

MS REACH Reporting Questionnaire

General Information	
Which Member State are you reporting for?	DK
What reporting period are you reporting on?	2010
Primary contact person's name.	Bent Horn Andersen
Please provide an email address for the primary contact person.	behan@mst.dk

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?	Danish Ministry of the Environment - Danish Environmental Protection Agency
What is the address of the organisation?	Strandgade 29 DK - 1401 Copenhagen K
What is the email address of the organisation?	mst@mst.dk
What is the telephone number of the organisation?	(+45) 7254 4000
What is the fax number of the organisation?	(+45) 3254 8361
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

- National use restrictions - Legislation on cosmetics, Directive 76/768/EEC - Volatile organic compounds (VOC) in paints and varnishes, Directive 2004/42/EC - Restricting in the use of certain hazardous substances in electrical and electronic equipment, Directive 2002/95/EF (ROHS) - Detergents, Regulation 648/2004 - Classification, labelling, packaging, notification Regulation 1272/2008 (CLP) - Import and Export of Hazardous Chemicals and Pesticides, Regulation 2455/92 - Regulation on ozone depleting substances, Regulation 2037/2000 - Regulation on Persistent Organic Pollutants, Directive 79/117 - Waste-legislation - IPPC-legislation - Other areas where the Danish EPA has authority regarding inspection of chemicals.

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.

Import/export Danish Tax and Customs Administration Østbanegade 123 DK - 2100 Copenhagen Ø Professional use of chemicals / REACH helpdesk The Danish Working Environment Authority P.O. Box 1228 DK - 0900 Copenhagen C E-mail: at@at.dk Phone +45 70 12 12 88

Does the Competent Authority outsource any of its work? Yes

Please provide details on who the Competent Authority outsources parts of its work to.

Inspection onboard ships: Danish Maritime Authority Vermundsgade 38 C DK - 2100 Copenhagen Ø E-mail: sfs@dma.dk Phone +45 3917 44 00; fax +45 39 17 44 01
Inspection on offshore installations: Danish Energy Agency Amaliegade 44 DK 1256 Copenhagen K E-mail: ens@ens.dk Phone +45 33 92 67 00
Safety data sheets and downstream user obligations: The Danish Working Environment Authority P.O. Box 1228 DK - 0900 Copenhagen C E-mail: at@at.dk Phone +45 70 12 12 88

How adequately resourced is the Competent Authority? 7

Space is available below to provide further comments on the resourcing of the Competent Authority.

The answer should be seen in relation to the size of the Danish population. The current National Chemicals Action Plan has allocated funds for national implementation of REACH in the period of 1. January 2010 - 31. December 2013. These funds are partly allocated to enable The Danish Competent Authority to fulfil its obligations under REACH, appointing members for the committees under ECHA and commenting on proposals and guidelines in general. The plan also enables the CA to make an active contribution to the efficient implementation of REACH through Dossier proposals and other tasks in the different committees under ECHA.

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? - The Circa website could be more user friendly

How effective is collaboration between MS for REACH? 7

How could effectiveness of collaboration between MS be improved?

Are there any special projects/cooperation on chemicals that the MS participates in with other MS outside of REACH? Yes

Please provide further information.

DK participates in various projects under the umbrella of the Authorities' Working Group on Chemicals under the Nordic Council of Ministers. DK participates in the Arctic Monitoring Assessment Program (AMAP) and The Arctic Contaminants Action Program (ACAP) both under Arctic Council. DK participates in the Strategic Approach to International Chemicals Management (SAICM) DK participates in the UN Commission for Sustainable Development (CSD) DK is a party to and actively involved in the further development of a number of chemicals and chemicals related UN Conventions and protocols, including: The Stockholm Convention on Persistent Organic Pollutants (POPs), The Rotterdam Convention on Prior Informed Consent and trade of certain chemicals (PIC) The Basel convention on hazardous waste The Montreal Protocol on substances that deplete the ozone layer The Vienna Convention for the Protection of the Ozone Layer The Convention on Long Range Transboundary Air Pollution (LRTAP) under the UN Economic Commission for Europe The regional OSPAR and HELCOM Conventions DK supports the UNEP Global Initiative on Mercury and is active in the work related to the elaboration of a global convention on mercury, where UNEP governing council decision 25/5 authorised the start of negotiations. DK and the authorities of California have recently initiated a cooperation on information sharing on chemicals management -As an active member of OECD, DK is taking part in the Joint Meetings of the Chemicals

