

## MS REACH Reporting Questionnaire

General Information	
Which Member State are you reporting for?	FR
What reporting period are you reporting on?	2010
Primary contact person's name.	Sylvie DRUGEON
Please provide an email address for the primary contact person.	Sylvie.DRUGEON@developpement-durable.gouv.fr

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?	Ministère de l'écologie, de l'énergie, du développement durable et de la mer - Direction générale de la prévention des risques - Bureau des substances et préparations chimiques ; French Ministry of Ecology and Sustainable Development - Department for Risk Prevention - Chemical Substances and Preparations Unit
What is the address of the organisation?	Ministère de l'écologie, de l'énergie, du développement durable et de la mer Direction générale de la prévention des risques Bureau des substances et préparations chimiques Arche de la Défense, paroi Nord 92055 La Défense Cedex France
What is the email address of the organisation?	reach@developpement-durable.gouv.fr
What is the telephone number of the organisation?	+ 33 1 40 81 86 98
What is the fax number of the organisation?	+ 33 1 40 81 20 72
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  
Ecotoxicity  
Enforcement  
Legal  
Policy  
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

The CLP competent authority appointed by France is the Ministry responsible for Workers Safety. However, it should be noted that this role is carried out closely with the both Ministries responsible for Sustainable Development (REACH CA) and Health. The REACH CA is also Biocides CA, POP CA, ODS CA and Import/Export CA. The REACH CA is not the Pesticides French CA (Pesticides CA = Agriculture Ministry) but is involved in.

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.

The REACH competent authority appointed by France is the Ministry of Sustainable Development. However, it should be noted that this role is carried out closely with both Ministries responsible for Workers Safety and Health. Furthermore, all Ministries involved on what concerns substances classification and risk management measures linked with the Reach regulation are informed and consulted. The SGAE (General Secretariat for European Affairs) is the entity that ensures the coordination between all Ministries. ANSES (French Agency for Food, Environmental and Occupational Health Safety) is central in the national expertise scheme needed to implement REACH and CLP regulations and could be considered as a national institution mandated by the French authorities. INERIS (Institut National de l'Environnement Industriel et des Risques) also plays a key role in the French expertise framework and is in charge of both Helpdesks REACH and CLP.

Does the Competent Authority outsource any of its work? Yes

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

The Ministry is mainly assisted by ANSES. ANSES recommends priorities for evaluation, authorisation and restriction. Based on these recommendations, the French authorities may propose for certain substances their inclusion in the Community rolling action plan or risk management measures at a community level (authorisation, restriction or harmonisation of the classification and labelling). ANSES is in charge of preparing the French dossiers of proposals of restriction, identification of substances of very high concern for their inclusion in Annex XIV of REACH and of harmonised classification and labelling. ANSES is also responsible for preparing evaluations of substances led by France. ANSES prepares the opinions to be submitted by the French authorities on the dossiers proposed by other Member States. ANSES takes part in the Risk Assessment Committee (RAC) of the European Chemicals Agency and in the Committee for Socio-Economic Analysis (SEAC). INERIS also takes part in the RAC and the SEAC. ANSES may participate in the Member State Committee (MSC) to advise / back the French representative from the Ministry of Sustainable development.

How adequately resourced is the Competent Authority? 5

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

The amount of work necessary to implement correctly the REACH regulation, the important responsibilities of Member States and the wide range of tasks allocated to them by the Commission and ECHA, in particular if we want to follow the work plan scheduled for the deposit of restriction or SVHC's dossiers by the Commission and the view expressed by ECHA concerning the tasks assigned concerning Reach enforcement, seem quite ambitious compared to the human resources that the Member States have available.

