Inspection requirements for REACH and CLP

Final Report

Submitted to
Bartlomiej Balcerzyk
European Commission
Directorate General Environment
6 December 2011

milieu
ENVIRONMENTAL LAW & POLICY

RPA

PACE

This Report has been prepared by Milieu Ltd., together with PACE (Mark Blainey) and Risk and Policy Analysts Ltd. (for Section 5 of the Report), under contract to the European Commission, DG Environment (Study Contract N° 070307/2010/580405/SER/D3). **The views expressed herein are those of the consultants alone and do not represent the official views of the European Commission**.

Milieu Ltd (Belgium), 15 rue Blanche, B-1050 Brussels, tel: 32 2 506 1000; fax 32 2 514 3603; e-mail: nathy.rassmasson@milieu.be

Table of contents

Executive Summary

One of the main tasks of the European Commission is to ensure the proper implementation of EU legislation. This includes the REACH and CLP Regulations, although the actual implementation and enforcement of this legislation is the responsibility of the Member States. Both REACH and CLP require the Member States to maintain systems of official controls, to monitor compliance, and to report on the results of the controls and other enforcement measures taken. The European Chemical Agency's FORUM for Exchange of Information on Enforcement coordinates the network of Member State authorities responsible for enforcement of REACH and CLP.

This report on ***Inspection requirements for REACH and CLP*** builds on the work already performed by the FORUM in the effort to secure proper implementation of REACH and CLP, including the Strategies for enforcement of REACH and CLP, the Minimum Criteria for REACH and CLP Inspections, and the REACH-EN-FORCE-1 and REACH-EN-FORCE -2 projects. For the purposes of setting priorities for enforcement, the report provides a list of the enforceable Articles under REACH and CLP, selects those considered particularly important in terms of the obligations imposed, and then groups these into three general areas: 1) Registration related duties; 2) Supply chain related duties; and 3) Use related duties.

The report then reviews other EU legislation with provisions on inspection and enforcement – both environmental and non-environmental instruments – to consider if they might suggest additional criteria for ensuring effective REACH and CLP controls. These include criteria concerning

- Qualifications and powers of inspectors
- Frequency of inspections by site/ Overall number of inspections per year
- Programme and scope of inspections
- Collaboration between Member States, between authorities and with stakeholders
- EU Commission's role in inspection procedures

In order to better understand enforcement practices at national level, six Member States with significant chemicals industries and a range of different legal cultures and inspection systems are then reviewed, with the aim of identifying best practices concerning strategies for inspections. Coordination between enforcement authorities is considered as best practice in both **Bulgaria** and **France,** with the latter having set in place a specific institutional structure for coordination between Ministries and between inspection bodies for REACH enforcement. Exchange of information between inspectors of different Member States was a concern in **Germany,** with the use of the ICSMS (European Market Surveillance System) mentioned as a potential solution in that it allows for easy exchange of information about chemicals placed on the market across the EU. The **Swedish Chemicals Agency** maintains a registry of chemical products placed on the national market, as well as the manufacturers and/or importers of those products; and this is used extensively in checking compliance with e.g. classification, content of specific substances in chemical products, etc. **Slovenia** highlighted its preventive approach in providing timely information to duty holders about their duties, before compliance deadlines. Finally, the **United Kingdom** found desktop studies and the campaign approach to be useful for optimising inspection time and for focusing efforts on key REACH enforcement issues.

On the basis of this survey, additional ways of enhancing the impact of the enforcement activities carried out by Member States were considered, and a strategy document developed with a view to achieving greater output with the same administrative resources in terms of checking compliance. The **Strategy** proposes that many of the objectives of REACH and CLP can be delivered by focusing compliance checking on just three elements of REACH – the Exposure Scenarios, information in the supply chain and substances in articles. In combination

and if compliance is achieved, these three elements can help deliver a large number of the different objectives of REACH and/or CLP.

The Strategy is also aimed at stimulating a more ambitious agenda for REACH and CLP inspections. It points out that the information gathered in REACH/CLP is relevant in the enforcement of other EU legislation, including worker health and safety, industrial pollution control and product requirements. In particular, it proposes that enforcing authorities for other relevant legislation could use the Exposure Scenarios to check compliance with the obligations in this other legislation and if necessary organise joint inspections with the REACH/CLP authorities where doubts over compliance are raised. It also discusses in some detail how risk analysis can be used to target resources for inspection so as to achieve the most gains in terms of protection of human health and the environment.

The Strategy concludes that coordinating REACH/CLP inspection activities with other enforcement authorities such as labour inspectorates, industrial pollution control inspectorates, and market surveillance authorities is important for achieving the maximum benefit from the REACH/CLP regime. It acknowledges this to be a medium to long-term effort and recognises that additional policy and guidance may be needed at EU-level to achieve these potential gains.

The report then assesses options for further EU legislation on REACH and CLP inspections, including the potential benefits. The options for legislative changes are in the form of criteria for various aspects of inspection, including frequency of inspection (by operator type and by type of inspection, i.e. desk-based versus site-based); ratio of announced versus unannounced site visits, programme of inspections; and training. These are then further developed to show a range of ambition levels (low, medium, high).

If setting a minimum number of inspections would ensure a level playing field within the European market, it could also result in a loss of flexibility at the national level. This could result in the diversion of resources from more targeted inspections (based on risk assessment) or from the development and provision of support and guidelines to companies. Furthermore an increase in the number of inspections would not necessarily lead to increased effectiveness, given differences in cultures, structures of sectors across the EU, ways in which inspectors interact, how inspections are handled, etc. In general, desk-based inspections are considered more cost-effective than site inspections, if appropriate follow-up measures are taken. Site inspections are however important when desk-based inspection indicates non-compliance. The assessment also found that the benefits from surprise (unscheduled) inspections are uncertain and may not provide enough additional value to become a major part of an inspection regime.

Finally, the report considers the role of the Commission with respect to Member State REACH and CLP inspection activities. While the Commission is entitled to attend meetings of the Forum and its working groups, the extent to which it can participate actively in Forum activities is not clear. The report considers several options for an expanded Commission role in REACH and CLP inspection, all of which have precedents in other EU legislation. These include (in order of increasing Commission involvement):

- Provision of more detailed guidance on Member State reporting on enforcement, including the possibility of introducing mandatory elements
- Provision of technical guidance concerning proposed expanded role for REACH & CLP enforcement, e.g., in worker health and safety or industrial pollution control
- Direct role for the Commission in trainings of Member State inspectors
- Commission power to request specific investigations by national authorities, including direct access to documents of operators
- Audits of national inspectorates' infrastructure and operations
- Powers to undertake direct inspections

While several of the options would require binding legislation in order to confer the Commission with the necessary powers, other options do not. For example, the Commission could already consider providing technical (non-binding) guidance on how to use REACH-generated exposure scenarios in enforcing other areas of EU legislation, such as worker health and safety or industrial pollution control. There is also a need for more detailed guidance related to targeting and subsequent reporting of inspections, e.g., on how to define and identify various categories of duty holders.

In short, the report concludes that it could be useful for the Commission to take a stronger role with respect to REACH and CLP inspections, and it makes a number of practical suggestions towards that end.

