quinquennial report as required under Article 117(4) of REACH is the subject of this study contract.***

## 1.6 Organisation of Report

The remainder of this report has been organised thematically to analyse the following:

- **Section 2:** The organisation of ECHA and other bodies in response to REACH;
- **Section 3:** Co-ordination, co-operation and information exchange undertaken to facilitate REACH;
- **Section 4:** The operation of the provisions for Registration;
- **Section 5:** The operation of the provisions for Information in the Supply Chain;
- **Section 6:** The operation of the provisions for Authorisation;
- **Section 7:** The operation of the provisions for Restrictions;
- **Section 8:** The operation of the provisions for Evaluation;
- **Section 9:** The impact of REACH on Animal Testing;
- **Section 10:** The Enforcement of REACH;
- **Section 11:** Guidance and Support to facilitate REACH;
- **Section 12:** An assessment of the REACH aim to enhance the Protection of Human Health & Environment;
- **Section 13:** An assessment of the REACH aim to enhance Competitiveness, Innovation and the Single Market;
- **Section 14:** A summary of Findings with Recommendations; and
- **Section 15:** Details of information sources referenced in this report.

Furthermore, there are tree Annexes:

**Annex 1**: Sets out the Study Specifications;
**Annex 2**: Contains the analysis of Article 117(1) Reports from Member States; and
**Annex 3**: Contains the analysis of Article 117(2 & 3) Reports from ECHA.

# 2. ORGANISATION

## 2.1 The European Chemicals Agency

Prior to the introduction of REACH the costs of establishing and running the European Chemicals Agency (ECHA) were estimated over a ten year time period. Under Article 96, the budget of ECHA may be funded from a combination of:

- subsidy from the Community;
- fees paid to ECHA under REACH; and
- voluntary contributions from MS.

It was estimated that approximately three quarters of the costs were predicted to be provided by fee income (Ecorys, 2004). However, the Commission Business Impacts Assessment originally estimated the costs to ECHA as being about €4 billion (Net Present Value over 10 years) (RPA, 2003), and the fee component of this estimate was predicted to amount to 13% of this figure. This second estimate would appear to be closer to the figures published in the ECHA Budget 2011 2nd Amendment (ECHA, 2011c) which would indicate that fee income currently accounts for approximately 10% of ECHA income (ECHA budget of €316 million).

Estimations of the basis for the costs were made, associated with the obligations placed on the Commission and MS for the establishment and application of REACH. These costs were based on varying assumptions regarding the extent of these obligations and the ability of the different parties to work well together and with ECHA. It was also assumed that the cost of setting up a new Agency to oversee REACH would be approximately equivalent to expanding an existing agency or DG to fulfil this role (Ecorys, 2004).

ECHA was established on 1 June 2007 in accordance with REACH Article 75(1), became operational in 2008. The composition and responsibilities of ECHA are primarily set out under Title X and under Article 76, comprising the bodies summarised in Table 2.1.

**Table 2.1: Summary of the Structure of ECHA**

| ECHA Body | Description of Function/Responsibilities | Key Article(s) |
|---|---|---|
| Management Board (MB) | Appoints and oversees ED. Produces annual reports and work programmes. Adopts and publishes ECHA rules. Controls ECHA's budget. Appoints members of ECHA committees and BA | 76, 78-82, 84, 85, 88, 89, 96, 97 and 103 |
| Executive Director (ED) | Overall management and administration of ECHA and its committees and ensuring that these meet their obligations as set out in REACH | 76, 83, 84, 88 |
| Committee for Risk Assessment (RAC) | Preparation of ECHA opinions on evaluations, applications for authorisation, proposals for restrictions, proposals for harmonised C&L, and any other REACH questions relating to risks to human health or the environment | 76, 77, 85, 87, 88 |
| Committee for | Preparation of ECHA opinions on evaluations, applications for | 76, 77, |

| Table 2.1: Summary of the Structure of ECHA | | |
|---|---|---|
| **ECHA Body** | **Description of Function/Responsibilities** | **Key Article(s)** |
| Socio-economic Analysis (SEAC) | authorisation, proposals for restrictions and any other REACH questions relating to risks to the socio-economic impact of possible legislative action on substances | 85, 87, 88 |
| Member State Committee (MSC) | Resolution of resolving potential divergences of opinions on draft decisions proposed by ECHA or MS for Evaluation (Title VI) and proposals for identification of SVHCs (Title VII) | 76, 77, 85, 87, 88 |
| Forum for Exchange of Information on Enforcement (the Forum) | Co-ordination of MS REACH enforcement agencies | 76, 77, 86- 88 |
| Secretariat | Provision of technical, scientific and administrative support to ECHA committees and Forum and the coordination of these. Undertake the work required of ECHA for (pre-)registration, evaluation, guidance preparation, database maintenance and information provision | 76, 77 |
| Board of Appeal (BoA) | Provision of decisions on appeals against ECHA's decisions. The Board of Appeal (BoA) is also part of ECHA but, for obvious reasons, acts independently of ECHA (ECHA, 2011a) | 76, 77, 89-93 |

ECHA considers itself to have been successfully established, to be fully operational and to be fulfilling all its tasks on time (ECHA, 2011a). The conclusions of the ECHA review (COM 2012b) start with the statement: "ECHA has had a good start-up as an organisation and implemented most of its REACH and CLP tasks effectively" thus supporting ECHA's self-evaluation. The overall assessment of fulfilment of tasks provided by that report shows that in the majority of work areas ECHA achieved its targets according to the consultant's assessment and this assessment corresponds with the opinions of stakeholders, in most cases. However, it is not clear whether or not all ECHA's key tasks were completed on time. For example, omissions are reported with regards to data sharing and the dissemination website which should have been operational since June 2008 is still only partially operational, and there have been several delays in the publication of the classification and labelling inventory.

### 2.1.1 ECHA Statistics

An overview of the number and contract types of ECHA's workforce over the first years of operation is given in Table 2.2.

| Table 2.2: Number of Staff Working at ECHA | | | | |
|---|---|---|---|---|
| **Year** | **Temporary Agents** | **Contract Agents** | **Seconded National Experts** | **Total** |
| 2008 | 210 | 9 | 5 | 224 |
| 2009 | 293 | 27 | 5 | 325 |
| 2010 | 381 | 43 | 6 | 430 |
| 2011 | 397 | 53 | 6 | 456 |
| Source: ECHA (2011a), Table 23, p. 80. | | | | |

The number of staff allocated to the tasks discussed in the ECHA report during 2010[9] is presented in Table 2.3.

| **Table 2.3: ECHA Staff Numbers by Task** | | | |
|---|---|---|---|
| **Tasks** | **Staff Numbers** | | |
| | **Internal** | **Competent Authority** | **Total** |
| (Pre-)Registration, Data Sharing | 56 | 7 | *63* |
| Evaluation | 69 | 2 | *71* |
| Authorisation & Restrictions | 32 | 1 | *33* |
| Guidance and Helpdesk | 40 | 5 | *45* |
| IT Support | 32 | 0 | *32* |
| Committees and Forum | 28 | 0 | *28* |
| Board of Appeal | 14 | 3 | *17* |
| Communications | 19 | 7 | *26* |
| Relations EU/ International | 4 | 1 | *5* |
| Management | 30 | 2 | *32* |
| Other | 84 | 22 | *106* |
| ***Total*** | ***408*** | ***50*** | ***458*** |

The coordination of these staff was found to be more challenging and resource demanding than anticipated, mainly due to the rapid growth of ECHA and the reorganisation of its internal structures (ECHA, 2011a). Also, the work load was unexpectedly high because of issues relating to data confidentiality, security modalities (access of MS CAs to REACH data) and the high number of pre-registrations received. However, in this respect it is noted by the Commission that little or no processing of pre-registrations was required of ECHA. This unforeseen additional workload is assessed as one reason why resources had to be shifted inside ECHA, which in turn led to reduced effectiveness in some other work areas (COM 2012b).

In addition to the number of directly employed staff, the numbers of members of ECHA Committees, nominated by MS, are set out in Table 2.4.

| **Table 2.4: Number of Members of RAC, SEAC and MSC Committees** | | | |
|---|---|---|---|
| **Committee** | **RAC** | **SEAC** | **MSC** |
| Total possible | 65 | 65 | 35 |
| Members | 36 | 30 | 29 |
| % of Total Members not yet nominated | 45 | 54 | 17 |
| Source: ECHA report on the operation of REACH, Figure 13, p. 64 | | | |

The high number of committee members not nominated by MS is of concern and may indicate that some MS are not fulfilling the obligation on them under Article 85(6) to provide 'adequate technical and scientific resources' to ECHA's committees.

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

ECHA reports that the Board of Appeal (BoA) is fully operational and that it believes that there is a high level of awareness by industry of the possibility to launch appeals. The results of the stakeholder survey in the ECHA review study support this and indicate that the organisation of the BoA is perceived as sufficient guarantee for its independence (COM 2012b). However, little experience exists to date due to the low number of cases submitted at the time of the Article 117(2) report. ECHA believes referral to the BoA to be preferable to court proceedings because the BoA has the power to act more quickly and the Commission has commented to the authors that the use of the BoA is more cost effective, noting that where the appeal is upheld appeal fees are returned to industry. Furthermore, although ECHA comments favourably on its activities to implement BoA decisions, it is noted that no substantive appeals had been decided at the time of drafting ECHA's Article 117 reports.

Details of BoA staffing are set out in Table 2.3 and an overview of BoA activities and membership is set out in Table 2.5.

**Table 2.5: Overview of BoA Activities and Member Appointments**

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

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

### 2.1.2 Resource Needs

ECHA believes that its resource needs were underestimated prior to its creation and that fee incomes are unpredictable (volume and timing), leading to contractual uncertainties, hampering capacity building and presenting structural challenges and difficulties for long-term planning. This analysis is supported also by the findings of the ECHA review study (COM 2012b). ECHA also states that current provisions and possibilities for funding and financing its activities are not sufficient. According to the current provisions, ECHA can only pay MS experts in the context of public procurement but would like greater flexibility to achieve a higher level of co-operation, e.g. through providing grants. In addition, ECHA requests that better account is taken of its resource and spending needs when considering a potential modification of the Fee Regulation and, among others, revenue arising from the raising of BoA fees should be taken into account.

However, it was ECHA as a whole that needed to balance its books. Constituent bodies such as the BoA may not therefore need to be self-sufficient of themselves. Furthermore, increasing such fees may hinder access to legal redress which would impact more severely on SMEs, an approach which could not be supported by the Commission. These comments were communicated by the Commission to ECHA before the publication of its Article 117 reports.

Based on ECHA (2011a), it is not possible to fully understand:

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

The ECHA review (COM, 2012b) states with regard to ECHA's budget: "The Agency's budgetary and management procedures and systems perform adequately, but […ECHA...] was also dealing with an uncertain environment. The result was that not all resources requirements could have been predicted fully […]. ECHA has taken a pro-active approach to (financial) risk management […], thus not allowing external circumstances to significantly thwart its efforts in implementing REACH and CLP." However, a detailed assessment of the use of resources in relation to the tasks performed and an analysis of future resource needs was not included in COM (2012b).

**Box 2.1: Recommendations Regarding ECHA's Finances**

- ECHA should clearly identify the costs of undertaking its activities (and expected future costs) and compare these with expectations and the current budget;
- the Commission should consider the findings of ECHA's review of its finances and make recommendations to ensure it has adequate funding for current and future activities; and
- MS should review current resourcing for ECHA committees to ensure their adequate resourcing.

## 2.2 Competent Authorities

### 2.2.1 Introduction

MS were each required to appoint at least one Competent Authority (CA) in accordance with Article 121 of REACH. Article 121 further states that CAs are responsible for:

> *performing the tasks allotted to competent authorities under this Regulation and for cooperating with the Commission and the Agency in the implementation of this Regulation. Member States shall place adequate resources at the disposal of the competent authorities to enable them, in conjunction with any other available resources, to fulfil their tasks under this Regulation in a timely and effective manner.*

Article 122 requires CAs to cooperate and provide other CAs with *all the necessary and useful support to this end.* CAs are required to inform the general public about risks associated with substances where this is necessary to protect to human health and the environment (Article 123). CAs are responsible for setting up MS Helpdesks

and for providing ECHA with information on registered substances where suspicions of risk have been identified from dossiers not containing the full information requirements set out in Annex VII (Article 124). CA's are also responsible for undertaking the substance evaluation (Article 45) and enforcement of REACH through their facilitation and support of the enforcement Forum (Article 86), including coordination between CA and MS Forum activities.

### 2.2.2 Competent Authority Statistics

Forty REACH CAs have been appointed, with seven of the thirty MS having appointed more than one CA (MS, 2010). Two-thirds of CAs derive their authority from the environment functions within MS and one-third derive authority from health functions. All CAs indicated that they had at least one other area of legislative responsibility outside of REACH, the most common of which were: import/export (27 CAs); biocides (21 CAs); detergents (16 CAs); pesticides (15 CAs); POPs (14 CAs); and CLP (12 CAs).

Figure 2.1 sets out the staff skills available to these CAs. Of note is that twenty-three CAs indicated that they also have access to external personnel including specialists/experts in a wide range of relevant disciplines. The expressed level of satisfaction with these experts varied widely but could be said to be average overall.

Twenty of the thirty CAs indicated that they worked in collaboration with at least one other organisation within their MS and all but one of the CAs (CZ) indicated that they work with a range of other organisations.

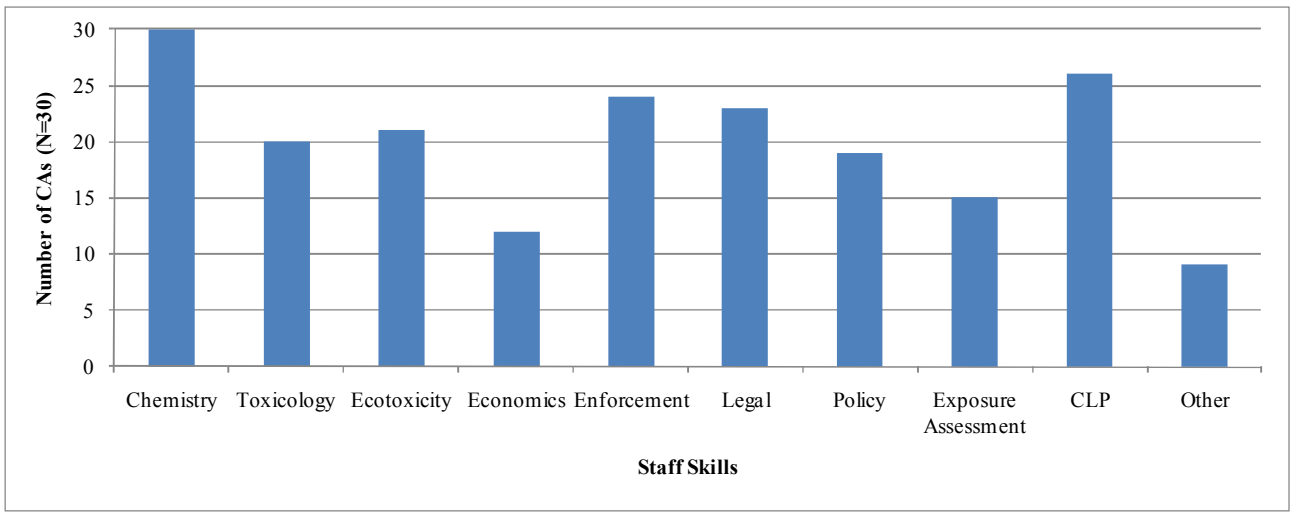



**Figure 2.1: Staff Skills Available to CAs**

The expressed level of satisfaction by CAs with the adequacy of their funding varied widely, but could be said to be about average overall. Causes of concern with regard to inadequate or limited resources were attributed to:

- an insufficient number of employees; and

- inappropriate skill sets (e.g. lack of expertise in socio-economic analysis and risk communication, and a lack of senior toxicology experts).

Some CAs also noted that operating funds were being reduced due to the current economic conditions.

**Box 2.2: Recommendations for the Improvement of CAs**

- MS should review current funding for CAs and ensure that funding is adequate for current and expected near future activities; and
- CAs should seek to share best practice and consider the sharing of expertise across MS boundaries.

## 2.3 Individual Companies

Information from the Commission studies into the impact of REACH on innovation and competitiveness (COM, 2012f and COM 2012g, respectively) indicate that many companies are investing significant resources in the form of additional staff or external consultants in order to deal with the demands of REACH, although the extent to which this occurs is not uniform across all company types. In this respect these studies found that:

- 50% of companies may have created internal REACH units (>60% of large companies and <40% of small or micro sized companies);
- typically dedicated REACH staff numbered <2 full-time equivalent jobs (FTEs) per company (inside or outside of any REACH unit). However, this figure would appear to be higher for chemical manufacturers (perhaps 2-5 FTE);
- large enterprises often have central REACH unit plus 1 full or part time member of staff in each business unit;
- REACH-related staff costs can represent a substantial (5%) increase in total wage costs for small companies;
- there is a shift of R&D staff and relevant resources to REACH-related activities which 60% of companies expect to be permanent. However, it was not clear to what extent the use of R&D staff should be considered to be an opportunity cost; and
- external consultants may be used as a replacement for internal staff but often such expertise is in addition to the above internal costs.

In spite of the resources invested by companies they have not always submitted registration dossiers that fully comply with REACH (ECHA, 2011a and ECHA, 2011b) or in other ways not complied with REACH (MS, 2010). However, it is not clear how much of this non-compliance is due to industry trying and failing to fulfil its obligations and how much is due to deliberate non-compliance. Furthermore, there are significant concerns regarding the current level of understanding of obligations under REACH, particularly by downstream users and SMEs (COM, 2012k).

**Box 2.3: Recommendations for Industry**

- Renewed efforts should be made by ECHA and CAs to inform all actors of their obligations under REACH, especially downstream users and SMEs.

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

## 3.1 Within ECHA

ECHA'S Article 117(2) report includes general description of ECHA's internal organisation but details of internal co-ordination, co-operation and information exchange are not specified. However, ECHA's general report details measures taken to improve internal communications in particular through the introduction of an intranet facility but without making any quantification of the improvements achieved.

## 3.2 Between CAs

### 3.2.1 CARACAL

The primary organisational body that brings CAs together is Competent Authorities for REACH and CLP (CARACAL) with the overall aim of cooperating with the Commission and ECHA in the implementation of these two regulations. CARACAL is made up of representatives of CAs (REACH and CLP) from the EU and EEA-EFTA countries, plus observers from non-EU countries, international organisations and other stakeholders and has the following four aims[10]:

1. Assist the Commission in the preparation of legislation or in policy definition;
2. Coordinate with Member States for exchange of views;
3. Monitor the development of national policies and the enforcement of EU legislation by national authorities; and
4. Provide expertise to the Commission when drafting of implementing measures, i.e. before the Commission submits these draft measures to a comitology committee

Many CAs made critical comments on the organisation and conduct of CARACAL, and in particular there was perceived to be a danger that CARACAL was becoming merely a dissemination Forum for ECHA and the Commission, providing a means for them to advise on decisions that had already been made rather than being regarded as a means of promoting effective engagement with individual MS. Recommendations made by CAs for the improvement of CARACAL, are summarised in Box 3.1.

**Box 3.1: Summary of Recommendations for Improving CARACAL**

- issues should be raised earlier before the positions of the CAs, ECHA and the Commission became fixed so that the views expressed at CARACAL can be taken into account;
- items for discussion should be included in the agenda – and documents circulated - well in advance (at least 2 weeks) of a meeting;
- agendas should be based on realistic agenda schedules and there was a need for improved

[10] Further details of the objective, aims and membership of CARACAL are published on the Commission Internet site (http://ec.europa.eu/transparency/regexpert/detailGroup.cfm?groupID=2385).

structuring of the agenda to ensure there is adequate time for discussion of each issue and that political and technical issues are each discussed within separate parts of the meeting;
- more active contribution to discussions should be sought from a wider range of MS. This might be facilitated by provision of a larger meeting room with translation services;
- the use of sub-groups to address particular issues was also suggested as a means of easing agenda congestion;
- a 'Manual of Decisions' should be kept on the implementation of REACH and CLP to enable tracking of agreements on implementation issues and related decisions; and
- there was a need for improvement in information exchange between CARACAL and the Forum to facilitate REACH enforcement.

### 3.2.2 Informal Between CAs

The large majority of CAs felt that the effectiveness of communication and collaboration on REACH activities between CAs was moderate or good. However, CAs felt that communication and collaboration could be improved by keeping contact lists for CAs up-to-date and readily available and by increasing the provision for translation into different languages. There was no apparent correlation between the effectiveness of communication/ collaboration between CAs as reported by CAs and their geographical location.

It is also of note that twenty-one CAs have special projects or cooperation with other CAs relating to chemicals other than in relation to REACH.

**Box 3.2: Recommendations to Improve Informal Communications between CAs**

- ECHA and CAs should keep contact details up-to-date; and
- ECHA, the Commission and MS should consider how to improve the provision of translation services for informal CA communication.

## 3.3 Between ECHA and CAs

### 3.3.1 Direct Contact

The large majority of CAs felt that the effectiveness of communication and collaboration on REACH activities between CAs and ECHA was moderate or good, and better than with other CAs. No correlation was identified between the effectiveness of communication or collaboration with ECHA as expressed by CAs and the geographical location of the CAs.

The CAs suggested that communication with ECHA could be improved if the following issues were to be addressed:

- lack of a direct contact person at ECHA for specific issues;
- response time from ECHA is often too long; and
- unnecessarily high levels of formality appear to operate within ECHA.

Furthermore, CAs, felt that ECHA could improve its collaboration with CAs by working with them more, rather than just keeping them informed of its activities.

No details are given in ECHA's Article 117(2) report on the extent or level of co-operation, co-ordination and communication undertaken directly with the MS; this aspect is only addressed in the context of the committees, Forum and the Helpdesk. It is also not clear in this report if ECHA receives feedback from the MS CAs on how notifications of non-compliance are enforced[11]. However, in its annual general reports ECHA states it has continuous contacts with MS (including visits to the CAs). In relation to more flexible instruments, ECHA describes that the intensification of co-operation with MS experts would be advantageous but would require the possibility to provide grants to make use of paid experts.

### 3.3.2 Within REACH Committees

ECHA considers its committees (MSC, RAC and SEAC) to have been operating effectively and reports that these committees have processed all received dossiers within the legal timeframes (Article 117(2) report). ECHA's statement that all committee decisions so far had been adopted either unanimously or by consensus was challenged by the Commission (*pers. comm.*) which drew attention to SEACs decision on lead in jewellery which was made by simple majority.

The ECHA review COM (2012b) states that all deadlines for Committee output have been met, that ECHA supported the Committees in an economic manner and that stakeholders and the majority of Members of the RAC, SEAC and MSC regard the decision making process as independent. However, some criticism is recorded regarding MS representatives bringing in national interests in discussions which could be avoided by delegating non-government bound technical experts rather than representatives of CAs.

In addition to MSC, RAC and SEAC there are a number of other official or semi-official groups involving MS (often CAs), the Commission and ECHA intended to assist in the functioning of REACH. CARACAL brings together CAs to support ECHA and the Commission considerations involved with the operation of REACH. The Forum is officially a part of ECHA and is solely focused on the enforcement of REACH. MSC and CARACAL are concerned with the functioning of REACH as a whole and are therefore considered here but those committees or groups with a more specific focus are considered in the context of that particular focus, as indicated below:

- Risk Assessment Committee (RAC) (see Section 6: Authorisation);
- Socio-economic Assessment Committee (SEAC) (see Section 6: Authorisation);
- Forum for Exchange of Information on Enforcement (the Forum) (see Section 10: Enforcement);
- Security Officer Network (SON) (see Section 10: Enforcement);

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

- REACH Helpdesk Correspondents' Network (REHCORN) and REACH Helpdesk Exchange Platform (RHEP) now HelpNet and HelpEx, respectively (see Section 11: Guidance and Support);
- Partner Expert Groups (PEGs) (see Section 11: Guidance and Support); and
- Risk Communication Network (RCN) (see Section 12: Protection of Human Health and the Environment).

All CAs considered the effectiveness of REACH committees in general to be above average. However, when the CAs were asked about the effectiveness of individual committees, a very different picture emerged with many (occasionally strongly worded) suggestions being proffered for improvement; together these give the impression that at least some CAs may have reservations regarding the operation of various committees.

In general terms, CAs felt that ECHA Committee functions would be improved if the terms of reference and working practices of these Committees were reviewed with a view to improving their efficiency and increasing the time available for discussion and reaching agreement on important issues. The need for increased efficiency of working is also echoed by ECHA in its Article 117(2) report.

Other concerns expressed by CAs related to the adequacy of the resources and facilities available to support the work of the Committees. In particular, there were concerns expressed by CAs that for some committees there were unrealistic expectations as to the level of contribution that was possible from members, given current resource funding arrangements. For its part, ECHA expressed concern that the level of participation by MS was lower than desired (see staffing levels set out in Table 2.2 and Table 2.3) but considered that its level of support for its committees was appropriate. Importantly, both CAs and ECHA have highlighted concerns that the resources available to committees will be insufficient for predicted future increases in work load.

ECHA recommends an improvement of the rules of procedure in general but, in contrast to the detailed suggestions made by some CAs, no detailed proposals are provided. Indeed, CAs provided detailed comments relating to potential improvements to CARACAL (CA Committee), MSC (MS Committee), RCN (Risk Communication Network), RAC, SEAC, Forum (Enforcement Forum), REHCORN (REACH Helpdesk Correspondents' Network, now renamed 'Helpnet'), RHEP (REACH Helpdesk Exchange Platform, now renamed HelpEx), SON (Security Officer Network) and the PEGs (Partner Expert Groups). In contrast ECHA only makes brief reference to its own committees, i.e. MSC, RAC and SEAC.

Recommendations made by CAs and ECHA for the improvement of REACH committees and groups in general are summarised in Box 3.3.

**Box 3.3: Summary of Recommendations for Improving REACH Committees Overall**

**Committee Organisation**

- documents should be made available on CIRCA well in advance of the meetings to ensure proper discussion within MS before the meetings;
- meeting calendars should be set-up at least for one year in advance;
- documents may be provided on the respective group's CIRCA site(s) or on various newsgroup CIRCA sites as well as via ordinary e-mails. Any actions leading to simplified communication would be welcome;
- terms of reference and efficient working procedures need to be given greater attention and kept under review;
- committee procedures are over complicated and should be streamlined;
- some issues should be considered by video conference/ specific internet platforms and also by written procedures; and
- the repetition of items on the agendas of more than one committee should be avoided, where possible.

**Business of Committees**

- the number of training events about specific topics should be increased;
- meeting agendas and presentations of information need to be less lengthy;
- greater human resources are needed from ECHA and MS;
- the choice of NGO representatives and other participants of open sessions should be more selective;
- the interpreter/translation provision should be increased;
- fewer procedures should be subject to restrictive time limitations;
- to avoid unequal workloads between different countries ways should be sought to engage all participants in the discussions and the work to be carried out by:
  - ensuring increased transparency and timely distribution of documents, and
  - greater use of smaller or informal meetings, e.g. break-out groups in workshops;
- closer cooperation is needed between CAs, ECHA and MS/EEA countries to keep the committees fully functional; and
- improved communication is needed between the CA's and the corresponding MSC members (especially when processing of draft evaluation decisions by ECHA).

CAs appeared to agree with ECHA that MSC was generally functioning satisfactorily. However, some CAs were able to make suggestions for further improvement as summarised in Box 3.4.

**Box 3.4: Summary of Suggestions for Improving MSC**

- although presentations at MSC meetings are helpful, agenda's should be modified to allow greater time for discussions;
- greater use should be made of working groups and through use of alternative discussion venues such as webinars;
- discussions would benefit from more active participation by a greater number of the members;
- communication should be improved between the CAs' and the corresponding MSC members, particularly with regard to the evaluation of draft decisions by ECHA; and
- adequate remuneration systems should be introduced for MSs support of co-rapporteurs contributions.

## 3.4 The Commission and other EU Bodies

ECHA states that it regularly liaises with the Commission but no further details or comment are provided on the level or adequacy of co-ordination, co-operation or information exchange between it and the Commission. A large majority of CAs considered the effectiveness of communication and collaboration with the Commission to be above average. However, CAs also provided specific recommendations regarding how the effectiveness of communication and collaboration with the Commission could be improved, as summarised in Box 3.5.

**Box 3.5: CA Suggestions for Improving Communication with the Commission**

- the Commission should work with MS as partners in drawing up the contents and agendas for the meetings;
- CAs and other relevant MS bodies should be more involved in the preparation of Commission proposals; and
- more key documents should be translated into a wider range of EU languages (may facilitate greater participation by some MS).

## 3.5 Other Stakeholders

### 3.5.1 Concerns Pre-REACH

The impact assessments prior to the introduction of REACH include discussion of serious concerns within industry regarding the disclosure of confidential business information. However, the confidentiality provisions considered by many of the impact assessments (e.g. Article 116 of the 2003 Commission Proposal (COM, 2003)) were not considered in earlier impact assessments and were significantly different from those finally adopted (e.g. Article 116 removed from final version of REACH). Therefore, if the confidentiality provisions of REACH have been effective then the estimates of high costs to industry from the loss of such information may be reduced or removed. However, if these provisions have not been effective then the reduction in cost estimates made in later studies would not be justified.

REACH, as adopted, includes the general principle that information provided within registration dossiers must be publically available (Article 77). However, Article 10 (xi) of REACH allows for registrants to request that confidential business information in registration dossiers is not published. Such a request must be accompanied by "a justification as to why publication could be harmful for his or any other concerned party's commercial interests". Similarly, a registrant may opt out of submitting a joint registration where "submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment" (Article 11(3), and Article 19(2) for intermediates). Information on the functioning of these provisions in practice will inform on the veracity of the assumptions made in the impact assessments.

A major factor in the calculation of costs to industry from registration is the mechanism for the sharing of non-animal test data and the mandatory sharing of animal test data within Substance Information Exchange Fora (SIEFs) via the submission of joint registrations. In this respect COM (2012g) estimated that access to data-studies/Letters of Access had so far cost each registration between €5,000 and €10,000 for a simple substance but that large SIEFs for complicated substances had resulted in some companies paying over €1 million for SIEF activities alone.

The supply of use information up the supply chain and of hazard, exposure and risk management information down the supply chain are also key assumptions in reducing costs to downstream users and reducing risks to health and environment, respectively.

### 3.5.2 Activities

The Commission, ECHA and MS co-operate and co-ordinate their REACH activities with other stakeholders via a number of fora, most notably the Directors' Contact Group (DCG) (comprising Commission, ECHA and six industry associations but not MS), and the Risk Communication Network. It would appear that the DCG is perceived by all involved as an important channel of communication for industry, the Commission and ECHA (DCG, 2011). However, although DCG documents are circulated to CARACAL and the Forum, it is clear that the lack of a similarly effective channel of communication with MS (including via CARACAL and the Forum) may have reduced the overall effectiveness of the DCG.

ECHA reports that it liaises with the EU Parliament and Council. It is also of note that working procedures are being developed between ECHA and other EU scientific bodies but ECHA calls for reciprocal legal obligations to be placed on these other bodies to ensure a more systematic exchange of information.

Stakeholder organisations are also involved as observers in many ECHA committees. However, ECHA notes that confidentiality needs to be balanced against transparency of decision-making and – in order to be of value - contributions from observers need to be within the established timeframes. CAs also expressed concerns about the suitability of some observers for participation in some of CARACAL's discussions without elaborating further on these concerns.

Furthermore, ECHA states that it has worked with organisations such as OSHA to raise awareness of registration issues among companies. ECHA has also involved over fifty relevant EU-level stakeholder organisations in its activities, in particular with regard to guidance and IT-tool development. However, reaching and communicating with all relevant organisations is stated as the greatest challenge facing ECHA (page 69 of ECHA, 2011a).

ECHA also describes its international activities in its annual work plan as involving multilateral organisations and conventions, OECD co-operation, contacts with regulatory counterparts outside of the EU, support to (potential) candidate countries, and dissemination of information on REACH implementation beyond the EU (OECD and non-EU countries have observers at CARACAL meetings).

Perhaps the greatest area of communication between stakeholders and the Commission, ECHA and MS, has been with regard to the provision of guidance, support and the dissemination of information to stakeholders, as described in Section 10. Furthermore, communication between duty holders for the purposes of registration (communication in the supply chain and within SIEFs) is considered in Section 4.

Suggestions by CAs for improving the communication with other stakeholders are summarised in Box 3.6 (MS, 2010).

**Box 3.6: Improving Communication between MS, COM and ECHA, and Other Stakeholders**

- improve communication between DCG, CARACAL and Forum by greater circulation of documents between these groups;
- greater care should be taken in selecting suitable observers for committees such as CARACAL; and
- further effort should be focused on co-operation with other stakeholders, particularly with regard to the provision of REACH support.

## 3.6 Coordination with EU Agencies beyond REACH

The recent study into REACH and CLP inspections (COM, 2012i) makes recommendations regarding the coordination of REACH agencies with those responsible for EU legislation other than REACH and CLP, as summarised in Box 3.7.

**Box 3.7: Recommendations for Wider Cooperation**

Information gathered in REACH/CLP is relevant in the enforcement of other EU legislation, including worker health and safety, industrial pollution control and product requirements.

- information generated under REACH should be made available to EU authorities tasked with the implementation or enforcement of other EU legislation.

# 4. OPERATION OF REACH: REGISTRATION

## 4.1 Introduction

### 4.1.1 Expectations

Costs to industry were identified related to the registration of substances by manufacturers and importers from each of the following steps:

- pre-registration;
- research into the properties of the substance;
- chemical safety assessment;
- preparation of safety data sheets; and
- submission of registration dossiers.

Based on the pre-registration information, ECHA expected 14,237 substances to be registered by the first phase-in deadline (i.e. before 1 December 2010) (DCG, 2011). However, by September 2010 ECHA had received information from industry that far fewer substances were likely to be registered by that deadline and in the November of 2010 the DCG estimated this figure to be 4,852.

In part, the costs to industry, MS and ECHA were based on assumptions as to the number of substances subject to the registration steps listed above and the hazards/risks associated with those substances. Many assessments did not consider the phase-in deadlines as finally agreed and therefore may have over or underestimated the costs of REACH.