## 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? 8

How could effectiveness of communication between MS be improved?	Higher frequency of CARACAL meetings (4/year) with regular closed sessions. Exchange of organisation charts of the REACH MSCA with nominative contacts (responsibilities and personal details) : these information could be uploaded (and updated) on a CIRCA group whose access should be granted only for MSCA, Commission and ECHA.
How effective is collaboration between MS for REACH?	7
How could effectiveness of collaboration between MS be improved?	See previous answer + Collaboration between MS for Annex XV dossiers preparation could be facilitated if MS could jointly submit Annex XV dossiers (concerning SVHC identification, Restriction proposal, C&L).
Are there any special projects/cooperation on chemicals that the MS participates in with other MS outside of REACH?	No
How effective is MS communication with ECHA?	7
How could effectiveness of communication with ECHA be improved?	A detailed organisation chart of ECHA with nominative contacts (responsibilities and personal details) could be given to the MSCA (and updated on a CIRCA group). Regarding Evaluation tasks, Echa could make available for each MS a personalised (excel) table listing national registrants whose dossiers are under Compliance Check or Testing Proposal Examination. This table could : - indicate the state of play : currently under examination, communication letter sent, outcome of /follow-up given to the communication letter, draft decision, decision, outcome/follow-up... - specify the dead-lines and target dates if appropriate, - and mention a link to the relevant documents.
How effective is MS collaboration with ECHA?	6
How could effectiveness of collaboration with ECHA be improved?	See previous answers (communication with Echa, communication / collaboration with MS) + Regarding Evaluation tasks, and in particular CCH, simple sum-up tools to follow and share the actions led by Echa, MSCA, Enforcement bodies are strongly needed. + Training sessions for MSCA on REACH-IT
How effective is MS communication with the Commission (specifically Article 133 Committee)?	7

How could effectiveness of communication with the Commission be improved?	A detailed organisation chart of the Commission (DG Env and DG Entr) with nominative contacts (responsibilities and personal details) could be given to the MSCA (and updated on a CIRCA group). Allocate sufficient time for commenting or approving of (written procedure) documents prepared by the Commission services. Improve capacity of planning in advance calendar and work plan.
How effective is MS collaboration with the Commission (specifically Article 133 Committee)?	6
How could effectiveness of collaboration with the Commission be improved?	See previous answers + Concerning CARACAL meetings : - Higher frequency of CARACAL meetings (4/year) with regular closed sessions, - Interpretation provided for CARACAL meetings. + Concerning Article 133 Committee : - Specific CIRCA group for REACH committee (whose access should only be granted for MSCA), - Improve capacity of planning in advance calendar and work plan, - Making draft regulations (and documents related) available in very advance could also facilitate the work to be done by the MS and therefore the collaboration with the Commission.
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.	INERIS (Institut National de l'Environnement Industriel et des Risques)
What is the address of the Helpdesk?	INERIS Service National d'Assistance Réglementaire REACH et CLP Parc Technologique Alata BP.2 60550 Verneuil-en-Halatte
What is the web page address of the Helpdesk?	www.reach-info.fr & www.clp-info.fr
What is the email address of the Helpdesk?	reach-clp-helpdesk@ineris.fr
What is the telephone number of the Helpdesk?	0 820 20 18 16
What is the fax number of the Helpdesk?	03 44 55 67 67
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	0
Social Scientist	0
Exposure Assessor	1-5
Other (please list)	0
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.	
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?	>1000
In what format can enquiries be received by the Helpdesk?	Phone Fax Letter Other (please list)
Please list the other format(s) of enquiries that can be received by the Helpdesk.	A web-form available on both Helpdesks websites
How are the majority of enquiries received?	Phone
Do you provide specific advice to SME's?	Yes
Who are the majority of enquiries from?	Large enterprises

What type of enquiries does the Helpdesk receive?

