MS REACH Reporting Questionnaire

General Information	
Which Member State are you reporting for?	SE
What reporting period are you reporting on?	2010
Primary contact person's name.	Sten-Åke Svensson
Please provide an email address for the primary contact person.	sten-ake.svensson@kemi.se

Theme 1 - Information on the Competent Authority	
How many Competent Authorities are responsible for REACH?	There is one Competent Authority responsible for REACH.

One Competent Authority Responsible for REACH	
What is the name of the organisation where the Competent Authority is situated?	Kemikalieinspektionen, The Swedish Chemicals Agency
What is the address of the organisation?	Kemikalieinspektionen P.O. Box 2 SE-172 13 Sundbyberg Sweden
What is the email address of the organisation?	kemi@kemi.se
What is the telephone number of the organisation?	+46 8 519 411 00
What is the fax number of the organisation?	+46 8 735 76 98
What part of REACH does this part of the Competent Authority deal with?	All
From what part of Government does this part of the Competent Authority have authority from?	Environment
Are employees in the Competent Authority directly employed by Government (civil servants)?	Yes
What skills do staff in this part of the Competent Authority have?	Chemistry Toxicology Ecotoxicity Economy Enforcement Legal Policy Exposure CLP
What other chemical legislation are the staff of the REACH CA involved in?	Import/Export Biocides Pesticides Other

If Other, please list the different legislations here	Classification, labelling and packaging of substances and mixtures Regulation 1272/2008 Restriction of Hazardous Substances Directive 2002/95/EC Volatile organic compounds (VOC) in paints and varnishes European Directive 2004/42/EC Detergents Regulation 648/2004/EC Persistent Organic Pollutants (POPs) Regulation 2004/850/EC
Are there any other institutions that the Competent Authority works with in relation to REACH issues?	Yes
Please list the other institutions that the Competent Authority works with.	Swedish Environment Protection Agency Swedish Work Environment Authority Swedish Consumer Agency Swedish Civil Contingencies Agency
Does the Competent Authority outsource any of its work?	No
How adequately resourced is the Competent Authority?	5
Space is available below to provide further comments on the resourcing of the Competent Authority.	As default we have stated 5, but it should be noted that in order to collect useful information some sort of benchmarking criteria for the expression “adequately resourced” would be needed. We perform the MS tasks as required by REACH. Swedish experts are present in committees and other working groups established under REACH, in many cases with dual representatives. Swedish experts are acting as (co)rapporteurs in RAC for classification proposals for 10-15 substances and jointly in RAC and SEAC for one restriction proposal. Sweden did initiate 2 of the current 30 substances on the candidate list and contributes to several projects for revised guidance under REACH. Also enforcement activities are performed, together with contributions to the development of REACH enforcement through Forum. Sweden has not yet initiated any new proposals for SVHC identification or restriction. This is partly due to the extensive demands in the legislation as well as in related guidance and working procedures for these kinds of proposals.

Theme 2 - Information on Cooperation and Communication with other Member States, the European Chemicals Agency (ECHA) and the Commission

How effective is communication between MS for REACH?	5
How could effectiveness of communication between MS be improved?	As default we have stated 5, but it should be noted that in order to collect useful information some sort of benchmarking criteria for “effectiveness of communication” would be needed.

How effective is collaboration between MS for REACH?	5
How could effectiveness of collaboration between MS be improved?	As default we have stated 5, but it should be noted that in order to collect useful information some sort of benchmarking criteria for “effectiveness of collaboration” would be needed.
Are there any special projects/cooperation on chemicals that the MS participates in with other MS outside of REACH?	Yes
Please provide further information.	• Strategic Approach to International Chemical Mangement (SAICM) under the UN Commission for Sustainable Development (CSD): projects concerning e.g. information on substances in articles • UN Conventions on Persistent Organic Pollutants (POPs), Long Range Transboundary Air Pollution (LRTAP), Mercury, Prior Informed Consent (PIC) • OECD: mainly work related to harmonized test methods • Nordic Chemicals Group under the Nordic Council of Ministers: cooperation between the five Nordic countries Denmark, Finland, Norway, Iceland and Sweden in various projects on REACH, GHS, biocides, product registers, enforcement, exposure and risk assessment
How effective is MS communication with ECHA?	5
How could effectiveness of communication with ECHA be improved?	As default we have stated 5, but it should be noted that in order to collect useful information some sort of benchmarking criteria for “effectiveness of communication” would be needed. Please note the cross links to questions under theme 5. From the responsible contact person’s perspective, it is a challenge to overview and manage contacts and documents related to committee work as well as to a number of other ECHA related tasks. In practice, documents may appear on the respective committee CIRCA site(s), on various newsgroup sites as well as via ordinary e-mails. Thus, any actions leading to improved overview of communication channels and more efficient/streamlined channels, would be welcome.
How effective is MS collaboration with ECHA?	5