taking part in the some meetings of the Environment Committee and the Working Party on Chemicals, Pesticides and Biotechnology. DK is an active contributor to the development of test methods under the OECD test guideline program, and often commenting on draft GD, DRPs and TGs. DK is lead for some TG projects and participates actively in a number of OECD Validation Management Groups relating to TGs for endocrine disruptors (VMG). DK is an active contributor to the activities related to the Endocrine Disrupter Testing and Assessment program, where DK last year hosted a workshop. DK also contributes to the OECD Hazard Assessment Task force, such as the development of the OECD QSAR toolbox, the SIAM program, and the task force on Exposure Scenarios. We have donated a large database with QSAR estimates to the OECD QSAR application toolbox project. DK is also participating in the OECD Working Party of Manufactured Nanomaterials (WPMN) DK has participated in the Environment and Health ministerial Process of the WHO, where DK has contributed to placing chemicals, including endocrine disrupting chemicals and combination effects high on the political Agenda. DK has been active in research on endocrine disrupters and combination effects. DK hosted an international expert workshop on combination effects of endocrine disrupters in January 2009 that was followed up by a survey of 2-year olds daily combined exposure to chemicals with a focus on endocrine disrupters. These activities served as the documentation for DK to raise the issue about combination effects in EU which led to Council Conclusions in December 2009.

How could effectiveness of communication with ECHA be improved?	ECHA's response time is often long, and sometimes the effectiveness of the communication and cooperation is hampered by a high level of formality. It would be beneficial for Member States to have a possibility of more direct and informal communication with ECHA staff and to have better access to e-mail address and/or telephone number of specific contact persons on various issues.
How effective is MS collaboration with ECHA?	7
How could effectiveness of collaboration with ECHA be improved?	The Danish CA acknowledges the challenges that ECHA has faced during its establishment phase and compliments ECHA for the important work accomplished so far. We have good expectations regarding our future collaboration with ECHA. However, as stated above DK would appreciate if ECHA would appoint specific contact persons on various practical issues to be solved such as e.g. difficult Helpdesk questions or specific (pre)registrations. The Danish EPA appreciates the different theme workshops for Lead registrants, SEAC, RAC, IUCLID 5, evaluation and test proposals.
How effective is MS communication with the Commission (specifically Article 133 Committee)?	8
How could effectiveness of communication with the Commission be improved?	
How effective is MS collaboration with the Commission (specifically Article 133 Committee)?	3
How could effectiveness of collaboration with the Commission be improved?	In general, we consider the collaboration with the Commission services as being good. However, we have experienced situations where legislative proposals have been scheduled for discussion and voting on the same day in the REACH & CLP Regulatory Committee, which seriously hampers the possibilities of MSCAs to influence the outcome. It would be beneficial to separate the technical discussions and the formal voting by organising preparatory discussions where the MSCA can provide technical and policy input to the Commission (e.g., via CARACAL or special working group meetings) before the proposal is finalised and scheduled for voting in the Regulatory Committee.

Has use been made of the safeguard clause of REACH (Art. 129)?	No
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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.	Danish Ministry of the Environment - Danish Environmental Protection Agency
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What is the address of the Helpdesk?	Danish Environmental Protection Agency Strandgade 29 DK - 1401 Copenhagen K
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What is the web page address of the Helpdesk?	www.reachhelpdesk.dk
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What is the email address of the Helpdesk?	reachspm@mst.dk
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What is the telephone number of the Helpdesk?	(+45) 70120211
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What is the fax number of the Helpdesk?	Fax has never been used (+45) 3254 8361
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Are there any more organisations responsible for operating the National Helpdesk for REACH?	No
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Please indicate the number of each type of staff that are involved in the Helpdesk.