Pre-registration  
SIEFs  
Registration  
REACH-IT  
IUCLID5  
Authorisation  
Downstream user obligations  
Obligations regarding articles  
Safety Data Sheets  
Enforcement  
SVHC  
CSR preparation  
CLP

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

Pre-registration (%)	4
Registration (%)	20
Authorisation (%)	2
Enforcement (%)	4
CSR preparation (%)	4
CLP (%)	8
SIEFs (%)	12
REACH-IT (%)	4
IUCLID5 (%)	4
Downstream user obligations (%)	4
Obligations regarding articles (%)	12
Safety Data Sheets (%)	12
SVHC (%)	10

**What proportion of enquiries received are deemed to be 1) straight forward, 2) complex,**

Straight forward (%).	15
Complex (%).	55
No information (%).	30

**How long, on average, does it take to respond to the following types of questions?**

Straight forward questions	1 day
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?	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 awareness raising activities?	Yes
What type of activities have been carried out?	Newspaper Leaflets Other (please list)
Please list the other types of activities that have been carried out.	Support plan in cooperation with the professional association UIC (French Union of the Chemical Industries, the professional body federating all the chemical companies) which gathers all chemical companies : webinars, coaching (1 day with a consultant), workshops.

### How effective was each type of activity?

Newspaper	2
Leaflets	2
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.	No information

### 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?

General comments :

- Interpretation / translation of the meetings (at least for CARACAL meetings)
- Planning calendar and workplan
- Documents made available far ahead
- Written procedure with constrained time limits limited

Comments regarding Echa Committees : We have some concerns related to the representation of the MS in Forum (and also to a lighter extent in the MSC) : REACH foresees that representatives are personally/nominally designated by their MS whereas they're representatives of the MS they belong to. This situation leads to some confusing situations. This could be noted to be corrected in a coming review of the regulation. For the time being, Echa may be more flexible and accept for example that a representative from the MSCA, even if he's not the MS nominally representative in the relevant committee, could send comments, answer a written consultation...

We also have serious concerns about the workload of the committees, in particular of the RAC but also of the MSC in the near future. To address these concerns, at this stage, we suggest the following :

- the possibility of alternates (already the case for the MSC) should be extended to each Echa committee : Forum, RAC and SEAC.
- higher flexibility could be introduced in the rules of procedure of Echa committees : an expert or adviser designated by the member should be authorised to take part in a working group of the committee, even if the member doesn't attend himself in this group. In some situations, the Forum position seems to us to be ambiguous and the border with the MSCAs, and CARACAL meetings, needs to be clarified.

## Theme 6 - Information on Substance Evaluation Activities

2010 Reporting

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

ANSES (French Agency for Food, Environmental and Occupational Health Safety) will recommend priorities for evaluation. Based on these recommendations, the French authorities may propose for certain substances their inclusion in the Community rolling action plan. ANSES will be responsible for preparing evaluations of substances led by France.

**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?

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 >9

Restriction 1-3

Identification of SVHC	>9
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.	

How many of each type of dossier are rapporteured?	
CLP	>9
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.	

How many of each type of dossier are co-rapporteured?	
CLP	>9
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.	

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 available for preparing dossiers?

Chemist	4-6
Toxicologist	7-9
Ecotoxicologist	7-9
Economist	1-3
Enforcement	
Legal	
Policy	1-3
Exposure	4-6
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.	It should be noted that experts listed above don't work full time for the preparation of Annex XV dossiers.
Is the MS able to access external specialists?	Yes
What types of external specialists does the MS have access to?	Toxicologists, Ecotoxicologists, Ecomists
Is the MS satisfied with the levels of access to expertise?	4
Has there been any industry involvement in the preparation of MS dossiers?	Yes
How much involvement has industry had?	3

### Theme 8 - Information on Enforcement Activities

#### General Information

Please enter the MAIN enforcing authority for REACH within the Member State.	REACH CA (Ministry of Ecology and Sustainable Development)
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.

In France, inspectors from different authorities shall control and assess in their area of competence whether any REACH obligations have been infringed. The main enforcing authorities are the following : - Inspectors of classified installations (environmental inspectors), under the authority of the REACH-CA (Ministry of Ecology) ; - Inspectors of labour law ; - Inspectors of General Directorate for Fair Trading, Consumer Affairs and Fraud Control ; - Customs agents.

