ANNEX 2

ARTICLE 117 REPORTS FROM MEMBER STATES

EXECUTIVE SUMMARY

1. Background

Article 117(1) of REACH states that:

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.

This section presents a summary of the analysis of the information from the first set of Article 117(1) reports submitted to the Commission by Competent Authorities (CAs) of the thirty ***EU and EEA Member States (MS).***

2. Competent Authorities

There are forty REACH Competent Authorities (CAs) operating in the thirty EU and EEA Member States (MS). This reflects seven of the MS having more than one CA. However, responses were received only from one CA per MS with, in most instances, these responses relating mainly to the activities of this respondent CA only. Hence only limited information was generally provided on the roles and activities of other CAs within the same MS.

The key REACH activities undertaken by the respondent CAs are summarised in Figure 1 (note that although CLP is closely related to REACH it does not form part of REACH).

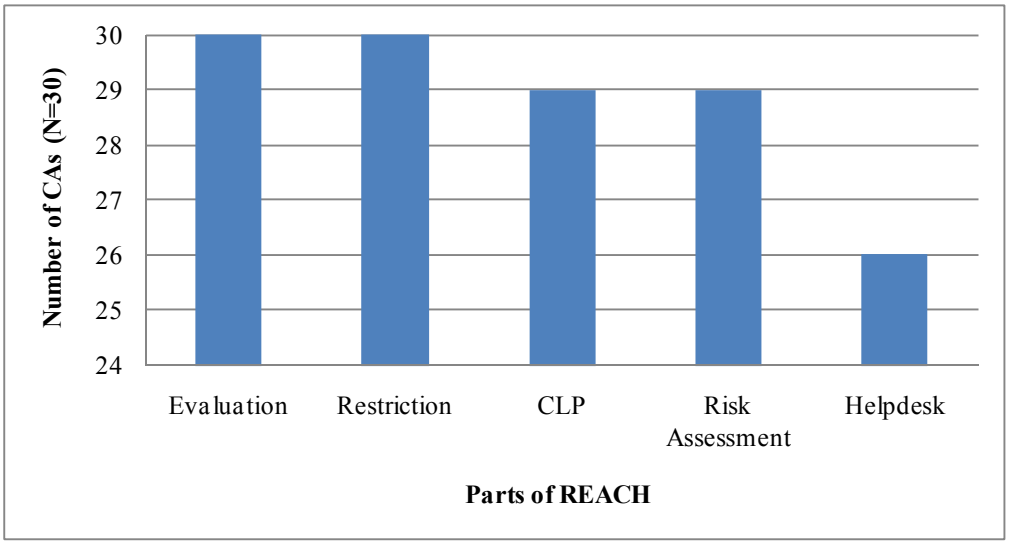

Figure 1: Parts of REACH Dealt with by Respondent CAs

From Figure 1, it can be seen that all but one CA (NL) also has responsibility for CLP. Four CAs (BE, IT, LU and PT) did not have responsibility for the helpdesk function, but in the case of Portugal, the helpdesk is the responsibility of another CA within the same MS. In Belgium and Italy the helpdesk function is undertaken by a government department separate from the CA. In Luxembourg the helpdesk is the responsibility of an external research centre.

Figure 2 sets out the staff skills available to the respondent CAs.

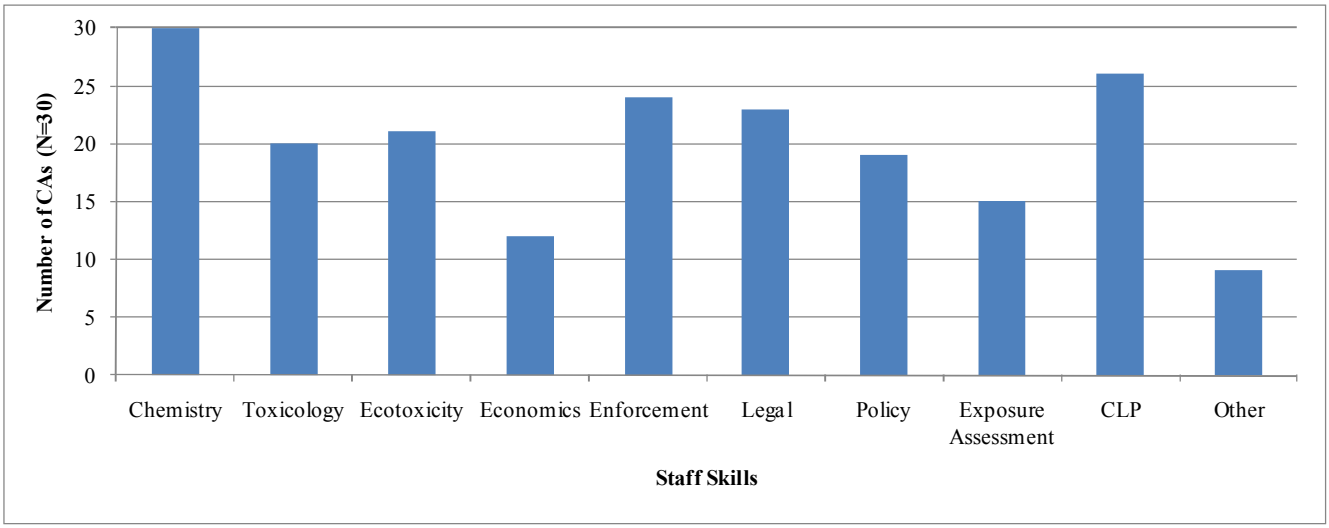

Figure 2: Staff Skills Available to Respondent CAs

In general, CAs consider that the resources allocated to them are inadequate or limited due to:

- an insufficient number of employees; and
- inappropriate skill sets (e.g. particular emphasis was placed on the lack of expertise in socio-economic analysis and risk communication and of senior toxicology experts).

All respondent CAs indicated that they had at least one other area of legislative responsibility, such as import/export, biocides, pesticides or food.

3. Co-ordination, Co-operation and Information Exchange

CAs in general felt the effectiveness of communication and collaboration to be above average, between themselves and:

- CAs of different MS;
- ECHA;
- the Commission; and
- the REACH Committees.

4. Operation of REACH: Registration

Risk Communication Network

The six CAs that commented on the Risk Communication Network (RCN) felt that this was a well organised body that was an important and valuable venue for sharing expertise/experiences of 'risk communication' between MS, as well as a source of training.

Duty Holders

Twelve CAs provided estimates of the total number of likely duty holders for each of the years 2007 and 2008 and fifteen CAs provided estimates for 2009. The remaining CAs submitted either a blank response or stated that such data were not maintained/ collected. However, there are reasons to suppose that the data provided may not relate to a common metric, a view supported by the fact that CAs had not been provided with guidance on how these estimates should be calculated. Hence no sound conclusions could be drawn.

5. Operation of REACH: Information in the Supply Chain

MS were not asked to report on the activities of duty holders regarding the supply and movement of information in the Supply Chain. However, in their responses regarding Helpdesk support provided to industry it is clear that advice was provided by MS on downstream user obligations, the operation of SIEFs, and safety data sheets.

6. Operation of REACH: Authorisation

Annex XV Dossiers

The identification of Substances of Very High Concern (SVHCs) is the key requisite for triggering the authorisation provisions of REACH.

Twenty-one CAs indicated that their MS had been involved in some Annex XV dossier related activity for the identification of SVHCs. Activities range from developing full dossier to commenting on a dossier prepared by another MS or ECHA.

In general, CAs felt that they did not have the experience to comment on the "reasonableness" of the time spent following up MS dossiers or acting as co-rapporteur. However, the Danish and Swedish CAs predicted that Annex XV dossier work would not be resource demanding but also stated that the time/resources requirements varied significantly between dossiers. These comments applied to all Annex XV dossiers and not just those for the identification of SVHCs.

Eight CAs indicated that industry was involved in the preparation of Annex XV dossiers for SVHC identification within their MS. However, the level of industry contribution varied greatly between MS.

Effectiveness of RAC and SEAC

The views on the effectiveness of the Risk Assessment Committee (RAC) and Socio-economic Analysis Committee (SEAC) were mixed with respondent CAs commenting on the usefulness of the secretariats and procedures on the one hand while raising concerns regarding the workload and availability of resources on the other hand.

7. Operation of REACH: Restriction

Annex XV Dossiers

Thirteen CAs indicated that their MS had been involved in some Annex XV dossier related activity. However, the activity may have only involved commenting on a dossier prepared by another MS or ECHA.

8. Operation of REACH: Dossier and Substance Evaluation

Nine CAs reported having been involved in substance evaluation. However, several CAs pointed out that as substance evaluation has not yet begun, they have not yet been involved.

9. Alternative Testing

Responses from all CAs indicate that twenty countries have made contributions to EU and/or OECD work on the development and validation of alternative test methods by participating in relevant committees.

Seventeen CAs provided data on overall public funding for national research and the development of alternative testing methodologies, with nine CAs reporting expenditure of more than Euro 100,000 per year each. However, from comments provided by CAs it is possible that the expenditure reported for some MS includes that contributed to EU and/or OECD work, rather than to national research projects only.

10. Enforcement

MS Enforcing Authorities

Twenty-four of the thirty CAs indicated that there was more than one enforcement authority for REACH in their MS.

MS Enforcement Strategies

Eighteen of the thirty CAs indicated that there was an overall strategy(ies) in their MS for the enforcement of REACH and twenty-five CAs indicated that their enforcement strategy(ies) were in line with those devised by the Forum. It is noted that eight MS have strategies that appear to align with the Forum strategies but that the respondent CAs did not consider to constitute an "overall" strategy(ies).

All CAs provided descriptions of their enforcement strategy(ies). These indicated that the strategies in place are specific to the countries concerned although some general trends are nonetheless discernable:

- strategies are generally based on those devised by the Forum with adaptations to better fit with national variations;
- in developing their strategies, MS have generally used their experience of enforcing other chemical legislation;
- varying prioritisation processes have been used to focus enforcement activities by different MS;
- education of companies with obligations under REACH was seen by some MS as an important tool for the enforcement of REACH.

Five CAs indicated that their national enforcement strategies were not fully in line with the Forum strategy and are unique to their MS.

MS Enforcement Sanctions

CAs typically described a mixture of civil and criminal measures available to them. However, the legal structures under which sanctions may be applied vary greatly between MS and reflect the variations in the national legal systems concerned but may include:

- 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 from those found guilty of breaching the provisions of REACH.

Enforcement Interaction with other Bodies

With the exception of the UK, CAs indicate that they have not received enforcement referrals from ECHA. A small number of enforcement referrals had been received from other MS by ten CAs.

For those MS where the CA and the enforcement authority(ies) are not one and the same, the most common mechanism used to share information within the MS is the organisation of regular (but infrequent) meetings between CAs and the relevant national enforcement agencies to facilitate communication and cooperation. Furthermore, CAs tend to oversee the activities of the enforcement bodies and provided them with training.

Effectiveness of the Forum

Ten CAs commented on the functionality of the Forum including favourable comments such as that it was well organised and effective. There were a limited number of suggestions for further improvements.

Effectiveness of SON

Three CAs made highly critical specific comments on the Security Officer Network (SON) and suggestions for improvement. No other CAs commented on the working of SON.

Enforcement Statistics

All CAs except those representing Italy and Luxembourg provided data regarding the number of inspections and investigations in which REACH was discussed or enforced that were carried out in years 2007, 2008 and 2009. These data show a very high degree of variation between different MS and supporting text indicates that CAs had reached different understandings as to the intended scope of activities that should be counted. Furthermore, it would appear that MS use inspections and investigations in markedly different ways within their overall enforcement strategies.

During the analysis, attempts were made to understand the level of inspections/investigations compared with the size of each nation's chemical industry using data recorded in The Eurostat Prodcom database[1] and those published by the European Chemical Industry Council (CEFIC). Regrettably, however, MS data were judged insufficiently robust for the relative activity of MSs to be reliably compared.

Analysis of data on the types of company subject to inspection showed that the main focus for inspection activities across Europe has been small-medium sized companies and that the proportions of each size of company inspected was similar across manufacturers, importers and downstream users, as displayed in Figure 3.

[1] Published on the European Commission Internet site (http://epp.eurostat.ec.europa.eu/portal/page/portal/prodcom/data/tables_excel)

The very high percentage of inspections of small-medium sized companies shown in Figure 3 does not correlate with available data on the size distribution of chemical companies in terms of either percentage number of companies, sales or employment levels for 2009 (based on data published by the European Chemical Industry Council (CEFIC)[2]).

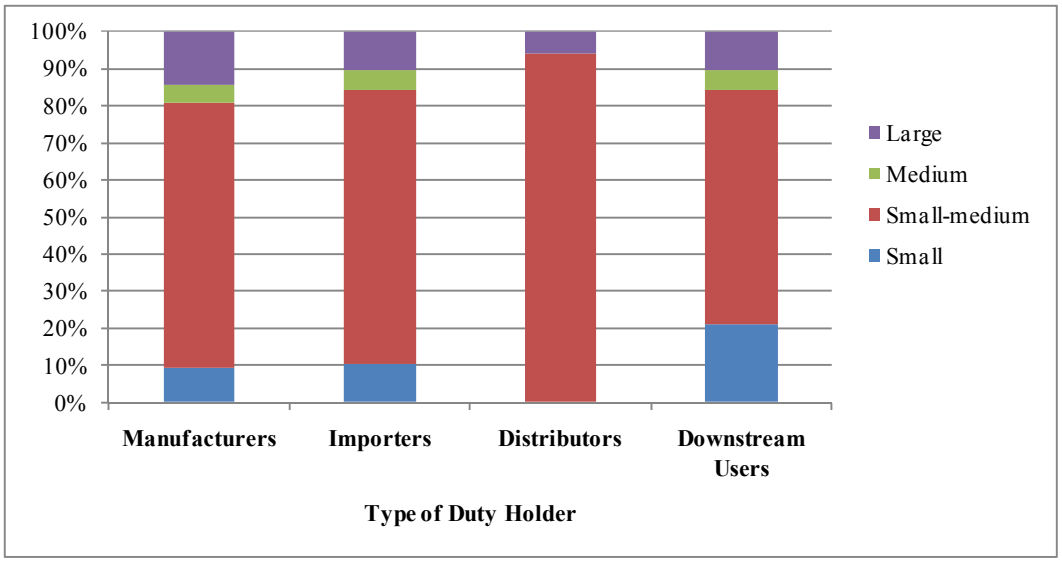

Figure 3: Percentage of Inspections conducted during 2009 by Company Size and Type of Duty Holder

Formal Enforcement Actions

The number of formal enforcement actions undertaken varied greatly between MS; the reasons for this are not clear but may reflect the varying emphasis placed on direct enforcement in the various national REACH enforcement strategies. Also, at least some of the variation may be accounted for by inconsistencies in interpretation of the nature of "duty holders" and of the phrase "formal enforcement action".

The greatest number of enforcement actions was directed towards downstream users, followed by distributors. However, there was a large degree of variation between MS in this respect.

For the years 2007, 2008 and 2009, approximately eighty to eighty-five percent of enforcement actions involved SMEs. In 2007, the majority of enforcement actions were taken against medium-sized companies. This was also the case in 2008 but with a greater proportion of small to medium sized companies. However, in 2009, small to medium sized companies were by far the greatest focus of enforcement action, followed by small companies, as shown in Figure 4.

[2] Reproduced from chart published by European Chemical Industry Council (CEFIC), available from (http://www.cefic.org/Facts-and-Figures/Profile-of-the-Chemical-Industry/EU-chemical-industry-number-of-enterprises-sales-and-employment-by-size-class/).

No correlation can be seen between the percentage of enforcement actions and the number of companies, sales or employees for chemical companies of different sizes (based on the CEFIC data).

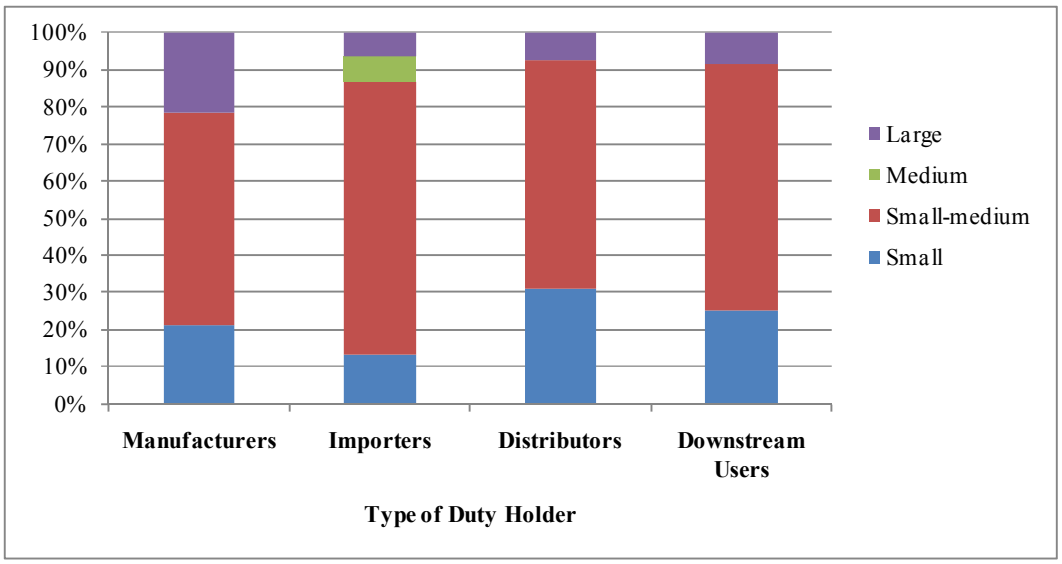

Figure 4: Percentage of Enforcement Actions during 2009 by Company Size, for various Industry Sectors

11. Guidance and Support

Helpdesk Organisation and Resources

All CAs manage their REACH helpdesks internally except for the Netherlands. However, the respondent CA for the Netherlands retains control of the MS helpdesk. A further six CAs indicated that they outsourced at least some helpdesk enquiries.

The greatest number of enquiries was received by email and then by telephone with a small minority of MS not having both of these options available.

Twenty-two MS helpdesks also handle enquiries relating to CLP and eighteen helpdesks provide specific advice to SMEs. No helpdesks receive funding from outside of MS governments.

Helpdesk Activities

The number of enquiries received by helpdesks varied significantly. However, two-thirds of the MS receive between one-hundred and one-thousand enquiries per year.

The greatest number of enquiries related to registration or pre-registration, the majority from small-to-medium sized enterprises. Sixty-four percent of enquiries were considered to be straight forward with thirty six percent described as complex.

On average, straight forward enquiries received a response within one week (and often within a day) while complex enquiries were dealt with within two weeks.

Cooperation between MS Helpdesks

For the majority of MS, the level of cooperation within the REACH Helpdesk Correspondents' Network (REHCORN, now renamed Helpnet) was significantly greater than the level of cooperation outside of REHORN. However, six CAs felt that there was no difference. Nineteen of the thirty helpdesks make use of REACH Helpdesk Exchange Platform (RHEP, now renamed HelpEx) at least weekly.

Awareness Raising Activities

In general, CAs employed a wide range of awareness raising activities, with the greatest level of activity focused on the entry into force of REACH. CAs found speaking events, telephone contact and leaflets most effective at awareness raising.

MS Websites

All MS except Austria and Greece have a REACH specific website or webpage(s). Ten MS have single webpages dedicated to REACH and the remaining eighteen MS have multiple such webpages as part of their website.

Topics of interest comprised REACH news/updates, company obligations, (pre-) registration, exemptions from registration, authorisation, SEA (IT only), classification and labelling and FAQs.

REACH Guidance Documents: Effectiveness of PEGs

The majority of MS had actively participated in Partner Expert Groups (PEGs). A minority of CAs was supportive of the organisation of PEGs although with some reservations.

12. REACH aims: Protection of Human Health and Environment

REACH Article 129

Only Estonia and Italy indicated that they had made use of the safeguard clause of REACH article 129.

Effectiveness of REACH for the Protection of Human Health and Environment

With the exception of Italy, all CAs felt the effectiveness of REACH in protecting human health and the environment was best assessed at the level of the EU rather than at a national level.

The limited data provided by CAs are insufficient to assess the effectiveness of REACH in this respect. However, it is anticipated that additional information identified during a separate Commission study to be commissioned to assess the health and environmental benefits of REACH, will contribute to the assessment of the nature and extent of health and environmental benefits that are attributable to REACH.

13. REACH aim: Enhancing Competitiveness and Innovation and the Single Market

All CAs except Italy stated that enhancing competiveness and innovation should be assessed at the EU not the national level.

While the nature of the data provided by CAs would, of itself, not provide a comprehensive picture of the impact of REACH on competiveness, innovation and the single market, it is anticipated that a more detailed picture should emerge from three other Commission studies that are to be conducted on specific aspects of the contribution of REACH in relation to:

- the development, commercialization and update of emerging technologies;
- innovation by the EU chemical industry; and
- the functioning of the European market.

14. Suggestions for Improving Article 117(1) Reporting

Responses from CAs (within and separate from Article 117(1) reports) and the legal requirements for MS reporting set out in REACH were analysed with the intention of identifying possible improvements to the content and format of future Article 117(1) reports. Technical suggestions regarding the submission process are set out in Box 1 and non-technical suggestions relating to the content of the reporting questionnaire are set out in Box 2.

Box 1: Technical Suggestions for Improving Article 117(1) Reporting

1. The processes of logging into the IPM tool and accessing functions should be made simpler, including functions to modify or delete submissions.

2. A warning should be given before a session is timed out and data lost.

3. Error messages should be more informative and allow for precise problem identification.

However, it is **not clear how feasible it will be to make technical amendments to the IPM tool**. One alternative would be to **employ a different software tool** to collect Article 117(1) reports. However, there is no guarantee that the alternative system will not have technical issues of its own. Furthermore, there may well be data security concerns about the submission of MS reports being received by third-party software and being hosted outside of the Commission by a third-party company.

One simple approach that would overcome the technical issues identified above, would be to **move away from an Internet-based tool entirely for submission of MS reports**. Since it proved necessary for in the first reporting round to supply the questionnaire in Word format to assist CAs in preparing their responses, little, if any, additional effort would be needed to make the electronic version of the questionnaire (Word or Excel format), the version to be submitted to the Commission. The transfer of MS reports supplied in Word or Excel format to a spreadsheet for analysis would be similar to the transfer of Excel format outputs from the IPM tool. If all submissions were in Word or Excel formats, there would be no need to manually input those responses that could not be uploaded to the IPM tool. The Word or Excel document could include the reporting format table prepared by the Forum[3]. Furthermore, given the small number of respondents, it would not be an onerous task for all contacts and data transmission between respondents and the Commission to be made via email

Box 2: Non-technical Suggestions for Improving Article 117(1) Reporting

Consideration should be given to amending the content of questions used to facilitate the Article 117(1) reports as follows:

1. Highlighting which questions relate to the legal reporting requirements of CAs (answering of which is hence mandatory).
2. The inclusion of questions asking for justification of sanctions as being effective, proportionate and dissuasive.
3. The inclusion of questions asking for justification that enforcement strategies were sufficient to ensure implementation of penalties.
4. Explanation should be added to allow CAs to understand the relevance and benefit from collecting 'optional' information;
5. Adding 'no data available' options to relevant questions (to take account of the availability to CAs of relevant information). However, where MS agreements or legislation require the collection and/or provision of data, this could be highlighted in the question (and no such option be provided). Failure to provide such 'required' data could be followed up with the CA by the Commission, separately from the questionnaire.
6. Adding a facility to enter data for more than one CA per MS. Perhaps accompanied by explanation that co-ordination between the involved CAs is required to avoid potential duplication of data counting.
7. Reviewing the definitions underlying the terms included within the questions and reviewing the consistency of such definitions between questions. Precise definitions could be stated in the questionnaire and/or associated guidance.
8. Using agreed definitions (such as Commission Recommendation of 6 May 2003 concerning the

[3] Forum Working Group on 'Member States Report to the Commission' Annex 2 – Report template.

definition of micro, small and medium-sized enterprises (2003/361/EC) and Forum definitions (e.g. that for 'duty holders'), wherever appropriate and available.

9. Using a consistent scoring system, applied throughout (e.g. either 1-5 or 1-10), and using a common logic as to what is regarded low/not adequate (1) and what is regarded high/adequate (5 or 10).
10. Encouraging a consistent use of the scoring system by the provision of descriptions of benchmarks as part of questions or in the guidance, where possible

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1. INTRODUCTION

1.1 Background to the Study

1.1.1 Main Obligations and Timescales for REACH

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:

- a high level of protection of human health and environment;
- free movement of substances on their own, in preparations, and in articles; while
- enhancing competitiveness and innovation.

Incorporated within REACH are various reporting obligations and deadlines that apply to the European Chemicals Agency (ECHA), Member States 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 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 refer 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 126 (Penalties) and Article 127 (Enforcement) of the REACH Regulation as set out in Box 1.1.

Box 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[4] 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*

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

Box 1.1: Reporting Obligations under REACH
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*
Article 127 *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*

1.2 Study Objective

The Specifications state that:

> *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.

1.2.1 Analysis of Member State Reports

The study team was given access to the individual Member State Reports submitted by 1 June 2010 to the Commission by each of the 30 countries considered here.

These reports had been made electronically by relevant Competent Authorities (CAs) for each MS using an Interactive Policy Making (IPM) tool, a internet-based consultation tool that used a questionnaire composed of 230 questions that had been specifically designed for this purpose. The questionnaire requested information of the completing CA on a wide range of issues including:

- composition and organisation of the Competent Authority;
- co-operation and communication with other Member States, the Agency and the Commission;
- operation and public perception of the National Helpdesk and public information;
- promotion of the development, evaluation and use of alternative testing;
- participation in the different bodies of REACH;
- evaluation activities and draft decisions prepared;
- preparation of and contribution to Annex XV dossiers;
- the effectiveness of REACH on the protection of health and environment and the effects of REACH on innovation and competitiveness; and
- individual comments (e.g. possibility to raise problems with implementation, language etc).

Some Member States provided additional input, comment and/or documentation to the Commission via electronic means other than the IPM reporting tool. Much of this information and the published discussions from the Meetings of Member States Competent Authorities for REACH and CLP (CARACAL) were also made available to the study team for consideration in our analysis. In particular, the answers provided by each MS were combined and summarised and initial conclusions drawn on the operation of REACH in different MSs.

As part of this task, the effectiveness of the IPM tool and suitability of the questionnaire used as assessed in the light of the feedback received from the CAs was also considered.

2. COMPOSITION AND ORGANISATION OF COMPETENT AUTHORITIES

2.1 Number of Competent Authorities per MS

Responses were received from all 30 countries, identifying a total of 40 Competent Authorities with REACH responsibilities across Europe.

Responses from seven of the countries stated that they have more than one body acting as a REACH Competent Authority (CA). Of these states, Germany, Finland, the Slovak Republic and Spain each have two CAs, and Ireland, Portugal and Romania have three CAs with responsibilities for REACH.

The CAs completing the survey indicated which of the key REACH activities they undertake, with their responses summarised in Figure 2.1 (note that although CLP is closely related to REACH it does not form part of REACH). **All 30 Responding CAs provided a response to this question.**

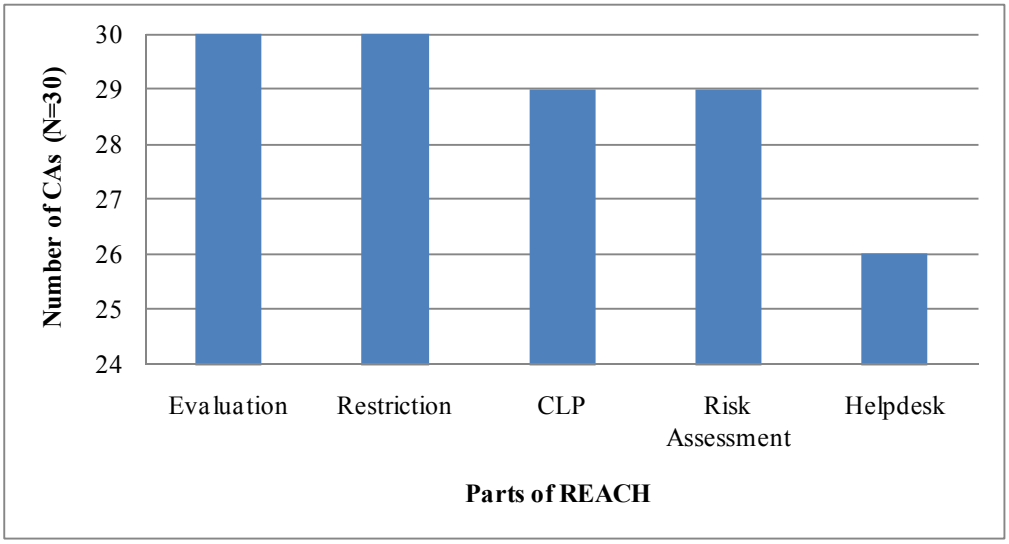

Figure 2.1: Parts of REACH Dealt With by CAs

From Figure 2.1 it is clear that all respondent CAs had responsibility for evaluation and restriction activities. The CA for the Netherlands was not responsible for CLP, although it had commented on CLP Annex XV dossiers. The Italian CA was not responsible for risk assessment although it employed staff with skills in toxicology, ecotoxicology and exposure assessment.

Four CAs (BE, IT, LU and PT) did not have responsibility for the helpdesk function. In Belgium and Italy the helpdesk function is undertaken by a government department separate from the CA. In Luxembourg the helpdesk is the responsibility of a research centre resulting from a collaboration between the Ministry for the Environment and a

private research organisation. There are three CAs operating in Portugal and the helpdesk is operated by a CA other than the respondent CA.

2.2 Source of CA Authority

Table 2.1 sets out the source of authority for the respondent CAs. Two-thirds of these CAs derive their authority from the environment functions within countries and one-third derives authority from health functions. The total number of CAs indicated in Figure 2.1 is greater than thirty as several CAs indicated that their authority derived from more than one source. For example, Spain indicated that its CA derived authority jointly from health, consumer protection and environment functions.

Table 2.1: Source of Authority of Respondent CAs

Source of Authority	Number of CAs
Environment	21
Health	10
Consumer protection	3
Economy*	2
Worker protection	2
Agriculture*	1
Enterprise, Trade and Innovation*	1

Note:
* "Other" sources of authority provided by CAs and not listed in the questionnaire

2.3 Skills Available to CAs

Figure 2.2 sets out the staff skills available to the respondent CAs. These do not necessarily include the skills of staff available to other CAs within the same MS. No information is available regarding the skills available to other CAs within countries with more than one CA. However, the analysis of helpdesks (Section 11.1) does include consideration of the skills of at least some additional staff employed by the separate Portuguese CA responsible for the national helpdesk. **All 30 Responding CAs provided a response to this question.**

From Figure 2.2 it is clear that all CAs have chemistry expertise. It is noted that three of the twenty-nine CAs with responsibility for CLP did not claim specific staff skills in this area. With regards to the thirty CAs with evaluation and restriction responsibilities, several report that they are without the key staff skills of toxicology or ecotoxicology and only half of the responding CAs indicate they have staff with exposure assessment skills. However, it appears that particularly lacking are economics skills with, for this area, eighteen CAs indicating that they do not have staff with this skill. Also, only twenty-four CAs report expertise in enforcement.

The "other" staff skills available to CAs included skills in chemical engineering, biotechnology (molecular), biology, ecology, risk assessment and risk management, biochemistry, agriculture, environmental sciences, medical sciences, occupational medicine, public health, forestry and pharmacy.