How could effectiveness of collaboration with ECHA be improved?	As default we have stated 5, but it should be noted that in order to collect useful information some sort of benchmarking criteria for “effectiveness of collaboration” would be needed. Please note the cross links to questions under theme 5. Any actions leading to simpler routines and working procedures would be welcome. At present the information from ECHA is handled by CIRCA interest groups. This is presented as an interim solution until REACH IT is in use. This interim solution is built on notification of physical contact persons. This has made MS CA work more complicated as it implies an interim solution also for each MS. We recognize that ECHA now has managed to solve most of the technical REACH IT issues, even though the work is not on schedule. The delay has, however, had implications for MSs in preparing for REACH IT and the related security issues. Discussions regarding MS access to data and REACH IT have been prolonged. Not all MS CAs are ready to sign the Declaration of commitment and the Standard Security Requirements, due to conflict with national law. Since the CIRCA interest groups are to be removed, it is a concern if this implies that some MSs will not be able to fulfil their tasks according to Reach. In that case, alternative solutions will be needed.
How effective is MS communication with the Commission (specifically Article 133 Committee)?	5
How could effectiveness of communication with the Commission be improved?	As default we have stated 5, but it should be noted that in order to collect useful information some sort of benchmarking criteria for “effectiveness of communication” would be needed. Please note the cross links to questions under theme 5. It is not always clear to whom in the MS invitations and documents to meetings are sent and it seems to vary from meeting to meeting. Furthermore, there is no web-site to check whether all documents for a meeting have been received. Two proposals to improve are 1) introduce and keep updated a contact/mail-list for the Article 133 Committee and 2) introduce a CIRCA site for the committee. It could also be clarified how MS CAs can communicate with the Commission between meetings and keep track of what happens or which comments are received. Two proposals to improve are 3) advice given by the Commission on how or whom to contact between meetings and 4) transparent compilation of comments received (and as far as possible, from internal Commission consultations).

How effective is MS collaboration with the Commission (specifically Article 133 Committee)?	5
How could effectiveness of collaboration with the Commission be improved?	As default we have stated 5, but it should be noted that in order to collect useful information some sort of benchmarking criteria for "effectiveness of collaboration" would be needed. A sub-group to CARACAL could be established, to allow for preparatory discussions of proposals before meetings with the Regulatory committee. More frequently updated mail-lists for CARACAL would be helpful, where appropriate also for areas like e.g. restrictions.
Has use been made of the safeguard clause of REACH (Art. 129)?	No

Theme 3 - Operation of the National Helpdesk and Provision of Communication to the Public of Information on Risks of Substances	
Please provide the name of the organisation responsible for operating the National Helpdesk for REACH.	Reach-upplysningen, Kemikalieinspektionen (The Swedish Chemicals Agency)
What is the address of the Helpdesk?	Reach-upplysningen Kemikalieinspektionen Box 2 SE-172 13 Sundbyberg Sweden
What is the web page address of the Helpdesk?	www.kemi.se/reach
What is the email address of the Helpdesk?	reach@kemi.se
What is the telephone number of the Helpdesk?	No telephone service is provided
What is the fax number of the Helpdesk?	+46 8 7357698 (The Swedish Chemicals Agency)
Are there any more organisations responsible for operating the National Helpdesk for REACH?	No

Please indicate the number of each type of staff that are involved in the Helpdesk.	
Toxicologist	1-5
Ecotoxicologist	1-5
Chemist	1-5
Risk Assessor	1-5
Economist	
Social Scientist	
Exposure Assessor	1-5
Other (please list)	6-10
If you have specified that there are a number of other staff that are involved in the Helpdesk, please list the type of staff here.	2 from Legal Service, 6 inspectors, 2 risk managers
Is the same Helpdesk used to provide help to Industry on CLP?	No

Does the Helpdesk receive any non-governmental support?	No
How many enquiries does the Helpdesk receive per year?	>1000
In what format can enquiries be received by the Helpdesk?	Email Fax Letter Other (please list)
Please list the other format(s) of enquiries that can be received by the Helpdesk.	In 2007 and 2008 enquiries were also received by phone service. No enquiries have been received by fax or letter.
How are the majority of enquiries received?	Email
Do you provide specific advice to SME's?	Yes
Who are the majority of enquiries from?	Small-medium enterprises
What type of enquiries does the Helpdesk receive?	Pre-registration SIEFs Registration REACH-IT Evaluation IUCLID5 Authorisation Downstream user obligations Restriction Obligations regarding articles Testing Safety Data Sheets Enforcement SVHC CSR preparation Other (please list) CLP
Please list the other types of enquiries that the Helpdesk receives.	National penalties and registration fees

For each type of enquiry received, please provide the proportion in percentage of the total enquiries.	
Pre-registration (%)	13
Registration (%)	30
Evaluation (%)	1
Authorisation (%)	2
Restriction (%)	1
Testing (%)	1
Enforcement (%)	1
CSR preparation (%)	0
CLP (%)	9
SIEFs (%)	1
REACH-IT (%)	1

IUCLID5 (%)	1
Downstream user obligations (%)	9
Obligations regarding articles (%)	10
Safety Data Sheets (%)	13
SVHC (%)	1
Other (%)	17

What proportion of enquiries received are deemed to be 1) straight forward, 2) complex, OR No information	
Straight forward (%).	50
Complex (%).	50
No information (%).	0

How long, on average, does it take to respond to the following types of questions?	
Straight forward questions	4 hours
Complex questions	2 weeks
Are any types of enquiry outsourced?	No
Does the Helpdesk seek feedback on its performance?	Yes
Does the Helpdesk review its performance and consider ways to improve its effectiveness?	Yes

What level of cooperation is there between Helpdesks?	
What level of cooperation is there between Helpdesks under REHCORN?	2
What level of cooperation is there between Helpdesks outside REHCORN?	1
How frequently do you use RHEP?	Monthly
Has the MS carried out any specific public awarness raising activities?	Yes
What type of activities have been carried out?	Leaflets Other (please list) Speaking events
Please list the other types of activities that have been carried out.	Translation of ECHA:s SIEF related FAQs and opening of a SIEF webpage with the ECHA SIEF banner. Pre-registration and registration campaigns. The latter was addressed to Swedish companies having pre-registrated a substance. In relation to the question below; The campaigns were effective in the sense that the number of helpdesk enquiries increased.