Toxicologist	1-5
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Ecotoxicologist	1-5
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Chemist	1-5
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Risk Assessor	1-5
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Economist	1-5
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Social Scientist	1-5
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Exposure Assessor	1-5
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Other (please list)	1-5
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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.	Legal Advisor
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Is the same Helpdesk used to provide help to Industry on CLP?	Yes
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Does the Helpdesk receive any non-governmental support?	No
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How many enquiries does the Helpdesk receive per year?	101-1000
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In what format can enquiries be received by the Helpdesk?	Email Phone Fax Letter Other (please list)
Please list the other format(s) of enquiries that can be received by the Helpdesk.	In principle, enquiries could be received in any format. However, until today the helpdesk has only received enquiries through e-mail or telephone.
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 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.	If we receive questions not related to any of the above topics, it would normally be questions that are not related to REACH or CLP and thus erroneously addressed to the REACH/CLP helpdesk

For each type of enquiry received, please provide the proportion in percentage of the total enquiries.

Pre-registration (%)	2
Registration (%)	14
Authorisation (%)	1
Restriction (%)	1
Testing (%)	0

Enforcement (%)	5
CSR preparation (%)	0
CLP (%)	61
SIEFs (%)	1
REACH-IT (%)	1
IUCLID5 (%)	1
Downstream user obligations (%)	2
Obligations regarding articles (%)	5
Safety Data Sheets (%)	4
SVHC (%)	4
Other (%)	0

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	3 days
Complex questions	2 weeks
Are any types of enquiry outsourced?	Yes
What types of enquiry are outsourced?	Safety Data Sheets
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?	3
What level of cooperation is there between Helpdesks outside REHCORN?	3
How frequently do you use RHEP?	Monthly
Has the MS carried out any specific public awareness raising activities?	Yes

What type of activities have been carried out?	Newspaper Leaflets Other (please list) Speaking events
Please list the other types of activities that have been carried out.	The Danish EPA provides regular funding for external information projects on REACH in different sectors. These projects are normally carried out as joint projects performed by stakeholders within the sector organisations and e.g. qualified consultants. The Danish EPA has in one project given financial support to a REACH-helpdesk run by the Confederation of Danish Industries. Moreover, a number of articles on REACH were provided to sector-specific magazines in the autumn of 2008. The Danish EPA has also run an information campaign in 2009 to raise public awareness of hazard labelling on consumer products in general and also to provide information on the new pictograms under CLP. This campaign included TV-interviews, newspaper advertisements and information on the Internet.

How effective was each type of activity?	
Newspaper	3
Speaking events	4
Leaflets	3
Other	5
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)?	101-500

Please describe the scope of the number of REACH webpage visits.

The most visited helpdesk pages on REACH topics during the last two month were pages with information on: 1) REACH terminology 2) Obligations on downstream users 3) Authorisation 4) Exemptions from registration 5) Registration in general The most visited helpdesk pages on CLP topics were pages with information on: 1) Hazard pictograms and -sentences 2) Labelling of substances and mixtures 3) GHS 4) How to classify according to CLP 5) FAQ's on classification

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? 8

How could the effectiveness of the Committees be improved?

CARACAL: The intention of this committee, which is not established in accordance with legal requirements, is to function as a discussion forum where the MSCAs can provide policy input to the Commission and to ECHA on both the practical implementation of REACH and CLP and further development of the legislation. However, the value of the contributions of CARACAL depends on whether issues are put on the agenda well before the positions of the MSCAs, ECHA and the Commission are fixed and on the openness of the various parties in taking the views of CARACAL into account. It would be beneficial if this could be considered during the review of the functioning of CARACAL.

ECHA committees: Most of the ECHA committees are now engaged in operational activities and delivering agreements (MSC) or opinions (RAC) on concrete cases. We recognise that the tasks and working procedures are new for most of the members and that it takes time to both develop the scientific and practical approaches. Nevertheless, considering the expected huge increase in workload in the years to come, it should be emphasised that the success of the committees depends on a substantial contribution to the work from all members of the committees. Another issue that could be reviewed is whether the comprehensive Rules of Procedure in some cases restricts the way of working thereby hindering the use of the most efficient ways to complete the tasks of the committees. As SEAC is still in the establishment phase, we have no comments on the efficiency at this stage. However we recognise the work that has been

...regulation of the regimes and how this has been done in ECHA getting practical and legal routines and procedures organised. The work in HELPNet would benefit from faster procedures and more support from the Commission on the task of finding a solution to unsolved issues. There have however, already been efforts to establish such procedures and we still need to see the effects of these efforts. The work in the Risk Communication Network (RCN) could be further enhanced if ECHA would act as a facilitator by preparing written suggestions e.g. for substances for which risk communication would be relevant in all MS, or general risk communication about substances on the candidate list. Such material could be useful in the MS.