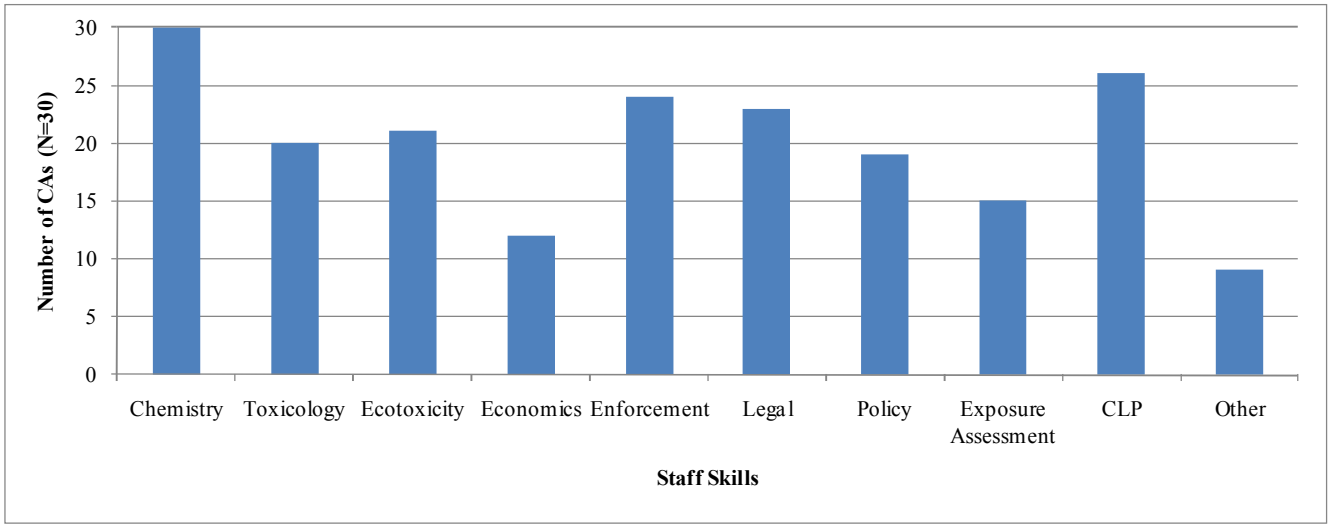

Figure 2.2: Staff Skills Available to Respondent CAs

Of note is that twenty-three CAs indicated that they also have access to external personnel including specialists/experts in:

- toxicology;
- epidemiology;
- ecotoxicology;
- nanotechnology;
- exposure assessment;
- PBT chemicals;
- economics and socio-economic analysis
- CLP;
- chemistry;
- Q(SAR) application;
- biology;
- pollution prevention;
- environmental risk management;
- mutagenicity; and
- occupational hygiene.

Several of the CAs included above stated that they have access to additional external expertise from other government departments/bodies, universities or other research/technical institutes.

The twenty-three CAs with access to such external expertise were asked to assign a score of between 1 (low) and 5 (high) to indicate their satisfaction with the availability of this expertise. The scores assigned by these CAs, which were quite variable, are set out in Figure 2.3.

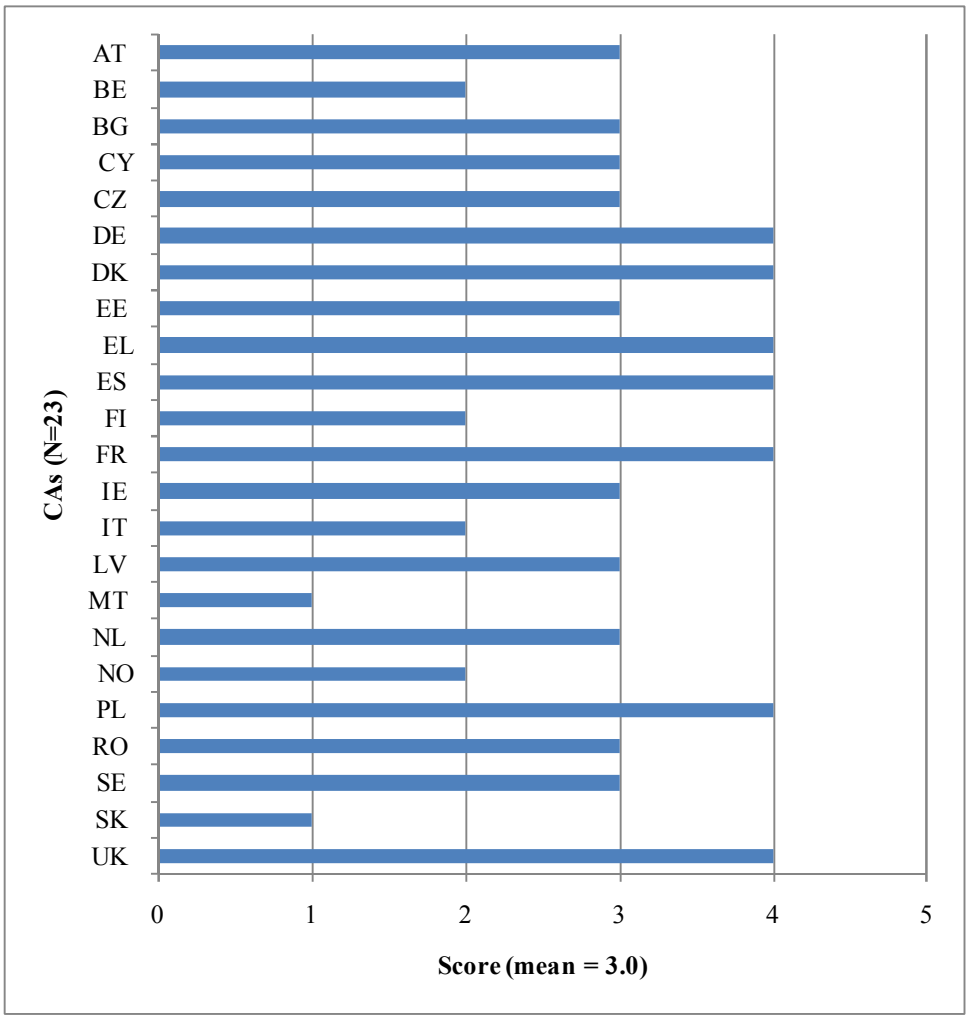

Figure 2.3: CA Satisfaction with the Availability of External Expertise

2.4 CA Responsibilities other than REACH

All CAs indicated that they had at least one other area of legislative responsibility. Figure 2.4 sets out these legislative responsibilities in addition to REACH that are held by the respondent CAs, as chosen from a short list of additional areas provided in the questionnaire. **All 30 Responding CAs provided a response to this question.**

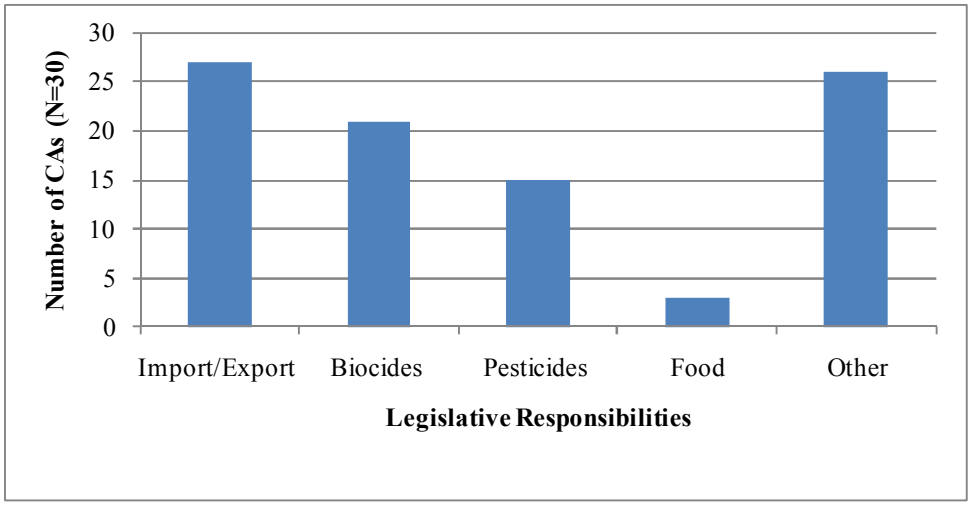

Figure 2.4: Legislative Responsibilities of CAs other than REACH

It is also clear that many of the CAs have a range of other legislative responsibilities that were not specifically listed in the questionnaire. Table 2.2 sets out the nature of these additional responsibilities, as reported by the respondent CAs. As can be seen, responsibilities in relation to detergents, persistent organic pollutants (POPs) and the CLP Regulations were most common.

Table 2.2: Other Legislative Responsibilities Named by CAs

Legislative Responsibilities	Number of CAs Naming Responsibility
Detergents	16
POPs	14
CLP	12
Volatile Organic Compounds (VOCs)	7
RoHS	6
Montreal Protocol (Ozone, ODS)	5
Chemical Accidents (Seveso II)	5
PIC	4
Fluorinated Gases	3
Mercury	3
SAICM	3
Chemical Weapons	3
Cosmetics	3
Waste	3
GLP Good Laboratory Practice	3
Nanotechnology	2
Dual Use Products	2
Plant Protection Products	2
Asbestos	2
Explosives	1
Consumer Protection	1

Table 2.2: Other Legislative Responsibilities Named by CAs	
Legislative Responsibilities	**Number of CAs Naming Responsibility**
CSD	1
OECD	1
IPPC	1
Drinking Water	1
GMOs	1
EMAS	1
Ecolabelling	1
Aerosols	1
Pollution Control	1
Precursors For Illicit Drugs	1
Fertilizers	1
Adverse Drug Reactions (ADR)	1

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

2.5 Adequacy of Funding of CAs

Figure 2.5 sets out the scoring by CAs of the adequacy of their funding (where 1 is low and 10 is high), with twenty-three of the thirty respondents CAs answering this question.

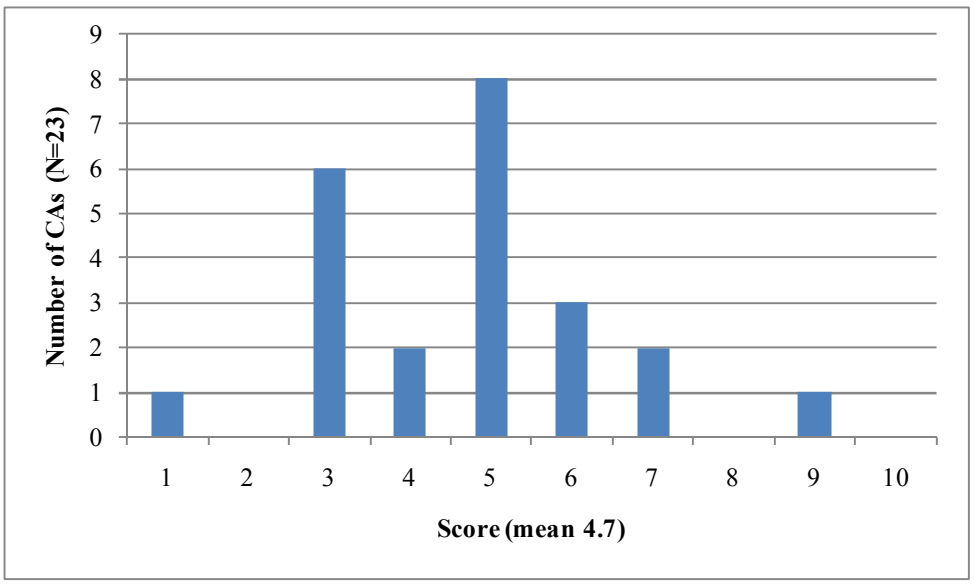

Figure 2.5: CA Opinions on Adequacy of Funding of CA

Almost all responding CAs scored the adequacy of their funding as between 3 and 7, with a mean score of 4.7. The comments provided by the CAs indicate that resources are considered to be inadequate or limited due 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.

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

3.1 Between National CAs

Figure 3.1 sets out the views of responding CAs regarding the effectiveness of communication and collaboration between themselves and the REACH CAs from other countries (where 1 is low and 10 is high). **All 30 responding CAs provided a response.**

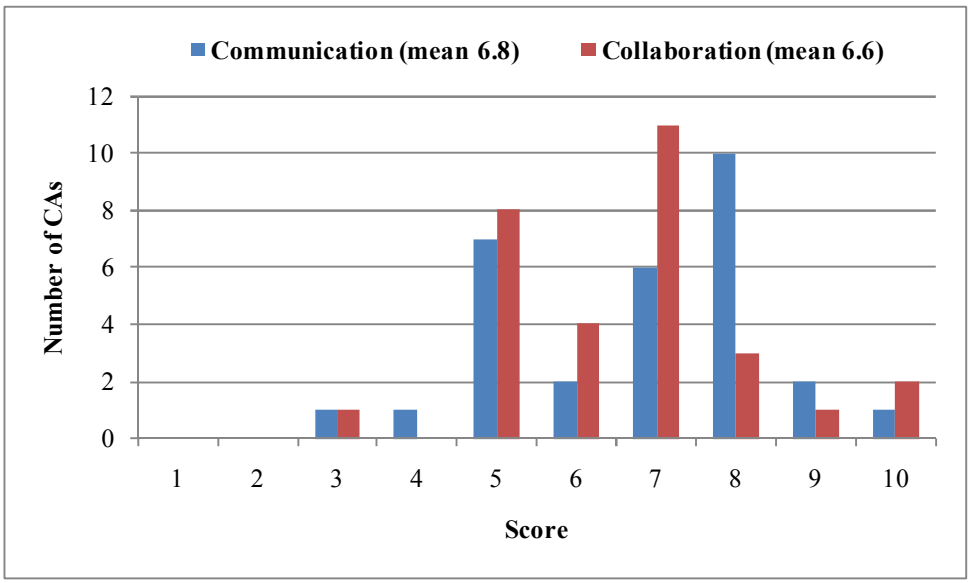

Figure 3.1: CA Opinions on the Effectiveness of Communication and Collaboration with other CAs

The mean score for communication given by CAs was 6.8 and the mean score given for collaboration was 6.6.

All but two of the CAs felt that the effectiveness of communication on REACH activities was moderate or good. However, CAs felt that communication between them 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.

Some CAs also felt that effective communication was difficult when short time limits are given. Individual scores given by CAs for the effectiveness of collaboration between them differed from the corresponding scores given for communication. However, the overall impression is very similar, as indicated by the closeness of the mean score values. Again, CAs felt that collaboration between them could be improved by keeping contact lists up-to-date. Figure 3.2 indicates the three countries whose CAs scored communication as nine or ten (green) and the two countries whose CAs scored communication as three or four (red).

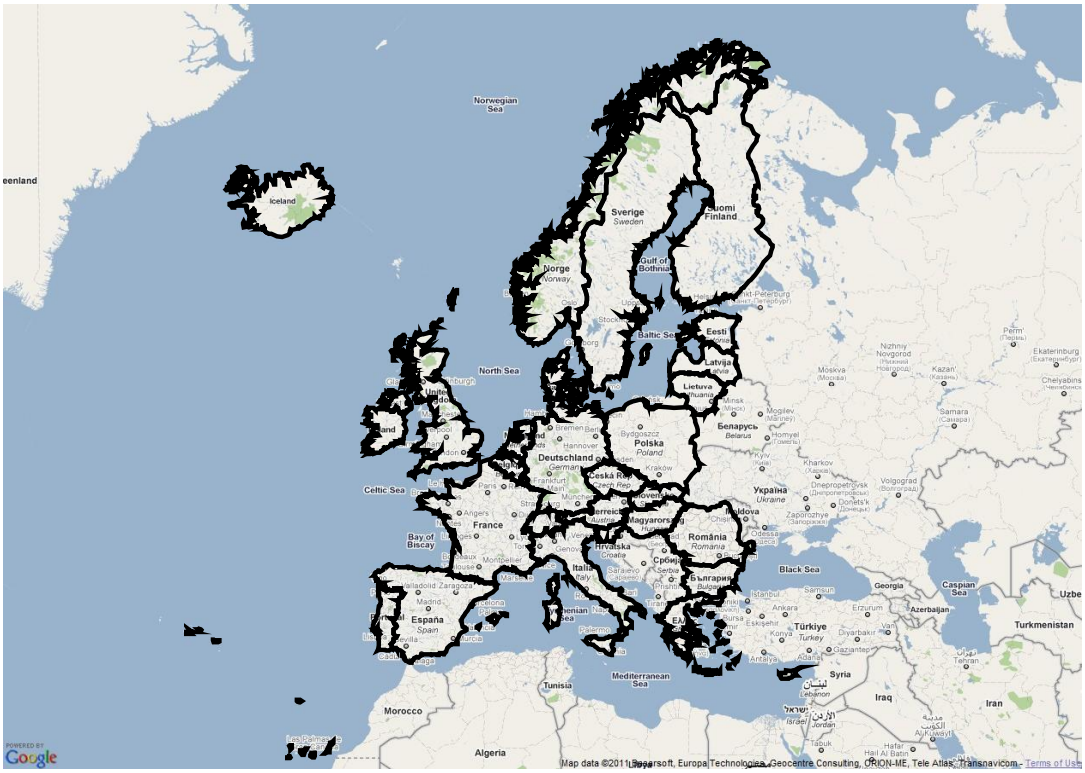

Figure 3.2: Effectiveness of Communication between CAs – Best (green) and Worst (red)

From Figure 3.2 it can be seen that there is no apparent correlation between the effectiveness of communication that exists between 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. Examples given by CAs include co-operation at the UN level (under several Conventions) and at the OECD level in respect of nanomaterials and as part of CLEEN. CAs also mentioned projects at a regional level (e.g. Nordic Area, Romania with Bulgaria, and Austria with other German speaking countries).

3.2 Between CAs and ECHA

Figure 3.3 sets out the scores awarded by CAs with regard to the effectiveness of communication and collaboration between themselves and ECHA (where 1 is low and 10 is high). **All 30 responding CAs provided a response to this question.**

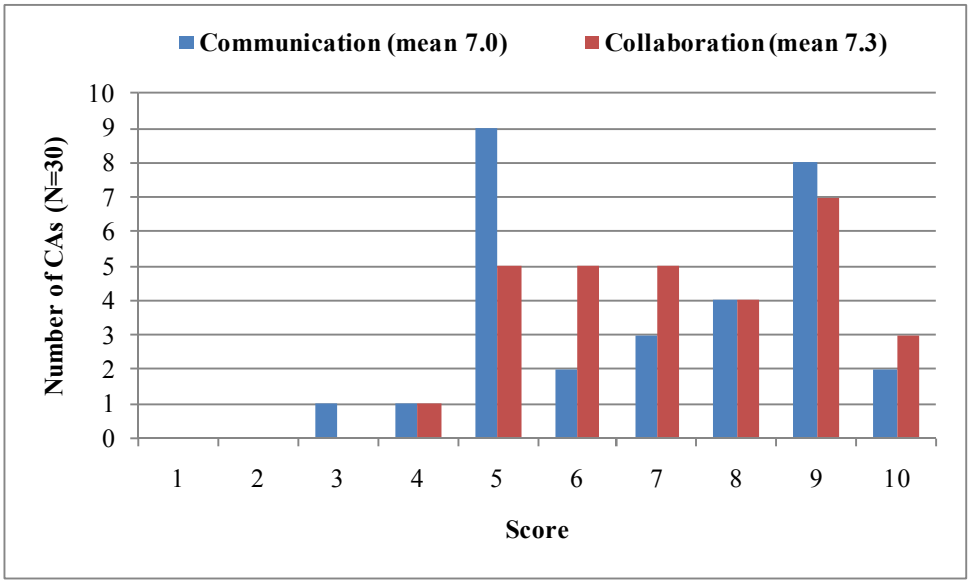

Figure 3.3: CA Opinions on the Effectiveness of Communication and Collaboration with ECHA

The mean score for communication given by CAs was 7.0 and the mean score given for collaboration was 7.3, with both of these scores indicating better levels of communication and collaboration with ECHA than with other CAs.

All but two CAs felt that the effectiveness of communication between themselves and ECHA was moderate or good. However, the CAs suggested that communication with ECHA could be improved if the following issues were to be addressed:

- no direct contact person at ECHA for specific issues;
- response time from ECHA is often too long; and
- unnecessarily high levels of formality within ECHA.

However, Estonian CA stated that generally communication is "effective" and UK CA stated that "formal communications are quite good". In more general comments some CAs praised ECHA for the progress it had made over a short time frame.

The individual scores given by CAs for the effectiveness of collaboration between themselves and ECHA differed from the corresponding scores given for communication. However, the overall impression is much the same, as indicated by the similar mean score values. CAs generally felt that their comments on communication with ECHA equally applied to collaboration.

CAs, however, also felt that ECHA could improve its collaboration with CAs by working with them more, rather than just keeping them informed of its activities. For example, the Belgian CA suggested that although CARACAL is not part of ECHA it should be used more as a working group in support of ECHA. ECHA staff could also visit CAs to get a better understanding of their operations and to run training on technical issues such as REACH-IT. The CA for the Slovak Republic also felt that

collaboration with ECHA could be improved if ECHA would take into account the unique legislative structures, resource constraints and administrative structures of the each MS and avoid as much as possible one unified approach.

Figure 3.4 displays the three countries whose CAs scored the effectiveness of either communication (red) or collaboration (orange) with ECHA as three or four.

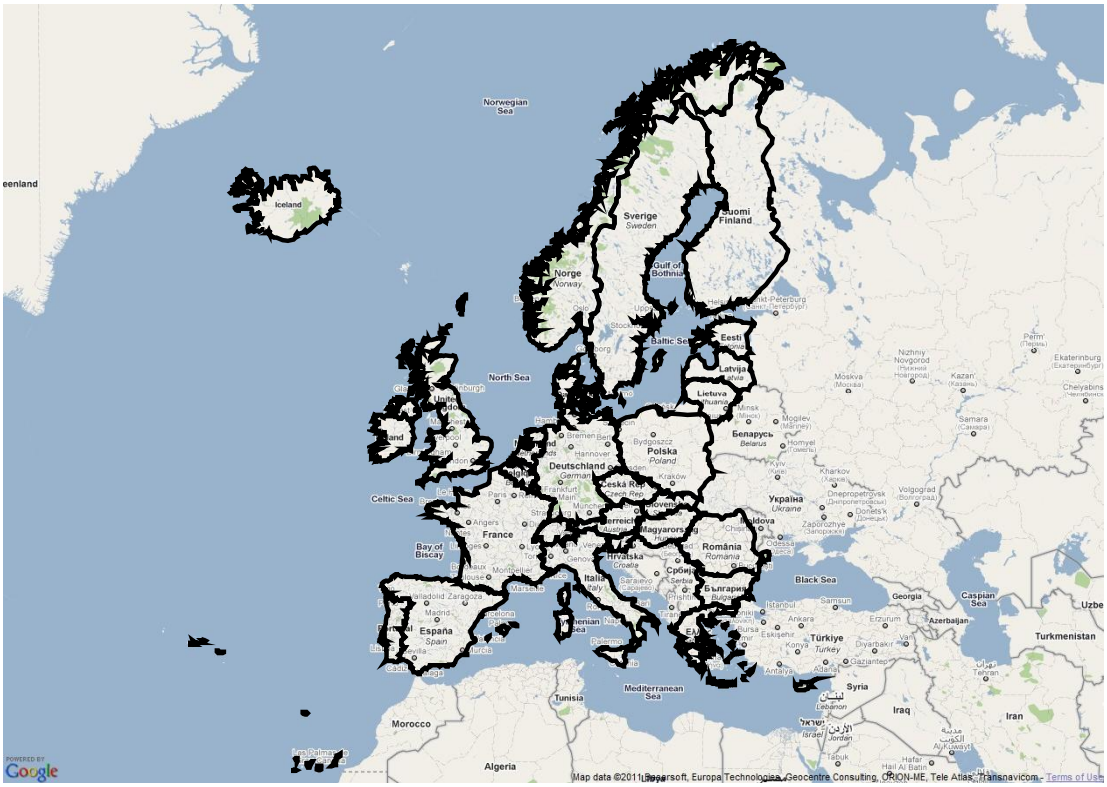

Figure 3.4: CAs Scoring the Effectiveness of Communication (red) or Collaboration (orange) with ECHA as Less than Five

From Figure 3.4 it can be seen that there is again no correlation between the effectiveness of communication or collaboration with ECHA and the geographical location of the CAs.

3.3 CAs and the Commission

Figure 3.5 sets out the scores awarded by CAs for the effectiveness of communication and collaboration between them and the Commission (where 1 is low and 10 is high). All 30 responding CAs provided a response to this question however those from Iceland or Lichtenstein were accompanied by the explanatory comment that "as an EEA country the communication with the Commission is quite low and mostly through the EFTA surveillance authority". The low scores from these two CAs were not therefore considered to represent comments on the quality of communication with the Commission (and are therefore not included in Figure 3.5). It is noted that the CA

of the third EFTA MS (Norway) was in more direct contact with the Commission via CARACAL and the Article 133 Committee and Norway's response has been included in Figure 3.5.

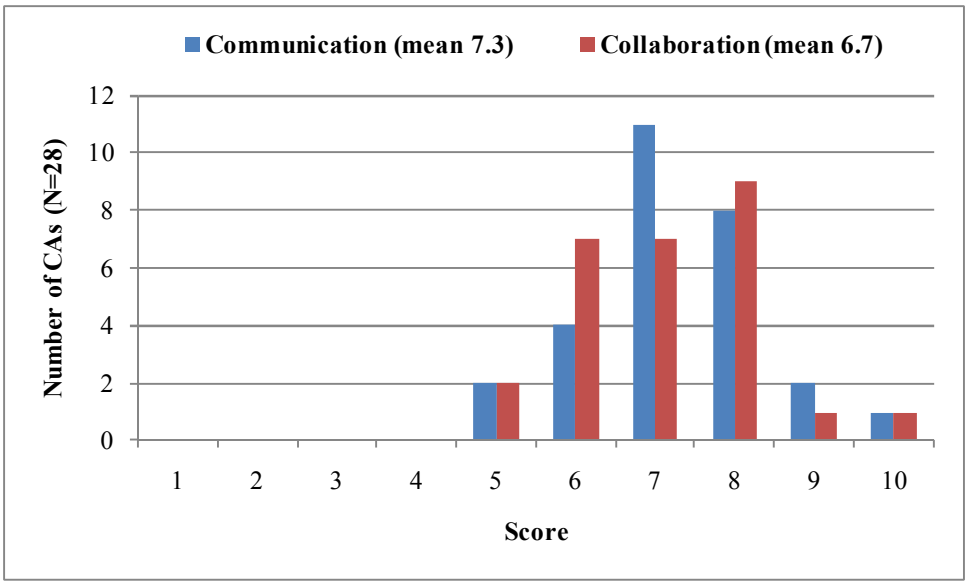

Figure 3.5: CA Opinions on the Effectiveness of Communication and Collaboration with the Commission

The mean score for communication with the Commission assigned by CAs was 7.3 and the mean score given for collaboration was 6.7. Furthermore, it is clear that the majority of CAs consider the effectiveness of communication and collaboration with the Commission to be above average.

CAs provided a great many specific recommendations regarding how the effectiveness of communication and collaboration with the Commission could be improved. With respect to the Article 133 Committee, CAs recommend that an up-to-date contact list be maintained and made available via CIRCA. In addition, CAs recommend that the contacts and methods of communication between meetings are clarified, proposals be accompanied by more explanation and that more advanced notice be given of meetings (including the early provision of documentation). However, it was noted that improvements had been apparent during 2010 with regard to these aspects.

The following comment by the CA for the United Kingdom could be said to sum up the comments by other CAs, "communication around CARACAL has improved but further work is still needed. In particular the Commission needs to work with MS as partners in drawing up the contents and agendas for the meetings".

Furthermore, the CA for Italy requested that key documentation be translated into more languages.

With regards to collaboration with the Commission, CAs reiterated the points made relating to communication. However, CAs also suggested that the effectiveness of collaboration could be improved by better communication between different parts of the Commission. For example, voting on legislative proposals should not be scheduled for the same time as CA meetings as this reduces the capacity of CAs to inform the voting.

It was also suggested that the effectiveness of collaboration could be improved if CAs and other relevant MS bodies (e.g. MS health and safety, environment, and industry/business departments) were involved more at the preparation stage of Commission proposals.

3.4 CAs and REACH Committees

Figure 3.6 sets out the scores awarded by CAs for the effectiveness of the REACH Committees, specifically Forum, MS, RAC, SEAC, CARACAL, PEG, RCN and REHCORN. **All 30 CAs provided a response.**

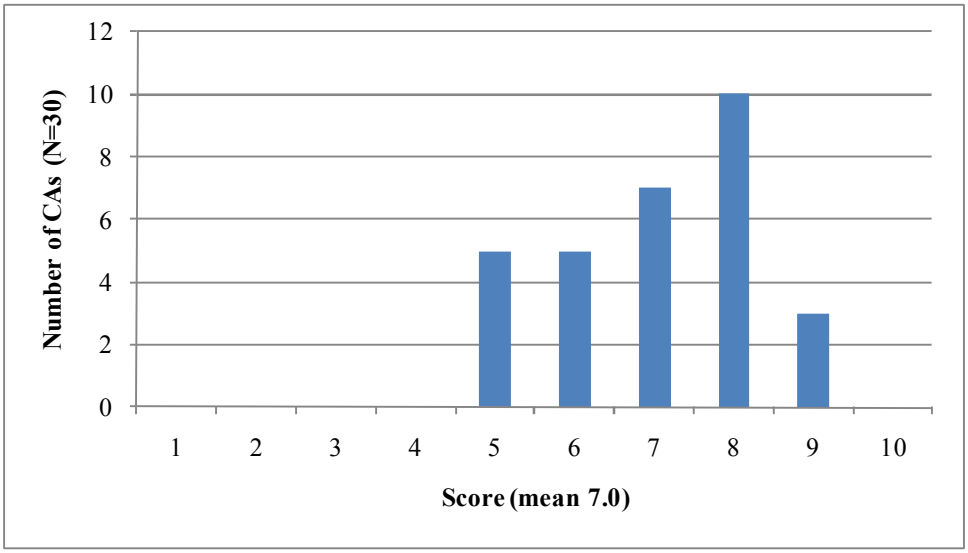

Figure 3.6: CA Opinions on the Effectiveness of REACH Committees

The CAs also provided a number of comments on the effectiveness of the various REACH committees including a number that were of a general nature. Other comments appeared to be specific to the each of the committees.

In the light of the comments provided by many CAs, it appears that in general terms CAs felt that REACH 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. Also, earlier establishment of meeting schedules and the circulation of agendas and working papers well in advance of the meetings would be widely welcomed. Other concerns related to the adequacy of the

resources and facilities available to support the work of the Committees. In particular, there were concerns that for some committees there were unrealistic expectations as to the level of contribution that was realistically possible from members, given current resource funding arrangements.

A more detailed description of the individual comments and suggestions made by CAs regarding the functioning of the REACH Committees in general and of the committee-specific comments made for CARACAL and MSC, are presented in Boxes 3.1.a-c below. Other committee-specific comments were provided by CAs but these have been included in those sections of the report where they were judged to be of most relevance, 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);
- 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).

It should be noted that the review of the detailed committee-specific comments gave an impression that many of the CAs might have awarded individual committees somewhat different scores for effectiveness than that given for the "overall committees" heading; this opinion is supported by the committee-specific scores awarded by the Irish CA and by the detailed comments provided by some CAs.

Box 3.1.a: Comments by CAs on General Effectiveness of REACH Committees

CAs were asked to make suggestions as to how the effectiveness of the REACH committees could be improved. The comments received included a number considered to be generally applicable that related to the organisation and business of the Committees. These are detailed below.

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;
- given that the committees are new, it is important that care and attention is paid to agreeing terms of reference and efficient working procedures, and that these are kept under review;

- changes in procedure leading to sufficient meeting time for dialogue and discussion with MSs on important issues, e.g. regarding interpretation of the legislation, are welcomed;
- 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 are often too lengthy;
- the effectiveness of the Committees is affected by the lack of human resources at MS/EEA level (no suggestion for improvement given);
- the selection 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;
- cooperation between CAs should be improved;
- closer cooperation is needed between 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).

Requests were also made for "benchmarking criteria for 'effectiveness'" to be included as part of the question asked.

Box 3.1.b: Effectiveness of CARACAL

Eleven CAs made generally highly critical comments on the organisation and conduct of the Competent Authorities for the REACH and CLP (CARACAL) committee. The main concern expressed was that 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 Member States. Several of the commenting CAs made similar suggestions as to how this problem might be addressed:

- 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;
- one CA expressed concerns regarding use of the written procedure and the time frame under which this should be conducted;
- 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.

Box 3.1.c: Effectiveness of MSC

The functioning and effectiveness of the Member State Committee (MSC) elicited little comment amongst CAs. France drew attention to the benefits that have accrued as a result of alternative MS representation being allowed for this committee, a situation that is not reflected in other ECHA committees. Eight CAs identified difficulties with regard to current procedures and facility provision that should be improved:

- documents submitted by ECHA should be circulated sufficiently in advance of meetings to allow review before the meeting and, in any event, new material should not be introduced during the course of a meeting;
- 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;
- adequate remuneration systems should be introduced for MSs support of co-rapporteurs contributions; and
- efforts should be made to improve meeting provisions in respect of the lack of direct LAN access in the Delegation room since this creates issues when WLAN access is not readily available and attention should be given to the lack of cell phone reception and absence of landline facilities.

4. OPERATION OF REACH: REGISTRATION

4.1 Duty Holders - Registrants

CAs were asked to provide estimates of the total number of duty holders within their MS, as well as of the number of such duty holders that were likely be registrants for the years 2007, 2008 and 2009. Twelve CAs provided figures for 2007 and 2008 and fifteen CAs provided figures for 2009. The other responding CAs providing either a blank response or stated that such data are not maintained/collected. Had a comprehensive dataset been submitted by all the CAs, comparison of the number of potential registrants and duty holders in each MS against the total numbers across all thirty countries would have provided an insight into the level of REACH activity and of registration activity likely within each of the countries, as well as for the thirty countries as a whole.
A further problem regarding the data provided by those CAs that submitted information is that, since the CAs had not been provided with guidance on how these estimates should be calculated it appears that the figures provided may not relate to a common metric.