### 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.

In 2007-2008, the “Grenelle of Environment” roundtable talks highlighted the need to strengthen enforcement actions in order to allow a better reactivity to safety and environmental alerts. The French authorities decided to ensure the consistency of such activities and to encourage the development of coordinated controls. The second national environment and health action plan (NEHAP 2) adopted in 2009 foresees in particular expanded chemical testing campaigns by the government enforcement bodies, particularly for products designed for children and/or pregnant women. A working-group gathering 5 ministries was set up in 2008 aiming at coordinating enforcement actions. In 2009 and 2010, an instruction dealing with the different legislations of chemical products entered into force :

- Each REACH enforcer works on his/her field : i.e. labour inspector on requirements related to the workers, customs officers on requirements related to importations. The targets of each REACH enforcing authority are the “usual” inspected targets : i.e. an environmental inspector enforces classified plants which manufacture chemical products. - Importance of the exchange of information between enforcers from different enforcing authorities. These exchanges are, since the publication of the law, possible when a non-compliance case is suspected. - Promotes the joint inspections and coordinated inspections between REACH enforcers. The instruction also lays out the enforcement priorities. Regarding REACH enforcement priorities, they follow Forum projects. French enforcement project

...they remain for an project... REACH enforcement project... will implement, as much as possible, the project of the Forum. The first controls of the annual circular start in 2009 and were mainly focused on the pre-registration and SDS requirements. In 2009, about 300 inspections were carried out on the basis of the common project REACH EN FORCE 1. N.B. we don't have any consolidated data related to the years 2007 and 2008.

### 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.

As several enforcing authorities are empowered by environmental law, an annual (2009 and 2010) inter ministerial instruction on the chemical products enforcement organises the work of REACH enforcers. The instruction states the following principles :

- Each REACH enforcer works on his/her field : i.e. labour inspector on the REACH requirements related to the workers, customs officers on the REACH requirements related to importations, etc...Then, the targets of inspections of each REACH enforcing authority are the "usual" inspected targets : i.e. an environmental inspector enforces classified plants which manufacture chemical products.
- Importance of the exchange of information between enforcers from different enforcing authorities. These exchanges are, since the publication of the law, possible when a non-compliance case is suspected.
- Promotes the joint inspections and coordinated inspections between REACH enforcers. The instruction also lays out the enforcement priorities. A report is made annually by the enforcing authorities. Since the WG was only established in 2008, and the first common instruction was launched in 2009, we don't have any consolidated data related to the years 2007 and 2008.

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).

REACH enforcers from the main enforcing authorities meet regularly at a national level to discuss enforcement objectives and issues. This national working group elaborates the annual inter ministerial instruction on the chemical products enforcement (see above) which states general principles but also defines specific enforcement projects (part of the circular which is not available to the public). These projects are often coordinated projects : they need cooperation and exchange of information between several REACH enforcing authorities. Some of the projects promote joint inspections at a local level. Regional meetings are encouraged. Main issues of Forum meetings are also discussed and followed up by enforcing authorities. The WG exchanges material like the training documents, the enforcement manual (etc). Most of the time, due to the different cultures of each enforcing authority, the documents are adapted. However, every training (especially at a local level) organised by one enforcing authority is always accessible to the other REACH Enforcers. Each REACH enforcing authority has its own chemical products network (repartition per area). Each network has regular meetings and customises the project of the national working group.

### 2010 Reporting

Describe the inspection and investigation strategy and methodology.

See previous answers. French enforcement of REACH implements, as much as possible, the projects of the Forum. The 2010 governmental instruction on the chemical products enforcement indicates that enforcement will be carried out on the basis of the REACH EN FORCE 1 project (pre-registration and SDS requirements), i.e : 250 inspections are planned by the environmental enforcing authorities.

Describe the level and extent of monitoring activities.

We would like to remind that many monitoring activities exist but not linked to REACH : environmental monitoring of emissions of industrial sites (all media : air, water, soil). At this stage : the only sampling operations from the market of substances / mixtures are led with reference to Rapex notifications, such as phthalates in toys, benzene/toluene/chloroform in glues. REACH monitoring activities will in the future overlap with REACH inspections.

Describe sanctions available to enforcing authorities.