Some registration costs are considered under other headings including those for MS (e.g. guidance and support, evaluation and enforcement), ECHA (e.g. staffing and structure, IT provision, guidance and support, information exchange and evaluation) and industry (e.g. information exchange, alternatives to testing). Of particular importance to cost predictions for industry were assumptions regarding the extent to which test minimisation measures (such as data waiving, read across and the use of (Q)SARs) would be effective. Further important assumptions regarding costs to industry were made regarding the reduced information requirements for lower tonnage substances (especially <10 tonnes) and for intermediates, as well as the exemption of polymers from registration as substances. The cost burden to industry from fees paid to ECHA was also assumed to be significant.

Indirect costs to industry were predicted to arise from manufacturers/ importers choosing not to register substances because the costs of registration outweighed the profit from the substance concerned (or could be only for certain uses not included in ES). There would be costs to manufacturers/ importers from lost business but the greatest costs were assigned to downstream users losing key ingredients (reformulation costs and/or lost products).

Two REACH provisions were, at least in part, intended to give downstream users prior notice where substances were not likely to be supported:

- publication of pre-registration list of substances (downstream users could check their ingredients against intentions to register); and
- communication of uses up the supply chain and registration intentions down the supply chain (downstream users could let manufacturers/importers know of their use of substances).

Furthermore, where a substance was to be registered but not for all applications, a downstream user has the option to undertake a Chemical Safety Assessment (CSA) and submit an Exposure Scenario (ES) to demonstrate safe use for any application not supported in their supplier's registration.

Not all impact assessments adopted adjusted estimates for the mitigating provisions listed above. Furthermore, some studies included assumptions that any impacts from substance withdrawals by producers would be magnified down the supply chain.

### 4.1.2 Provisions

The key provisions of REACH related to registration are summarised in Table 4.1. In general REACH requires all companies that manufacture or import substances in quantities greater than one tonne per year to register their substances before placing them on the market in the EU. This requirement seeks to address the concerns detailed in the Commission White Paper (COM, 2001) regarding the lack of information available on 99% of chemicals on the market in the EU. Registration also places the burden of demonstrating that chemical substances are safe on industry rather than on the regulator. Failure to register would result in a manufacturer or importer being unable to legally place their substance on the market in the EU.

**Table 4.1: Key Registration Provisions under REACH**

| Article | Details |
|---|---|
| ***General Registration*** | |
| 4 | Provision for third party representatives to act for EU companies for the purposes of registration |
| 5 | Manufacture or placing on the market of substances on their own, in mixtures or in articles only after registration: General obligation to register – no data, no market |
| 6 (1) | All manufacturers or importers of a substance, in quantities of one tonne or more per year to submit a registration to ECHA |
| 6(2) | Registration for monomers that are used as on-site intermediates or transported isolated intermediates |
| 6(3) | Registration of monomer substance(s) or any other substance(s) in polymers that have not already been registered by an actor up the supply chain |
| 7(1) | Producer or importer of articles to register substances with intended release |
| 8 | Provision for only representatives for the registration of substances by companies based outside of the EU |
| 10 | Information for registration shall contain the technical dossier and the CSR |
| 11 | Provision for joint submission of data by multiple registrants of the same substance |

| **Table 4.1: Key Registration Provisions under REACH** | |
|---|---|
| **Article** | **Details** |
| 12(1) | Requirement to include in the technical dossier all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant |
| 12(2) | Manufacturers and importers to notify ECHA with additional information when a substance reaches the next tonnage threshold |
| 13 | General provisions for hazard data generation, including general provisions for minimising testing on vertebrate animals (more detail in Annexes VI to XI) |
| 14(1), | A CSA and CSR needed for all substances subject to registration in quantities of 10 tonnes or more per year per registrant |
| 14(3) and (4) | Outline for CSA process |
| ANNEX I | Under the Exposure Assessment the CSR should identify the waste management measures to reduce or avoid exposure of humans and the environment to the substance during waste disposal and/or recycling |
| 14(6) | Requirement on a registrant to identify and apply the appropriate measures to adequately control the risks identified in the CSA and where suitable recommend them in SDS |
| 14(7) | The CSR shall be kept available and up to date |
| 20 | Duties of ECHA to assign registration numbers, undertake completeness checks and to notify MS of registrations |
| 21(1) | Manufacture or import of a substance or production or import of an article may start or commence within three weeks of the registration submission date, unless ECHA indicates otherwise |
| 21(2) | Manufacture or import of a substance may continue after ECHA has informed the registrant that they must submit further information and further information has been submitted, within three weeks of the submission date, unless ECHA indicates otherwise |
| 22(1) | Responsibility of registrant to update registration as necessary and without undue delay |
| 22(2) | Requirement for a registrant to submit to ECHA an updated registration providing the information required by an ECHA decision |
| | |
| 25 | Rules for data sharing for joint submission, to reduce testing especially testing on vertebrate animals |
| 26 | Duty of registrants to inquire of ECHA whether there are previous registrants |
| 27 | Provisions for the sharing of data from previous registrations and requirement on registrants to seek such data from previous registrants |
| 29 | Requirement for registrants to share information in their SIEF(s) |
| 30 | Rules for the sharing of data in SIEFs |
| 37 | Provisions for downstream users to provide information on their use(s) of a substance to a registrant |
| 41 | Provisions for compliance checking by ECHA |
| ***Phase-in (Pre-registration) Provisions*** | |
| 23 | Provisions for the phase-in of registrations for substances already on the market in the EU (existing substances) according to the following registration deadlines:<br>• 1 December 2010: substances CMR > 1 tpa, R50/53 under Directive 67/548/EEC > 100 tpa, and/or > 1,00 tpa;<br>• 1June 2013: substances > 100 tpa < 1,000 tpa; and<br>• 1 June 2018: substances > 1tpa < 100 tpa |
| 28 | Requirement to pre-register to benefit from phase-in provisions |

| **Table 4.1: Key Registration Provisions under REACH** | |
|---|---|
| **Article** | **Details** |
| ***Reduced Information Requirements or Exemptions*** | |
| 2(1) and 2(2) | Radioactive substances, substances in transit, non-isolated intermediates and waste are not subject to REACH, including registration provisions |
| 2(3) | MS may allow exemptions from any provision of REACH, including registration, where necessary for defence |
| 2(5) | Substances used in medicinal products, food or feedingstuffs are exempt from registration |
| 2(7) | Substances listed in Annex IV or Annex V are exempt from registration |
| 2(7) | Substances registered and re-imported are exempt from registration |
| 2(7) | Substances registered and recovered from waste are exempt from registration |
| 9 | Reduced registration requirements for substances used for product and process orientated research and development (PPORD) |
| 12(1) | Greater reductions in information requirements for lower tonnages in the following order <1,000 tonnes, >100 & <1,000 tonnes, >10 & < 100 tonnes, and < 10 tonnes, respectively |
| 15 | Plant protection products and biocidal products are regarded as being registered |
| 17(1) and (2) | Reduced registration requirements for the registration of on-site isolated intermediates |
| 18(1), (2) and (3) | Reduced registration requirements for the registration of transported isolated intermediates |
| 19 | Provision for the joint registration of isolated intermediates by multiple registrants |
| 20(2) | Requirement to complete the registration and to submit it to ECHA within the deadline set in case of incomplete registration. |
| 24(1) | The previous notification of a substance by a company under Directive 67/548/EEC (NONS) is regarded as being a registration by that company |
| 24(2) | Requirement on a registrant to notify ECHA, when a substance notified under Directive 67/548/EEC (NONS) reaches the next REACH tonnage threshold |
| ***Substances in Articles*** | |
| 7(2) and (4) | Producer or importer of an article to notify ECHA regarding SVHCs |
| 7(3) | Producer or importer to supply appropriate instructions to the recipient of the article containing SVHCs with controlled exposure |
| 7(5) | Registration of substances in articles where ECHA has decided that the substance released from the article is suspected of presenting risks to human health or the environment |
| General notes.<br>Registration provisions under REACH do not apply to substances manufactured or imported in quantities of less than one tonne per year per registrant.<br>Provisions for the evaluation of registration dossiers are considered in Section 8 and are not reproduced here.<br>The highlighted provisions have been identified by COM (2012k) as key drivers for the benefits to human health and the environment (see also Section 12). | |

A registration dossier may potentially include information on physicochemical, toxicological and ecotoxicological hazard endpoints, with the amount of information required for registration increasing with increasing amounts of the substance manufactured or imported. Manufacturers and importers are required to submit a technical dossier, for substances registered in quantities of 1 tonne or more. The technical dossier contains information on the properties, uses and on the classification of a substance as well as guidance on safe use. For substances registered at quantities greater than 10 tonnes per annum, a chemical safety assessment (CSA) also needs to be conducted and documented in a chemical safety report (CSR) which accompanies the technical registration dossier.

For substances classified as hazardous, the CSA includes the development of exposure assessments and risk characterisations for all the considered uses of the substance. The CSA must also include an exposure assessment for all substances that meet the criteria for being Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) substances as set out in Annex XIII to REACH.

Please note that the assessment of registration as a driver for benefits to **human health and the environment**, and recommendations are set out in Section 12.

## 4.2 Pre-registration

REACH includes provision for the phased registration of substances already on the market in the EU prior to the introduction of REACH by the following deadlines, where the tonnages indicated are per manufacturer/importer (Article 23):

- 1 December 2010: Substances manufactured or imported in quantities greater than 1,000 tonnes per year;
- 1 December 2010: Substances meeting the criteria for classification as a carcinogen, mutagen or reprotoxin (CMR) Cat. 1 or 2 (under Directive 67/548/EEC) manufactured or imported in quantities greater than 1 tonne per year;
- 1 December 2010: Substances meeting the criteria for R50/53 (under Directive 67/548/EEC) manufactured or imported in quantities greater than 100 tonnes per year;
- 1 June 2013: Substances manufactured or imported in quantities greater than 100 but less than 1,000 tonnes per year; and
- 1 June 2018: Substances manufactured or imported in quantities greater than 1 but less than 100 tonnes per year.

To be eligible for this phased approach, potential registrants must have pre-registered with ECHA their intention to register in the period 1 June 2008 to 1 December 2008. Pre-registration was intended to facilitate the formation of SIEFs (and thus avoid duplication of testing, especially testing involving vertebrate animals), to allow downstream users to discover whether or not their substances are likely to be registered and also to allow ECHA to anticipate the volumes of registrations to be handled (implicit within Recital 54, Article 28 and ECHA 2011a).

ECHA reports that it received 2.7 million pre-registrations with respect to 146,000 phase-in substances, including 41,000 substances without an EC number[12] (18%). Also, 14,500 substances were submitted as multi-constituent substances. The number

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

of pre-registrations was 15-times higher than had been estimated[13]. The reason for this discrepancy between predicted and actual numbers of pre-registrations is not known. However, as there were no fees for pre-registration it is possible that many companies pre-registered substances before they were clear whether or not they had registration obligations (i.e. may have adopted a "just in case" approach to this stage). Whatever the reason, the high number of pre-registrations led to a temporary overload of the ECHA IT-systems, and communications with industry on the system usability. ECHA managed well to effectively process pre-registrations by flexibly relocating resources (COM 2012b).

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

ECHA also reports that only 10% of pre-registrations for the 2010 phase-in deadline actually resulted in registrations by that time. This discrepancy caused some fear for downstream users regarding continued supply of substances but ECHA had no evidence to suggest that these fears were coming true (COM, 2012f and COM, 2012k). In response to the issues described above ECHA (ECHA, 2011a) and the REACH benefits study (COM, 2012k) made the recommendations for the improvement of the functioning of pre-registrations ahead of future phase-in registration deadlines summarised in Box 4.1.

**Box 4.1: Suggestion for Improving Pre-registration**

- ECHA should encourage pre-registrants to voluntarily remove or amend unnecessary or inaccurate pre-registrations (already implemented by ECHA); and
- ECHA should improve its system for collecting information from registrants on reasons for not registering pre-registered substances (already being attempted by ECHA).

## 4.3 Registration

### 4.3.1 Numbers of Registrations

The first phase-in deadline of 1 December 2010 has now passed and therefore all of the following substances should have been registered by this date: the substances manufactured or imported in quantities of 1,000 tonnes or more per year; carcinogens, mutagens and reprotoxins category 1 and 2 under Directive 67/548/EEC manufactured or imported in quantities of 1 tonne or more per year; and substances with a risk phrase of R50-53 under the same Directive (PBTs or vPvBs) manufactured or imported in quantities of 100 tonnes or more. In addition to these phase-in

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

substances, all non-phase-in substances manufactured or imported in quantities of 1 tonne or more per year will have been registered.

ECHA understands the registration process to date to have been a success, pointing to the important contribution made by its IT-system and IT-tools for industry. The DCG agree with this assessment, attributing at least some of the success to the work of the DCG (DCG, 2011).
Approximately 26,000 registration dossiers have been successfully processed by ECHA[14], including for phase-in and non-phase-in substances, as set out in Figures 4.1 and 4.2, and intermediates, as set out in Table 4.1.

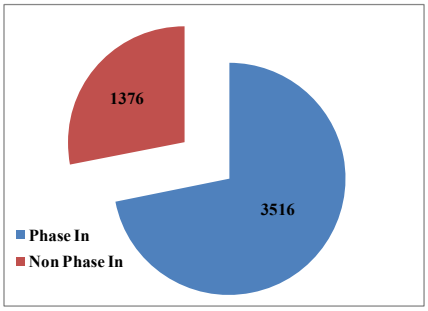



**Figure 4.1: Number of Registered Substances (June 2008 – May 31, 2011)[15]**

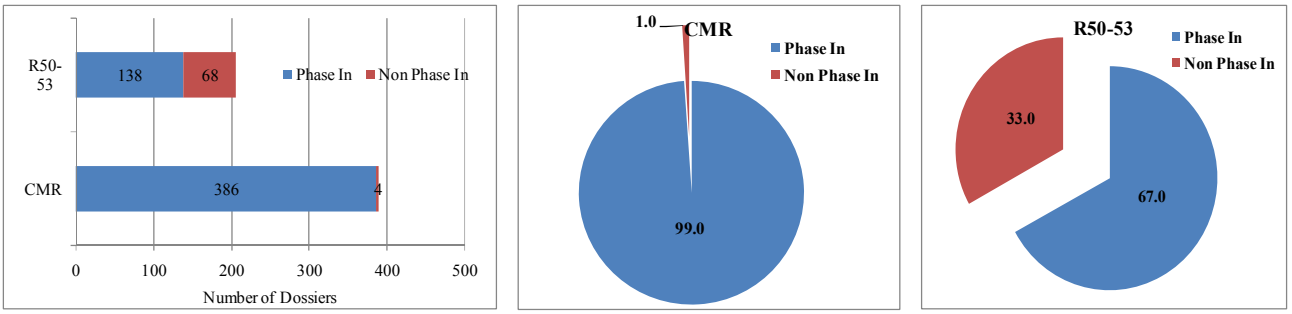



**Figure 4.2: Total Number and Proportions of Phase-In and Non-Phase-In Substances in Notified Substances with a Classification as CMR or R50-53 (June 2008 – May 31, 2011)[16]**

| **Table 4.1: Number of Registered Substances** | | | | | |
|---|---|---|---|---|---|
| **Completed dossiers** | **2008** | **2009** | **2010** | **2011 (Q1)** | **Total** |
| Registration of on-site isolated intermediates | 12 | 85 | 1,373 | 70 | 1,540 |
| Registration of transported intermediates | 46 | 196 | 3,426 | 247 | 3,915 |
| Regular registration dossiers | 10 | 217 | 18,969 | 1,686 | 20,882 |
| ***Total registrations*** | ***68*** | ***498*** | ***23,768*** | ***2,003*** | ***26,337*** |
| Source: ECHA report on the operation of REACH, Table 1, p. 10. | | | | | |

14 According to the ECHA's Evaluation Report 2011 (ECHA, 2012), a total of 25,378 complete registration dossiers had been received by the end of 2011 but the reason for this discrepancy in the number of dossiers is not explained.

15 Additional information provided by ECHA, on request.

16 Additional information provided by ECHA, on request.

The size of the companies that registered in 2010 is shown in Figure 4.3.

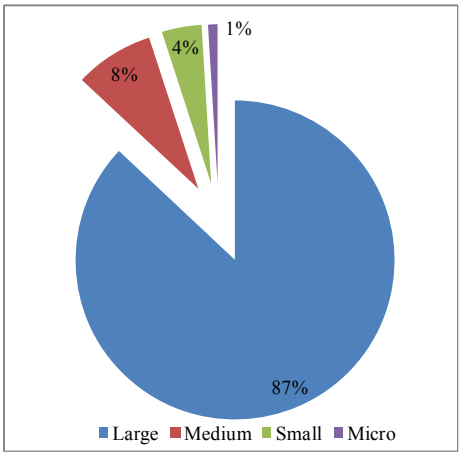



**Figure 4.3: Company Size of Registrants in 2010**[17]

In all 19% of all dossiers were submitted by Only Representatives (ORs), 940 Notifications of New Substances (NONS) under Directive 67/548/EEC were updated (for 51% of NONS, a registration number was claimed), and 679 notifications for Product and Process Orientated Research and Development (PPORD) were completed.

From ECHA (2011a) it is clear that almost 75% of registrants were based in only 7 MS. CAs provided information regarding the number of registrants and other duty holders within their MS (MS, 2010). However the metrics used were not consistent and, consequently, no consistent numbers could be calculated across the EU27/EEA as a whole. Furthermore, mechanisms were put in place by ECHA to allow a small number of companies that were unable to submit their registration by the 2010 deadline due to no fault of their own, not to be penalised as recommended by the DCG.

Looking forward to future registrations the Commission sponsored studies have identified concerns with regards to the capacity of testing laboratories to meet the spikes in demand predicted in the run-up to the next two phase-in registration deadlines (COM, 2012g and COM, 2012k). If realised, these concerns could result in the withdrawal of some substances from the market, delayed registrations and/or the submission of incomplete (possibly illegal) dossiers.

***Nanomaterials***

An ongoing Commission study looking at the registration of nanomaterials (COM, 2012c) found the identification of dossiers that included nanomaterials to be very challenging. The version of IUCLID 5.2 available at the time of the 1 December phase-in registration deadline did allow registrants to identify their substance as a nanoform or as containing a nanoform but these sections of IUCLID were optional

[17] ECHA report on the operation of REACH, Figure 1, p. 10.

and, therefore, not always completed. Furthermore, the absence of an agreed definition of nanomaterials at that time[18] may have left registrants unsure whether or not it was appropriate to identify their substance in this way and it proved impossible for joint registrants to submit some key data on their nanomaterial if this was not included by the lead registrant (see also Section 4.4).

Overall, it was therefore up to each registrant to decide:

- whether their substance should be considered to be a nanomaterial;
- whether such materials should be registered on their own or as a nanoform together with other forms of a substance;
- the nature and extent of nano-specific information to provide; and
- which nano-specific issues to address in the registration dossier and what nano-specific conclusions to draw in the assessments in various part of the dossier.

Since the publication by the Commission of a recommended definition of nanomaterials it was noted that registrants generally had not provided information on the constituent/primary particle size distribution that would be needed to determine whether or not a substance met the Commission definition (Commission Recommendation 2011/696/EU). This is not an unexpected finding however, given that this information is not required for registration, but some registrants did include particle size distribution with information on granulometry or on substance identity.

Draft options for the improvement of the provisions for the registration of nanomaterials are under consideration in COM (2012c). However, these are very much 'in development' at the time of writing this report and have not therefore been reproduced or summarised here.

### 4.3.2 Costs of Registrations

The studies to assess the impacts of REACH on competitiveness (COM, 2012g) have identified cost drivers and estimated costs for registration, as set out here:

- the typical cost per registration was between €50,000 and €100,000. However, the cost distribution was very wide, varying by type of substance and size of SIEF;
- the main cost drivers stated by registrants were:
    - ECHA fees (often represent 50% or more of the total costs, especially in the case of more simple substances);
    - access to data-studies/Letters of Access (€5,000 to €10,000 for a simple substance); and
    - human resources;

[18] A Commission Recommendation on the definition of namomaterial has since been published (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF).

- the estimated total costs from registration so far estimated by industry are between €1.1 billion and €2.3 billion (i.e. 26,000 registration dossiers at €50,000 to €100,000 per dossier);
- registration costs have amounted to <0.5% of annual turnover for 60% of registrants;
- lead registrants generally incurred higher costs;
- in general larger firms report higher average registration costs; and
- the registration costs for intermediates are typically around €10,000.

The COM (2012g) estimates are based on responses from industry and relate to registrations to date. In this respect ECHA report that 90% of registrations to date are for greater than 1,000 tonne substances, and 87% of these were submitted by large companies (ECHA, 2011a).

Figure 4.4, reproduces a summary of the registration cost data gathered by these two studies (COM, 2012g).

| Value in €s | Importers of chemicals | | Manufacturers of chemicals | | Total | |
|---|---|---|---|---|---|---|
| | No. | % | No. | % | No. | % |
| 0-10,000 | 7 | 7.6% | 11 | 4.3% | 21 | 5.6% |
| 10,001-25,000 | 18 | 19.6% | 20 | 7.9% | 41 | 11.0% |
| 25,000-50,000 | 22 | 23.9% | 51 | 20.2% | 80 | 21.4% |
| 50,001-100,000 | 24 | 26.1% | 74 | 29.2% | 106 | 28.4% |
| 100,001-250,000 | 19 | 20.7% | 57 | 22.5% | 80 | 21.4% |
| 250,001-500,000 | 2 | 2.2% | 24 | 9.5% | 28 | 7.5% |
| 500,001-1,000,000 | | 0.0% | 7 | 2.8% | 8 | 2.1% |
| >1,000,000 | | 0.0% | 9 | 3.6% | 9 | 2.4% |
| Total | 92 | 100% | 253 | 100% | 345 | 100% |

**Figure 4.4: Average Costs for Single Registrations**

In addition, the cost of a single intermediate registration was estimated to be approximately €10,000 (COM, 2012g). However, this figure will include the costs of the registration of transported intermediates over 1,000 tonnes (as for 1 to 10 tonne substances). This latter consideration is likely to have significantly increased the average cost given that 72% of intermediate registrations at the time of the CSES study were for transported intermediates and 90% of registrations were for substances over 1,000 tonnes (ECHA, 2011a).

### 4.3.3 Benefits to Human Health and the Environment

The Commission study into the human health and environmental benefits of REACH produced a number of recommendations for obtaining the information needed to fully identify and quantify the benefits (or not) resulting from registration (COM, 2012k). Recommendations are also made to potentially increase these benefits, which are set out in Section 12, and not repeated here for brevity.

## 4.4 Joint Submission

The provision for the joint submission of registration dossiers was a concept largely new to REACH and, at the time, some industry representatives expressed uncertainty that that this would work in practice (Abelkop *et al*, 2012). However, with experience these same representatives now accept that data sharing and joint submission has worked better than they expected; although, these provisions were also considered to be burdensome.

Nearly 90% of all dossiers were submitted jointly, resulting in a total of 2,945 lead dossiers and 19,610 joint dossiers (the average ratio of member to lead dossiers was 6.7), leading ECHA to consider the joint submission process to be generally working well. However, ECHA noted that there had been difficulties in establishing lead registrants because of the high work load involved and a general lack of understanding of the obligations of this role. The late submission of lead dossiers also caused time pressure on other SIEF registrants. Given the pivotal role of lead registrants in the effective functioning of joint registration ECHA has made the recommendation shown in Box 4.2. This suggestion is in addition to the work already being undertaken by ECHA to encourage lead registrants to make themselves known to ECHA, including the provision of additional support available only to lead registrants.

**Box 4.2: Recommendations for Improving Joint Submission**

- ECHA should introduce incentives to promote the timely submission of lead dossiers and to raise the awareness of member registrants on the timing of dossier submission.

Opt-outs from joint registration for one or more endpoints were noted to have occurred in 135 cases across all dossiers. Of all dossiers in the range >1000 tpa considered, 82 dossiers covering 60 substances included opt-outs. Opt-outs related to a total of 1,437 endpoints; typically two opt-outs were included per dossier. Furthermore, ECHA received either multiple joint submissions (of lead and joint dossiers) or more than one individual (lead) dossier, in addition to a joint submission for 250 substances and is investigating the causes for this.

***Nanomaterials***

The study into the registration of nanomaterials (COM, 2012c) identified granulometry data as being important for the identification of nanomaterials but, as granulometry is dependent upon the manufacturing process used, members of joint submissions would need to all have provided separate data on this endpoint. However, members of a joint submission are unable to submit their own individual granulometry data, indeed, to do so would require an amendment to the legal text. Alternatively, potential joint registrants would have to opt out of joint registration to provide this individual data. It should be noted that, under the current provisions of REACH, the consequences had each registrant provided separate granulometry data (i.e. opted out) would have included reduced data sharing opportunities (registrant

not part of a SIEF), higher registration fees and the possibility for prioritisation of the dossier for compliance check. A simple recommendation is therefore set out in Box 4.3 to allow registrants to submit more accurate source-specific physicochemical data as part of a joint registration.

**Box 4.3: Recommendations for Improving Joint Submission of Physicochemical Data**

- ECHA, the Commission and industry should seek ways to allow non-lead registrants to provide registrant specific data on granulometry and other physicochemical endpoints while remaining within a joint registration. This may include the addition of safeguards to ensure that any hazard or risk assessment undertaken by the lead registrant is updated, as appropriate.

## 4.5 Substance Information Exchange Fora

Figure 4.4[19] shows the number of substances for which SIEFs were in a certain size range (number of potential participants). However, as stated above, a significant number of potential registrants that pre-registered substances for registration in 2010 did not actually proceed to register the substances by this deadline. For example, approximately 32,000 substances were pre-registered for this deadline by just one company.

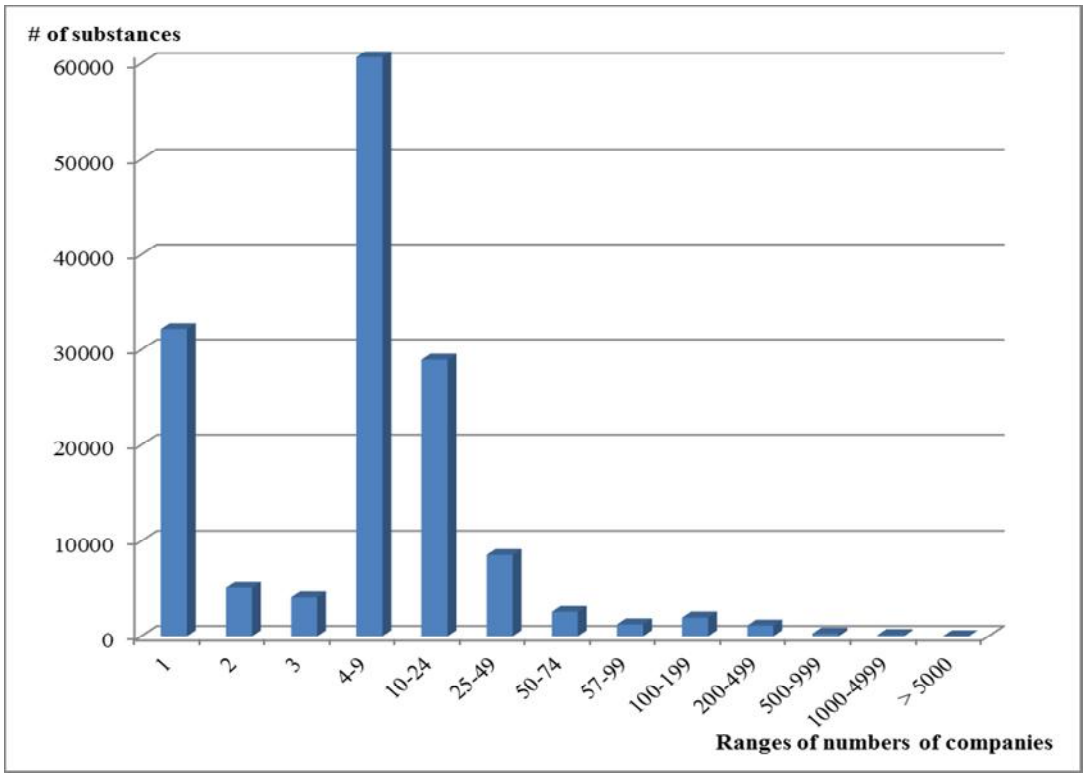



**Figure 4.4: Size Distribution of SIEFs related to Number of Substances[20]**

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

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

After pre-registration, industry was required to form SIEFs and 2,176 lead registrants identified themselves voluntarily to ECHA. ECHA reports that in practice SIEFs appear to have suffered due to the large number of (potential) members, making communication and co-operation complex, resource needs intensive and causing delays. This assessment of the operation of SIEFs is supported by DCG (2011), which also indicates that SIEFs present specific additional challenges to SMEs who have fewer resources and, hence, are more vulnerable to unequal treatment and language barriers[21]. Also, as SMEs generally cannot invest as much time in the SIEFs as bigger companies, they are subject more easily to misunderstandings. ECHA extended these concerns to include companies which did not form part of existing consortia (in particular importers, ORs and SMEs). Overall, ECHA understands data sharing is succeeding in avoiding vertebrate animal testing (c.f. Section 9).
Information from COM (2012f) and COM (2012g) would seem to paint a mixed picture that partially supports both the opinion of ECHA and that of the DCG, with the operation and effectiveness of SIEFs varying a great deal in the following ways:

- SIEFs are generally considered by industry to be effective in reducing the costs of registration;
- problems have been identified with respect to communication and coordination within SIEFs, linked to the very large number of pre-registrations and the existence of many dormant or inactive registrants;
- SIEFs vary greatly in terms of size and the capacity of managers/lead registrants;
- the consortia are most often seen as having a positive role within SIEFs, as summed up by the following industry comment "this is where most of the work is being done"; and
- there is a lack of clarity with regards to the setting of prices for Letters of Access. This is seen as having a disproportionate impact on SMEs with the potential for such companies to be forced to exit the market.

Only a small number of data sharing disputes have been forwarded to ECHA and all were resolved within the deadlines. ECHA believes the existence of the dispute settling mechanism has encouraged data sharing in the SIEFs. However, ECHA notes that penalising breaches of data sharing obligations is difficult due to the different organisation of enforcement authorities in the Member States. In this respect the innovation and competitiveness studies also identified concerns regarding breaches of competition rules and abuse of the dominant position of some companies within SIEFs. The key issues underlying these concerns are listed here but it should be noted that these studies could not find robust evidence with which to either substantiate or repudiate these concerns:

- the high costs of Letters of Access was a particular concern for small firms but this may be mainly an issue of transparency of charges;
- industry was found to be largely aware of competition legislation issues which are closely monitored but concerns persist; and

[21] It seems that most SIEFs use English as the common language.

- concerns in relation to business intelligence appear inherent to the whole SIEF/registration process.

Finally, ECHA recommends that industry produce 'best practice' for SIEFs and the DCG believes that industry needs to provide further tools and guidance to SIEFs, including developing IT solutions for improving transparency and communication within SIEFs.

## 4.6 Only Representatives

The studies on innovation and competitiveness (COM, 2012f and COM, 2012g) found companies were positive overall with the REACH support and cost of Only Representatives (ORs), with the ORs themselves ranging in size from single individuals to large companies. Concerns were expressed by companies regarding the quality of the services offered by some ORs and the communication of information to their clients and other importers. Indeed, the expected roles and obligations of ORs with regards to communication in the supply chain and authorisation, were found to be unclear.

## 4.7 Exemptions Assessments

### 4.7.1 Low Tonnage Substances

The more limited registration requirements for the registration of substances in quantities less than 10 tonnes per year per registrant (1 to 10 tonne substances) must be reviewed by 1 June 2012, in the light of experience to date. The Commission study to undertake that review is still underway but it has identified potential options for changes to these registration requirements (COM, 2012d). Furthermore, early indicative cost and benefit estimates of these options have been compared with the current 'baseline' situation indicating possible overall benefits from some increase in the registration requirements for 1 to 10 tonne substances but no benefits from reducing these requirements still further.

### 4.7.2 Polymers

COM (2012d) is also considering whether changes may be justified to the current exemption of polymers from registration. This work was still in progress at the time of writing but it was noted that information on the range of polymers on the market, their hazards and uses, appeared to be very limited. This lack of information could lead to recommendations for some form of registration to fill this information gap (a key motivation for the development of REACH (see COM (2001)). Alternatively, it may be concluded that more information must be gathered before a robust case can be made for or against such action.

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

## 5.1 Introduction

Manufacturers and importers are required to provide hazard, exposure and risk management information to their customers, primarily via (extended) Safety Data Sheets ((e)SDS), including Exposure Scenarios (ESs) where required as part of a Chemical Safety Assessment (CSA), and documented in a Chemical Safety Report (CSR). The ESs communicated should not include those for uses where adequate control cannot be demonstrated. Where such uses are identified in the CSA they should be explicitly advised against. Downstream users may not use a substance for an application that falls outside of the ESs supplied to them unless they produce their own CSR for that use.

Further REACH provisions requiring companies to communicate information up and down the supply chain include:

- (e)SDS should be communicated down the supply chain, together with a relevant ES where required;
- where SDS are not required, companies are still required to communicate hazard information down the supply chain for substances subject to restriction, authorisation or which require specific risk management;
- new hazard information or information questioning the validity of risk management measures must be communicated up the supply chain;
- suppliers of articles that contain substances identified as Substances of Very High Concern (SVHCs) and that are included on the candidate list for authorisation must, on request, provide the information available to them down the supply chain including to consumers, to enable safe use of those articles (at a minimum this should be the name of the SVHC); and
- downstream users have to identify, apply and recommend risk management measures.

With respect to the communication of information in the supply chain the SDS is the core instrument for communicating information down the supply chain from the manufacturer, importer and formulator. The requirement to implement recommended conditions of use is expected to lead to the actual changes in risk management (COM, 2012k).