In some cases it is possible that the inconsistencies in data definition are relatively small but for others there appear to be significant differences in the way data has been defined. For example, Germany estimates that it has approximately 210,000 duty holders compared to Austria with 300,000, whereas the relative size of the chemical and ancillary industries of these two countries would imply that the figure for Germany should be the significantly greater. Similarly, France indicated that it had only 3,600 duty holders, a figure similar to the 2,700 estimate provided by Estonia which does not fit with the relative sizes of the chemical industries in these countries. Furthermore, the figures provided by some CAs are rounded and remain unchanged for 2007, 2008 and 2009 (e.g. estimates for Austria, Denmark and Sweden) whereas others appear very precise and vary upwards and downwards between years (e.g. estimates for Germany, Bulgaria and Latvia).

The estimates of the number of registrants would appear to have similar inconsistencies to those described above for all duty holders. In some instances (e.g. France and Cyprus), the number of registrants matches the number of duty holders given previously. However, most of the inconsistencies in the data on the percentage of registrants compared to the total number of duty holders cannot be so easily identified.

For the reasons provided above no further analysis of data relating to the number of duty holders or registrants has been possible, suggesting this aspect of the questionnaire should be subject to revision and clarification if this aspect is to be investigated in future.

5. OPERATION OF REACH: INFORMATION IN THE SUPPLY CHAIN

MS were not asked to report on the activities of duty holders regarding the supply and movement of information in the Supply Chain. However, in their responses regarding Helpdesk support provided to industry it is clear that advice was provided by MS on downstream user obligations, the operation of SIEFs, and safety data sheets.

6. OPERATION OF REACH: AUTHORISATION

6.1 Annex XV Dossiers

6.1.1 National Activity

The identification of SVHCs is the key requisite for triggering the authorisation provisions of REACH. Levels of activity by MS related to the preparation of Annex XVI dossiers for the identification of SVHCs are set out in Table 6.1. **Twenty one CAs** indicated that their MS had been involved in some Annex XV dossier related activity for the identification of SVHCs.

Table 6.1: Activities Related to the Production of Annex XV for SVHC Identification

Member State	Number of Annex XV SVHC Dossiers				
	Prepared	Rapporteur	Co-rapporteur	Commented Upon (MS Dossier)	Commented Upon (ECHA Dossier)
Austria	1-3	-	-	7-9	-
Belgium	1-3	-	-	7-9	1-3
Bulgaria	-	-	-	1-3	-
Czech Republic	-	-	-	1-3	1-3
Denmark	1-3	-	-	-	-
Estonia	-	-	-	-	-
Finland	-	-	-	-	-
France	>9	-	-	>9	1-3
Germany	>9	-	-	>9	1-3
Hungary	-	-	-	-	-
Ireland	-	-	-	>9	1-3
Latvia	-	-	-	>9	
Netherlands	1-3	7-9	-	>9	1-3
Norway	1-3	-	-	1-3	-
Poland	-	-	-	1-3	-
Portugal	-	-	-	4-6	-
Slovakia	-	-	-	4-6	1-3
Slovenia	-	-	-	1-3	-
Spain	1-3	1-3	-	-	-
Sweden	1-3	-	-	>9	1-3
United Kingdom	1-3	-	-	>9	1-3

CAs were asked to provide a score of between 1 (lowest) and 10 (highest) for the "reasonableness" of the time spent following up MS dossiers and acting as co-rapporteur. However, CAs generally felt that they had not yet had sufficient experience to be able to provide a sensible answer to such questions. This was a mandatory question for CAs. Therefore, scores were provided but these were not answers to the question asked. For example, the Belgian CA stated, "As default, we have stated 5. The SVHC Annex XV dossiers are due to be submitted in the first half of 2010; therefore estimating the time spent following up the dossier is not yet relevant" and the Lithuanian CA state, "we did not prepare any Annex XV Dossiers;

however the program required mandatory answer to the next question that is why we chose the lowest number".

The Danish and Swedish CAs predicted that Annex XV dossier work would not be resource demanding while also stating that the time/resources requirements varied significantly between dossiers. The Danish CA also commented that for future answers to this question to be of statistical use the Commission would need to add some sort of benchmarking as to what is a reasonable amount of time. These comments have been taken into consideration in relation to suggestions for improving the reporting format used (see Section 15).

The Irish CA gave a score of 7, but commented that additional and unnecessary work had been required in relation to transitional dosser preparation because decisions were made very late in the process in relation to the IUCLID 5 dossier preparation. The Irish CA also made suggestions for future improvements necessary for unnecessary work to be avoided in the future, as set out in Box 6.1.

Box 6.1: Improvements to Future Dossier XV Preparation

The CA felt that "for future Annex XV dossier preparation, robust procedures need to be in place well in advance of work commencing, to ensure, where changes to the process are necessary or decisions need to be made, that these are taken promptly and communicated efficiently"

6.1.2 Expertise Available

Figure 6.1 and Figure 6.2 set out the number of staff with specified skill sets that are available for working on the different elements of Annex XV dossier preparation. However, some CAs have stated that most or all of their staff possess a range of the skills indicated. Therefore, the numbers of staff shown will not be indicative of the total number of staff in the CAs. Fifteen CAs provided responses to this question.

In addition to the skills listed in Figures 6.1 and 6.2, the Italian CA had access to linguistic specialists and the Hungarian CA had access to a biologist, pharmacist and medical doctor. It will also be recalled from the discussion presented in Section 2 that twenty-three CAs stated that they also had access to external specialists.

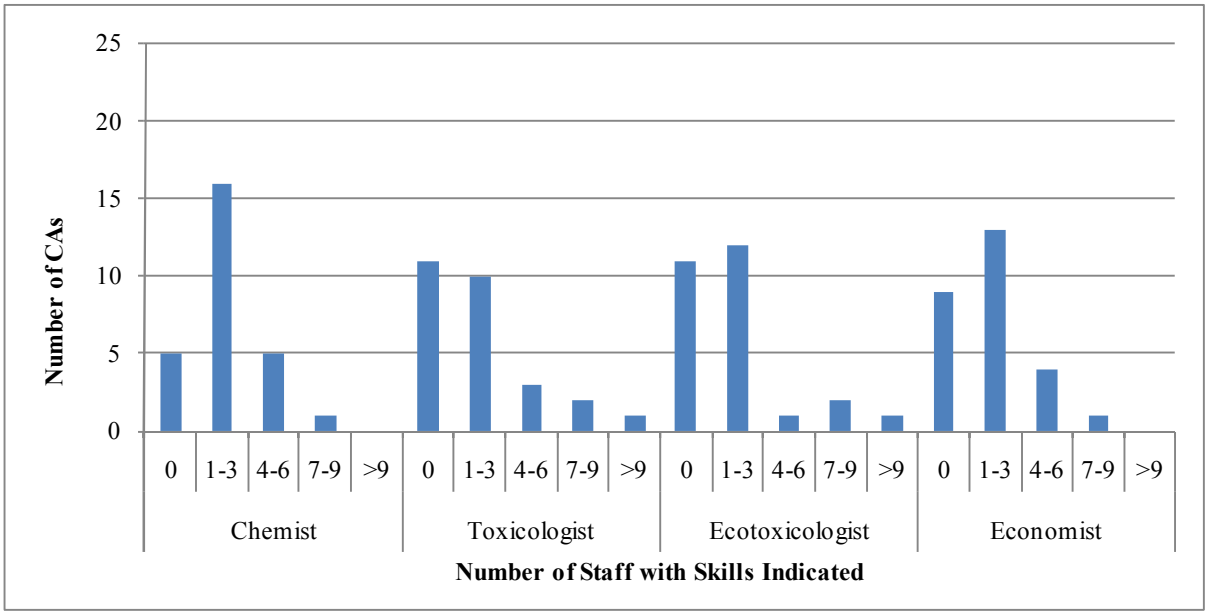

Figure 6.1: Number of Staff with Specified Skills Available for Annex XV Dossier Preparation (Part One)

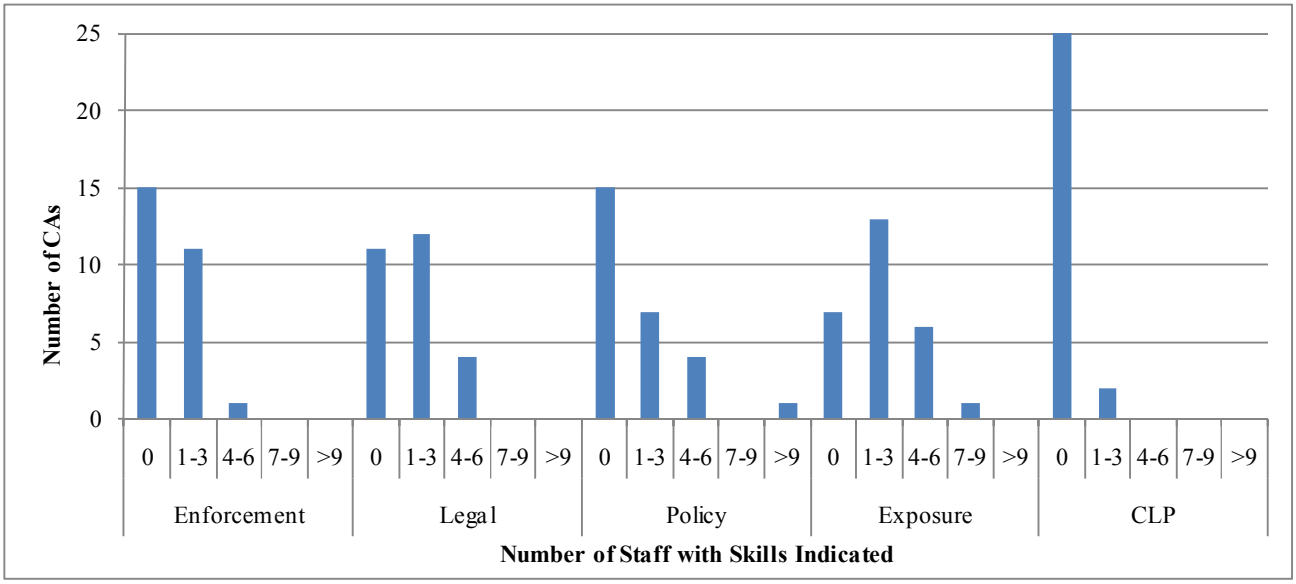

Figure 6.2: Number of Staff with Specified Skills Available for Annex XV Dossier Preparation (Part Two)

6.1.3 Industry Involvement in Dossier Preparation

Eight CAs indicated that industry had some involvement in the preparation of Annex XV dossiers within its MS. These CAs were then asked to score the level of such involvement from between 1 (low) and 5 (high), with the responses as set out in Figure 6.3.

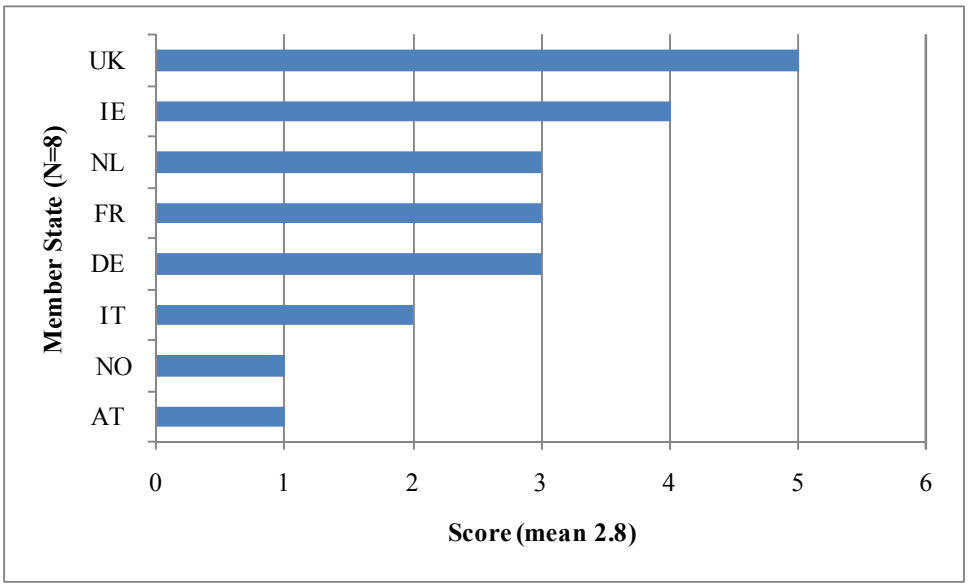

Figure 6.3: Level of Industry Involvement in Dossier Preparation

From Figure 6.3 it can be seen that the level of that industry involvement in dossier preparation varied greatly between different countries.

6.2 Effectiveness of RAC and SEAC

6.2.1 Effectiveness of RAC

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 below).

Ten CAs provided comments on the effectiveness of RAC, including a brief comment by Hungary that RAC was well organised and by Belgium that the RAC Secretariat was particularly helpful. There were however a number of reservations expressed by the ten CAs who also provided suggestions for improvement (see Box 6.2).

Box 6.2: Comments by CAs on Improving Effectiveness of RAC

Reservations expressed by ten CAs focused on concerns as to the ability of the current structure and procedures to handle the anticipated growth in Committee workloads. Particular concern was expressed regarding the limited number of Members that possess expertise across all necessary disciplines, especially in relation to CMR and classification issues.

A number of CAs stated that the current Rules of Procedure are considered to pose a substantial risk to the future effectiveness of the Committee, for example, the Procedure for Article 77(3) was considered particularly burdensome. While some suggestions reflected the generic comments already highlighted as being common to all REACH Committees, there were some suggestions for improvement specific to this committee, including:

- allow more time for substance-specific discussion;
- while use of 'written procedure' should continue, it should not be regarded as negating the need to schedule appropriate discussion time at meetings;
- consideration should be given to establishing topic specific subgroups within RAC to work in parallel on different aspects (e.g. classification, health and environment, restriction and authorisation) or to scheduling topic specific meetings;
- consideration should be given to establishing procedures for prior checking the completeness of classification dossiers before submission to RAC for considerations (although this may involve consideration of the legal basis of CLP regulations);
- rebalancing the focus of activities to include the environment, rather than human health and classification issues only;
- ECHA should ensure that other stakeholders (e.g. industry) present at meetings contribute only in accordance with Stakeholder rules;
- lessons should be learned with regard to the current inefficient process for harmonisation of classifications by consideration of previous (pre-REACH/CLP) procedures; and
- improvement is needed in inter-committee interactions by careful scheduling of agendas and meeting schedules of RAC and SEAC.

CAs also expressed concerns that few RAC members possess individual expertise across the whole range of subject areas, making the current approach of expecting individual Members to cover classification, restriction and authorisation issues unsustainable. Furthermore, the workload expectations on RAC members are likely to be become unsustainable or require an exceptional level of commitment. These concerns might be mitigated by:

- providing substantial remuneration to committee members and co-rapporteurs for all aspects of activities undertaken in support of the Committee, to ensure full participation;
- recognising that despite the anticipated workload, it is unrealistic to schedule more than 5-6 meetings per year, each of 3-4 days; and
- permit nominated Experts/Advisors to participate in Work Groups even in the absence of a relevant RAC member.

6.2.2 Effectiveness of SEAC

There are relatively fewer comments by CAs specific to the functioning of the Socio-Economic Analysis Committee (SEAC). The extensive work by ECHA in establishing practical and legal procedures were recognised by some and several CAs commented that to date the Committee appeared to function well. There are however some concerns as to SEACs ability to cope with growing future demands as set out in Box 6.3.

Box 6.3: Comments by CAs on Improving Effectiveness of SEAC

CAs expressed particular concern that the established Rules of Procedure may impair the future effectiveness and efficiency of SEAC and made the following suggestions as to ways to address this concern:

- allocating less time to discussion of theory and procedure, and focus plenary discussions on restriction and authorisation cases;
- allowing greater flexibility of working by permitting nominated Experts/Advisors to participate in Work Groups even in the absence of the relevant SEAC member; and
- ensuring the continuation of joint meetings and workshops with RAC to facilitate exchange of information and discussion.

Particular concerns were expressed as to the capacity of the SEAC to cope with anticipated workloads and similar suggestions as to those for RAC were made regarding remuneration of members and co-rapporteurs. Concern was also expressed that SEAC members have limited practical experience of SEA.

Finally, the training provided was considered to be beneficial but it was felt important that lessons learned during early restriction and authorisation considerations are identified and disseminated to Members.

7. OPERATION OF REACH: RESTRICTION

7.1 Annex XV Dossiers

7.1.1 National Activity

The activities undertaken by Member States in relation to the preparation of Annex XV dossiers for restrictions are set out in Table 7.1. **Thirteen CAs** indicated that their MS had been involved in some Annex XV dossier related activity

Table 7.1: Activities Related to the Production of Annex XV Restriction Dossiers

Member State	Number of Annex XV Restriction Dossiers				
	Prepared	Rapporteur	Co-rapporteur	Commented Upon	
				Dossier Prepared by MS	Dossier Prepared by ECHA
Austria	-	-	1-3	-	-
Belgium	-	-	1-3	-	-
Bulgaria	-	-	-	1-3	
Czech Republic	-	-	-	1-3	1-3
Denmark	-	1-3	1-3	1-3	-
Estonia	-	-	-	1-3	-
Finland	-	-	-	1-3	-
France	1-3	1-3	1-3	-	-
Hungary	-	-	1-3	-	-
Netherlands	-	-	-	1-3	-
Norway	1-3	-	-	-	-
Sweden	-	1-3	1-3	1-3	1-3
United Kingdom	-	-	1-3	-	-

CAs were also asked to provide a score of between 1 (lowest) and 10 (highest) for the "reasonableness" of the time spent following up MS dossiers and acting as co-rapporteur. Only thirteen CAs had any experience of working with Annex XV dossiers and CAs generally felt that they had not yet had sufficient experience to be able to provide a sensible answer to these questions (see Section 6.1.1 for more details).

The Danish and Swedish CAs predicted that Annex XV dossier work would not be resource demanding while also stating that the time/resources requirements varied significantly between dossiers. However, the Norwegian CA felt that the work it had spent preparing a restriction proposal was far more time and resource consuming than expected.

7.1.2 Expertise Available

The expertise available to CAs to work on Annex XV dossiers is discussed in Section 6 above, with this being similar to that available for working on authorisation dossiers.

7.2 Effectiveness of RAC and SEAC

The effectiveness of the RAC and the SEAC is discussed in Section 6 above.

8. OPERATION OF REACH: DOSSIER AND SUBSTANCE EVALUATION

Figure 7.1 sets out the number of staff with specified skill sets that are involved in substance evaluation. N**ine CAs** had been involved in substance evaluation. The other CAs either left this question blank or entered zeros for each skill set. These blank or "zero" responses are not included in Figure 8.1.

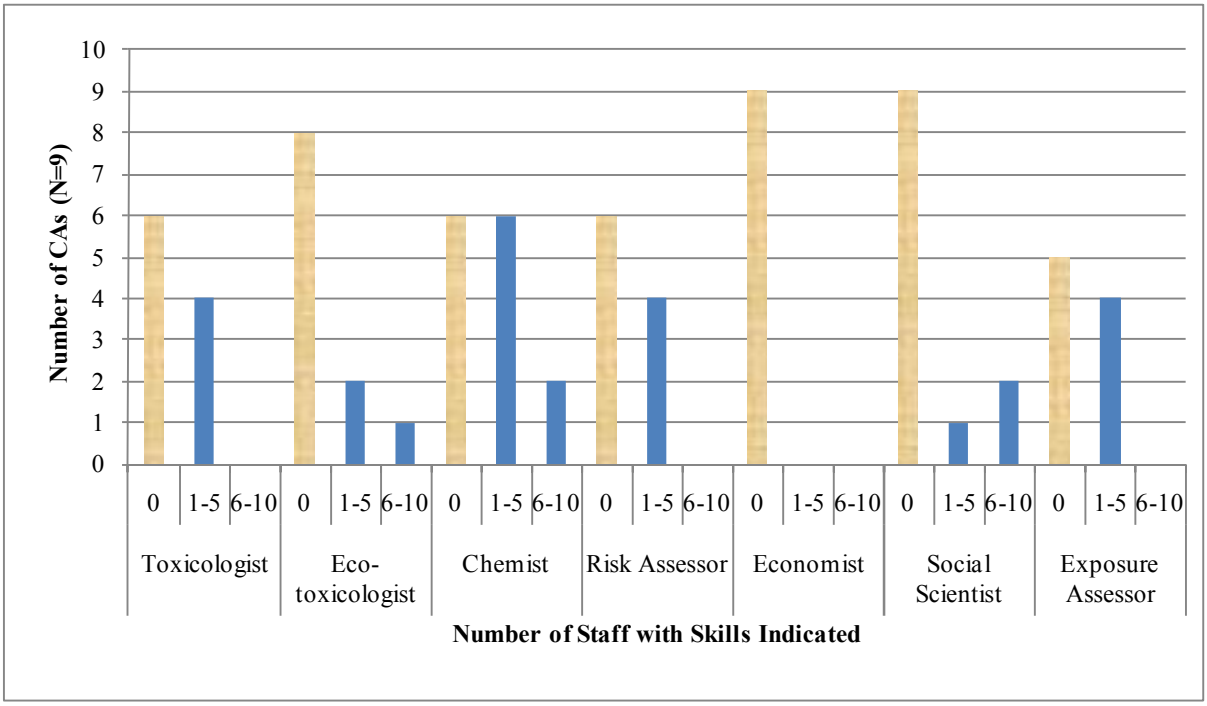

Figure 8.1: Staff Involved in Substance Evaluation

It is apparent that the skills as listed in Figure 8.1 vary markedly from those available to the respondent CAs as set out in Figure 2.2.

From Figure 8.1, it can be seen that only four out of 15 CAs reported using exposure assessment expertise whereas such skills were available to fifteen CAs. A similar picture exists in respect of the use of toxicologists, ecotoxicologists and risk assessors. Less surprising is the fact that economists are not involved in this process.

The comments provided by the CAs supply an explanation for the results displayed in Figure 8.1. Firstly, several CAs point out that as substance evaluation has not yet begun, no staff have been involved in this activity. Also, some CAs entered zeros while others have simply not provided an answer and so are not included in the dataset represented by Figure 8.1. Other CAs appear to have understood this question to refer to dossier evaluation or other registration comments provided to ECHA (e.g. with regard to testing proposals).

Some CAs also noted that staff who possess more than one of the skill sets will be

recorded more than once and so the number of skills reported as being used for evaluation will not necessarily equate to the number of staff that actually undertaking this activity.

Given the differences in interpreting this question by the different CAs, no firm conclusions can be drawn from these data.

9. ALTERNATIVE TESTING

Responses from **all CAs** show that twenty countries have made contributions to EU and/or OECD work on the development and validation of alternative test methods by participating in relevant committees. The countries that did not contribute to such activities were Cyprus, Greece, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta and Slovakia.

Seventeen CAs provided data on overall public funding for national research and the development of alternative testing methodologies each year, with nine CAs each reporting expenditure of more than Euro 100,000, as set out in Table 9.1. However, there is no indication whether CAs understood these figures to represent funding for:

- national R&D only (assumed here and implied by the question);
- EU and/or OECD only (i.e. providing figures for the preceding question); and/or
- national, EU and OECD (i.e. all sources of public funding).

Hence any interpretation of these data would need to be approached with a degree of caution.

Table 9.1: 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*, DK, ES, FR, NL, NO, SE, and UK
Note: * The German CA provided a separate note stating that Germany contributed more than the one million Euro maximum allowed by the electronic questionnaire.	

The Dutch CA expressed its hope that ECHA could provide data on the number and percentage of registration dossiers that contain alternative test data. Furthermore, the Irish CA felt that it would not be possible to assess the development of alternative testing across the EU unless the Commission first establishes establish common indicators.

In addition to its questionnaire, the German CA provided the Commission with a copy of a research paper entitled, 'Research Expenditure for 3R Alternatives: A Review of National Public Funding Programmes in European Countries'[5]. This study provides data on expenditure from public funds for the years 2004 to 2007 by Switzerland and the following fifteen MS: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Netherlands, Norway, Slovakia, Spain, Sweden, and the United Kingdom. The total expenditure 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 9.1.

[5] Devolder et al (2008): Research Expenditure for 3R Alternatives: A Review of National Public Funding Programmes in European Countries, Altex, Number 25, Issue 3, 2008, Available for download from the Altex Internet site (http://www.altex.ch/resources/Devolder_ALTEX_3_08.pdf).

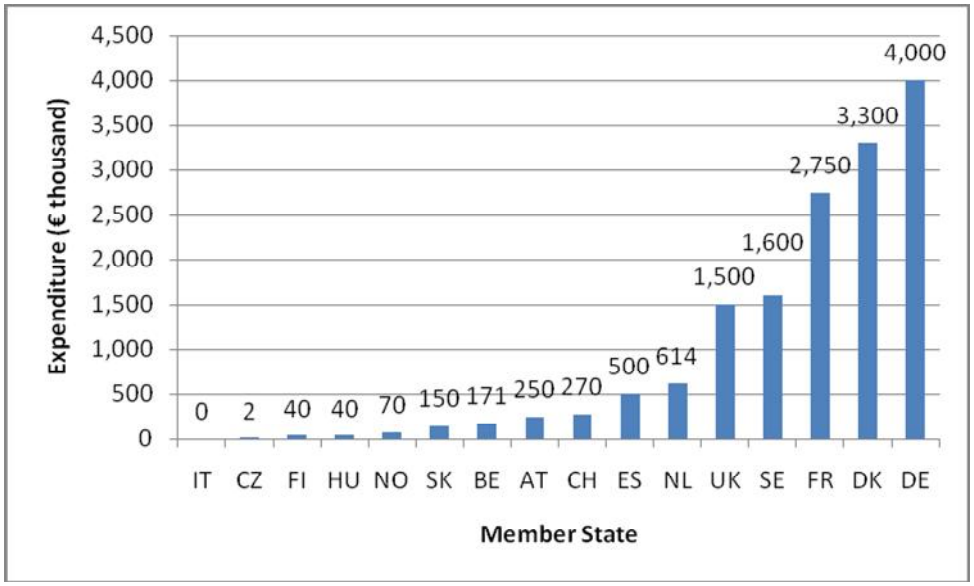

Figure 9.1: Annual Public Expenditure on 3R Alternatives

It is noted that the amounts set out in Table 8.1 generally do not match those displayed in Figure 9.1. For example, Figure 8.1 identifies five countries as contributing more than €1 million per annum where only one is identified in Table 9.1.

10. ENFORCEMENT

10.1 Enforcing Authorities

Twenty-four of the thirty CAs indicated that there was more than one enforcement authority for REACH in their MS.

10.2 National Enforcement

10.2.1 Agreed Forum Enforcement Strategies

The Forum for Exchange of Information on Enforcement (Forum) is hosted by ECHA and made up of members nominated by each MS plus up to 5 co-opted members to undertake the following tasks, as required under REACH article 76(1)f:

- spreading good practice and highlighting problems at Community level;
- proposing, co-ordinating and evaluating harmonised enforcement projects and joint inspections;
- co-ordinating exchange of inspectors;
- identifying enforcement strategies, as well as best practice in enforcement;
- developing working methods and tools of use to local inspectors;
- developing an electronic information exchange procedure;
- liaising with industry and other stakeholders, including relevant international
- organisations; and
- examining proposed chemical restrictions to advise on enforceability.

In 2009 the Forum produced agreed strategies for the enforcement of REACH[6]. The 2009 strategy document was not legally binding on national enforcement authorities, rather, it provided a framework within which REACH compliant national REACH enforcement strategies could be developed. This framework is made up of five elements:

1. **Policy Objectives:** Clear policy objectives and priorities are developed, based on desired behaviours, the risks of non-compliance and prioritisation of target groups.

2. **Organisation:** An organisation is created that is able to achieve effective, efficient, transparent and systematic enforcement of the Regulation, including:

- elaboration of an appropriate regulatory regime;
- ensuring equal treatment of all the duty holders regulated;

[6] **Strategies for enforcement of Regulation (EC) no. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), March 2009**, superseded and no longer available. It is noted that the 2009 strategies document was superseded in March 2011, available from (http://echa.europa.eu/doc/about/organisation/Forum/strategies_enforcement_reach_2011.pdf).

- development of a clear enforcement programme;
- providing the necessary resources (regulatory powers, staff, finance, administration and experts);
- development of appropriate standards for enforcement and compliance tools; and establishment of effective communication and guidance on REACH issues with the industry and other stakeholders.

3. **Performance of Enforcement:** Measures include promoting and enforcing compliance, as well as seeking the imposition of sanctions such as via civil or criminal proceedings.

4. **Progress Monitoring and Measurement:** Procedures for periodic monitoring and measurement of enforcement are developed and implemented, with special attention placed on the level of compliance, resources spent, information and organisation.

5. **Review, Evaluation and Update:** Procedures for review, evaluation and development of the enforcement strategy are developed and implemented, based on the monitoring procedures (see 4 above).

The 2009 Forum strategies document describes the five elements set out above as being applied in an iterative manner as shown in Figure 10.1 which reproduces Diagram 1 from that document.

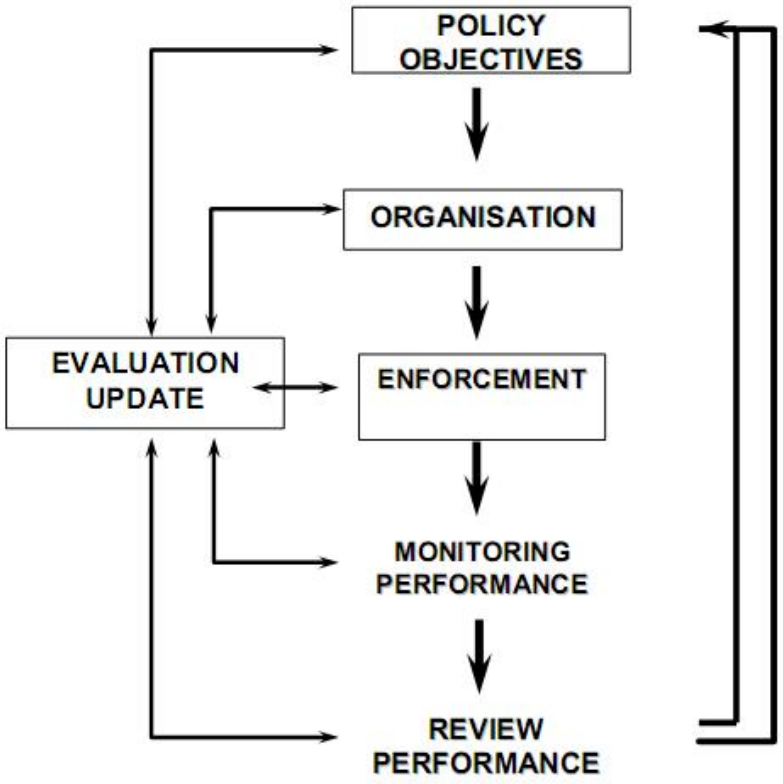

Diagram 1. Enforcement process for the REACH Regulation

Figure 10.1: The Iterative Process within Forum Enforcement Strategies

10.2.2 National Enforcement Strategies

Eighteen of the thirty CAs indicated that there was an overall strategy(ies) in their MS for the enforcement of REACH and twenty-five CAs indicated that their enforcement strategy(ies) were in line with those devised by the Forum (see 10.2.1). It is noted that eight MS have strategies in line with the Forum strategies that the respondent CAs did not consider to constitute an "overall" strategy(ies).

All CAs provided descriptions of their enforcement strategy(ies), the details of which are very specific to the countries concerned. Nonetheless, some general trends are discernable:

- strategies are generally based on those devised by the Forum with adaptations to better fit with national variations (see comments above);
- in their strategies, MS have generally used their experience of enforcing other chemical legislation such as Directives 67/548/EEC, 1999/45/EC and 76/769/EEC to provide a template for their enforcement of REACH;
- some CAs describe varying the prioritisation processes used to focus their enforcement activities on those areas where widespread non-compliance has been identified e.g. by "whistle blowers" informing the CA of illegal activity. However, other CAs describe much inspection/enforcement activity as occurring during inspections undertaken for purposes other than REACH (e.g. Health and Safety inspections). A combination of market surveillance and complaints ("whistle-blowing") are used by CAs and their national enforcement bodies; and
- many CAs see education of companies with obligations under REACH as an important tool for the enforcement of REACH.