How effective was each type of activity?	
Speaking events	3

Leaflets	3
Other	3
Do you have a REACH webpage/website?	Yes
Do you have a single webpage for REACH or multiple pages?	Multiple webpages
How frequently is the REACH webpage visited (per month)?	501-5,000
Please describe the scope of the number of REACH webpage visits.	On average 3 000 visits/month and 10 700 page views/month in 2009 The most visited single REACH web pages in 2008 (number of visits) 1.The first REACH page with an overview of news and links 36 305 2.This is REACH – a short description of REACH 13 395 3.The Titles in REACH 9 718 4.REACH Helpdesk 7 965 5.Roles and obligations under REACH 7 421 6.Keml:s Questions and Answers on REACH(in Swedish) 5 707 The most visited single REACH web pages in 2009 (number of visits) 1.The first REACH page with an overview of news and links 24 295 2.This is REACH – a short description of REACH 8 125 3.REACH Helpdesk 3 867 4.The Titles in REACH 3 557 5.Roles and obligations under REACH 3 221 6.REACH and articles 3 008

Theme 4 - Information on the Promotion of the Development, Evaluation and Use of Alternative Test Methods

Does the MS contribute to EU and/or OECD work on the development and validation of alternative test methods by participating in relevant committees?	Yes
What has been the overall public funding on research and development of alternative testing in your MS each year?	Euros 100,001-1,000,000

Theme 5 - Information on Participation in REACH Committees (FORUM, MS, RAC, SEAC, CARACAL, PEG, RCN, REHCORN)

On a scale of 1-10, how effective do you think the work of the Committees associated with REACH are?	5

How could the effectiveness of the Committees be improved?	As default we have stated 5, but it should be noted that in order to collect useful information some sort of benchmarking criteria for “effectiveness” would be needed. In general, Swedish experts participating in REACH-related committees and working groups have expressed that meeting agendas are extensive and that presentations of information often get lengthy. We welcome changes in procedure leading to sufficient meeting time for dialogue and discussion with MSs on important issues, e.g. regarding interpretation of the legislation. In order to have fruitful discussions, the necessary document should reach participants well in advance of the meeting so that they can prepare contributions to the discussion. It is currently a challenge to overview the documents as they may appear 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 simpler routines and more efficient communication would be welcome. Any actions to overcome the challenge of too many and too late documents would be welcome. The implementation of REACH-IT for MSCAs is expected to increase efficiency. In addition to what is proposed under the relevant questions in Theme 2 and to what has been put forward in previous questionnaires, carried out by ECHA, we have the following comments for individual committees and working groups: REACH Article 133 Committee It is an observation that insufficient preparatory discussions with MSs have lead to non-voting comitology meetings. Currently, the rules of procedures allow only 3 weeks which may be too short for MS preparations in the case of substantially new proposals. Such proposals should be given at least 5 weeks consultation time, at least in cases where no deadlines are given in the legislation. The rules of procedure could be amended to reflect this. An alternative solution could be to arrange CARACAL subgroups for preparatory discussion with MSs. CARACAL Documents for issues that need comments and/or discussion should be provided 2 weeks beforehand. A CARACAL subgroup could be established for discussion on Restriction dossiers and proposals. Risk Assessment Committee (RAC), Socio-Economic Analysis Committee (SEAC), Member State Committee (MSC) In order to have a sufficiently high level of activity in the committees, efforts should be made to ensure that the remuneration system for MSs supporting (co)rapporteurs will cover all the work, not only parts of it. Remuneration of work by (co)rapporteurs should be introduced also for Classification. Forum Forum had an early start, probably due to the preparatory work in the EU REACH Enforcement Project (Final report, February 2008). In a very early stage, the Forum established their rules of procedure and a Work Programme that started several working groups. The Forum secretariat has facilitated the work in a very competent and deserving way. HelpNet (previously REHCORN) The effectiveness in HelpNet could be improved with more dialogue and discussions at meetings, especially with difficult questions of general character in the HelpEx database. One suggestion could be to mark questions in HelpEx as suitable for discussion

with a tick-box, generating an e-mail. It is also suggested that statistics presentations from the helpdesks could be briefer and more general. Security Officers' Network (SON) Initially there was active work concerning information availability for MS, Reach-IT and security issues. ECHA has been overloaded but has managed to solve most of the technical Reach-IT issues, although not on schedule. The delays have had implications for MSs' preparations for Reach-IT and the related security issues. Currently there are two meetings per year, mostly consisting of information and status reports from ECHA. Time for discussion is limited and rather few MS are active in the discussions. Often information from previous meetings is repeated. Risk Communication Network (RCN) This network started in autumn 2008 and has up to now held three meetings. Initially there was a discussion regarding the need for an additional working group. The need for training and workshops was identified and MSs finally agreed that there was a need to exchange experience, emphasizing that it is a voluntary network with semi-active status. "Good experiences" from MS and European Agencies/Community bodies have been presented at each meeting and a training course has been held. The meetings mostly consist of information, the "formal frame" of the meeting reduce the discussions and rather few MS are active.