Theme 6 - Information on Substance Evaluation Activities

2010 Reporting

Please name the organisations/institutions that are involved in the evaluation process.

The following questions are not answered, because until today only dossier evaluations have been done.

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

Toxicologist

Ecotoxicologist

Chemist

Risk Assessor

Socio-Economic Analyst

Exposure Assessor

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? 0

Theme 7 - Annex XV Dossiers

How many of each type of dossier has the MS prepared?

CLP 1-3

Restriction 0

Identification of SVHC 1-3

Is the time spent following up your MS dossiers reasonable? 6

Space is available below to provide further comments on how reasonable the time spent following up your MS dossiers was. - The time spent on dossiers varies significantly. A clear answer to a tick the box question above would require some sort of benchmarking as to what is a reasonable amount of time. However, It has not been unforeseen that it would be a relatively resource demanding task to develop a dossier, and thus, the time spent does not seem unreasonable.

How many of each type of dossier are rapporteured?

CLP 1-3

Restriction 1-3

Identification of SVHC 0

Is the time spent following up rapporteured dossiers reasonable? 6

Space is available below to provide further comments on how reasonable the time spent following up your rapporteured dossiers was. - Time spent on dossiers seems reasonable. - Rapporteurs are not appointed on dossiers for identification of SVHC's

How many of each type of dossier are co-rapporteured?

CLP 0

Restriction 1-3

Identification of SVHC 0

Is the time spent following up co-rapporteured dossiers reasonable? 6

Space is available below to provide further comments on how reasonable the time spent following up your co-rapporteured dossiers was. - There is not much difference in the time spent on the tasks of being rapporteur and co-rapporteur respectively - Time spent on dossiers seems reasonable.

How many dossiers prepared by other MS has the MS contributed to or commented upon?

CLP 7-9

Restriction 1-3

Identification of SVHC 0

How many dossiers prepared by ECHA has the MS contributed to or commented upon?

Restriction 0

Identification of SVHC 0

What expertise is available for preparing dossiers?

Chemist 1-3

Toxicologist 4-6

Ecotoxicologist 4-6

Economist 1-3

Enforcement 1-3

Legal	1-3
Policy	1-3
Exposure	1-3
CLP	4-6
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?	The reported number of available expertise in the previous question is based on in-house employees only. The Danish EPA has access to most types of expertise through consultancy services. It is not considered a problem finding the right expertise.
Is the MS satisfied with the levels of access to expertise?	4
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.	The Danish Environmental Protection Agency, The Chemical Inspection Service Strandgade 29, DK 1402 Copenhagen K E-mail: mst@mst.dk Phone: +45 72544000 (responsible for the enforcement of REACH, except for those Articles mentioned under the other enforcement authorities for REACH)
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 Danish Working Environment Authority P. box 1228 DK 0900 Copenhagen C E-mail: at@at.dk Phone +45 7012 1288 (Responsible for the enforcement of Article 14(6) and section IV and V except Article 38(4) and the restrictions regarding asbestos fibres (annex XVII, Entry 6) and Chromium VI (annex XVII, Entry 47) Danish Maritime Authority, Vermundsgade 38 C, DK 2100 Copenhagen Ø, E-mail: sfs@dma.dk, Phone +45 3917 4400; fax: +45 3917 4401 (Responsible for the enforcement of Article 31(7) litra 1 and 2, Article 34-36, Article 37(4-8) and Article 38 (1-3 and 5) on ships) Danish Energy Agency Amaliegade 44 DK 1256 Copenhagen K Phone: +45 33 92 67 00 E-mail: ens@ens.dk (Responsible for the enforcement of Article 14(6), section IV and V except Article 33(2) and Article 38(4) on Offshore Installations under The Danish Act on Health and Safety on Offshore Installations (no. 1424 of 21. December 2005))

Enforcement Strategy

Has an overall strategy (or strategies) been devised and implemented for the enforcement of REACH? No

If No, are there any plans for making an enforcement strategy (or strategies)? No

Comments

Denmark has no overall national strategy for the enforcement of REACH. It is up to each Enforcement Authority to make 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. Those strategies are 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. 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.

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.