Summaries of those strategies that were described as being in line with those devised by the Forum are provided in Table 10.1.

Table 10.1: Summaries of Enforcement Strategies in line with the Forum

MS	Additional Details of Enforcement Strategy(ies)
AT	• based on experience of previous Directives for chemicals, especially 67/548/EEC, 1999/45/EC and 76/769/EEC; • starts with the "no data no market" rule; • seeks to control all relevant aspects like registration, authorisation, restrictions, information dissemination etc. • monitoring activities cover the complete supply chain by checking producers, importers, distributors, including both wholesalers and retailers, and downstream users; • to ensure comprehensive enforcement, inspection schemes are prepared by the Inspectorates and coordinated with the BMLFUW; • companies, branches, products are selected on a regular basis as the focus for enforcement authorities; and • Chemical Inspectorates report to the BMLFUW on their activities and meet for coordination and training twice a year
BE	• Forum recommendations regarding harmonized campaigns throughout the EU and EEA countries are followed; and • inspection services may establish supplementary specific inspection plans and execute

Table 10.1: Summaries of Enforcement Strategies in line with the Forum	
MS	**Additional Details of Enforcement Strategy(ies)**
	them
BG	• strategy outlined in order No 250/8.4.2009 **Guidelines for enforcement of REACH 2009 – 2010** (to be updated in 2011); • target groups and the enforcement priorities are identified; • emphasis on the coordination and cooperation of the enforcement authorities and provide information about how the planning, performing, reporting and follow-up of REACH inspections should be done, as well as what penalty and administrative measures (mandatory improvement notices, fines, sanctions, restrictions on placing on the market or the production, etc.) should be applied; and • 2009/2010 the priorities are checking compliance with the requirements for (pre-) registration for manufacturers and importers, the availability and the quality of the SDS's within the supply chains, and identification of companies, which produce, place on the market or use SVHCs
CY	• strategy planned and revised annually based on the Forum priorities and analysis of the special circumstances and needs at national leve; • enforcement activities include: o targeted campaigns for the inspection of restricted or banned chemicals (Annex XVII); o investigation of complaints; and o participation in Forum and CLEEN campaigns
CZ	• enforcement strategy developed in 2009; • communication and coordination with enforcement authorities in other MS is performed via direct communication with members of the Forum and via RAPEX notifications; • enforcement action is determined by inspectors on a case-by-case basis; • administrative sanctions are imposed for non-compliance; • enforcement activities are monitored and annually evaluated; and • strategy updated based on monitoring and evaluation (see above)
DE	• strategy by developed by expert group developed by the REACH federal / provincial working group Chemical Safety (BLAC); • strategy includes the developed control concept which is largely identical to the compulsory and voluntary part of the EU-wide surveillance project REACH-EN-FORCE-1; • market monitoring according to the following guidelines: o Guide to Market Surveillance (transnational principles of market surveillance in the area of chemical safety); o Guide to Good Internet Policy for the chemical trade; o market surveillance program for Regulation (EC) No 765/2008; o Monitoring approach to pre-register by 13.02.2008 (prepared by the Committee on technical issues and execution (AS-IV) expert group on monitoring REACH); and o Project Manual for pre-registration / registration of phase-in substances and MSDS for REACH-EN-FORCE
EL	• enforcement is investigated in two steps: o in cooperation with custom authorities for imported products; and o on a basis of an annual inspection plan and/or targeted inspections
ES	• enforcement strategy is set out in Spanish Sanctions Regime Law. (Ley 8/2010, de 31 de marzo. BOE 1 de abril de 2010); • enforcement in Spain is the responsibility of the regional enforcement authorities (Autonomous Communities); • two central CAs ensure the coordination between all regional enforcement authorities; • central CAs and regional enforcement authorities supply and share criteria, information and any other issue useful for the normal application of their duties including defining policy objectives and priorities. Results of inspections, investigations and formal enforcements are shared annually; • a National Network for Surveillance, Inspection and Enforcement and a Fast Information Exchange System for chemicals has been developed, allowing

Table 10.1: Summaries of Enforcement Strategies in line with the Forum	
MS	**Additional Details of Enforcement Strategy(ies)**
	Enforcement Authorities to disseminate obtained data, to alert the rest of Autonomous Communities of any risk when it is deemed necessary and compile all the information available deciding how it can be used; • proposals and projects coming from the Forum are taken into account in the activities related with inspections and enforcement of REACH
FI	• strategy based on the principle that inspections to the sites dealing with chemicals are carried out by regional and local authorities that are already enforcing other (chemicals related) legislation in those sites • generally, enforcement of REACH when carrying out enforcement of other legislation e.g. Occupational Safety Act, Environment Act, Consumer Safety Act, Customs Act. Coordination; • special enforcement campaigns in addition to other enforcement activities; • enforcement authorities have prepared their individual enforcement strategies. E.g. SYKE and Valvira have prepared a common three year action plan for REACH implementation that covers also enforcement-related issues and SYKE has a more detailed plan that defines yearly objectives, necessary actions and priorities of its enforcement actions. Valvira and SYKE have also produced a three year enforcement programme for municipal supervisory authorities for chemicals that covers similar issues; • coordination provided by central authorities, ministries for regional authorities and CAs for local authorities; • ongoing national joint project aiming at defining national outlines and common principles for REACH enforcement
FR	• In 2007-2008, the "Grenelle of Environment" roundtable talks highlighted the need to strengthen enforcement actions in order to allow a better reactivity to safety and environmental alerts. The French authorities decided to ensure the consistency of such activities and to encourage the development of coordinated controls. The second national environment and health action plan (NEHAP 2) adopted in 2009 foresees in particular expanded chemical testing campaigns by the government enforcement bodies, particularly for products designed for children and/or pregnant women. A working-group gathering 5 ministries was set up in 2008 aiming at coordinating enforcement actions. In 2009 and 2010, an instruction dealing with the different legislations of chemical products entered into force : o each REACH enforcer works on his/her field : i.e. labour inspector on requirements related to the workers, customs officers on requirements related to importations. The targets of each REACH enforcing authority are the "usual" inspected targets : i.e. an environmental inspector enforces classified plants which manufacture chemical products; o importance placed on the exchange of information between enforcers from different enforcing authorities when a non-compliance case is suspected; o joint inspections and coordinated inspections between REACH enforcers promoted; o enforcement priorities set out by the Instruction and follow Forum projects; and o enforcement will implement, as much as possible, Forum recommendations
IE	• REACH enforced under the Chemicals Act of 2008 which enacts REACH and other EU chemicals legislation; • enforcement strategy developed by CA in 2007; • strategy deals with identification of resources and technical supports, training etc. required for REACH enforcement, types of enterprises likely to be targeted, as well as the overall approach; • strategy is reviewed and updated annually in light of inspection findings from previous year and also taking into account pertinent deadlines, new obligations coming into force, etc. • strategy is informed by the work of the Forum and is underpinned by CAs Strategy Statement; and • strategy incorporated into the various Competent Authority annual work programmes

Table 10.1: Summaries of Enforcement Strategies in line with the Forum	
MS	**Additional Details of Enforcement Strategy(ies)**
IS	• no special strategy has yet been implemented; • an extensive work is now being put into harmonizing chemical inspection and putting together a future strategy; • strategy so far focuses on CA educating chemical inspectors and harmonizing national chemical inspection; • CA is leading a project with the Public Health Authority to harmonise chemical inspection nationally. This project is expected to finish in November 2010; and • a new project on making procedure policy for chemical inspectors will start autumn 2010, with the main focus on REACH
IT	• enforcement strategy agreed October 2009; • strategy incorporates procedures for checking compliance with CLP; • compliance checks are performed in all the steps of the supply chain; • Enforcing Authority has a central pool of inspectors and also hopes to use resources of other national agencies; • CA coordinates a Working Group (WG) for surveillance involving the REACH national enforcement coordinator (Forum member), experts from several Regions and other members actively involved in relevant CA activities. The main aim of the WG is to coordinate enforcement activities nationally; • WG promotes surveillance plans involving the 21 regional enforcing authorities who act through existing territorial units represented by Local Health Boards (ASL) and Regional Environmental Agencies (ARPA); and • training courses specifically for REACH enforcement have been attended by central and by regional inspectors
LI	• no special enforcement strategy implemented; • enforcement is an integrated part of the strategic policy of the enforcement authorities; • enforcement of REACH is included with other activities; • a supervisory function (for the CA?) is planned for the future; • strategy for enforcement is organised into: o planning and preparation (such as description and determination of relevant companies, selection of companies, maintaining of databases and registers, checklists, etc); o performing activities and inspections (monitoring and inspections of enterprises and articles, information policy, case-reports, notification to the police, etc.); and o evaluation (in a kind of follow up of reporting and updating in the national databases and registers, project reports, press releases about legal developments, internal and external information)
LT	• strategy in line with the Strategy devised by the Forum; • some of Forum's 5 principle elements have been already been introduced and applied in daily practice; • enforcement is the constituent part of all chemical legislation enforcement of Lithuania; • national Forum of REACH enforcing authorities meets regularly; • joint inspections are performed and training events are planned for inspectors of all four enforcing authorities; • each enforcing authority is establishing its annual work plan, including REACH enforcement plan, according to the scope and in line with the annual strategy of corresponding ministry; • an annual inspection plan is drawn at the beginning of each year and is complemented by detailed monthly plans; • inspections are performed by specialized chemical inspectors; • on-site inspections are the preferred method of enforcement; • priorities and annual inspection activities are being focused on the Forum's suggestions on essential enforceable requirements; • inspections are being carried out in these general areas: preregistration, registration, SDS, supply chain and use; • current enforcement priorities will be slightly refocused taking into account experience gained, the improved data base of duty holders, the behaviour of each identified target

Table 10.1: Summaries of Enforcement Strategies in line with the Forum	
MS	**Additional Details of Enforcement Strategy(ies)**
	industry group and evaluation of the enforcement gaps identified
LV	• focuses for national monitoring and control of chemical companies : • 2007 – 2009: safety data sheets quality and provision monitoring, corporate information on the chemical pre-registration / registration; and • 2009 – 2010: years - pre-registration / registration requirements and supervision of the requirements for safety data sheets; • criteria for choosing companies: o Latvian offers for sale of dangerous chemicals that are manufactured in this company, and / or imported from third countries amount 1t and more per year; and o Latvian offered for sale for hazardous chemicals in mixtures, mixtures are produced and / or imported in quantities this plant, and / or imported from third countries and the substance per year would be 1t and more
NL	• strategy based on a risk analysis and prioritisation; • impact and probability of non-compliance with the regulations have been prioritised; • target groups identified based on priorities (see above); • strategy consists of a mix of general interventions that apply to all target groups and interventions geared towards the specific features of the target groups based on a staged assessment and T11 pointers; • strategy consists of the following elements: o analysis of the target group; o informative communication to the sector and the companies in it; o announcement and implementation of actions; o (positive) communication of results, emphasising the level playing field; and o using supply chain information for subsequent actions. • mix of enforcement tools to be used, ranging from information and compliance assistance to enforcement and sanctions; • enforcement focuses on the supply chain where possible; • three elements played a key role in determining the activities and the sequence in which they are to be tackled: o the year in which the various REACH articles enter into force; o the priority these articles have been given; and o the scope to gather information on unknown or non-organised businesses earlier or later in the supply chain in specific target groups (supply chain tactics)
NO	• strategy aims: o to protect the environment and human health (Inspection and control are necessary to ensure compliance with the legislation; o to ensure equality before the law (Enterprises which do not comply with the legislation, may enjoy unfair financial benefits. Inspection and control mean equal competition for business and industry); and o to safeguard experience (Control is important for building the competence of the authorities, so that they can make the right demands and choose the right instruments of response); • application of strategy organised into planning and preparation, performing activities/inspections and evaluation/follow-up; • planning activities include: o description/determination of the target group – relevant companies; o selection of companies for audits and inspections; o methods to find them,(history, different national databases & registers); and o make preparations as project plans, checklists, etc. • supervisory activities include: o site inspections and desk table monitoring – relevant internal & external documents available, checklist, etc. o monitoring & inspection of the enterprises (activities, management systems); o inspection of articles, monitoring, analyses, etc. o handling of cases – reports/written orders, coercive fines, withdrawal, notify to the police; and

Table 10.1: Summaries of Enforcement Strategies in line with the Forum	
MS	**Additional Details of Enforcement Strategy(ies)**
	○ common procedures have been established for enforcement activities (including report format and definition of non-compliance) to be followed by all SHE enforcing authorities; • follow up activities include: ○ reporting & updating in the national databases; ○ evaluation & categorisation of the findings; ○ collection of statistics; ○ project reports, press release, internal & external information, etc. and ○ contacts with legal advisors, other authorities, etc. (if problems occur with compliance or regulations)
PL	• control measures are executed by all enforcement authorities in accordance with the annually prepared plans/schemes; • details of strategy can be found in section "2010 Reporting. Inspection and investigation strategy and methodology"; • each year, the members of the national Forum of Inspections select an industry for routine control, as part of the implementation of supervision activities; • compliance of national strategies with the strategy developed by the ECHA is ensured by the presence of the Polish representative in the ECHA's Forum in the work of Polish Forum of Inspections
PT	• 2009: CA developed a communication strategy with 3 different industrial sectors which enabled the identification of compliance behaviour; • 2010: IGAOT is developing a specific inspection report for the REACH inspection as well as REACH guidance for the inspectors; • 2010: project is being developed to establish risk criteria to build a risk assessment for future planning of the REACH inspections; and • 2010 – 2011: CA plans site visits in support of the Forum REACH project for downstream users
RO	• enforcement strategy will be in line with the strategy established by the Forum
SE	• general strategy divided into three processes: planning and preparation, performing activities/inspections and evaluation/follow-up; • process of planning describes: ○ companies concerned; ○ selection of companies for inspections; ○ methods to find them; ○ preparations as project plans, checklists, etc. • process of performing inspections describes: ○ site inspections and letter/mail inspections (not at site) – material to bring, protocols, checklist, minutes, etc. ○ handling of complaints, tip, etc. ○ inspection of articles, monitoring, analyses, etc. ○ handling of cases – verbal or written advice, injunctions, report to police, environmental sanction fees; • process of evaluation/follow up describes: ○ collection of statistics; ○ project reports, seminars, press release, information, etc. ○ contacts with legal advisors, commission, other authorities etc. (if problems with compliance or regulations impossible to comply with); • no special strategy for enforcement has been developed for REACH and enforcement activities are not subdivided into "inspection, investigation, monitoring and other measures"; • a general strategy for enforcement is implemented through a quality and environmental management system (ISO 9001 & ISO 14001); and • Forum strategy enforcement activities are subdivided into "inspection, investigation, monitoring and other measures", as described in the Forum Working Group paper regarding Member States Report to the Commission
SI	• enforcement of REACH integrated with enforcement of other chemicals legislation;

Table 10.1: Summaries of Enforcement Strategies in line with the Forum	
MS	**Additional Details of Enforcement Strategy(ies)**
	• annual plan of inspection prepared each year; • a list of legal and natural persons with authorisation for the production and trade of chemicals or for the use toxic and highly toxic chemicals is used to identify companies; • a list is maintained of legal and natural persons with authorizations; • preparations for inspections focused on the Safety Data Sheets and C&L are based on national data held on chemicals (substances and preparations) on the market classified as hazardous; • site inspections are carried out; and • each year specific actions are prepared the regarding the enforcement of the restrictions and bans on placing on the market certain hazardous substances specially in the articles
SK	• Ministry of Economy (MoE SR) is responsible authority for determining enforcement strategy; • European collaboration assisted strategy development; • strategy based on the creation of a legislative framework involving all relevant inspection and enforcement authorities; • different authorities have different internal structures and activities and have therefore to use their specific strategies; • co-ordination of the authorities involved is ensured by the legislative framework, bilateral co-ordination (e.g. joint inspections), co-ordination by the MoE SR, as well as by the activities of the national coordinator (international inspection projects); • inspectors are specifically trained for REACH; and • nationwide Slovak labour inspection performances were focused on the workplaces where workers may be exposed to dangerous chemical agents to check that employers took action to protect workers as required by chemical OSH legislation and also in terms of safety data sheets. The aim of these inspections was to find that the companies that are manufacturers and importers of chemicals. This procedure was chosen because the **labour inspection departments did not have access to the database of ECHA**
UK	• UK REACH Enforcement Liaison Group (see below for details) has agreed a UK REACH Enforcement Strategy which is about to be published on the internet (www.hse.gov.uk/reach/enforcement.htm); • overall strategy is to create and operate enforcement processes that make best use of the skills of enforcing authorities' staff to secure compliance, using two principal approaches: • the provision of education, advice and help to dutyholders, and the promotion of REACH, as increased awareness and understanding will lead to increased levels of compliance; and • the use of a range of interventions (both proactive and reactive), backed up by formal enforcement where necessary; • principal focus of interventions on those provisions which are most important to enforce in order to make REACH work effectively (as listed in the Strategy document); and • the term "enforcement" is used in a broad sense and encompasses a number of different interventions aimed at securing compliance

Five CAs indicated that their national enforcement strategies were not fully in line with the Forum strategy. The national enforcement strategies described by these five CAs are unique to their MS; details are presented in Table 10.2. It should also be noted that enforcement strategies for Denmark and Hungary are to a large extent in line with that of the Forum, while Estonia indicated that it is working towards producing a strategy in line with the Forum.

Table 10.2: Summaries of the Five Enforcement Strategies not in line with the Forum	
MS	**Enforcement Strategy(ies)**
DK	• no overall national strategy; • each Enforcement Authority devises their own strategy for the enforcement of the regulations for which they are responsible; • all Enforcement Authorities have strategies for their own enforcement activities and the enforcement of REACH is a part of these activities. Therefore, there is no need for a specific strategy for the enforcement of REACH by the Authorities or an overall national strategy for the enforcement of REACH; • some Enforcement Authorities have a strategy for their enforcement activities which is **in line with the strategy devised by Forum** based on risk analysis in order to prioritize enforcement in those areas, where there is most risk of violations of the rules and in areas where the violation can lead to serious risk to health and the environment; and • other Enforcement Authorities have fixed frequencies for the inspections and make inspections of all or part of the duty-holders within their responsibility area within a specific time-period e.g. once a year. This is **not in line with the strategy devised by Forum**, but the prioritization and the focus of the inspections are grounded on a risk based approach
EE	• strategy is not developed and remains at an early stage; • meetings between enforcement authorities are held on regular (once per one or two months) in order to develop a new Chemicals Act with more specified enforcement tasks; • discussions started about the preparation of national enforcement strategy in line with the strategy devised by the Forum and cooperation agreements between enforcement authorities; and • proposals made to prepare cooperation agreements between Health Board and Labour Inspectorate and Health Board and Environmental Inspectorate
HU	• priority setting in each year for enforcers which also covers REACH enforcement that is in line with the strategies prepared by the Forum
LU	• limited resources allotted for enforcement activities; • no specific enforcement strategy developed; and • enforcement activities are mainly reactive and dealt with on a case by case basis
MT	• strategy mostly based on the REACH-EN-FORCE 1; • type of companies inspected chosen on a random basis at the start of the year covering importers, manufacturers and downstream users; and • further inspections carried out during the year to inspect any other company with regards the REACH, as required

10.2.3 National Enforcement Sanctions

The legal structures under which sanctions may be applied vary greatly between countries and reflect the variations in the national legal systems concerned. CAs describe a wide range of enforcement sanctions that are available to them 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 civil and criminal measures available to them. However, some enforcement bodies (e.g. Lithuania) would appear to have only civil

measures available. The punitive measures described are typically preceded by non-punitive measures designed to bring companies into compliance, such as compliance orders coupled with guidance on REACH obligations.

10.2.4 National Enforcement Statistics

The data available for 2007 were fragmentary, with nine of the twenty-seven EU MS (BE, CZ, FR, HU, IT, LU, MT, PT and UK) stating that the questions asked for the year 2007 were not applicable. Furthermore, it should be noted that EEA countries did not implement REACH until 2008.

10.3 Enforcement Interaction with other Bodies

10.3.1 Enforcement Referrals from ECHA

With one exception, CAs indicate that they have not received enforcement referrals from ECHA. The UK CA describes receiving several referrals concerning UK legal entities that had created multiple party IDs in REACH IT and used these to pre-register a large number of substances. It appears that the basis for the concern expressed by ECHA was that these legal entities had been created specifically to exploit the opportunities which pre-registration presents to gain access to commercially valuable information.

10.3.2 Enforcement Referrals from other Countries

Ten CAs reported receiving enforcement referrals from other MS. However, in each case these were few in number, as shown in Table 10.3.

Table 10.3: 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
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 National Enforcement Communication and Cooperation

Where the CA and the enforcement authority are not one and the same, the most common mechanism used to share information within the MS is the organisation of regular but infrequent (e.g. Austria has two per year) meetings between CAs and national enforcement agencies to facilitate communication and cooperation. As a general rule, the arrangements for holding these meetings have been formalised at a national level involving mandatory and voluntary information sharing. It is also likely that further formal and informal meetings and other communications (e.g. emails) may occur between operational staff of CAs and enforcement agencies, as described by the CAs of Denmark and Malta.

Furthermore, CAs tend to provide oversight to the activities of the enforcement bodies and provide them with training.

10.3.4 Effectiveness of the Forum

Ten CAs commented on the functionality of the Forum, with four making strongly favourable comments including that it was well organised by the Secretariat and had been very effective. The issues raised by other CAs essentially constituted suggestions as to ways that its performance might be improved still further as set out in Box 10.1.

Box 10.1: Comments by CAs on Improving Effectiveness of Forum

Comments made relevant to improving the effectiveness of Forum included:

- shortening of the review period for draft minutes;
- increasing MS resource provision since this has limited the Forum's ability to undertake some projects; and
- improving communication and coherence between the Forum and CARACAL.

A further concern identified was the anomalous role played by the MS representative to the Forum since this role was felt to be open to confusion or misinterpretation. REACH foresees the representative as attending as a nominee of a national government – which would suggest they were intended to act as nominated but independent member – yet they have also assumed the role of representative for the nominating MS. Their status/remit within Forum is therefore considered unclear and it was suggested that consideration should be given to clarifying their position during review of the regulation. It was suggested that, for the time being, the situation would be eased if ECHA were to adopt a more flexible attitude and, for example, accept that a Representative from a CA, even if not the countries nominee in the committee, could send comments, answer written consultations, etc.

10.3.5 Effectiveness of SON

Only three CAs - Belgium, Sweden and Norway - made specific comments on the Security Officer Network (SON). However, these were somewhat critical in nature and are set out in Box 11.2.

Box 11.2: Comments by CAs on SON

It was noted that SON was initially active – though rather slow to start - on issues such as information availability for MS, Reach-IT and security issues; this was attributed to ECHA resources having been overloaded. Although most technical Reach-IT issues were recognised as now being resolved, this was not to schedule and had resulted in negative impacts on the ability of MSs to prepare for Reach-IT and related security issues. One CA highlighted a failure to communicate to Member State Security Officers the discussions/decisions of other fora (including some considered as not according with the overall strategy). This had complicated the process of development and ratification of Standard Security Requirements. It was further suggested that there had been a failure to meet Mission requirements under the Terms of Reference.

Although now meeting only twice yearly, it was noted that agendas now mostly comprised presentations (sometime repeating previous given information) and status reports by ECHA. Also, discussion time was limited and generally involved only few Member States. Suggestions to improve the situation were limited and included:

- papers should be circulated to members well in advance of meetings to allow adequate time for review; and
- SON officers should be notified of all decisions in relation to security and better linkage to communications and decisions by CARACAL established

10.4 Enforcement Statistics

10.4.1 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, as set out in Table 10.4.

Table 10.4: Inspections and Investigations in which REACH was Discussed or Enforced

Year	Number of Responses	Number of Inspections and Investigations per CA			Number of Inspections or Investigations across EU and EEA
		Maximum	Mean	Minimum	
2007	18	15,654	1,952	14	35,141
2008	28	22,500	2,115	0	57,115
2009	28	25,700	2,710	2	73,178

All CAs except those representing Italy and Luxembourg provided data that were used to construct Table 10.4. However, there was a very high degree of variation between different MS with Germany, Denmark and Poland undertaking tens of thousands of such actions per year, some MS, such as Iceland, Portugal and Malta undertaking less than ten, while other MS such as the United Kingdom, Sweden and Austria reported undertaking less than five hundred such actions, as displayed in Figure 10.2.

From the information described here, it would appear that MS use inspections and investigations in very different ways within their overall enforcement strategies. It is

also likely that different MS had differing interpretations of the phrase in the question "in which REACH was discussed or enforced".

A range of questions follow-on from that described above which ask for the numbers of different types of duty holder that have been the subject of inspections or investigations. However, given the established lack of consistency between answers from different MS as well as the lack of consistency between them with regard to their understanding of the phrase "duty holder" as discussed in Section 4.3, robust statistical analysis could not be undertaken using the data provided.
Attempts were made to understand the level of inspections/investigations compared to the size of national chemical industries. In order to do this metrics of national chemical industry size were sought. The Eurostat Prodcom database[7] holds data on the production of chemical goods for 2007, 2008 and 2009 in terms of value, sold volume and total volume. These Prodcom data cover the EU27 states, plus Croatia and the EEA countries Iceland and Norway but not Lichtenstein. However, data for many chemical product types have not been provided by many countries or such data have been provided to Eurostat but is considered confidential and so is not published. Such Prodcom data could not therefore be used to analyse the data set out in Figure 10.2.

[7] Published on the European Commission Internet site (http://epp.eurostat.ec.europa.eu/portal/page/portal/prodcom/data/tables_excel)

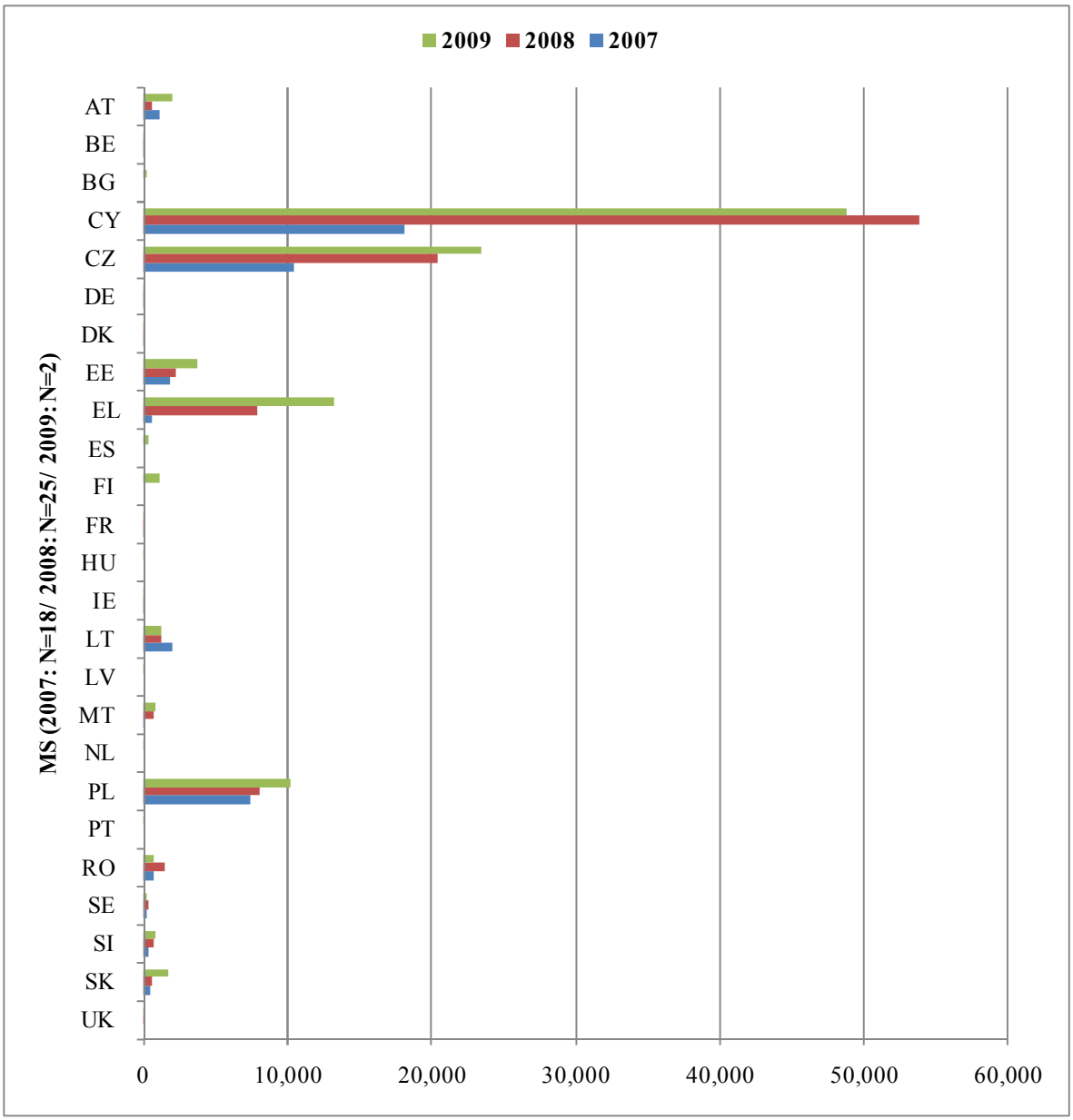

Figure 10.2: Number of Inspections or Investigations in which REACH was Discussed or Enforced

The European Chemical Industry Council (CEFIC) publish data on chemical industry sales by EU MS[8], as set out in Table 10.5.

[8] Published on the European Chemical Industry Council Internet site (http://www.cefic.org/Facts-and-Figures/Profile-of-the-Chemical-Industry/EU-chemical-industry-sales-by-geographic-breakdown/)

Table 10.5: EU Chemical Sales by Geographical Breakdown	
MS	**Percentage of Total Chemical Industry Sales**
	% Total
DE	25.5
FR	15.1
IT	9.7
UK	9.7
NL	8.4
ES	7.5
BE	7.1
IE	6.0
PL	2.1
SE	1.4
AT	1.4
FI	1.3
CZ	1.1
DK	1.1
PT	0.7
Others	2.9
Source: European Chemical Industry Council Internet site (http://www.cefic.org/Facts-and-Figures/Profile-of-the-Chemical-Industry/EU-chemical-industry-sales-by-geographic-breakdown/)	

These CEFIC data do not include EEA states but represent the most complete relevant data set publically available.

Had the data provided by CAs been sufficiently consistent (see discussion above) the number of inspections or investigations undertaken per MS could have been divided by the percentage national share of EU chemical industry sales set out in Figure 10.2. These figures would have provided an approximate representation of the relative activity of MSs compared to the size of their national chemical industries.

CAs were also asked to indicate whether inspections or investigations were primarily focused on companies that were small, medium-small, medium or large companies. These data are assumed to be consistent for all responding CAs[9] and are set out in Table 10.6.

[9] 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, however this could not be verified from the data provided by CAs.

Table 10.6: Company Size Focus of Inspections and Investigations												
Type of Duty Holder	**2007**				**2008**				**2009**			
	Company Size				**Company Size**				**Company Size**			
	S	**S-M**	**M**	**L**	**S**	**S-M**	**M**	**L**	**S**	**S-M**	**M**	**L**
Manufacturers	5%	50%	30%	15%	14%	50%	23%	14%	10%	71%	5%	14%
Importers	14%	36%	36%	14%	14%	50%	23%	14%	11%	74%	5%	11%
Distributors	0%	68%	16%	16%	0%	68%	16%	16%	0%	94%	0%	6%
Downstream Users	14%	45%	27%	14%	14%	50%	23%	14%	21%	63%	5%	11%

Considering the most recent data available (for 2009), it is clear that the main focus for inspection activities has been small-medium sized companies (see Figure 10.3) and that the proportions of each size of company inspected was similar across manufacturers, importers and downstream users. The inspection pattern for distributors has, however, been largely focused on small-medium sized operations with only a few other large companies having been subject to inspection.