The legislation is enforced through both administrative and criminal law. Administrative level : the national legal provisions describing breaches of the REACH obligations contain “catch-all provisions” (letter of formal notice). If the formal notice is not satisfied within the delay granted by the local competent authority, REACH authorities can propose to the administrative competent authority a wide range of penalties : - a maximum fine of 15000 euros and daily periodic penalty payments of 1500 euros, - ban the import, the manufacture or the placing on the market of substances, mixtures and articles. - order the importer of substances to send back the substance, mixture, or product outside the EU or to ensure its disposal. - order producers that manufactured substances, mixtures, or articles to ensure their disposal. - require the producer, importer or downstream user to deposit to a public accounting officer an amount of money for the establishment of data, tests and studies to be realised in order to register a substance - etc.

Criminal level : 2 types of environmental crimes are identified in France. Major crimes may be punished by two years of imprisonment and a fine of 75000 euros. These criminal offences relate to the violations of the main requirements of REACH : - non registration (or registration obtained by fraudulent means), - non respect of a restriction measure (any non compliance with the Annex XVII of the REACH regulation), - non respect of the manufactures, imports or uses of a chemical substance submitted to Authorisation



(chemical substance listed on the Annex XIV of the REACH regulation), - for a downstream user, non submission of a Chemical Safety Report if conditions under article 38 apply, - to not provide for a supplier of a safety data sheet (SDS) the SDS according to the article 31 of the REACH regulation (this crime is punished by three months of imprisonment and a fine of 20000 euros). - - non compliance of the delay granted by the administrative competent authority in a formal notice Furthermore, France has completed penalties for infringements of Reach with 19 fines whose amounts range from 300 euros to 1500 euros.

Describe the referrals from ECHA.

No referral received from Echa (as far as we understand the question raised).

Describe the referrals from other Member States.

As far as we understand the question raised, we received 1 referral from another MS. The referral was related to one French company responsible for the putting on the market of 2 articles which may not meet the requirement laid out by Annex XVII, entry 23 (content of cadmium). Indeed, we were informed the polyvinyl chloride packages of two articles contain cadmium in a concentration of more than 0,01 % by weight. Following up this information, fraud agents enforced the company. They learnt that both articles were not anymore produced in France since 2002. Therefore, package of the articles controlled by the other MS bodies was actually made in September 2007, certainly in China. Following the request of the French Enforcement agents, company carried out analysis of 8 samples located in their storage in France during the inspection visit. The results show a concentration of cadmium of 5 ppm in the package. Moreover, the company checks in a systematic way the concentration of cadmium in the package after each production. Copies of these results shows that the concentration of Cadmium is less than 2 ppm. Furthermore, company declares to carry out random check on the goods coming to European Union Market.

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.

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? 0

State the number of manufacturer dutyholders subject to inspections and investigations. 0

Were these mainly: Not applicable

State the number of importer dutyholders subject to inspections and investigations. 0

Were these mainly: Not applicable

State the number of distributors subject to inspections and investigations. 0

Were these mainly: Not applicable

State the number of downstream users subject to inspections and investigations. 0

Were these mainly: Not applicable

### 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. 0

State the number these cases which were non-compliant. 0

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.	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

## 2008

### Dutyholders

Provide an estimate of the total number of dutyholders who are likely to have duties imposed on them by REACH.	0
Provide an estimate of the above dutyholders who are likely to constitute registrants as defined by REACH.	0
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?	0
State the number of manufacturer dutyholders subject to inspections and investigations.	0
Were these mainly:	Not applicable
State the number of importer dutyholders subject to inspections and investigations.	0
Were these mainly:	Not applicable
State the number of distributors subject to inspections and investigations.	0
Were these mainly:	Not applicable
State the number of downstream users subject to inspections and investigations.	0
Were these mainly:	Not applicable

### 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.	0
State the number these cases which were non-compliant.	0
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.	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

## 2009

### Dutyholders

Provide an estimate of the total number of dutyholders who are likely to have duties imposed on them by REACH. 3600

Provide an estimate of the above dutyholders who are likely to constitute registrants as defined by REACH. 3600