Theme 6 - Information on Substance Evaluation Activities

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Please name the organisations/institutions that are involved in the evaluation process.	Only dossier evalution so far.

Please indicate the number of each type of staff that are involved in substance evaluation.

Toxicologist	0
Ecotoxicologist	0
Chemist	0
Risk Assessor	0
Socio-Economic Analyst	0
Exposure Assessor	0
Other (please list)	
If you have specified that there are a number of other staff that are involved in substance evaluation, please list the type of staff here.	
Please list the names of the substances covered in the dossiers that the MS has commented upon.	
Please list the names of the substances covered in the dossiers where a draft decision has been made.	
Please list the names of the substances covered in the dossiers that the MS has rapporteured.	
Please list the names of the substances covered in the dossiers that the MS has completed.	
How long, on average, does evaluation of a dossier take?	
How many transitional dossiers has the MS completed?	1-3
How many substances has the MS added to the Community Rolling Action Plan?	0
How many of ECHA's draft decisions on dossier evaluation has the MS commented on?	1-3

Theme 7 - Annex XV Dossiers

How many of each type of dossier has the MS prepared?	
CLP	4-6
Restriction	0
Identification of SVHC	1-3
Is the time spent following up your MS dossiers reasonable?	5
Space is available below to provide further comments on how reasonable the time spent following up your MS dossiers was.	As default we have stated 5, but it should be noted that in order to collect useful information some sort of benchmarking criteria for “reasonable” would be needed. The time spent varies significantly between dossiers. Overall we would say that the time spent is reasonable.

How many of each type of dossier are rapporteured?

CLP	4-6
Restriction	1-3
Identification of SVHC	0
Is the time spent following up rapporteured dossiers reasonable?	5
Space is available below to provide further comments on how reasonable the time spent following up your rapporteured dossiers was.	For CLH: Time spent varies significantly between dossiers. For restrictions: Proposal submitted very recently For identification of SVHC: No rapporteurs are appointed Overall we would say that the time spent is reasonable, but in order to collect useful information some sort of benchmarking criteria for “reasonable” would be needed.

How many of each type of dossier are co-rapporteured?	
CLP	1-3
Restriction	1-3
Identification of SVHC	0
Is the time spent following up co-rapporteured dossiers reasonable?	5
Space is available below to provide further comments on how reasonable the time spent following up your co-rapporteured dossiers was.	Only minor difference between being rapporteur and co-rapporteur. Overall we would say that the time spent is reasonable, but in order to collect useful information some sort of benchmarking criteria for “reasonable” would be needed. For CLH: Time spent varies significantly between dossiers. For restrictions: Proposal submitted very recently For identification of SVHC: No co-rapporteurs are appointed

How many dossiers prepared by other MS has the MS contributed to or commented upon?	
CLP	>9
Restriction	1-3
Identification of SVHC	>9

How many dossiers prepared by ECHA has the MS contributed to or commented upon?	
Restriction	1-3
Identification of SVHC	1-3

What expertise is available for preparing dossiers?	
Chemist	1-3
Toxicologist	1-3
Ecotoxicologist	1-3
Economist	1-3
Enforcement	1-3
Legal	1-3
Policy	1-3
Exposure	1-3
CLP	1-3
Other (please list)	
If you have specified that there is other expertise is available for preparing CLH dossiers, please provide details here.	
Is the MS able to access external specialists?	Yes
What types of external specialists does the MS have access to?	Most types, depending on needs and funding.
Is the MS satisfied with the levels of access to expertise?	3
Has there been any industry involvement in the preparation of MS dossiers?	No

Theme 8 - Information on Enforcement Activities

General Information	
Please enter the MAIN enforcing authority for REACH within the Member State.	Kemikalieinspektionen, the Swedish Chemicals Agency
Is there more than one enforcing authority for REACH within the Member State?	Yes
Please provide details on the other enforcing authorities for REACH within the Member State.	The responsibility for enforcement of REACH in Sweden is mainly placed on the Swedish Chemicals Agency, except for enforcement of the REACH Provisions concerning safety for workers which are placed on the Swedish Work Environment Authority. However, the REACH organization enforcement is not yet finally decided by the Government. The organization might be further developed during 2010.

Enforcement Strategy

Has an overall strategy (or strategies) been devised and implemented for the enforcement of REACH?	Yes
If Yes, is the strategy (or strategies) in line with the strategy devised by the Forum?	Yes
Please outline the enforcement strategy within the Member State in a maximum of 2000 characters.	The general strategy for enforcement is divided into three processes: planning and preparation, performing activities/inspections and evaluation/follow-up. Each process is further described in both flow-charts and in manuals. The process of planning describes: •companies concerned, •selection of companies for inspections, •methods to find them, •preparations as project plans, checklists, etc. The 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 The process of evaluation/follow up describes: •Collection of statistics •Project reports, seminars, press release, information etc •If problems with compliance or regulations impossible to comply with – contacts with legal advisors, commission, other authorities etc. In relation to the two questions above; 1. 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). 2. In the 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. The definitions used in the Forum Working Group paper would have been helpful for this questionnaire.