Abbreviations

AMS	Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products
BAuA	Federal Institute for Occupational Safety and Health (Germany)
BLAC	Working Committee of the Federal Government and the States on Chemical Safety (Germany)
CA	Competent authority
CLEEN	Chemical Legislation European Enforcement Network
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
CPD	Continual Professional Development
CSR	Chemical Safety Report
DALYs	Disability Adjusted Life Years
DEFRA	Department for Environment, Food and Rural Affairs (UK)
ECHA	European Chemicals Agency
EEA/EFTA	European Economic Area / European Free Trade Association
EU	European Union
Forum	Forum for Exchange of Information on Enforcement
ICSMS	European Market Surveillance System
MIDs	Manufacturers, Importers and Downstream Users
MoU	Memorandum of Understanding (UK)
NACE	Statistical Classification of Economic Activities in the European Community
NRW	North-Rhine Westphalia (Germany)
ODS	Regulation (EC) No 1005/2009 on substances that deplete the ozone layer
QALYs	Quality Adjusted Life Years
RAPEX	Rapid Information Exchange System
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMCEI	Recommendation providing for minimum criteria for environmental inspections
SDS	Safety Data Sheet
SLIC	Senior Labour Inspectors' Committee
SMEs	Small and Medium sized Enterprises
SVHC	Substances of Very High Concern
UK	United Kingdom
VOSL	Value of Statistical Life
WEEE	Directive 2002/96/EC on waste electrical and electronic equipment

1. Introduction

1.1. Background

Background to the study

The European Commission, as guardian of the Treaty, is charged with ensuring that the Member States apply EU law in their jurisdictions. Under this duty, the Commission has taken a number of actions to improve implementation of the EU environmental requirements. For example, it has proposed a number of legislative measures adopted at EU level aimed at improving the implementation and enforcement of EU environmental requirements, such as the Recommendation providing for minimum criteria for environmental inspections,[1] the Directive on the protection of the environment through criminal law,[2] and the Directive on environmental liability.[3]

The Recommendation providing for minimum criteria for environmental inspections (RMCEI) outlines policies for planning and carrying out inspections, investigating irregularities, and reporting. However, ten years later, the horizontal approach of the RMCEI has proven to be insufficient and the focus is now on the introduction of specific inspection obligations into sectoral legislation.

This study considers the role of inspection and enforcement with respect to the implementation of the REACH[4] and CLP[5] Regulations. Together, these two acts provide a comprehensive system of chemicals-related controls. REACH encompasses every chemical substance, mixture or substance in articles manufactured or placed on the market in the EU, except for those specifically exempted. A significant innovation of REACH is its shifting of the burden of proof to industrial actors, to demonstrate that the substances they produce or place on the market are safe, rather than leaving it to national authorities to determine when they are not safe. Under REACH, enterprises must register the substances they manufacture or import, and provide a Chemical Safety Report (CSR) describing the health or environment hazards posed and the foreseen exposure scenarios. REACH also requires an authorisation for placing on the market substances of very high concern (SVHC), and places certain restrictions on the manufacturing, placing on the market and use of certain dangerous articles.

CLP imposes a comprehensive classification and labelling regime intended to implement the United Nations Globally Harmonised System of classification and labelling in the EU. CLP places the responsibility on manufacturers, importers and downstream users for classifying and labelling substances and mixtures according to any intrinsic hazardous properties, regardless of their REACH status. Under CLP, with certain exceptions, manufacturers or suppliers must classify and label any hazardous substance or mixture they manufacture or place on the market in the EU. Labels should indicate the physical, health and environmental hazards present, *inter alia* through warnings and pictograms.

[1] Recommendation of the European Parliament and of the Council of 4 April 2001 providing for minimum criteria for environmental inspections in the Member States *Official Journal L 118,* 27.04.2001, p. 41 – 46.
[2] Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law, *Official Journal L 328,* 06.12.2008, p. 28 –37.
[3] Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage, *Official Journal L 143,* 30.04.2004, p. 56 – 75.
[4] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), *Official Journal L 396*, 30.12.2006, p. 1.
[5] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 *Official Journal L 353*, 31.12.2008, p. 1–1355.

The enforcement of the obligations of the two acts lies with the Member States. Both acts require the Member States to maintain 'a system of official controls' (Article 125 of REACH and Article 46(1) of CLP), and oblige them to report on enforcement (Article 127 of REACH and Article 46(2) of CLP). To ensure sufficient enforcement , Member States (particularly those with significant chemicals industries) have developed a range of approaches to the organisation of efficient and effective chemicals inspection systems. Indeed, because of the comprehensive nature of both REACH and CLP, a strong uniform enforcement throughout the EU is important, both to ensure compliance and to avoid interfering with the common market. An indispensable precondition for strong and uniform enforcement is a robust inspections regime.

The European Chemicals Agency's Forum for Exchange of Information on Enforcement (the Forum) is charged with coordinating REACH and CLP enforcement at the European level. The Forum has developed Strategies for enforcement of REACH and CLP,[6] as well as Minimum criteria for REACH and CLP inspections.[7] It has also undertaken projects to check compliance with REACH (REACH-EN-FORCE projects).

Objectives of the study

This project has four main objectives:

- to secure and strengthen proper implementation and enforcement of the REACH and CLP Regulations;
- to identify criteria and enforcement strategy for Member States (building on the work already performed by the Forum on enforcement) on how to effectively conduct REACH and CLP controls and inspections;
- to assess the potential benefits and options for further legislation on REACH and CLP inspections at EU level; and
- to assess whether the current requirements of the REACH and CLP Regulations could potentially be reinforced and how.

1.2. Methodology of the study

The methodology of this study relied on four main tasks.

Task 1: Compilation and assessment of relevant information

Firstly, under this task, Milieu has identified enforceable Articles under REACH and CLP. Secondly, Milieu has assessed criteria for controls and inspections in existing EU instruments regulating health and environmental risks. The assessment focuses on factors such as location of responsibility for inspection, proactive versus reactive inspection, risk analysis, scheduled versus surprise inspections, frequency, reporting and recording, and EU-level oversight. Thirdly, the work already performed by the Forum on enforcement has been reviewed.[8] The main starting point of the review is the document on REACH and CLP Minimum Criteria. In addition, the enforcement strategies for REACH and CLP and the reports of REACH-EN-FORCE have received particularly close scrutiny. Fourthly, six Member States (Bulgaria, France, Germany, Slovenia, Sweden and United Kingdom) have been selected in order to assess specific examples of enforcement and inspections practices at national level. These elements are reflected in Sections 1 to 3 of this Report.

[6] Strategies for enforcement of Regulation (EC) no. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and of Regulation (EC) no. 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP) (latest version adopted at the 9th meeting of the Forum on 1-3 March 2011).

[7] Minimum Criteria for REACH and CLP Inspections 1 March 2011, First version adopted at the 6th meeting of the Forum on 8/10 December 2010.

[8] The relevant documents have been provided by the Forum.

Tasks 2 and 3: Identification of specific criteria for REACH/CLP inspections and elaboration of a strategy for inspections

The two following tasks were carried out in parallel:

- the establishment of a list of criteria for inspections
- the preparation of a strategy for inspections.

The analysis of the criteria was based on the documents assessed under Task 1. In parallel, a strategy was prepared and was submitted to the Forum for comments. The results of this task are reflected in Section 4 and Annex I to this Report.

Task 4: Options & benefits of new legislative requirements

Task 4 involved three different steps:

- the development of new legislative requirements,
- the assessment of the benefits of the various legislative options identified.
- the analysis of the potential role of the Commission.

The legislative options and the assessment of their impact can be found in Section 5 of the Report. Section 6 provides different scenarios regarding the role of the Commission in terms of monitoring and supervision of REACH and CLP inspections, while Section 7 provides a number of conclusions.

1.3. The priority REACH and CLP legal requirements

Enforcement of the REACH and CLP requirements should ideally focus on those requirements that are the most fundamental for ensuring adequate control of risks to human health and the environment. Identification of these priority requirements is crucial in order to ensure that the efforts of national enforcement authorities are concentrated on those aspects where maximum results can be achieved.

The basic components of the REACH regime are:

- **Registration** with the European Chemical Agency (ECHA) of all substances manufactured or imported into the EU in quantities of one or more T/yr per manufacturer/importer
- **Evaluation** of registration dossiers (by ECHA) and substances (by Member States)
- **Authorisation** of uses for substances of very high concern (SVHC)
- **Restrictions** on the marketing and use of substances where the risks to human health and the environment are considered unacceptable

REACH places a wide range of duties on manufacturers, importers, suppliers and downstream users in order to implement this Regulation.

CLP similarly places duties on manufacturers, importers and downstream users **to classify, label and package substances and mixtures** according to any intrinsic hazardous properties that have been identified, before they are placed on the market. The information on classification must be passed down the supply chain so that downstream users receive correct hazard information about the substances and mixtures they use.

Milieu prepared a list of enforceable Articles setting forth the components of the REACH and CLP regimes, and then selected those Articles considered particularly important in terms of the obligations they impose on the duty holders. For the purpose of setting priorities for enforcement, these are

grouped according to the scheme used in the Forum's "Strategies for enforcement" document, which divides the basic duties under REACH into three general areas:[9]

1. Registration related duties
2. Supply chain related duties
3. Use related duties

With respect to CLP, the basic obligation of classification is considered as part of the section on REACH registration related duties, together with the obligation on manufacturers and importers to notify the classification to ECHA under certain circumstances.[10] The CLP requirements to label and package substances and mixtures according to hazards are discussed as part of the section on supply-chain related duties.