The key provisions of REACH that related to communication in the supply chain are summarised in Table 5.1.

| **Table 5.1: Key Provisions under REACH for Communication in the Supply Chain[1]** | |
|---|---|
| **Article** | **Details** |
| 31(1) | Substance or a mixture suppliers are to provide recipient with a SDS compiled in accordance with Annex II |
| 31(2) | Requirements for downstream user CSAs to show adequate control for uses outside of ESs in supplier's SDS |
| 31(3) | Additional requirements on a supplier to provide SDS for a mixture containing substances with specified hazard properties, on request |
| 31(4) | Additional requirements on a supplier to provide a downstream user or distributor with a SDS for a hazardous substance or mixture which is offered or sold to the general public, on request |
| 31(5) | SDS to be provided in the language of the MS to which a substance/mixture is supplied |
| 31(6) | Headings required for REACH SDS |
| 31(7) | Requirement on actors in the supply chain to place the relevant ESs in an annex to the SDS and include ESs in their own SDS. Distributors are also required to pass on relevant exposure scenarios and use other relevant information from SDS supplied to them when compiling their own SDS |
| 31(8) and 31(9) | SDS to be provided free of charge either electronically or on paper. SDS should be updated by suppliers and provided free of charge to all former recipients |
| 32 (1) | Information to be provided when a SDS is not required |
| 33(1 and 2) | Requirement for suppliers of articles containing SVHCs to provide the recipient, on request, with sufficient information to allow safe use, including as a minimum the name of the SVHC, free of charge and within 45 days of the request |
| 34 | Every actor (including distributor) in the supply chain is required to communicate the information on new information or any other information that might call into question the appropriateness of the risk management measures to the next actor or distributor up the supply chain |
| 35 | Employers must provide workers and their representatives with access to information received in relation to substances or mixtures which they may use or be exposed to in the course of their work |
| 37(2) | Right of downstream users to make a use known and the obligation for distributors to pass on such information to the next actor up the supply chain |
| 37(4) | Downstream users must prepare a CSR for any use outside either the conditions described in an exposure scenario or a use and exposure category in a SDS or for any use his supplier advises against |
| 37(5) | Downstream users must identify, apply and recommend appropriate measures to adequately control risks identified |
| 37(6) | Downstream users must identify and apply appropriate risk management measures needed to ensure that the risks to human health and the environment are adequately controlled |
| 37(7) | Downstream users must keep their CSRs up to date and available |
| 38(1) | Requirement for downstream users to report information to ECHA on substances used outside of their suppliers registration (own CSA/CSR or used below 1 tonne) before commencing or continuing with a particular use of a substance |
| 38(2) | Information to be reported to ECHA under Article 38(1) |
| 38(3) | Requirement to update the information reported under Article 38(1), without delay |
| 38(4) | Requirement that a downstream user report to ECHA if its classification of a substance is different to that of its supplier |
| 39 | Article 37 obligations must be complied with at the latest 12 months after receiving a registration number.<br>Article 38 obligations must be complied with at the latest 6 months after receiving a registration number |
| Note 1: All of the provisions set out here are identified as potential drivers of benefits to human health and the environment (COM, 2012k). | |

Please note that the assessment of information in the supply chain as a driver for benefits to **human health and the environment**, and recommendations are set out in Section 12.

## 5.2 Communication of Information

The Director's Contact Group (DCG, 2011) indentified the need to improve communication in the supply chain and had particular concerns about the ability of downstream users to assert their communication rights under REACH, to make their uses know to registrants and to have these covered in CSRs. There were particular concerns with respect to registrants only including intermediate uses in dossiers even where they have advised the supplier that they have other uses. The DCG therefore recommended that the Commission and ECHA produce more comprehensive 'best practice' guidance on this issue with work on this to begin in 2011. Such guidance had not been published at the time of writing but this issue is addressed in the Frequently Asked Questions Section of the ECHA Internet site (http://echa.europa.eu/reach/faq_en.asp). The DCG also requested that industry representatives publicise and encourage downstream users to make their uses known up the supply chain to manufacturers and importers. In this respect it is noted that industry have subsequently produced guidance that goes some way towards meeting these recommendations by the DCG[22].

Articles manufacturers, importers, distributors and retailers have also expressed concerns with regards to the requirements for retailers to be able to provide information on SVHCs to consumers (COM, 2012g). COM (2012g) found that there had been very few consumer requests to date but concern remained regarding the ability of supply chain communication to provide the information promptly.

MS describe providing advice to downstream users via their helpdesks and this may go some way to addressing the above issue until further guidance becomes available (MS, 2010). Furthermore, ECHA intends to set up a discussion platform for registrants and downstream users to share and discuss experience on exposure scenarios which may also address this issue, as well as the concern identified by ECHA regarding a lack of harmonisation of ESs prepared by registrants to date (ECHA, 2011a).

The studies on the REACH impacts on innovation and competitiveness (COM, 2012f and COM, 2012g) concluded (e)SDS development and handling was problematic for companies at this early stage of the implementation of REACH and identified the following issues in particular:

- no consistent/common format for the (e)SDSs (even though this is set out in Annex II to REACH);

[22] *Communication of uses along the supply chain for 2013 registration*, produced jointly by **Cefic, DUCC** and **FECC** (http://www.cefic.org/Documents/IndustrySupport/REACH%20Implementation/Letter_on_use_of_communication.doc).

- ESs are long documents that are difficult to handle, leading to the loss or obscuring of relevant information; and
- varying familiarity exists among companies regarding the processes/ mechanisms involved.

The Forum reports that 9% of companies did not have SDS available for inspection and the SDS provided by 16% of companies did not meet the requirements prescribed for SDS under REACH (Forum, 2011). Furthermore, the provision of extensive ES information has been identified as having the potential to seriously interfere with the effective communication of safety information down the supply chain via eSDS (COM, 2012k). It is, however, noted that ECHA has produced additional guidance on the preparation of (e)SDS which may serve to improve the quality of SDS but even so the REACH benefits study still recommend further action to improve this situation, as detailed in Section 10.

## 5.3 Quality of Information

The Eurostat baseline update (COM, 2012a) found that over the previous five years there has been a marked increase in the quality of the data which were available for assessment of substances now registered under REACH. More specifically, the study found that:

- the quality of the underlying data has improved considerably between 2007 and 2011;
- the improvement in quality is evident in all of the four impact areas considered by this study (i.e. in relation to workers, consumers, environment and humans via the environment);
- for the majority of HPV and SVHC substances, the quality of the data underlying the exposure estimate and the toxicity estimate has improved;
- for the first time, some of the reference substances monitored have attained the best possible 'quality score' in some, but not all, of the four impact areas; and
- registration has resulted in DNELs, PNECs and more detailed information on uses becoming available for communication in the supply chain for a large number of substances.

## 5.4 Cost of Communication

COM (2012f) and COM (2012g) identified the following cost drivers for companies communicating information in the supply chain:

- staff costs for the preparation and/or handling of (e)SDS;
- investment in IT systems; and
- the time consuming nature of communication in the supply chain, often due to a low level of awareness of this aspect of REACH among many companies,

mainly with regard to small downstream users and those based outside of the EU.

The typical cost to companies was estimated to be approximately the cost of one full-time equivalent (FTE) member of staff plus the cost of IT system installation and maintenance (per business unit). Communication in the supply chain was found to be easier for companies from sectors with an existing integrated supply chain structure, such the automotive sector. Furthermore, it was not clear how these costs might change over time, with the possibility of cost reductions from the dissemination of experience and the availability of better communication tools/IT potentially balancing an increase in the number of companies (and substances) involved with communication in the supply chain.

## 5.5 Barriers to Supply Chain Communication

The REACH benefits study found overall trends which identified the following factors which are currently hampered supply chain communication (COM, 2012k):

- *a general lack of knowledge on how and what to communicate on uses, visible by extensive lists of use descriptors being exchanged and difficulties in specific identifications of uses*
- *the fear from non-compliance and lack of knowledge on the legal requirements leading to many actors requesting confirmations from their suppliers e.g. on the SVHC content of products*
- *a lack of time and understanding of the information needs of other actors.*

Furthermore, downstream users had concerns regarding the failure of suppliers to provide meaningful information on future registration intentions of substances of importance to them and related concerns about the effectiveness of communication from them up the supply chain to manufacturers and importers (COM, 2012k). The recommendations set out in Box 5.1, are made in response to the barriers to effective supply chain communication identified here.

**Box 5.1: Recommendation for Improvements to Communication in the Supply Chain**

- ECHA should publish best practice guidance on the communication of uses; and
- ECHA and/or the Commission should, in collaboration with industry, consider whether current guidance provides sufficient clarification of the legal requirements of downstream users and based on this assessment consider amending current guidance.

# 6. OPERATION OF REACH: AUTHORISATION

## 6.1 Introduction

The authorisation procedure set out under Title VII of REACH is aimed at progressively reducing the risks posed by Substances of Very High Concern (SVHCs) and ensuring that they are properly controlled and progressively replaced by suitable alternatives where these are technically and economically feasible. A substance may be identified as a SVHC if it fulfils the criteria set out in Article 57, summarised here:

- carcinogenic, mutagenic or toxic to reproduction category 1 or 2 in accordance with Directive 67/548/EEC or category 1A or 1B in accordance with CLP;
- persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances as defined by Annex XIII to REACH; or
- substances of equivalent concern to CMR and PBT/vPvB substances, such as endocrine disrupting substances.

The list of substances subject to Authorisation is set out in Annex XIV to REACH, accompanied by the intrinsic properties that led to their identification as an SVHC and details of any uses exempt from Authorisation.

Authorisations for the continued use of such substances by a company may be granted if the risks to human health or the environment from the use of the substance are demonstrated as being adequately controlled as documented in the substance's chemical safety report. Where an applicant cannot demonstrate adequate control, then in order to have an authorisation granted, the company is required to demonstrate that the socio-economic benefits of use outweigh the risks to human health or the environment and that there are no suitable alternatives (technologies or substances).

Although applications are submitted to ECHA, decisions on authorisations are taken by the Commission following receipt of opinions from the RAC (Risk Assessment Committee) and the SEAC (Socio-Economic Analysis Committee). Authorisation is granted for a limited time period only and must be reviewed after that period. Following review, a decision is made by the Commission on whether or not to renew an Authorisation. Furthermore, Authorisations (or renewals) should not be granted where alternatives exist that pose reduced risks to human health and the environment; such alternatives can include alternative technical processes and products, as well as alternative substances. Applications should also include a substitution plan for the substance in question.

The process for the identification of SVHCs for inclusion in Annex XIV is principally set out in Article 59. However, the process leading to Annex XIV inclusion is principally set out in Article 58, based on the criteria set out in Article 57 (see above). Substances with PBT/vPvB properties, wide dispersive uses or high use volumes should be given priority for Authorisation.

MS or ECHA (where requested by the Commission) may prepare a dossier according to Annex XV of REACH to identify a SVHC. These dossiers may be limited to identifying the intrinsic properties that may identify the substance as a SVHC. Intentions to prepare a dossier are published by ECHA, as are the dossiers already submitted to ECHA, to allow for consultation with interested parties before a decision is taken to identify the substance as SVHC and include it in the Candidate List.

If the Member State Committee (MSC) unanimously agrees to the identification of a substance as a SVHC and to its inclusion, that substance is automatically included in the Candidate list. If no unanimous decision is reached, the provisions of Regulation (EU) No 182/2011 are used to reach agreement.

Substances from the Candidate List are prioritised by ECHA and recommended for inclusion in Annex XIV. In parallel to the inclusion in Annex XIV, a sunset date is set after which that substance may not be used without authorisation.

The key provisions for authorisation are summarised in Table 6.1.

**Table 6.1: Key Provisions for Authorisation under REACH**

| Article | Details |
|---|---|
| 55 | Applicants for authorisations must analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution |
| 56(1) | A substance may not be placed on the market for a use if that substance is included in Annex XIV unless that use has been authorised |
| 56(2) | Downstream users may only use an Annex XIV substance in accordance with the conditions of the authorisation granted to an actor up his supply chain |
| 56(3) | Authorisation does not apply to the use of substances used for R&D, and PPORD uses may be exempted from Annex XIV inclusion |
| 56(4) | The use of substances in plant protection products, biocidal products, as motor fuels or as fuel in combustion plants are exempt from Authorisation |
| 56(5) | The use of substances in cosmetic products and food contact materials is exempt from registration where authorisation is on the basis of hazards (CMR or equivalent concern) to human health only |
| 56(6) | Concentration limits are stated for mixtures containing an Annex XIV substance that are exempt from authorisation |
| 57 | The intrinsic properties that may result in a substance being included in Annex XIV (CMR, PBT/vPvB or equivalent concern) |
| 58 | Rules governing the inclusion of substances in Annex XIV, with priority normally given to substances with PBT/vPvB properties, wide dispersive use or high volumes |
| 59 | Rules governing the process of identification of SVHCs and their inclusion in the Candidate List |
| 60 | Rules governing the granting of authorisations |
| 60(2) | Authorisation should be granted where the risks to human health and the environment are adequately controlled<br>The risks from the use of a substance in medical devices should not be assessed for authorisation |
| 60(3) and 60(4) | It is not possible to demonstrate adequate control for non-threshold effects, PBT/vPvB substances, or substances of equivalent concern with PBT/vPvB properties. In such cases authorisation may only be granted where there are no suitable alternatives and the socio-economic benefits outweigh the risks |
| 60(8) | Requirement for time-limited review of any authorisation and for monitoring of conditions |
| 60(10) | Requirement on a holder of an authorisation to ensure that the exposure is reduced to as low a level as is technically and practically possible. |

| Table 6.1: Key Provisions for Authorisation under REACH | |
|---|---|
| **Article** | **Details** |
| 61 | Conditions for the review of authorisations including those for the submission of updates to assessments of alternatives and substitution plans and provision for review ahead of that set in the authorisation |
| 62 and 63 | Details of how the first and subsequent applications may be submitted to ECHA and what should be included |
| 64 | Rules governing the decision making process for authorisation, including the roles of RAC and SEAC |
| 65 | Authorisation holders and downstream users must include the authorisation number on the label before they place the substance or mixture on the market |
| 66(1) | Downstream users of substances subject to Authorisation need to notify ECHA within three months of the first supply |
| 66(2) | ECHA must establish and maintain a register of downstream users that have notified it under Article 66(1) which should be available to CAs |
| The highlighted provisions have been identified in COM (2012k) as key drivers for the benefits to human health and the environment (see also Section 12) | |

Prior to the introduction of REACH, estimates are made of the number of substances that would be subject to authorisation (approximately 4,000) and the costs to industry per substance (approximately €50,000) (Ecorys, 2004).

Please note that the assessment of authorisation as a driver for benefits to **human health and the environment**, and recommendations are set out in Section 12.

## 6.2 Introduction to Work undertaken so far by MS and ECHA

ECHA's work has focused on generating and processing Annex XV dossiers for SVHC identification and the preparation of prioritisation proposals for inclusion of candidate substances on the authorisation list (ECHA, 2011a). In addition, a process for evaluating the regulatory effectiveness of different risk management instruments has been established in co-operation with the MS. The so-called 'risk management options analysis' (RMO-analysis) is voluntary for CAs and at the time when CAs submitted their Article 117(1) reports, they had little experience of the Authorisation process and were reluctant to comment until their involvement had increased (MS, 2010).

ECHA reports that no authorisation application had been received at the time of its Article 117(2) report but that it expected to receive rising numbers of such applications (estimating 200 in 2013, rising to 400 in 2014). The ECHA review recommends developing scenarios to estimate future workloads to challenge the existing work procedures (COM 2012b). However, ECHA fulfilled its obligations in relation to the authorisation procedure, and both CAs and stakeholders are positive about the procedures put in place (COM 2012b).

## 6.3 Annex XV Dossiers

The identification of SVHCs is the key requisite for triggering the authorisation provisions of REACH and twenty-one CAs indicated that their MS had been involved in some Annex XV dossier related activity for the identification of SVHCs (MS, 2010). However, CAs generally felt that they had not yet had sufficient experience of dossier preparation to be able to provide a sensible evaluation of the functioning of this process. ECHA initially reported that it had focused a significant effort on the generation and processing of Annex XV dossiers for SVHC identification (ECHA, 2011a). In its later Article 117(2) report, ECHA updates this understanding by stating that dossier preparation and consultation required considerable effort (not specified or quantified) by MS and that the CAs appear to be suffering from a lack of resources for this task. Nevertheless, ECHA had found that CAs continued to express a willingness to contribute to reaching the target number of 136[23] SVHCs on the candidate list by the end of 2012.

Eight CAs indicated that industry had some involvement in the preparation of Annex XV dossiers within its MS. It would appear that such involvement varied greatly between different countries but it seems likely that these activities refer to different levels of consultation regarding the robustness of data to be included in Annex XV dossiers.

## 6.4 SVHC Identification Overall

The identification of SVHCs started slowly but actions related to authorisation have now reached the expected pace, as summarised in Table 6.2 (ECHA, 2011a).

**Table 6.2: Authorisation Overview (2008 – 2011)**

| **Actions Related to Authorisation** | **Number** |
|---|---|
| Notifications for SVHC identifications in registry of intentions received | 81 |
| Notifications in registry of intentions confirmed | 64 |
| SVHC dossiers received | 57 |
| Consultations opened for SVHC | 58 |
| Comments received in consultations | 1432 |
| Substances on the candidate list | 53[1] |
| Consultations opened on recommendations for the authorisation list | 28 |
| Comments received on recommendations for authorisation list | 431[2] |
| Substances recommended for authorisation list | 15[3] |

Notes.
1. There were 73 entries in the Candidate list at the time of writing.
2. Further consultations began in August 2011 which are due to close on 12 April 2012, after the completion of this study.
3. A further 13 entries had been added to the list of substances recommended for authorisation, at the time of writing.
Source: ECHA Report on Operation of REACH, Table 11, p. 34.

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

According to ECHA, the identification of potential SVHCs is being hampered by the lack of consistency between Chemical Safety Reports (CSRs) and the low quality of many of the submitted CSRs, as well as by a lack of information[24] on uses and exposures in some Annex XV dossiers. There have also been difficulties in considering UVCBs (substances of unknown or variable composition, complex reaction products or biological materials) for potential SVHC status and there is a lack of agreement on how to identify substances of equivalent concern under Article 57(f): ECHA has asked the Commission for clarification on these issues and on this final point the Commission commented (*pers. comm.)* that a common understanding is being built and widely discussed. Concerning endocrine disruptors (EDs) in particular, the Commission states that initiatives driven by the needs of the PPP Regulation for the development of ED criteria could also be applied under other EU legislation such as REACH. As regards other types of Article 57(f) substances, e.g. sensitisers, there is a general agreement between MS, COM and ECHA that these three bodies should start preparing dossiers for this type of substance in order to build experience first, before starting to develop a general approach to their identification. Furthermore, MS are already working on several dossiers of this type.

In June 2011, the candidate list contained 53 substances identified as SVHCs for the reasons displayed in Figure 6.1.

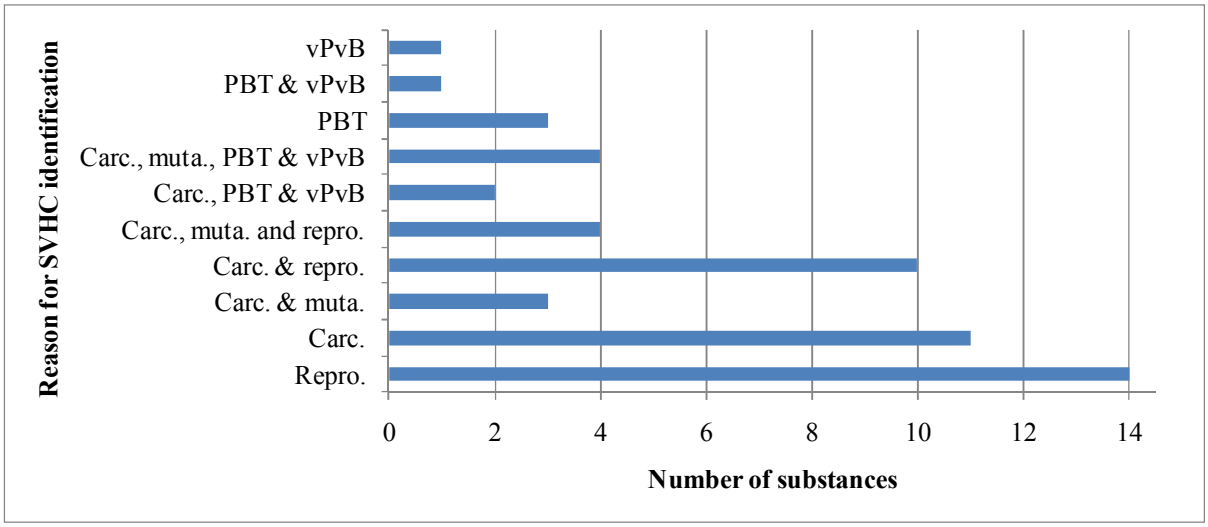



**Figure 6.1: Reasons for SVHC Identification[25]**

ECHA understands that industry is struggling to manage its notification and communication obligations (Article 7 and Article 33) following inclusion of substances in the candidate list. In this respect, ECHA also reports that CAs are struggling to provide industry with the support it needs. Furthermore, ECHA makes a specific request that provision be added to REACH to allow for a substance to be removed from the candidate list.

[24] Only available information is required for Annex XV dossiers.

[25] Source: own evaluation of candidate list.

## 6.5 Recommendations for Inclusion in Annex XIV

An approach for prioritisation has been agreed and clarified during the two prioritisation processes conducted by ECHA at the time of its Article 117(2) report, resulting in six substances being included in the authorisation list in early 2011. A further eight substances were added via Comitology under Regulation (EU) No 125/2012 of 14 February 2012. In parallel, ECHA (2011a) stated that it was already working on a third prioritisation exercise and is considering to recommend inclusion of further thirteen substances[26]. In this respect, ECHA (2011a) notes that the authorisation process has been slowed and made more difficult by the factors listed below but the Commission (*pers. comm.*) does not see all of these resulting in actual delays to the process overall:

- low quality or missing data on uses and exposures in Annex XV dossiers;
- difficulties deciding on appropriate Annex inclusion and sunset dates;
- the scope of research and development and PPORD activities; and
- a lack of an agreed interpretation of intermediate uses.

ECHA also states that the prioritisation process is hampered by the frequent lack, or low quality, of information on uses and exposures in the Annex XV dossiers (c.f. above). Further challenges include the setting of appropriate application and sunset dates, the scope of R&D, PPORD and entry specific exemptions, as well as a consistent and industry-shared interpretation of the definition of intermediate uses[27]. ECHA does not specify any recommendations on how these issues may be resolved, except to promote clarification of 'intermediate uses'.

Industry has complained about a lack of transparency to the process of identifying and prioritising SVHCs (COM, 2012g). These concerns extend to all aspects of these processes including, MS decision making and Commission decisions regarding the selection of substances for dossier preparation, consultation, and Commission decisions regarding prioritisation for Annex XIV inclusion (COM, 2012k). There is also a perception by industry that the subjectivity in SVHC prioritisation has led to inconsistent decision making by authorities involved with this process (COM, 2012k). Furthermore, there is concern that once added, there is no mechanism for removing a substance from the Candidate List or Annex XIV.

The discussion above has led to the recommendations set out in Box 6.1.

[26] Subsequently, ECHA issued its third recommendation to the Commission in December 2011 (http://www.echa.europa.eu/web/guest/view-article/-/journal_content/84f13bf9-d6fd-41ee-aeeb-cdf2e7e9cdee)

[27] In December 2010 ECHA published updated its guidance on intermediates and in January 2011 it published guidance on application for authorisation (http://echa.europa.eu/documents/10162/17235/authorisation_application_en.pdf).

**Box 6.1: Recommendation for Improvements to the Annex XIV Inclusion Process**

- ECHA, the Commission and MS should introduce greater transparency into all areas of the Annex XIV inclusion process; and
- the Commission should examine and clarify whether the current legal framework enables removal of substances from the candidate list and Annex XIV.

## 6.6 Applications for Authorisation

From consultation with industry it would appear that substance manufacturers and importers are disinclined to make an application for authorisation (COM (2012g) survey and COM (2012k) analysis). This situation also applies to downstream users. Potential applicants for authorisation are concerned about the high cost of preparing an application with the perceived high risk of an authorisation not being granted. Industry therefore favours substitution of substances but here companies are often facing difficulties in replacing substances with equivalent alternatives. Furthermore, available alternatives are often similar in structure to the substance replaced, resulting in concerns that these too will soon be subject to authorisation and that the cost of moving to these alternatives will be wasted.

## 6.7 Public Consultations

ECHA reports that industry and other stakeholders lack understanding of the procedures for public consultation and proposes that additional information be provided to stakeholders throughout each consultation process.

In addition to the consultation processes on which ECHA reported, there is also an additional type of consultation in cases when authorisation applications, or requests for authorisation reviews, were submitted to ECHA. When this occurs ECHA makes available 'broad information on uses' with a deadline by which interested third parties are invited to submit information on possible alternative substances or technologies (REACH Article 64(2)). So far, no applications have been submitted but ECHA has started considering how they would conduct such consultation. In this respect, the Commission (*pers. comm.*) comment that it will be crucial to understand how much information ECHA would publish from the individual applications to be able to obtain a useful and sensible information from this consultation that will be adequate to inform making a decision on whether or not the authorisation should be granted, under which conditions, and for how long. This Commission opinion would seem justified, particularly with respect to the assessment of availability of alternatives, as consultees will only be able to provide information based upon the use descriptions provided by ECHA.

## 6.8 SVHCs in Articles

There is evidence of some confusion among articles manufacturers, importers, distributors and retailers regarding the requirements to notify ECHA of the presence of a SVHC in their articles (COM, 2012k). This confusion is compounded by the presence of unofficial lists of substances that should be controlled/removed such as the ChemSec SIN Lists. COM (2012k) therefore makes the recommendation set out in Box 6.2.

**Box 6.2: Recommendation to Improve Notification of SVHCs in Articles**

- the Commission should clarify and, together with ECHA and CAs, disseminate information on the legal role of the Candidate List under REACH and the role of actors in the supply chain.

## 6.9 Risk Assessment Committee

The Risk Assessment Committee (RAC) has a key role to play in the identification of SVHCs and will have an increasingly large role assessing authorisation applications. RAC also has responsibilities for assessing restriction proposals (see Section 7). ECHA (2012a) states that it regards RAC as functioning well at this early stage in its existence. CAs (MS, 2010) gave some limited endorsement to the functioning of RAC but were primarily concerned with important issues with regards to the following:

- the ability of the current structure and procedures to handle the anticipated growth in RACs workload;
- too few members are available to cope with an increasing workload, a statement endorsed by ECHA itself which makes the point that 45% of the expected number of RAC members have not yet been appointed by MS (36 of 65 possible members)[28];
- the burdensome nature of the current Rules of Procedure;
- limitations in the relevant expertise held by committee members as a group, including CMR and classification; and
- the level of commitment required of members, which may well be unsustainable.

Concerns regarding the increasing workload are shared also by the authors of the ECHA review study who recommend an urgent revision of the rules of procedure, as well as strict adherence to the core discussion topics (COM 2012b).

Box 6.3 summarises the recommendations for safeguarding the future performance of RAC set out above.

[28] This relates to the participation in the Committees in 2010 and the beginning of 2011.

**Box 6.3: Recommendations for Safeguarding the Future Performance of RAC**

- MS should identify and appoint members in order to fill this committee;
- consideration should be given to the simplification of the Rules of Procedure and any other measures that may be taken to facilitate the increased efficiency of the working of this committee; and
- ECHA should assess the skill sets expected to be needed for the future working of RAC and work with MS to ensure all key skill sets are available to RAC, especially CMR and classification expertise

## 6.10 Socio-Economic Analysis Committee

There were fewer comments by CAs specific to the functioning of the Socio-Economic Analysis Committee (SEAC) (MS, 2010). The extensive work by ECHA in establishing practical and legal procedures was recognised by some and several CAs commented that to date the Committee appeared to function well. ECHA stated that the workload of its committees (including SEAC) had been increasing continuously. However, the Commission (*pers. comm.*) note that currently the workload has stabilised, but the Commission expects the workload of SEAC to increase again once authorisation dossiers are submitted.

Concerns were expressed by CAs regarding SEAC's ability to cope with growing future demands. These concerns were echoed by ECHA which, in its Article 117(2) report, stated that 54% of the expected number of SEAC members (30 of 65 possible members in 2010/beginning 2011) had not yet been appointed by MS. CAs also felt that the Rules of Procedure are burdensome and may, in their opinion, impair the future effectiveness and efficiency of SEAC.

The suggestions for safeguarding the future performance of RAC set out in Box 6.1, would appear to be equally applicable to SEAC.

# 7. OPERATION OF REACH: RESTRICTION

## 7.1 Introduction

The restrictions procedure under Title VIII of REACH can involve the placing of conditions or prohibitions on the manufacture, placing on the market or use of particular substances in the EU. Restrictions may be applied where there are demonstrated risks to human health or the environment that can only be addressed through Community–wide action. Restrictions may include the use of a substance in articles or may refer to specific uses of a substance but may also extend to a complete ban on the marketing and use of a substance. However, the provisions of any restriction should not overlap with those of an authorisation for the same substance. It must also be demonstrated that a restriction is the most appropriate risk management measure in terms of effectiveness, practicality (implementation, management, and enforcement) and monitorability.

The list of substances subject to restrictions, including conditions and derogations, is set out in Annex XVII to REACH.

From the description above, it is clear that the restrictions procedure under REACH is very similar to that available under preceding legislation governing the imposition of marketing and use restrictions under Directive 76/769/EEC. Indeed, any restrictions adopted under Directive 76/769/EEC have been transferred to the list of restrictions set out in Annex XVII to REACH.

Restriction dossiers according to the criteria set out in Annex XV to REACH are prepared either by ECHA (at the request of the Commission) or by MS. The decision on whether or not to adopt a proposed restriction is taken by the Commission following receipt of opinions from the RAC and SEAC.

The provisions governing restrictions under REACH are set out under Title XIV of REACH and the provisions concerning the transfer of restrictions from Directive 76/769/EEC to REACH are set out under Title XV, as summarised in Table 7.1.

**Table 7.1: Provisions for Restrictions under REACH**

| Article | Details |
|---|---|
| 67(1) | General provisions for the prohibition of the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article |
| 67(2) | Restrictions based on human health concerns may not be applied to the use of substances in cosmetic products |
| 67(3) | Provision for MS to have more stringent national controls until 1 June 2013 and for the Commission to compile and publish a list of such restrictions |
| 68 | Rules governing the introduction and amendment of restrictions |
| 69 | Rules setting out the roles available for the Commission, ECHA and MS for the preparation of restriction proposals, including the requirement to compile proposal dossiers according to Annex XV criteria |
| 70 | Requirement and timescale for the provision to the Commission of an opinion from RAC |
| 71 | Requirement and timescale for the provision to the Commission of an opinion from SEAC |
| 72 | Requirement for ECHA to provide the Commission with RAC and SEAC opinions drafted under Articles 71 and 72, respectively, and for ECHA to publish these |

| Table 7.1: Provisions for Restrictions under REACH | |
|---|---|
| **Article** | **Details** |
| 73 | Rules governing the decision process to be undertaken by the Commission for making restriction decisions and for the consultation with MS. |
| 137 | Requirement for restrictions imposed under Directive 76/769/EEC to be transferred to Annex XVII to REACH |
| Note: The highlighted provisions have been identified by COM (2012k) as key drivers for the benefits to human health and the environment (see also Section 12). | |

Please note that the assessment of restriction as a driver for benefits to **human health and the environment**, and recommendations are set out in Section 12.

## 7.2 Overview of Restriction Activities

ECHA believes itself to be well-prepared to develop restriction proposals and has the capacity to support RAC and SEAC in their opinion making, based on its initial experience in this area (ECHA, 1011a). Furthermore, ECHA considers its opinion forming on new restrictions to be progressing well but also notes a lack of common understanding of the interplay between the restriction and authorisation provisions of REACH, including the consideration of restrictions by MS after the inclusion of substances in the authorisation list.

In 2008, ECHA examined twenty-six non-finalised dossiers of substances prioritised under the Existing Substances Regulation but no recommendations for a restriction were reached. Since that time, ECHA has completed the restrictions process for one substance, conducted consultations for four further substances and was preparing to review six more. Furthermore, in 2011 ECHA knew of twelve further intentions by MS to prepare Restrictions proposals involving 14 substances.

The ECHA review study concludes that ECHA fulfilled its obligations in relation to the restriction procedure and that both MS CAs and stakeholders are positive about the procedures put in place (COM 2012b).

With regards to existing restrictions, there is evidence to suggest variation in the level of implementation between different restrictions and a need for further efforts to harmonise the level of compliance across all current restrictions (COM, 2012j). Furthermore, overlaps have been identified between some restrictions under REACH with similar controls of the same substance under other legislation, and in some cases these overlaps result in inconsistent controls (COM, 2012h). For example, overlapping restrictions are in place on some substances under REACH and the PCB/PCT Directive 96/59/EC and the Toy Safety Directive 2009/48/EC. These overlaps have prompted the recommendations set out in Box 7.1.

**Box 7.1: Recommendations for Resolving Restriction Overlaps and Inconsistencies (based on information from COM (2012h))**

- ECHA should set up an inventory of all substance restrictions/controls under REACH and other legislation. In this way any overlaps will be more evident; and
- the Commission should develop proposals to amend REACH or overlapping legislation to remove duplications.

## 7.3 Annex XV Dossiers

By June 2010, thirteen MS had been involved in some activity related to the preparation or assessment of Annex XV Restriction dossiers but only two had prepared such dossiers within the time frame of their Article 117(1) reports (MS, 2010).

Regarding the dossiers themselves, ECHA found it challenging to identify an appropriate level of dossier quality (ECHA, 2012a). This was due, in particular, to the unique nature of each Restriction proposal but it was also felt that the use of information generated by the wider provisions of REACH (including from registration dossiers and dossier evaluation) had not been optimal. Furthermore, Annex XV Restriction Dossiers tended not to be as clear or concise as would have been preferred for the support of decision making; in particular, it was suggested that greater prioritisation should be used within supporting socio-economic analyses. Given that the restriction process existed prior to the introduction of REACH, it is not clear why problems exist with respect to dossier preparation but this may be due to differences in the nature of the information requested under the different pieces of legislation.

## 7.4 Effectiveness of RAC and SEAC

In addition to the discussion on RAC and the SEAC in Section 6, ECHA found the timeframes within which these committees are to use inputs from consultation within the Restrictions process to be particularly challenging. ECHA called for consultation on RAC Restriction opinions similar to that for SEAC opinions and for the extension of the timeframes within which these committees are required to provide opinions. Furthermore, ECHA called for a shortening of the consultation process (for SEAC and RAC, if introduced) stating that shortening the consultation period *"would not compromise the quality of comments but would facilitate an optimal use of them"*. However, this assertion was not fully justified by ECHA.

At the time of drafting Article 117 reports, there was no experience available to MS or ECHA on the usefulness of the committees' opinions for the subsequent decision making process in the Commission. However, subsequently one restriction proposal has now progressed most of the way through the process (DMFu: EC no. 210-849-0 and CAS No. 624-49-7). In this instance, the Commission followed the opinions of RAC and SEAC while drafting this restriction proposal. It went through Inter-Service Consultation within the Commission and was then adopted unanimously during the

REACH Committee in September 2011. At the time of writing this proposal was under the scrutiny of the Council and Parliament.

