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MS REACH Reporting Questionnaire

General Information	
Which Member State are you reporting for?	IE
What reporting period are you reporting on?	2010
Primary contact person's name.	Anne-Marie Finlay
Please provide an email address for the primary contact person.	Annemarie.Finlay@deti.ie

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

More than one Competent Authority Responsible for REACH

First Competent Authority	
What is the name of the organisation where the Competent Authority is situated?	Health and Safety Authority (HSA)
What is the address of the organisation?	Head Office, Metropolitan Building, James Joyce Street, Dublin 1, Ireland
What is the email address of the organisation?	wcu@hsa.ie
What is the telephone number of the organisation?	+353 1890 289389
What is the fax number of the organisation?	+3531 6147020
What part of REACH does this part of the Competent Authority deal with?	All Other (please list)
Please list the other parts of REACH that this part of the Competent Authority deals with here.	All parts of REACH are dealt with by the Health and Safety Authority in relation to all substances with the exception of pesticides and biocides, which fall under the remit of the Department of Agriculture, Fisheries and Food (DAFF).
From what part of Government does this part of the Competent Authority have authority from?	Other (please list)
Please list the other parts of Government that this part of the Competent Authority has authority from.	Department of Enterprise, Trade and Innovation (DETI)
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 Policy CLP
What other chemical legislation are the staff of the REACH CA involved in?	Import/Export Other
If Other, please list the different legislation here	Detergents CLP Seveso Chemical and Biological Agents Protection of workers from asbestos

Second Competent Authority	
What is the name of the organisation where the Competent Authority is situated?	Department of Agriculture, Fisheries and Food (DAFF)
What is the address of the organisation?	Pesticide Registration & Control Division, Department of Agriculture Fisheries and Food Backweston Campus Young's Cross Celbridge Co. Kildare IRELAND
What is the email address of the organisation?	pcs@agriculture.gov.ie
What is the telephone number of the organisation?	+3531 6157552
What is the fax number of the organisation?	+3531 6157575
What part of REACH does this part of the Competent Authority deal with?	Evaluation Restriction CLP Risk Assessment Other (please list)
Please list the other parts of REACH that this part of the Competent Authority deals with here.	Note: Remit under REACH is in relation to pesticides and biocides
From what part of Government does this part of the Competent Authority have authority from?	Other (please list)
Please list the other parts of Government that this part of the Competent Authority has authority from.	The Department of Agriculture, Fisheries and Food
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 Enforcement Policy Exposure CLP
What other chemical legislation are the staff of the REACH CA involved in?	Import/Export Biocides Pesticides Food

Third Competent Authority		
What is the name of the organisation where the Competent Authority is situated?	Environmental Protection Agency (EPA)	
What is the address of the organisation?	PO Box 3000, Johnstown Castle Estate, Co. Wexford, Ireland	
What is the email address of the organisation?	info@epa.ie	
What is the telephone number of the organisation?	+353 91 60600	
What is the fax number of the organisation?	+353 91 60699	
What part of REACH does this part of the Competent Authority deal with?	Evaluation Risk Assessment Other (please list)	
Please list the other parts of REACH that this part of the Competent Authority deals with here.	Note: Remit under REACH is in respect of the prevention of environmental pollution	
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?	Other (please list)	
Please list the other skills that staff in this part of the Competent Authority have.	Environmental science (relates to staff directly involved in REACH)	
What other chemical legislation are the staff of the REACH CA involved in?	Other	
If Other, please list the different legislation here	Persistent Organic Pollutants, PCBs, Ozone Depleting Substances, F-gases, ROHS, Deco-Paints, WEEE, Batteries, IPPC, Waste, Water Framework Directive	

How effective is MS collaboration with ECHA?