The list providing the references and a summary of the obligations applicable under REACH and CLP is provided in Annex II to this report.

1.3.1. Registration-related duties

Registration, evaluation and authorisation under REACH

Registration is one of the pillars of REACH and fundamental to its "no data, no market" rule. Registration requires the active involvement of manufacturers and importers, who are to provide basic information on the substances they produce or import. Correct implementation is essential for ensuring that health and safety information for the substances put on the market is sufficient to ensure a safe use of the substance.

Title II presents the requirements regarding registration of substances. The main obligation here is provided by Article 5, which sets the "no data, no market" rule. Articles 6 and 7 requiring registration are directly related to this Article. Articles 17 and 18 on the other hand provide for the obligation to register for isolated intermediates. It may be argued that since those provisions are the direct consequence of Article 5, they do not have to be enforced on their own. At the same time, one may consider that Article 5 and the other articles may be enforced separately, as the breach of these obligations would result in two slightly different offences, one being the placing on the market without registration, the other being the absence of registration as such.

Articles 10 to 12, 14, 17, 22 and 24 indicate the detailed information to be provided for registration. Their enforcement ensures that the data produced are complete, accurate and up to date, and therefore these provisions are also priorities for enforcement.

Other Articles in Title II are enforceable but not necessarily priorities for enforcement. These include requirements on fees since they are, as a matter of fact, self-enforcing. So is Article 20(2) (procedure in case of incomplete dossier for registration) and Article 9(2) (submission of relevant information when seeking to rely on exemption for PPORD).

For a few Articles, enforcement implies an exchange of information between ECHA and the Member States competent authorities and/or the national enforcement authorities, as only the Agency will be able to inform the authorities and the enforcers as to the data provided to them by the companies, and whether there is a problem with them (e.g. conditions imposed by ECHA, as in Article 9(4), joint submission, as in Article 11 or 19, limitation of testing as in Article 13). The ECHA will receive this information directly. Nonetheless, the role of the national authorities remains important.

[9] This grouping has also been used in the UK government's strategy for enforcement of REACH.

[10] Note that the Forum's "Strategies for enforcement" document divides the enforceable CLP requirements into two general areas: notification related duties (on manufacturers and importers) and supply chain related duties (applicable to all target groups).

Articles 21.1 and 21.2 were not identified as priorities in the Forum Strategies for enforcement. However, now that the first registration deadline has passed and ECHA has completed its completeness checks, it is timely to check on whether substances have made it through the registration hurdle.

Title III presents the requirements regarding data sharing and avoidance of unnecessary testing. None of the requirements under Title III were classified by the Forum as priority for enforcement, and Milieu concurs that none of the enforceable articles are priorities at this time.

Title VI covers the requirements on evaluation. Articles 40(4), 41(4) and 46(2) have been identified as a priority for enforcement. These articles require the submission of information for ECHA. Here also enforcement requires an exchange of information between ECHA and the Member States enforcement authorities/Member States competent authorities, and thus these Articles may be enforced only at the request of ECHA.

Inspections monitoring compliance with registration requirements may also includ monitoring for compliance with the Title VII requirements concerning authorisation of substances of very high concern (SVHC).

Classification under CLP

When developing the Chemical Safety Assessment (CSA), the classification and labelling developed in accordance with CLP should be presented and justified. CLP requires manufacturers, importers and downstream users to classify, label and package substances and mixtures according to any intrinsic hazards before they are placed on the market and to pass classification information down the supply chain so that downstream users receive correct hazard information about the substances and mixtures they use. Priority provisions setting the classification obligations are listed in Annex II, Table 3.

1.3.2. Supply-chain related duties

Information in the supply chain, authorisation and restrictions under REACH

Another pillar of REACH is the principle of communication between the actors of the supply chain. It is crucial to ensure that any person who will at one point use the substance or mixture knows all information regarding the substance or mixture and its risks. The main instrument of communication in the supply chain is the safety data sheet (SDS) presented in Article 31 of the Regulation. As noted in the Forum's "Strategies for enforcement" document,[11] the SDS is a well-known document for enforcement authorities, and they are well-experienced at controlling it.

However, under REACH, inspectors will have to take into account new elements, including exposure scenarios annexed to safety data sheets, along with information requirements when a safety data sheet is not needed, information about SVHC in articles, and requirements to pass information back up the supply chain in certain circumstances.

Besides Article 31 on the requirements for SDS, all articles ensuring that the relevant actors will be provided with the relevant information on substance or mixtures are considered as priorities for enforcement, be it between actors of the supply chain (Articles 32(1), 33, and 34) or for workers (Article 35).

[11] "Strategies for enforcement", p.19.

In addition to the Title IV duties, the actors in the supply chain are also obliged to comply with the Title VII requirements concerning authorisation of substances of very high concern (SVHC) placed on the authorisation list and the Title VIII requirements on restrictions. The provisions on authorisation and restrictions are particularly important for enforcement so as to ensure that the placing on the market of the substances posing the greatest risks will be strictly regulated, and that those potentially exposed to the substances will be particularly protected.

This control over the use of the most dangerous substances is crucial, and in that respect should be enforced by the enforcement authorities. Article 56 provides for the obligation of authorisation as such for the use of SVHC. Article 60(10) is aimed at limiting exposure to SVHC. Articles 61 to 65 require the submission of information. Article 65 is particularly important for enforcement as it ensures a direct protection of the user of the substance.

Labelling & packaging under CLP

As noted above, CLP requires that classification information be transmitted down the supply chain so that downstream users receive correct hazard information about the substances and mixtures they use. The label and the SDS are the means for communicating this information. Table 6 of Annex II lists the priority provisions on labelling, including in advertisements. It also notes the specific safety requirements set in CLP for packages containing hazardous substances or mixtures.

1.3.3. Use-related duties

To ensure an efficient protection of health and the environment while enabling the free movement of substances, on their own, in mixtures and in articles, and enhancing competitiveness and innovation at all stages of use of the substance, REACH implies an involvement not only of manufacturers and importers, but also of downstream users.

Article 37, together with Article 38(1) and 39, requires downstream users to identify, apply and recommend risk reduction measures and to report information within a certain period of time. These obligations have been designated as 'the most important of all articles for enforcing authorities' by the Forum,[12] and the incorrect use of a substance should systematically result in the authorities taking measures to remedy the situation.

In addition to the key Title V requirements, the Title VII authorisation requirements also apply to users of substances and mixtures. Article 55, while describing the aim of authorisation as the effective functioning of the internal market together with the control of SVHC, requires a consideration of substitution for the SVHC for which uses are subject to authorisation. Article 56 prohibits the use of a SVHC unless that use is in accordance with the conditions of an authorisation. Article 60(8) requires that the conditions linked to the authorisation be respected.

The Title VIII requirements on restrictions are particular use-related duties, and important priorities for inspections monitoring the compliance of downstream users.

Finally, Article 66(1) imposes on the downstream user an obligation of notification to ECHA after the first supply. ECHA has to keep a register of these notifications, which is accessible by Member State competent authorities. This will allow the national enforcement authorities to check whether the conditions of authorisation are respected at the end of the chain.

[12] Ibid., p.21.

Specific use-related requirements under CLP

Mixtures prepared by downstream users are also required to be classified and labelled according to any hazard properties. CLP provides that downstream users may use the hazard classification of a substance or mixture derived by an actor in the supply chain, if they do not change the composition of the substance or mixture.

1.4. The Forum's work on inspections to date

The harmonisation of enforcement amongst Member States was a key issue during the development of REACH. The REACH preamble stresses the importance of strengthening enforcement, and indicates that '*the Agency should provide a Forum for Member States to exchange information on and to coordinate their activities related to the enforcement of chemicals legislation. The currently informal cooperation between Member States in this respect would benefit from a more formal framework*'.[13] This led to the introduction of the Forum. REACH provides for the establishment of the Forum to coordinate a network of Member State authorities responsible for the Regulation's enforcement.[14] CLP also states that the Forum is responsible for the enforcement of CLP.[15] For both acts, the Forum is entrusted to develop enforcement, amongst others, by proposing, coordinating and evaluating harmonised enforcement projects and joint inspections, coordinating exchange of inspectors, identifying enforcement strategies, as well as best practice in enforcement and, finally, developing working methods and tools of use to local inspectors.