# 8. OPERATION OF REACH: EVALUATION

## 8.1 Introduction

Title VI of REACH describes three types of evaluation under REACH:

1. Dossier Evaluation (Chapter 1: Article 40 to Article 43), including:
   - evaluation of testing proposals (Article 40); and
   - compliance checks on registration dossiers (Article 41).
2. Substance Evaluation (Chapter 2: Article 44 to Article 48).
3. Evaluation of Intermediates (Chapter 3: Article 49).

Furthermore, Chapter 4 of Title (VI) sets out the common provisions for the functioning of evaluations, the adoption of evaluation decisions and their publication (Article 50 to Article 54).

The overall aims of dossier evaluation are to allow for (Recitals 20 and 21):

- checks for compliance;
- the generation of information in addition to that required for registration, in response to concerns; and
- the prioritisation of substances for further evaluation.

Evaluation may lead to improved risk management of substances by manufacturers and importers, but also to authorisation or restriction. The evaluation processes may also be the first mechanisms within REACH where an implementation issue or the scientific and technical process is identified that triggers improvement to the functioning of REACH e.g. by the updating of guidance. Furthermore, evaluation should function as an important enhancer of benefits from REACH.

## 8.2 Dossier Evaluation

Dossier evaluation should ensure that registration dossiers are compliant with the requirements of REACH. ECHA, via legally binding decisions, can require individual registrants to address deficiencies observed during compliance checking. MS are empowered to act in cases of non-compliance with these decisions. Dossier evaluation for non-compliance is also intended to act as a deterrent to non-compliance and an encouragement to compliance, leading to higher quality dossiers overall.

### 8.2.1 Compliance Checks

ECHA is required to check at least 5% of registration dossiers for compliance with all of the requirements of REACH and may require the registrant to provide additional information within a reasonable timeframe set by ECHA. ECHA should give priority

to the evaluation of dossiers for joint registration with classification or hazard study data submitted separately from that of the lead registrant, substances claimed to meet the criteria of Annex III or substances included in the Community Rolling Action Plan for substance evaluation (CoRAP) (see below).

ECHA states that up to 1,000 dossiers (5%) submitted by the first registration deadline are to be checked for compliance by the end of 2013 and 600 dossiers per year thereafter, for an unspecified length of time (ECHA, 2011a). To assist in these activities ECHA is currently developing an IT-tool that should support the prioritisation of registration dossiers for evaluation, but no time frame for this was provided.

In parallel to the preparations for the expected peak of compliance checks starting in 2011, first dossier evaluations were initiated during 2008 to 2011, as summarised in 8.1 (ECHA, 2011a).

**Table 8.1: Overview of Compliance Checks on Registration Dossiers (2008 to 2011)**

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

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

In 2011, a total of 239 dossiers were under evaluation, of which 81 were initiated in 2011 and 158 were carried over from 2010 (ECHA, 2012). The number of compliance checks was higher than planned, due to the need to check the description of the substance identity in the context of examining testing proposals. 146 dossier evaluations were completed in 2011. In 105 cases, a final decision was taken and quality observation letters were sent out in 19 cases. There were 12 dossiers closed without action and 10 were closed after the draft decision (ECHA 2012).

ECHA was not able to identify any significant change in the quality of registration dossiers over time (ECHA, 2011a and ECHA, 2012). However, improvements in risk assessment compared to the situation pre-REACH have been identified as part of the REACH Baseline study (COM, 2012a). The most frequent non-compliance and shortcomings[29] identified by ECHA were:

- unclear substance identity;
- lack of proper justification for waiving and application of read-across;
- insufficient level of detail in robust study summaries; and
- quality of chemical safety assessments.

[29] ECHA provides an extensive list of non-compliances and shortcomings observed as well as recommendations on how to provide (improved) information in the dossiers in its Evaluation Progress Report of 2010 and 2011. Only the overarching core aspects have been included in this report. For further detail the original sources should be consulted.

In ECHA (2011a), ECHA notes that where it finds a dossier to be non-compliant it can only ask the registrant to provide hazard information but has no mandate to require the modification or correction of risk management measures (RMMs), leading to the recommendation set out in Box 8.1.

The process of dossier evaluation is one important means of bringing information on technical and scientific progress into REACH, i.e. by checking testing methods and introducing respective alternative methods. Furthermore, experience and lessons learned would, if integrated (e.g. through guidance updates), significantly enhance this process.

**Box 8.1: Recommendation for Resolving Enforcement of ECHA Decisions on RMMs**

- the Commission should consider whether provisions should be added to REACH to require registrants to amend RMMs where concerns are identified. A transparent procedure will need to be developed to support the implementation of any such provisions.

### 8.2.2 Testing Proposals

The evaluation of testing proposals is intended to ensure that testing involving vertebrate animals is tailored to the real information needs of REACH (see Recital 63) and that tests are not performed when the information is already available, thus avoiding unnecessary animal testing (see Recital 64). The identification of non-compliance in the dossiers evaluated and subsequently requiring action by individual registrants through legally binding decisions, allows non-compliance to be addressed and enables enforcement, where necessary.

Dossier evaluation includes the examination by ECHA of all testing proposals submitted in support of registrations. In this respect, ECHA should give priority to the evaluation of proposals relating to substances that have, or may have, PBT, vPvB, sensitising and/or carcinogenic, mutagenic or toxic for reproduction (CMR) properties, or substances manufactured/imported in quantities above 100 tonnes per year per registrant with uses resulting in widespread and diffuse exposure and which fulfil the criteria for the range hazard endpoints set out in Article 40.

Any testing proposals that involve the use of vertebrate animals must be published on the ECHA Internet site for consultation. Following any consultation ECHA is required to make a decision on whether to accept, reject or modify the proposals submitted to it.

In 2011 ECHA 566 dossiers containing testing proposals were submitted. Examinations were carried out on 587 of these dossiers, of which 542 were for phase-in substances and 45 for non-phase-in substances. By the end of 2011 ECHA had completed 14% of all opened cases (80 testing proposals), 144 were still to be decided and 363 were expected to be carried over to 2012 (ECHA, 2012).

The evaluation outcomes were as follows:

- 50% of cases subject to a draft decision;
- 20% closed[30];
- 6% of the testing proposals were accepted (18); and
- 1% of the proposals were modified (4).

In 23% of the testing proposals examined, the work was postponed due to the need to clarify the substance identification via a compliance check; hence the dossier was prioritised for that procedure and the testing proposal examination was stopped.

Up to now, all testing proposals, except one, have been processed within the legal deadlines (ECHA, 2011b: See Section 9 for more details). Of the 22 final decisions, nine were taken without referral to the MSC whereas 13 received at least one proposal for amendment by a Competent Authority (ECHA, 2012).

The target of checking 250 dossiers with testing proposals was not met (216 were checked) because the substance identity had to be checked first (67 cases for compliance check) and secondly due to the decision not to send out draft decisions over the holiday period in winter 2011.

### 8.2.3 Evaluation of NONS Dossiers

Prior to the introduction of REACH, companies wishing to place a substance onto the market in the EU that was not included in the ELINCS database of existing substances had first to submit a Notification of a New Substance (NONS) according to Directive 67/548/EEC. NONS notification was similar to that required under REACH and, under Article 24 of REACH, a NONS for a substance submitted by a company is regarded as a registration under REACH by that company for the tonnage notified. Where the tonnage increases from that set out in the original notification, additional information may be required to be submitted to ensure that the information requirements for that tonnage matches those set out under REACH.

According to the Evaluation Progress Report of 2010, ECHA has assessed dossiers relating to NONS in amounts above 1,000 tonnes per annum. Twenty-six NONS dossiers were subject to a compliance check resulting to date in thirteen draft decisions, one final decision and three conclusions without action; nine evaluations are still on-going. ECHA (2012) further specifies that dossiers which had to be brought into compliance (deadlines elapsed) were followed-up by ECHA sending reminders. In total, 67 dossier updates were received.

ECHA expresses the belief that NONS notifications are not adequately compatible with registrations under REACH provisions and therefore would like the legal text

[30] The closing of evaluations was due to a range of factors, including withdrawal of the proposal or the dossier by the registrant, the cessation of manufacture or import or inadmissibility of the testing proposal. However, ECHA does provide further details.

amended as set out in Box 8.2.

**Box 8.2: ECHA Request for Change to REACH Legal Text Regarding NONS**

- the Commission should consider whether a deadline should imposed by which NONS dossiers for manufacture/import of substances above 1,000 tonnes per year should be fully compliant with the requirements of REACH; and
- the Commission should consider whether a deadline should be imposed, after which any notification under NONS must be fully compliant with the registration requirements of REACH.

## 8.3 Substance Evaluation

The substance evaluation procedure enables the identification of hazards and risks which not be adequately addressed by the standard information requirements and safety assessments required for registration. Where concerns are identified, substance evaluation may result in registrants being required to provide additional (non-standard) information on hazards and/or to conduct further risk assessment which, for example, may include assessment of accumulated exposures to the environment.

ECHA, in co-operation with MS, is required to prioritise substances that are considered to constitute a risk to human health or the environment. Substances are to be evaluated as part of Community Rolling Action Plans (CoRAPs) covering a period of three years. The CoRAP is adopted by ECHA which is required to publish this on its Internet site and identify the MS that will be responsible for each evaluation.

ECHA is then responsible for co-ordinating substance evaluation supported by the CAs. CAs undertaking substance evaluation can require the registrant to provide information in addition to that provided in its registration dossier to assist the CA in its evaluation.

Following evaluation, CAs are required to inform ECHA of whether and how the results of the evaluation should be used, information that ECHA must then pass on to the registrant, the Commission and other CAs.

The full provisions of the legislation have not yet been implemented and no substance evaluation had been started prior to either MS (2010) or ECHA (2011a). In preparation for the future tasks that will be required, ECHA organised a workshop with MSs on the criteria that should be adopted for prioritising substances for evaluation and to agree on timelines and processes to develop a first Community Rolling Action Plan (CoRAP) (ECHA 2011a). The first CoRAP was published 29 February 2012 and contained 90 substances to be evaluated between 2012 and 2014 (ECHA, 2012). This CoRAP was established based on proposals by ECHA (using an IT-supported screening of registration dossiers and an additional selection step) and proposals by the MSs, taking the relevant selection criteria into account. The first CoRAP will cover a three year period and the plan will be revised annually thereafter.

Nine CAs stated that they had already been involved in the preparation for substance evaluation by June 2010 (MS, 2010). However, it is likely that some of these CAs may have been referring to dossier evaluation or the provision of other registration comments to ECHA (e.g. with regard to commenting on animal testing proposals).

## 8.4 Evaluation of Intermediates

The normal REACH provisions for dossier and substance evaluation do not apply to on-site isolated intermediates. However, where a CA has concerns that the conditions for designation as an on-site isolated intermediate are not being met, the CA can require the registrant to provide it with the information needed to assess this concern. Following its evaluation, the CA with concerns must inform ECHA and other CAs of its findings.

Furthermore, ECHA has screened 303 dossiers of on-site and transported, isolated intermediates registered in 2009 to check if reduced registration for isolated on-site or transported intermediates was justified according to Article 17 or Article 18, respectively. This process called "verification of intermediate status" was carried further in 2011 when 400 dossiers were selected (ECHA, 2012). Several of these were found to contain insufficient information to document strictly controlled conditions (SCC), resulting in 40 letters being sent to request further information on intermediate status and SCC (to lead registrants and in 3 cases to member registrants) relating to 17 substances.

Eleven compliance checks were undertaken on intermediate dossiers which all resulted in requests for additional information in support of claimed intermediate status. ECHA observed that, in many cases, registrants had provided insufficient information to verify the claimed intermediate status but this may have been influenced by the non availability of guidance (ECHA guidance on intermediates was only made available in December 2010).

## 8.5 Industry Perspective

Concerns have been raised by industry regarding a perceived lack of transparency (or perhaps understanding) with regards to the processes of evaluation, particularly substance evaluation (COM, 2012k). This may be due to the limited experience of industry (and authorities) with regards to evaluation however this concern has led to the recommendation set out in Box 8.3.

**Box 8.3: Recommendation for the Improvement of Evaluation**

- ECHA and MS should continue ensuring a high level of involvement of stakeholders in the evaluation processes while addressing industry concerns regarding a lack of transparency and understanding of the processes involved;
- ECHA should seek ways to increase the speed and efficiency of compliance checking in order to meet the targets for dossier evaluation;
- ECHA and MS should consider improving selection and targeting compliance checks to increase the regulatory impact of the evaluation process; and
- ECHA should monitor evaluation experience (ECHA, MS and stakeholders) and update its guidance, as appropriate.

In addition to the recommendations set out in Box 8.3, it should be noted that the evaluation processes presents an opportunity to integrate technical and scientific progress into the REACH processes. The learning from the examination of testing proposals and the dossier evaluation can, in addition, result in important contributions to the development and improvement of guidance and IT tools.

# 9. ALTERNATIVE TESTING

## 9.1 Introduction

The provisions in REACH promoting the principle of "one substance – one registration" encourages the sharing of test data to reduce registration costs and requires the sharing of data from tests involving the use of vertebrate animals to minimise the number of such tests needed to satisfy the registration requirements of REACH. The key provisions for the minimisation of animal testing are set out in Articles 11, 13 and 19, and Title III of REACH, as summarised in Table 9.1.

**Table 9.1: Key Provisions for Data Sharing to Avoid Unnecessary Testing under REACH**

| Article | Details |
|---|---|
| 11 | General provisions for the joint submission of data by multiple registrants, including for lead registrants, joint registrants and grounds under which registrants may opt-out of these provisions |
| 13 | Provisions for the generation of data based upon the principle that tests involving vertebrate animals should only be used as a last resort. Alternative methods are encouraged |
| 19 | Provisions for the joint submission of data on isolated intermediates |
| 25 | Testing on vertebrate animals must only be carried out as a last resort |
| 26 and 27 | Rules requiring the sharing of data for non-phase-in substances |
| 29 | The requirement for all registrants of phase-in substances to be part of a SIEF |
| 30 | Rules encouraging the sharing of data and requiring the sharing of data from tests involving vertebrate animals |

Testing proposals must be submitted to ECHA prior to the carrying out of vertebrate animal tests which must be evaluated by ECHA to ensure that no such test is carried out unnecessarily, as described in Section 8.

Furthermore, Recital 47 of REACH requires that the application of the principles of replacement, reduction and refinement (3R) of the use of animals in procedures should be fully taken into account in the design of the test methods, in particular when appropriate validated alternative methods and approaches become available (for more information on the 3R concept, see Russell & Burch (1992)).

### 9.1.1 Comment on Information Sources Used

ECHA's Article 117(3) report (ECHA, 2011b) and parts of the registration information in the Article 117(2) report (ECHA, 2011a) provide a good overview of the use of animal/ non-animal test data to fulfil REACH registration requirements. Furthermore, the MS Article 117(1) reports (MS, 2010) provide additional information on MS funding for the development of alternative test methods (3R research). However, it should be noted that ECHA (2011b) rarely made explicit differentiation between the use of replacement, reduction and refinement (3Rs) approaches.

## 9.2 Use of Non-Animal Test Methods

### 9.2.1 Application of Provisions

Based on the observation that 90% of registration dossiers[31] had so far been submitted jointly, ECHA expresses the opinion that - while there is some room for improvement regarding aspects of data sharing and avoiding of new animal testing - these provisions of REACH are working adequately (ECHA, 2011b). However, of the 14,875 dossiers for phase-in substances registered in amounts exceeding 1,000 tonnes per year, there were only 19 opt-outs concerning endpoints that would have required animal testing.

In total, between 2008 and February 2010, 574 testing proposals were received covering 1,175 tests, of which 711 related to *in vivo* vertebrate animal studies (ECHA, 2011b), as listed in Table 9.2.

**Table 9.2: Testing Proposals for Registration**

| Type of Animal Test | Number of Proposals |
|---|---|
| Developmental Toxicity | 239 |
| Toxicity to Reproduction | 231 |
| Repeated Dose Toxicity (oral) | 121 |
| Long-term Toxicity to Fish | 38 |
| Repeated Dose Toxicity (inhalation) | 27 |
| Genetic Toxicity (*in vivo*) | 25 |
| Bioaccumulation: Aquatic / Sediment | 17 |
| Repeated Dose Toxicity (dermal) | 6 |
| Long-term Toxicity to Birds | 4 |
| Carcinogenicity | 3 |
| ***Total*** | ***711*** |

Source: ECHA (2011b), Table 3, p. 52.

The most frequently requested tests in the final decisions on testing proposals were the pre-natal development toxicity study (10), the sub-chronic toxicity study (8) and testing viscosity (5) (ECHA, 2012).

In total ECHA conducted consultations on testing proposals for 431 dossiers covering 715 end-points. 394 of these consultations are closed[32]. In none of these cases was the testing proposal rejected because of the specific information obtained from third parties[33] (ECHA, 2011b and ECHA, 2012).

ECHA analysed the endpoint summary records of 1,862 individual dossiers for substances registered in amounts exceeding 100 tonnes per annum (excluding those

[31] The remaining 10% include individual submissions of non-phase in substances.

[32] ECHA website on consultation of testing proposals as of March 8th 2012.

[33] As of March 8th 2012 seven reports are published on the outcome of consultations of testing proposals on ECHA's website. In average, 4.4 institutions commented on a testing proposal.

for non-isolated intermediates, PPORD notifications, NONS substances and category dossiers[34]) to determine the source of the data used, as set out in Figure 9.1.

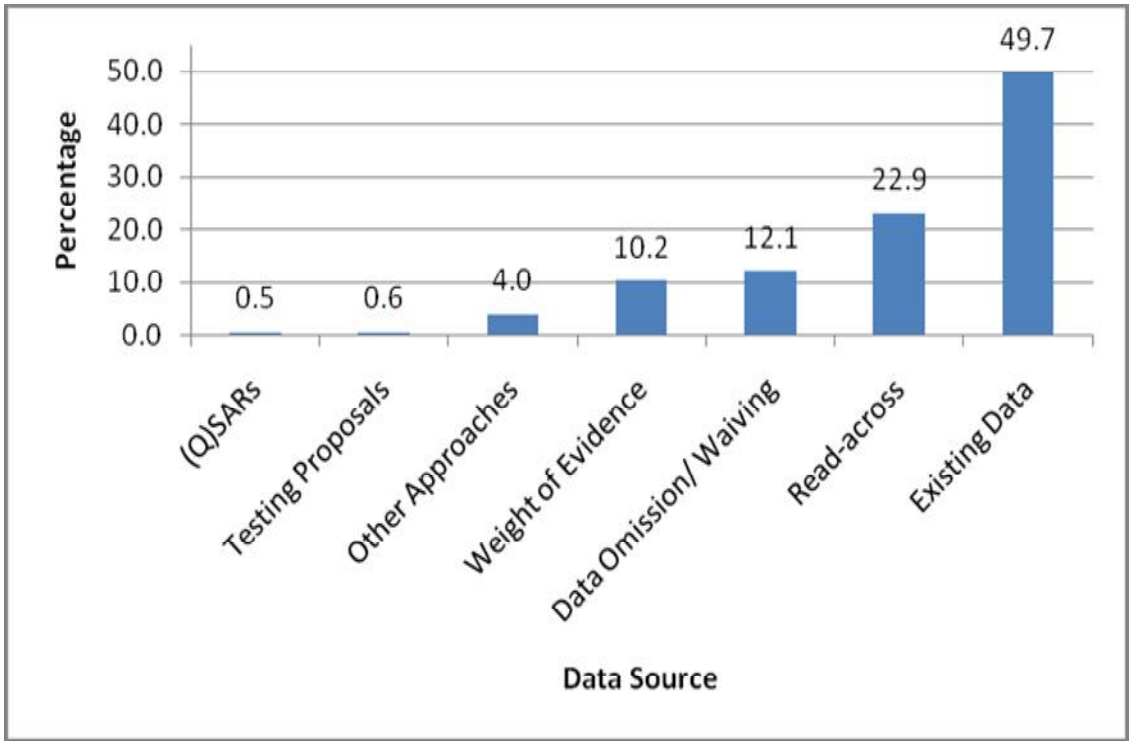



**Figure 9.1: Data Sources for Registration Dossiers**

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

**Table 9.3: Share of Information Types used to fulfil Obligations for the Different Endpoints**

| Endpoint | % ES[1] | % TP | % AM | % ND |
|---|---|---|---|---|
| Acute Toxicity | 85 | - | 15 | - |
| Skin Irritation | 78 | - | 22 | - |
| Eye Irritation | 75 | - | 25 | - |
| Skin Sensitisation | 63 | - | 37 | - |
| Repeated Dose Toxicity | 67 | 7 | 26 | - |
| Genetic Toxicity *In Vitro* | 77 | - | 23 | - |
| Genetic Toxicity *In Vivo* | 41 | - | 32 | 26 |
| Toxicity to Reproduction | 42 | 10 | 48 | - |
| Developmental Toxicity | 47 | 10 | 43 | - |
| Bioaccumulation Fish | 15 | - | 85[2] | - |
| Toxicity to Fish | 75 | - | 25 | - |
| Long-term Toxicity to Fish | 16 | - | 82[3] | - |

[34] Intermediate registrations, PPORD notifications and NONS dossiers were excluded because of limited or different information requirements. Category dossiers were excluded because of the complex interrelationships between endpoints which made a reliable data analysis impossible. Category dossiers are those that utilise data from substances in the same or a similar chemical category.

| Table 9.3: Share of Information Types used to fulfil Obligations for the Different Endpoints | | | | |
|---|---|---|---|---|
| **Endpoint** | **% ES[1]** | **% TP** | **% AM** | **% ND** |
| Long-term Toxicity to Birds | 7 | - | 92[4] | - |
| Long-term Toxicity to Mammals | 1.8 | - | 7 | 91 |
| Toxicity to Other Terrestrial Organisms | 4 | - | 4 | 92 |

Source: ECHA (2011b), Section 3, pp. 45 – 47.
Notes.
1. Experimental studies include *in vivo* and, where validated, *in vitro* studies.
2. Experimental data on invertebrates were counted as alternative methods.
3. Justification for omission.
4. Currently the share of information provided by (Q)SARs is only 0.5% of all registration dossiers.
5. Due to notes 1 to 4 above, not all percentages total 100%.

Endpoint study records show that for greater than 100 tonne substances registrants used data produced prior to the introduction of REACH as their main source of data for core and higher tier endpoints (ECHA, 2011b). The second most used source of information came from the application of read-across, especially for endpoints that would otherwise require longer term animal studies.

### 9.2.2 Issues Identified

ECHA notes that the information quality and the quality of justifications for not conducting tests (including animal tests) in registration dossiers were frequently insufficiently robust. Furthermore, ECHA believes that a reduced number of testing proposals were received due to the (inappropriate) adoption of alternative approaches.

In respect of the submission of incomplete or insufficiently robust dossiers, it is noted that the relevant ECHA guidance was not available within the guidance for "Information Requirements and Chemical Safety Assessment" before the registration deadline of 30 November 2010 and "*in preparing their dossier submissions, registrants can resort to existing guidance when applying their own best judgement on their most appropriate action to fulfil their obligations under REACH. They also need to be aware of the potential need to update their registration dossier at a later stage"* (DCG, 2011). This situation may, potentially, account for some of the data quality issues since identified by ECHA.

ECHA also reports that 107 higher tier animal tests seem to have been conducted without prior submission of a testing proposal. Justifications for these tests include that testing was triggered from non-EU legislation or requested by CAs (e.g. under NONS).

Furthermore, on a more fundamental level, under the Animal Test Directive 2010/63/EU the use of live cephalopods is controlled in a manner similar to vertebrate animals (COM, 2012h). However, under REACH cephalopods are not included in the additional provisions to reduce vertebrate animal testing such as the mandatory sharing of test data, leading to the recommendation set out in Box 9.1.

**Box 9.1: Recommendation for the Minimisation of Testing**

- ECHA should monitor the robustness/compliance of the use of alternatives to testing to fulfil REACH information requirements and consider appropriate action in response to that monitoring;
- ECHA should monitor improvements or advancements in procedures such as data sharing, and test proposals and alternative methodologies and assess how these may legitimately be used to fulfil information requirements. Guidance should be updated in line with this work; and
- the Commission should take action to ensure that REACH is brought into line with Directive 2010/63/EU and has equivalent provisions for cephalopods and vertebrate animals.

## 9.3 Development and Encouragement of Alternatives

### 9.3.1 Contributions by ECHA

ECHA states that it is actively supporting the development of alternative methods by contributing to, and providing funding for, the OECD QSAR toolbox[35] and by cooperation with the JRC Computational Toxicology Group to promote the use of computer-based prediction methods. ECHA also disseminates information from the endpoint summary records in its database in order to enable future registrants to (better) predict the properties of their substances by read-across from analogous substances.

In September 2010, ECHA organised a workshop in order to clarify uncertainty with regard to the use of non-test methods and develop a common understanding on the use of these methods in the regulatory context. A report on the workshop results is however not available and no details of participants were provided in ECHA (2011b).

ECHA (2011b) did not include any quantification of its support of the development of alternative methods. Furthermore, no clear overview is given on the existence of (validated) *in vitro* tests that could replace animal tests but this may simply reflect the increasing use of a more strategic, top-down, approach to the choice of alternative methods (testing and non-testing) where alternatives are identified as part of an information requirement strategy.

### 9.3.2 Member State Contributions

Twenty MS appear to have made contributions from public funds to EU and/or OECD work on the development and validation of alternative test methods with seventeen CAs providing quantification, as set out in Table 9.4 (MS, 2010).

[35] Currently the share of information provided by (Q)SARs is only 0.5% of all registration dossiers.

| Table 9.4: Member State Funding for National R&D of Alternative Testing Methodologies | |
|---|---|
| **Level of Funding (Euros per year)** | **MS** |
| 0 to 10,000 | CY, IS, LI, LV, PL and SI |
| 10,001 to 100,000 | BE and CZ |
| 100,001 to 1,000,000 | BG, DE[1], DK, ES, FR, NL, NO, SE, and UK |
| Note:<br>1. The German CA provided a separate note stating that Germany contributed more than the one million Euro maximum allowed by the electronic questionnaire used for Article 117(1) reporting. | |

The German CA provided further research data on expenditure from public funds for the years 2004 to 2007 (Devolder *et al*, 2008), indicating that total annual expenditure by MS was at least €15.25 million, with over €13 million being contributed by five MS (Germany, Denmark, France, Sweden, and the United Kingdom), as summarised in Figure 9.2.

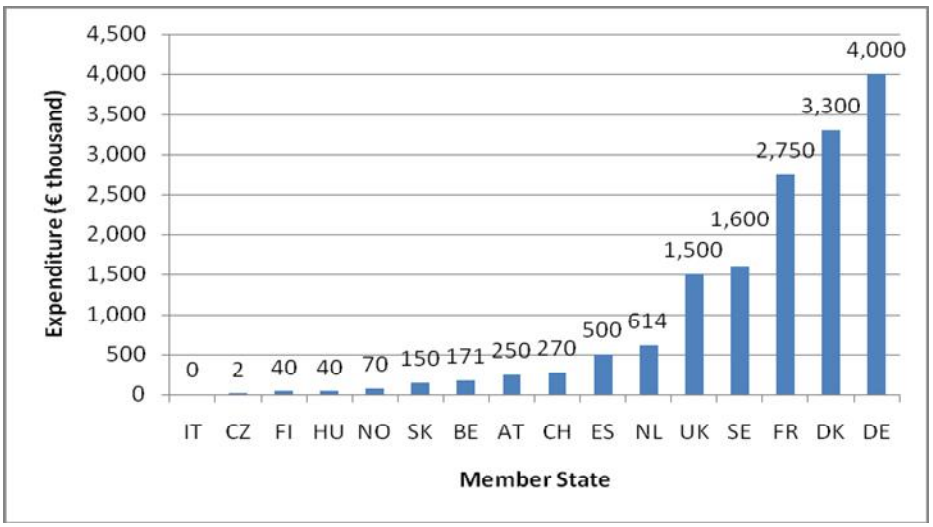



**Figure 9.2: Annual Public Expenditure on 3R Alternatives**

It is apparent that the amounts set out in Table 9.4 do not match those displayed in Figure 9.2. For example, Figure 9.2 shows that five MS are contributing more than €1 million per annum whereas only one such MS is identified in Table 9.4. These discrepancies may be due to inconsistencies in data provision criteria between the different data collation exercises.

Possible causes, for example, are that it is unclear if the reporting by CAs was uniform with respect to inclusion of data on funding for:

- national R&D only (as implied by the Article 117(1) enquiry form);
- EU and/or OECD only; and/or
- national, EU and OECD (i.e. all recipients of public funding).

Furthermore, due to inconsistencies between information provided by different CAs, it was not possible to establish a robust estimate of the overall funding patterns for 3R research from MS (2010) information.

### 9.3.3 Nanomaterials

Draft findings of the study into 'Emerging Technologies' (COM, 2012e) noted that manufacturers and importers of nanomaterials stated that there is a need for better testing methods for these substances.

The issue of test methods and guidance relating to Nanomaterials is currently being addressed by the OECD Working Party on Manufactured Nanomaterials (WPMN) through its Steering Group 4. The WPMN and SG4 met most recently in December 2011.

The main focus of SG4 to date has been to update the Guidance Document on Sample Preparation and Dosimetry and the work priorities in 2012 are to finalise this Guidance Document and to work on the following test guidelines:

- TG 209 (C.11) Biodegradation – Activated Sludge Respiration Inhibition;
- TG 302B (C.9) Biodegradation – Zahn-Wellens Test;
- TG 310 (C.30) Ready Biodegradability - CO2 in sealed vessels (Headspace Test);
- TG 316 (C.X) Phototransformation of Chemicals in Water - Direct Photolysis;
- TG 403 (B.2) Acute Toxicity (Inhalation);
- TG 412(B.8) Repeated Inhalation Dose (28 days) Toxicity Study;
- TG 413 (B.29) 90-day Repeat Inhalation Dose Study using Rodent Species; and
- TG 436 (B.X) Acute Inhalation Toxicity - Acute Toxic Class (ATC) Method.

The process of identifying further test methods for update is also ongoing.

The WPMN agreed that "horizontal" meetings (along the model of the Hague Expert Meeting on Inhalation Toxicity Testing for Nanomaterials) are useful to identify which TGs, Guidance documents or Guidance Notes should be updated. It should however be noted that the development of new alternative testing methods for the assessment of nanomaterials is still at the research and development stage.

### 9.3.4 Further Research Projects

The information recorded here was supplied by the Commission (*pers. comm.*). Between 2007 and 2011 the Commission made available funding of about € 240 million[36] for the development of alternative methods as well as their evaluation and the promotion of the regulatory acceptance and use. These funds were complemented by a further € 25 million from industry as part of a public-private partnership initiative, as summarised in Table 9.5.

[36] Commission General Report based on requirement of REACH Article 117(4b) on: The amount and distribution of funding made available by the European Commission for the development and evaluation of alternative methods.

| **Table 9.5: Projects on Alternative Methods/Approaches funded by the Framework Programmes (FPs)[37]** | | | |
|---|---|---|---|
| **Project Name/Acronym** | **Programme** | **Total Grant (million €)** | **Period** |
| Predictomics | FP6 | 2.3 | 2004 - 2007 |
| CONAM | FP6 | 0.15 | 2004 - 2007 |
| NOMIRACLE | FP6 | 10 | 2004 - 2009 |
| TOXDROP | FP6 | 1.6 | 2005 - 2006 |
| ReProTect | FP6 | 9.1 | 2005 - 2009 |
| ACuteTox | FP6 | 9.0 | 2005 - 2009 |
| MODELKEY | FP6 | 8.4 | 2005 - 2009 |
| Sens-it-iv | FP6 | 11.0 | 2005 - 2010 |
| EXERA | FP6 | 2.2 | 2005 - 2010 |
| CAESAR | FP6 | 1.5 | 2006 - 2009 |
| VITROCELLOMICS | FP6 | 2.9 | 2006 - 2009 |
| MEMTRANS | FP6 | 1.9 | 2006 - 2009 |
| EUPRIM-NET | FP6 | 4.8 | 2006 - 2010 |
| carcinoGENOMICS | FP6 | 10.4 | 2006 - 2011 |
| SCARLET | FP6 | 0.11 | 2007 - 2008 |
| InViToPharma | FP6 | 0.58 | 2007 - 2008 |
| INVITROHEART | FP6 | 2.7 | 2007 - 2009 |
| LINTOP | FP6 | 2.9 | 2007 - 2009 |
| ForInViTox | FP6 | 0.29 | 2007 - 2009 |
| ARTEMIS | FP6 | 2.0 | 2007 - 2010 |
| COMICS | FP6 | 2.2 | 2007 - 2010 |
| OSIRIS | FP6 | 10.0 | 2007 - 2011 |
| START-UP | FP7 | 0.32 | 2008 - 2010 |
| CONTAMED | FP7 | 3.5 | 2008 - 2011 |
| REEF | FP7 | 2.9 | 2008 - 2011 |
| NANOMMUNE * | FP7 | 3.4 | 2008 - 2011 |
| NanoTEST | FP7 | 3.0 | 2008 - 2011 |
| OpenTox | FP7 | 3.0 | 2008 - 2011 |
| DEER | FP7 | 3.5 | 2008 - 2012 |
| NANORETOX * | FP7 | 3.2 | 2008 - 2012 |
| ESNATS | FP7 | 11.9 | 2008 - 2012 |
| PREDICT-IV | FP7 | 11.3 | 2008 - 2013 |
| ENFIRO | FP7 | 3.2 | 2009 - 2012 |
| ENNSATOX | FP7 | 2.8 | 2009 - 2012 |
| ENPRA | FP7 | 3.7 | 2009 - 2012 |
| INLIVETOX | FP7 | 2.4 | 2009 - 2012 |
| CADASTER | FP7 | 2.7 | 2009 - 2012 |
| RISKCYCLE | FP7 | 1.0 | 2009 - 2012 |
| SYSTEQ | FP7 | 2.7 | 2009 - 2013 |
| EUROECOTOX | FP7 | 1.0 | 2010 - 2012 |
| ACROPOLIS | FP7 | 3.0 | 2010 - 2013 |
| NANOHOUSE * | FP7 | 2.4 | 2010 - 2013 |
| AXLR8 | FP7 | 0.56 | 2010 - 2013 |
| CHEMSCREEN | FP7 | 3.5 | 2010 - 2014 |
| SCR&Tox ** | FP7 | 4.7 | 2010 - 2015 |
| HeMiBio ** | FP7 | 4.7 | 2010 - 2015 |
| DETECTIVE ** | FP7 | 4.3 | 2010 - 2015 |

[37] All listed FP6 and FP7 projects have a funding period covering at least part of the reporting period (2007-2011), except for 'TOXDROP' that ended in 2006 already. Nevertheless, the latter has been included for reasons of comprehensiveness.

| **Table 9.5: Projects on Alternative Methods/Approaches funded by the Framework Programmes (FPs)[37]** | | | |
|---|---|---|---|
| **Project Name/Acronym** | **Programme** | **Total Grant (million €)** | **Period** |
| COSMOS ** | FP7 | 3.3 | 2010 - 2015 |
| NOTOX ** | FP7 | 4.9 | 2010 - 2015 |
| ToxBank ** | FP7 | 1.6 | 2010 - 2015 |
| COACH ** | FP7 | 1.5 | 2010 - 2015 |
| **Total funding by FP6 and FP7** | | **196.9** | |

The projects given above and marked with one or two asterisks form part of two research clusters as follows:

* NANOSAFETY cluster

** SEURAT-1 cluster, the funding of which was via a joint venture between the European Commission (in the framework of FP7) and the European Cosmetics Association (COLIPA), each providing € 25 million. Thus, on top of the sum mentioned above (€ 196.9 million) COLIPA made available additional € 25 million.