5

How could effectiveness of collaboration with ECHA be improved?	Provision of a regularly updated organogram of ECHA & Commission indicating who / what groups are working on particular aspects of REACH, and related legislation, would improve communications.
How effective is MS communication with the Commission (specifically Article 133 Committee)?	5
How could effectiveness of communication with the Commission be improved?	Provision of a regularly updated organogram of Commission Services, indicating who / what groups are working on particular aspects of REACH and related legislation, would improve communications.
How effective is MS collaboration with the Commission (specifically Article 133 Committee)?	5
How could effectiveness of collaboration with the Commission be improved?	Early and ongoing identification and communication of planned legislative developments in relation to REACH and related legislation.
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.	Health and Safety Authority
What is the address of the Helpdesk?	Health and Safety Authority, Metropolitan Building, James Joyce Street, Dublin 1, Ireland.
What is the web page address of the Helpdesk?	www.reachright.ie
What is the email address of the Helpdesk?	reachright@hsa.ie
What is the telephone number of the Helpdesk?	1890 289 389
What is the fax number of the Helpdesk?	+3531 6147020
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	0
Economist	0
Social Scientist	0
Exposure Assessor	0
Other (please list)	1-5
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.	General Scientists Occupational Hygienists
Is the same Helpdesk used to provide help to Industry on CLP?	Yes
Does the Helpdesk receive any non-governmental support?	No
How many enquiries does the Helpdesk receive per year?	101-1000
In what format can enquiries be received by the Helpdesk?	Email Phone Fax 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?	Medium enterprises

What type of enquiries does the Helpdesk receive? Pre-registration SIEFs
Registration

Registration REACH-IT IUCLID5 Authorisation

Downstream user obligations

Restriction

Obligations regarding articles

Testing

Safety Data Sheets

Enforcement

SVHC

Other (please list)

CLP

Please list the other types of enquiries that the Helpdesk Substance i.d. OR duties Exemptions Enquiry process receives.

NoNs PPORDs Distributors duties

For each type of enquiry received, please provide the proportion in percentage of the total enquiries.		
Pre-registration (%)	15	
Registration (%)	7	
Authorisation (%)	3	
Restriction (%)	4	
Testing (%)	1	
Enforcement (%)	3	
CLP (%)	2	
SIEFs (%)	14	
REACH-IT (%)	3	
IUCLID5 (%)	1	
Downstream user obligations (%)	9	
Obligations regarding articles (%)	9	
Safety Data Sheets (%)	4	
SVHC (%)	1	
Other (%)	25	

What proportion of enquiries received are deemed to be 1) straight forward, 2) complex, OR No information		, 2) complex,
Straight forward (%).	60	
Complex (%).	40	
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	1 week
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?	4
What level of cooperation is there between Helpdesks outside REHCORN?	2
How frequently do you use RHEP?	Weekly
Has the MS carried out any specific public awarness raising activities?	Yes
What type of activities have been carried out?	Newspaper Leaflets Radio Other (please list) Speaking events
Please list the other types of activities that have been carried out.	- E-Bulletin that users can sign up to - email circulation lists - SMS messaging campaigns - direct mail campaigns - publication of reports highlighting issues regarding chemicals and the environment, including REACH

How effective was each type of activity?	
Newspaper	4
Radio	3
Speaking events	5
Leaflets	5

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)?	501-5,000
Please describe the scope of the number of REACH webpage visits.	Between January 2007 and March 2010, we had over 60,000 hits to our REACH web site. This corresponds to just under 40,000 unique views of our Homepage. Most users click on the latest news, and on the preregistration, registration and exemptions pages.

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?	No information

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 5 of the Committees associated with REACH are?

How could the effectiveness of the Committees be improved?

Risk Assessment Committee Rating: 7 The work of the RAC to date has focused on assessing proposals for harmonized classification and labelling rather than on the authorization or restriction process. Expertise on the committee for the assessment of CMR endpoints is confined to a number of members and therefore the ability to process such dossiers quickly and effectively is very resource dependant. Consideration should be given to establishing either a RAC working group or preferably a separate committee to prevent the RAC workload on classification coming at the expense of its functions on authorization and restriction. REACH presently has no requirement to undertake a completeness check of a classification dossier. In the absence of such a requirement, the committee could spend unnecessary time and resources seeking the necessary information. ECHA can address this absence in its procedures and processes, but giving it a legal basis in a future review of the CLP regulation may also be necessary. Socio Economic Committee Rating: 7 Training in the area of socio-economic analysis as it applies to the development of opinions on restriction or authorisation applications has been useful as Committee members have varied backgrounds and experience. It will be important that lessons learned from the processing of the SEA elements of the first dossiers is captured and made available to the full Committee to inform future rapporteurships. Holding joint meetings and workshops with the RAC has been beneficial and should be continued if possible. The improved understanding of the work and processes