The Forum has developed several documents illustrating its approach of enforcement, and more particularly regarding inspections. The main ones are:

- the Strategies for enforcement of REACH and CLP
- the Minimum Criteria for REACH and CLP Inspections
- the REACH-EN-FORCE-1 related documents.

Strategies for enforcement of REACH and CLP

In December 2008, the Forum adopted a paper on REACH Enforcement Strategies. It was amended in March 2011 to cover also CLP. This document aims at providing a general framework for the elaboration of enforcement strategies by Member States authorities in order to ensure a minimum level of consistency and compatibility between the different national strategies. According to this paper, an effective enforcement strategy for REACH and CLP must: (a) have clear policy objectives and priorities; (b) have the necessary organization to achieve efficient, transparent and systematic enforcement of the Regulation; (c) actually perform the enforcement measures; (d) develop and implement procedures for periodic progress monitoring and measurement; (e) develop and implement procedures for review, evaluation and update of the enforcement strategies.[16]

The paper indicates how to define the priorities for enforcement via a risk analysis. The risk should be assessed by looking at a) the target groups, b) the legal obligations and duties to fulfil, and c) the effect of non-compliance (i.e., an estimation of the consequences of non-compliance for human health and the environment). The results of the analysis should then be coupled with an assessment of the expected compliance behaviour of the target groups identified, to define priorities for enforcement. Even though this method is set for general enforcement of REACH and CLP, it can more particularly be used to target inspections.

[13] Recital 105 of REACH.
[14] Article 76(1)(f) of REACH.
[15] Article 46(3) of REACH.
[16] 'Strategies for enforcement' p. 5-7.

According to the REACH and CLP Enforcement Strategies, once enforcement priorities are set, the enforcing authorities of Member States should adopt enforcement measures.[17] Enforcement programs should comprise of compliance promotion activities complemented with appropriate, proactive and reactive, compliance monitoring (*inspections* and *investigations*).[18] The REACH Enforcement Strategies provide that enforcement decisions should be taken on a case-by-case basis and that they should be guided by the legal requirements and the enforcing authority's policy and procedures. The paper lists a number of factors that could be taken into consideration when deciding what kind of action should be enforced:[19]

- the hazards presented by the substance in question and the risks resulting from the activities under consideration;
- the tonnage of the substance being manufactured, imported, supplied or used;
- the level of actual harm to human health or the environment which has arisen as a consequence of the contravention;
- the extent of the contravention, i.e. how far away from the required standards the duty holder is judged to be;
- where a contravention is shown to be due (in part or in full) to the acts or omissions of another person, whether the duty holder took all reasonable precautions and exercised all due diligence to avoid the contravention;
- the size of the duty holder and its position and influence in the supply chain;
- the inspection history of the duty holder, including whether they have received previous relevant advice;
- the intention of the duty holder in non-compliance, e.g. whether non compliance is deliberate in order to gain commercial advantage;
- the standard of general conditions and the attitude of the duty holder.

The REACH and CLP Enforcement Strategies stress the importance of ensuring a level playing field for the industries of the different countries and a high level of protection for both humans and the environment. They note that the setting of clear objectives and priorities for enforcement plays a key role in the proper implementation of the two acts.

The establishment of priorities and a strategic approach of the targeting of duty holders for inspections are crucial elements of an effective strategy. The lists of elements to take into account for prioritisation , when brought together, provide a good overview of the factors for setting priorities for inspections. In addition, the strategies emphasise the importance of collaboration between authorities in the Member States for the enforcement of REACH and CLP, as different areas are covered by REACH and CLP and different enforcement authorities are likely to be involved.

Both the criteria listed for setting priorities and deciding on enforcement and the cooperation between enforcement authorities show that these strategies have been developed with a focus on compliance with REACH and CLP as is the Forum's purpose. However, other possibilities for enhancing the links between the enforcement of REACH and CLP, and other related EU legal acts could add value, e.g. the link to enforcement of occupational health and safety legislation.

[17] *Ibid*, p. 10.
[18] *Ibid*, p. 11.
[19] *Ibid*, p. 12.

Minimum Criteria for REACH and CLP Inspections

The Forum mandated in December 2008 a Working Group to develop minimum criteria for REACH inspections to ensure the level playing field within the internal market and the better coordination of REACH enforcement within Member States and EEA – EFTA States. In December 2009 the Forum published the Minimum Criteria for REACH Inspections ("REACH Minimum Criteria"). In March 2011, a new version including CLP was adopted ("Minimum Criteria for REACH and CLP Inspections").

The document, which is to be applied alongside the enforcement strategies mentioned above,[20] stresses the importance of inspections in the overall enforcement of REACH and CLP. It points out that, given the competence of Member States in the area of enforcement, their strategies adopted for inspections, and their systems and practices of inspections will vary from one Member State to another. The document intends nevertheless to "establish guidelines, in the form of minimum criteria, to be applied as a common basis for the performance of REACH and CLP inspections activities within the Member States and EEA-EFTA States".[21]

The Forum used as a working basis for this document the Recommendation providing for minimum criteria for environmental inspections (RMCEI) developed by IMPEL, and followed more or less the same structure. However, it also considered that, even though the criteria set under the RMCEI provide a "*useful foundation upon which a structured system for REACH and CLP inspections can be created*", these are not directly applicable to REACH and CLP as RMCEI fails to take human health into account.[22] It should be noted that the Forum, as well as the Commission, consider that the REACH and CLP Minimum Criteria operate within the framework of the Market Surveillance Regulation.[23]

The document defines "REACH and CLP inspections" as the "range of activities an enforcing authority may undertake in order to assess, secure or promote a duty holder's compliance with REACH and/or CLP. Such activities may be routine (proactive) or non-routine (reactive), and include inspection, investigation, monitoring, formal enforcement and other measures [...].[24] As such, the term "inspection" refers to the *proactive* process during which the enforcement authority collects information to assess the duty holder's current level of compliance by comparing their activities to the legal requirements and benchmark standards relevant to the activities in question;[25] on the contrary, the term "investigation" refers to the *reactive* process that follows a specific event (accident, incident, complaint, referral from another enforcing authority or an identified non-compliance). The terminology differs from that provided in the RMCEI, as the RMCEI defines 'inspection' as covering both routine and non-routine activities, and does not distinguish investigation from inspection. In that view, it would be useful to provide an harmonised definition of the term 'inspection'.

The REACH and CLP Minimum Criteria further provide national enforcement authorities with guiding principles to be observed when exercising their powers; as such, REACH should be effectively enforced but in a way that minimizes the burden of checking compliance for both duty holders and for enforcing authorities.[26] In addition, it is essential that comprehensive risk assessment is undertaken to ensure that enforcing authorities concentrate their resources to the areas of greatest

[20] REACH Minimum Criteria, recitals vii, ix.
[21] Minimum Criteria for REACH and CLP Inspections, ECHA Forum for Exchange of Information on Enforcement, December 2009 , recital v.
[22] Minimum Criteria for REACH and CLP Inspections, ECHA Forum for Exchange of Information on Enforcement, December 2009, recital viii.
[23] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance.
[24] *Ibid*, article 2(c).
[25] *Ibid*, article 2(c)(i).
[26] *Ibid*, article 3(2)(b).

need.[27] Again here, optimisation could be achieved through a more holistic approach of enforcement of REACH and CLP and other related acts.

The Minimum Criteria provided in this document aim not only at targeting inspections, but also cover other elements to ensure the effectiveness of inspections. Four different elements of inspections are covered: the organisation, the planning, the implementation (including the actual inspections and the follow-up), and the review of the arrangements for strategy.

With regard to organisation, enforcing authorities are encouraged to cooperate with other enforcing authorities both within and outside their national territory.[28]The Forum also suggests the establishment of formal arrangements between national authorities to optimise the articulation of the different enforcing authorities implied in inspections. It also states that sufficient resources should be made available for inspections and that inspectors should be trained and have the appropriate qualifications and powers for enforcement.