During the period 2007 to 2011 the EURL ECVAM received 48 test methods for evaluation and finalised the validation of 7 alternative methods. At present, 10 methods undergo validation studies for which ECVAM has the lead and an additional 6 methods are validated by other organisations with the support of ECVAM. In the same period the peer review of 15 methods by the ECVAM Scientific Advisory Committee (ESAC) was completed and the peer-review is currently in progress for an additional 3 methods.

The introduction of 7 test methods into European legislation (Council Regulation 440/2008)19 was accomplished in the reporting period and the international acceptance of 8 methods by the OECD Test Guidelines Programme was achieved (acute oral toxicology (2), acute aquatic toxicity (1), genotoxicity (1), skin sensitisation (1) and irritation (3), as well as eye irritation (2) – some overlap of study endpoints). Further OECD test guidelines are also under development, e.g. in the fields of eye corrosion/irritation and carcinogenicity.

In some toxicological areas, such as skin irritation and corrosion, skin absorption and penetration as well as phototoxicity, full replacement has been achieved. However, for other more complex toxicological endpoints the science is not yet sufficiently advanced for the development of alternatives to animal testing. In particular, there are five areas of concern, i.e. toxicokinetics, repeated dose toxicity, carcinogenicity, skin sensitisation and reproductive toxicity, in which further efforts in research are needed. In addition, a gap between the outcome of research projects in terms of developed test methods and the fitness for application of such methods in practice, is evident. Many new methods need further optimisation and adaptation to the needs of the users, including for the purpose of REACH registration. However, a suitable funding strategy for optimisation activities is lacking at both EU and MS level.

With respect to the fulfilment of legislation, animal tests have a long history of application leading to much experience in interpreting results. In contrast to this, the majority of *in vitro* and *in silico* methods, as well as the 'read-across' approach (Annex XI to REACH) have not yet reached this status. It will, therefore, take further efforts

to build up the same level of confidence for alternative methods and, subsequently, improve the acceptance by regulators.

Toxicology is undergoing a transition in safety assessment towards a more mechanistic, pathway-based, cell- and computer-based approach to assessing a substance's toxic 'mode of action'. As current approaches do not always provide the complete mechanistic information on how chemicals exert toxicity, large uncertainties remain in extrapolating data across dose, species and life stages. It is therefore necessary to develop a robust understanding of the networks of biological pathways, many of which are not yet described in full. Although several initiatives already focus on the pathway-based approach (e.g. the SEURAT-1 cluster), much remains to be done in this respect.

### 9.3.5 General Recommendations

Box 9.2 sets out general recommendations with regards to the minimisation of animal testing in support of REACH.

**Box 9.2: Recommendations for the Minimisation of Animal Testing**

- the Commission should ensure that funding for the development of alternative methods is spent in a strategic manner with the aim of increasing the understanding of chemical toxicity, with a particular focus on the needs under legislation such as REACH; and
- the Commission should assess currently available test methods including alternative testing methods and, where necessary, update these for the assessment of nanomaterials.

# 10. ENFORCEMENT

## 10.1 Introduction

The aim of the enforcement system is to verify the compliance of REACH duty holders. The enforcement of REACH is primarily the responsibility of MS overseen by National Enforcement Authorities which are often, but not always, the CA. MS are required to maintain 'a system of official controls' (Article 125), and are obliged them to report on enforcement (Article 127). A strong and uniform enforcement throughout the EU/EEA is crucial to achieve the expected benefits for human health, the environmental and industry (competitiveness, innovation and functioning of the single market) (COM, 2012f, COM, 2012g, and COM, 2012k).

The harmonisation of enforcement amongst Member States was a key issue during the development of REACH (COM, 2001). In this respect, Recital 105 stresses the importance of strengthening enforcement, and indicates that ECHA *should provide a Forum for Member States to exchange information on and to coordinate their activities related to the enforcement of chemicals legislation. The currently informal cooperation between Member States in this respect would benefit from a more formal framework.*

The intention of Recital 105 is implemented by Article 76(1)(f) with the formation of the Forum for Exchange of Information on Enforcement (the Forum). Since its formation, the Forum has developed several documents illustrating its approach of enforcement, principally:

- strategies for enforcement of REACH (ECHA, 2011d);
- minimum criteria for REACH inspections (ECHA, 2011e); and
- documents related to Forum's EU/EEA wide harmonised enforcement projects (REACH-EN-FORCE projects) to check compliance with REACH, available from the Forum section of the ECHA Internet site (http://echa.europa.eu/web/guest/about-us/who-we-are/enforcement-forum).

ECHA itself does not have enforcement powers but may request MS to undertake enforcement actions to ensure compliance with REACH. For example, ECHA has referred at least three cases to the UK CA (MS 2010). These all concerned UK legal entities that had created multiple party IDs in REACH-IT, and used these to pre-register a large amount of substances. ECHA was concerned that these legal entities had been created specifically to exploit the opportunities which pre-registration presented to gain access to commercially valuable information. ECHA asked the UK to investigate the situation further, with a view to identifying any areas of non-compliance with REACH.

## 10.2 The Forum

Article 77(4) stipulates the Forum shall undertake the following tasks with regards to the enforcement of REACH:

> *(a) spreading good practice and highlighting problems at Community level;*
> *(b) proposing, coordinating and evaluating harmonised enforcement projects and joint inspections;*
> *(c) coordinating exchange of inspectors;*
> *(d) identifying enforcement strategies, as well as best practice in enforcement;*
> *(e) developing working methods and tools of use to local inspectors;*
> *(f) developing an electronic information exchange procedure;*
> *(g) liaising with industry, taking particular account of the specific needs of SMEs, and other stakeholders, including relevant international organisations, as necessary;*
> *(h) examining proposals for restrictions with a view to advising on enforceability.*

The Forum is a part of ECHA and is made up of members nominated by each MS plus up to 5 co-opted members. ECHA states that procedural rules and work procedures for this group are in place. However, only 85% of the possible Forum members have yet been nominated (30 of 35 possible members as in ECHA 2011a). The Executive Director of ECHA, or his representative, and representatives of the Commission are also entitled to attend all the meetings of the Forum and its working groups. Stakeholders may also be invited to attend the meetings as observers.

The Forum's workload is increasing and ECHA stresses that its members should receive full scientific, technical and administrative support from MS but also indicates that the efficiency of the Forum should be improved (ECHA, 2011a). However, ECHA does not provide evidence to justify these statements. For their part, CAs made highly favourable comments about the Forum, including that it was well organised by the ECHA Secretariat and had been very effective (MS, 2010). CAs and COM (2012j) also made recommendations as to ways that its performance might be improved still further, as summarised in Box 10.1.

**Box 10.1: Recommendations for the Improvement of the Forum**

- shorten the review period for draft minutes;
- increase resourcing received from MS (CAs identified that resource limitations were reducing the Forum's ability to undertake some projects);
- prioritise inspection/enforcement activities across EU to target limited resources where most benefit may be expected, including activities relating to current restrictions;
- more desktop research and information campaigns on areas of concern may reduce the burden on the stretched resources of Forum and its members;
- Forum should consider facilitating exchange programmes between MS to allow for the dissemination of best practice and increase harmonisation of enforcement activities;
- Forum should be able to speak for enforcement authorities on issues of common concern. For example, it could negotiate improved access for MS enforcement authorities to information held by ECHA;

- improve communication and coherence between the Forum and CARACAL; and
- further clarify the role of MS representatives (are they representatives on MS or independent Forum members, nominated by MS)?

### 10.2.1 Agreed Forum Enforcement Strategies

The Forum has established a work program and developed, among others, minimum inspection requirements for MS and made recommendations for cooperation (with customs authorities and on enforcement of restrictions requirements). The Forum had also carried out two joint enforcement projects (ECHA, 2011a and Commission, *pers. comm.*). In this context, in 2009 the Forum agreed an iterative framework of non-legally binding strategies for the national enforcement of REACH, as summarised in Figure 10.1 (ECHA, 2011c).

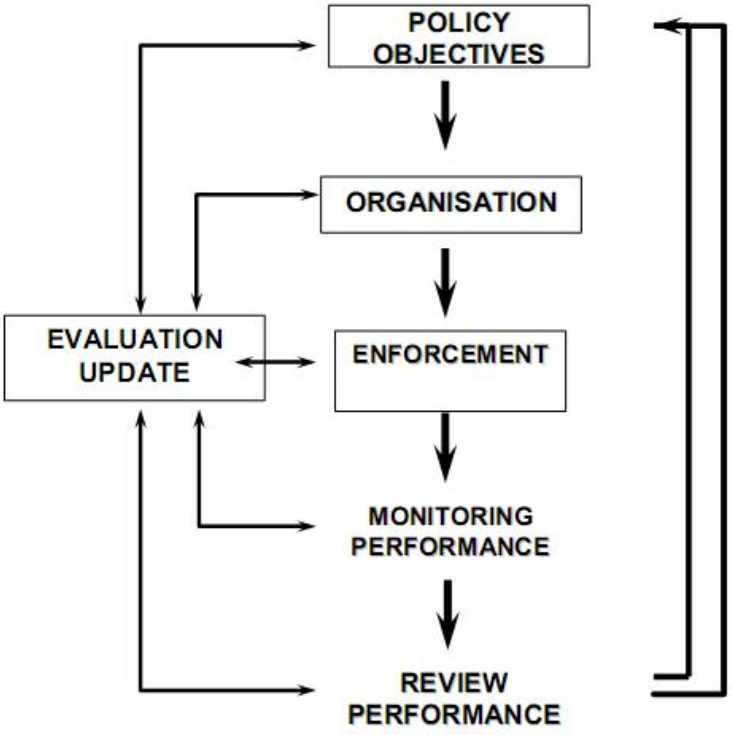



**Diagram 1.** Enforcement process for the REACH Regulation

**Figure 10.1: The Iterative Process within Forum Enforcement Strategies**

In their Article 117(1) reports, twenty-five of the thirty MSs indicated that they had an enforcement strategy(ies) that were in line with those devised by the Forum. Each MS enforcement strategy was unique to that MS so as to better fit with the legislative administrative structures of each MS. Of the five national enforcement strategies not fully in line with the Forum strategy(ies), two was clearly very close to the Forum strategy(ies) and one MS indicated that it was working towards meeting the Forum strategy(ies).

The Article 117(1) reports describe a wide range of enforcement sanctions that are available to national enforcement bodies which may lead to the following measures:

- the exclusion of a company's products (substances, mixtures or articles) from the market;
- large fines and/or prison sentences; and
- the confiscation of illegal goods for those found guilty of breaching the provisions of REACH.

CAs typically describe a mixture of administrative and criminal measures available to their enforcement authorities but some enforcement bodies would appear to have only administrative measures available. The punitive measures described by CAs are typically preceded by non-punitive measures designed to bring companies into compliance.

Even with a common strategy(ies), ECHA observes that the harmonised enforcement of REACH across MS was proving very difficult. ECHA therefore asks the Commission to consider possible legal remedies that ECHA can initiate where it discovers cases of severe non-compliance. The sort of cases described by ECHA include incomplete dossiers and where a dossier is not brought into compliance after a compliance check decision and/or enforcement action by a MS. Potential respective provisions include the power to withdraw registration numbers (ECHA 2012).

It is however of note that, with one exception, CAs indicate that they have not received enforcement referrals from ECHA within the timeframe for their Article 117(1) reports. The referrals described by the UK CA concerned the pre-registration of large numbers of substances to gain access to commercially valuable information by UK-based legal entities. It may therefore be premature to recommend changes in REACH enforcement until the current arrangements have been tested more thoroughly.

The recent study into inspection and enforcement requirements (COM, 2012i) included a proposed strategy for the enhancement of enforcement activities, as summarised in Box 10.2.

**Box 10.2: COM (2012i) Recommendations for Enhancing Enforcement (see also Box 10.1)**

Many of the objectives of REACH and CLP can be delivered by focusing compliance checking on just three elements of REACH in combination:

- exposure scenarios;
- information in the supply chain; and
- substances in articles.

Furthermore:

- inspection and enforcement activities under REACH/CLP should be coordinated and/or combined with those for other EU legislation including that for worker health and safety, industrial pollution control and product requirements. This recommendation is in line with an assessment of REACH and other legislation which identified significant overlaps (COM, 2012h); and
- the Commission should take a stronger role with respect to REACH inspections.

## 10.3 Enforcement Interaction with other Bodies

This sub-section considers interactions other than those that occur as part of the Forum, discussed above.

### 10.3.1 ECHA

Information in REACH–IT databases, e.g. on companies and substances, is needed for enforcement purposes and so ECHA has established an information portal for enforcement authorities (RIPE).

Some CAs stated that their lack of direct access to REACH-relevant data held by ECHA was causing their enforcement authorities significant difficulties in the planning and execution of their duties (MS, 2010). By the time of the publication of ECHA (2011a), ECHA was able to state that it had provided the CAs from each MS with rights to access the REACH-IT system and that by May 2011, 22 EU/EEA MS had access to that data for their enforcement activities. However, the extent to which MS, and particularly the remaining 8 MS without access to the REACH-IT system in May 2011[38], are still experiencing difficulties is not known.

### 10.3.2 Enforcement Referrals from other Member States

Ten CAs reported receiving enforcement referrals from other MS (MS, 2010). However, in each case these were few in number, as shown in Table 10.1.

**Table 10.1: Enforcement Referrals from other Countries**

| MS | Summary of Referral |
|---|---|
| Austria | A few (unspecified number) referrals via RAPEX |
| Czech Republic | One referral relating to Article 67 |

[38] It is understood that all MS now have access to the REACH-IT system (Commission, *pers. comm.*).

| Table 10.1: Enforcement Referrals from other Countries | |
|---|---|
| **MS** | **Summary of Referral** |
| Denmark | One referral regarding the registrations of a Danish company |
| Estonia | Exchanges of information on cement with chromium VI content, DMF pre-registration and toluene issue in glue |
| Finland | A couple of informal requests received |
| France | One referral regarding an article with excessive chromium content |
| Ireland | Two referrals requesting confirmation of pre-registration numbers |
| Latvia | Two referrals regarding one restricted mixture |
| Netherlands | A few (unspecified number) referrals regarding the exchange of information on pre-registrations, registrations, or status of specific companies and REACH compliance of safety datasheet information |
| Poland | One referral regarding Internet trading |
| Sweden | Two referrals, one regarding a poor quality safety data sheet and the other regarding the pre-registration of a non phase-in substance |
| United Kingdom | An unspecified number of referrals relating either to requests for information (majority) (e.g. regarding pre-registrations) or requests for enforcement action (not described) |

### 10.3.3 Enforcement Communication and Cooperation within MS

The most common mechanism used to share information (formal or informal) within MS is the organisation of regular but infrequent meetings between CAs and national enforcement agencies (e.g. Austria holds two per year) (MS, 2010). Furthermore, CAs provide oversight to the activities of the enforcement bodies and most CAs provide training.

## 10.4 Inspections and Investigations

CAs were asked for data on the number of inspections or investigations undertaken during 2007, 2008 and 2009 "*in which REACH was discussed or enforced*" (MS, 2010). However, it was clear that various MS use inspections and investigations in very different ways within their overall enforcement strategies. It would appear likely that different MS have differing interpretations of the scope of actions included within the phrase "*in which REACH was discussed or enforced*".

Furthermore, a lack of consistency between answers relating to different MS has meant that data from Article 117(1) reports relating to the enforcement and inspection burden on duty holders of different types and sizes could not be subjected to statistical analysis of any robustness. However, from the most recent data available (for 2009), the main focus for inspection activities to that time would appear to have been on "small-medium[39]" sized industries (SMEs) from the duty holders displayed in Figure 10.2.

[39] CAs were asked to differentiate between "small, small-medium, medium and large" companies rather than between "micro, small, medium and large" companies, as defined by Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (2003/361/EC). It was assumed that different CAs interpreted these categories as representing the corresponding category under Recommendation 2003/361/EC, but this could not be fully verified from the data provided by CAs.

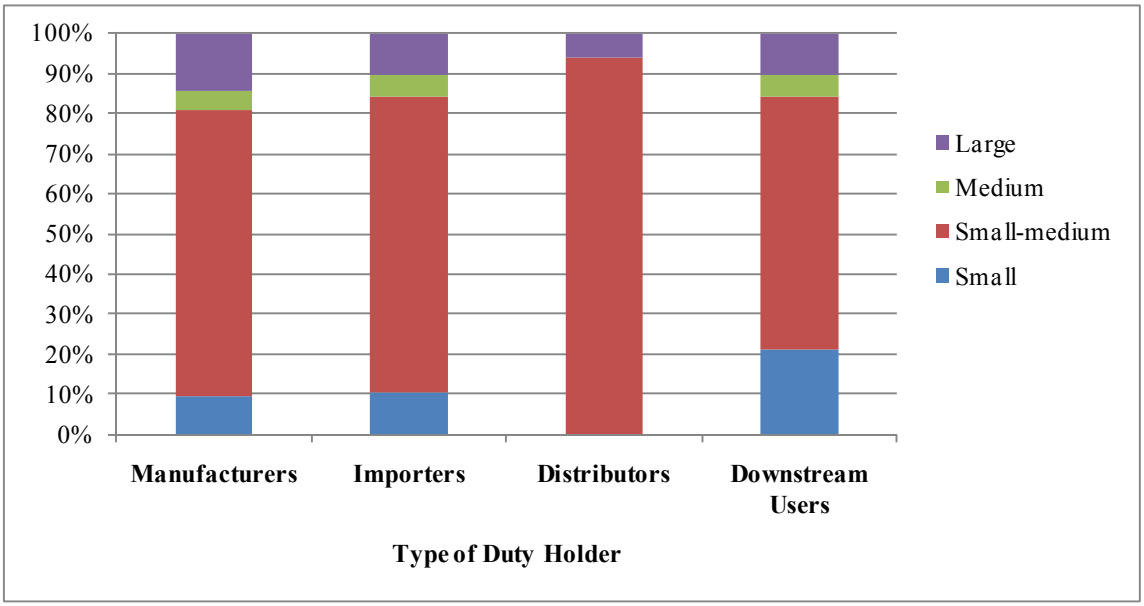



**Figure 10.2: Percentage of Inspections conducted during 2009 by Company Size and Type of Duty Holder**

The Forum REF-1 enforcement project focused on the duty holders shown in Figure 10.3 (Forum, 2011).

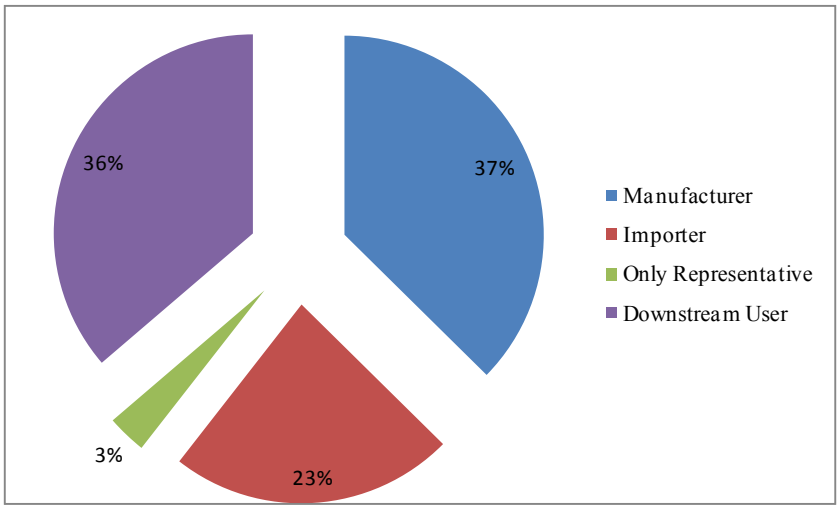



**Figure 10.3: Percentage of Inspections under the REF-1 Project (Forum, 2011)**

The Forum found that approximately 4% of companies inspected were not compliant with their registration requirements under REACH (Forum, 2011). Furthermore, the Forum reports that 9% of companies did not have SDS available for inspection while the SDS provided by 16% of companies did not meet the requirements prescribed for SDS. Overall, the Forum found that 20% of companies were not in full compliance with their obligations under REACH.

The recent study into REACH and CLP inspections (COM, 2012i) makes recommendations that may increase the efficiency of inspections, as summarised in Box 10.3.

**Box 10.3: COM (2012i) Recommendations for Expanding the Scope of Inspections**

- consideration should be given to coordinating or combining inspection activities under REACH with those under other EU legislation including those covering worker health and safety, industrial pollution control and product requirements.

## 10.5 Formal Enforcement Actions

CAs were asked for data on the number of 'formal enforcement'[40] actions undertaken during 2007, 2008 and 2009 involving different types of duty holders, as summarised in Table 10.2 (MS, 2010).

**Table 10.2: Total Number of Enforcement Actions across EU and EEA**

| Type of Duty Holder | Number of MS Responses | 2007 | 2008 | 2009 |
|---|---|---|---|---|
| Manufacturers | 11 | 125 | 147 | 528 |
| Importers | 11 | 212 | 139 | 367 |
| Distributors | 11 | 3,391 | 843 | 2,752 |
| Downstream Users | 11 | 4,585 | 9,949 | 10,413 |

The number of formal enforcement actions undertaken varied greatly between MS, with the exact reason(s) being unclear but there was some evidence to suggest a combination of:

- varying emphasis placed on direct enforcement in the different MS enforcement strategies; and
- inconsistencies in the interpretation of the nature of "duty holders" and of the phrase "formal enforcement action" between CAs.

From the most recent data available (for 2009), the main focus for enforcement activities so far have would appear to again have been on "small-medium" sized industries, from the duty holders displayed in Figure 10.4.

[40] 'Formal enforcement' was not defined in the questionnaire provided by the Commission to CAs.

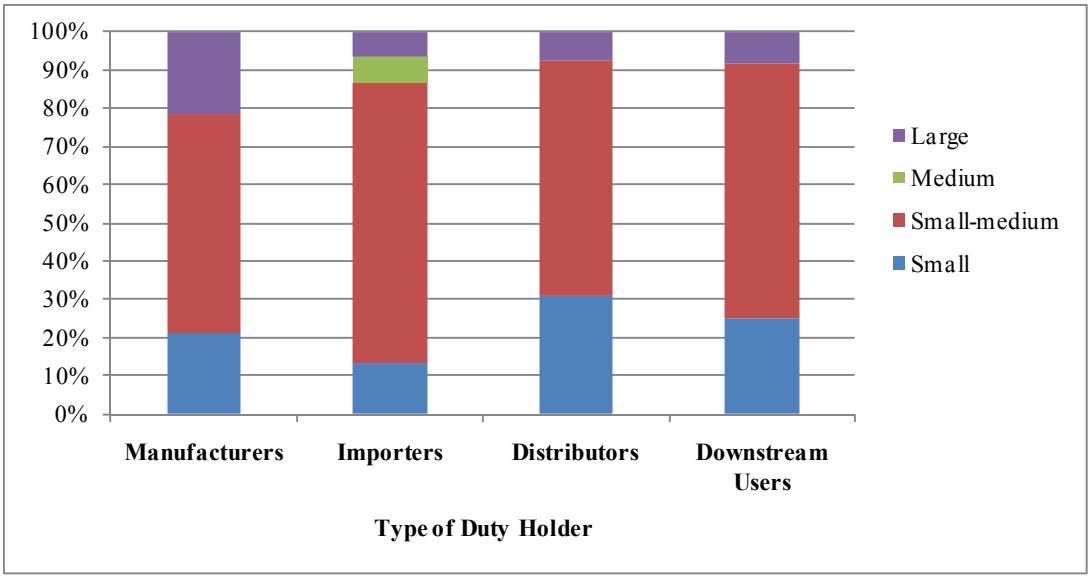



**Figure 10.4: Percentage of Enforcement Actions during 2009 by Company Size, for various Industry Sectors**

Thus, the main focus for both inspections and formal enforcement actions by MS has been small-medium sized companies with, apparently, a high proportion of inspections of small companies leading to formal enforcement action. However, the large degree of uncertainty regarding the consistency between the data provided for different MS make this observation tentative at best. One of the issues contributing to this lack of consistency was the apparent discrepancies in the definitions of different duty holders amongst MS and the lack of harmonisation in the gathering of information on inspections, enforcement and (non-)compliance (MS, 2010 and COM, 2012k).

With respect to enforcement the Forum REACH-EN-FORCE-1 (REF-1) enforcement project reported the application of the sanctions shown in Figure 10.5 (Forum, 2011).

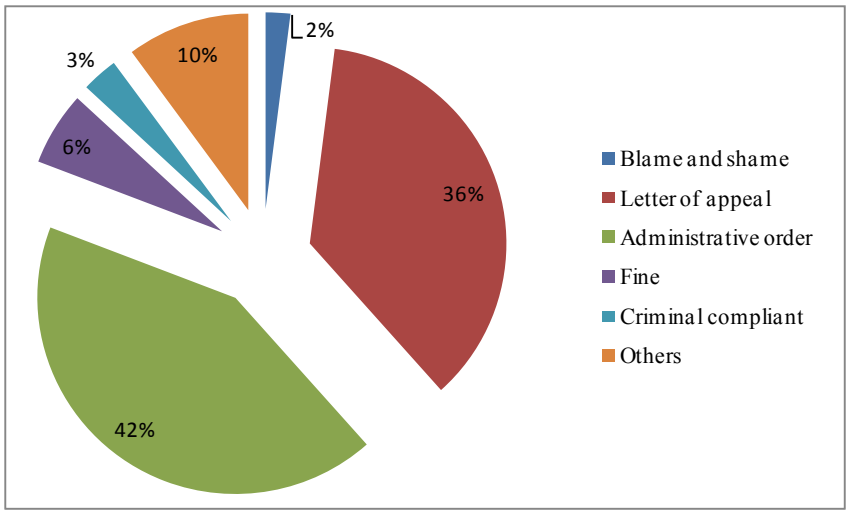



**Figure 10.5: Enforcement Sanctions under the REF-1 Project (Forum, 2011)**

The discussion above has led to the recommendations set out in Box 10.4.

**Box 10.4: Recommendations for Harmonising Enforcement and the Evaluation of Enforcement**

- the Commission should use greater clarity in the wording of Article 117(1) information requests to CAs including clear definitions of duty holders, inspections and enforcement activities; and
- CAs and the Commission should develop a more harmonised and systematic approach to the collection of information on the number and type of duty holders subject to inspections and enforcement, including for the assessment of outcomes from these activities.

## 10.6 Industry View

The studies to assess innovation and competitiveness found that 45% of companies had as yet no experience of REACH inspection or enforcement (COM, 2012f and COM, 2012g). The remaining companies were positive overall regarding their experience of such activities by regulators.

Companies also commented on the significant differences in approach between MS with regards to inspection requirements, penalties and the role of customs, without specifying the size and experienced impacts of these differences (COM, 2012g). Furthermore, given the very different regulatory and enforcement regimes in place in different MS, it is difficult to identify solutions to this issue. Comments were also received regarding the lack of resources for inspection and/or enforcement available to authorities in some MS. Suggestions for the improvement of enforcement from an industry perspective are set out in Box 10.5.

**Box 10.5: Recommendation from Industry**

- the Forum should consider how it may facilitate greater harmonisation of inspection and enforcement of REACH across MS, including the level and use of sanctions.

## 10.7 Links with OSH Legislation

Draft findings of the study into emerging technologies (COM, 2012e) concluded that the chemical sector regulations concerned with occupational health and safety (OHS) are not well linked into REACH (e.g. Seveso II (Directive 96/82/EC), the Chemical Agents Directive 98/24/EC and the Carcinogens and Mutagens Directive 2004/37/EC). On this point, there is evidence that such cooperation is happening in some MS but the mechanisms for cooperation, and the extent of such cooperation, would appear to vary greatly between MS (MS, 2010). This has led to a suggestion for the improvement of REACH, as set out in Box 10.6.

**Box 10.6: Recommendation: Links with OSH Legislation**

- the Forum should consider how it may facilitate greater coordination of the enforcement of REACH, CLP and OSH legislation, within and across MS, to reduce the administrative burden of both companies and authorities.

# 11. GUIDANCE AND SUPPORT

Guidance and support on the operation of REACH is provided to varying degrees by ECHA, the Commission, MS and industry duty holders. This assessment is primarily based upon consideration of the guidance and support provided by ECHA and MS, as described in the Article 117 reports to the Commission from these bodies.

## 11.1 Guidance Documents

ECHA is required to provide official technical and scientific guidance on the operation of REACH of relevance to industry, MS, the Commission and other stakeholders (Article 77). Such guidance has been developed, amended or revised by a process involving input from an appropriate Partner Expert Group (PEG)[41], ECHA's Committees and/or the Forum, the Commission, and CAs via CARACAL (ECHA, 2011f). In addition, the ECHA Secretariat identifies, and consults with, relevant stakeholders. The validation of guidance is currently undertaken by ECHA staff and, to a lesser extent, staff from CAs. Due to the extent of input from a wide range of interested parties, official ECHA guidance represents the consensus interpretation of the REACH legal text that is accepted by ECHA, CAs and national REACH enforcement authorities.

With respect to this official guidance documents, industry comments that, *the stability and predictability of the availability of the ECHA guidance is essential for a company's efficient planning for and preparing of a registration dossier* (DCG, 2011). ECHA and the DCG also comment that the publication of new, amended or revised guidance document can result in industry having to update submitted registration dossiers and/or the revision of dossiers in preparation. A moratorium on the publication of guidance documents was therefore introduced in the immediate run up to the 1 December 2010 deadline, and DCG (2011) reports that a further moratorium is recommended ahead of the 1 June 2013 deadline. Furthermore, there is evidence to suggest that by late 2011 the majority of industry had found ECHA's guidance documents to be "quite helpful" and to be improving over time (COM, 2012f and COM, 2012g).

ECHA reports that it has published 71 information documents which are freely available from its the Internet site; these include the official guidance documents but also fact sheets, nutshell guidance, practical guides, Q&A documents and FAQs (ECHA, 2011a). Furthermore, the majority of stakeholders would appear to be positive about the quality of these information documents (COM 2012b). Much, but not all, of this guidance has been made available in all 23 official languages of the EU which is of particular value to smaller companies (DCG, 2011). On this last point, ECHA experienced difficulties with respect to the validation of translations (ECHA, 2011a). ECHA also had problems with its preparation of the official guidance documents due to changes in terminology during the legislative process, time

[41] PEGs are composed of experts from the various stakeholders from industry, CAs and the Commission.

pressures, the high quality demands on the guidance and the limitations of staff resources from ECHA and CAs. The need to obtain legal interpretations of REACH and related policy issues is also reported to have caused problems for ECHA which delayed guidance document development.

CAs were not directly asked to report on the guidance prepared within their MS. However, from comments made it would appear that many MS provide summaries of the REACH requirements on the Internet site of their CA while directing enquirers requiring more detailed information to the ECHA guidance.

### 11.1.1 Effectiveness of PEGs

CAs were not specifically asked to comment on the working of Partner Expert Groups (PEGs) as part of their Article 117(1) report to the Commission (MS, 2010), but some feedback on the working of these groups was provided within general comments. From these comments PEGs would appear to be well organised and effectively managed but there may be problems with regard to the workability of deadlines for consultation and for dealing with comments from ECHA committees, such as RAC. The performance of individual PEGs was considered to be variable and CAs made recommendations for improvements (See Box 11.1).

**Box 11.1: Recommendations for ECHA by CAs on Improving PEGs**

- consideration should be given to having longer meetings and/or use of teleconferencing or other communication media, as required, to improve efficiency and the level of input from all participants;
- the process of PEG consultation, particularly in the latter stages, should be clarified and more realistic timetables set;
- more time should be available within a PEG following consultation for commenting and addressing concerns; and
- the PEG consultation stage should move to an earlier stage of document development.

## 11.2 Helpdesks

All MS and ECHA report that they provide REACH helpdesks (MS, 2010 and ECHA, 2011a, respectively).

Under Article 124 (Title XIII) MS are required to set up national helpdesks,

> *to provide advice to manufacturers, importers, downstream users and any other interested parties on their respective responsibilities and obligations under this Regulation, in particular in relation to the registration.*

ECHA is not specifically required under REACH to provide a helpdesk but Article 77(2)h does require ECHA to support CAs and MS helpdesks.

To fulfil their obligations under REACH without duplicating effort, CA helpdesks have provided support for actors within their MS while focusing on registrants (MS,

2010) and the ECHA helpdesk has focussed on providing support for MS helpdesks, non-EU companies, lead registrants, and on the functioning of the REACH-IT.

### 11.2.1 MS Helpdesks

***Functioning of MS Helpdesks***

All CAs manage their MS REACH helpdesks internally, except the Netherlands, where the Helpdesk function is undertaken by the National Institute for Public Health and the Environment (RIVM). The expertise available to MS helpdesks varied greatly between MS however all but one such helpdesk had access to a chemist and approximately one third had access to (eco)toxicology expertise. However, it is clear that some MS helpdesks have access to additional expertise from either other CA staff or external consultants.

Figure 11.1 sets out the means by which national REACH helpdesks may be contacted and which of these are most utilised.