Regular meetings and discussions have been held between the Competent Authority and the different Authorities responsible for the enforcement during the negotiations and the implementation of REACH. The Authorities have organised their work with REACH in small “working-groups” responsible for different areas of REACH and have appointed contact persons/focal points for each area e.g. helpdesk, information and evaluation. Furthermore, the different Enforcement Authorities have appointed contact persons at different levels and in different areas in order to ensure good cooperation and exchange of information. The contact persons from the Competent Authority and the different Enforcement Authorities are part of this network where information is exchanged by email and by regular meetings at different levels.

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).

As both the Competent Authority and the Chemical Inspection Service are placed in the Danish EPA, there has been a very close cooperation during the negotiations; the implementation of REACH and after it has entered into force. Weekly meetings have been conducted between people from helpdesk, information, restrictions, lawyers and the Chemical Inspection Service. Since REACH entered into force, regular meetings between the Enforcing Authorities have been held prior to each Forum-meeting, where the agenda is discussed. Between the meetings, information from Forum and the working groups is exchanged by email and when topics of great interest have been discussed separate meetings have been conducted. The Enforcement Authorities have participated in workshops for consultants organised by the Competent Authority, and the Nordic Enforcement Authorities under the Nordic Council of Ministers have organised a common workshop for Enforcement Authorities in the Nordic countries regarding the enforcement of REACH. The plan is that a written agreement between the Danish EPA, the Chemical Inspection Service and the Danish Working Environment Authority will be prepared in 2010-2011, concerning the cooperation at the different levels, including instructions for the inspectors about when and how to contact the other Enforcement Authorities both nationally and in other MS. Good personal contact will be established between inspectors from the Danish EPA and the Danish Working Environment Authority to ensure good enforcement of REACH and particularly SDS. Workshops and joint inspections with the Danish EPA will be a part of the training of the inspectors from the Danish Working Environment Authority. Depending on the outcome and the needs, the plan is that in the years ahead such agreements will be prepared between all the enforcement authorities as well as with the Customs Office.

Describe the inspection and investigation strategy and methodology.

Denmark has no overall national strategy for the enforcement of REACH, but each Enforcement Authority has their separate strategy. The Chemical Inspection Service, which is the main enforcing authority, has an overall strategy for the enforcement activities and every year the Inspection prioritises which area and regulations are to be controlled. As a part of the Danish Government's Chemical Action Plan for 2010-2013, the Chemical Inspection Service must perform 2-3 enforcement projects on REACH (registration, restrictions) each year, based on risk analysis in order to prioritise enforcement in those areas where there is the most risk for violations of the rules and in areas where the violation can lead to serious danger to health and the environment. The enforcement project may be performed in many ways e.g. as inspections at companies, by taking samples of specific articles at the retailers for analysis or as desk-studies. The Danish Working Environment Authority performs general inspections where all aspects of the work environment are inspected. These inspections include chemistry when relevant and thereby REACH. The inspections on chemistry will typically include talk about personal protection, ventilation, the chemical risk assessment and safety data sheet. A special unit performs the inspections and investigations of the content in the safety data sheet and ES and other issues regarding importers and producers of chemicals. As part of the general inspections, The Danish Maritime Authority has included some additional questions regarding SDS and information in the supply-chain to the survey questionnaire used by the ship surveyors. The Danish Energy Agency performs general inspections where all aspects of the work environment on offshore installations are inspected, which also include REACH.

Describe the level and extent of monitoring activities.

The Chemical Inspection Service will perform 2-3 enforcement projects per year on the duty to register and/or on some of the restrictions in Annex VXII. The other Enforcement Authorities have frequent inspections at companies, vessels and offshore installations, and the monitoring will be a part of these inspections.

Describe sanctions available to enforcing authorities.

The available sanctions are stated in the consolidated Act. No. 1755 of 22. December 2006 on Chemical Substances and Products with subsequent amendments. The applicable administrative sanctions are advice, enforcement notice and order incl. the recall of illegal products from the market and/or destruction. The penalty for violations of REACH is fine, unless more severe penalties are applicable under other legislation. The penalty may be increased to imprisonment for up to two years if the violation was committed intentionally or through gross negligence and the infringement has caused damage to human or animal life or health, damage to the environment or the violator has obtained or sought a financial advantage, including cost savings, for himself or others.

Describe the referrals from ECHA.

Denmark has not received any.

Describe the referrals from other Member States.