Planning is the most important step regarding the proper targeting of inspections. National enforcing authorities should ensure that their REACH and CLP inspection activities are planned in advance and take into consideration all the territory of the Member States and of the known target groups. The Forum suggests the adoption of plan(s) for inspections under REACH and CLP following the strategies adopted at national level. The plan(s) should be produced on the basis of:

a) the enforcing authorities' objectives and targets, their overall statutory responsibilities and competencies, and the provisions of REACH and/or CLP they are responsible for enforcing;

b) the known duty holders / target groups within the area(s) covered by the plan;

c) the resources available to the enforcing authorities;

d) a general analysis of major public, occupational health and environmental risks within the area(s) covered by the plan, taking into account the hazards arising from the activities of the duty holders / target groups, the likelihood of the hazards occurring, and the vulnerability of those who could be affected by those activities (workers, the general public, the environment);

e) a general appraisal of the likelihood of non-compliance by the duty holders / target groups with REACH and/or CLP requirements, taking into account factors such as previous inspection records and potential future risks.

The plan(s) should take into account the resources available for inspections, the number and size of duty holders and the information available, and should set priorities to ensure effectiveness in terms of compliance.

The document also lists the criteria that the Forum considers should be applied when carrying out inspections. Inspectors should ensure that once the role of a duty holder is identified, the check of compliance corresponds to this role and to the scope of inspections. For site visits carried out by more than one enforcing authority, they should exchange information and co-ordinate visits. The essential requirements of REACH and CLP, as prioritised in the national REACH and CLP enforcement strategies, relevant for the given duty holder / target group should be taken into account, and the risks to, and impact on, human health and the environment should be considered. Complaints made by third parties should be investigated as soon as possible and serious accidents or incidents should be investigated without undue delay.

The document emphasises the importance for inspectors to promote the knowledge and understanding of duty holders, while ensuring compliance by formal enforcement where appropriate.

[27] *Ibid*, article 3(2)(c).
[28] *Ibid*, article 5(1)

The findings of inspections should be contained in reports, and enforcing authorities should preserve confidentiality of commercial secrets and personal data, while ensuring the dissemination of information to relevant enforcing authorities and to the public.[29] The document also refers to the application of the AMS Regulation[30] if products identified during REACH and/or CLP inspection activities present a serious risk requiring rapid intervention, or if hazards are identified related to any product, or in case of recall or withdrawal of products, or prohibitions on making products available on the market.

The document also refers to the follow-up of inspections, and the content of the inspections reports. It requires appropriate checks to be made to ascertain that a duty holder has taken action in answer to an inspection if asked to do so.

Finally the document asks for the enforcing authorities to check regularly, and review as necessary, their arrangements for the organisation, planning and carrying out of REACH and CLP inspections.

The Minimum Criteria are based on the Strategies for enforcement of REACH and CLP and further develop the elements relevant for inspections. The two documents, read in conjunction, provide a good basis for planning and carrying out inspections in order to enforce the two regulations. They present a broad scope of criteria to be taken into account for inspections. However, as the two documents only aim at providing a framework to be further developed by Member States authorities according to their national specificities, the elements provided remain quite general, and could be completed with more concrete, practical and detailed measures regarding both procedural rules for the organisation and the course of inspections.

REACH-EN-FORCE-1 project's results

In August 2010, the Forum published the Project Report of the REACH-EN-FORCE-1[31] containing the results of inspections that had taken place in 1,600 companies in 25 Member States of the EEA in the period May-December 2009.[32] The goal of the project was to verify the compliance of manufacturers and importers of substances with REACH obligations on the (pre)registration and Safety Data Sheets (SDSs).[33] Non-compliance with REACH obligations was observed in 24% (378) of the inspected companies with the majority of such cases concerning SDS provisions (293).[34] Apart from the statistical data, it was concluded that the execution of such projects contributes to the harmonization of REACH enforcement as well as further harmonization of the national enforcement and sanction strategies in REACH enforcement between Member States.[35] These findings demonstrate the utility of inspections, and the potential benefits of comprehensive and coordinated inspection regimes.

[29] *Ibid*, point 7.
[30] Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (hereinafter AMS Regulation)
[31] REACH-EN-FORCE-1, Results of the Forum coordinated REACH enforcement project on registration, pre-registration and safety data sheets, August 2010 (REACH-EN-FORCE-1).
[32] *Ibid*, p.1.
[33] *Ibid*, p. 3.
[34] *Ibid*, p.2 and 6.
[35] *Ibid*, p.8.

2. Criteria for enforcement in other EU legislation

While the Member States are responsible for ensuring that the obligations set forth in EU law are implemented and enforced within their territories, a number of EU-level instruments set specific requirements concerning how enforcement is to be carried out on the national level. This section reviews and assesses the legal requirements and criteria relating to national-level inspections found in other EU legislation. It first reviews the provisions relevant for inspections found in other EU environmental legislation. It then considers provisions on inspections found in the legislation covering other sectors. A list of the EU acts analysed for this study with the corresponding provisions relevant for inspections is provided in Annex III to this Report.

2.1. Environmental legislation

DG Environment has taken a number of actions to improve implementation of the EU environmental requirements. Regarding the implementation of EU environmental law and policy, the Communication from the Commission on the Commission Work Programme for 2011 lists the strengthening of effectiveness of inspections as one of the main issues to be addressed.[36]

RMCEI

The Recommendation providing for minimum criteria for environmental inspections[37] provides a framework for common elements of inspections in the area of environment. The RMCEI outlines policies for planning and carrying out inspections, investigating irregularities, and reporting. As has been mentioned earlier, the elements provided by the RMCEI do not cover the health-related obligations that are also provided under REACH and CLP, and its application for these two acts would therefore not ensure that all aspects are taken into account. However, the criteria set in this document provide a basis for inspections under REACH and CLP, and were used as a working basis for the document on Minimum criteria for REACH and CLP prepared by the Forum.

Such criteria include elements regarding:

1. The planning:
   - The preparation of plans for inspections at national, regional or local levels, based on the EU legal requirements to be enforced, a register of controlled installations, a general assessment of major environmental issues and data regarding previous inspections.
   - The plans should correspond to the inspections tasks of the relevant authorities and take into account relevant information in relation to specific sites or types of controlled installations.
   - Each plan should indicate a geographical area of coverage, a defined time period, provisions for revision. It should list specific sites or types of controlled installations. It should prescribe the programmes for routine inspections based on risks to the environment (including frequency), and procedures for non-routine inspections. It should also provide for coordination between inspecting authorities.

2. Site visits (routine and non-routine):
   - Compliance with EU requirements should be checked.
   - Information is exchanged among inspecting authorities.

[36] Annexes to the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Commission Work Programme 2011 (COM(2010) 623 final VOL. II).

[37] Recommendation of the European Parliament and of the Council of 4 April 2001 providing for minimum criteria for environmental inspections in the Member States *Official Journal L 118, 27/04/2001 P. 0041 – 0046.*

- Findings of inspections are reported, and exchanged among authorities within the country as needed.
- Inspectors are empowered to access information and premises.
- All environmental impacts are looked at.
- The accent is placed on the promotion of knowledge and understanding of their legal obligations under EU law for the operators.
- Non-routine sites visits should be carried out following serious environmental complaints, serious environmental accidents, incidents and occurrences of non-compliance, and when issuing first authorisations, permits and licences, and when these are reissued, renewed or modified.

3. Reports and conclusions following site visits:
- After each site visit, the inspection data, the findings, an evaluation and conclusions are processed or stored.
- These should be recorded and maintained accessible, and at least the conclusions should be provided to the inspected operator. The reports should be made publicly available after two months.

In addition, serious accidents, incidents or occurrences of non compliance should be investigated to clarify the causes and responsibilities, mitigate or remedy the environmental impacts, determine the action to be taken as well as potential sanctions or enforcement measures. The follow-up by the operator should be ensured.

Other EU environmental acts

In addition to the criteria to be found in the RMCEI, other indications related to the criteria have been developed in other EU environmental acts. In particular, some criteria which have been defined in these acts might be of use in the context of inspections for the enforcement of REACH and CLP.