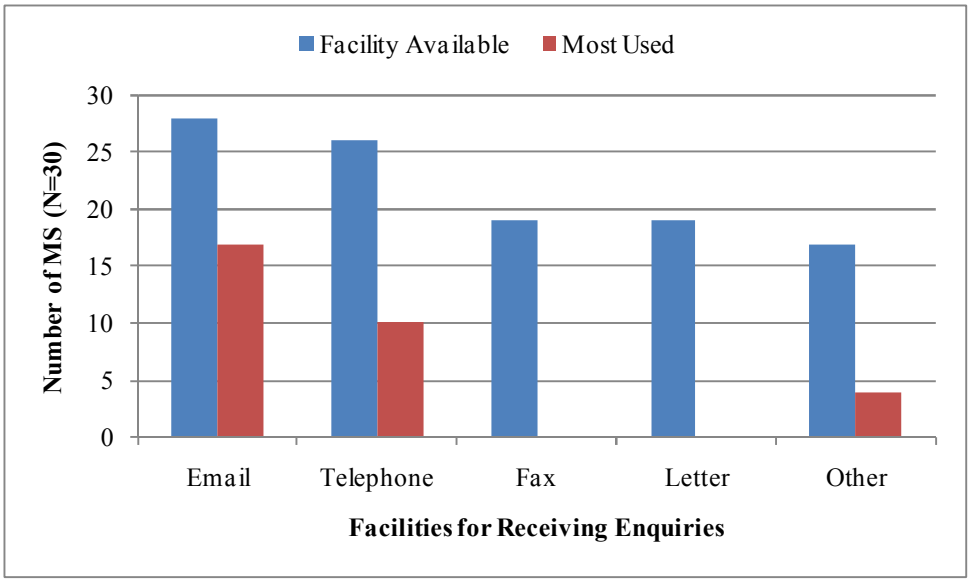



**Figure 11.1: Means by which Helpdesks may be Contacted and their Popularity**

The "Other" means of contacting helpdesks shown in Figure 11.1 relates to:

- face-to-face meetings (usually by appointment only);
- seminars/workshops/conferences; and
- web-based registration/enquiry facilities.

Furthermore, where helpdesks received the majority of their enquiries via "other" means, these enquiries were via a web-based enquiry facility.

The majority of CAs seek feedback from users to assist them to review and improve their helpdesks and eighteen CAs stated that their helpdesks provide specific advice to

SMEs. Industry also drew attention to *high impact national programmes to assist companies to prepare for registration*, giving specific mention to the activities of the French and Belgian helpdesks (DCG, 2011).

The studies on innovation and competitiveness, found the industry opinions on the contribution of MS helpdesks to be variable commenting that this may in part be due to companies expecting services beyond the remit of these helpdesks (COM, 2012f and COM, 2012g, respectively). However, these studies do state that when faced with enquiries that are beyond their remit, some MS helpdesks did still seek to help.

The number of enquiries received by CA helpdesks can vary significantly, as set out in Figure 11.2. However, the greatest number of enquiries related to registration or pre-registration and the vast majority of enquiries were from SMEs (a conclusion endorsed by COM (2012f) and COM (2012g)), which found that SMEs were more likely to seek MS rather than ECHA support.

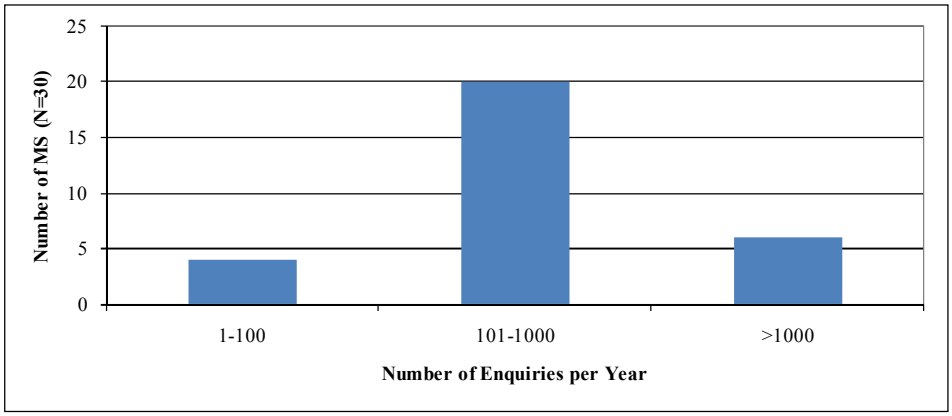



**Figure 11.2: Approximate Number of Helpdesk Enquires per Year**

There is evidence to suggest that industry had a positive view of the role of national helpdesks as well as other support mechanisms at the national and European level (COM, 2012g). There were however some criticisms from industry on the "legalistic" approach followed by some helpdesks. It is also likely that SMEs have tended to rely more on national support structures than on EU associations or support from ECHA. Recommendations for the improvement of MS Helpdesks are summarised in Box 11.2.

**Box 11.2: Recommendations for Improving MS Helpdesks**

- CAs, in consultation with helpdesk users, should take steps to ensure that their helpdesks avoid taking a legalistic approach to dealing with enquiries and offer support that is as practical as possible;
- more resources should be provided by MS to their helpdesks, especially in the run-up to phase-in deadlines; and
- MS should seek to share best practice among themselves and offer more mutual assistance, especially to those from MS with fewer resources to dedicate to their helpdesks.

***Support of MS Helpdesks by ECHA***

ECHA reported that it supported the MS helpdesks through (ECHA, 2011a):

- participation and secretarial support for the network of national helpdesks originally called REHCORN, but which subsequently changed its name to HelpNet;
- establishing an IT-platform HelpNet Exchange (originally RHEP and now known as HelpEx) to assist the working of HelpNet;
- organising face-to-face meetings as part of the HelpNet Steering group;
- providing and training and webinars for CA helpdesk staff; and
- visiting national helpdesks to better understand them.

Furthermore, FAQs from HelpNet discussions were agreed and published by ECHA.

ECHA and CAs generally viewed HelpNet and HelpEx as valued discussion platforms and resources, and approximately two thirds of CAs use HelpEx at least weekly. There is evidence to suggest that HelpNet is having a positive effect on the implementation of REACH (COM 2012b). However, CAs also felt that HelpNet and HelpEx could be made to work more effectively and efficiently and ECHA is of the opinion that the Commission could provide legal interpretations to questions from the ECHA helpdesk and HelpNet, in a more timely manner. Recommendations for the improvement of the support provided by ECHA to MS Helpdesks are summarised in Box 11.3.

**Box 11.3: Recommendations for the Improvement of ECHA's Support to MS Helpdesks**

- all HelpNet presentations should be made available via the internal communications facility 'Circa' in advance of meetings to facilitate meeting discussions;
- procedures for HelpNet should be streamlined and more time provided for discussion and exchange of opinion;
- particular emphasis should be given to discussing generic questions relating to the HelpEx database while statistical presentations about helpdesks should be brief and less detailed;
- greater participation in discussions should be encouraged by, for example, the use of break-out groups;
- alternative training and dissemination media (e.g. webinars, teleconferences) should be used where appropriate;
- majority voting should be used for decision making to allow HelpNet to function more efficiently;
- the FAQ process should be revised by adoption of the assumption that a lack of response indicated agreement with a proposal;
- the level of human resources available to MS helpdesks should be improved and efforts made to improve cooperation between MS Helpdesks outside of the REHCORN (Helpnet) structure;
- increased Commission support should be available for HelpNet on difficult issues; and
- the Commission should seek to speed up its provision of legal interpretation of REACH.

### 11.2.2 ECHA Helpdesk

As with MS helpdesks the greatest proportion of companies contacting the ECHA helpdesk were SMEs (at least 40%) with at least 25% coming from larger companies[42] (ECHA, 2011a). However, this may simply be due to the greater number of SMEs in the marketplace, as COM (2012g) noted that SMEs tended to seek guidance from bodies within their own MS. With regards to practicalities, ECHA was able to receive enquiries via email, web form, telephone, letter and face-to-face meetings. Queries to the ECHA helpdesk should be in English but queries in other languages were accepted where the language skills of individual helpdesk staff made this possible. Figure 11.3 gives an overview of the issues raised by companies.

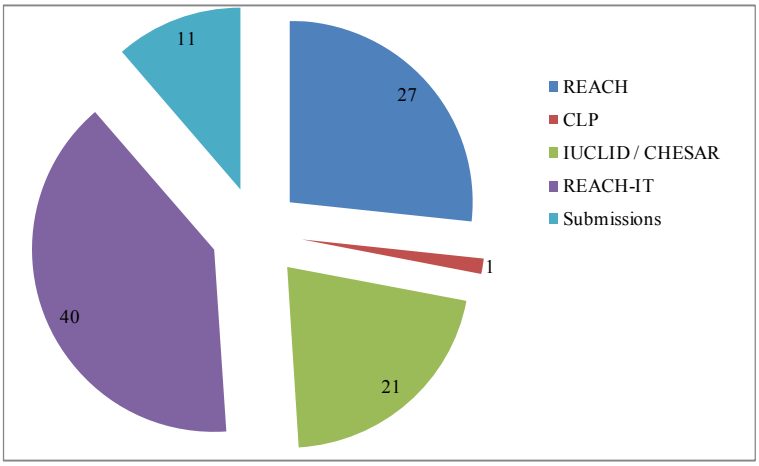



**Figure 11.3: Share of Topics of Questions to ECHA's Helpdesk[43]**

Industry appreciated the increase in direct communication between ECHA and companies in advance of the first phase-in registration deadline and asked for this to continue, especially in the run-up to the 2013 deadline, while recommending that ECHA should consider how it could further support SMEs ahead of the next phase-in deadline (DCG, 2011). However, there were some criticisms regarding delays to responses to queries (COM, 2012g).

## 11.3 Internet Sites

ECHA makes little direct mention of its Internet site in its Article 117 reports but, by inference from other information provided, it is clear that this Internet site is perhaps the host of the most comprehensive and authoritative collection of guidance and support applicable across the EU. In this respect ECHA notes that its website has grown from 40 to approximately 500 Internet pages, most of which are available in

[42] Company size was not recorded for 35% of enquiries.

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

the 23 official languages of the EU. ECHA counts 270,000 visits per month from 200 different countries[44].

With the exception Austria and Greece, all MS have a dedicated REACH Internet site, separate from other MS sites, receiving a wide range of monthly visits, as set out in Figure 11.4 (MS, 2010).

Only Iceland indicated that it had one-hundred or less visits to its webpage(s) per month. However, it is possible that some of the six CAs that did not provide information on this matter have equally low numbers of visits. The introductory or summary pages were visited most often however it is likely that many such visits will have been in order to access other pages or links to further information on REACH. Furthermore, in general CA webpages often display information on more than one aspect of REACH and so CAs were unable to provide statistically robust data on the interests of visitors to these webpages. However, specific topics of interest to visitors mentioned were REACH news/updates, company obligations, (pre-)registration, exemptions from registration, authorisation, SEA (IT only), classification and labelling and FAQs.

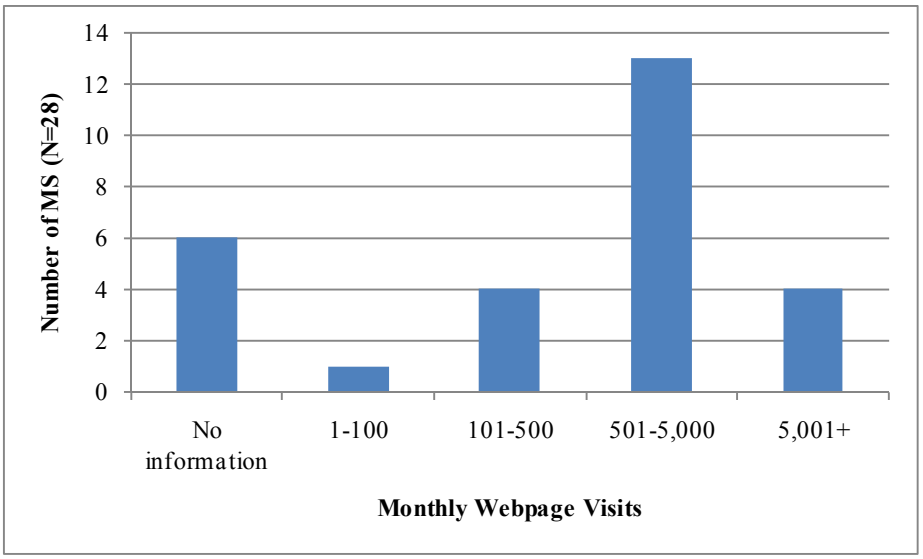



**Figure 11.4: Frequency of Visits to CA Webpages**

## 11.4 IT Tools

Under Article 77(2) ECHA is required to provide technical and scientific tools to assist in the functioning of REACH. ECHA has therefore set up an IT-infrastructure to manage and facilitate information generation and communication under REACH, particularly via the REACH-IT portal and the IUCLID 5 software (including plug-ins to IUCLID), as discussed below.

[44] In December 2011, ECHA rolled out a new website which is restructured and more user-friendly than that commented upon in this study.

There is indication that industry overall has had positive experiences with the use and utility of IT tools provided by ECHA, however where problems occurred these sometimes lead to additional costs to companies (COM, 2012g). Based on this experience, industry has commented that the stability and predictability of updates to the existing software systems is of key importance to companies planning or preparing registrations (DCG, 2011). Furthermore, the availability of IT tools in all EU languages was considered to be of particular importance to many SMEs. It was also stressed that changes to REACH-IT or other IT tools required industry to invest time and other resources in order for companies to understand the changes and adapt appropriately. Industry would therefore like such changes to be kept to a minimum in the periods running up to phase-in registration deadlines (DCG, 2010), but overall industry found ECHA's IT tools, including REACH-IT to be "quite helpful" and to be improving over time (COM, 2012f and COM, 2012g). A recommendation for the improvement of IT tools is set out in Box 11.4.

**Box 11.4: Recommendations for the Improvement of IT Tools**

- ECHA should make every effort to make all IT tools and guidance on the use of these tools available in a wide range of EU languages, as soon as possible.

### 11.4.1 REACH-IT: ECHA's Perspective

ECHA describes the REACH-IT system as the "backbone of the implementation of the REACH and CLP Regulations" and considers this system to have been well developed during its first three years of operation (ECHA, 2011a). It is via REACH-IT that (pre-)registrations are received by ECHA and it provides a means of communication between registrants and ECHA, as well as between different registrants for the formation of SIEFs.

Some initial instability was reported due to the unexpectedly high number of organisations submitting pre-registrations in 2008. However, after "intense development" ECHA reports that REACH-IT functioned well during the period of the first REACH phase-in deadline during which it received 25,000 registration dossiers and during the period for classification and labelling notifications under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP), during which it received three million notifications.

The process of registration submission via REACH-IT is now reported to have become mostly automated, requiring manual intervention by ECHA only in exceptional circumstances but ECHA provided only very limited information on the actual functions of this system (ECHA, 2011a).

ECHA has commented that the set-up of an IT-infrastructure in support of REACH demanded considerably more resources than it had been foreseen but does not quantify this statement nor does it quantify its predicted future resource needs (ECHA, 2011a). In addition, industry noted that the continuous round the clock

availability of REACH-IT in the period close to the 2010 phase-in registration deadline gave companies additional work time to meet the deadline (DCG, 2011).

### 11.4.2 IT Tools: ECHA's Perspective

ECHA developed the IUCLID database programme to make it into a tool suitable for drafting and submitting registrations to ECHA via REACH-IT (ECHA, 2011a). ECHA also developed several IUCLID plug-ins, including tools to perform a technical completeness check, calculate fees etc.

CHESAR was the IT-tool developed by ECHA to support the preparation of chemical safety reports, as specifically mentioned in Article 77(2)g[45]. ECHA further reports that it intends to undertake additional development of CHESAR to make it fully functional by the 1 June 2013 phase-in registration deadline. However, neither details nor assessment of the missing functionality are provided in ECHA (2011a).

ECHA has developed a prioritisation tool for dossier evaluation (CASPER) and a tool to support dossier evaluation (ODYSSEY), for its own use, a portal for enforcement authorities (RIPE) has been established and the dissemination portal has been available to all interested parties, as described below.

Finally, ECHA has stressed that it expects to face great demands on its available resources in the future. However, little explanation was provided as to the reasons for these anticipated demands.

## 11.5 General Information Dissemination by ECHA

ECHA reports that it has developed information channels for the dissemination of information related to all aspects of the operation of REACH, and that this activity is ongoing (ECHA, 2011a). The list of substances pre-registered for registration was published in 2008 to provide downstream users an indication of whether their substances would be registered and to facilitate the formation of SIEFs.

Non-confidential information from registration dossiers began to be published in December 2009 with the automatic publication of registration information starting in March 2011. By June 2011 information from individual and lead registrants' dossiers had been published for 3,079 phase-in and 332 non-phase-in substances. However, the search and data collection functionality is limited, and it is not always possible to download data for further analysis. It is therefore difficult to analyse the information disseminated in a practicable manner. A recommendation for the improvement of the dissemination of information is set out in Box 11.5.

[45] The algorithms used in CHESAR were adapted from those developed for use in the EUSES II and ECETOC TRA risk estimation tools.

**Box 11.5: Recommendation to Improve Dissemination of Information**

- ECHA should take steps to improve the search and data collection functionality of information that it makes available.

## 11.6 Other Activities

ECHA describes providing guidance and support to industry and Member States in form of (ECHA, 2011a):

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

However, details of the nature and extent of the activities listed above were not provided.

CAs employed a wide range of awareness raising activities within their MS, with speaking events, telephone contact and leaflets being considered most effective (MS, 2010). CAs reported that these activities mostly took place immediately prior to the entry into force of REACH or shortly after that time, and also included:

- radio advertisements;
- television advertisements;
- newspaper advertisements;
- multi-media awareness raising campaigns around the time of the entry into force of REACH;
- pilot case studies;
- letters to companies;
- emails to companies, including regular e-bulletins;
- presence at trade fairs;
- newspaper/magazine/trade press articles;
- provision of translated guidance;
- video lectures/presentations;
- website hosting of resources;
- joint campaigns with other governmental bodies;
- joint campaigns with stakeholders; and
- webinars/videoconferences.

# 12. REACH AIM: PROTECTION OF HUMAN HEALTH AND THE ENVIRONMENT

REACH Article 1(1) states that, t*he purpose of this Regulation is to ensure a high level of protection of human health and the environment*. In this context the REACH Benefits Study (COM, 2012k) has identified an extensive series of REACH provisions that are expected to deliver environmental and human health benefits.

## 12.1 Introduction to Benefits Assessment

REACH Article 1(1) states that, "The purpose of this Regulation is to ensure a high level of protection of human health and the environment." In this context the REACH Benefits Study (COM, 2012k) has identified an extensive series of REACH provisions that are expected to deliver environmental and human health benefits. At the request of the Commission, the text that follows represents a reproduction of the Executive Summary of COM (2012k), unless stated otherwise.

The framework for assessing these benefits involved the identification of:

- The **drivers of benefits** within REACH, where these are the set of legal provisions which are expected to trigger direct or indirect human health and/or environmental benefits;
- The **pathways** through which the drivers deliver these benefits, in other words they describe the cause and effect links between the drivers and benefits;
- **Indicators** of benefits, which can act as a direct measure or a proxy of the effects stemming from any cause-effect link; and
- **Enhancers**, which are those provisions that help to realise the benefits through support, control and enforcement and thus assist or ensure compliance with the main obligations.

The drivers of particular relevance to the generation of human health and environmental benefits were identified as:

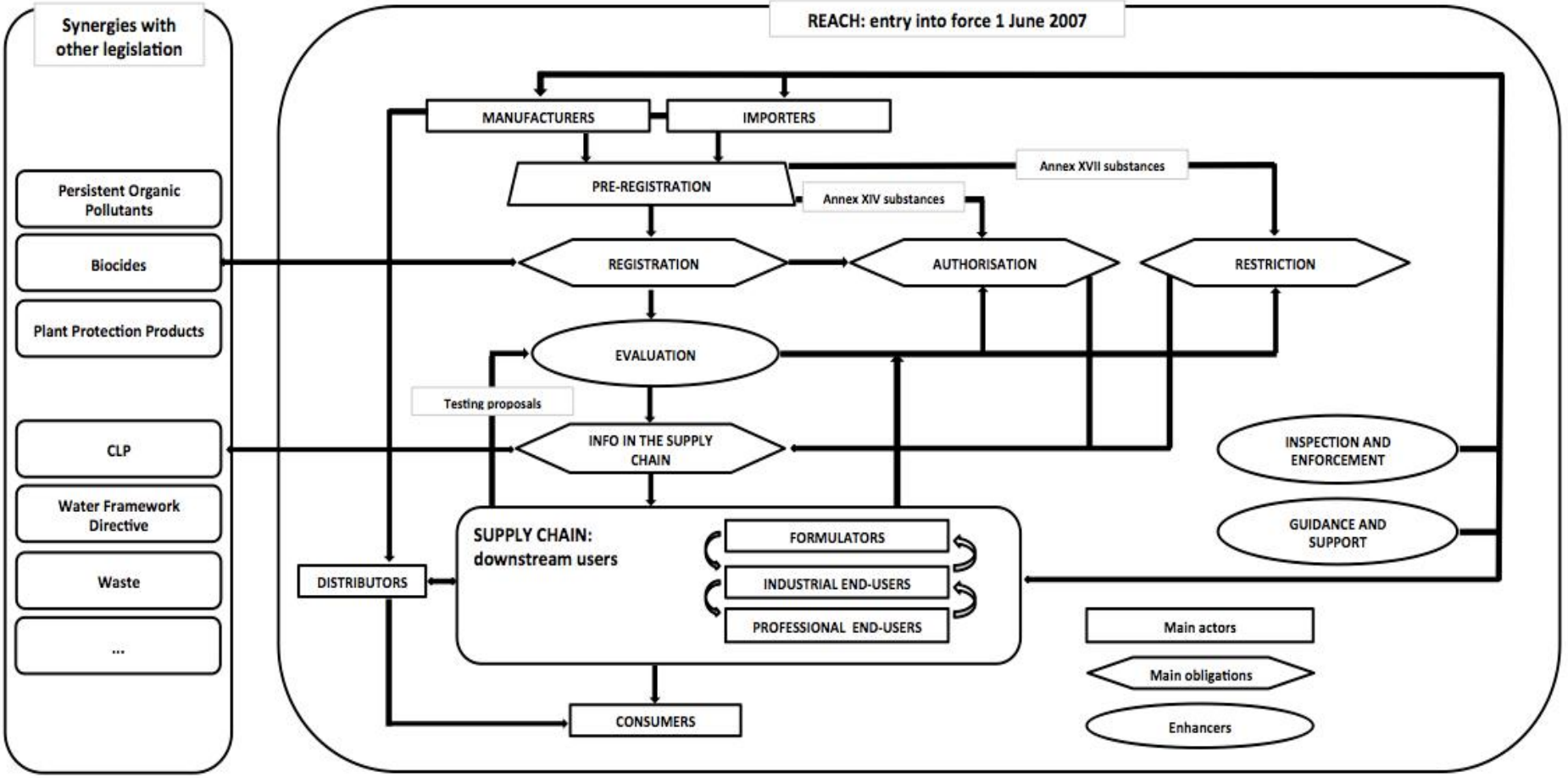
- registration (see also Section 4);
- information through the supply chain (see also Section 5);
- authorisation (see also Section 6); and
- restriction (see also Section 7).

The key enhancers of the benefit drivers were

- the provision of guidance (see also Section 11);
- evaluation (see also Section 8); and
- inspections and enforcement activities (see also Section 10).

Figure 12.1 sets out the framework for the assessment, illustrating the drivers, enhancers and main actors.

**Figure 12.1: Main Actors, Main Obligations, Enhancement Tools and Synergies with Other Legislation**



## 12.2 Overarching Remarks

REACH is a system for the management of chemical risks at the EU level, which defines the roles and responsibilities for industry and authorities as well as procedures for the assessment and reduction of risks. Under REACH, all stakeholders share the common objective of protecting human health and the environment from chemical risks, while enhancing competitiveness and innovation in European industry.

The legislation is built upon the principle that industry should take responsibility for managing chemical risks and that the precautionary principle should be applied when appropriate to ensure risk prevention rather than minimization of damage. The shared responsibility within industry for the safe use of chemicals was envisioned to act as "enforcement in the supply chain" by providing quality checks of safety data sheets and exposure scenarios. However, the high level of flexibility in how to fulfil (and enforce) the requirements of REACH is challenging to all actors, as is the lack of a clear "right or wrong" in its practical implementation.

Many of these core features of the legislation differ significantly from the earlier EU system based on a number of directives, with this being particularly the case for the shift of responsibility from authorities to industry and the need to identify and communicate information on the safe use of substances through the supply chain. The fundamental basis for successful implementation of the Regulation – trust, cooperation and communication – needs to be built over time and requires transparency, predictability and clarity of all actors towards each other. In this respect it is noted that the industry has recently published guidance on communicating substance uses along the supply chain[46].

The implementation of REACH requires that the theoretical change in mind-set, as well as the (new) tasks and obligations as laid out in the legislation, actually trickles down to all actors in the supply chain and that the capabilities and capacity to actually fulfil the different roles develop. This requires awareness raising, information and training; it also requires transparency in how the system works and why decisions are taken or actions are enforced in a particular way. Furthermore, judgements on the performance of "the others" should be guided by trust in each other's intentions and willingness to perform rather than by mistrust and allegations.

Thus, in order to ensure that REACH does result in the desired shift in mind-set and deliver its intended human health and environmental benefits, ECHA and the European Commission should continue and build upon the level of their activities aimed at building trust and cooperation by:

- involving stakeholders in development work and decision making; this regards, e.g. guidance and IT-tools as well as the discussion of Annex XV Dossiers;

[46] Communication of uses along the supply chain for 2013 registration, produced jointly by Cefic, DUCC and FECC (http://www.cefic.org/Documents/IndustrySupport/REACH%20Implementation/Letter_on_use_of_communication.doc).

- providing reasons and justification for any decisions at both the policy and technical / scientific levels, including indications of the balance between gains in risk management and changes in needed implementation efforts; and
- identifying solutions for addressing any areas where legal clarity is lacking as soon as possible to avoid situations, such as concerning substances in articles, where different legal interpretations exist.

It was envisioned from the beginning that REACH would be a "learning system". Therefore, when considering benefits to human health and the environment, it is important to provide sufficient time for that learning to take place and to collect sufficient information about the system before modifying the rules, where necessary or appropriate, to maximise its net social benefits. Therefore, the timing of any changes should be judged carefully and be based on sufficiently robust information on the actual performance of REACH in meeting its desired objectives. The first registration phase, although an important milestone, is too early in the Regulation's implementation for these purposes. There is insufficient information to provide clear indications of what types of modifications should be made to the legal text or to the guidance at this point in time, as all actors are still getting acquainted with the provisions.

However, it is clear that for REACH to deliver its intended human health and environmental benefits, priority has to be given to supporting the less experienced registrants and smaller companies who will have less capacity to respond to its requirements. It is also essential that supply chain communication functions more smoothly than is currently the case.

## 12.3 Registration

### 12.3.1 Pathways to Benefits

Registration under REACH involves the mandatory generation, collation and assessment of hazard and exposure data, risk assessment and the identification of risk management measures to ensure the safe use of chemicals. These different elements are expected to be the key drivers for the control and reduction of harmful impacts on human health and the environment. For the purposes of COM (2012k), four key hypotheses were examined:

- The preparation of chemical safety assessments for substances registered at greater than 10 t/y and which have hazardous properties should create benefits through a reduction in unsafe uses;
- The generation of new (test) data will lead to improved information on the properties of chemicals, improved reliability of classifications and thus improved information on safe use and handling. It will also improve the information base for the implementation and enforcement of other legislation;

- The requirement to carry out a PBT assessment as part of the CSA should help ensure that substances of Very High Concern are identified and can be subject to more detailed evaluation and potentially authorisation (or restriction); and
- The requirement to register substances will create benefits for human health and the environment where a substance is no longer supported by registrants due to its hazardous properties and is withdrawn from the market.

In addition, the evaluation of dossiers should act as an enhancer of benefits if it helps registrants learn how to improve their registration dossiers. Guidance should also act as an enhancer by providing tools or assessing safe use. Similarly, inspection and enforcement should act as enhancers by ensuring there is an incentive to comply with the registration provisions within the Regulation.

### 12.3.2 Key Findings of COM (2012k)

From an analysis carried out for this study of substances being monitored as part of the REACH Baseline Study[47], it is clear that the information being generated by REACH is resulting in changes in classification, with the majority of these being more restrictive classifications. This is particularly noticeable for endpoints such as acute toxicity, sensitisation, reproductive toxicity and aquatic toxicity (acute and chronic). Overall, the percentages classified after registration increased across all of the endpoints being considered. This suggests that classifications are becoming more reliable as more and improved information on substances' properties is generated and as registrants harmonise classifications. These findings are important as classifications drive the need for a Chemical Safety Assessment, for the development of exposure scenarios and, in response to these, for registrants to put forward recommended risk management measures in their extended Safety Data Sheets (SDS). There are some outstanding issues, such as the continued existence of multiple self-classifications which is giving rise to problems for formulators. However, these should reduce over time as more substances go through registration.

With respect to the duty to prepare a Chemical Safety Assessment, the findings support the hypothesis that this should lead to safer use as new or more stringent risk management measures than those currently in place are being recommended by registrants to their downstream supply chains. This should lead to benefits for workers, to the environment (through reduced emissions) and to the general public through reductions in exposures, particularly as the lower tonnage substances go through registration. However, there are also concerns that registrants are carrying out exposure modelling using default assumptions only and that this is resulting, in some cases, to overly stringent recommendations on operating conditions and risk management measures.

An analysis of selected substances registered in the first phase-in period suggests that registrants have not yet fully responded to the need to provide a clear assessment of PBT and vPvB properties. More work on this aspect may be required across the first

[47] Oko-Insitut, op.cit., p 1.

tranche of registration dossiers; such assessments are likely to become more important in the next registration phase, as the lower volume substances are likely to have had less data available on their properties prior to registration under REACH than the higher volume substances had pre-REACH.

With regard to substance withdrawal, there is evidence that substances have been "dropped" from the market or otherwise not registered due to their properties (in particular CMRs) and the potential costs of supporting them through authorisation as well as registration. It is also clear that substance withdrawal may be taking place as part of the rationalisation of product portfolios. It is less clear however that, where substances have been withdrawn, they have been replaced by a less hazardous alternative as, in some cases, manufacturers are offering alternative substances of a similar hazard profile. This is an issue that should be investigated again in future research.

### 12.3.3 Recommendations from COM (2012k)

There is a need for ECHA, MS and the Commission to support the continued learning of all actors with regards to what constitutes a good registration dossier. Ensuring the better fulfilment of existing rules should be given priority over improving the rules. The recommendations from COM (2012k) are set out in Box 12.1.

**Box 12.1: Recommendations related to Registration**

- the evaluation of registration dossiers shows that the quality of information is not sufficient and it is expected that this problem will be more pronounced with the lower volume substances. For its part, it is essential that industry increases its effort to provide high quality dossiers which would ensure the safety of substances placed on the market. It is also important that ECHA effectively communicates its learnings from the first registration phase in easy to use and concise guidance documents as well as illustrative best practice examples. This communication should be accompanied by (separate) documentation of the reasons for requesting additional information from registrants, including a justification for how this contributes to proper risk management. The aim should be to ensure that dossiers are brought into compliance with REACH requirements. Member States should focus enforcement activities on addressing those quality aspects that result in registration dossiers being non compliant;
- industry should increase its efforts with respect to the requirements for a PBT assessment. Annex XIII prescribes that if a substance at a screening level is found to be either P, B or T or vB or vP it should be subject to further testing by the registrant, unless sufficient RMM are implemented. ECHA may want to consider providing further guidance on the need for these assessments and Member States should take actions to check on such assessments as part of evaluation and enforcement activities;
- support tools to facilitate information generation and transmission should be further developed and optimised in cooperation with industry. ECHA should continue to offer training, in particular for the use of CHESAR and conducting chemical safety assessments. The further development of CHESAR should consider integrating available assessment tools and risk management measures from other legal areas;
- existing methods and approaches for exposure assessment, in particular in the field of workers protection, such as control banding, exposure modelling and standardised operating procedures, should be applied to develop realistic exposure scenarios. Where possible monitored values should be used where modelled values cannot be generated or are not precise enough. Registrants should also make better use of downstream user information on RMMs already in place, rather than recommending more generic measures that conflict with what industry has adopted over time and is agreed with national health and safety and environmental protection authorities. ECHA should

further emphasise the value of these approaches in its guidance; industry associations should organise events for experience exchange and discussion between "new" and "old" registrants; and
- ECHA and the Commission may wish to consider increasing their efforts for supporting SME registrants in order to avoid unwanted withdrawal of substances that would lead to no additional benefits to human health and the environment.

## 12.4 Information in the Supply Chain

### 12.4.1 Pathways to Benefits

Effective supply chain communication is essential for the functioning of REACH both in terms of registrants relying on information for the assessment of risks and of downstream users relying on good information to implement safe use. Manufacturers and importers of hazardous substances are required to provide hazard, exposure and risk management information to their recipients, primarily via an extended SDS (eSDS). In addition, suppliers of articles that contain chemicals identified as Substances of Very High Concern (SVHCs) have obligations (under Art 33) to provide information available down the supply chain and to consumers, to enable the safe use of those articles.

For these provisions, three main work hypotheses were examined by COM (2012k) which can be summarised as follows:

- The communication of information through SDS and eSDS creates benefits because new information is passed to downstream users to enable them to check their handling and use of chemicals;
- The requirement to communicate information upstream on operating conditions or risk management measures creates benefits because new and appropriate RMMs are identified and included in up-dated safety assessments and the overall quality of safety data sheets is improved; and
- The need for article producers to communicate the presence of an SVHC on the candidate list within an article leads to benefits by helping to ensure the safe use of articles; triggering requests from retailers for the phase-out of SVHCs in articles; and enabling consumers to take the presence of an SVHC into account in their purchasing decisions.

### 12.4.2 Key Findings from COM (2012k)

The obligation on registrants to set out safe operating conditions (OCs) and RMMs and to provide such information to downstream users is new. It should therefore have generated benefits during this first phase but is likely to be even more important for those substances about which there is currently less knowledge.

With respect to the quality and value of SDS and eSDS, the findings are mixed. The quality of SDSs will have improved because the information on classification (and hence labelling) contained within them is regarded as more reliable. In addition, the

information being provided on DNELs is useful for workplace safety assessments (as a substitute for an OEL) and can contribute to better targeted RMMs. However, communication of information on PNECs would appear of less value given the difficulties in linking environmental emissions at a particular site to environmental concentrations; in this respect they are of more value to authorities than to downstream users.