Denmark has received one referral from another MS regarding the registrations of a Danish company.

Describe any other measures/relevant information.

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. Some of the figures listed below are rough estimates, as the authorities do not list all the information required.

2007

Dutyholders

Provide an estimate of the total number of dutyholders who are likely to have duties imposed on them by REACH. 138000

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? 11500

State the number of manufacturer dutyholders subject to inspections and investigations. 50

Were these mainly:	No information
State the number of importer dutyholders subject to inspections and investigations.	100
Were these mainly:	No information
State the number of distributors subject to inspections and investigations.	130
Were these mainly:	No information
State the number of downstream users subject to inspections and investigations.	11000
Were these mainly:	Small-Medium

Inspections	
State the number of inspections that addressed registration.	0
State the number these cases which were non-compliant.	0
State the number of inspections that addressed information in the supply chain.	0
State the number these cases which were non-compliant.	0
State the number of inspections that addressed downstream use.	11500
State the number these cases which were non-compliant.	2900
State the number of inspections that addressed authorisation.	0
State the number these cases which were non-compliant.	0
State the number of inspections that addressed restriction.	0
State the number these cases which were non-compliant.	0
State the number of inspections that addressed other REACH duties.	0
State the number these cases which were non-compliant.	0

Investigations	
State the number of investigations prompted by complaints and concerns raised.	1
State the number of investigations prompted by incidents or dangerous occurrences.	1

State the number of investigations prompted by monitoring.	0
State the number of investigations prompted by results of inspection/follow up activities.	6
State the number of inspections and investigations resulting in no areas of non-compliance.	8500
State the number of inspections and investigations resulting in verbal or written advice.	400
State the number of inspections and investigations resulting in formal enforcement short of legal proceedings.	2500
State the number of inspections and investigations resulting in initiation of legal proceedings.	0
State the number of convictions following legal proceedings.	0

Enforcement

State the number of manufacturers subject to formal enforcement.	2
Were these mainly:	No information
State the number of importers subject to formal enforcement.	0
Were these mainly:	No information
State the number of distributors subject to formal enforcement.	2500
Were these mainly:	No information
State the number of downstream users subject to formal enforcement.	2500
Were these mainly:	Small-Medium

2008

Dutyholders

Provide an estimate of the total number of dutyholders who are likely to have duties imposed on them by REACH.	138000
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?	22500

State the number of manufacturer dutyholders subject to inspections and investigations.	90
Were these mainly:	No information
State the number of importer dutyholders subject to inspections and investigations.	200
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.	21000
Were these mainly:	Small-Medium

Inspections	
State the number of inspections that addressed registration.	0
State the number these cases which were non-compliant.	0
State the number of inspections that addressed information in the supply chain.	0
State the number these cases which were non-compliant.	0
State the number of inspections that addressed downstream use.	22500
State the number these cases which were non-compliant.	7500
State the number of inspections that addressed authorisation.	0
State the number these cases which were non-compliant.	0
State the number of inspections that addressed restriction.	0
State the number these cases which were non-compliant.	0
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.	0

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.	9
State the number of inspections and investigations resulting in no areas of non-compliance.	5000
State the number of inspections and investigations resulting in verbal or written advice.	1000
State the number of inspections and investigations resulting in formal enforcement short of legal proceedings.	6500
State the number of inspections and investigations resulting in initiation of legal proceedings.	0
State the number of convictions following legal proceedings.	0

Enforcement

State the number of manufacturers subject to formal enforcement.	0
Were these mainly:	Not applicable
State the number of importers subject to formal enforcement.	0
Were these mainly:	Not applicable
State the number of distributors subject to formal enforcement.	0
Were these mainly:	Not applicable
State the number of downstream users subject to formal enforcement.	6500
Were these mainly:	Small-Medium

2009

Dutyholders

Provide an estimate of the total number of dutyholders who are likely to have duties imposed on them by REACH.	138000
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?	25700
State the number of manufacturer dutyholders subject to inspections and investigations.	100
Were these mainly:	No information
State the number of importer dutyholders subject to inspections and investigations.	240
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.	24000
Were these mainly:	Small-Medium