The **qualifications and the powers of inspectors** are criteria that have not been much developed in the legislation due to the different practices of enforcement of the Member States. The powers of inspectors are mentioned in the RMCEI, which indicates that inspectors shall have the legal right of access to sites and information. This element also appears to some extent in the most recent texts, such as Directive 2010/75/EU on industrial emissions and the Proposal for a new Seveso Directive, which both state that the operators should afford competent authorities all necessary assistance.[38] This provides the basis for sanctions in case the operator does not cooperate with inspectors. This is an important aspect to ensure the effectiveness of inspections. The Proposal for Seveso III also mentions that sufficient staff with the skills and qualifications needed should be provided for inspections,[39] and that the exchange of experience should be encouraged, including at EU level. These elements are particularly relevant for the enforcement of acts like REACH and CLP which entail a lot of obligations to be checked by inspectors, and which are of a very technical nature.

The **frequency of inspections** is an element that has been developed in almost all acts mentioning inspections that have been analysed for this study. Most acts refer to an annual inspection. However, some acts set a frequency based on a risk analysis. Directive 2010/75/EU and the Proposal for SEVESO III require an inspection every year for the most dangerous installations and every three years for the less dangerous ones. Directive 2010/63/EU on animal testing also bases the frequency of inspections on risk analysis. The Directive sets a target of one third of users inspected each year, with the exception of breeders of non-human primates, to be controlled once a year. It also requires an 'appropriate proportion' of inspections without prior warning. There is currently no such frequency set

[38] This is also provided in the other harmonised areas via the application of the AMS Regulation, whose aim is to cover any lacuna in EU/national law in harmonised areas.
[39] Idem

in REACH or CLP. Given the large number of potential targets for inspections, a periodicity of inspections based on risk would seem to be the most appropriate.

Another element that might be of relevance for REACH and CLP inspections is the **role given to the EU in overseeing inspections** carried out at national level. Besides the implementation reports to be submitted to the Commission by national authorities, other mechanisms implying a bigger involvement of the Commission in inspections have been adopted under some acts. Three levels of implication of the Commission are presented here:

- Under Directive 2002/96/EC (WEEE), the results of inspections on treatment are communicated to the Commission. This ensures a proper level of exchange of information and a close monitoring of the actual implementation of this requirement of the Directive by the Commission. Given the enforcement structure of the REACH and CLP Regulations at EU level, an equivalent system for these two acts would imply that the communication would be made to ECHA.

- Under Directive 2010/63/EU (animal testing), a system of control of Member States inspections by the Commission has been put in place. According to this, the Commission can undertake controls of the infrastructure and operation of national inspections in case of concern. Member States shall provide all necessary assistance to the Commission, and once the report has been communicated to them, shall take the measures needed to take account of the results of the control. As inspection is the key for enforcement of REACH and CLP, this kind of system would ensure that the inspections mechanisms are appropriate for the purpose of the proper application of these acts.

- Under Regulation No.1005/2009 (ODS), the Commission may ask CA to conduct investigations, and provides its assistance to the CA in carrying out these investigations. The Commission is also entitled to all information necessary for the exercise of its role, including from undertakings. If the Commission asks information to undertakings, it should however inform the CA thereof. This system gives a very active role to the Commission in enforcement itself, along national authorities.

Another element that could present an interest in the context of the enforcement of REACH and CLP is the possibility given in the ODS Regulation for one Member State to ask another Member State to carry out inspections or investigations on undertakings suspected of being engaged in the illegal movement of controlled substances. For REACH and CLP, this system might be useful in case of companies with activities in several Member States, or if the inspection has revealed a possible infringement of another actor in the supply chain based in another EU Member State.[40]

The table on the next page provides an overview of criteria for environmental inspections provided in selected EU law. The last column indicates the relevance of the criteria identified in each act for inspections in the context of REACH and CLP.

[40] Please note however that the Forum has put into place RIPE, via which inspections can have access to the contact details of inspectors in the other Member States. In the future, inspectors will also be able to communicate via EIES.

Table 10 Overview of criteria for environmental inspections

EU ACTS	*Planning*		*Actual Inspection*				*Follow-up*		RELEVANCE FOR REACH AND CLP
	Inspection plan(s)	**Risk based**	**Routine/non-routine**	**Scheduled/ unscheduled**	**Inspectors**	**Frequency**	**Follow-up**	**EU-oversight**	
Directive 2010/75/EU (Industrial emissions)	Yes (art.23.2)	Yes (art. 23.4)	Both (art. 23.4 and 23.5)	Both (art. 23.4 and 23.5)	Operators should afford CA all necessary assistance for site visits, taking samples and gathering information (art.23)	Based on risk level, every year to every three years , Six months after observing non-compliance (Art. 23.4)	Yes (art.23.6) (report + follow-up)	--	The criteria correspond to those in the RMCEI. Their emphasis on risk-based planning and frequency of inspection, and on follow-up to inspection are relevant to REACH & CLP.
Directive 96/82/EC (SEVESO II)	Yes (programme for each establishment) (art.18.2)		Routine	--	--	At least once a year (Article 18(2)(a))	Yes (art. 18.2(c)) (report + follow-up)	--	The safety report and follow-up will provide information useful for REACH & CLP inspections, such as identify of substances on site.
Proposal SEVESO III	Yes (inspection plan) (art.19.3) + programmes	Yes (art.19.3)	Both (art.19.4 and 19.6)		Sufficient staff with the skills and qualifications needed. Exchange of experience encouraged (incl. at EU level). Operators should afford CA all necessary assistance.	One year for the upper tier and three year for the lower tier Six months after observing non-compliance (art. 19.4)	Yes (art.19.7) (report + follow-up)	--	Aligned with the criteria in the RMCEI and the Industrial Emissions Directive. Particularly relevant for REACH & CLP is the emphasis on the qualifications of inspectors.
Directive 2010/63/EU (Animal testing)	--	Yes (art.34)	Both (art. 34.4)	Appropriate proportion without prior notice	--	Based on risk analysis (art. 34.2) 1/3of users		Yes (art.35.1)	Empowers the Commission to undertake direct controls of the infrastructure and operation of national

EU ACTS	*Planning*		*Actual Inspection*				*Follow-up*		RELEVANCE FOR REACH AND CLP
	Inspection plan(s)	**Risk based**	**Routine/non-routine**	**Scheduled/ unscheduled**	**Inspectors**	**Frequency**	**Follow-up**	**EU-oversight**	
						each year + once a year for testing on non-human primates			inspections in a MS when there is due reason for concern. Could be relevant for REACH & CLP if a MS systematically failed to intervene in cases of non-compliance.
Reg. No. 1013/2006 (Shipments of Waste)	--	--	Both (art. 50.2 -inspections - establishments - and spot checks -waste)	--		--	--	Yes (implementation report- art. 51)	Lists specific physical elements to be checked during inspections, incl. documents & confirmation of identity of the waste. Due to its subject, refers to cross-border cooperation.
Directive 2008/98/EC on Waste	--	--	--	--	--	Periodic inspections (art. 34.1)	--	Yes (implementation report- art. 37)	Lists the elements to be inspected (origin, nature, quantity & destination of the waste)
Directive 2002/96/EC on WEEE and Proposal for recast of WEEE	--	--	--	--	--	At least once a year for treatment (art.6)	--	Yes (results of inspections communicated to Member State and the Commission)	Refers to the RMCEI in Recital (23). Sets minimum monitoring requirements; provides that additional rules on inspections and monitoring can be adopted via comitology.
Directive 2006/21/EC (waste from extractive industry)	--	--	--	--	--	Prior to commencement of operations and regularly afterwards (Article 17(1))	--	--	Provides for the adoption of technical guidelines for inspections via comitology. Could be useful in case of REACH & CLP where inspection can cover highly technical issues.
Directive 1999/31/EC (landfill of waste)	--	--	--	--	--	Regularly (Article 11(2))	--	Yes (11(2))	
Reg.1005/2009 (ODS)	--	Yes (art. 28.1)	--	--	--	Related to the amount of the	--	Yes (art. 23.4 and 28.2)	COM can require theCA to carry out investigations which

EU ACTS	*Planning*		*Actual Inspection*				*Follow-up*		RELEVANCE FOR REACH AND CLP
	Inspection plan(s)	**Risk based**	**Routine/non-routine**	**Scheduled/ unscheduled**	**Inspectors**	**Frequency**	**Follow-up**	**EU-oversight**	
						controlled gas (art. 23.2)			COM considers necessary, & COM can assist the CA in these investigations. COM may obtain all necessary information from gvts, CA and undertakings, and a MS can ask another MS to conduct investigations. These powers could be useful in certain cases where REACH authorisations or restrictions needed special enforcement.
Directive 2009/31/EC (storage of carbon dioxide)	--	Non routine inter alia where the reports have shown insufficient compliance with the permit conditions	Yes (Article 15(1)) Routine inspection cover facilities and relevant effects from the storage complex on envt and health	--	--	At least once a year, Article 15(3))	Yes (report)	--	Inspections include: visits of installations, assessment of operations and checking of all relevant records.