However, there are clear problems with regard to the content and format of current eSDS. The role of these in delivering health and environmental benefits can only be fulfilled if the information being provided to downstream users is in a more usable format than is the case for many of the current eSDS. The fear is that unless the quality of these improves, there may be a reduction in the usefulness of the documents to downstream users. Many consultees noted that due to the large amount of information contained in the eSDS that is either not relevant, not useful or confusing, the information needed to ensure safe use can be "hidden" or "diluted". As a result, some actors are not circulating eSDS if they believe that they will not be understood by downstream users, and thus that basic safety information could be ignored.

Thus, until eSDS for substances are understandable and concise, enforcement authorities may wish to stress that formulators should focus on including the most prominent information in mixture SDS (e.g. uses advised against, RMMs which are known to not have existed before). This should prevent formulators from forwarding "useless and extensive" information in order to ensure legal compliance. They should also be encouraged to communicate with suppliers on the improvement of their information. Linked to the above, there may be value in research which looks into the details of changes in risk management measures arising from the chemical safety assessment in comparison to the risk management measures triggered by classification alone. An open discussion of what information from the exposure scenario is of most value should be identified so that this can be communicated.

Despite the above, players at the bottom of the supply chain, such as article producers, have benefited from an increased level of knowledge on the properties and/or the possible uses of chemical substances. This can only have been the result of supply chain communication requirements. The same is true for end-users, whose responses to the CSES surveys (COM, 2012f and COM, 2012g) indicate that REACH had increased their level of knowledge on the properties and/or the possible uses of chemicals.

With respect to communication on SVHCs through the supply chain, the starting hypothesis was that human health and environmental benefits would be delivered through the "announcement effect" associated with the candidate listing of SVHC. It was also hypothesised that the requirement for the provision of information on SVHCs in articles, in concentrations above 0.1%, to end-users of articles could lead to article recipients (e.g. retailers) avoiding articles containing SVHCs or, as a minimum, would ensure the communication of information on safe use and disposal.

Both of these propositions would appear to be supported. Candidate listing is leading to early action towards substitution by formulators and demands for substitution

within their supply chains by article producers. Thus, it is expected that SVHCs will gradually be withdrawn from use, particularly from supply chains that produce end-consumer goods. It less clear whether substitution is taking place to the same extent where use of the SVHC is in an industrial process, and where the substance is not present in the final product. There are however concerns that the substitutes are not necessarily better from a human health or environmental perspective. In this respect, there may be value in considering groups of substances with similar properties together when assessing substances for entry onto the candidate list.

It can also be concluded that the need to communicate on SVHCs has delivered benefits, in that it has made companies more aware of raw materials in their products. In the longer term, this will lead to much greater awareness throughout the supply chain of chemical management issues and the replacement of SVHCs in articles. However, in the short term, it is proving difficult for EU article producers and retailers to put in place the necessary information management systems. Although work has started to put in place the necessary information systems to manage supply chain communication and to undertake the necessary compliance checks, article producers and retailers are worried that, as the candidate list increases in size, it will become more difficult for them to manage these activities. It is therefore important that they increase efforts in this regard.

There is a problem with the interpretation of the 0.1% concentration threshold in articles, with there being inconsistencies across the EU as to how an article is being defined. While most countries have adopted the Commission and ECHA's definition, some Member States have adopted an alternative approach. The Commission's interpretation means that, in many "final" articles, the 0.1% will not be exceeded although the article may be composed of (exposure relevant) parts with high levels SVHCs. This interpretation means that information on the presence of SVHCs in those parts does not reach the user of the article, potentially reducing the benefits of these communication requirements. These differing interpretations also give rise to problems with regard to the internal market.

### 12.4.3 Recommendations from COM (2012k)

The recommendations from COM (2012k) are set out in Box 12.2.

**Box 12.2: Recommendations related to Information in the Supply Chain**

- the first step in supply chain communication is the basis of all further communication and therefore has to be improved first:
  - ECHA (in cooperation with industry) should progress their work on CHESAR and derive from that the core information structure for communication on uses in order to facilitate respective supply chain communication;
  - ECHA should prepare a revised ES Format for supply chain communication as soon as possible, based on a review of best practice. A standardised IT format should also be developed; a harmonised IT template is required so that processing (merging and scaling) can be done through the use of software (e.g. CHESAR);
  - industry should use the CHESAR information structure to develop their software tools to provide safety data sheets;
  - industry's work on standard phrases for conditions of use and risk management measures should be continued; however, it appears that more commitment is needed as well as stringency

in meeting internal deadlines and targets, as trust that such tools will be developed in time has been lost; and
  - downstream users should (be encouraged to) provide information on conditions of use in ECHA's information structure in a targeted way. Standardised sector tools like spERCs should be further developed to comprehensive assessment support instruments;
- formulators have an essential role in the supply chain communication with regard to the information on safe use, because they have to provide their safety data sheet in a way that it gives orientation to the downstream user on what to actually do. Although not legally required, a consolidation of information is necessary and respective guidance is (still) not available, except for the concept of DPD+ by CEFIC. ECHA should develop specific guidance for formulators on how to identify and process information that should be forwarded to the customers and information that should not[48];
- communication on the presence of candidate list substances in articles is being hampered by the different interpretations of the legal text between the COM and Member States. This issue should be clarified and a legally binding interpretation should be found;
- challenges in the communication on candidate substances have two aspects: a) identification of the content; and b) what to communicate if a candidate substance is contained above 0.1%. Industry should consider building up electronic systems which allow for the identification of candidate substances in articles and article parts (such as the IMDS material management system of the automotive industry). This would support the implementation of all article related requirements. The content of communications on SVHC should be further explained to avoid only the name of the substance being communicated (with this being of little benefit); and
- consideration should be given to assessing and listing groups of substances on the candidate list to avoid formulators and downstream users shifting to unsuitable alternatives. As part of this, ECHA and the Competent Authorities of the Member States should ensure greater transparency on how substances are identified for candidate listing. These processes may also benefit from early consultation with industry experts and registrants.

## 12.5 Authorisation and Restriction

### 12.5.1 Pathways to Benefits

The authorisation provisions within REACH are aimed at assuring that risks from substances with properties of very high concern (SVHCs) are properly controlled, which includes the progressive phasing out of their use. It is a hazard based concept, although the prioritisation of SVHCs does take into account factors such as production volumes and whether there is wide-dispersive use of the substance as proxies for potential risks.

REACH also includes a separate provision allowing restrictions to be placed on the manufacture (or import), placing on the market or specific uses of either a substance, mixtures and/or articles (subject to some exemptions), where these can be shown to pose an unacceptable risk to human health or the environment that should be addressed on an EU-wide basis. The restriction provisions are not dissimilar to those established under the earlier combination of the Existing Substances Regulation

[48] Since the writing of COM (2012k) industry have produced guidance that goes some way towards meeting this recommendation: see *Communication of uses along the supply chain for 2013 registration*, produced jointly by **Cefic, DUCC** and **FECC** (http://www.cefic.org/Documents/IndustrySupport/REACH%20Implementation/Letter_on_use_of_communication.doc).

(EEC) 793/93 and the Marketing and Use Directive 76/769/EEC. However, the restriction process under REACH is expected to speed up the time taken for measures to be adopted and implemented and to allow for more targeted assessments.

The two work hypotheses were tested in relation to these provisions:

1. Candidate listing and the possibility of a future authorisation requirement trigger benefits because they provide incentives for the substitution of SVHCs. This is achieved by: discouraging manufacturers from the registration of listed substances; triggering requests for phase-out by article producers; triggering the reformulation of mixtures; and triggering the promotion/ identification of alternatives by manufacturers (and may trigger innovation).

2. Restriction triggers benefits by placing controls on activities giving rise to risks and, through the registry of intentions, by providing an incentive to substitute away from the substance of concern.

### 12.5.2 Key Findings from COM (2012k)

At the time of writing COM (2012k), 73 substances had been entered onto the candidate list, with 36 substances prioritised for authorisation. From the above information, it is clear that both Annex XIV Listing and candidate listing are having their desired effect: substances placed on the lists are being withdrawn from use (whether all uses or only partially across some uses) and downstream users are moving to substitutes where possible. Thus, these instruments are beginning to deliver their intended benefits of removing substances of very high concern from use in the EU.

As anticipated, substance withdrawal is taking place because manufacturers and importers are reluctant to bear the risks of registering a substance that may be subject to authorisation, which would lead to further costs associated with having to make applications for continued use. There are clear cases though, where the use of a substance is considered essential, and both manufacturers and downstream users appear to be willing to support such critical substances through the authorisation process.

There is also concern amongst downstream users that substitutes may not be better from a human health or environmental perspective. Another concern is that substances which deliver particular performance characteristics for which there are no good substitutes at present may be lost. The latter may impact on processing requirements (higher resource use and thus emissions of other substances to the environment), on product quality (which could lead to increased maintenance, frequency of replacement and wastes), or on product availability, with all of these having potentially negative health and environmental implications.

At the same time, there is a need for transparency in the judgements underlying the decision making by MS and the Commission when deciding which chemicals should

have dossiers prepared and then on deciding those which should be prioritised. Further explanation and justification could help address this issue and build understanding and trust.

Companies have also indicated that there are difficulties in handling information on the presence of a SVHC following candidate listing within the timeframes allowed under REACH. This is a particular issue for complex supply chains where inputs have to be organised across a number of different sectors or actors. The current requirement is for such communication to take place immediately, which is impractical. Extending the timeframe briefly after listing would ensure that complex supply chains were able to fulfil their obligations and reduce the likelihood that suppliers make false declarations (thereby negating the intended benefits).

With regard to the restriction provisions, it is too soon to comment on whether or not the Registry of Intentions is acting as a signal to manufacturers and downstream users to consider developing or moving to alternatives. The processing of individual substances through the restriction process is operating more quickly than that which took place under the Existing Substances Regulation and Marketing and Use Directive. However, it is of note that not many substances have been processed in total. This aspect is disappointing as it is limiting the human health and environmental benefits observed so far. More proposals were expected by this point in REACH implementation from both Member States and the Commission.

### 12.5.3 Recommendations from COM (2012k)

In order to protect against substitution with similarly hazardous substances, recommendations were made in COM (2012k), as set out in Box 12.3.

**Box 12.3: Recommendations related to Authorisation and Restriction**

- ECHA and MS should consider listing substance groups that include SVHCs, where substitution with a substance within the same group is likely;
- industry should develop guidance and training on alternatives assessment;
- industry, MS and ECHA should compile information, from commenting and other information sources, on possible alternatives to the use of the SVHC, to ensure the "exclusion" of substances known to be preferred alternatives but which also have problematic properties; and
- the Commission and/or ECHA should undertake research to determine whether or not substitution takes place with less hazardous substances and what impact candidate listing is having in this respect.

## 12.6 Enhancers

COM (2012k) identified four main enhancers of benefits to human health and the environment within REACH, with these being:

- evaluation;
- inspection and enforcement;
- synergies with other legislation; and

- guidance and other support, including the dissemination of information to external stakeholders.

The role of these pathways to benefits has not been explored through interviews with individual companies or with industry associations, except to ask about inspections in a general sense and the usefulness of guidance and other support. Discussions were held with ECHA, however, and other information from published or soon to be published sources was drawn upon by COM (2012k).

### 12.6.1 Dossier Evaluation

Dossier evaluation undoubtedly has the potential to ensure that the health and environmental benefits that should arise from the proper fulfilment of the main provisions of REACH are in fact achieved. It is essential to ensuring the quality (through a quality control function) of registration dossiers and that this improves over time. In particular, ECHA may want to check carefully the claimed status of a substance (if it is effectively an intermediate or not, which may have repercussions on the information requirements and on the evaluation process[49]), the plausibility of the suggested RMM and the reliability of default assumptions used in the exposure scenarios (as industry consultees highlighted issues in this respect). ECHA may also want to consider including additional prioritisation criteria for dossier evaluation to those already prescribed under art.41(5) of the Regulation, e.g. dossiers of substances classified for chronic aquatic toxicity end-point, that may suggest persistent and/or bio-accumulation properties, given that this appears to be an aspect needing attention more generally. Such dossiers might then feed into the substance evaluation process.

The transfer of experience from the evaluations to the evaluation progress report and FAQs, etc. is seen as a helpful and effective way to promote learning. If learning points from the evaluation processes were included in guidance updates as well, this would be an important step in the improvement of registration dossiers in the future. Furthermore, direct contact between ECHA and registrants was also stressed as an important opportunity to learn how dossiers could be improved.

The success of evaluation may also depend on the existence of a common understanding of quality between ECHA, Member States and industry. Although most feedback shows a generally positive picture, ECHA's decisions do not always appear to be well supported by technical or scientific justifications (with this highlighted as an issue with regard to testing proposals and queries over the use of read across methods). More generally, it is clear that there is a need to further inform registrants about the evaluation process itself, because there still appear to be misunderstandings on its scope and implications.

The inclusion of lessons from compliance checks in the related guidance documents is important; it ensures that common shortcomings are specifically addressed, increasing

[49] Art. 49: "*For on-site isolated intermediates that are used in strictly controlled conditions, neither dossier nor substance evaluation shall apply*".

the likelihood of avoiding such issues in the next registration phase. This would also be an appropriate way of documenting an "agreed understanding" of dossier quality. In order to actually measure the effect of dossier evaluation, statistics could be collected on the type of responses to evaluation decisions and in particular to quality observation letters, as the latter are non-binding. Furthermore, it should be ensured that the Member States undertake enforcement of evaluation decisions in order to ensure the credibility of dossier evaluation.

### 12.6.2 Inspection and Enforcement

In this first phase of the implementation of REACH, inspections were more focused on ensuring a broad understanding of the Regulation by the duty holders, with resources allocated so as to provide guidance to companies to increase levels of compliance. This type of approach should help ensure that the obligations placed on different actors are met and that registration and the other requirements are carried out to an adequate quality. It is likely therefore to act as an enhancer to the benefits delivered through the main drivers.

As reported above, interviewees highlighted the concerns that they have regarding the fact that extended Safety Data Sheets do not yet appear to be being produced in the numbers expected, with this resulting in a lack of exposure scenario information being passed down the supply chain. In terms of enforcement, the failure for eSDS (even if in a simplified form as suggested above) to be provided downstream is an issue that should be considered further following publication of the results of the REACH-EN-FORCE-2 project focused on formulators of mixtures.

It has been suggested that conformity statements on the absence of SVHC are being signed by suppliers even though they lack knowledge of the actual SVHC content. Thus, passing the burden of compliance down to retailers. This non-compliance is in part due to chemical impurities, use of different batches of input materials, etc. combined with a lack of sufficiently high penalties and a fairly low probability of being caught. MS and enforcement authorities should consider increasing penalties for improper declarations and increasing inspection activities on this aspect.

Similarly, increased inspections of imported articles would help ensure a level playing field for EU producers as well as importers. The Forum should consider if the current arrangements are adequate and set out an EU-wide strategy on random checking of importer articles.

### 12.6.3 Synergies between REACH and Sectoral Legislation

A project conducted on the scope of REACH and other relevant EU legislation (Milieu, 2011) has identified many synergies between REACH and other legislation, with these being the result of in-built mechanisms expressly provided for in REACH or in the other legislation, such as cross-references. In other cases the synergy is by providing a better information base for the regulation. The existence of such synergies highlights the enhancing effect that the information being generated under

REACH is having and will continue to have on delivering human health and environmental benefits more generally.

## 12.7 Information from Article 117 Reports

### 12.7.1 MS Information for the Assessment of Impacts

CAs felt that their MS could provide the Commission with information to inform future assessments of impacts on human health and the environment resulting from the implementation of REACH, making the recommendations set out in Box 12.4.

**Box 12.4: CA Recommendations for the Assessment of REACH Impacts**

- the effectiveness of REACH for the protection of human health and the environment is best assessed at the level of the EU rather than at a national level;
- data requests should be harmonised at the EU level; and
- the level of data gathering currently undertaken and the resources available to MS to undertake data gathering varied greatly between MS. This should be taken into consideration when drafting any information requests.

### 12.7.2 Risk Communication Network

CAs felt that the role of the Risk Communication Network (RCN) had become increasingly clear and that this voluntary body was a valuable venue for MS to share expertise and experiences of risk communication. CAs also suggested ways in which the functioning of this "well run" body could be maintained or improved, as set out in Box 12.5.

**Box 12.5: Recommendations for the Improvement of RCN**

- greater cooperation between network members should be encouraged;
- training sessions and workshops should continue or increase; and
- ECHA should take a more proactive role in the network where issues are of EU-wide concern.

## 12.8 Nanomaterials

As noted in Section 5, the Commission study on REACH and nanomaterials (COM, 2012c) identified difficulties in the identification of nanomaterials under REACH and that the extent of any hazard, exposure or risk assessment specific to substances in the nanoform was very much up to each registrant to decide. However, it was not clear whether these areas of uncertainty were adding in any way to the risks to human health or the environment. A further finding of note was that many nanomaterials are being manufactured/imported in quantities of less than 1 tonne per year per company. Therefore, the risks to human health and the environment will not be assessed unless the companies involved increase the amounts that they bring to the market in the future.

If there turn out to be impacts on human health or the environment from nanomaterials, such impacts are likely to be focussed on the EU, and particularly Germany, as these geographical areas have been identified as the greatest source of nanomaterial patents in the world, after the USA (draft findings of the study into the REACH contribution to the development, commercialisation and uptake of products of emerging technologies).

# 13. REACH AIM: ENHANCING COMPETITIVENESS, INNOVATION AND THE SINGLE MARKET

This section is, to a large extent, based upon information from the Commission studies into the impact of REACH on Innovation (COM, 2012f) and the impact of REACH on the Single Market and Competitiveness (COM, 2012g). When reading this section it is important to note that these studies focused on industry perceptions of these issues and that these industry perceptions were strongly influenced not only by REACH, but also by the prevailing economic climate. This context is well expressed by the following quotation from COM (2012f), which is echoed in the text of COM (2012g).

> *Arguably the most important factor that has influenced the perceived impact of the Regulation on innovation has been the evolving economic situation. When the Regulation became active at the beginning of 2007 the world was on the verge of what was to become the greatest financial crisis since the 1930's, and while there was some hope of improvement in economic conditions, at time of writing the Eurozone crisis has resulted in a further setback to the chances of sustainable recovery.*
>
> *In this context company finances have become highly strained, especially for SMEs, and recruitment constraints have also impacted company operations. While such constraints can and do act as a spur to innovation, it is not generally considered an auspicious environment for the launch of new investments in innovative projects.*

## 13.1 Expectations

COM (2012g) identified the following key potential costs and benefits to industry from REACH:

1. **Chemical production:** *Costs* from the withdrawal of critical substances or from an increase in prices.

2. **Innovation**: *Costs* from the diversion of investment and human resources away from productive R&D and innovation activities, towards compliance with REACH. Industry concerns regarding confidentiality and protection of business intelligence may cost innovation. *Benefits* from the development of new less dangerous substances and the identification of new uses of existing chemical substances, creating a competitive advantage (subject of COM, 2012f).

3. **Portfolio rationalisation and specialisation**: *Costs* from the rationalisation of product portfolios and withdrawal from certain market segments to reduce REACH costs. *Benefits* from additional opportunity for new market entries based on new less hazardous chemicals.

4. **SMEs**: *Costs* of compliance proportionately greater for SMEs intended to be balanced by the *benefits* from special provisions with regards to lower fees and lower registration requirements for lower tonnages (SMEs assumed to benefit from the latter to a greater extent than larger companies).

5. **Communication in the supply chain:** Initial *costs* of developing communication networks. Medium and long term *benefits* from greater cooperation and more efficient supply chain linkages.

6. **Business strategy:** *Costs* from increased time-to-market. *Benefits* from safer and more cost-effective products.

7. **Profit margins:** *Costs* from compliance are expected to reduce profit margins in the short term, however some of these costs may be distributed through the supply chain via price increases. *Benefits* margins are expected to increase in the longer term following the marketing of new substances and new uses for substances into markets with limited competition.

8. **Trade/exports:** *Costs* from compliance could lead to price increases making EU chemicals less competitive compared to chemicals supplied from outside of the EU. *Benefits* from increased innovation may increase the level of exports.

9. **Customer and investor confidence:** *Benefit* of the improved image of the EU chemicals industry with customers and investors.

10. **Demand:** A *cost transfer* is expected with a reduction in demand for more hazardous chemicals resulting in *costs* for some companies and an increase in demand for less hazardous chemicals providing *benefits* for others. In this respect COM (2012g) states that, *the capacity of the industry to respond to such changes – if applicable - will be important in determining the extent of the impact.* Further increases to demand could result from any boost to the image of the chemical industry in the EU.

11. **Access to finance:** Increased demand and reduced liabilities may lead to *benefits* from increased investor confidence and improved access to finance.

12. **Single market:** *Benefits* from a framework to create a single market for chemicals and avoid fragmentation, and thus improve the operation of the internal market.

However, while industry has been able to point to costs there is little evidence available to estimate the benefits, to date.

## 13.2 Assessment of Business Impacts by Authorities

With the exception of Italy, there was general agreement among CAs that the enhancing of competiveness and innovation should be assessed at EU rather than national level. Furthermore, the Article 117 reports from CAs and ECHA provided no specific information on the enhancing competitiveness, innovation and single market that may have resulted from the operation of REACH.

## 13.3 Competitiveness

The study to assess the impact of REACH on competitiveness (COM, 2012g), found the following responses to REACH costs:

- between 50% and 60% of companies prefer to absorb costs, rather than increase prices, with some impact on profit margins. On this issue, 50% of downstream/end users referred to an increase in the costs of the substances they use;
- 16% of manufacturers and 37% of importers of chemicals stated that they sometimes or frequently withdrew chemical products or otherwise consolidated their product portfolio;
- some companies (mainly smaller size firms) indicated that they had reduced their production volume to avoid costs; and
- little evidence of the relocation of production and, where this is being considered, there are multiple parameters underlying this, of which REACH is not the most crucial. There may, however, be more articles producers relocating production outside of the EU.

The extent to which companies adopt the responses described above was found to be very dependent upon the type of substance and market competition, with company interviews suggesting a difference between the basic and specialty/consumers chemicals sectors.

## 13.4 Availability of Substances

COM (2012f) and COM (2012g) indicate that 60% of formulators (35% of all companies) had experienced the withdrawal of a substance but this has tended to result in a reduction in the number of suppliers rather than a total lack of availability of a substance.

The main drivers for substance withdrawal were identified by these studies as registration costs and retailers/producers requiring that suppliers do not use certain chemicals (e.g. those on Candidate List, SIN List or other lists). In response companies were mostly able to either change supplier or substitute the substances concerned. With respect to the latter option, some companies stated that some substances that had been substituted were becoming obsolete and were already likely

to be substituted, with or without REACH. However, some sectors were finding it particularly difficult to substitute substances or re-formulate products due to the long time frames required for the regulatory acceptance of the products that they produce, e.g. products for the automotive or aerospace sectors.

## 13.5 Impacts on Trade and Competitiveness

COM (2012f) and COM (2012g) found no data that show impacts due to REACH at the level of intra-EU trade and REACH was seen as an incentive to enter non-EU markets by only 10% of companies. Some companies indicated that there could be some shifting of sourcing chemicals from importers to intra-EU suppliers, to avoid registration costs, but there was insufficient data on imports to test this suggestion.

With regards to impacts on the competitiveness of EU industry, the innovation and competitiveness studies identified significant compliance costs, which may well be higher than initially expected, and may also fall disproportionately on SMEs. There are direct, short term impacts on the availability of substances for some downstream users, especially where substitution is difficult, e.g. the automotive sector.

There is some evidence of increased chemical prices being paid by EU chemical users as compared to such companies outside of the EU, but this was not considered to be widespread throughout EU industry. The profit margins of EU chemical manufacturers and downstream users have been reduced as a result of REACH, at least in the short term, but there has been no evidence indicating a loss of markets so far due to REACH. However, there is evidence indicating that REACH has contributed to some market concentration. Furthermore, the regulatory framework provided by REACH had produced a level of business uncertainty which may continue until the full implementation of this regulation in 2018.

The Commission study into REACH and emerging technologies (COM, 2012e) found there to be major differences between REACH and the legislative structures in other countries (including China and the USA) that are major competitors and markets for the EU chemical industry. These differences were considered to be less of an issue for large multinational companies than for SMEs. However, the challenge of complying with such different national legislation is identified as being a considerable challenge to companies of all sizes.

With regards to competitiveness benefits, REACH was found to have had a positive impact on the promotion of cooperation with customers/suppliers[50], and supply chain integration that may lead to medium-long term benefits to industry (COM, 2012g). Further benefits from the availability of new knowledge were not expected to materialise and provide competitive advantage in the short term.

[50] In survey, there were more formulators who thought that it has not led to greater cooperation with suppliers / customers than formulators who thought that it had led to greater cooperation with suppliers / customers.

### 13.5.1 Research and Development

Recent information indicates that, for larger companies, REACH compliance was built into their R&D programmes, adding to cost but not the innovation from R&D (COM, 2012e). Smaller companies felt more strongly that REACH was having a negative impact on their R&D, commercialisation and overall levels of innovation. The disparity between larger and smaller companies was in part explained by SMEs expressing being more confused by the complexities of REACH.

The study into emerging technologies also concluded that the increased data available to formulators and other downstream users would most likely bring benefits to their R&D.

With respect to nanomaterials REACH and CLP may have (COM, 2012e):

- had a negative effect on marginal cost structure;
- created administrative burden and additional information requirements;
- had a negative effect on new business opportunities for nanomaterials applications; and
- led to a competitive edge when customers are European.

These impacts were perceived to be more negative by companies that had already been involved in the registration of substances. Impacts are also likely to be greatest for SMEs (particularly micro enterprises) as most nanomaterial manufacturers/importers are of this size. Any future modifications to REACH and CLP that focus on nanotechnologies are perceived by companies as being likely to have a negative impact on administrative burden and time-to-market.

The EU, and particularly Germany, is identified as the greatest source of nanomaterial patents in the world, after the USA. Therefore, any trade and competitiveness impacts may be significant for the EU, and disproportionately affect Germany.

Finally, COM (2012e) concluded that, at least for larger companies, the challenges with regards to the development of nanomaterials posed by REACH were considered to be significantly less than other challenges related to the public perception of the risk uncertainty.

## 13.6 Impacts on the Single Market

With respect to the single market, the objective of REACH to provide a single regulation covering the supply of chemicals has generally been achieved (COM, 2012f and COM' 2012g). Although there is no evidence of impacts on trade flows to date, the analysis of impacts on the single market undertaken as part of these studies was considered to be a work in progress at the time of writing this report. These studies also stressed the importance to the single market of continued market

surveillance and the application of a unified approach to the implementation of REACH across all MS.

Furthermore, the differences between MS on the definition of articles (as opposed to components within articles) is identified as a possible danger to the functioning of the single market, particularly with respect to the resultant significant differences between MS in the level of identification and control of SVHCs in articles.

## 13.7 Impacts on Innovation

COM (2012f) found that a key REACH driver of innovation *is the view that innovation occurs at intersections between industries, and that the presence of and access to data provides support for conception of innovative ideas. REACH introduced industrial information transfer mechanisms aimed at capturing and disseminating data across industries and throughout the supply chain to support and stimulate the development of safe chemicals and practices.* The principle REACH mechanisms behind this driver were identified as:

- the submission of registration dossiers;
- Substance Information Exchange Fora (SEIFs)/Consortia;
- Safety Data Sheets (SDS) and extended SDS (eSDS),
- Chemical Safety Reports (CSRs); and
- the ECHA dissemination portal.

When investigating this driver COM (2012f) found that 70% of companies felt that REACH had led to an increase in access to, and scrutiny of, information about chemicals. However, interviews indicated that data creation, capture and sharing under REACH had not always been possible without conflict. Breaking down this response to see the influence of different REACH processes, it was found that 25% of companies found SDS to be valuable in this respect (especially SMEs), 17% found registration dossiers including the technical dossier and CSR information to be valuable, and 10% felt that SIEFs had made a valuable contribution.

Although there was, therefore, a greater availability of information, only 25% of companies indicated that they were able use this availability to benefit innovation in their company. Furthermore, the cost of generating this extra data is identified as a drain on R&D resources that could have been used for innovation. However, many companies increased R&D expenditure to ensure that innovation could continue at pre-REACH levels and undertake REACH compliance activities. This may be a result of the fact that many factors have a greater impact on innovation and the need to innovate than REACH, most notably the *state of markets and technology*. COM (2012f) further predicts that compliance pressures on R&D for innovation will be greater for substances yet to be registered as there will generally be less available information on these substances to fulfil the REACH registration requirements.

It would also appear that the exemptions from REACH provisions designed to support R&D were not working as expected, as set out in Table 13.1.

| **Table 31.1: Impact of Exemptions from REACH on Innovation.** | | |
|---|---|---|
| **Exemption** | | **Response** |
| **Reference** | **Summary** | |
| Articles 56, 67 | Substances used in scientific experimentation, analysis or chemical research in a volume less than 1 tonne per year are exempt from REACH registration, authorisation or restriction | 90% of industry felt that this has not led to increased R&D activity |
| Articles 9, 56 | PPORD substances are exempt from registration for 5 years, and are considered separately for authorisation and restriction | No quantification of effect but provision sufficient for innovation, in principle |
| Article 2, Title II (Ch. 3), Title VI (Ch. 3) | Isolated intermediates have much reduced registration requirements, limited evaluation provisions (exempt from normal provisions) and are exempt from restrictions | Does not contribute greatly to increased innovation but COM (2012f) did not address the negative impact on innovation of not having this provision |
| Article 2 | Polymers are exempt from registration and restriction | The majority view was that this did not contribute to increased innovation. However, some did believe that this would stimulate additional R&D |

### 13.7.1 REACH Costs and Innovation

Companies report that the costs of REACH (see Section 13.8) are having a negative impact on innovation and that they are more closely scrutinising innovation costs and risks before going ahead. There is also evidence that companies see REACH as a barrier to innovation and are finding ways to work around these barriers as the following text from COM (2012f) illustrates:

> *Some dynamic and highly innovative research companies are expressly following a strategy of staying small and passing on their innovations to larger multinationals with whom they have relationships that will do piloting and marketing, so that they can stay under the relevant tonnage bands.*

### 13.7.2 Overview

Information is being gathered to inform an assessment of the impact of REACH on innovation, but it would appear to be too early in the implementation process to be able to identify these. However, it is clear from COM (2012f) that industry is able to see the costs, but has limited information to provide on benefits. The overall impression is provided by the following quotation from the Executive Summary to COM (2012f):

> *As a qualitative view of the impact of REACH on innovation ("outputs"), survey respondents were asked what they thought the effect of REACH has been on innovation at their firms to the present, as compared to the pre-REACH situation. About one eighth of respondents consider the effect of*

*REACH on innovation at their firms as somewhat positive when compared to the pre-REACH situation. Over 40% saw it as negative and about a third indicated that it had no effect.*

## 13.8 Industry Costs and Benefits

### 13.8.1 Costs

The extended impact assessment of 2003 (COM-EIA, 2003) estimated the total costs of REACH to be €2.8 billion over 11 years and €5.2 billion over 15 years. Health benefits were estimated to be €50 billion over 30 years. Furthermore, DHI (2004) estimated benefits to the environment to amount to up to a further €50 billion over 25 years and Ökopol (2007) identified a range of benefits to industry, but these additional benefits were not quantified.

In COM (2012g) industry identified the following elements that may contribute to the cost to industry of compliance with REACH:

1. **Human resources:** dedicated to the various REACH-related activities: 1 to 5 Full Time Equivalents (FTEs) for about half of companies dropping to 0.5 to 1 FTE for smaller firms and rising to 100+ FTE in exceptional cases.

2. **Pre-registration:** 0.5 FTE/€500 per pre-registration for 2.7 million pre-registrations could total €1.35 billion. However, this figure does not seem to take bulk pre-registrations into account e.g. some companies pre-registered all 140,000 substances in EINECS but it is unlikely that this cost them €28 million each.

3. **Registration:** wide variation in reported costs so far with a 'typical' registration costing between €50,000 and €100,000 and with 70% of registrations costing between €25,000 and €250,000. For simple registrations ECHA fees could amount to 50% of total costs and for more complicated substances SIEF/consortia costs could exceed €100,000. Total registration costs were estimated to be between €1.1 billion and €4.1 billion. It should however be noted that registrations to date cover >1,000 tonne substances, SVHCs and new substances, almost exclusively.

4. **Authorisation and restriction:** Industry expressed concerns about future costs but these provisions had not been sufficiently implemented for cost estimates to be developed at this stage.

5. **Information exchange in the supply chain**: Industry considered that REACH had increased these costs. The typical costs for the preparation of an SDS were estimated to be around €200, over €500 for an eSDS, and up to €2,500 in the case of translations in all European languages. IT systems for handling eSDS were estimated to cost a few thousand to over one million Euros. However, no allowance was made for the level of costs incurred for the preparation of SDS

pre-REACH nor for the costs of new/updated IT systems that would have occurred irrespective of the introduction of REACH.

6. **Notification for articles**: No costs provided but comment was made regarding concern over differing interpretations by enforcement authorities.

7. **Downstream users' chemical safety reports**: No costs provided.

8. **Costs for changes** in production and relevant R&D activity, management of risk and other necessary investments: No costs provided

### 13.8.2 Benefits

COM (2012g) found that an important part of the potential benefits still remain to be seen as the implementation of the Regulation goes forward. With respect to competitiveness benefits, the potential of REACH to stimulate innovation and development of new substances and of the presence of relevant mechanisms is yet to be realised. However, the information used in COM (2012f) primarily came from a survey of industry and COM (2012f) comments that industry was able to see clear costs, whereas the potentially greater costs from multiple different regulations being developed across the EU in the absence of REACH may not have been so apparent to respondents. *Thus, the comments made focused on implementation problems and ignore the clear benefits of the presence of a single regulation across the EU.*

Overall, industry would appear to lack confidence that REACH will bring benefits in terms of enhanced competitiveness or innovation. In this context, COM (2012f) documented four key areas where industry respondents did not feel that benefits from REACH to them were particularly great (percentages assume that consultation is representative of industry as a whole):

1. **Increased consumer confidence**: Less than 20% believe this to be true (no input was sought from consumer organisations or other relevant NGOs).