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? 2637

State the number of manufacturer dutyholders subject to inspections and investigations. 300

Were these mainly: Large

State the number of importer dutyholders subject to inspections and investigations. 142

Were these mainly: Large

State the number of distributors subject to inspections and investigations. 24

Were these mainly: Large

State the number of downstream users subject to inspections and investigations. 216

Were these mainly: Large

### Inspections

State the number of inspections that addressed registration. 300

State the number these cases which were non-compliant. 4

State the number of inspections that addressed information in the supply chain. 300

State the number these cases which were non-compliant. 67

State the number of inspections that addressed downstream use. 216

State the number these cases which were non-compliant. 2

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.	63
State the number these cases which were non-compliant.	160
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.	0
State the number of investigations prompted by incidents or dangerous occurrences.	0
State the number of investigations prompted by monitoring.	4
State the number of investigations prompted by results of inspection/follow up activities.	300
State the number of inspections and investigations resulting in no areas of non-compliance.	230
State the number of inspections and investigations resulting in verbal or written advice.	300
State the number of inspections and investigations resulting in formal enforcement short of legal proceedings.	70
State the number of inspections and investigations resulting in initiation of legal proceedings.	6
State the number of convictions following legal proceedings.	2

Enforcement	
State the number of manufacturers subject to formal enforcement.	300
Were these mainly:	Large
State the number of importers subject to formal enforcement.	142
Were these mainly:	Large
State the number of distributors subject to formal enforcement.	24
Were these mainly:	Large
State the number of downstream users subject to formal enforcement.	216
Were these mainly:	Large

## Theme 9 - Information on the Effectiveness of REACH on the Protection of Human Health and the Environment, and the Promotion of Alternative Methods, and Innovation and Competition

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?

- Analysis of data reported from REACH inspections and progression over time (hopefully decreasing) of non-compliances to REACH requirements (all procedures). - Data resulting from environmental monitoring of emissions of classified / industrial sites (all media : air, water, soil). Data resulting from monitoring of emissions from all media (ex: water framework directive, ...) - Enumeration of the occupational diseases declared or recognized by the health insurance resulting from occupational chemical exposures. - France has adopted a national health and environment plan (called "Plan national santé environnement" or "PNSE"). This plan aims to address questions raised by French people regarding the short- and mid-term health impacts of exposure to certain environmental pollutants. This plan includes a proposal to conduct an epidemiological study of children (called "ELFE"), in association with the American "National Children's Study" to assess levels of exposure to the main environmental pollutants and to analyse the links between exposure and child health. This cohorte study aims at measuring the individual contamination of the children to the chemicals and to observe occurrences of associated pathologies, like neurotoxic disorders and disturbances by endocrine disruptor's substances. The estimate of the exposure will be adressed through biological tests while being born (blood of the cord, urinates and hair of the mother...). For the child, the chemical exposure will be assessed at other key periods of the child's development. - An assessment of the data monitoring the progression over time (hopefully decreasing) of poisoning cases due to chemicals (for consumers, with a specific attention to childs, as for workers) could be performed. - We could also imagine to launch phone surveys to assess the development of the awareness of general public.



## Theme 10 - Other Issues/Recommendations/Ideas

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

Guidance : 1st issue (Translation) : Huge efforts have already been made. They need to be carried on and a focus on translating guidance and other documents aiming at facilitating SMEs to succeed in REACH should be put. 2nd issue (Authorisation) : Although the concerns raised about the relevant research and development activities (article 62.4e)) and the substitution plan (article 62.4f)), already expressed in the note from the French authorities on 11 October 2007 and reiterated in March 2010, have not been taken into account in the current draft, they won't oppose the endorsement of the guidance at this stage. The main reasons for this is that we have well noted that: - the Commission agrees on the principle that the substitution plan must be required for both routes under authorisation process, i.e. the "adequate control route" and the "socio-economic route" and on the fact that this will have to be clarified during the revision of Reach (2012), - - the endorsement of the guidance as it is could facilitate the rapid adoption of the first Annex XIV and of an also long-awaited amended Annex XIII which takes into account all available information in a weight of evidence approach to identify PBT/vPvB substances. We will pay particular attention to these commitments in the next future. Articles and parts of articles : 1st issue: application of the 0.1 % threshold (articles 7.2 and 33 of the REACH regulation) Resulting from the inclusion of substances on the candidate list, companies have some legal obligations, in particular if the substances are contained in articles. These information obligations