of the RAC that develops through formal and informal discussions during these joint sessions will assist when RAC and SEAC are required to work closely together to develop opinions within tight deadlines. MSC Rating: 8. Committee is quite effective, however, it would benefit considerably from increased participation in discussions by more members. REHCORN (now HelpNet) Rating: 5. Some suggestions for improving the effectiveness are: -Use of webinars for training and information dissemination. - Greater use of teleconferences for discussions on difficult questions and FAQ proposals -Discussions on difficult issues and where disagreements arise for resolution of such issues during meetings -Foster cooperation between MS Helpdesks outside of the Helpnet structure FORUM: Rating 8 The FORUM has been very effective in fulfilling the tasks assigned to it, especially in relation to the extensive work done by a number of working groups consisting of Forum members assisted by experts which present their progress reports for discussion at each Forum meeting. The first harmonised enforcement project instigated by the Forum was successfully completed in 2009, and a very useful REACH Enforcement Train the Trainer session was held in 2010 to assist the training of enforcement inspectors in member states. The main suggestion for improvement is to improve communications/coherence between FORUM and CARACAL. Caracal Meetings Rating: 6 Difficulties arise from the very busy agenda for each meeting which does not allow much time for عالا المسابقين بالماعان والماع بالمعاعلة لماني المسابعة والمسابق بالماعات المسابقة

discussion on any item. In addition the wide range of stakeholders at the table means that agreement is difficult to achieve on contentious topics. As a result the meeting is becoming more of an information dissemination forum for the Commission and ECHA on issues they have already agreed on. Areas for improvement include limiting the number of Agenda items and having more time to discuss important items. The provision of translation services may also help in the increased participation of members. A list of CARACAL members, regularly updated and circulated would also be beneficial. PEG: Rating varied between 3 and 6, depending on the PEG Allowing more time for collation of comments by ECHA in advance of the meetings, would be beneficial, as well as providing for longer commenting periods by participants. Scheduling of meetings for longer times, i.e. more than 1 day, or back to back with similar PEG meetings, as well as the use of teleconferencing may help improve efficiency. In relation to the composition of PEGs, it was found that small groups worked better than large ones, and the potential added value of adding new members to the PEG at a late stage in the process needs to be considered.

Theme 6 - Information on Substance Evaluation Activities

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

Health and Safety Authority Department of Agriculture, Fisheries and Food Environmental Protection Agency

Toxicologist	0
TOXICOTOSISE	
Ecotoxicologist	0
Chemist	0
Chemist	
Risk Assessor	0
Socio-Economic Analyst	0
Exposure Assessor	0
Other (please list)	0
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.	No substance evaluation involvement as of yet (2010) as no substance evaluation work is ongoing
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?	
How many substances has the MS added to the Community Rolling Action Plan?	
How many of ECHA's draft decisions on dossier evaluation has the MS commented on?	

Theme 7 - Annex XV Dossiers

	How many of each type of dossier has the MS prepared?
CLP	1-3

Restriction	0
Identification of SVHC	0
Is the time spent following up your MS dossiers reasonable?	7
Space is available below to provide further comments on how reasonable the time spent following up your MS dossiers was.	Experience to date has only been in relation to transitional dossiers, where decisions were made very late in the process in relation to the IUCLID 5 dossier preparation, resulting in unnecessary work being carried out by staff in the HSA. For future Annex XV dossier preparation, robust procedures need to be in place well in advance of work commencing, to ensure, where changes to the process are necessary or decisions need to be made, that these are taken promptly and communicated efficiently.

How many of each type of dossier are rapporteured?	
CLP	1-3
Restriction	0
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.	IE MS is the assigned rapportuer for two dossiers under RAC. However, we are not yet in a position to comment as we are • still awaiting submission of dossiers by MS • still awaiting end of public consultation period to commence rapporteur tasks

How many of each type of dossier are co-rapporteured?	
CLP	0
Restriction	0
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 corapporteured dossiers was.

How many dossiers prepared by other MS has the MS contributed to or commented upon?		
CLP	>9	
Restriction	0	
Identification of SVHC	>9	

How many dossiers prepared	by ECHA has the MS contributed to or commented upon?
Restriction	0
Identification of SVHC	1-3

What expertise is avail	able for preparing dossiers?
Chemist	1-3
Toxicologist	1-3
Ecotoxicologist	1-3
Economist	1-3
Enforcement	7-9
Legal	0
Policy	4-6
Exposure	0
CLP	4-6
Other (please list)	0
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 toxicology, ecotoxicology, and pesticide specialists, also experts in various areas of pollution prevention, e.g. IPPA licensing, Water Framework Directive. We also have access to socioeconomic expertise.

Is the MS satisfied with the levels of access to expertise?

Has there been any industry involvement in the preparation of MS dossiers?

How much involvement has industry had?