2. **Increased knowledge on the properties and uses of substances**: This benefit was felt to be occurring, but that it had not yet transferred into benefits that companies could recognise.

3. **Communication in the Supply Chain**: Potential benefits were not recognised by companies which, at this stage, tended to focus on the costs incurred.

4. **Improved risk management**: It was felt to be too early to be able to identify cost reductions related to the implementation of occupational health and safety obligations.

## 13.9 Recommendations

The overall recommendations for the improvement of REACH's ability to enhance competitiveness, innovation and the single market are set out in Box 13.1.

**Box 13.1: Overall Recommendations**

- impacts on competitiveness, innovation and the single market should be assessed at an EU level (MS, 2010);
- the Commission should monitor and gather data on the factors expected to bring business/trade impacts to the chemical industry in the EU/EFTA. With this data a more accurate assessment of impacts should be undertaken; and
- the Commission, ECHA and industry associations should work together to develop an action plan to find ways of enhancing the effectiveness of the key information driver to innovation benefits, including consideration of training and education, especially that focused on SMEs.

# 14. FINDINGS AND RECOMMENDATIONS

This section summarises the information and recommendations set out in earlier sections of this report. Further information on the implementation of REACH and more extensive recommendations for improvement are made in Annex 2 (MS Reporting), Annex 3 (ECHA Reporting) and in the other parallel studies (COM, 2012a-k) referenced in this report.

## 14.1 Organisation

The **Agency** for overseeing and facilitating the operation of REACH (ECHA) has been established and would appear to be fulfilling its anticipated role, overall, however not always on time. The ECHA committees required under REACH (e.g. RAC and SEAC) have been created and are operating in a satisfactory manner, as far as can be assessed at this stage, and additional groupings have been formed to further facilitate REACH (e.g. HelpEx). ECHA believes that its resource needs were underestimated prior to its creation but has been able to operate within agreed budgets.

Each of the MS from the EU27 and EFTA have created at least one **Competent Authority** (CA) as required under REACH. However, the activities and skill sets of different CAs vary greatly between MS. Furthermore, it is not clear whether all MS are allocating adequate resources to their CA(s). CARACAL has been established as the principle body that brings together all CAs to facilitate cooperation between CAs, and between CAs and the Commission and ECHA.

Many **companies**, principally manufacturers and importers, have invested significant resources towards ensuring their compliance. In spite of the resources invested by companies they have not always submitted registration dossiers that fully comply with REACH (ECHA, 2011a and ECHA, 2011b) or in other ways not complied with REACH (MS, 2010). Furthermore, there are significant concerns regarding the current level of understanding of obligations under REACH, particularly by downstream users and SMEs (COM, 2012k).

**Box 14.1: Recommendations – Organisation**

**ECHA**

- ECHA should clearly identify the costs of undertaking its activities (and expected future costs) and compare these with expectations and the current budget;
- the Commission should consider the findings of ECHA's review of its finances and make recommendations to ensure it has adequate funding for current and future activities; and
- MS should review current resourcing for ECHA committees to ensure their adequate resourcing.

**CAs**

- MS should review current funding for CAs and ensure that funding is adequate for current and expected near future activities; and
- CAs should seek to share best practice and consider the sharing of expertise across MS boundaries.

**Companies**
- Renewed efforts should be made by ECHA and CAs to inform all actors of their obligations under REACH, especially downstream users and SMEs.

## 14.2 Co-ordination, Co-operation and Information Exchange

Details of the co-ordination, co-operation and information exchange activities within **ECHA** are not available but ECHA does state that it has taken steps to improve the functioning of these activities. CARACAL has been established as the principle body that brings together all **CAs** to facilitate cooperation between CAs, and between CAs and the Commission and ECHA. Outside of CARACAL CAs feel that they work together moderately well but would like CAs and ECHA to ensure that the list of CA contacts is kept fully up-to-date.

**ECHA and CAs** report being moderately happy with the quality of their interactions with one another, both informally and as part of the ECHA committees. The work of the committees was considered by CAs to be above average however numerous recommendations were also made for their improvement. ECHA and CAs are largely positive regarding their communication etc. with the Commission, however, again specific recommendations for improvement are also made.

Co-ordination, co-operation and information exchange also occurs with other stakeholders. Primarily, ECHA disseminates registration information and guidance. However, other stakeholders can provide information to ECHA as part of official consultation exercises and industry representatives have access to the Directors Contact Group. Stakeholders are also involved as observers in many ECHA committees. ECHA also describes relevant activities with organisations outside of the EU such as the OECD and non-EU Countries (which may also act as observers at CARACAL meetings).

**Box 14.2: Recommendations – Co-ordination, Co-operation and Information Exchange**

**CARACAL**
- issues should be raised earlier before the positions of the CAs, ECHA and the Commission became fixed so that the views expressed at CARACAL can be taken into account;
- items for discussion should be included in the agenda – and documents circulated - well in advance (at least 2 weeks) of a meeting;
- agendas should be based on realistic agenda schedules and there was a need for improved structuring of the agenda to ensure there is adequate time for discussion of each issue and that political and technical issues are each discussed within separate parts of the meeting;
- more active contribution to discussions should be sought from a wider range of MS. This might be facilitated by provision of a larger meeting room with translation services;
- the use of sub-groups to address particular issues was also suggested as a means of easing agenda congestion;
- a 'Manual of Decisions' should be kept on the implementation of REACH and CLP to enable tracking of agreements on implementation issues and related decisions; and
- there was a need for improvement in information exchange between CARACAL and the Forum to facilitate REACH enforcement.

**Informal Communications between CAs**

- ECHA and CAs should keep contact details up-to-date; and
- ECHA, the Commission and MS should consider how to improve the provision of translation services for informal CA communication.

**Member State Committee**

- although presentations at MSC meetings are helpful, agenda's should be modified to allow greater time for discussions;
- greater use should be made of working groups and through use of alternative discussion venues such as webinars;
- discussions would benefit from more active participation by a greater number of the members;
- communication should be improved between the CAs' and the corresponding MSC members, particularly with regard to the evaluation of draft decisions by ECHA; and
- adequate remuneration systems should be introduced for MSs support of co-rapporteurs contributions.

**REACH Committees Overall: Committee Organisation**

- documents should be made available on CIRCA well in advance of the meetings to ensure proper discussion within MS before the meetings;
- meeting calendars should be set-up at least for one year in advance;
- documents may be provided on the respective group's CIRCA site(s) or on various newsgroup CIRCA sites as well as via ordinary e-mails. Any actions leading to simplified communication would be welcome;
- terms of reference and efficient working procedures need to be given greater attention and kept under review;
- committee procedures are over complicated and should be streamlined;
- some issues should be considered by video conference/ specific internet platforms and also by written procedures; and
- the repetition of items on the agendas of more than one committee should be avoided, where possible.

**REACH Committees Overall: Business of Committees**

- the number of training events about specific topics should be increased;
- meeting agendas and presentations of information need to be less lengthy;
- greater human resources are needed from ECHA and MS;
- the choice of NGO representatives and other participants of open sessions should be more selective;
- the interpreter/translation provision should be increased;
- fewer procedures should be subject to restrictive time limitations;
- to avoid unequal workloads between different countries ways should be sought to engage all participants in the discussions and the work to be carried out by:
  - ensuring increased transparency and timely distribution of documents, and
  - greater use of smaller or informal meetings, e.g. break-out groups in workshops;
- closer cooperation is needed between CAs, ECHA and MS/EEA countries to keep the committees fully functional; and
- improved communication is needed between the CA's and the corresponding MSC members (especially when processing draft evaluation decisions by ECHA).

**CAs and the Commission**

- the Commission should work with MS as partners in drawing up the contents and agendas for the meetings;
- CAs and other relevant MS bodies should be more involved in the preparation of Commission proposals; and
- more key documents should be translated into a wider range of EU languages (may facilitate greater participation by some MS).

**MS, COM and ECHA, and Other Stakeholders**

- improve communication between DCG, CARACAL and Forum by greater circulation of documents between these groups;
- greater care should be taken in selecting suitable observers for committees such as CARACAL; and
- further effort should be focused on co-operation with other stakeholders, particularly with regard to the provision of REACH support.

**Wider Cooperation**

- information generated under REACH should be made available to EU authorities tasked with the implementation or enforcement of other EU legislation.

## 14.3 Operation of REACH: Registration

ECHA received 2.7 million **pre-registrations** with respect to 146,000 phase-in substances, including 41,000 substances without an EC number (18%). Also, 14,500 substances were submitted as multi-constituent substances. The number of pre-registrations was 15-times higher than had been estimated. The reason for the huge number of pre-registrations is not fully identified, but many companies appear to have been uncertain about their obligations and thus they pre-registered substances just-in-case. Inaccurate pre-registrations have hampered the formation of SIEFs and made it difficult for ECHA to predict future workloads.

The first phase-in deadline of 1 December has now passed and therefore all substances manufactured/imported in quantities equal to, or greater than, 1,000 tonnes should have been registered, as should all potential CMR/PBT/vPvB SVHCs and non-phase-in substances subject to **registration**. Overall, more than 26,000 registration dossiers for almost 5,000 substances have been received by ECHA, 75% of which came from just 7 countries. Provisions for joint submission appear to be working well with 90% of dossiers being submitted in this way, however problems were encountered due to the late submission of lead registrations.

The **costs** of preparing a registration dossier are reported to have varied widely, between a few thousand Euros to over one million Euros.

**Box 14.3: Recommendations – Registration (see also Box 14.11)**

- ECHA should encourage pre-registrants to voluntarily remove or amend unnecessary or inaccurate pre-registrations (already implemented by ECHA);
- ECHA should improve its system for collecting information from registrants on reasons for not registering pre-registered substances (already being attempted by ECHA);
- ECHA should introduce incentives to promote the timely submission of lead dossiers and to raise the awareness of member registrants on the timing of dossier submission; and
- ECHA, the Commission and industry should seek ways to allow non-lead registrants to provide registrant specific data on granulometry and other physicochemical endpoints while remaining within a joint registration. This may include the addition of safeguards to ensure that any hazard or risk assessment undertaken by the lead registrant is updated, as appropriate.

## 14.4 Operation of REACH: Information in the Supply Chain

REACH does appear to have increased the flow of information in the supply chain but there are many concerns about failings in this process. Furthermore, the quality of the information going down the supply chain would seem to have improved since REACH came into force. However, downstream users have encountered difficulties communicating their uses up the supply chain to registrants. Furthermore, the new eSDS used to communicate information down the supply chain are often unwieldy and do not always facilitate the easy transfer of safety information to downstream users.

**Box 14.4: Recommendations – Information in the Supply Chain (see also Box 14.11)**

- ECHA should publish best practice guidance on the communication of uses; and
- ECHA and/or the Commission should, in collaboration with industry, consider whether current guidance provides sufficient clarification of the legal requirements of downstream users and based on this assessment consider amending current guidance.

## 14.5 Operation of REACH: Authorisation

ECHA's work has focused on generating and processing Annex XV dossiers for SVHC identification, and the preparation of prioritisation proposals for inclusion of candidate substances on the authorisation list. It reports that 53[51] substances were on the candidate list, with 15[52] recommended for Annex XIV inclusion at the time of its Article 117(2) report. Furthermore, ECHA and MS have had a limited amount of 'risk management options analysis' (RMO-analysis). It is considered too early to assess the practicality and effectiveness of the authorisation provisions under REACH, at this early stage of their implementation. However, it is noted that provisions do not currently exist to remove a substance from the candidate list or from Annex XIV, should this be necessary.

ECHA reports that no authorisation application had been received at the time of its Article 117(2) report but that it expected to receive increasing numbers of such applications (estimating 200 in 2013, rising to 400 in 2014). Industry reports being reluctant to submit applications, preferring to consider substance replacement due to the high cost of dossier preparation, the perceived high risk of failure and the time limitation to granted applications. There is also a high degree of uncertainty surrounding the legal obligations of companies using SVHCs and potential SVHCs, including uncertainties around the accurate identification of these substances. Industry also perceive that the process lacks transparency overall.

The ECHA committees central to the functioning of authorisation (RAC and SEAC) appear to be functioning reasonably well so far. However, weaknesses are noted and

[51] There were 73 entries in the Candidate List at the time of writing.

[52] At the time of writing further 13 entries have been added to the list of substances recommended for authorisation.

concern is expressed about their ability to fulfil their obligations as the number of substances entering the authorisation process increases and authorisation applications begin to be received.

**Box 14.5: Recommendations – Authorisation (see also Box 14.11)**

**Process in General**

- ECHA, the Commission and MS should introduce greater transparency into all aspects of the Annex XIV inclusion process;
- the Commission should develop proposals for the removal of substances from the candidate list and Annex XIV; and
- the Commission should clarify and, together with ECHA and CAs, disseminate information on the legal role of the Candidate List under REACH and the role of actors in the supply chain.

**RAC and SEAC**

- MS should identify and appoint members in order to fill this committee;
- consideration should be given to the simplification of the Rules of Procedure and any other measures that may be taken to facilitate the increased efficiency; and
- ECHA should assess the skill sets expected to be needed for the future working of RAC and work with MS to ensure all key skill sets are available to RAC, especially CMR and classification expertise.

## 14.6 Operation of REACH: Restriction

In 2008, ECHA examined 26 non-finalised dossiers of substances prioritised under the Existing Substances Regulation but no recommendations for restrictions were reached. Looking forward, ECHA considers itself to be well-prepared to develop restriction proposals however, as addressed for authorisation, there are concerns about whether or not RAC and SEAC will have the capacity and resources to cope. There are also concerns regarding overlaps and inconsistencies between current restrictions under REACH and controls under other EU legislation.

**Box 14.6: Recommendations – Restriction (see also Box 14.11)**

- ECHA should set up an inventory of all substance restrictions/controls under REACH and other legislation. In this way any overlaps will be more evident; and
- the Commission should develop proposals to amend REACH or overlapping legislation to remove duplications.

## 14.7 Operation of REACH: Evaluation

Between 2008 and 2011 ECHA evaluated 249 **dossiers** for compliance with REACH. From this limited evaluation ECHA identified shortcomings with respect to substance identity, justification for data waiving, and the level of detail within robust study summaries. ECHA was unable to identify improvements to risk assessment over time, however improvements in risk assessment compared to the situation pre-REACH have been identified as part of the REACH Baseline study.

Eight of the twelve draft evaluation decisions (75%) by ECHA were commented on by the CAs and no referrals to the Commission comitology procedure were needed. None of the evaluation decisions have resulted in an appeal to date. Looking to the future, ECHA has plans in place to ensure that it evaluates 1,000 dossiers (5%) by the end of 2013, as required, and to evaluate 600 dossiers annually, thereafter.

The full provisions for **substance evaluation** have not yet been implemented and no substance evaluation had been started prior to the drafting of this report. However, in preparation for the future tasks, ECHA and MS are working to agree on timelines and processes for the first Community Rolling Action Plan (CoRAP). The first CoRAP is to be established in February 2012 and should cover a three year period; the plan will be revised annually thereafter. At this early stage industry is concerned about a lack of transparency in the substance evaluation process.

ECHA has screened 303 dossiers of on-site and transported **intermediates** to check whether the claims made for intermediate status are sufficiently robust. In eleven cases ECHA was concerned and requested additional information from registrants.

**Box 14.7: Recommendations – Evaluation**

**Dossier Evaluation**

- the Commission should consider whether provisions should be added to REACH to require registrants to amend RMMs where concerns are identified. A transparent procedure will need to be developed to support the implementation of any such provisions;
- the Commission should consider whether a deadline should imposed by which NONS dossiers for manufacture/import of substances above 1,000 tonnes per year should be fully compliant with the requirements of REACH; and
- the Commission should consider whether a deadline should be imposed, after which any notification under NONS must be fully compliant with the registration requirements of REACH.

**Substance Evaluation**

- ECHA and MS should continue ensuring a high level of involvement of stakeholders in the evaluation processes while addressing industry concerns regarding a lack of transparency and understanding of the processes involved;
- ECHA should seek ways to increase the speed and efficiency of compliance checking in order to meet the targets for dossier evaluation;
- ECHA and MS should consider improving selection and targeting compliance checks to increase the regulatory impact of the evaluation process; and
- ECHA should monitor evaluation experience (ECHA, MS and stakeholders) and update its guidance, as appropriate.

## 14.8 Alternative Testing

The provisions for the sharing of data from tests on vertebrate animals for the purposes of joint registration are reported by ECHA have been reasonably effective, with 90% of registration dossiers so far being submitted jointly. Registrants used data produced prior to the introduction of REACH as their main source of data. The second most used source of information came from the application of read-across, especially for endpoints that would otherwise require longer term animal studies.

To date no testing proposals have been refused following consultation. However, ECHA also reports that 107 higher tier animal tests seem to have been conducted without prior submission of a testing proposal. Justifications for these tests include that testing was triggered from non-EU legislation or requested by CAs (e.g. under NONS). Furthermore, inconsistencies have been identified between the provisions in REACH and those in the Animal Test Directive 2012/63/EU and there are questions regarding the applicability of standard test data for the registration of nanomaterials.

**Box 14.8: Recommendations – Alternative Testing**

- ECHA should monitor the robustness/compliance of the use of alternatives to testing to fulfil REACH information requirements and consider appropriate action in response to that monitoring;
- ECHA should monitor improvements or advancements in procedures such as data sharing, and test proposals and alternative methodologies and assess how these may legitimately be used to fulfil information requirements. Guidance should be updated in line with this work;
- the Commission should take action to ensure that REACH is brought into line with Directive 2010/63/EU and has equivalent provisions for cephalopods and vertebrate animals;
- the Commission should ensure that funding for the development of alternative methods is spent in a strategic manner with the aim of increasing the understanding of chemical toxicity, with a particular focus on the needs under legislation such as REACH; and
- the Commission should assess currently available test methods including alternative testing methods and, where necessary, update these for the assessment of nanomaterials.

## 14.9 Enforcement

The **Forum** to coordinate a network of MS enforcement authorities has been established, as required under REACH, and would appear to be functioning well. However, only 85% of possible Forum members have been appointed so far (30 of 35 possible members at the beginning of 2010), and there are concerns regarding its ability to cope with future commitments (ECHA, 2011a and ECHA, 2012). The Forum has agreed a non-legally binding framework for MS enforcement of REACH so that enforcement may be as harmonised as possible while respecting the national differences in enforcement structure. However, it would appear that harmonised enforcement is proving very difficult in practice.

REACH allows for a wide range of **enforcement powers** and MS enforcement authorities typically have a mixture of administrative/civil and criminal measures at their disposal. The **inspection** activities so far have covered manufacturers (37% of inspections), importers (23%), Only Representatives (3%), and downstream users (36%). Numerically move inspections focusing on SMEs than larger companies. The main focus of enforcement activities would also seem to be on SMEs.

A large proportion of companies have not yet had any experience of REACH inspection or enforcement however companies are currently positive overall regarding their experience of such activities by regulators. Potential efficiencies in both inspection and enforcement were identified from synergies between the enforcement of REACH and other EU legislation.

**Box 14.9: Recommendations – Enforcement**

**Forum**
- shorten the review period for draft minutes;
- increase resourcing received from MS (CAs identified that resource limitations were reducing the Forum's ability to undertake some projects);
- prioritise inspection/enforcement activities across EU to target limited resources where most benefit may be expected, including activities relating to current restrictions;
- more desktop research and information campaigns on areas of concern may reduce the burden on the stretched resources of Forum and its members;
- Forum should consider facilitating exchange programmes between MS to allow for the dissemination of best practice and increase harmonisation of enforcement activities;
- Forum should be able to speak for enforcement authorities on issues of common concern. For example, it could negotiate improved access for MS enforcement authorities to information held by ECHA;
- improve communication and coherence between the Forum and CARACAL;
- further clarify the role of MS representatives (are they representatives on MS or independent Forum members, nominated by MS?); and
- the Forum should consider how it may facilitate greater harmonisation of inspection and enforcement of REACH across MS, including the level and use of sanctions.

**Enforcement**
- inspection and enforcement activities under REACH/CLP should be coordinated and/or combined with those for other EU legislation including that for worker health and safety, industrial pollution control and product requirements. This recommendations is in line with an assessment of REACH and other legislation which identified significant overlaps (COM, 2012h); and
- the Commission should take a stronger role with respect to REACH inspections.

**Inspection**
- Consideration should be given to coordinating or combining inspection activities under REACH with those under other EU legislation including those covering worker health and safety, industrial pollution control and product requirements.

**Harmonisation**
- the Commission should use greater clarity in the wording of Article 117(1) information requests to CAs, including clear definitions of duty holders, inspections and enforcement activities; and
- CAs and the Commission should develop a more harmonised and systematic approach to the collection of information on the number and type of duty holders subject to inspections and enforcement, including for the assessment of outcomes from these activities.

**Links with Occupational Health and Safety Legislation**
- the Forum should consider how it may facilitate greater coordination of the enforcement of REACH, CLP and OSH legislation, within and across MS, to reduce the administrative burden of both companies and authorities.

## 14.10 Guidance and Support

**ECHA** has published 71 technical and scientific **guidance documents** that are freely available over the Internet including, detailed guidance documents, fact sheets, nutshell guidance, practical guides, Q&A documents and FAQs. Due to the extent of input from a wide range of interested parties, official ECHA guidance documents represent the consensus interpretation of the REACH legal text that is accepted by ECHA, CAs and national REACH enforcement authorities. Such guidance is

essential for a company's efficient planning for and preparing of a registration dossier and is made available in a wide range of EU languages.

In general **MS** refer to the agreed ECHA guidance documents and limit their activities to providing access to, and comment on, these documents, as well as providing summaries of the provisions of REACH. However, are involved in the preparation of ECHA guidance documents via their participation in **Partner Expert Groups** (PEGs). PEGs appear to be working well overall but recommendations for improvement were also made by CAs.

All **MS** have **helpdesks** to provide advice on responsibilities and obligations under REACH. Most helpdesks have access to a broad range of expertise and interested parties can contact these via a range of methods but email and telephone communication have proved to be the most popular with enquirers. The MS helpdesks appear to be functioning effectively particularly in assisting with registration, however the effectiveness of functionality and effectiveness of helpdesks varied between MS. Industry was positive about the contribution of MS helpdesks to date but had some criticisms regarding the "legalistic" approach followed by some helpdesks. Helpdesks reported receiving a greater percentage of enquiries from SMEs compared to larger companies and SMEs were more reliant on the advice of helpdesks, overall.

The **ECHA helpdesk** has been established to deal with enquiries that could not be handled by MS helpdesks, e.g. IUCLID and REACH-IT support. As with MS helpdesks, the ECHA helpdesk received more requests from SMEs than from larger companies. Queries to the ECHA helpdesk were requested to be in English but queries in other languages were accepted where the language skills of individual helpdesk staff made this possible. The principle topics considered by the ECHA helpdesk were REACH-IT (40%), general operation of REACH and IUCLID/CHESAR.

**ECHA** has developed and made available **IT tools** to assist in the operation of REACH, particularly IUCLID 5, REACH-IT, and CHESAR, as required under REACH. There were difficulties with REACH-IT around the pre-registration deadline but these have not been repeated since. IUCLID and CHESAR have been positively received by industry but updates have sometimes lead to additional costs.

**ECHA** has also **disseminated** information on (pre-)registration via its Internet site, as required of it. However, limitations in the functionality of the relevant sections of the ECHA Internet site have limited the usefulness of this information.

**Box 14.10: Recommendations – Guidance and Support**

**PEGs (recommendations for ECHA)**

- consideration should be given to having longer meetings and/or use of teleconferencing or other communication media, as required, to improve efficiency and the level of input from all participants;
- the process of PEG consultation, particularly in the latter stages, should be clarified and more realistic timetables set;

- more time should be available within a PEG following consultation for commenting and addressing concerns; and
- the PEG consultation stage should move to an earlier stage of document development.

**MS Helpdesks**

- CAs, in consultation with helpdesk users, should take steps to ensure that their helpdesks avoid taking a legalistic approach to dealing with enquiries and offer support that is as practical as possible;
- more resources should be provided by MS to their helpdesks, especially in the run-up to phase-in deadlines; and
- MS should seek to share best practice among themselves and offer more mutual assistance, especially to those from MS with fewer resources to dedicate to their helpdesks.

**ECHA's Support of MS Helpdesks**

- all HelpNet presentations should be made available via Circa in advance of meetings to facilitate meeting discussions;
- procedures for HelpNet should be streamlined and more time provided for discussion and exchange of opinion;
- particular emphasis should be given to discussing generic questions relating to the HelpEx database while statistical presentations about helpdesks should be brief and less detailed;
- greater participation in discussions should be encouraged by, for example, the use of break-out groups;
- alternative training and dissemination media (e.g. webinars, teleconferences) should be used where appropriate;
- majority voting should be used for decision making to allow HelpNet to function more efficiently;
- revise the FAQ process by adoption of the assumption that a lack of response indicates agreement with a proposal;
- improve the level of human resources available to MS helpdesks and seek to improve cooperation between MS Helpdesks outside of the REHCORN (Helpnet) structure;
- increased Commission support should be available for HelpNet on difficult issues; and
- the Commission should seek to speed up its provision of legal interpretation of REACH.

**IT Tools**

- ECHA should make every effort to make all IT tools and guidance on the use of these tools available in a wide range of EU languages, as soon as possible.

**Dissemination of Information**

- ECHA should take steps to improve the search and data collection functionality of information that it makes available.

## 14.11 REACH aim: Protection of Human Health & Environment

The key elements of REACH that are expected to act as drivers for benefits to human health and the environment are:

1. **Registration:** through the increased provision of information, risk assessment and risk management;
2. **Information in the supply chain:** through the communication of safety information up and down the supply chain;
3. **Authorisation:** risks posed by Substances of Very High Concern (SVHC) are expected to be progressively reduced; and
4. **Restriction:** greater control of risks from substances at the EU-wide level.

To date the level of information to robustly estimate benefits to human health and the environment from REACH, is not available. However, there is some evidence to show that overall REACH may be resulting in benefits:

- hazard classifications are becoming more reliable;
- more information is available for risk assessment and thus risk assessment has become more robust;
- some additional risk management is being implemented;
- SDS and eSDS are facilitating the communication of information on safe use down the supply chain;
- some uses of substances which may have posed risks to human health and the environment are no longer supported; and
- some substances are being replaced with less hazardous alternatives.

There has been marked a decrease in the nominal risk to humans and the environment associated with the chemicals over the previous five years, which is largely believed to be due to REACH. However the realisation of the benefits from enhanced communication of safety information via eSDS is being hampered by overly long eSDS and confusion by industry on how to provide succinct information while legally complying with REACH. Furthermore, gaps have been identified between the provisions of REACH and other EU legislation that could reduce the benefits outlined here.

**Box 14.11: Recommendations – Human Health and the Environment**

**Registration**

- the evaluation of registration dossiers shows that the quality of information is not sufficient and it is expected that this problem will be more pronounced with the lower volume substances. For its part, it is essential that industry increases its effort to provide high quality dossiers which would ensure the safety of substances placed on the market. It is also important that ECHA effectively communicates its learnings from the first registration phase in easy to use and concise guidance documents as well as illustrative best practice examples. This communication should be accompanied by (separate) documentation of the reasons for requesting additional information from registrants, including a justification for how this contributes to proper risk management. The aim should be to ensure that dossiers are brought into compliance with REACH requirements. Member States should focus enforcement activities on addressing those quality aspects that result in registration dossiers being non compliant;
- industry should increase its efforts with respect to the requirements for a PBT assessment. Annex XIII prescribes that if a substance at a screening level is found to be either P, B or T or vB or vP it should be subject to further testing by the registrant, unless sufficient RMM are implemented. ECHA may want to consider providing further guidance on the need for these assessments and Member States should take actions to check on such assessments as part of evaluation and enforcement activities;
- support tools to facilitate information generation and transmission should be further developed and optimised in cooperation with industry. ECHA should continue to offer training, in particular for the use of CHESAR and conducting chemical safety assessments. The further development of CHESAR should consider integrating available assessment tools and risk management measures from other legal areas;
- existing methods and approaches for exposure assessment, in particular in the field of workers protection, such as control banding, exposure modelling and standardised operating procedures, should be applied to develop realistic exposure scenarios. Where possible monitored values should be used where modelled values cannot be generated or are not precise enough. Registrants should

also make better use of downstream user information on RMMs already in place, rather than recommending more generic measures that conflict with what industry has adopted over time and is agreed with national health and safety and environmental protection authorities. ECHA should further emphasise the value of these approaches in its guidance; industry associations should organise events for experience exchange and discussion between "new" and "old" registrants; and
- ECHA and the Commission may wish to consider increasing their efforts for supporting SME registrants in order to avoid unwanted withdrawal of substances that would lead to no additional benefits to human health and the environment.

**Information Through the Supply Chain**
- the first step in supply chain communication is the basis of all further communication and therefore has to be improved first:
  - ECHA (in cooperation with industry) should progress their work on CHESAR and derive from that the core information structure for communication on uses in order to facilitate respective supply chain communication;
  - ECHA should prepare a revised ES Format for supply chain communication as soon as possible, based on a review of best practice. A standardised IT format should also be developed; a harmonised IT template is required so that processing (merging and scaling) can be done through the use of software (e.g. CHESAR);
  - industry should use the CHESAR information structure to develop their software tools to provide safety data sheets;
  - industry's work on standard phrases for conditions of use and risk management measures should be continued; however, it appears that more commitment is needed as well as stringency in meeting internal deadlines and targets, as trust that such tools will be developed in time has been lost; and
  - downstream users should (be encouraged to) provide information on conditions of use in ECHA's information structure in a targeted way. Standardised sector tools like spERCs should be further developed to comprehensive assessment support instruments;
- formulators have an essential role in the supply chain communication with regard to the information on safe use, because they have to provide their safety data sheet in a way that it gives orientation to the downstream user on what to actually do. Although not legally required, a consolidation of information is necessary and respective guidance is (still) not available, except for the concept of DPD+ by CEFIC. ECHA should develop specific guidance for formulators on how to identify and process information that should be forwarded to the customers and information that should not[53];
- communication on the presence of candidate list substances in articles is being hampered by the different interpretations of the legal text between the COM and Member States. This issue should be clarified and a legally binding interpretation should be found;
- challenges in the communication on candidate substances have two aspects: a) identification of the content; and b) what to communicate if a candidate substance is contained above 0.1%. Industry should consider building up electronic systems which allow for the identification of candidate substances in articles and article parts (such as the IMDS material management system of the automotive industry). This would support the implementation of all article related requirements. The content of communications on SVHC should be further explained to avoid only the name of the substance being communicated (with this being of little benefit); and
- consideration should be given to assessing and listing groups of substances on the candidate list to avoid formulators and downstream users shifting to unsuitable alternatives. As part of this, ECHA and the Competent Authorities of the Member States should ensure greater transparency on how substances are identified for candidate listing. These processes may also benefit from early consultation with industry experts and registrants.

[53] Since the writing of COM (2012k) industry have produced guidance that goes some way towards meeting this recommendation: see *Communication of uses along the supply chain for 2013 registration*, produced jointly by **Cefic, DUCC** and **FECC** (http://www.cefic.org/Documents/IndustrySupport/REACH%20Implementation/Letter_on_use_of_communication.doc).

**Authorisation and Restriction**
- ECHA and MS should consider listing substance groups that include SVHCs, where substitution with a substance within the same group is likely;
- industry should develop guidance and training on alternatives assessment;
- industry, MS and ECHA should compile information, from commenting and other information sources, on possible alternatives to the use of the SVHC, to ensure the "exclusion" of substances known to be preferred alternatives but which also have problematic properties; and
- the Commission and/or ECHA should undertake research to determine whether or not substitution takes place with less hazardous substances and what impact candidate listing is having in this respect.

**Assessment of REACH Impacts**
- the effectiveness of REACH for the protection of human health and the environment is best assessed at the level of the EU rather than at a national level;
- data requests should be harmonised at the EU level; and
- the level of data gathering currently undertaken and the resources available to MS to undertake data gathering varied greatly between MS. This should be taken into consideration when drafting any information requests.

**Risk Communication Network**
- greater cooperation between network members should be encouraged;
- training sessions and workshops should continue or increase; and
- ECHA should take a more proactive role in the network where issues are of EU-wide concern.

## 14.12 REACH aim: Enhancing Competitiveness, Innovation and the Single Market

The information was not available to clearly determine the enhancement of competitiveness, innovation and the single market resulting from the introduction of REACH. With respect to the **single market** there is no evidence of impacts on trade flows to date. With regards to **trade and competitiveness** there are some positive impacts on intra-EU trade which industry are being attributed to REACH. It has also been possible to identify costs which industry claim are harming their competitiveness but it is too early in the implementation of REACH for industry to see the anticipated benefits.

Estimates are available of the types and potential size of **costs** to industry with the principal costs resulting from:

1. **Human resources**: from REACH-related activities;
2. **Pre-registration**: human resource costs;
3. **Registration**: wide variation in reported costs so far and cost items but for simple registrations ECHA fees could amount to 50% of total costs. SIEF/consortia costs have also been significant for many;
4. **Authorisation and restriction**: Industry expressed concerns about future costs but these provisions had not been sufficiently implemented for cost estimates to be developed at this stage;
5. **Information exchange in the supply chain**: Industry considered that REACH had increased these costs;

6. **Notification for articles**: No costs provided but comments were made regarding concern over differing interpretations by enforcement authorities;
7. **Downstream users' chemical safety reports**: from amending those provided; and
8. **Others**: Costs for changes in production and relevant R&D activity, management of risk and other necessary investments.

**Benefits** may be occurring in the following areas, but these conclusions are currently very tentative:

1. **Increased consumer confidence**: A minority view by industry;
2. **Increased knowledge on the properties and uses of substances**: This benefit was felt to be occurring but that it had not as yet transferred into benefits to recognised by companies;
3. **Communication in the Supply Chain**: Potential benefits were not recognised by companies which at this stage tended to be focus on the costs incurred; and
4. **Improved risk management**: It was felt to be too early to be able to identify cost reductions related to the implementation of occupational health and safety obligations. However, there is evidence of improvements in risk assessment.

**Box 14.12: Recommendations**

- impacts on competitiveness, innovation and the single market should be assessed at an EU level (MS, 2010);
- the Commission should monitor and gather data on the factors expected to bring business/trade impacts to the chemical industry in the EU/EFTA. With this data a more accurate assessment of impacts should be undertaken; and
- the Commission, ECHA and industry associations should work together to develop an action plan to find ways of enhancing the effectiveness of the key information driver to innovation benefits, including consideration of training and education, especially that focused on SMEs.

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***Parallel Studies***

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