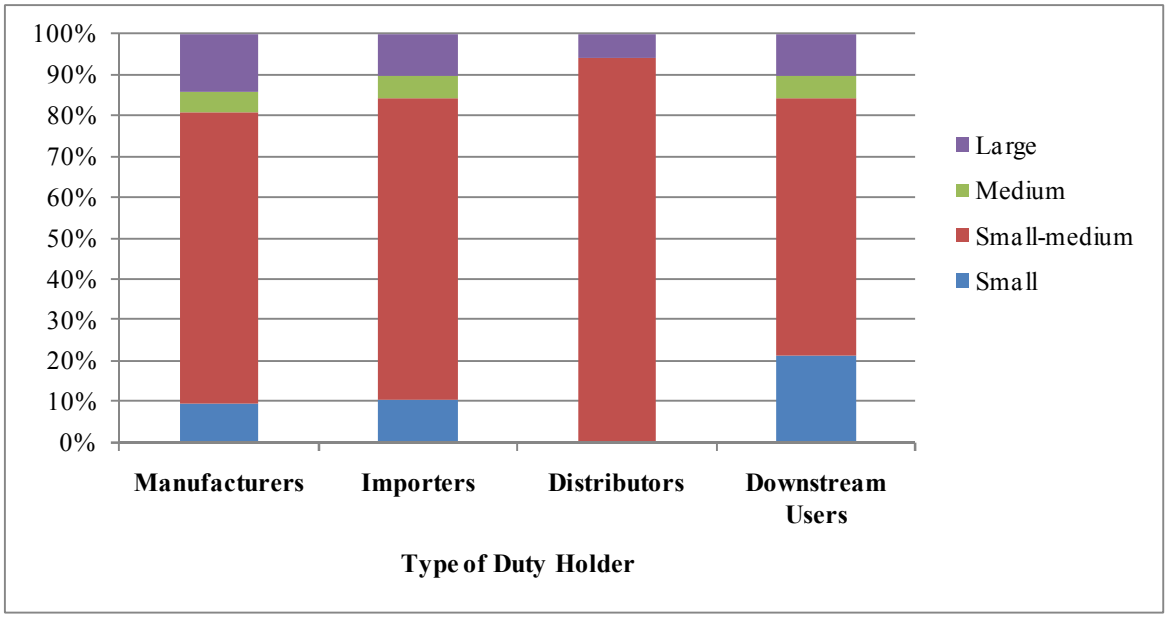

Figure 10.3: Percentage of Inspections conducted during 2009 by Company Size and Type of Duty Holder

The European Chemical Industry Council (CEFIC) publish data for 2009 on the size distribution of chemical companies in terms of percentage number of companies, sales and employment, as reproduced in Figure 10.5[10].

[10] Reproduced from chart published by European Chemical Industry Council (CEFIC), Available from (http://www.cefic.org/Facts-and-Figures/Profile-of-the-Chemical-Industry/EU-chemical-industry-number-of-enterprises-sales-and-employment-by-size-class/).

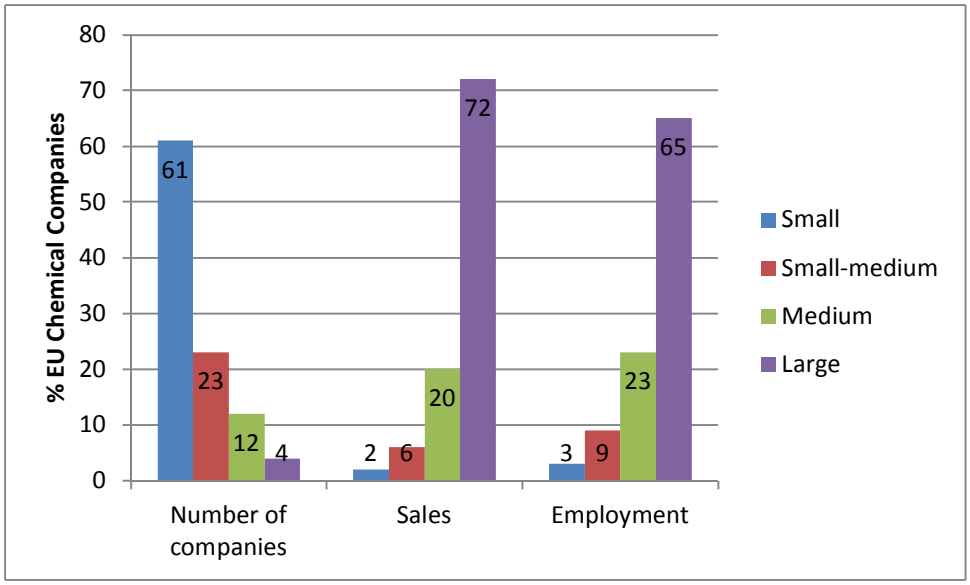

Figure 10.4: EU Chemical Industry Statistics by Company Size (2009)

From Figure 9.4 it can be seen that small-medium sized companies represent twenty three percent of all companies, six percent of EU sales and nine percent of employment by the chemical industry. Therefore, the very high percentage of inspections of small-medium sized companies shown in Figure 10.3 does not correspond in any way with the profile of such companies shown in Figure 10.4.

10.4.2 Formal Enforcement Actions

CAs were asked for data on the number of formal enforcement actions undertaken during 2007, 2008 and 2009 involving different types of duty holders. Tables 9.7 to 10.9 set out this data for 2007, 2008 and 2009 respectively.

Table 10.7: Formal Enforcement Actions in 2007 Involving Different Types of Duty Holder

Type of Duty Holder	Number of Enforcement Actions (per CA)				Total Number of Enforcement Actions across EU and EEA
	Number of Responses	Maximum	Mean	Minimum	
Manufacturers	11	51	11	0	125
Importers	11	92	19	0	212
Distributors	11	2,500	308	0	3,391
Downstream Users	11	2,500	417	0	4,585

Table 10.8: Formal Enforcement Actions in 2008 Involving Different Types of Duty Holder

Type of Duty Holder	Number of Enforcement Actions (per CA)				Total Number of Enforcement Actions across EU and EEA
	Number of Responses	Maximum	Mean	Minimum	
Manufacturers	13	76	11	0	147
Importers	13	42	11	0	139
Distributors	13	381	65	0	843
Downstream Users	13	6,500	765	0	9,949

Table 10.9: Formal Enforcement Actions in 2009 Involving Different Types of Duty Holder					
Type of Duty Holder	**Number of Enforcement Actions (per CA)**				**Total Number of Enforcement Actions across EU and EEA**
	Number of Responses	**Maximum**	**Mean**	**Minimum**	
Manufacturers	21	300	25	0	528
Importers	21	142	17	0	367
Distributors	20	1357	138	0	2,752
Downstream Users	20	6,500	521	0	10,413

From Tables 9.7 to 9.9, it can be seen that the number of formal enforcement actions undertaken varied greatly between MS. The reasons for this are not clear. However, it may reflect the varying emphasis placed on direct enforcement in the different national REACH enforcement strategies (see Section 10.2). It is also possible that at least some of the variation may be due to inconsistencies in the interpretation of the nature of "duty holders" and of the phrase "formal enforcement action", similar to the inconsistencies discussed in Section 10.4.1.

There is some evidence from the manner in which answers were provided that the increase in the number of responses from 2007 to 2009 may in some cases reflect CAs beginning to undertake formal enforcement actions for the first time. It would also appear that the greatest number of enforcement actions was directed towards downstream users, followed by distributors. However, there was a large degree of variation between CAs in this respect.

A range of questions ask for the numbers of different types of duty holder that have been the subject of enforcement actions. However, given the lack of consistency between answers from different CAs, as discussed above, as well as the lack of consistency with regard to their understanding of the phrase "duty holder" as discussed in Section 4.3, meaningful statistical analysis could not be undertaken using these data.

As for investigations, CAs were also asked to indicate whether enforcement actions were primarily focused on small, medium-small, medium or large companies. These data are assumed to be consistent for all responding CAs[11] and are set out in Table 10.10.

Table 10.10: Focus of Enforcement Actions in relation to Company Size												
Type of Duty Holder	**2007**				**2008**				**2009**			
	Company Size				**Company Size**				**Company Size**			
	S	**S-M**	**M**	**L**	**S**	**S-M**	**M**	**L**	**S**	**S-M**	**M**	**L**
Manufacturers	5%	25%	55%	15%	5%	30%	50%	15%	21%	57%	0%	21%
Importers	0%	32%	53%	16%	5%	30%	50%	15%	13%	73%	7%	7%
Distributors	10%	29%	48%	14%	10%	19%	57%	14%	31%	62%	0%	8%
Downstream Users	5%	30%	50%	15%	10%	29%	48%	14%	25%	67%	0%	8%

[11] Based on the assumption that CAs understood the company size categories listed to be equivalent to the micro, small, medium and large size companies as defined by Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (2003/361/EC).

From Table 10.10, it can be seen that for the years 2007, 2008 and 2009 approximately eighty to eighty-five percent of enforcement actions involved SMEs. In 2007, the majority of enforcement actions were taken against medium sized companies. This was also the case in 2008 but with a greater proportion of small to medium sized companies. However, in 2009, small to medium sized companies were by far the greatest focus of enforcement actions, followed by small companies (see Figure 10.5).

When compared to the pattern of inspection evident from Figure 10.3, it can be seen that the main focus for both inspection and enforcement was small-medium sized organisations, with actions being taken on medium-sized companies only amongst importers. Interestingly, although enforcement actions were reported for a number of cases involving small distributors, no inspection activity was reported as having been undertaken.

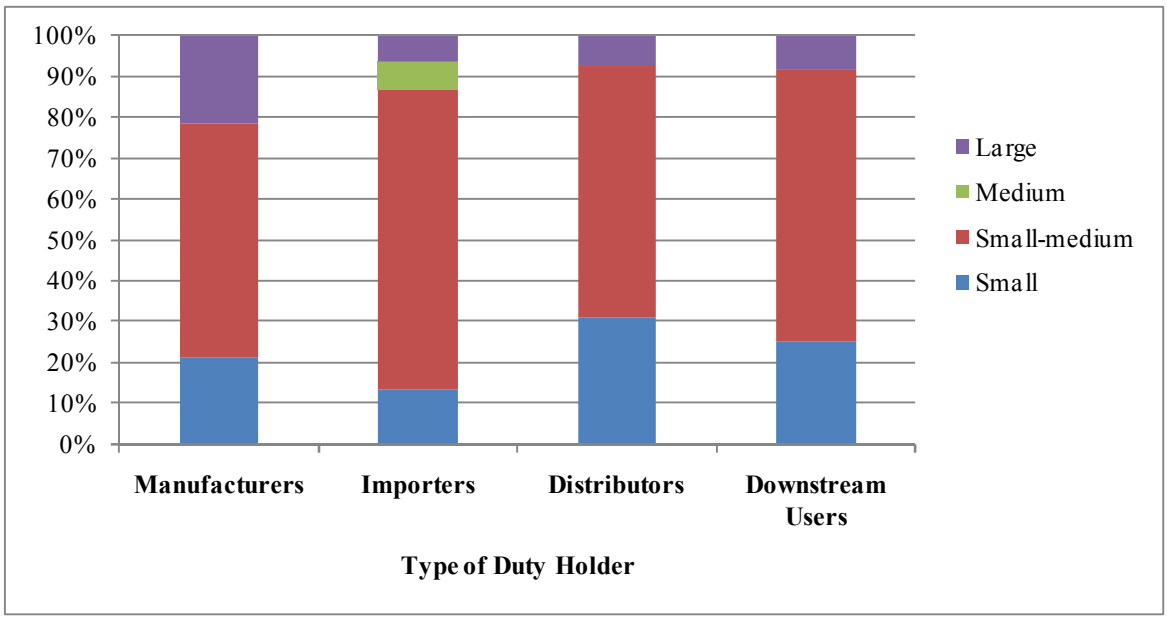

Figure 10.5: Percentage of Enforcement Actions during 2009 by Company Size, for various Industry Sectors

No correlation can be seen between the percentage of enforcement actions shown in Figure 10.5 and the number of companies, sales and employment represented by chemical companies of different sizes shown in Figure 10.4.

10.5 Further Enforcement Comments

The Austrian CA stated that the lack of direct access for enforcement authorities to REACH-relevant data at ECHA constitutes a major obstacle in the efficiency of planning and control actions. This comment was supported by the Danish CA which stated that "**as long as there is no secure electronic information exchange system to enable the inspectors to follow up on OR´s in other MS, it is difficult for the inspectors to verify if the substance has, in fact, been registered by the OR**".

Slovakia commented that inspections had been carried out to find the companies that are manufacturers and importers of chemicals because the "**labour inspection departments did not have access to the database of ECHA**" (see Table 10.1).

To allow it and other CAs to ensure that they have the required enforcement data available, the Polish CA stated that it is important that full details of all aspects of reporting expectations are provided by ECHA at least one year in advance.

11. GUIDANCE AND SUPPORT

11.1 CA Helpdesks

11.1.1 Helpdesk Organisation and Resources

All CAs manage their REACH helpdesks internally **except the Netherlands**, where the Helpdesk function is undertaken by the National Institute for Public Health and the Environment (RIVM).

Figure 11.1 sets out the number of staff available for the helpdesk facility of MS and includes data relating to the activities of RIVM on behalf of the CA for the Netherlands.

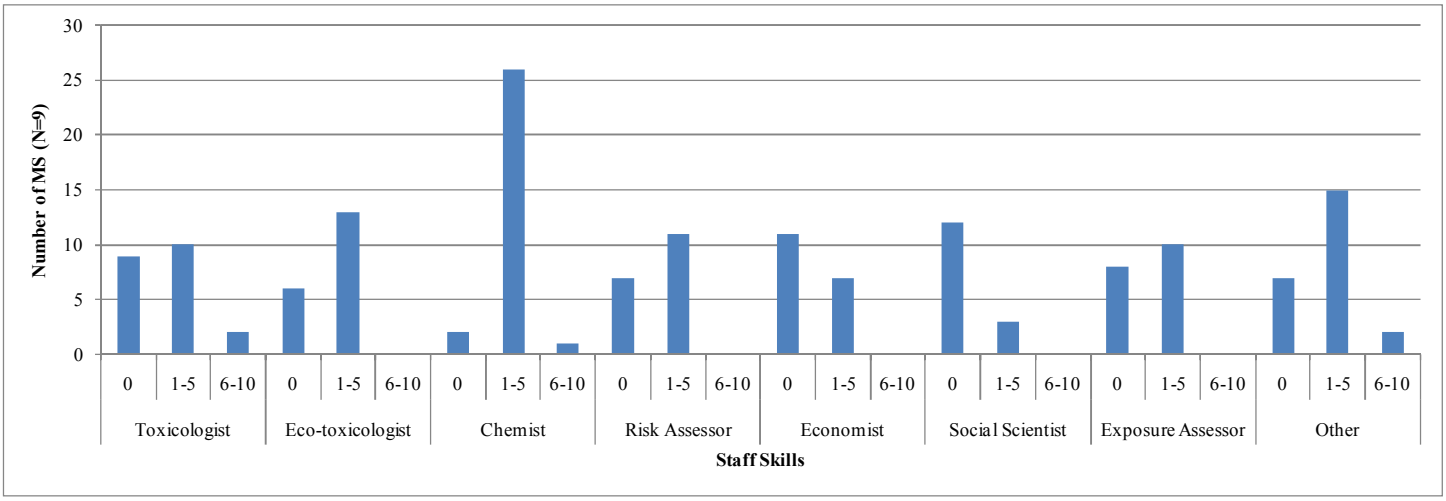

Figure 11.1: Staff Skills Available to Helpdesks

Details of the "Other" staff skills named by CAs as being available as part of their helpdesk are listed in Table 11.1.

Table 11.1: "Other" Staff Skills Available to Helpdesks

Staff Skills	Number of CAs with Staff Skills
Legal Advisors	9
IT experts	7
Environmental scientists	5
Biologists and biochemists	4
Risk managers	3
Inspectors	3
Occupational hygienists	1
Geologists	1

Slovakia has indicated that its response provides an over-estimate of helpdesk staff capacity as individual staff may each provide several of the skill sets reported. It is possible that this comment may apply equally to the responses from other CAs. Furthermore, it was reported that the entire CA staff of the Netherlands and Poland are available to support the helpdesk, if required.

Six CAs (BE, DK, ES, MT, PL and NO) indicated that they outsourced at least some helpdesk enquiries. Where explanation was provided, it was reported that some outsourcing was for subject areas not covered by the REACH helpdesk, such as CLP, or for more complex subjects where the support of other staff from other government departments or CAs from other MS would be sought. In addition, the CA for Italy can draw upon the support of consultants where required, e.g. for toxicology or ecotoxicology advice.

Figure 11.2 sets out the means by which national REACH helpdesks may be contacted and which of these are most utilised (responses were received from **all thirty CAs**). However, Norway indicated outside of the IPM tool that the majority of its enquiries arrived by both telephone and email.

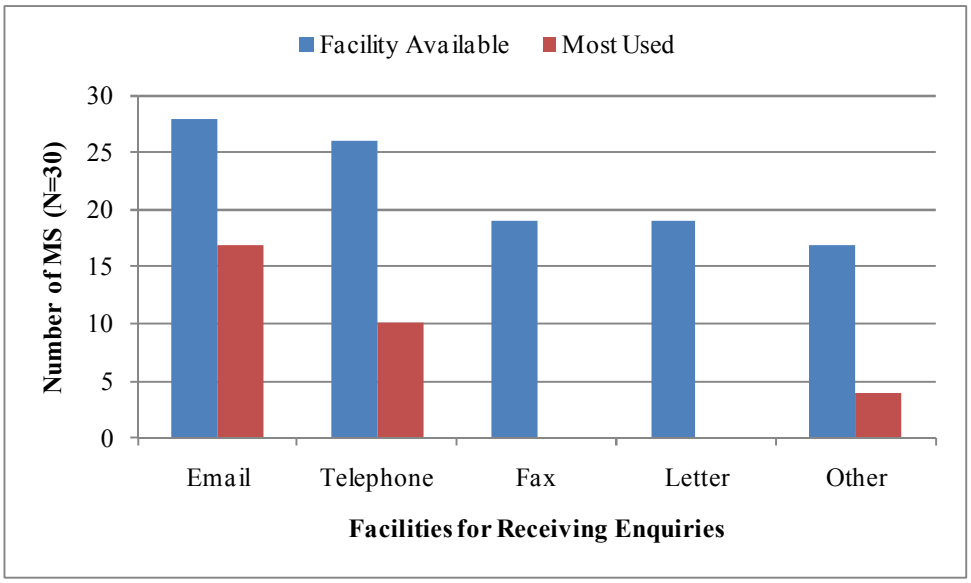

Figure 11.2: Means by which Helpdesks may be Contacted and their Popularity

"Other" means of contacting helpdesks reported were: face-to-face meetings (usually by appointment only); seminars/workshops/conferences; and web-based registration/enquiry facilities. In each case where helpdesks received most of their enquiries via "other" means, these enquiries were via a web-based enquiry facility.

Twenty-one national helpdesks (from thirty CA responses) seek feedback on their performance and twenty-six of helpdesks review their performance and consider ways to improve effectiveness (from twenty-eight CA responses).

Twenty-two of the national REACH helpdesks also handle enquiries relating to CLP. No helpdesks receive funding from outside of national governments. Eighteen helpdesks provide specific advice to SMEs.

11.1.2 Helpdesk Activities

REACH Article 124 requires countries to:

> *'establish 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 of substances in accordance with Article 12(1), in addition to the operational guidance documents provided by the Agency under Article 77(2)(g)'.*

The number of enquiries received by these helpdesks can vary significantly, as set out in Figure 11.3. **All CAs answered this question.**

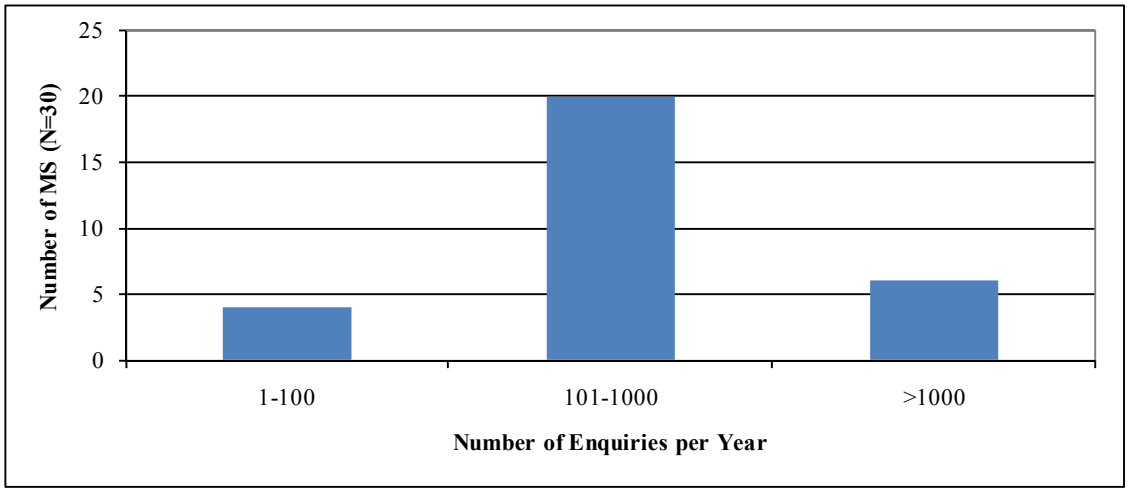

Figure 11.3: Approximate Number of Helpdesk Enquires per Year

Estonia, Malta, Liechtenstein and Iceland each received between one and one-hundred enquiries per year, Germany, Finland, France, the Netherlands, Sweden and the United Kingdom received over one thousand enquiries per year and the remaining twenty MS received enquires somewhere between these figures.

All MS provided data on the percentage of helpdesk enquiries for specific subjects named in the reporting questionnaire. The percentages for each subject have been averaged for all CA helpdesks and set out in Figure 11.4.

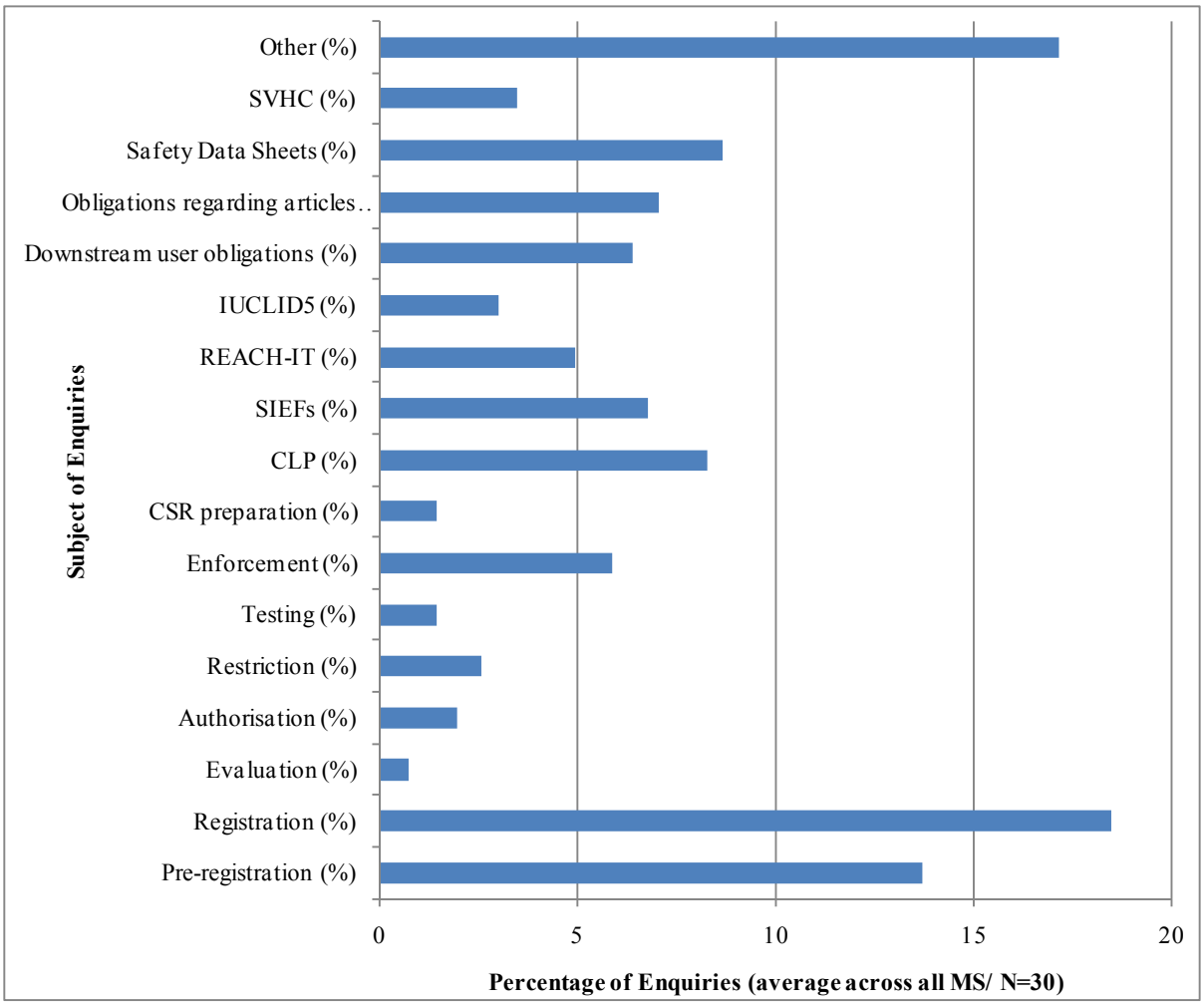

Figure 11.4: The Percentage Helpdesk Enquiries on the Subjects Specified

From Figure 11.4, it can be seen that the greatest number of enquiries related to registration or pre-registration. A high percentage of helpdesk enquiries also related to "other" subjects, which have included:

- waste;
- scope of REACH;
- exemptions from registration requirements;
- national penalties;
- substance identification;
- monomer / polymer import;
- only representative responsibilities; and
- legal advice.

Figure 11.5 displays the size of companies making the majority of enquiries (all responding CAs answered this question).

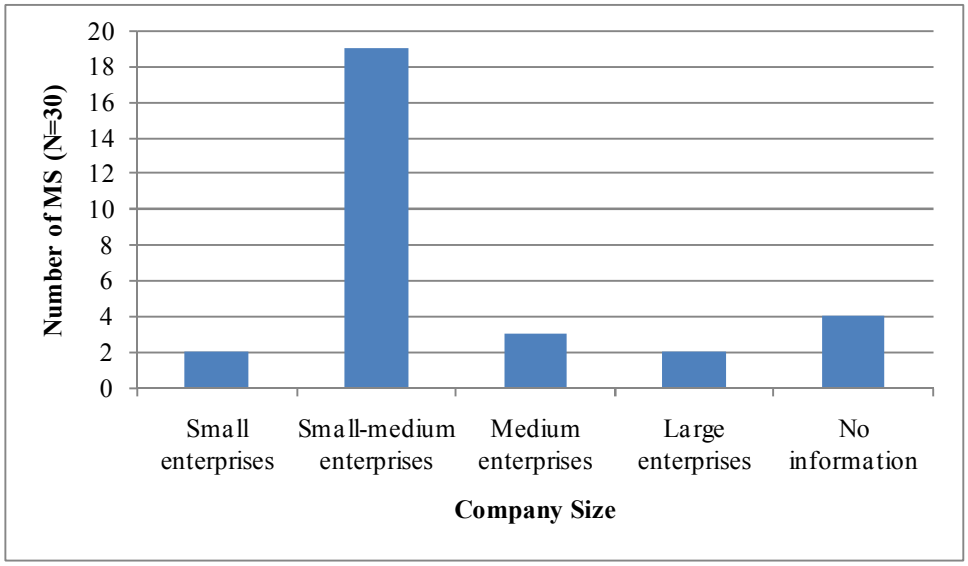

Figure 11.5: Size of Companies Making the Majority of Enquiries

From Figure 11.5, it can be seen that the majority of enquiries were from small-to-medium sized enterprises. However, no definition of what constituted an enterprise falling within each of the above categories was provided (although it is likely that most respondents are familiar with the general size breakdowns for the different categories).

Twenty-seven CAs were able to provide data on the percentage of enquiries that were "complex" and the percentage that were "straight forward". Using these data, 64% of enquiries were considered to be straight forward and 36% were considered to be complex.

Figure 11.6 sets out the average response times for straight forward and complex enquiries respectively (all thirty respondent CAs provided data).

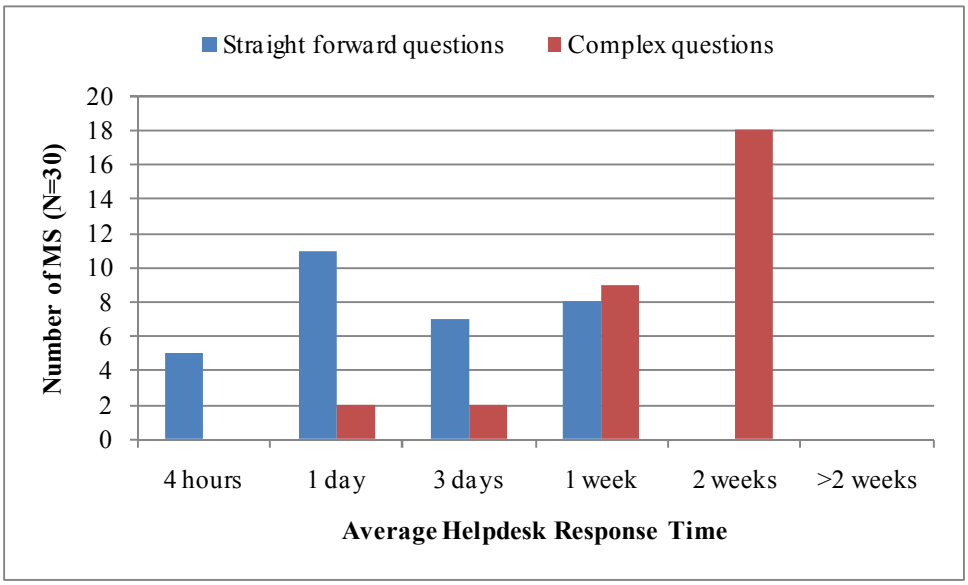

Figure 11.6: Average Response Times for REACH Helpdesks

From Figure 11.6, it can be seen that, on average, straight forward enquiries received a response within one week (and often within a day) while complex enquiries were dealt with within two weeks.

11.1.3 Cooperation between MS Helpdesks

Figure 11.7 sets out the scores awarded by CAs for the level of cooperation between helpdesks within and outside of the REACH Helpdesk Correspondents' Network (REHCORN, now renamed Helpnet) (where 1 is low and 5 is high). All thirty CAs provided a response.

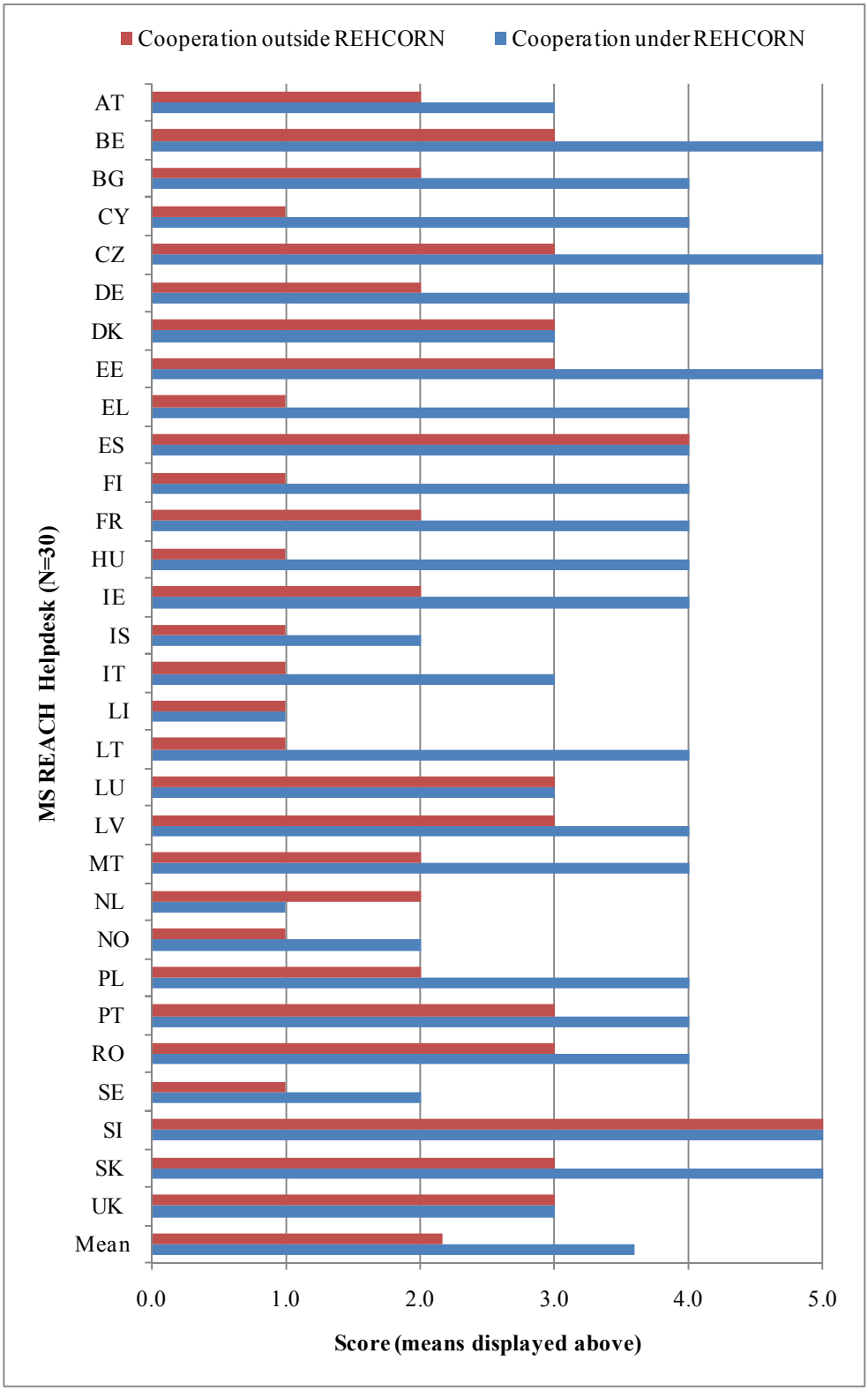

Figure 11.7: Level of Cooperation between National REACH Helpdesks

From Figure 11.7 it is clear that, for the majority of CAs, the level of cooperation within REHCORN (mean level 3.6) was significantly greater than the level of

cooperation outside of REHORN (mean level 2.2). No CA felt that the level of cooperation was greater outside of REHORN but six CAs felt that there was no difference (DK, ES, LI, LU, SI and UK). No clear geographical or political similarity was apparent between the MS represented by these six CAs.