4

Theme 8 - Information on Enforcement Activities

General I	nformation
Please enter the MAIN enforcing authority for REACH within the Member State.	Health and Safety Authority (HSA) Head Office, Metropolitan Building, James Joyce Street, Dublin 1, Ireland
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.	Pesticide Registration & Control Division, Department of Agriculture Fisheries and Food (DAFF) Backweston Campus Young's Cross Celbridge Co. Kildare IRELAND Environmental Protection Agency (EPA), PO Box 3000, Johnstown Castle Estate, Co. Wexford, Ireland

Enforceme	ent 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 REACH Regulation is enforced under the Chemicals Act of 2008 which gives further effect in Ireland to REACH and other EU chemicals legislation, and appoints the HSA as the lead Competent Authority for REACH. This Act nominates the relevant competent authorities, provides for powers of inspectors, enforcement tools, and other legal provisions, as well as a number of administrative provisions. A broad based REACH enforcement strategy was developed by the HSA in 2007; this deals with identification of resources and technical supports, training etc. required for REACH enforcement, types of enterprises likely to be targeted, as well as the overall approach. This strategy is reviewed and updated annually in light of inspection findings from previous year and also taking into account pertinent deadlines, new obligations coming into force, etc. The national REACH strategy is informed by the work of the FORUM and is underpinned by the HSA's Strategy Statement, a key element of which is the promotion of safe and sustainable management of chemicals. The national REACH strategy is incorporated into the various Competent Authority annual work programmes.

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 Chemicals Act 2008 provides for 3 competent authorities for REACH - the Health and Safety Authority, the Environmental Protection Agency, and the Minister for Agriculture, Fisheries and Food - each with a specific remit. Included in the remit of the Health and Safety Authority is a co-ordinating role among the competent authorities. The Act also provides for the putting in place of co-operation arrangements between the competent authorities Arrangements for ensuring coordination include regular bilateral meetings between the national REACH CAs, as well as Interdepartmental/Interagency meetings for all those who have responsibilities under the Chemicals Act to ensure good coordination of activities and communication flow. A key mechanism for coordination of arrangements is by way of Memoranda of Understanding between the lead CA and other CAs. Also, as prescribed under the Act, national authorities are required to report annually via the HSA to the lead Government Dept. with responsibility for REACH on their REACH related activities including, enforcement and inspection activities. The HSA REACH Enforcement Strategy outlines how REACH enforcement is to be carried out by the HSA, what resources are required, how enforcement policy is implemented and inspections planned and delivered. Specialist chemicals inspectors are assigned to carry out REACH inspections and these are supported and trained by a team of REACH policy experts. The HSA is represented on the FORUM, facilitating efficient consultation and feedback on REACH Enforcement policy issues on a regular basis.

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).

An overall umbrella interdepartmental/agency group is in place to support the implementation of REACH across the competent authorities, and to support the development of common strategic policy approaches. This group meets approximately 4 times a year. It is chaired by the Department of Enterprise, Trade and Innovation, which is the lead government Department for REACH and CLP. • Regular bilateral meetings have been held between the HSA and other the 2 CAs with responsibility for REACH (2-3 per year). • A Memorandum of Understanding (MoU) was signed with EPA on the REACH regulation and one is in progress with DAFF. • The HSA is responsible for preparing an annual report to the relevant Government Minister on the operation at a national level of the Chemicals Act, which includes REACH.

2010 Reporting

Describe the inspection and investigation strategy and methodology.

The REACH enforcement objective under the current Chemicals Enforcement Programme is to carry out 1500 inspections focusing on the chemical / pharmaceutical processing, electronics, electroplating, printing, woodworking, spray painting, wholesale and distribution sectors. These inspections will examine: - Registration and pre-registration of substances under REACH - Hazard communication (safety data sheets and hazard labels for dangerous substances and preparations, including detergents). A question set proforma addressing these topics is available on our custom designed inspection application, known as Geosmart; the proforma is based on this reporting template allowing for efficient and accurate data collection and transmission. Operators who are likely to have registration duties as Manufacturers of substances are mainly the Pharmachem sector, and some limited number of bulk chemical manufacturers, and inspections in these premises can check for compliance with registrations provisions. Importers of substances /preparations and articles containing substances are another group likely to have registration obligations and these likely will be primarily distributors/ logistics firms etc. Inspections in these type of organisations is better carried out as a planned audit type of activity, as many will be office based, rather than workplace activity based, and it will be necessary to organise to meet with relevant personnel. Finally, some downstream users, and formulators may also be importing substances from outside the EU/EEA and therefore may have obligation duties and this can also