Co-ordination, co-operation and exchange of information

Please outline of the mechanisms put in place to ensure good cooperation, coordination and exchange of information on REACH enforcement between enforcing authorities and the Competent Authority.	The responsibility for enforcement of REACH in Sweden is for the moment placed on central level at the Swedish Chemicals Agency (KemI), which also is the Competent Authority. There has not been any formal cooperation or information exchange yet with other authorities concerning REACH enforcement. However, activities such as training and information to authorities at central, regional and local level have been carried out. Concerning other chemicals legislation, the inspectors at KemI co-operate with regional and local enforcement authorities, the Swedish Rescue Services Agency and the Swedish Work Environment Authority. Local inspectors are contacted by KemI before inspections are carried out. Co-operation is also carried out with other EU enforcement authorities in different inspection projects within the network CLEEN (Chemical Legislation European Enforcement Network) and with the Nordic countries. Cooperation, coordination and exchange of information will be further developed when the organization of REACH enforcement has been finally decided by the Government.
Describe how these mechanisms have operated in practice during the reporting period (e.g. regular meetings, joint training, joint inspections, co-ordinated projects and so on).	•Training for inspectors at central level has been performed during 2007 •Seminars/Information to authorities concerned at central, regional and local level was performed at eight occasions (1 day/occasion). •Inspectors from the Nordic countries meet once a year to exchange experience and present reports on inspection activities •Inspectors within the CLEEN network meet once a year and exchange experience and perform joint enforcement project.

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Describe the inspection and investigation strategy and methodology.	Keml's inspectors inspect companies that are manufacturer, importers, downstream users, distributors of chemical products and pesticides. Also companies that import or distribute articles are inspected by Keml. Inspections take place throughout the country. The inspector checks that the legislation is complied with, for example that the labeling is correct, that pesticides on sale have been authorized and that articles do not contain any prohibited substances. Inspections are focused on risk reduction. Companies are selected in those areas where there is a potential for improvement, e.g.: •companies that import/manufacture products which contain substances of high concern, •when new regulations start to apply •information regarding poor compliance of a specific piece of legislation, •information on companies or sectors of industry with poor compliance, •companies having high-volume products with a wide circulation, •products containing hazardous substances which are used by sensitive groups (e.g. children) etc. Keml keeps a product register that contains basic facts on nearly 145,000 chemicals and around 2900 companies. Companies that manufacture chemical products or import them to Sweden have to notify this to the Products Register, which can consequently provide information on status, development and trends in the use of chemicals. Keml and other agencies use the information in inspection and enforcement and in various types of preventive activity. When it comes to articles, companies have to be found by other means, e.g. through trade associations, customs, advertising, internet etc In relation to Reporting information - Dutyholders; About 2900 companies are registered in the products register. These companies are importers, manufacturers, distributors and formulators of chemical products (substances or mixtures). A total number of dutyholders is very difficult to estimate as the companies that import, distribute or manufacture articles and some downstream users as end-users, are not to be found in any register. About 500 companies are likely to constitute registrants according to the list of preregistered companies in Sweden. Manufacturers of substances are about 60.

Describe the level and extent of monitoring activities.	KemI normally inspects 300 to 400 companies peryear. These companies could be manufacturers, importers, distributors or downstream users of chemical products, pesticides or articles. Inspections concerning chemical products and/or pesticides are focused on classification, labeling, safety data sheets, new legislation etc. Inspections concerning articles mostly focus on prohibited substances or substances of high concern in articles.
Describe sanctions available to enforcing authorities.	Non-compliance of core provisions in REACH is specifically criminalized in the national Environmental Code. The rules of enforcement through administrative measures are generally applicable to all legislations which fall under the environmental code. This means that there is no provision which specifically concerns the use of administrative sanctions with respect to non compliance of REACH. But, in practice all provisions of REACH can be enforced by the use of administrative measures. This system is equivalent to a “catch all provision”. The administrative measures do not necessarily mean that the addressee will have to pay a fine. The enforcement authorities can use issue injunctions with or without a fine. However, they cannot effectuate a set fine. If the company in question does not comply with the demands in an injunction the enforcement authority must file a complaint to a court of law which looks at the case and decides whether the company is required to pay the fine and if the fine is proportional. The administrative measures used by the enforcement authorities thus have a coercive effect more than a punitive effect. Infringement of core provision of REACH (registration and authorization) will be subject to criminal sanctions and the sentence will most likely include a company fine which can vary between 500 EUR and 100 000 EUR. There is also an environmental sanction fee related to language in the safety data sheet (500 EUR). Please note that answers to this question have already been compiled and reported for the Commission: Report on penalties applicable for infringement of the provisions of the REACH Regulation in the Member States. Also, this report has been discussed at a Commission workshop in February 2010.
Describe the referrals from ECHA.	None so far.

Describe the referrals from other Member States.	•From Poland: Safety data sheet of poor quality from a Swedish company. Heading 3 didn't give the proper name of substance. After contact with Swedish company, the SDS was corrected. •From UK: concern about a non-phase in substance (that seems to have been pre-registered) supplied from a Swedish company to a UK company. The Swedish company is not on the list of companies that have notified the substance and got an ELINCs number. After investigation, the Swedish company was a downstream user, buying the substance from a Belgian company that have notified the substance, and also are entitled to receive a registration number from ECHA.
Describe any other measures/relevant information.	