2.2. Health and safety legislation

The occupational health and safety legislation places requirements on employers at the workplace. Their proper implementation can only be observed through inspections. However, the health and safety legislation itself does not contain very detailed indications about inspections.

The references to inspections in the EU occupational health and safety acts orientate mostly to the law applicable at national level. It relates to inspection by 'a competent person within the meaning of national laws and/or practices', which is distinct from 'competent authorities'. With regard to the inspection of work equipment (Directive 2009/104/EC), the competent person is in charge of an initial inspections of the safety of work equipment, and after this has been assembled, and thereafter, for periodic and special inspections. A 'competent person' is also mentioned for inspections under Directive 92/57/EEC on temporary or mobile construction sites. Directive 92/29/EEC on medical treatment on board vessels places the responsibility of annual inspections on 'a competent person or a competent authority'.

The Community Strategy 2007-2012 on health and safety at work[41] emphasises the importance of a proper implementation of the EU health and safety acquis. As part of that, it asks for an increased involvement of labour inspectors to promote compliance with the legislation through education, persuasion and encouragement, and when necessary coercive measures. It indicates that 'it is essential that national legislation transposing the Community acquis on health and safety at work be applied effectively and in a uniform manner in order to guarantee comparable levels of protection in all the Member States'. The strategy paper indicates that 'appropriate steps should be taken to enable [national] labour inspectorates to ensure that those concerned meet their obligations and are able to exercise their rights, including carrying out checks which result in the imposition of dissuasive and proportionate penalties and prosecution for failure to abide by health and safety rules'. The strategy also supports the work of the Senior Labour Inspectors' Committee (SLIC) at EU level 'with a view to improving the effectiveness of control and monitoring of the application of the legislation, facilitate cooperation between labour inspectorates and step up joint action with regard to specific sectors or risks.' The SLIC is *inter alia* invited to 'assess the impact of the REACH Regulation, to examine the role of labour inspectorates and develop synergies in cooperation with other inspection bodies responsible for market surveillance and environmental policy'.[42]

The SLIC has prepared in 2004 'Common Principles for Labour Inspection' throughout the EU. These principles were used in the evaluations of labour inspections arrangements of all EU-27 carried out by SLIC. The Common Principles include:

- The preparation of annual plans of work setting priorities and a programme and the setting up of systems of monitoring progress;
- The appropriate qualifications, training, competencies of inspectors, as well as their impartiality and independency, as well as the possibility for them to obtain assistance from specialists, and practical support (office, transport and other expenses covered);
- The prevention, protection and assistance for inspectors to ensure safe inspections;
- The requirements for inspectors to have the powers necessary to carry out their duties (entry into workplaces without notice, possibility to carry out inspections and investigations at the workplace, to require employers and employees to supply information, examination of relevant records and reports, application (directly or through another authority) of sanctions, possibility to require the immediate cessation of working activities in the case of serious risk).
- The existence of a guidance for inspectors for site visits

[41] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Improving quality and productivity at work: Community strategy 2007-2012 on health and safety at work {SEC(2007) 214} {SEC(2007) 215} {SEC(2007) 216}, 21.2.2007, COM(2007)0062 final.

[42] Idem, point 4.2, p.7

- The existence of good communications links (use of a suitable information system).

The Common Principles set four priorities for inspections. Firstly, they shall ensure compliance with EU law. Secondly, they shall aim at judging whether the employer's policy is directed to ensure the health and safety of the employees. Thirdly, they shall assess whether the organisation and arrangements (including hazard identification and risk assessment) of the employer are sufficient to address deficiencies. Fourthly, a particular assessment shall be made of the employer's arrangements for the effective organisation, implementation and monitoring of the protective and preventive measures adopted, for securing expert advice and assistance on health and safety matters; for dealing with emergencies and providing the employees and/or their representatives with comprehensible and relevant information; for training the employees in health and safety; and for ensuring consultation with the employees and/or their representatives on matters relevant to health and safety.

The Common Principles also indicate the actions to be taken by inspectors as a result of an inspection. The inspectors must decide on the action necessary and take the measures to secure compliance by the employer. They also have to ensure that employees are informed about the conclusions of the inspections. They should also liaise with other enforcing bodies as necessary. Finally, they have to make a written record of their decisions and actions (including core data, level of compliance with standards, hazards identified, advice given or enforcement action taken, assessment of the scope for improvement).

At a more general level, the Common Principles also lists developmental principles to take into account for the improvement of the worker protection. It indicates that Member States shall 'take action to:
(i) develop better understanding of the integrated, holistic approach, to encourage an open-minded culture in the labour inspectorate and make inspectors more aware of the role they can play in the promotion of well-being at work;
(ii) encourage the development of partnership working between the labour inspectorate and other stakeholders who can influence the well-being at work approach;
(iii) ensure that work plans and priorities take into account the changing economy, changing patterns of employment and their influence upon health and safety issues and priorities;
(iv) ensure that inspectors are suitably trained in the emerging issues, and that specialist support is aligned with the changing priorities and perspectives;
(v) develop systems for monitoring inspection processes, techniques and activities, which take into account international approaches to quality management.'

The European Agency for Safety and Health at Work issued in 2009 a Working Paper on 'Labour inspectorates' strategic planning on safety and health at work', which looks *inter alia* at the setting of inspections priorities by the national inspectorates of the EU Member States and EEA/EFTA countries.[43] It indicated that, based on the strategy and the SLIC Common principles, the Member States have developed priorities for inspections. Several of the national labour inspectorates use a system of risk classification or analysis to target enterprises for inspections. This includes:

- the existence of particular hazards (also based on information from previous inspections)
- the sector or size
- the existence or incidence of complaints or accidents.

The groups of workers concerned by the controlled activity and elements of management (risk assessment, safety data sheets, external health and safety services, safety committees) also play a role in setting priorities.

[43] Labour inspectorates' strategic planning on safety and health at work, European Risk Observatory Working Paper, European Agency for Safety and Health at Work, 2009, available at http://osha.europa.eu/en/publications/reports/TE-80-09-641-EN-N_labour_inspectorates.

The elements provided in the area of occupational health and safety are very close to the elements developed by the Forum in the Strategies (for instance with regard to the importance of cooperation between authorities and stakeholders, training of inspectors and monitoring of inspections) and in the Minimum Criteria (in particular for the elements to take into account for the targeting of inspections). Therefore, no additional criteria were listed based on the analysis of the occupational health and safety legislation.

2.2 Other legislation

Other pieces of EU law also provide criteria to take into account when targeting inspections.

The Market Surveillance Regulation
The Market Surveillance Regulation is of particular relevance here. It requires "appropriate checks on the characteristics of products."[44] It is based on principles and activities broadly similar to those that underpin RMCEI and the REACH Minimum Criteria, such as requiring documentation from undertakings, taking action based on complaints, testing, and observing confidentiality where necessary.[45] This act is particularly relevant in the context of REACH and CLP, as it concerns products placed on the market.

The Market Surveillance Regulation provides obligations for Member States regarding organisation. This includes:

- the establishment of appropriate communication and coordination mechanisms between their market surveillance authorities, and of adequate procedures for following up complaints or reports on issues relating to risks, for monitoring accidents and harm to health, for verifying that corrective action has been taken, and for following up scientific and technical knowledge concerning safety issues,
- the fact that market surveillance authorities have the sufficient powers, resources and knowledge for the proper performance of their tasks, and that they exercise their powers in accordance with the principle of proportionality,
- the establishment, implementation and regular updates of market surveillance programmes, to be communicated to other Member States and the Commission, and to be made publicly available,
- regular reviews and assessment of the functioning of the surveillance activities in the country (at least every fourth year), communicated to other Member States, the Commission and made publicly available.