Figure 11.8 sets out the frequency with which helpdesks make use of the REACH Helpdesk Exchange Platform (RHEP).

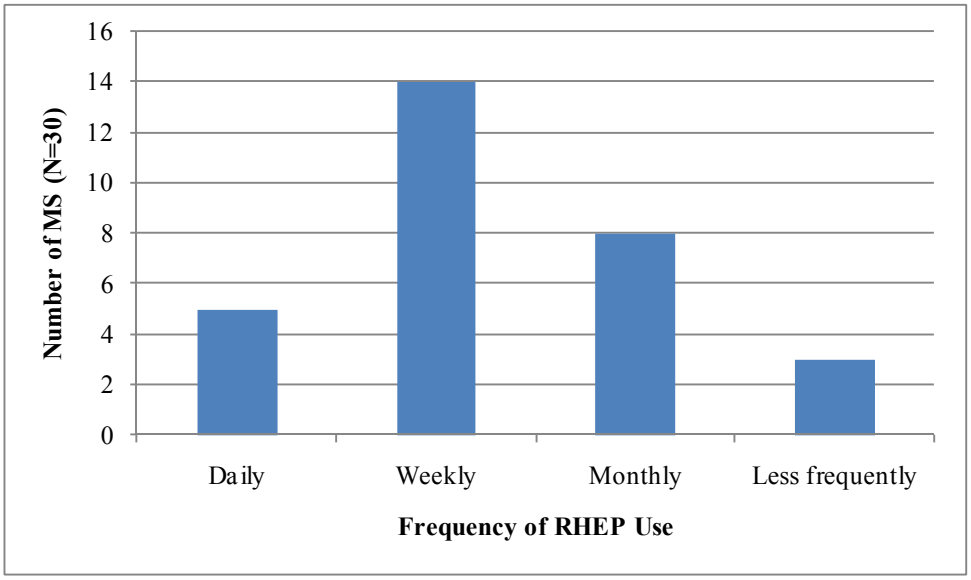

Figure 10.8: Frequency with which Helpdesks use RHEP

From Figure 11.8 it can be seen that nineteen of the thirty helpdesks make use of RHEP at least weekly. REHCORN received specific comments by eight CAs but no comments were made solely relating to the REACH Helpdesk Exchange Platform (RHEP, now renamed HelpEx). Based on many of the comments from CAs, the underlying concern about REHCORN is the inefficiency of the current practices.

11.1.4 Effectiveness of RHEP and REHCORN

CAs were able to provide a number of suggestions that may improve the performance and effectiveness of RHEP and REHCORN, as set out in Box 11.1.

Box 11.1: Comments by CAs on Improving Effectiveness of RHEP and REHCORN

Suggestions made by CAs relevant to improving the performance or effectiveness of RHEP and REHCORN included:

- making all presentations available via Circa in advance of meetings to facilitate meeting discussions;
- streamlining of procedures and increased Commission support on difficult issues;
- agendas should give more time for discussion and exchange of opinion and there should be less emphasis on formal procedures (A particular emphasis should be given to discussing generic

questions relating to the RHEP (HelpEx) database while statistical presentations about helpdesks should be brief and less detailed);

- number of members participating in discussions should be increased by, for example, use of break-out groups;
- seek to adopt alternative training and dissemination approaches (e.g. webinars, teleconferences);
- improve speed of reaching agreement at meetings by adoption of majority voting to stop blocking by individual parties;
- revise the FAQ process by adoption of the assumption that a lack of response indicated agreement with a proposal; and
- improve the level of human resources available to MS helpdesks and seek to improve cooperation between MS Helpdesks outside of the REHCORN (Helpnet) structure

11.1.5 Awareness Raising Activities

CAs were asked to identify awareness raising activities that they had undertaken, with their responses detailed in Figure 11.9. CAs were then asked to rate the effectiveness of these activities using a score of between 1 and 5 (it is assumed that 5 corresponds to a very effective and 1 corresponds to not effective), as set out in Figure 11.10. All CAs provided a response, except Latvia.

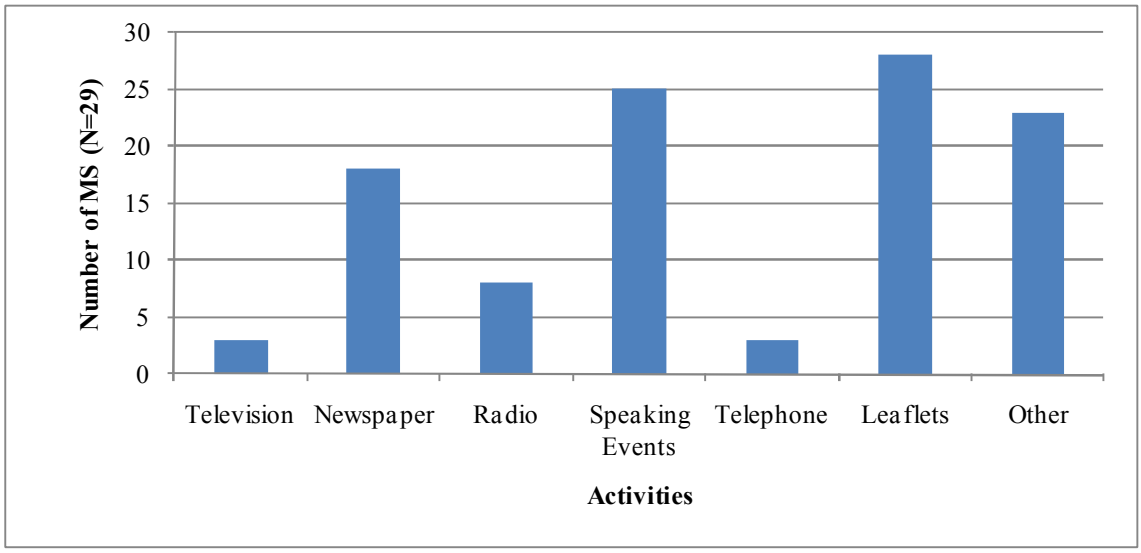

Figure 11.9: Awareness Raising Activities Undertaken by CAs

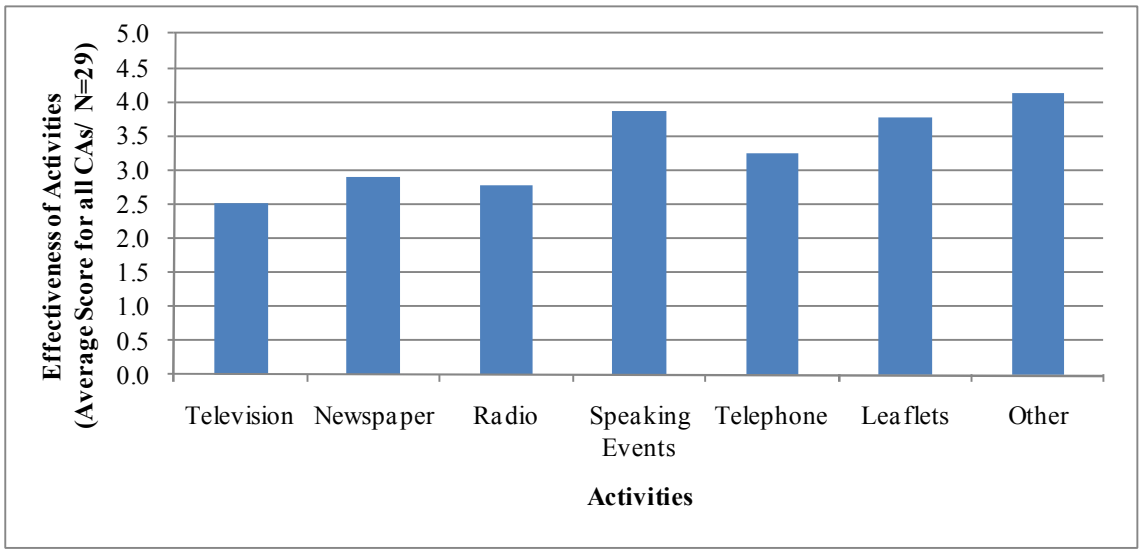

Figure 11.10: Effectiveness of Awareness Raising Activities by CAs

The "other" activities undertaken by CAs may be summarised as:

- 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.

In general, CAs employed a range of awareness raising activities with the greatest level of activity centred around the entry into force of REACH. From CA comments on "other" activities, it would appear that activities focused on reaching key stakeholders and on their concerns were considered to have been particularly effective. Furthermore, from the phrasing of some of these comments, it is likely that this observation applies to those activities specifically identified in the reporting questionnaire (activities presented in Figures 11.9 and 11.10). Comments also included mention of the importance of CA and Helpdesk websites for awareness raising.

11.1.6 CA Websites

All respondent CAs, except those for Austria and Greece, have a REACH specific website or webpages. Ten of these CAs have single REACH webpages and the remaining eighteen have multiple such webpages.

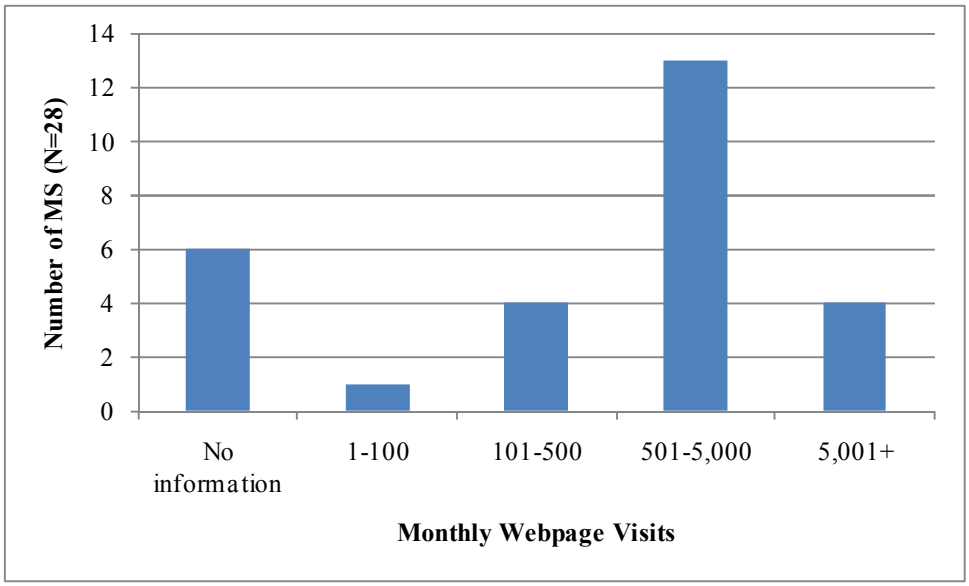

Figure 11.11: Frequency of Visits to CA Webpages

Of the reported usage of webpages (Figure 11.11), 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 record the number of visits to their webpage/s may have received equally low numbers of visits. The five MS whose websites were receiving more than 5,000 visits per month were Germany, Italy, Poland and the United Kingdom.

When asked to "Please describe the scope of the number of REACH webpage visits":

- ten MS (BG, DE, FI, IE, IS, IT, LT, LU, NO and SE) provided some statistical data which varied from data on one metric (e.g. visits per month (IS)) to a more thorough breakdown of the number of visits, e.g. per month, per day etc. (SE);
- eight MS provided some qualitative information only (CY, CZ, DK, EE, HU, PL, PT and UK); and
- twelve MS (AT, BE, ES, FR, EL, LI, LV, MT, NL, RO, SI and SK) either provided no information or indicated that they do not record this information.

In respect of the scope of the visits received, a general point made by CAs was that individual webpages often contained information about a range of topics. Hence, records of the number of times webpages were accessed would not necessarily inform on the specific interest of the visitor.

Introductory or summary pages were those visited most often. However, many such visitors may have been using these pages merely as a means to reach other more detailed pages. It is likely that many were looking for simple guidance and this view is supported by the statement from the UK CA that the host page for its simple guidance leaflets was the most popular on its site and the comment by the Swedish CA that after its introductory page the most visited webpage was "This is REACH – a short description of REACH". 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.

11.2 REACH Guidance Documents

11.2.1 Effectiveness of PEGs

One CA reported that they had not actively participated in Partner Expert Groups (PEGs) up to this point, while Hungary considered that these were well organised and the Belgium CA was generally supportive although with some reservations. However, a number of CAs made suggestions of ways to improve PEGs, as set out in Box 11.3.

Box 11.3: Comments by CAs on PEGs

While noting that ECHA appeared to have been generally effective in managing the process, a number of CAs suggested that experience had shown that the performance of individual PEGs was variable. A number of specific suggestions were offered as to ways to improve this:

- in some cases, longer duration meetings and/or use of teleconferencing or other communication media may improve efficiency and the level of input;
- the process of consultation, particularly in the latter stages, is unclear and may involve imposition of unrealistic deadlines for commenting raising concerns as to the extent to which the final output is supported by the PEG; and
- the PEG consultation stage should move to an earlier stage of document development

12. REACH AIM: PROTECTION OF HUMAN HEALTH

12.1 REACH Article 129

Only Estonia and Italy indicated that they had made use of the safeguard clause of REACH Article 129.

Italy reports taking action to ban the manufacture, use, import or placing on the market of alkyl nitrite compounds between 19 November 2009 and 19 November 2010.

From its detailed response, it appears that the Estonian entry under the article 129 question relates to the activities of the Tax and Customs Board in stopping suspected chemicals and article on the border for further investigation (conducted under regulation 339/93/EC until January 2010). The products thus affected were: asbestos-containing cord and seal from Russia in 2007 and 2008; toluene-containing aerosol paints from the USA in 2009; and dibutylphthalate-containing nail glue from Korea in 2009. Estonia also states that the Estonian Health Board and Consumer Protection Board continues to make regular use of the RAPEX to provide information to support inspectors in their organisation of control activities on Estonian market.

12.2 Effectiveness of REACH for the Protection of Human Health

With the exception of Italy, all CAs felt the effectiveness of REACH for the protection of human health was best assessed at the level of the EU rather than at a national level.

CAs were also asked "*What parameters are available at MS level that could be used to assess the effectiveness of REACH in a baseline study?"* The nature of the answers provided varied greatly between CAs, with CAs providing the following range of responses (often in combination):

- statements that they did not understand what the question required of them;
- comment on the appropriateness of assessment of REACH at EU rather than national level or on the interplay between assessment at both levels;
- discussion of how to determine appropriate and measureable metrics, particularly with regards to the protection of human health and the environment;
- suggestions of potential metrics that could form part of the baseline, with some including reference to other studies such as the Eurostat Baseline Study and a baseline scoping study undertaken on behalf of the UK CA;
- suggestions that any data requests be harmonised at the EU level; and
- details of the data (parameters) that would be available at national level that could be used to assess the effectiveness of REACH (general and more detailed responses received).

Table 12.1 sets out the information provided by CAs on the availability of national data (parameters) for the assessment of the effectiveness of REACH.

Table 12.1: National Data Available for an Assessment of the Effectiveness of REACH	
MS	**Details of Data Available**
AT	• number of restriction and authorisation dossiers submitted by Austria; • number of C&L dossiers submitted by Austria; • number of chemical inspections carried out annually; • number of inspections of chemicals at workplace; • statistics of the legal conformity with respect to restrictions to certain chemicals in Annex XVII; • results of health related examinations of workers exposed to selected chemicals assessment of the number and quality of safety data sheets (e.g. through exposure scenarios covered) and a database of safety data sheets is available at the Umweltbundesamt; • long term measurements of selected chemicals (e.g. heavy metals) at selected surveillance water monitoring sites; • statistics on the consultations of the Austrian REACH Helpdesk; • statistical assessment of REACH awareness in industry through questionnaire (not yet done in Austria) ; • statistical assessment of consumer´s knowledge about certain elements of chemicals policy by opinion polls (not yet done in Austria). This could cover parameters such as: knowledge of hazards from certain chemicals, use and knowledge of the public domain data base on chemical properties at ECHA; knowledge of the meaning and significance of CLP labels, application of article 33 for SVHC substances in articles; and • export/import statistics of certain chemicals (available at different aggregation level with respect to individual chemicals)
BE	• environmental monitoring (air and water) data at the regional level, but it is quite unrealistic to monitor all substances covered by REACH; • human biomonitoring data at the federal level; and • analysis contaminants found in the food chain from the FASFC (The Belgian Federal Agency for the Safety of the Food Chain).
BG	• progress in registration, authorisation and restriction; • changes in classification and labelling; • changes in quality of safety data sheets; • data on the production of toxic chemicals; and • monitoring data on persistent and bioaccumulative chemicals
CY	• results of inspections and those of the targeted campaigns to enforce provisions of Annex XVII of REACH (phthalates, Nickel, azocolours). The targeted campaigns were carried out during 2008 – 2009 and will continue during 2010. The results of these campaigns were provided as part of CA reporting to the Commission
CZ	• brief suggestions of general metrics but no information on data availability
DE	• registration numbers of occupational diseases in the SDS retrograde RAPEX notifications
DK	• regular monitoring data for a number of substances in the aquatic environment and in various food items. However the substances monitored are mainly substances that were already identified as a problem and subject to e.g. use restrictions before REACH was adopted; • additional data on classified substances and mixtures placed on the market for professional use from the Danish Product Register; and • non-confidential data from all national Nordic Product Registers are compiled in the so-called SPIN database. However, the SPIN database and the Nordic registers are not aimed at monitoring the effectiveness of REACH
EE	• REACH enforcement data from 01.06.2007 – 31.12.2010; • results of REACH-EN-FORCE-1 project; • data on pre-registrations/registrations of phase-in substances; and • data on information flow in supply chain and its compliance with REACH requirements

Table 12.1: National Data Available for an Assessment of the Effectiveness of REACH	
MS	**Details of Data Available**
EL	At this time there is no sufficient data to assess a baseline study.
ES	• data on R&D focused on the replacement of substances of very high concern and the development of alternative technologies; and • data on industrial sectors affected by REACH and level of compliance
FI	• information received via the enforcement activities; • measurements of exposures (concentrations) at workplaces from the Finnish Institute of Occupational Health; • data on the concentrations of chemicals mainly in the aquatic compartment from the Finnish Environment Institute; • data on chemicals in the Baltic Sea area from the HELCOM (Baltic Marine Environment Protection Commission)
FR	• analysis of data reported from REACH inspections and progression over time (hopefully decreasing) of non-compliances to REACH requirements (all procedures); • data resulting from environmental monitoring of emissions of classified / industrial sites (all media : air, water, soil); • data resulting from monitoring of emissions from all media (ex: water framework directive, ...); • enumeration of the occupational diseases declared or recognized by the health insurance resulting from occupational chemical exposures; • data from PNSE: France has adopted a national health and environment plan (called "Plan national santé environment" or "PNSE"). This plan aims to address questions raised by French people regarding the short- and mid-term health impacts of exposure to certain environmental pollutants. This plan includes a proposal to conduct an epidemiological study of children (called "ELFE"), in association with the American "National Children's Study" to assess levels of exposure to the main environmental pollutants and to analyse the links between exposure and child health. This cohort study aims at measuring the individual contamination of the children to the chemicals and to observe occurrences of associated pathologies, like neurotoxic disorders and disturbances by endocrine disruptor's substances. The estimate of the exposure will be addressed through biological tests while being born (blood of the cord, urinates and hair of the mother…). For the child, the chemical exposure will be assessed at other key periods of the child's development; • an assessment of the data monitoring the progression over time (hopefully decreasing) of poisoning cases due to chemicals (for consumers, with a specific attention to children, as for workers) could be performed; and • data from phone surveys to assess the development of the awareness of general public
HU	• number of inspections carried out; • amount of fines; and • number of non-compliances
IE	• detailed discussion of how a baseline may be constructed with suggestions for metrics but no information on data availability
IS	• information from enforcement activities including a database with information on inspection activities around Iceland will in the future help to assess the effectiveness of REACH
IT	• number of substances out of the market; • number of available CSR; • number of identified SVHC; • number of SDS compliant with the provisions of Annex II; • number of alternative tests; • number of available QSAR; • waiting time to receive information within the supply chain; • communication between CA and category associations (number of meetings, number of events); • number of available experts in the relevant areas under REACH impact; • number of tracked importation of restricted, authorized substances;

Table 12.1: National Data Available for an Assessment of the Effectiveness of REACH	
MS	**Details of Data Available**
	• number of goods not released for free circulation by Customs; • number of inspections/investigations conducted; and • number of undertaken measures after inspections/investigations
LI	• data on enforcement activities and projects of other MS
LT	• amounts of SVHCs on the market (information from Lithuanian chemical substances and preparations data base); and • number of imported chemical substances and preparations; and • may have data on quality of SDS
LU	• general data and statistics of the national structure and activities from the Central Statistical and Economic Studies Service STATEC (Service central de la statistique et des études économiques)
LV	• % of firms that had to carry out the registration; • % of controlled companies under REACH; and • % of controlled substances / mixtures
MT	• import statistics and information on enforcement activities
NL	• detailed discussion of how a baseline may be constructed with suggestions for metrics but no information on data availability
NO	• data from Norwegian processing industry with respect to annual discharge/emissions, processing conditions, waste generated from the Norwegian Pollutant and Transfer Register (PRTR) (PRTR may give supportive information to identify use, calculate exposure scenarios and in general indicate the impact on environment from substances used in the different processing activities); and • data on substances in preparations (use categories, tonnage, release estimates) from the Norwegian Product Register in the Climate and Pollution Agency and the Nordic SPIN data base
PL	• did not understand the question
PT	• brief comment on merits of EU level assessment of effectiveness of REACH
RO	• brief comment on constructing an assessment framework
SE	• detailed discussion of how a baseline may be constructed with suggestions for metrics but no information on data availability
SI	• level of compliance at national level
SK	• brief comment on merits of EU level assessment of effectiveness of REACH
UK	• detailed discussion of how a baseline may be constructed with suggestions for metrics but no information on data availability

It is anticipated that the information types suggested by CAs in Table 11.1, together with any additional information that are identified during a separate Commission study to be commissioned to assess the health and environmental benefits of REACH, will contribute to the assessment of the nature and extent of benefits that are attributable to REACH.

12.3 Risk Communication Network

The functioning of the Risk Communication Network (RCN), which was initiated in autumn 2008, was specifically commented on by only six CAs, including Hungary which noted only that it was well organised. Norway commented that although the role of the Network had been somewhat unclear initially it was becoming increasingly defined; and Belgium noted that, despite being a voluntary body, it had attracted attendance by the majority of Member States.

Belgium also highlighted its particular value as a venue for sharing expertise / experiences of 'risk communication' between members with varying levels of experience while Sweden commented that inclusion of training sessions and workshops had been of particular benefit. The comments made by CAs for maintaining or improving the effectiveness of RCN are set out in Box 4.1.

Box 4.1: Comments by CAs on Maintaining or Improving Effectiveness of RCN

CAs made the following suggestions regarding ways that the functioning of the RCN might be enhanced, including:

- amend the focus of agendas and procedures so as to promote inter-active discussion and engage more Member States in active roles, possibly including the establishment of sub-groups focused on difference scientific disciplines;
- continue to allow RCN to be a venue for sharing expertise and experience
- continue to include training sessions and workshops
- ECHA should take a proactive role in suggesting subjects for discussion (e.g. a particular chemical) where it believes that risk communication might become a generic issue across Member States; and
- there was a need for procedures to be implemented to ensure that Guidance Documents are updated on a regular basis.

13. REACH AIM: PROTECTION OF ENVIRONMENT

All CAs except Italy stated that the protection of the environment should be assessed at EU rather than national level.

The responding CAs provided information on the availability of information (parameters) that might be of use in assessing the extent to which the REACH aim of protecting the environment. Table 13.1 sets out this information, together with references made by the CAs to planned data collection activities or additional data gathering activities that are under consideration. It should be noted that many of the information types listed here are considered to be also likely to be of relevance to assessing the level of human health protection provided by REACH (see Table 12.1 above).

Table 13.1: National Data Available for an Assessment of the Effectiveness of REACH in relation to Protection of the Environment

MS	Details of Data Available
AT	• number of restriction and authorisation dossiers submitted by Austria; • number of C&L dossiers submitted by Austria; • number of chemical inspections carried out annually; • number of inspections of chemicals at workplace; • statistics of the legal conformity with respect to restrictions to certain chemicals in Annex XVII; • results of health-related examinations of workers exposed to selected chemicals, including assessment of the number and quality of safety data sheets (e.g. through exposure scenarios covered) and a database of safety data sheets is available at the Umweltbundesamt; • long term measurements of selected chemicals (e.g. heavy metals) at selected surveillance water monitoring sites; • statistics on the consultations of the Austrian REACH Helpdesk; • statistical assessment of REACH awareness in industry through questionnaire (not yet done in Austria); • statistical assessment of consumer´s knowledge about certain elements of chemicals policy by opinion polls (not yet done in Austria). This could cover parameters such as: knowledge of hazards from certain chemicals, use and knowledge of the public domain data base on chemical properties at ECHA; • knowledge of the meaning and significance of CLP labels, • application of article 33 for SVHC substances in articles; and • export/import statistics of certain chemicals (available at different aggregation level with respect to individual chemicals)
BE	• environmental monitoring (air and water) data at the regional level, but it is quite unrealistic to monitor all substances covered by REACH; and • analysis contaminants found in the food chain from the FASFC (The Belgian Federal Agency for the Safety of the Food Chain)
BG	• progress in registration, authorisation and restriction; • changes in classification and labelling; • changes in quality of safety data sheets; • data on the production of toxic chemicals; and • monitoring data on persistent and bioaccumulative chemicals
CY	• results of inspections and those of the targeted campaigns to enforce provisions of Annex XVII of REACH (phthalates, Nickel, azocolours). The targeted campaigns were carried out during 2008 – 2009 and will continue during 2010. The results of these campaigns were provided as part of CA reporting to the Commission
CZ	• brief suggestions of general metrics but no information on data availability

Table 13.1: National Data Available for an Assessment of the Effectiveness of REACH in relation to Protection of the Environment	
MS	**Details of Data Available**
DE	• no relevant data specified
DK	• regular monitoring data for a number of substances in the aquatic environment and in various food items. However the substances monitored are mainly substances that were already identified as a problem and subject to, e.g., use restrictions before REACH was adopted; • additional data on classified substances and mixtures placed on the market for professional use from the Danish Product Register; and • non-confidential data from all national Nordic Product Registers are compiled in the so-called SPIN database. However, the SPIN database and the Nordic registers are not aimed at monitoring the effectiveness of REACH
EE	• REACH enforcement data from 01.06.2007 – 31.12.2010; • results of REACH-EN-FORCE-1 project; • data on pre-registrations/registrations of phase-in substances; and • data on information flow in supply chain and its compliance with REACH requirements
EL	• at this time there is no sufficient data to assess a baseline study.
ES	• data on R&D focused on the replacement of substances of very high concern and the development of alternative technologies; • data on industrial sectors affected by REACH and level of compliance
FI	• information received via the enforcement activities; • data on the concentrations of chemicals mainly in the aquatic compartment from the Finnish Environment Institute; • data on chemicals in the Baltic Sea area from the HELCOM (Baltic Marine Environment Protection Commission)
FR	• analysis of data reported from REACH inspections and progression over time (hopefully decreasing) of non-compliances to REACH requirements (all procedures); • data resulting from environmental monitoring of emissions of classified / industrial sites (all media : air, water, soil); • data resulting from monitoring of emissions from all media (ex: water framework directive, ...); and • data from phone surveys to assess the development of the awareness of general public
HU	• number of inspections carried out; • amount of fines; and • number of non-compliances
IE	• detailed discussion of how a baseline may be constructed with suggestions for metrics but no information on data availability
IS	• information from enforcement activities, including a database with information on inspection activities around Iceland will in the future help to assess the effectiveness of REACH
IT	• number of substances out of the market; • number of available CSR; • number of identified SVHC; • number of SDS compliant with the provisions of Annex II; • waiting time to receive information within the supply chain; • communication between CA and category associations (number of meetings, number of events); • number of available experts in the relevant areas under REACH impact; • number of tracked importation of restricted, authorized substances; • number of goods not released for free circulation by Customs; • number of inspections/investigations conducted; and • number of undertaken measures after inspections/investigations
LI	• data on enforcement activities and projects of other MS
LT	• amounts of SVHCs on the market (information from Lithuanian chemical substances and preparations data base); • number of imported chemical substances and preparations; and

Table 13.1: National Data Available for an Assessment of the Effectiveness of REACH in relation to Protection of the Environment	
MS	**Details of Data Available**
	• possibility of data on quality of SDS
LU	• general data and statistics of the national structure and activities from the Central Statistical and Economic Studies Service STATEC (Service central de la statistique et des études économiques)
LV	• % of firms that had to carry out registration; • % of controlled companies under REACH; and • % of controlled substances/mixtures
MT	• Import statistics and information on enforcement activities
NL	• detailed discussion of how a baseline may be constructed with suggestions for metrics but no information on data availability
NO	• data from Norwegian processing industry with respect to annual discharge/emissions, processing conditions, waste generated from the Norwegian Pollutant and Transfer Register (PRTR) (PRTR may give supportive information to identify use, calculate exposure scenarios and in general indicate the impact on environment from substances used in the different processing activities); and • data on substances in preparations (use categories, tonnage, release estimates) from the Norwegian Product Register in the Climate and Pollution Agency and the Nordic SPIN data base
PL	• did not understand the question
PT	• brief comment on merits of EU level assessment of effectiveness of REACH
RO	• brief comment on constructing an assessment framework
SE	• detailed discussion of how a baseline may be constructed with suggestions for metrics but no information on data availability
SI	• level of compliance at national level.
SK	• brief comment on merits of EU level assessment of effectiveness of REACH
UK	• detailed discussion of how a baseline may be constructed with suggestions for metrics but no information on data availability

It is anticipated that the information types suggested by CAs in Table 12.1, together with any additional information that are identified during a separate Commission study to be commissioned to assess the health and environmental benefits of REACH, will contribute to the assessment of the nature and extent of benefits that are attributable to REACH.

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

All CAs except Italy stated that the enhancing competiveness and innovation should be assessed at EU rather than national level.

The CAs did not provide any data that directly informs on the REACH aim of enhancing competiveness and innovation or that relates to the impact of REACH on the single market. However, a few of the information types suggested by the CAs principally in relation to assessment of changes in the level of protection of human or environmental health, may be of some value with respect to informing on the issues of competitiveness, innovation and single market functioning. These are summarised in Table 14.1 below.