2007

Dutyholders	
Provide an estimate of the total number of dutyholders who are likely to have duties imposed on them by REACH.	2900
Provide an estimate of the above dutyholders who are likely to constitute registrants as defined by REACH.	500
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?	300
State the number of manufacturer dutyholders subject to inspections and investigations.	7
Were these mainly:	No information
State the number of importer dutyholders subject to inspections and investigations.	7
Were these mainly:	No information
State the number of distributors subject to inspections and investigations.	250
Were these mainly:	No information
State the number of downstream users subject to inspections and investigations.	20
Were these mainly:	No information

Inspections	
State the number of inspections that addressed registration.	0
State the number these cases which were non-compliant.	
State the number of inspections that addressed information in the supply chain.	200

State the number these cases which were non-compliant.	50
State the number of inspections that addressed downstream use.	0
State the number these cases which were non-compliant.	
State the number of inspections that addressed authorisation.	0
State the number these cases which were non-compliant.	
State the number of inspections that addressed restriction.	0
State the number these cases which were non-compliant.	
State the number of inspections that addressed other REACH duties.	0
State the number these cases which were non-compliant.	

Investigations	
State the number of investigations prompted by complaints and concerns raised.	40
State the number of investigations prompted by incidents or dangerous occurrences.	0
State the number of investigations prompted by monitoring.	0
State the number of investigations prompted by results of inspection/follow up activities.	0
State the number of inspections and investigations resulting in no areas of non-compliance.	50
State the number of inspections and investigations resulting in verbal or written advice.	200
State the number of inspections and investigations resulting in formal enforcement short of legal proceedings.	0
State the number of inspections and investigations resulting in initiation of legal proceedings.	0
State the number of convictions following legal proceedings.	

Enforcement	
State the number of manufacturers subject to formal enforcement.	5
Were these mainly:	No information
State the number of importers subject to formal enforcement.	10
Were these mainly:	No information
State the number of distributors subject to formal enforcement.	20
Were these mainly:	No information

State the number of downstream users subject to formal enforcement.	20
Were these mainly:	No information

2008

Dutyholders	
Provide an estimate of the total number of dutyholders who are likely to have duties imposed on them by REACH.	2900
Provide an estimate of the above dutyholders who are likely to constitute registrants as defined by REACH.	500
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?	400
State the number of manufacturer dutyholders subject to inspections and investigations.	7
Were these mainly:	No information
State the number of importer dutyholders subject to inspections and investigations.	7
Were these mainly:	No information
State the number of distributors subject to inspections and investigations.	300
Were these mainly:	No information
State the number of downstream users subject to inspections and investigations.	70
Were these mainly:	No information

Inspections	
State the number of inspections that addressed registration.	0
State the number these cases which were non-compliant.	
State the number of inspections that addressed information in the supply chain.	300
State the number these cases which were non-compliant.	110
State the number of inspections that addressed downstream use.	0
State the number these cases which were non-compliant.	
State the number of inspections that addressed authorisation.	0
State the number these cases which were non-compliant.	
State the number of inspections that addressed restriction.	0

State the number these cases which were non-compliant.	
State the number of inspections that addressed other REACH duties.	0
State the number these cases which were non-compliant.	

Investigations	
State the number of investigations prompted by complaints and concerns raised.	50
State the number of investigations prompted by incidents or dangerous occurrences.	0
State the number of investigations prompted by monitoring.	0
State the number of investigations prompted by results of inspection/follow up activities.	0
State the number of inspections and investigations resulting in no areas of non-compliance.	80
State the number of inspections and investigations resulting in verbal or written advice.	200
State the number of inspections and investigations resulting in formal enforcement short of legal proceedings.	15
State the number of inspections and investigations resulting in initiation of legal proceedings.	0
State the number of convictions following legal proceedings.	

Enforcement	
State the number of manufacturers subject to formal enforcement.	5
Were these mainly:	No information
State the number of importers subject to formal enforcement.	10
Were these mainly:	No information
State the number of distributors subject to formal enforcement.	80
Were these mainly:	No information
State the number of downstream users subject to formal enforcement.	20
Were these mainly:	No information

2009

Dutyholders	
Provide an estimate of the total number of dutyholders who are likely to have duties imposed on them by REACH.	2900

Provide an estimate of the above dutyholders who are likely to constitute registrants as defined by REACH.	500
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?	350
State the number of manufacturer dutyholders subject to inspections and investigations.	10
Were these mainly:	No information
State the number of importer dutyholders subject to inspections and investigations.	25
Were these mainly:	No information
State the number of distributors subject to inspections and investigations.	250
Were these mainly:	No information
State the number of downstream users subject to inspections and investigations.	60
Were these mainly:	No information

Inspections	
State the number of inspections that addressed registration.	48
State the number these cases which were non-compliant.	0
State the number of inspections that addressed information in the supply chain.	250
State the number these cases which were non-compliant.	70
State the number of inspections that addressed downstream use.	0
State the number these cases which were non-compliant.	
State the number of inspections that addressed authorisation.	0
State the number these cases which were non-compliant.	
State the number of inspections that addressed restriction.	120
State the number these cases which were non-compliant.	5
State the number of inspections that addressed other REACH duties.	0
State the number these cases which were non-compliant.	