Inspections	
State the number of inspections that addressed registration.	50
State the number these cases which were non-compliant.	5
State the number of inspections that addressed information in the supply chain.	37
State the number these cases which were non-compliant.	14
State the number of inspections that addressed downstream use.	25000
State the number these cases which were non-compliant.	5600
State the number of inspections that addressed authorisation.	0
State the number these cases which were non-compliant.	0
State the number of inspections that addressed restriction.	117
State the number these cases which were non-compliant.	1
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.	6
State the number of investigations prompted by incidents or dangerous occurrences.	0
State the number of investigations prompted by monitoring.	1
State the number of investigations prompted by results of inspection/follow up activities.	24
State the number of inspections and investigations resulting in no areas of non-compliance.	20000
State the number of inspections and investigations resulting in verbal or written advice.	1000
State the number of inspections and investigations resulting in formal enforcement short of legal proceedings.	4500
State the number of inspections and investigations resulting in initiation of legal proceedings.	0
State the number of convictions following legal proceedings.	0

Enforcement

State the number of manufacturers subject to formal enforcement.	1
Were these mainly:	Small
State the number of importers subject to formal enforcement.	15
Were these mainly:	Small
State the number of distributors subject to formal enforcement.	1
Were these mainly:	Small
State the number of downstream users subject to formal enforcement.	6500
Were these mainly:	Small-Medium

Theme 9 - Information on the Effectiveness of REACH on the Protection of Human Health

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?

The effectiveness of REACH should be evaluated at the EU level, but this would require also assessments at the national levels. In determining the effectiveness of REACH in reaching the goals, the way REACH is intended to function should guide the identification of possible indicators. The way REACH is intended to function could be described schematically as:

1. Obtain appropriate information on the intrinsic (hazard) properties of chemical substances
2. Obtain appropriate information on the manufacturing and uses of chemical substances
3. Determine the possible risks to humans and the environment for each emission scenario
4. Identify and implement/recommend appropriate Risk Management Measures
5. This will lead to reduced exposure of humans and the environment
6. Which in turn will lead to improved protection of humans and the environment

Thus, ideally measurements of the efficiency of REACH in reaching the overall goals of improved protection of human health and the environment should be made on humans and the environment. However, even if it was possible to measure improved human health or status of the environment, it would be extremely difficult to link such effects to REACH, as a direct causal relationship is difficult to establish due to the distance in time and space between the possible exposure and any impact or effect that can be measured. Thus, as it is hardly possible to conduct meaningful measurements of the efficiency of REACH on item 6 above, the possibilities of using the other items should be discussed. Item 5: Reduced exposure Monitoring data can be valuable

..... exposure monitoring data can be obtained measured for determining whether REACH in fact reduces the exposure of humans and the environment. In particular for the working environment, a good measure can be obtained, as there is a direct relationship between the measured concentrations and the use of chemicals can be established. However, no regular chemical monitoring takes place in the working environment. In Denmark, regular monitoring of a number of substances in the aquatic environment and in various food items is conducted. 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. Item 4: RMMs The Exposure Scenarios attached to the SDS will provide instructions to downstream users on the Operational Conditions and Risk Management Measures recommended to ensure safe use. The degree to which these are implemented in practice would be a measure for the effect of REACH. In Denmark, the control of Safety Data Sheets and the use of chemicals in the working environment is conducted by the Danish Working Environment Authority. Furthermore, the Ministry of Environment and the municipalities are both approving and controlling the environmental aspects of industries including the emissions to the environment. However, no specific programme for measuring the impact of REACH has been established until now. Item 3: Risk assessment This is conducted by registrants as part of their registration dossier and controlled by ECHA (dossier evaluation) or the MSCA (substance evaluation). Item 2:

evaluation) or the MSCA (substance evaluation). Item 2: Manufacturing and use Information on the manufacturing, import and use of substances is provided in the registration dossiers. In Denmark, additional information on classified substances and mixtures placed on the market for professional use is registered in the Danish Product Register. The non-confidential data together with non-confidential data from all national Nordic Product Registers are compiled in the so-called SPIN database, which is publicly available. From this register different datasets can be drawn on the use of chemicals. However, the SPIN database and the Nordic registers are not aimed at monitoring the effectiveness of REACH.

Theme 10 - Other Issues/Recommendations/Ideas

Please provide any further information on the implementation of REACH that the MS considers relevant.

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 led 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

...provisions 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.

Do you wish to upload documents in support of this submission No

Meta Informations

Creation date	01-06-2010
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User name	ReachDK
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