for the benefit of customers and of the supply chain are immediately triggered by MSC agreement on identification of SVHC. Several Member States, including FR, have questioned the approach of the current guidance of applying the 0.1 % threshold to the articles as produced, imported or supplied when implementing articles 7.2) and 33 of Reach to complex articles (i.e. consisting of many parts). The fact that a complex article may comply with the definition of article 3.3) while, at the same time, several parts of it may also still comply with this definition must not be omitted. Therefore, the approach consisting in applying the 0.1 % threshold to any parts of an article which complies with the definition of article 3.3) should be preferred. Furthermore, as shown in a recent report from the Nordic Council of Ministers ([www.norden.org/en/publications/publications/2010-514?set\\_language=en](http://www.norden.org/en/publications/publications/2010-514?set_language=en)), the current approach given in the guidance is detrimental from several points of view:

- loss of information through the supply chain which can affect the level of health and environment protection,
- obstacle to business (workability problems for producers of complex articles, decreased ability to anticipate the need for substitution of substances likely to be included into the candidate list, inequality between economic operators),
- difficulties of chemical analyses of complex articles that enforcement authorities will be facing.

As a consequence and in conclusion, we support the principle "once an article, always an article".

always an article . 2nd issue : Annex XVII provisions : Regarding the wording articles / parts of article, we note that in the majority of the Annex XVII provisions, the word article includes part of articles. We believe it's relevant to remain consistent with these provisions. Therefore, we are not in favour of putting the words "parts thereof" in Annex XVII entries. We support the idea that the word "article" already means in itself "article and every part of article". It does not make a difference whether or not such an article has been joined together with other articles to form a larger article. This definition means that any object which, at a certain step in its life has become an article, will normally remain an article until it eventually becomes waste after end use. An assembled article may comply with the definition of REACH article 3(3), while at the same time several parts or components of that same article may also comply with the definition of an article. An article can be both simple and complex. However, many components of complex articles are in essence still also articles. We consider that the limit values, mentioned in each Annex XVII entry related to a restriction concerning articles, shall apply to articles and parts that a complex article consists which comply with the definition of an article in Article 3(3) of REACH.

Specific substances of interest : We support the development of assessment tools dedicated to specific substances (id nanomaterials and endocrine disruptors), and also to combined effects; in order to improve their consideration by the REACH regulation. We will pay

particular attention to the follow-up given by the Commission to the Environment Council Conclusions of December 2009. Enforcement : We would like to draw the attention on the relevance of developing communication tools between enforcement bodies from 27 MS. A specific attention to the coordination with Customs needs to be paid. We would like to highlight that investigations on importations should be a priority in order to ensure equity between EU producers and non-EU. The consistency between the Community Customs Code and REACH needs to be clarified and further explored. We would like to remind the Commission the importance of working at European level in collaboration with customs authorities to build the capacity of an exact match between the tariff and customs code and CAS or EC numbers for chemicals. This approach would greatly facilitate monitoring import and export traffic of banned or restricted substances, and also investigations by Customs officers of substances subject to registration. We would like also to raise specific attention concerning the importance of making available a french translation of ECHA decisions taken in compliance for example with article 41 in order to make it enforceable correctly under french law. IT-tools : We have some concerns about access to REACH-IT. Moreover, we consider training sessions for MSCAs are needed. Regarding RIPE, we would like to point out our serious concerns about the final content , which could appear as slightly poor (example : no data available for legal entity located in other members states). and about

the time progress.

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

### Meta Informations

Creation date	09-09-2010
Last update date	
User name	ReachFR
Case Number	386167632411425210
Invitation Ref.	
Status	N