Investigations	
State the number of investigations prompted by complaints and concerns raised.	80

State the number of investigations prompted by incidents or dangerous occurrences.	0
State the number of investigations prompted by monitoring.	30
State the number of investigations prompted by results of inspection/follow up activities.	0
State the number of inspections and investigations resulting in no areas of non-compliance.	50
State the number of inspections and investigations resulting in verbal or written advice.	200
State the number of inspections and investigations resulting in formal enforcement short of legal proceedings.	20
State the number of inspections and investigations resulting in initiation of legal proceedings.	12
State the number of convictions following legal proceedings.	

Enforcement	
State the number of manufacturers subject to formal enforcement.	5
Were these mainly:	No information
State the number of importers subject to formal enforcement.	20
Were these mainly:	No information
State the number of distributors subject to formal enforcement.	30
Were these mainly:	No information
State the number of downstream users subject to formal enforcement.	20
Were these mainly:	No information

Theme 9 - Information on the Effectiveness of REACH on the Protection of Human Health and	
Do you think that the effects of REACH would be better evaluated at a Member State (MS) or EU level?	EU

What parameters are available at MS level that could be used to assess the effectiveness of REACH in a baseline study?	As a comment to the tick-box question above, we think that it would be natural to evaluate effectiveness of REACH on the EU level. But there may of course be reasons for a MS to perform national assessments, using its own parameters and tools. Therefore, it would seem important to actively involve MSs when discussing such an EU level evaluation. MSs would need to agree in which situation or state REACH is "effective" before finding the parameters to study and follow the effectiveness. Using this questionnaire could only be a very first starting point. Unfortunately, it has not been made clear for MSs in which way the results of this questionnaire will be used. It is also important to look at recent developments in the methodology before performing such an assessment, so that the EU level evaluation can be efficient. Some main principles worth mentioning here: •Keep it simple, so that future iterations will be possible even with slimmed resources •Use parameters related to the societal or technical spheres, i.e. certain actions according to requirements in the regulation, rather than observations in the biosphere (knowledge levels in certain sectors of the economy could be an example) •Pinpoint which issues that are of special interest to follow Should the flow of information through the supply chain be pinpointed for assessing the effectiveness of REACH, one parameter could be findings related to two questions under theme 8 Information on Enforcement Activities: the total number of inspections addressing information in the supply chain and the number of non-compliant cases.

Theme 10 - Other Issues/Recommendations/Ideas	
Please provide any further information on the implementation of REACH that the MS considers relevant.	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 •Nanomaterials •MS tasks under REACH and resources to carry out these tasks

Do you wish to upload documents in support of this submission	Yes
Please provide a brief description of the documents that you are uploading. Note: You may upload more than one document.	1.The 0.1% limit trigger for information on SVHC in articles REACH introduces information obligations for producers and importers of articles that contain substances of very high concern (SVHC). 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 trigger limit for complex articles. This situation creates uncertainty for companies manufacturing or importing articles – and for enforcement authorities as well. It has been shown in an interview study that applying the limit according to the current guidance implies that different requirements will apply to the same article when sold separately and when it is incorporated into another (complex) article, and consequently leads to gaps in the flow of information. The report from the study is uploaded. It is shown in this study that in many cases the SVHC information will not follow the article through the supply chain. For some types of articles it was even possible to show that the extent of the SVHC information loss was quite substantial. Also, the interviews clarified that the information obligations will be "diluted away" at random, without relation to exposure or risk. More recently these findings have been confirmed through chemical analysis in articles from the market in a national enforcement project. These observations on the generation of SVHC information are worrying, as they will influence the possibility to achieve the protection goal which the legislators had in mind. 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 is would be more workable for existing information routines in 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 has a shape, surface or design which entails compliance with the definition of an article in REACH Art. 3 (3). Thus, it should not make a difference for the triggering of information requirements if an article has been joined together with other articles to form a larger article or not. Rationale for this interpretation has also been submitted to the European Commission, when CARACAL was consulted. This document is uploaded.
2.Ensuring compliance of registration dossiers It has been argued that the formal decisions in ECHA´s compliance check under REACH Art 41 are legally limited to deficiencies in relation to the information requirements in Annexes VI – X including adaptations (Annex XI) and presence of the elements of a Chemical safety report (CSR) as required by Annex I. ECHA would not have the mandate to take compliance check decisions if, for instance, a DNEL/PNEC value is incorrectly derived or a risk management measure is clearly inadequate. It has been suggested that the responsibility to take legal action with respect to inadequate CSR and RMM falls upon the member states. A MS cannot, however, request a registrant to provide new information in order to bring the registration dossier into compliance. Nor can the MS request a company further down the supply chain to change any information in the safety data sheet (SDS) as long as it corresponds to information in the registration dossier. The possibilities for the MS to take action are in fact very limited and cannot have effect along the entire supply chain in the way a corrected/revised registration would have. Should non-compliant registrations only lead to a note in letters from ECHA, instead of formal decisions according to Article 41.3, compliance checking would be discriminatory against companies who comply with requirements in the legislation. Those with non-compliant registrations would be given advantages, something that may affect the credibility of the system. The proper functioning of REACH relies upon that the information provided in the registration dossier is accurate. Correct information in a registration dossier is particularly important if the chemical is widely spread in the Community. The recommended risk management measures shall be conveyed through the supply chain via the SDS in order to prevent adverse effects on human health and the environment. Inadequate risk management measures in a CSR will give incorrect information in the SDS and the exposure scenarios and may consequently result in risks down the supply chain. It must be clearly stated that Art 41(3) enables ECHA to take formal action to ensure compliance of registration dossiers, for instance with respect to information such as RMM in the CSR.
3.Nanomaterials Nanomaterials (NM) are encountered in