be examined during inspections of such premises, by checking chemical inventories. In relation to registrant obligations, the main objective of inspection activities will be to ensure that substances which are subject to registration have been registered with ECHA at the correct tonnage level. (A registration identifier no. will be issued by the ECHA once a substance has been registered.). This will be done mainly by checking the inventory of chemicals, checking for the correct identity of substances, and physical checking of warehouses / storage areas for inventories of chemicals. If a substance is not registered it cannot be manufactured or placed on the market, (no data, no market), which is a

key principle within REACH, and therefore a major focus for enforcement activity. A complete list of all of those Irish companies who signed on for pre-registration will be available as a basis for targeting operators who may have registration duties - this will likely be most useful for planned audit type of inspections, but could also be

referred to as part of general preparation for

inspections.

Describe the level and extent of monitoring activities.	Specialist chemical inspectors in the HSA carry out a planned number of inspections each year, ramping up each year, based on a proforma question set, and detailed guidance. Approximately 1,500 such inspections were carried out in 2009. Inspections are targeted at chemical / pharmaceutical processing, electronics, electroplating, printing, woodworking, spray painting, wholesale and distribution sectors. During 2009 the HSA also carried out 30 detailed audit type inspections as part of the REACH ENFORCE-1 Project, checking on registration duties and information through the supply chain, based on the list of companies who have preregistered in Ireland.
Describe sanctions available to enforcing authorities.	Sanctions available to enforcement authorities range from verbal / written advice, to enforcement notices, to criminal prosecution as provided for in The Chemicals Act 2008.
Describe the referrals from ECHA.	None received
Describe the referrals from other Member States.	Two referrals from MS requesting confirmation of pre registration numbers for substances submitted to ECHA from Irish based registrant were received and processed.
Describe any other measures/relevant information.	

Dutyholders	
Provide an estimate of the total number of dutyholders who are likely to have duties imposed on them by REACH.	
Provide an estimate of the above dutyholders who are likely to constitute registrants as defined by REACH.	
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?	372
State the number of manufacturer dutyholders subject to inspections and investigations.	45
Were these mainly:	Small-Medium

State the number of importer dutyholders subject to inspections and investigations.	110
Were these mainly:	Small-Medium
State the number of distributors subject to inspections and investigations.	20
Were these mainly:	Small-Medium
State the number of downstream users subject to inspections and investigations.	327
Were these mainly:	Small

Insp	ections
State the number of inspections that addressed registration.	45
State the number these cases which were non-compliant.	
State the number of inspections that addressed information in the supply chain.	327
State the number these cases which were non-compliant.	
State the number of inspections that addressed downstream use.	327
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.	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.	0
State the number of inspections and investigations resulting in no areas of non-compliance.	0
State the number of inspections and investigations resulting in verbal or written advice.	0
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.	0

Enforce	cement
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.	0
Were these mainly:	Not applicable

Dutyholders
Provide an estimate of the total number of dutyholders who are likely to have duties imposed on them by REACH.
Provide an estimate of the above dutyholders who are likely to constitute registrants as defined by REACH.

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?	1004
State the number of manufacturer dutyholders subject to inspections and investigations.	61
Were these mainly:	Small-Medium
State the number of importer dutyholders subject to inspections and investigations.	93
Were these mainly:	Small-Medium
State the number of distributors subject to inspections and investigations.	250
Were these mainly:	Small-Medium
State the number of downstream users subject to inspections and investigations.	870
Were these mainly:	Small

Insp	ections
State the number of inspections that addressed registration.	1004
State the number these cases which were non-compliant.	
State the number of inspections that addressed information in the supply chain.	1004
State the number these cases which were non-compliant.	
State the number of inspections that addressed downstream use.	1004
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.	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.	0	
State the number of inspections and investigations resulting in no areas of non-compliance.	0	
State the number of inspections and investigations resulting in verbal or written advice.	0	
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.	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.	0	
Were these mainly:	Not applicable	

Dutyholders		
Provide an estimate of the total number of dutyholders who are likely to have duties imposed on them by REACH.		
Provide an estimate of the above dutyholders who are likely to constitute registrants as defined by REACH.		
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?	1480	
State the number of manufacturer dutyholders subject to inspections and investigations.	69	
Were these mainly:	Small-Medium	
State the number of importer dutyholders subject to inspections and investigations.	104	
Were these mainly:	Small-Medium	
State the number of distributors subject to inspections and investigations.	360	
Were these mainly:	Small-Medium	
State the number of downstream users subject to inspections and investigations.	1277	
Were these mainly:	Small	

li .	spections	
State the number of inspections that addressed registration.	1480	
State the number these cases which were non- compliant.		
State the number of inspections that addressed information in the supply chain.	1480	
State the number these cases which were non- compliant.		
State the number of inspections that addressed downstream use.	1480	
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.	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.	0	
State the number of inspections and investigations resulting in no areas of non-compliance.	277	
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.	0	
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 0 enforcement.