Table 14.1: MS Data Available for an Assessment of the Effectiveness of REACH in relation to Competitiveness, Innovation and the Single Market

MS	Details of Data Available
AT	• number of C&L dossiers submitted by Austria; • Statistics of legal conformity with respect to restrictions to certain chemicals in Annex XVII; • statistics on the consultations of the Austrian REACH Helpdesk; • export/import statistics of certain chemicals (available at different aggregation level with respect to individual chemicals)
BG	• progress in registration, authorisation and restriction; and • data on the production of toxic chemicals
CY	• results of inspections and those of the targeted campaigns to enforce provisions of Annex XVII of REACH (phthalates, Nickel, azocolours).
DK	• additional data on classified substances and mixtures placed on the market for professional use from the Danish Product Register; and • Non-confidential data from all national Nordic Product Registers are compiled in the so-called SPIN database
EE	• REACH enforcement data from 01.06.2007 – 31.12.2010; • results of REACH-EN-FORCE-1 project; • data on pre-registrations/registrations of phase-in substances; and • data on information flow in supply chain and its compliance with REACH requirements
EL	• at this time there is no sufficient data to assess a baseline study
ES	• data on R&D focused on the replacement of substances of very high concern and the development of alternative technologies; • data on industrial sectors affected by REACH and level of compliance
FI	• information received via the enforcement activities
FR	• analysis of data reported from REACH inspections and progression over time of non-compliances to REACH requirements (all procedures)
HU	• amount of fines; and • number of non-compliances
IE	• detailed discussion of how a baseline may be constructed with suggestions for metrics but no information on data availability
IS	• information from enforcement activities will in the future help to assess the effectiveness of REACH
IT	• number of substances out of the market; • number of available CSR; • number of identified SVHC; • waiting time to receive information within the supply chain;

Table 14.1: MS Data Available for an Assessment of the Effectiveness of REACH in relation to Competitiveness, Innovation and the Single Market	
MS	**Details of Data Available**
	• number of available experts in the relevant areas under REACH impact; • number of tracked importation of restricted, authorized substances; • number of goods not released for free circulation by Customs; and • number of undertaken measures after inspections/investigations
LI	• data on enforcement activities and projects of other MS
LT	• amounts of SVHCs on the market (information from Lithuanian chemical substances and preparations data base); and • number of imported chemical substances and preparations
LU	• general data and statistics of the national structure and activities from the Central Statistical and Economic Studies Service STATEC (Service central de la statistique et des études économiques)
LV	• % of firms that had to carry out registration; • % of controlled companies under REACH; and • % of controlled substances/mixtures
MT	• import statistics and information on enforcement activities
NL	• detailed discussion of how a baseline may be constructed with suggestions for metrics but no information on data availability
NO	• data from Norwegian processing industry with respect to annual discharge/emissions, processing conditions, waste generated from the Norwegian Pollutant and Transfer Register (PRTR); and • data on substances in preparations (use categories, tonnage, release estimates) from the Norwegian Product Register in the Climate and Pollution Agency and the Nordic SPIN data base
SE	• detailed discussion of how a baseline may be constructed with suggestions for metrics but no information on data availability
UK	• detailed discussion of how a baseline may be constructed with suggestions for metrics but no information on data availability

While the nature of the information identified in Table 14.1 would, of itself, not provide a comprehensive picture of the impact of REACH on competiveness, innovation and the single market, it is anticipated that a more detailed picture should emerge from three other Commission studies that are to be conducted on specific aspects of the contribution of REACH in relation to:

- the development, commercialization and update of emerging technologies;
- innovation by the EU chemical industry; and
- the functioning of the European market.

15. CA REPORTING FORMAT: ISSUES FOR IMPROVEMENT

The Specifications require this study to identify and assess issues regarding the use and usefulness of the reporting system and questionnaire format provided to respondent CAs. For this purpose, a range of data sources that inform on the comments and feedback by CAs and discussions that have occurred between CAs and other national representatives on this issue at various fora were analysed. To this end, consideration was given to not just comments directly submitted by the individual CAs via e-mail over the course of the reporting process but also to review of the minutes arising from CARACAL meetings and the reports from a Forum working group that took place during the development of the reporting system. Consideration has also been given to comments provided by CAs within their report to the Commission and issues that arose during the analysis of CA responses.

15.1 Member State Reporting Obligations

Under REACH, the obligations placed on MS to report are defined within Article 117 (Reporting), Article 126 (Penalties) and Article 127 (Enforcement).

The principle requirement for MS reporting on the operation of REACH is set out in 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.

> Article 127:
> *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.*
>
> Articles 125:
> *Member States shall maintain a system of official controls and other activities as appropriate to the circumstances*; and
>
> 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*

Considering the provisions of Articles 117(1), 125, 126, and 127, an assessment of the legal minimum reporting requirements on Member States is set out in Table 15.1.

Table 15.1: Legal Requirements from REACH for Member State Reporting			
Required to Report on:	**Article**	**Note**	**Ref. No.**
Reporting on Activities other than Enforcement			
Operation of REACH within MS	117(1)	No definition of 'operation' beyond evaluation and enforcement considered below	1
Evaluation	117(1)	No further definition of scope of 'evaluation'. 'Evaluation' could refer to formal substance and/or dossier evaluation activities required under REACH but could be understood to refer to an evaluation of the operation of REACH more generally	2
Reporting of Enforcement Activities			
Enforcement	117(1)	Further definition of scope of 'enforcement' is set out in Article 127, which in turn refers to Articles 125 and 126	3
Results of official inspections	127	No definition of 'official' or 'inspection' therefore scope open to interpretation by MS. Furthermore there is no requirement to include details of the frequency of inspections. Reporting of 'official inspections' could be taken as limited to the results of activities carried out solely for the enforcement of REACH by dedicated REACH inspectors or could include all chemical related inspections by inspectors from any 'official' body	4
Monitoring carried out	127	No clarification of what monitoring should be carried out or of scope, e.g. it would be possible for a MS to fulfil this requirement by stating that no monitoring took place or for a MS to detail all chemicals related monitoring activities. Furthermore there is no requirement to include details of the frequency of monitoring activities	5
Penalties provided for	127	Requires a list and description of penalties/sanctions available to MS authorities. Further defined by the need to consider the operation of the provisions set out in Articles 125 and 126	6
Penalties applicable for infringement	126	Requires a list and description of penalties/sanctions available to MS authorities	7
Measures to ensure penalties are implemented and appropriate	126	Requires details of measures. Some consideration of the justification for these measures being sufficient to ensure implementation of penalties may be implied. It may also be implied that some consideration should be included of the justification for these being effective, proportionate and dissuasive	8
System of official controls and other enforcement activities relevant to circumstances	125	General requirement to report on system of enforcement, including other enforcement activities	9
Common issues on enforcement	127	Common issues to be covered in the MS reports, including those set out in this table are to be agreed by the Forum	10

The Forum delegated the task of elaborating the common issues for reporting on enforcement to its Working Group on the Member States Report to the Commission[12]. The common issues to be covered are set out in Table 15.2[13].

Table 15.2: Common Issues for Reporting on Enforcement

Area Covered	Common Issues	Ref. from Table 15.1
General information	Details of enforcing authorities and their roles and responsibilities	1
	Details of dutyholders with duties under REACH[1] i.e. numbers of different types and some differentiation under other areas covered	10[2]
Enforcement strategy	Whether an overall strategy or strategies for REACH enforcement has been devised and, if it has, whether it reflects the Forum strategy	9
Co-ordination, co-operation and information exchange	A description of the mechanisms put in place to ensure good co-operation, co-ordination and exchange of information between enforcing authorities of the Member State, between these enforcing authorities and the competent authority, and between these enforcing authorities and the enforcing authorities or competent authorities of other Member States.	1 and 9
	Information on how these mechanisms operate in practice	1 and 9
Enforcement activities	A description of the different sanctions available to enforcing authorities in the case of contraventions of REACH (if this has changed since the last reporting period or is different to that provided by virtue of article 126)	6 and 7
	Details of the number and types of inspection, investigation and formal enforcement undertaken within the reporting period	4
	Information about the duty holders subject to inspection, investigation and formal enforcement in terms of their role in the supply chain (manufacturer, importer, distributor or downstream user) and their size (for SMEs the definitions are as set out in the Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium size enterprises)	4
	The subject-matter of inspection and investigation, that is, the duties in REACH that were under consideration (registration, information in the supply chain, downstream use, authorisation, restriction or other duties), and the amount of non-compliance found	4
	The outcome of inspections and investigations, and whether compliance or non-compliance was found. In particular, whether they resulted in no action, verbal / written advice, or formal enforcement. For legal proceedings, this includes information on the number of convictions	4
	Information on what prompted an investigation to commence (an incident or dangerous occurrence, a complaint received by an enforcing authority, or as a result of monitoring or inspection activity)	4
	Details of the inspection and investigation strategy, and the methodologies / techniques used. This includes the criteria governing selection of duty holders for inspection, and selection of incidents, dangerous occurrences or complaints for investigation[1]	8 and 9
	Details of the level and extent of monitoring activities undertaken. This	5

12 **Minimum Criteria for REACH and CLP Inspections**, Adopted at the 9th Meeting of the Forum on 1-3 march 2011, Available from (http://echa.europa.eu/doc/about/organisation/forum/mcri_minimum_criteria_reach_inspections_2011.pdf)

13 **Forum Working Group on 'Member States Report to the Commission' Annex 1 – Common issues regarding enforcement**.

Table 15.2: Common Issues for Reporting on Enforcement		
Area Covered	**Common Issues**	**Ref. from Table 15.1**
	includes the criteria by which substances, preparations, articles etc. were selected for monitoring	
Other enforcement activity not covered elsewhere	Requests for enforcement action from ECHA / other Member States. Other measures taken pursuant to articles 125 and 126 of REACH; any other comments / details not covered elsewhere	10[2]
Notes. *1. Optional information.* 2. Reference to 10 (common issues could) be included for all rows but has been reserved for those that refer to no other section of Table 14.1		

The Common Issues set out in Table 15.2 would appear to cover all of the legal reporting requirements set out in Table 15.1. However, it is noted that very little detail is required on item 8, particularly with regard to an assessment of whether or not sanctions are effective, proportionate and dissuasive. In addition, no mention is made of consideration of whether or not enforcement systems or measures are sufficient to ensure implementation of penalties. Furthermore, the only request for information to inform item 8 is optional.

15.2 Issues Identified during Reporting Format Development

A number of issues were identified during the process of developing and implementing the CA reporting system at CARACAL and Forum.

Issues Raised at CARACAL

The reporting tool was first introduced to the CARACAL in October 2009[14] and four Member States (MSs) volunteered to test it. The adoption of the IPM tool was agreed to be performed by written procedure in that meeting.

According to the CARACAL minutes dated 22 March 2010[15], two MS objected to the obligatory nature of some questions, particularly where these went beyond regulatory requirements.

It was requested by some MS to enable the download of a printer friendly word-version of the reporting format, since this would facilitate data collection from different institutions and its compilation and processing by the appropriate CA.

[14] Final Summary record, 3rd Meeting of Competent Authorities for REACH and CLP of 12-13 October 2009, Brussels, 02 February 2010 (Doc CA/20/2010 rev 1).

[15] Final Summary Record, 4th Meeting of Competent Authorities for REACH and CLP of 2-3-4 February 2010, Brussels, 22 March 2010 (Doc. CA/38/2010)

No further discussions of CARACAL on the reporting format are documented in publicly available meeting minutes.

Issues Raised at Forum

A working group of the Forum on CA reporting[16] requested the Commission to include the following information items in the IPM tool:

- general organisational details of national Enforcement Authorities;
- existence and description of any enforcement strategy;
- co-ordination, co-operation and information exchange within national and at EU level;
- enforcement activities, including number of duty holders, inspections, investigations and sanctions and monitoring activities; and
- requests for enforcement action from other MS, ECHA or COM.

All of the above mentioned aspects were addressed in the IPM tool that was subsequently used by CAs to submit their reports.

15.3 Issues Identified Relating to Member State Reporting

15.3.1 Technical Issues with the Reporting System

A number of technical problems or difficulties were experienced by CAs while attempting to submit data using the IPM tool, as listed here:

1. Three CAs reported that they had experienced difficulties in logging onto the IPM tool or gaining access to the system. However, the technical or procedural cause of these difficulties was not identifiable and such issues were not reported by most CAs.

2. The submission of completed (filled) questionnaires failed in four cases. Standard error messages were received but consideration of these did not contribute to the positive identification of the actual underlying technical problem(s) in all cases. For example, failure of submission was found to be due to exceedance of the maximum session time of 90 minutes in two of these cases but the reasons for failure in the other two cases are not clear. Importantly, the content of questionnaires that could not be sent was found to have been lost (i.e. empty file found) which necessitated complete re-entry of the information in each case.

3. A further issue identified was that in some instances multiple submissions were made as a result of operator mistakes during the submission entry process or in response to receipt of a system's error message despite the file having actually

[16] Report of the Forum Working Group 'Member States Report to the Commission', Active through: 15/05/08 – 31/01/09.

been sent and received in two cases. One CA also reported difficulties in modifying or deleting wrongly submitted files.

4. One CA experienced problems because the IPM tool reported the presence of an "invalid property" in one of the fields. In order to pass that question and proceed with the questionnaire, the CA chose to enter zeros in all the fields. In contrast, other CAs successfully completed the questionnaire including that field. Finland also reported that they had apparently entered "wrong data" under Section 10 of the questionnaire such that some parts of the questionnaire could only be passed by entering "wrong" information and then providing a pdf-document containing the correct information. This necessitated subsequent manual intervention in the report analysis to compare and amend the data and might have led to analyses being conducted using the incorrect data.

5. The need to include the report by Latvia was unfortunately forgotten during the system programming and it proved impossible to incorporate this directly using the tool at a later stage. Although it might be hoped that forgetting the need to include data from a particular CA would be unlikely to happen again, there are other possible reasons why reports might need to be added or re-included later in the report process on future occasions. As a consequence, any revisions to the reporting system should ensure that it is possible to flexibly integrate new/changed information files and should also allow inclusion of additional CAs.

15.3.2 Issues Relating to the Reporting Format

In addition to the technical problems relating to data entry or the ability of the software to utilize submission data, detailed analysis of the responses generated by each individual CA and comparison of the responses has indicated that the questionnaire and supporting documentation used in reporting incorporated a number of weaknesses that have impacted on the quality and robustness of the data gathered. These included:

1. A number of the difficulties identified during the analysis of CA responses appear to possibly be a consequence of differences in the precise interpretation or translation of a definition in the questionnaire or associated guidance provided to CAs. This has resulted in different CAs providing data relating to subtly different metrics. Also, in some instances where the questionnaire and/or guidance did not provide adequate definition, it appears that individual CAs have reported on very different (incompatible) metrics making cross-State comparison of data unreliable.

2. For example, some CAs did not understand the phrase "dutyholder", despite the use of this phrase in the Forum's enforcement strategies document[17]. Furthermore, CAs had different interpretations of the highlighted section of the question "What was the total number of inspections and investigations carried out by enforcing authorities in which REACH was **discussed and/or enforced** for this year?" (see Section 10.2) and in relation to the scoring systems used throughout the questionnaire (e.g. see Section 3.4 and more detailed consideration of the scoring systems under item 4 below).

3. A further related issue appears to relate to a lack of clarity in the phraseology of some questions resulting in some CAs having difficulties in deciding on the appropriate/relevant entry. For example, the apparently simple compulsory question "What part of REACH does this part of the Competent Authority deal with?" provides CAs with the following options:

   - All;
   - Evaluation;
   - Restriction;
   - Helpdesk;
   - CLP;
   - Risk Assessment; and
   - Other (please list)

   However, the options 'All' and 'Other' resulted in a degree of confusion. Some CAs appear to have understood 'All' to encompass 'all' to be limited to next five options, while other CAs appear to have interpreted "All" as referring to 'all' parts of REACH (which may or may not exclude CLP). From the detailed responses received from CAs it is often unclear as to how each of the CAs understood the entry option "All". It is also of note that one CA provided a detailed listing of its non REACH-related activities under the 'Other' entry option.

4. It is noted that key data under Theme 1 of the questionnaire relates to the respondent CA only (i.e. for the seven countries that have more than one CA there is no information relating to the other CAs).

5. Analysis of the responses on the possible legislative responsibilities outside of REACH for CAs listed under Theme 1 indicates that there is a need to consider extending the possible entries from Import/Export, Pesticides, Biocides and Food to also include a number of more popular responsibilities identified by the CAs (see Table 15.3). However, 'Food' was only selected by three CAs so perhaps this might be omitted.

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[17] **Strategies for enforcement of Regulation (EC) no. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), March 2009**, superseded and no longer available. It is noted that the 2009 strategies document was superseded in March 2011, available from (http://echa.europa.eu/doc/about/organisation/Forum/strategies_enforcement_reach_2011.pdf).

Table 15.3: Additional Legislative Responsibilities Named by CAs	
Other Legislative Responsibilities	**Number of CAs naming Responsibility**
Detergents	16
POPs	14
CLP	12
(Others – decreasing prevalence): Volatile Organic Compounds (VOCs), RoHS, Montreal Protocol (Ozone, ODS), Chemical Accidents (Seveso II), PIC, Fluorinated Gases, Mercury, SAICM, Chemical Weapons, Cosmetics, Waste, GLP Good Laboratory Practice, Nanotechnology, Dual Use Products, Plant Protection Products, Asbestos, Explosives, Consumer Protection, CSD, OECD, IPPC, Drinking Water, GMOs, EMAS, Ecolabelling, Aerosols, Pollution Control, Precursors For Illicit Drugs, Fertilizers and ADR	<10

6. Where countries have more than one CA, consideration may be given to gathering information on the structure and responsibilities of all CAs rather than focusing on the respondent CA only.

7. In several places CAs are asked to use a score between 1 and 10 or between 1 and 5 (e.g. to indicate adequacy of funding). However, no criteria are provided to assist CAs to score consistently (e.g. what should be regarded as 'adequate funding' – adequate to undertake all tasks currently asked of CA, adequate for all legal obligations under REACH, adequate to fully implement and monitor REACH, etc.). Furthermore, it may assist CAs to score consistently and would aid analysis if a single scoring scale were to be used, e.g. 1 to 5 or 1 to 10.

8. The format used to request data on staff skills is not consistent throughout the questionnaire making it difficult to compare answers or to analyse the distribution of what skills are available throughout CAs or are available for different functions. Several smaller CAs also noted that many of their staff have multiple skill sets and so the number of staff with skills indicated by their response would not equate to the number of staff. This comment was repeated by the Slovak CA in its response to the consultation undertaken as part of this study (see Table 14.2).

9. Iceland stated that "it should be noted that in order to collect useful information some sort of benchmarking criteria for "effectiveness of communication" would be needed." In general the provision of benchmarks and greater clarity in the questions may reduce the level of subjectivity in CA answers.

10. There was a large degree of overlap/repetition between answers provided by CAs to questions asking for descriptive answers about their enforcement arrangements. Consideration may therefore be given to reducing the number of these questions and/or improving the clarity of the questions themselves.

11. Finland suggested that the information requested by the questionnaire was too detailed and that, for many issues, no information was available on which to base

an evaluation. It is not clear how this suggestion may be addressed. However, greater clarity and simplicity may reduce the impression that the questionnaire is too detailed.

12. During the analysis of data, it was found that CAs were asked questions relating to company size with reference to categories that were similar but not identical to those set out in Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (2003/361/EC). It is therefore suggested that reference be made to 2003/361/EC to avoid possible misunderstandings.

13. There was a near consensus of opinion amongst the CAs that monitoring of the REACH aims should be undertaken at an EU level rather than attempted at the individual state level.

14. Sweden recommended that elements/descriptions of the Forum's enforcement strategies document be included in future questionnaires.

15.4 CA Concerns over Potential Misrepresentation

The study team was made aware that the Commission had received verbal comments from some CAs that the details provided in their official reporting may not completely describe the activities that they have carried out or the outcomes achieved and, hence, could result in some degree of misinterpretation or misunderstanding. On 4 April 2011, therefore, each CA was contacted to determine whether or not they had such concerns and, if so, to provide an opportunity for them to explain these concerns in more detail. CAs were given until 29 April 2011 to provide a response.

The responses received from the CAs, are summarised in Table 15.4.

Table 15.4: Concerns of Misrepresentation Expressed by CAs

CA	Response Date	Details of Concern
AT	13/4/11	No specific concerns*
BE	4/5/11	Concerns regarding evaluation activities as NONS evaluations undertaken are not included in report
BG	-	No response
CY	6/4/11	No specific concerns*
CZ	8/4/11	No specific concerns*
DE	26/4/11	No specific concerns at present. Potentially issues may rise eventually regarding enforcement. Issues have been previously expressed regarding aspects of the questionnaire and the potential for these to be misinterpreted
DK	6/5/11	No specific concerns
EE	-	No response
EL	-	No response
ES	-	No response
FI	13/4/11	Not concerned about the contents of our report but wished to clarify that correct (PDF format) version of report was being analysed. PDF report was attached
FR	-	No response
HU	29/4/11	Concerns that enforcement activities may be misrepresented. CA did not

Table 15.4: Concerns of Misrepresentation Expressed by CAs		
CA	**Response Date**	**Details of Concern**
		understand what was required for the questions, "Describe the referrals from ECHA" and "Describe the referrals from other Member States."
IE	4/5/11	No specific concerns*
IS	28/4/11	No specific concerns
IT	19/4/11	Concerns over misrepresentation of evaluation, SVHC and communication/ collaboration activities stating that at the time of writing CA was starting up several major new activities relating to these areas which could not be included in its report
LI	18/5/11	No specific concerns. However, accompanying email expressed concern that "*the questionnaire was very detailed and complex. The intention for the use of the answers was not clear, therefore it was difficult to find what level of details are needed when preparing the answers. In order to collect useful information it would be useful to note some sort of benchmark criteria for some of the questions*"
LT	-	No response
LU	-	No response
LV	-	No response
MT	26/4/11	No specific concerns
NL	6/4/11	No specific concerns*
NO	5/4/11	No specific concerns*
PL	28/4/11	No specific concerns
PT	28/4/11	No specific concerns
RO	-	No response
SE	11/5/11	No specific concerns. However, accompanying email drew attention to comments by CA for SE explaining why some questions will not result in useful information from which meaningful conclusions can be drawn
SI	-	No response
SK	7/4/11	Concerns over misrepresentation of enforcement, evaluation, SVHC and restriction activities stating true understanding of these activities required detailed knowledge of the CA and its operating conditions (criticising use of Yes/No in questionnaire used). Also, staff have multiple skills so responses provided regarding skills available to CA do not represent the total number of staff. Requests that future questionnaire asks for total number of employees dealing with REACH tasks
UK	-	No response
Note: * Several CAs stated that this does not preclude misrepresentation or misunderstanding of their activities by readers of any subsequent report based on their submitted data		

The CAs for the Czech Republic, Ireland and Finland have stated that they would be willing to review suggestions for improving the Article 117(1) reporting format. However, only the CA for Slovakia stated that they would not be willing to review these suggestions, with the remaining CAs leaving this question unanswered.

15.5 Final Comments from CAs

Theme 10 of the questionnaire provided CAs with the opportunity to submit any additional comments or information they felt may be of relevance to the Commission.

Fifteen CAs chose not to provide any response and the comments made by the other fifteen CAs varied greatly.

It appears from the UK comment "We have nothing further to add on implementation issues within the UK" that this CA may have understood this question to be an opportunity to elaborate on the specific issue of within-MS implementation of REACH. As might be anticipated given the somewhat unspecific nature of this question which permitted inclusion of free-text responses, the topics raised and the level of detailed commentary or information provided by the other responding CAs were very diverse. Comments ranged across aspects such as: the need for further policy development; the functioning of ECHA; the functioning of the REACH-IT system; CA functions; and concerns of industry that had been made known to the CA (see Table 15.5 (summary) and Appendix 1 to this Annex (full text)).

Table 15.5: Summary of Additional Comments Provided by CAs*

Topic/ aspect	Competent Authority														
	AT	**BE**	**DE**	**DK**	**EL**	**ES**	**FI**	**FR**	**HU**	**IE**	**IT**	**NL**	**PL**	**SE**	**SK**
Policy development															
Consistency with other legislation	X									X		X			
Compatibility with international agreements/ WTO rules	X									X					
Lack of clarity in regulations				X			X	X							
Procedural difficulties/ uncertainties within REACH processes				X						X		X	X		
Authorisation	X														
Substances in articles	X	X		X				X						X	
Nanotechnology issues	X			X								X			
Biological agents	X														
ECHA															
Guidance Inadequacies/	X							X				X			
Guidance incompatibility with REACH legislation	X														
Need for versions in more languages	X							X							X
Establishment of expert networks		X													
Improving Registration dossier compliance														X	
REACH-IT															
Technical limitations	X	X						X					X		
Training gaps								X							X
EC/ ECHA															
Improvements in MS consultation arrangements/meeting arrangements												X	X		

Table 15.5: Summary of Additional Comments Provided by CAs*															
Topic/ aspect	**Competent Authority**														
	AT	**BE**	**DE**	**DK**	**EL**	**ES**	**FI**	**FR**	**HU**	**IE**	**IT**	**NL**	**PL**	**SE**	**SK**
Need for harmonisation of sanctions across MSs													X		
Competent Authority Specific															
Info re other national CAs			X												
Helpdesk functions/ data		X													X
Information provision/ training activities						X			X		X				X
Enforcement Data			X												X
Enforcement –Need for national and/or international co-operative arrangements	X				X			X				X			
Burden on resources							X							X	X
Undue burden on smaller MS							X							X	X
Industry															
General burden on industry							X								
Burden on SMEs	X							X	X						
Industry involvement	X														
Other issues															
Alternative testing activities			X												
Need for assessment tools for specific types of substances (eg EDCs & nanomaterials)								X							
Need for review of Themes and establishment of common indicators for future reporting										X					
Procedural question on intended use of MS reports														X	
No. topic areas subject to comment	13	4	3	4	1	1	4	9	2	4	1	6	4	4	6
NOTE * Only CAs making substantive comments presented															

While in some instances the comments from the CAs were elaborations or repetitions of information presented in their response to other questions, some CAs took this opportunity to make comments of a novel nature or to provide additional information that they had not included elsewhere in the questionnaire. Information relating to other aspects of a CAs report were considered and included if necessary in the

relevant analysis of that CAs report. However, it is this additional information that is commented upon in the text that follows.

Austria provided the greatest number of additional comments, including the following:

- the need to address apparent anomalies within the existing REACH legislation and, hence, a need of further policy development in relation to Authorisation;
- concern regarding the current ECHA guidance on the interpretation of the 0.1% threshold limit for substances in articles – an aspect also raised by Belgium, Denmark, France and Sweden;
- emphasis – together with France – on the need for greater co-operation between chemical and labour inspectorates and between ECHA and enforcement authorities;
- opinions gathered from Austrian industry regarding the undue burden the regulation imposes on industry, particularly SMEs, and the limited involvement of industry in the review and decision process;
- concerns about the use of the DMEL concept;
- concerns with regard to regulation of specific substance types such as nanomaterials (which were also raised as an issue by Denmark, France and The Netherlands); and
- concerns over the inclusion of microbes as 'active ingredients' in products.

The lack of REACH-related documentation available in a sufficiently wide range of EU languages was an issue raised by the CAs for Austria, France and Slovakia, with particular criticism focusing on the restricted range of language options available for the ECHA guidance materials.

Germany included data on other institutions that the German CA undertook work with and also discussed the difficulties in reporting enforcement activities because of issues regarding differences in recording practice. The CA also provided data on the level of funding of alternative test development.

The CAs for Finland, Sweden and Slovakia expressed concern regarding the regulatory burden imposed by REACH. For example, the commentary by Finland focused on the frequent change in interpretation of the legal text and the unrealistic expectations REACH procedures placed on smaller States.

Amongst other comments, Sweden questioned the lack of clarity as to the intended use to which the MS reports would be put, while Ireland suggested there was a need to review some of the reporting themes (citing Theme 8) and to establish common indicators for future data collections.

16. SUGGESTIONS FOR IMPROVEMENT

The comments set out in Section 15 have been analysed to identify potential improvements to the reporting content, format and process. This section sets out suggestions made that may, if implemented, result in the Article 117(1) reporting process being as simple and straightforward as possible for CAs while ensuring that the Commission is provided with data sufficient for it to meet its own reporting requirements under REACH.

16.1 Technical suggestions for Improving Article 117(1) Reporting

The technical suggestions regard the submission process of CA reports to the Commission are detailed in Box 16.1.

Box 16.1: Technical Suggestions for Improving Article 117(1) Reporting

1. The processes of logging into the IPM tool and accessing functions should be made simpler, including functions to modify or delete submissions.

2. A warning should be given before a session is timed out and data lost.

3. Error messages should be more informative and allow for precise problem identification.

However, it is **not clear how feasible it will be to make technical amendments to the IPM tool**. One alternative would be to **employ a different software tool** to collect Article 117(1) reports. However, there is no guarantee that the alternative system will not have technical issues of its own. Furthermore, there may well be data security concerns about the submission of MS reports being received by third-party software and being hosted outside of the Commission by a third-party company.

One simple approach that would overcome the technical issues identified above would be to **move away from an Internet-based tool entirely for submission of MS reports**. Since it proved necessary for in the first reporting round to supply the questionnaire in Word format to assist CAs in preparing their responses, little, if any, additional effort would be needed to make the electronic version of the questionnaire (Word or Excel format), the version to be submitted to the Commission. The transfer of MS reports supplied in Word or Excel format to a spreadsheet for analysis would be similar to the transfer of Excel format outputs from the IPM tool. If all submissions were in Word or Excel formats, there would be no need to manually input those responses that could not be uploaded to the IPM tool. The Word or Excel document could include the reporting format table prepared by the Forum[18]. Furthermore, given the small number of respondents, it would not be an onerous task for all contacts and data transmission between respondents and the Commission to be made via email

[18] **Forum Working Group on 'Member States Report to the Commission' Annex 2 – Report template**.

16.2 Suggestions for Improving the Content of Article 117(1) Reporting

The following suggestions (Box 16.2) relate to improving the content of Article 117 reports. They include proposals for guidance to CAs, omission of unnecessary questions and more precise wording.

Box 16.2: Non-technical Suggestions for Improving Article 117(1) Reporting

Consideration should be given to amending the content of questions used to facilitate the Article 117(1) reports as follows:

1. Highlighting which questions relate to the legal reporting requirements of CAs (answering of which is hence mandatory).
2. The inclusion of questions asking for justification of sanctions as being effective, proportionate and dissuasive.
3. The inclusion of questions asking for justification that enforcement strategies were sufficient to ensure implementation of penalties.
4. Explanation should be added to allow CAs to understand the relevance and benefit from collecting 'optional' information;
5. Adding 'no data available' options to relevant questions (to take account of the availability to CAs of relevant information). However, where MS agreements or legislation require the collection and/or provision of data, this could be highlighted in the question (and no such option be provided). Failure to provide such 'required' data could be followed up with the CA by the Commission, separately from the questionnaire.
6. Adding a facility to enter data for more than one CA per MS. Perhaps accompanied by explanation that co-ordination between the involved CAs is required to avoid potential duplication of data counting.
7. Reviewing the definitions underlying the terms included within the questions and reviewing the consistency of such definitions between questions. Precise definitions could be stated in the questionnaire and/or associated guidance.
8. Using agreed definitions (such as Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (2003/361/EC) and Forum definitions (e.g. that for 'duty holders'), wherever appropriate and available.
9. Using a consistent scoring system, applied throughout (e.g. either 1-5 or 1-10), and using a common logic as to what is regarded low/not adequate (1) and what is regarded high/adequate (5 or 10).
10. Encouraging a consistent use of the scoring system by the provision of descriptions of benchmarks as part of questions or in the guidance, where possible

APPENDIX 1
(TO FINAL REPORT ANNEX 2)

FINAL COMMENTS AND SUGGESTIONS FROM COMPETENT AUTHORITIES

1. APPENDIX 1 TO ANNEX 2: FINAL COMMENTS AND SUGGESTIONS

The complete text of the final comments and suggestions provided by CAs under Theme 10 of the questionnaire are set out in Table A3.11.1.