wide ranges of consumer products and products intended for professional use. The number of new products on the market is expected to increase over the next few years. At present, information is lacking on how NM are dispersed in society and how humans and the environment are exposed to NM in the short and long run. The available knowledge on whether and how certain NM affects human health and the environment is limited. NM are covered by REACH. However, there are no rules specifically regulating NM in REACH. This means that NM in the registration procedure may in some cases be considered the same as the bulk material substance and subject to the same information requirements even though they may have totally different properties. As a consequence, information on NM will not be available for chemical safety assessment and considerations on safe use in REACH. In this context, the applicability of available risk assessment methods, including test methods, with regard to risks to humans and the environment is not yet evaluated and validated for NM. Consequently it may not be possible to ensure that risks to health and the environment associated with NM can be avoided. A number of processes and areas have been identified in REACH where there is a need for guidance or modified regulation for NM. These areas include identification of substances, registration and consequences of the tonnage system for NM, assessment of chemical safety and risk management measures and information in the distribution chain. If NM are not identified as substances of their own when appropriate and necessary, information on NM will not be available and REACH will not be applicable. Possible solutions The Swedish Competent Authority has stated in a recent report that REACH will need specific amendments in order to effectively deal with any risks associated with NM. This will need to be dealt with in the REACH assessment review in 2012. Further it is important to develop guidance, risk assessment methodology as well as detailed requirements for companies. For this to be done, the on-going work in expert groups and committees in EU (e.g. CASGnano) needs to be even more strengthened. For a successful application of REACH to NM, further consideration is needed in order to find out whether the general provisions regarding registration (e.g. information requirements), chemical safety assessment and communication of recommendations for safe use etc also in practice will cover the NM within a reasonable time frame. An issue which should be the object of investigation is the introduction of a system for mandatory notification of NM on the EU market. In order to be more workable for industry, a common reporting system on NM could be linked to the REACH registration procedure. As mentioned above, guidance for NM in REACH needs to be developed. For instance, point 2 in Annex VI, substance identification, needs to be adjusted in order to make sure that NM are registered as substances on their own when appropriate. Finally, as knowledge on test methods, risk assessment methods and risks is very limited today there may be a special need to continuously update and revisit REACH regarding NM as soon as further information is available. 4 MS tasks

such as further information is available. MS tasks under REACH and resources to carry out these tasks The Commission estimated in 2006 that in year 3 and 4 after the entry into force of REACH, an average MSCA would need 21 to 25 man-years for REACH related tasks. This estimate may no longer be relevant, but nevertheless indicates that intense activity in the committees with many proposals is expected to accomplish the intentions of REACH. Updated estimates may help to moderate expectations, but unfortunately the questions regarding MSCA resources in this questionnaire will not provide that kind of information. It is an observation that few MSs seem to find the resources to prepare Annex XV dossiers for restrictions or SVHC identifications. Up to now, no proposals have been put forward for SVHC identification of substances giving rise to equivalent level of concern (SELC). It would seem important to get discussions started on the identification of endocrine disruptors as SVHCs. With results from such discussions, some uncertainties and concerns regarding the issue of "combination effects" could be substantiated. The fact that only some MS CA tasks can be reimbursed (i.e. acting as rapporteur for restriction proposals or authorization applications and performing substance evaluations), together with the possibility that remunerations will only partly cover the work, add further resource uncertainties. Possibly resource conflicts may lead to insufficient support for the work of committee members or imbalanced decisions on tasks depending on reimbursement and complexity of the work. It has been proposed by ECHA that some tasks relating to IUCLID helpdesk service for registrants should be transferred to MSCAs. That would, however, create problems for MSCAs with respect to resources and IUCLID competence. For industry, such a transfer could give quite a variety of views and understanding of how to deal with difficult IT issues. Taken together, these factors may influence the possibility for ECHA to reach their work plan aims for 2009-2012, where increased MS resources would be needed for the development in many areas. This includes methodology and decision making for dossier evaluations, substance evaluations and authorizations. Thereby the possibilities for a head start of several important REACH elements may be seriously affected. Also expected development in emerging issues like SELCs, including endocrine disruptors, and combination effects might be delayed. We suggest therefore: 1.that initiatives for the development of issues like SELCs, including endocrine disruptors, should be encouraged and prioritized 2.that ECHA should strive to simplify working procedures and facilitate the work with restriction and SVHC dossiers as far as possible. 3.that the logics and practicalities of the remuneration system should be analysed, to ensure that it does not provide imbalanced incentives. As a minimum, the task to be rapporteur in RAC for harmonized classification proposals should be reimbursed. It should be possible to overcome the fact that it was never introduced into CLP legislation by mistake. 4.that transfer of ECHA tasks to MSCAs should be avoided. ECHA should be encouraged to take a larger share of the work load to compile SVHC dossiers, especially for substances already classified as CMR

especially for substances already classified as CMR.

Meta Informations

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