Were these mainly:

Not applicable

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

EU

Do you think that the effects of REACH would be better evaluated at a Member State (MS) or EU level?

What parameters are available at MS level that could be used to assess the effectiveness of REACH in a baseline study?

Given the EU wide application of REACH, and the implications of the Regulation on the circulation of chemicals within the EU, an evaluation framework would seem to be best designed and co-ordinated at the EU level. Some of the problems relating to evaluations undertaken at Member State level are the possibility of being undertaken in a non-uniform or uneven manner, and under representation of certain aspects of REACH relating to cross border activities. The nature of parameters required to evaluate REACH is guided by the Regulation's objectives (protection of human health and environment, promotion of alternative methods for assessment of hazards of substances, free circulation of substances on the internal market and enhancing competitiveness and innovation). Data exists for the construction of parameters in a number of these domains (e.g. human health and the environment), but not for all (impact of REACH on firm competitiveness). Uniform data collection systems relating to these parameters do not exit across Member States, and so it may be difficult for a Member State led approach to parameter identification to produce a uniformly applicable standard. Indeed, many elements of REACH may require the creation of entirely new datasets for the purposes of the Regulation's evaluation and monitoring. For these reasons it may seem expedient to suggest that parameters be determined at EU level, with a response from Member States relating to their ability to provide data that satisfies the parameter's design. Evaluation design in this area is complex. Ouantification

of the Regulation's impacts on health and the environment, as well as its other objective areas, is difficult to achieve. Expertise in this area exists in a number of member states, but it would seem most appropriate if responsibility for the design of an evaluation framework be undertaken at EU level, where submissions could be directed for the development of the evaluation methodology. Such an approach would ensure a pooling of evaluation expertise in this area across the community. How an evaluation was to be executed, whether at Member State or EU level, would depend on its design and cannot be determined at this stage.

Theme 10 - Other Issues/Recommendations/Ideas

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

The following are some issues that could be considered under REACH review. • RISK MANAGEMENT OPTIONS: REACH has two risk management options for hazardous chemicals with CMR, PBT and vPvB properties authorisation and restriction. Choosing the right risk management option is critical for the success of REACH. Authorisation of a chemical is currently a two-step process involving a) identification of a substance on a candidate list and b) eventual inclusion of substances on the candidate list in Annex XIV. In moving a substance from the Candidate List to Annex XIV, REACH requires the Agency to give priority to substances with a)PBT or vPvB properties; b) wide dispersive use and c) high volumes. Additional information such as information on use of the chemical and availability of alternatives would be valuable in determining if authorisation is indeed the most appropriate option for the chemical, or whether restriction might not be a more effective risk management option. As experience is gained on the two risk management options in REACH, the Commission may need to review the current prioritization list in Article 58(3). • OVERLAP WITH OTHER LEGISLATION (e.g., RoHS, POPs, Detergents, etc...) REACH is the primary legislation covering manufacture, import and use of chemicals. As such, REACH should be used as the basis and framework for streamlining wider EU chemicals legislation, and the mechanisms under REACH used to manage risk should be the first point of decision making in dealing with a particular hazardous chemical. Procedures under sectoral legislation. for example.

RoHS, cosmetics, detergents, toys, should be with reference to the procedures under REACH. The EU obligations and interests in the context of the Stockholm Convention on POPs and the Rotterdam Convention on Prior Informed Consent could also be included under this framework. This would help to avoid the emergence of two parallel risk management schemes for the same substance, with extra regulatory costs for administrations and economic operators but without any corresponding health or environmental gain. The following should be considered with regard to future reporting on implementation of REACH: • Theme 4: Future data collection will first require an initiative from the Commission to establish common indicators. • Theme 8 should be reviewed. The subject matter for reporting emanated from a FORUM Working Group some time before the main report was designed, but was not subject to later review by MSCAs.

Do you wish to upload documents in support of this submission

No

Meta Informations		
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