Table A1.1: Final Comments and Suggestions from CAs	
CA	**Comments and Suggestions**
AT	Individual aspects of implementation issues are addressed in brief written documents listed below. 1. Experiences with authorisation policy: On occasion of their visit to ECHA both Commissioners Mr. Potočnik and Mr Tajani, expressed clearly their interest in the progressive development of authorisation policy. Austria proactively supports this initiative as it considers the authorisation as an important supplementary legal instrument of chemicals policy. The authorisation regime strongly motivates industry to develop alternatives to substances with undesirable intrinsic properties but at the same time provides the opportunity for industry to continue the use of such substances for specific applications if there are no alternatives available. The Austrian REACH Implementation Law (REACH-DFG, BGBl. I Nr. 88 (2009)) stipulates the general objective that at least two authorisation dossiers pursuant to REACH article 59 (3) should be submitted by Austria every year. So far, Austria has submitted three candidate substances to ECHA and is dedicated to continue this activity through the next years. Based on the previous experience the following issues are considered as important for the development of authorisation policy under REACH: a. Given the administrative and technical burden connected with the submission of an authorisation dossier it is obvious that co-operation between Member States will be crucial for achieving progress. Both, ECHA and the Commission have encouraged Member States to co-operate on the submission of authorisation dossiers. This co-operation is, however, not as such foreseen in the REACH legislation as, for example, article 59 (3) states that "any Member State" may submit a dossier which would not allow - according to ECHA´s interpretation - that several Member States jointly submit a dossier. The Commission is, therefore, asked to consider this issue and to find ways by which co-operation of Member States in the field of authorisation could be formalised appropriately. b. In the context of authorisation it has been found that SVHC substances which have similar effects and uses (and therefore may be used as one other´s substitute) should be considered as groups of substances rather than individually (examples are chromium or cobalt compounds). This aspect has been considered, to a certain extent, by the informal group of Member States who have developed in a co-operation a list of priority substances for the authorisation. However, REACH does not seem to provide such a grouping approach formally. The Commission is, therefore, asked to develop further ideas and concepts to integrate the aspect of grouping into title VII of REACH. c. Because of a number of excemptions foreseen in REACH, the scope of authorisation is quite narrow. For example, REACH excludes intermediate substances from the authorisation, including e.g. monomers. On the other hand, the legislator has given monomers a specific status in so far as they do not benefit from certain exemptions granted to other intermediates in the registration process (see article 6 (2) of the REACH Regulation). This seems well justified in view of the fact that monomers can be released to the environment during the use of the respective polymer (either as non-reacted impurities in polymers or as polymer degradation products). Monitoring data demonstrate the relevance of such exposure routes for certain monomers. Against this background it seems not justified that monomers are excluded from the authorisation regime. AT has addressed this issue in a discussion paper within the CIRCA discussion Forum (which refers to the substance 4-tert-butylphenol as a concrete example). The Commission is asked to analyse this issue and to consider possible solutions, including the option of an appropriate revision of the REACH Regulation in 2012.

Table A1.1: Final Comments and Suggestions from CAs	
CA	**Comments and Suggestions**
	d. Another exemption from the authorisation concerns the use of articles containing SVHC substances from the authorisation regime. The introduction of the authorisation procedure for European companies producing articles which contain SVHC substances imposes certain bureaucratic burden as opposed to their competitors outside Europe. This fact creates a significant resistance of the European industry to authorisation policy in general which may significantly hamper its development. The Commission is also asked to consider this issue in the first revision of REACH in 2012. 2. Substances in articles: Austria is amongst the Member States that have so far not endorsed the ECHA "Guidance on Substances in Articles" (SiA) with respect to the interpretation of the 0,1% threshold referred to in articles 7 and 33 of the REACH regulation. The criticism concerns the interpretation in the guidance that, in the essence, the percentage refers always to the whole article, despite of its complexity. Recently, the Danish Environment Ministry has proposed, on the basis of findings reported in a study carried out on behalf of the Nordic Council (www.norden.org/en/publications/publications/2010-514?set_language=en) an alternative interpretation which simply assumes that "the 0.1 % trigger limit must be calculated as the average concentration of any object that has a shape, surface or design which entails com-pliance with the definition of an article in REACH (art. 3(3)). It does not make a difference whether or not such an article has been joined together with other articles to form a larger article." This interpretation seems well justified from a legal point of view, and is probably the only operable definition from an enforcement point of view. It is also supported by consumer and worker protection organisations. Industry has raised concerns that this interpretation may trigger, in the case of very complex articles, disproportionate expenses for companies. It is obvious that the alternative interpretation needs to be further elaborated, considering special or boundary cases for which the interpretation may not be practical (compare boundary cases between articles and mixtures discussed in the SiA). The current situation that guidance is in parts not generally accepted is quite undesirable. Therefore, the Commission is asked to reconsider its position in the light of the study of the Nordic Council and the recently distributed documents, and to propose a possible compromising interpretation. In this context, it is noted that an enforcement project which was recently finalised has demonstrated the existence of SVHC substances in consumer articles above 0,1%. The project focused on plastic shoes. 24 samples have been collected by Chemical Inspectors and analysed for different substances, including various phthalates, by the Austrian Environment Agency (Umweltbundesamt GmbH). In 9 of the 24 samples the 0,1% threshold for at least one of three phthalates which are SVHC substances was exceeded. Most of these products came from low prize supermarkets. 3. Co-operation between Chemical and Labour Inspectorates: The enforcement of REACH lies with the Chemical Inspectorates of the Länder (provinces). However, REACH has significant relevance for the occupational health and safety policy. Therefore, the co-operation between Chemical and Labour Inspectorates is important. The current status in Austria is briefly summarised in an attached document (Document A). 4. Co-operation of ECHA with enforcement authorities: The effectiveness of enforcement has an important impact on the implementation of REACH. The flow of information from ECHA to both, the CAs and the enforcement authorities plays a key role. As already stated under theme 8, the current lack of direct access for enforcement authorities to REACH relevant data at ECHA constitutes a major obstacle to the efficiency of planning and control actions at local level. Chemical inspectors need to obtain direct access to all registration data which fully allow them to enforce REACH. It will also be necessary to establish simple and efficient information channels between ECHA and the enforcement bodies in order to ensure that deficiencies which are identified by ECHA can be quickly followed up by chemical inspectors. For this purpose it will be necessary that relevant data, including non-public data from registration dossiers, be transmitted from ECHA to enforcement authorities. The Commission is invited to consider this issue and to make arrangements with ECHA so as to

Table A1.1: Final Comments and Suggestions from CAs	
CA	**Comments and Suggestions**
	ensure a quick solution in this area. 5. Experiences of the Austrian industry with the (pre)registration procedure The Austrian industry is represented in the Austrian REACH platform by the Wirtschaftskammer Österreich (WKO, Austrian Chamber of Commerce) and the Fachverband der chemischen Industrie (Association for the Austrian chemicals industry), which is a member of the WKO. Industry has been explicitly invited to express their view on the recent experiences with the (pre)registration process. In response to this industry has made some recommendations, especially with respect to SMEs which can be summarised as follows. The registration fees are generally considered as too high, taken into particular account that many companies have additional costs because of the necessity to consult external experts. To improve the situation it is proposed that ECHA should allow for the payment of fees by instalment and to review the level of fees after the experience of the first registration wave. The practical processes in SIEFs are still unsatisfactory, especially for SMEs. Therefore, ECHA and the Commission are invited to pay more attention to the practicalities in the SIEFs. SMEs should be better supported in the participation in SIEFs, e.g. through workshops, guidance or Help-Desk actions particularly targeted to SMEs. The functioning of REACH-IT still needs improvements. It is requested that: all guidance on REACH-IT be made available in all official languages of the EU a Software-tool for a completeness check should be made available well in advance of the first registration deadline in order to clarify simple (e.g. technical) problems quickly, direct contact of companies with ECHA staff should be made possible participation of companies that recover/recylce substances in SIEFs should be made possible by ECHA The quality of guidance should be generally improved. For this purpose it is requested that industry should be more involved in PEGs and that all guidance should be made available in all official languages of the EU. It is also requested that industry should be more actively involved in the REHCORN. Consistency of other EU legislation (e.g. directives such as the RoHS) with the REACH regime is considered insufficient and should be improved. "Parallel concepts" to the ones developed under REACH in other EU legislation should be generally avoided. The compliance of REACH with the WTO-rules should be permanently monitored. Companies from outside the EU need more and better information about their specific obligations with respect to REACH. The Fachverband der chemischen Industrie has provided a written document which is attached to this report (Document B) It is noted that the presented position represents the opinion of the Austrian industry and does not necessarily reflect the opinion of the Austrian CA (BMLFUW). 6. The concept of DMELs: The concept of DMELs (Derived Minimal Effect Levels), which is not as such foreseen in the REACH regulation but was introduced in the ECHA guidance on the information requirements for the chemical safety report, chapter R.8, has been heavily criticised by experts on Occupational and Health Protection in Austria. The problem is illustrated by an attached paper from the General Accident Insurance Institution (Document C). 7. Information in the supply chain: The information in the supply chain (title IV) is a key element of the REACH regulation, and the safety data sheet plays a central role. Therefore, the Austrian enforcement authorities consider the examination of safety data sheets as a priority in enforcement activities. For the purpose of efficient controls, a leaf-let (focusing on points 1-3 and 15 under REACH Annex II) and a check-list have been developed and used for inspections. These documents are provided with the Austrian report (Documents D and E). According to REACH article 31 para 3 c) a safety data sheet must be provided by the supplier if “Community workplace exposure limits” are in place. The Chemicals Agents

Table A1.1: Final Comments and Suggestions from CAs	
CA	**Comments and Suggestions**
	Directive, 98/24/EC, lays down both, binding as well as indicative occupational exposure limits and highlights in recital 13 the importance of data sheets which enable industrial users "to take the measures necessary to ensure the protection of the safety and health of workers." As the Chemicals Agents Directive requires Member States to lay down national occupational exposure limits (based on the binding as well as indicative values), it is essential that REACH article 31 para 3 c) is amended to cover also national occupational exposure limits rather than only Community exposure limits, thus triggering the transmission of a safety data sheet. 8. The Austrian Nanotechnology Action plan: Austria considers the control of possible risks to human health and environment from nanotechnology of high importance. Therefore, an action plan has been developed by the BMLFUW in co-operation with a number of organisations including ministries, industrial stakeholders and health and consumer protection institutions. A number of recommendations were made for action on national, European and international level was elaborated, and a nanotechnology information platform was created. The Nanotechnology Action plan is attached to this report and provides further details (Document F). 9. Environmental. health and legal aspects of cleaners containing living microbes as active ingredients: A study on cleaners containing living microbes has been carried out on behalf of the BMLFUW. The objectives of this study were (i) to provide an overview on the technology, products, and applications, (ii) to discuss the application of existing legislation, (iii) to identify and discuss possible environmental and health risks as well as environmental benefits, and (iv) to provide recommendations to regulators for further research and policy action. The study is attached to this report (Document G)
BE	1. Information: Within the Theme 3, concerning the question regarding the proportion of enquiries deemed to be (1) straight forward, (2) complex, we replied "100% No information" because we received no data from the National Helpdesk. 2. Recommendations: Access to external specialists: Due to budget restrictions, the access to external specialists is quite limited. Difficulties are also encountered in identifying and contacting the Belgian expert networks (e.g. economists). It seems that ECHA is in a better position to identify the experts available in the different fields of REACH and therefore to develop such expert networks. Data for nanomaterials: Currently, the MSs have no access to the data provided by industry on nanomaterials within the registration framework. An overview of the type of data on nanomaterials provided by industry is needed by the MSs in order to obtain information on, e.g., the possible adaptations made to the proposed tests, the eventual specific characterization of the nanomaterials, the availability of a review containing information on (eco)toxicity of the nanomaterial, etc. In order to examine the sufficiency of information on nanomaterials provided by industry through REACH, BE requested ECHA for access to the IUCLID information on a substance having nanoforms. According to ECHA however, this information can only be made available through the substance evaluation framework. BE is currently investigating the legal basis of ECHA's position. 3. Issue - The 0.1% limit trigger for information on SVHC in articles: REACH in its art. 7 and 33 introduces information obligations for producers, importers and suppliers of articles that contain substances of very high concern (SVHC). We consider that a uniform application of the triggering SVHC limit would be essential for the proper functioning of the Internal Market. However, it has not yet been possible to find a common understanding on how to interpret and apply this limit for complex articles. This situation creates uncertainty for companies manufacturing or importing articles – and for enforcement authorities as well. The current interpretation in the guidance on requirement for substances in articles leads to

Table A1.1: Final Comments and Suggestions from CAs	
CA	**Comments and Suggestions**
	gaps in the flow of information. In many cases the SVHC information will not follow the article through the supply chains. For some types of articles it seems that the loss of information on SVHC is quite substantial. The problems described above can largely be avoided with an interpretation that strictly refers to the REACH article definition when applying the threshold in cases of complex articles. This would be more workable for existing information routines for industry, more enforceable for authorities and it would improve the generation of SVHC information. It should be clearly stated in the guidance that the 0.1% trigger is to be applied on the average concentration of a SVHC in any object that complies with the definition of an article in REACH Art. 3 (3). This interpretation would lead to a largest flow of information on SVHC's in the supply chain and would be to the benefit of human health and environment (REACH art.1 (1))
BG	None
CY	None
CZ	None
DE	Additional Information which could not be filled in to the corresponding themes: Theme 1 - Information on the Competent Authorities: First Competent Authority (BMU). Other Institutions that the Competent Authority works with in relation to REACH: Bundesministerium für Arbeit und Soziales (BMAS) Rochusstrasse 1 53123 Bonn, Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz (BMELV) Rochusstrasse 1 53123 Bonn, Bundesministerium für Wirtschaft und Technologie (BMWi) Villemombler Str. 76 53123 Bonn, Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA) Friedrich-Henkel-Weg 1-25 44149 Dortmund, Umweltbundesamt (UBA) Wörlitzer Platz 1 06844 Dessau, Bundesinstitut für Risikobewertung (BfR) Thielallee 88-92 14195 Berlin; Second Competent Authority (BAuA). Other Institutions that the Competent Authority works with in relation to REACH: Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit (BMU) Robert-Schuman-Platz 3 53175 Bonn, Bundesministerium für Arbeit und Soziales (BMAS) Rochusstrasse 1 53123 Bonn, Umweltbundesamt (UBA) Wörlitzer Platz 1 06844 Dessau, Bundesinstitut für Risikobewertung (BfR) Thielallee 88-92 14195 Berlin, Bundesanstalt für Materialforschung und –prüfung (BAM) Unter den Eichen 87 12205 Berlin. Theme 4 - Information on the Promotion of the Development, Evaluation and Use of Alternative Test Methods: The overall public funding on research and development of alternative testing in Germany each year is : > 1,000,000 Euros. An amount higher than 1,000,000 Euros is not given in the selection list of Theme 4 in the electronic questionnaire. Since an answer is compulsory consequently a wrong amount has to be marked with a cross. A report "A review of national public funding programmes in European Countries" which gives a reference for the higher amount has been sent to the functional mail box. Theme 8 - Information on Enforcement Activities: All questions in the part "Reporting information for 2007 to 2009" can only be answered with bare numbers. It is not possible to give any explanations as e.g. how many of the 16 Federal States of Germany have provided information to each of these questions. Without this explanation the number is useless. Furthermore it is not possible to answer a question with "no information available" instead the question has to be answered with a "0". But the meaning of "0" and "no information available" is totally different. It is not possible to give the information "more than" (>): 2007: number of dutyholders: >207,500 above dutyholders who are likely to constitute registrants: >717 2008: number of dutyholders: >208,000 above dutyholders who are likely to constitute registrants: >738 2009: number of dutyholders:

Table A1.1: Final Comments and Suggestions from CAs	
CA	**Comments and Suggestions**
	>206,760 above dutyholders who are likely to constitute registrants: >1988
DK	DK would like to highlight 4 issues under this theme: 1) Calculation of the 0.1 % trigger limit of articles 7(2) and 33 of the Regulation. It must be made clear how the 0.1% trigger of articles 7(2) and 33 of the regulation shall be calculated in the case of complex articles. The legal text does not distinguish between articles sold separately (such as e.g. spare parts) and articles that have been joined together with other articles to form a larger more complex article. This has lead to different interpretations in the MS, and thus an urgent need for further clarification. 2) Nanomaterials. There is a need to ensure that registrants clearly identify substances on the nanoscale in the registration dossiers and document the safe manufacture and use of these forms. Furthermore, adequate operational conditions and risk management measures for nanomaterials must be described in the Exposure Scenarios and passed on through the chemical supply chain. 3) Evaluation of Registration dossiers. Under REACH, manufacturers and importers of substances must submit a registration dossier containing information on the intrinsic hazards of the substance and, for substances in a quantity ≥ 10 tonnes/year and meeting the classification and/or PBT criteria, a CSR documenting the safe manufacture and use. Based on an evaluation of registration dossiers, ECHA may request the registrant to submit any information needed to bring the registration into compliance with the requirements. However, no clear provisions are given on what action to take in case ECHA concludes that the registrant has not documented the safe manufacture and use. Such provisions could, e.g., include a mandate to ECHA to request the registrant to update the registration dossier and document the safe manufacture and use or specify that ECHA should inform the national enforcement authorities which would then be required to take action. 4) Scope of exposure assessment. REACH Annex I specifies in section 5.0 that an exposure assessment "shall cover any exposures that may relate to the hazards identified". The Commission's Legal Service has confirmed that this is not restricted to endpoints for which the criteria for classification are met. It should be clarified that the purpose of the exposure assessment is to feed into the risk characterisation and, as generally agreed, risk is defined as the relationship between the exposure and the intrinsic hazards. Numerous examples are available demonstrating risks also for endpoints where the classification criteria are not met. Only in certain cases is it possible to conclude from information on the intrinsic hazards of substances that they cause only a minimum risk (cf. REACH, Article 2(7)(a) and Annex IV), which should be clearly defined in guidance
EE	None
ES	Many activities promoting and informing about REACH Legislation have been carried out by Spanish MSCAs. For instance, MSCAs have organised workshops aimed at all dutyholders. Furthermore, several seminars about REACH have been celebrated all-around Spain since 2005. The Ministry of Health an Social Policy Website has been modified to provide deep information about REACH processes. In addition, we have sent leaflets to inform potential registrants of their obligations
FI	REACH is an extensive and complicated piece of legislation and we are concerned that the interpretation of the legal text is changing frequently. This makes the implementation of the regulation challenging to the industry, the CAs and the enforcement authorities especially in the early years from entry into force. Furthermore, the lack of resources in the Finnish CAs makes the situation more demanding. We feel that it is not realistic to assume a similar kind of contribution from a small MS with few resources than from a bigger MS, for example in proposing SVHC substances or harmonised classification and labelling. In our opinion, there

Table A1.1: Final Comments and Suggestions from CAs	
CA	**Comments and Suggestions**
	are too many meetings which take more time than expected and less time is left for actual chemicals' evaluation and enforcement activities. As a smaller issue, we find this reporting questionnaire far too detailed and question the usability of the results as for many questions there is no data available. Reporting period should have been clearly stated in the questionnaire
FR	Guidance : 1st issue (Translation) : Huge efforts have already been made. They need to be carried on and a focus on translating guidance and other documents aiming at facilitating SMEs to succeed in REACH should be put. 2nd issue (Authorisation): Although the concerns raised about the relevant research and development activities (article 62.4e)) and the substitution plan (article 62.4f)), already expressed in the note from the French authorities on 11 October 2007 and reiterated in March 2010, have not been taken into account in the current draft, they won't oppose the endorsement of the guidance at this stage. The main reasons for this is that we have well noted that: the Commission agrees on the principle that the substitution plan must be required for both routes under authorisation process, i.e. the "adequate control route" and the "socio-economic route" and on the fact that this will have to be clarified during the revision of Reach (2012); the endorsement of the guidance as it is could facilitate the rapid adoption of the first Annex XIV and of an also long-awaited amended Annex XIII which takes into account all available information in a weight of evidence approach to identify PBT/vPvB substances. We will pay particular attention to these commitments in the next future. Articles and parts of articles: 1st issue: application of the 0.1 % threshold (articles 7.2 and 33 of the REACH regulation) Resulting from the inclusion of substances on the candidate list, companies have some legal obligations, in particular if the substances are contained in articles. These information obligations for the benefit of customers and of the supply chain are immediately triggered by MSC agreement on identification of SVHC. Several Member States, including FR, have questioned the approach of the current guidance of applying the 0.1 % threshold to the articles as produced, imported or supplied when implementing articles 7.2) and 33 of Reach to complex articles (i.e. consisting of many parts). The fact that a complex article may comply with the definition of article 3.3) while, at the same time, several parts of it may also still comply with this definition must not be omitted. Therefore, the approach consisting in applying the 0.1 % threshold to any parts of an article which complies with the definition of article 3.3) should be preferred. Furthermore, as shown in a recent report from the Nordic Council of Ministers (www.norden.org/en/publications/publications/2010-514?set_language=en), the current approach given in the guidance is detrimental from several points of view: loss of information through the supply chain which can affect the level of health and environment protection, obstacle to business (workability problems for producers of complex articles, decreased ability to anticipate the need for substitution of substances likely to be included into the candidate list, inequality between economic operators), difficulties of chemical analyses of complex articles that enforcement authorities will be facing. As a consequence and in conclusion, we support the principle "once an article, always an article". 2nd issue : Annex XVII provisions: Regarding the wording articles / parts of article, we note that in the majority of the Annex XVII provisions, the word article includes part of articles. We believe it's relevant to remain consistent with these provisions. Therefore, we are not in favour of putting the words "parts thereof" in Annex XVII entries. We support the idea that

Table A1.1: Final Comments and Suggestions from CAs	
CA	**Comments and Suggestions**
	the word "article" already means in itself "article and every part of article". It does not make a difference whether or not such an article has been joined together with other articles to form a larger article. This definition means that any object which, at a certain step in its life has became an article, will normally remain an article until it eventually becomes waste after end use. An assembled article may comply with the definition of REACH article 3(3), while at the same time several parts or components of that same article may also comply with the definition of an article. An article can be both simple and complex. However, many components of complex articles are in essence still also articles. We consider that the limit values, mentioned in each Annex XVII entry related to a restriction concerning articles, shall apply to articles and parts that a complex article consists which comply with the definition of an article in Article 3(3) of REACH. Specific substances of interest : We support the development of assessment tools dedicated to specific substances (id nanomaterials and endocrine disruptors), and also to combined effects; in order to improve their consideration by the REACH regulation. We will pay particular attention to the follow-up given by the Commission to the Environment Council Conclusions of December 2009. Enforcement: We would like to draw the attention on the relevance of developing communication tools between enforcement bodies from 27 MS. A specific attention to the coordination with Customs needs to be paid. We would like to highlight that investigations on importations should be a priority in order to ensure equity between EU producers and non-EU. The consistency between the Community Customs Code and REACH needs to be clarified and further explored. We would like to remind the Commission the importance of working at European level in collaboration with customs authorities to build the capacity of an exact match between the tariff and customs code and CAS or EC numbers for chemicals. This approach would greatly facilitate monitoring import and export traffic of banned or restricted substances, and also investigations by Customs officers of substances subject to registration. We would like also to raise specific attention concerning the importance of making available a French translation of ECHA decisions taken in compliance for example with article 41 in order to make it enforceable correctly under French law. IT-tools: We have some concerns about access to REACH-IT. Moreover, we consider training sessions for MSCAs are needed. Regarding RIPE, we would like to point out our serious concerns about the final content which could appear as slightly poor (example : no data available for legal entity located in other members states), and about the time progress
EL	From our experience in the implementation and enforcement of REACH at national level so far, we strongly believe that a harmonised enforcement in EU level is needed in order to avoid cases where a MS enforces more strictly REACH (like Greece has done) thus resulting in low competitiveness of the national products
HU	In Hungary there are lots of SMEs that can hardly comply with REACH requirements because of financial causes, so it's possible that some of them go bankrupt. As REACH is an extremely difficult piece of legislation even for a jurist, everyday people in industry and economy cope with the requirements of REACH only with great efforts and little success. Inspectors in enforcement would need more and more training for their work
IE	The following are some issues that could be considered under REACH review. RISK MANAGEMENT OPTIONS: REACH has two risk management options for hazardous chemicals with CMR, PBT and vPvB properties – authorisation and restriction.

Table A1.1: Final Comments and Suggestions from CAs	
CA	**Comments and Suggestions**
	Choosing the right risk management option is critical for the success of REACH. Authorisation of a chemical is currently a two- step process involving a) identification of a substance on a candidate list and b) eventual inclusion of substances on the candidate list in Annex XIV. In moving a substance from the Candidate List to Annex XIV, REACH requires the Agency to give priority to substances with a) PBT or vPvB properties; b) wide dispersive use and c) high volumes. Additional information such as information on use of the chemical and availability of alternatives would be valuable in determining if authorisation is indeed the most appropriate option for the chemical, or whether restriction might not be a more effective risk management option. As experience is gained on the two risk management options in REACH, the Commission may need to review the current prioritization list in Article 58(3). OVERLAP WITH OTHER LEGISLATION (e.g., RoHS, POPs, Detergents, etc): REACH is the primary legislation covering manufacture, import and use of chemicals. As such, REACH should be used as the basis and framework for streamlining wider EU chemicals legislation, and the mechanisms under REACH used to manage risk should be the first point of decision making in dealing with a particular hazardous chemical. Procedures under sectoral legislation, for example, RoHS, cosmetics, detergents, toys, should be with reference to the procedures under REACH. The EU obligations and interests in the context of the Stockholm Convention on POPs and the Rotterdam Convention on Prior Informed Consent could also be included under this framework. This would help to avoid the emergence of two parallel risk management schemes for the same substance, with extra regulatory costs for administrations and economic operators but without any corresponding health or environmental gain. The following should be considered with regard to future reporting on implementation of REACH: Theme 4: Future data collection will first require an initiative from the Commission to establish common indicators. Theme 8 should be reviewed. The subject matter for reporting emanated from a Forum Working Group some time before the main report was designed, but was not subject to later review by MSCAs
IT	In order to increase the overall knowledge and capability to perform risk assessment, Italy believes it is necessary to implement the educational system starting with new orientation courses on "sustainable chemistry" for secondary school to lay the foundations for higher education courses up to specific master degrees. With this in mind, Italian CA together with the Ministry of Education, University and Research, is planning training courses for teaching body of secondary school and prize-winning competitions in order to increase the awareness of young people on what it has been done and it is planned to be done at European level for the management of chemicals. Furthermore, Italian CA has already promoted several master degrees on REACH
LT	None
LU	None
LV	None
MT	None
NL	1) We are concerned that the frequency of placing substances from the candidate list to the authorisation list (currently only once each 2 years) is too low for speeding up safe use of SVHC substances during the coming 10 years and does not gain public confidence in REACH. 2) We are pleased with the initiatives of the Forum to perform concerted enforcement projects, but we would like to see more emphasis on harmonisation in monitoring and

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CA	**Comments and Suggestions**
	enforcement actions. 3) For a successful application of REACH to nano-materials further consideration is needed in order to find out whether the general provisions regarding registration will cover the nano-materials within a reasonable time frame. Directly related to this issue we would like to draw the attention again to the importance of solving the current discussions on the identity issue of nano-materials. 4) The European Commission could further improve the collaboration and decision-making process between Member States by creating more opportunities to meet/consult each other, allowing participants sufficient time for studying the meeting documents and for internal consultation before meetings, and improving the meeting management. 5) Based on our experience in enforcement of Article 8 (OR), we suggest that guidance should be developed on practical conditions regarding legal entities (the procedure to control, change or wipe out companies, claimed to be legal entities for the role of only representatives). 6) The Commission is requested to further improve or develop interfaces between REACH and other regulations dealing with chemicals such as ROHS, waste, surface water, occupational protection, etc., to avoid overlap and contradictions. As the current discussions on the waste guidance and specifically the ROHS regulation show, taking pro-actively the possibilities of REACH restrictions or authorisations in the deliberations on ROHS, could improve the proposals for a directive already in an early stage of the negotiations
PL	1. Insufficient harmonization of sanction among the Member States may be, in our opinion, the problem regarding REACH implementation in the future. 2. We believe that further work is needed on developing Annex IV, considering for example ethyl alcohol. 3. More work should be devoted to the end of waste status of substance (Art. 6 of Directive 2008/98/EC) 4. It would be beneficial to have CARACAL meeting in countries holding the rotating Presidency of the EU. 5. Performing tasks by Competent Authority is undermined if there is no full access for MSCA to REACH-IT system and therefore to updated data concerning registration and pre-registration. It would also be beneficial for implementing REACH to provide MSCAs with data concerning registration and pre-registration of substances from the whole EU
PT	None
RO	None
SE	The intended uses for the results of this questionnaire are not very clear. Will the Commission use them internally or will it be discussed with the European Parliament? Will the Commission bring it to CARACAL or to the ECHA Management Board for discussion and future planning? An overview of the aims would have been helpful for finding the appropriate level of details when providing answers. We recommend that the following issues should be taken into consideration by the Commission: • The 0.1% limit trigger for information on SVHC in articles Ensuring compliance of registration dossiers

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	•Nanomaterials •MS tasks under REACH and resources to carry out these tasks
SI	None
SK	Other activities directly connected to REACH implementation tasks which require a lot of effort, time and capacity are: 1. - the preparation of the national legislation harmonized with the REACH. 2. - the translation of basically all guidance, relevant documents, review and correction of translated EU legislative documents and consultation on terminology for the EU Translation Centres,. 3. - work in Council when needed, and in Commission when EU legislation is under preparation. 4. - MS CA - CCSP sent a Seconded National Expert to ECHA for 2 years (January 2007 - May 2009). This one expert represents about 10 % of the staff and could not be substituted. 5. - Preparation for the access to REACH IT and fulfillment of Standard Security Requirements needs extra resources. 6. - In 2009 there were 1636 messages sent through CIRCA interest groups: REACH&CLP CA, MSC, Registration, Annex XV, Evaluation. (Further large number of messages were received from REHCORN, SEAC and RAC). Such overload of information is not manageable by the small CA. 7. - Since 14 June 2007 Slovak helpdesk provided 255 positions to 255 questions through HELPEX (RHEP) system. Further information: 1. National Labour Inspectorate reported for 2007: There where 7 accidents investigated in regard to dangerous substances by labour inspectors in Slovakia (1 of all 7 was mortal) 2. National Labour Inspectorate Reported: There where 68 accidents registered in regard to dangerous chemicals in 2007 by labour inspection in Slovakia. 3. No record of verbal advice is available. 4. National Labour Inspectorate reported for 2008: There where 11 accidents investigated in regard to dangerous substances by labour inspection in Slovakia (neither of 11 was mortal). 5. National Labour Inspectorate reported for 2008: There were 85 accidents registered in regard to dangerous chemicals in 2008 by labour inspection in Slovakia
UK	We have nothing further to add on implementation issues within the UK
NO	We would appreciate if the following issues would be considered on the future implementation of REACH: The 0.1% trigger limit in articles: The Norwegian CA's view is that an entire complex article as well as parts/components of the complex article, comply with the definition of an article

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	given in the REACH regulation, article 3(3). Consequently, the 0.1 % trigger limit should also apply to parts/components of complex articles, not only to the entire article. The principle "Once an article - Always an article" should apply. The 0.1 % trigger limit should be calculated as the average concentration of any object that has a shape, surface or design which entails compliance with the definition of an article (article 3(3)). It does not make a difference whether or not such an article has been joined together with other articles to form a larger article. This interpretation of the 0.1 % trigger limit is significant in order to secure sufficient information in the supply chain to allow safe use of substances of very high concern (SVHC) in articles in accordance with article 33. It will benefit both the human health (employees, consumers) and the environment. In addition this interpretation is important in order to make sure that companies are prepared for potential applications for authorisation of SVHC substances being added to the Annex XIV list. Compliance check regarding dossier evaluation (REACH article 41): It is of importance that ECHA in addition to compliance checks of the information requirements in Annexes VI-XI, also takes compliance checks of other information in the registration dossiers - as for instances industries estimates of DNEL and PNEC values. If DNEL/PNEC values are inadequately derived, this can result in incorrectly conclusions in the chemical safety reports and the risk management measures proposed. Human health and the environment may suffer if the risks are not properly controlled. Nanomaterials: Even though nanomaterials (NM) are covered by REACH, there are still in our view concern whether the legislation and its guidance's are sufficient to secure safe nanomaterials. One of our main concerns is that NM with different properties than their bulk counterpart will be subject to the same information requirements, as one substance in one dossier. We are of the opinion that in general NM should be regarded as substances on their own, to ensure safe use. We appreciate the initiative from the Commission regarding the three REACH implementation projects on nanomaterials. The outcome of these projects should be used to consider specific amendments of REACH, for instance introduction of additional information requirements in point 2 in Annex VI (identification of the substance). This is necessary to make sure that information requirements and risk assessment procedures for NM detects potential risk as efficient as for other chemicals
LI	In general, this questionnaire is very detailed and complex. The intention for the use of the answers is not clear. Ttherefore it is difficult to find what level of details are needed when preparing the answers. In order to collect useful information it would be useful to note some sort of benchmark criteria for some of the questions. In addition, we would appreciate if the following issue would be considered on the future implementation of REACH. Nanomaterials: Even though nanomaterials are covered by REACH, there is still no sufficient legislation or guidance to secure safe nanomaterials. Nanomaterials with different properties than their bulk counterpart should be subject to the same information requirements as one substance in one dossier. In general, nanomaterials should be regarded as substances on their own to ensure their safe use. We appreciate the initiative from the Commission regarding the REACH implementation projects on nanomaterials
IS	As a comment to this questionnaire, it is very detailed and complex and we do not have answers to nearly all the questions. Also the intention for the use of the answers are not clear and therefore it is difficult to find what level of details are needed when preparing the answers.

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	We recommend that the following issues should be taken into consideration by the Commission: The 0.1% limit trigger for information on SVHC in articles; Ensuring compliance of registration dossiers; MS tasks under REACH and resources to carry out these tasks; Do you wish to upload documents in support of this submission