It also gives more specific indications as to the measures to be undertaken for market surveillance, such as:

- appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks, or physical and laboratory checks on the basis of adequate samples, taking into account established principles of risk assessment, complaints and other information;
- the possibility to require economic operators to make documentation and information available as necessary, and, where it is necessary and justified, to enter premises and take the necessary samples of products. Inspectors shall also be entitled to destroy or otherwise render inoperable products presenting a serious risk;
- alerting users of hazards relating to any product so as to reduce the risk of injury or other damage;
- cooperation with economic operators regarding actions to prevent or reduce risks caused by products;

[44] AMS Regulation, article 19.1.
[45] AMS Regulation, article 19.

- in case of withdrawal in one Member State of a product manufactured in another Member State, informing the economic operator concerned;

The Regulation states that Market surveillance authorities shall carry out their duties independently, impartially and without bias, and shall observe confidentiality. The Regulation also requires that products which present a serious risk (based on risk assessment) are recalled, withdrawn or that their being made available on their market is prohibited, and that the Commission is informed without delay thereof.

Member States shall ensure that any measure taken to prohibit or restrict the product's being made available on the market, to withdraw it from the market or to recall it, is proportionate and states the exact grounds on which it is based. Such measures shall be communicated without delay to the relevant economic operator, which shall at the same time be informed of the remedies available. Member States shall ensure efficient cooperation and exchange of information between their market surveillance authorities and those of the other Member States and between their own authorities and the Commission. Cooperation between Member States involves assistance on an adequate scale by supplying information or documentation, by carrying out appropriate investigations or any other appropriate measure and by participating in investigations initiated in other Member States.

The Market Surveillance Regulation provides for the possibility to share resources and expertise between CA through initiatives set up by the Commission or the Member States concerned. In addition, the Commission must develop and organise training programmes and exchanges of national officials, and develop, organise and set up programmes for the exchange of experience, information and best practice, programmes and actions for common projects, information campaigns, joint visit programmes and the consequent sharing of resources. Member States shall ensure that their competent authorities participate fully in the above activities. The Regulation also foresees the possibility of cooperation with third countries.

Finally, the authorities of the Member States in charge of the control of products entering the EU market shall have the powers and resources necessary for the proper performance of their tasks. They shall carry out appropriate checks on the characteristics of products on an adequate scale before those products are released for free circulation. The Regulation also indicates that where, in a Member State, more than one authority is responsible for market surveillance or external border controls, those authorities shall cooperate with each other, by sharing information relevant to their functions and otherwise as appropriate.

As noted above, this act is particularly relevant in the context of REACH and CLP, as it concerns products placed on the market, whether substances, mixtures, or (substances in) articles. The Forum, as well as the Commission, considers that the REACH and CLP Minimum Criteria operate within the framework of the Market Surveillance Regulation.

Directive 95/21/EC on port State control

Directive 95/21/EC on port State control provides a detailed explanation of the procedure and the criteria applicable for inspections. It sets three different levels of inspections (inspections, more detailed inspections, expanded inspections). Inspections shall be carried out in priority on certain types of ships which constitute a greater risk of infringement (first entry in a port of a Member State, ships on which deficiencies have been observed during previous inspections, ships with reported deficiencies, etc.). More detailed inspections rely on additional grounds (report or notification by another Member State, report or complaint by a person with a legitimate interest, inaccuracies in documents revealed, etc). The Directive also lists the categories of ships subject to expanded inspection (oil tankers, bulk carriers older than 12 years, passenger ships, gas and chemical tankers).

This gradation of the level of detail of the inspections depending on the observation of certain risks allows for more targeted inspections, also with the identification of infringements with different degrees of seriousness. This is an option that might be considered for REACH and CLP inspections,

where the level of inspections would depend on the risks of non-compliance identified by the authorities.

In addition, this Directive provides for minimum criteria for inspectors (Annex VII). It states that the inspector must be authorized to carry out port-State control. The inspector must either have a certain level of experience (one year as inspector, five years as officer) and be in possession of certain certificates, or hold a relevant university degree, have been trained and qualified as an inspector, have served two years as an inspector. He must also be able to communicate in the language most commonly spoken at sea and have a good knowledge of the provisions of international Conventions and procedures on port-State control. Such level of detail ensures sufficient qualification of inspectors in their area of inspection. As mentioned earlier, the complexity and the technicality of the enforcement of REACH and CLP require particularly well-qualified inspectors, and a detailed description of the profile of such inspectors could be useful to ensure a harmonized level of controls over the EU.

Directive 95/53/EC on animal nutrition
Regulation No.882/2004 on controls for food and feed law

Directive 95/53/EC on animal nutrition and Regulation No. 882/2003 on controls for food and feed law, animal health and animal welfare rules both provide for controls at all stages. They are based on the risk, and for the Directive, on 'experience gained', which is a very important factor for the proper targeting of inspections. REACH and CLP imply requirements at different stages of the life of a chemical substance or mixture, and thus requirements imposed on different stakeholders. More advice on where and when to inspect to ensure that all stages are covered could help to ensure implementation of the EU requirements down the supply chain. In addition, Directive 95/53/EC refers in the legislation itself to the elements that should be taken into account for the targeting of inspections, which might also be an option for REACH and CLP.

The table next page provides an overview of criteria for inspections provided in the EU acts listed above. The last column indicates the relevance of the criteria identified in each act for inspections in the context of REACH and CLP.

Table 11 Overview of the criteria for inspections in other selected EU acts

	Planning		*On-site*				*Follow-up*		**RELEVANCE FOR REACH AND CLP**
EU ACTS	**Inspection plan(s)**	**Risk based**	**Routine/non-routine**	**Scheduled/ unscheduled**	**Inspectors**	**Frequency**	**Follow-up**	**EU-oversight**	
Reg.765/2008 (Market surveillance)	Yes (programmes) (art.18.5)	Yes (art. 19.1)	Both (art. 19.1)	--	Powers, resources and knowledge necessary May require documents, enter premises, take samples, destroy products or render them inoperable (art.19.1)	--	Yes (alerting users, economic operators) (art.19)	Yes (market surveillance initiatives (art. 25)	Concerns products placed on the market, whether substances, mixtures, or (substances in) articles. Both the Forum and COM consider the REACH and CLP Minimum Criteria to operate within the framework of the Market Surveillance Regulation.
Directive 95/21/EC (Port state control)	--	Yes (ships to be considered for priority inspection listed in Annex I) (art.5.2) Clear grounds for more detailed inspection (examples in Annex III)	Procedures and guidelines for inspections according to the Directive and international agreements listed. Three levels of inspections (inspections, more detailed inspections, expanded inspections) (art.2)	--	Member State shall maintain CA and shall take whatever measures are appropriate to ensure that the CA perform their duties (art.4) Minimum criteria for inspectors are listed in Annex VII.	Every year: 25% of the ships entering the port + not tested in the previous 6 months unless certain conditions are met (Art. 5.1 and 5.2)	--	--	Sets three levels of inspections (inspections, more detailed inspections, expanded inspections) which could be relevant for different categories of dutyholders under REACH. In addition, it provides minimum criteria for the qualification of inspectors, which could be relevant also given the technical nature of REACH & CLP.
Directive 95/53/EC (animal	--	Yes (art.4) 'in the light	--	Generally, without	Confidentiality	At regular intervals (art. 1(a))	--	--	Inspections cover all stages of production and

	Planning		*On-site*				*Follow-up*		**RELEVANCE FOR REACH AND CLP**
EU ACTS	**Inspection plan(s)**	**Risk based**	**Routine/non-routine**	**Scheduled/ unscheduled**	**Inspectors**	**Frequency**	**Follow-up**	**EU-oversight**	
nutrition)		of the risks and experience gained'		warning (art. 4.3)					manufacture, the intermediate stages before marketing, including importation and the use of products.
Reg. 882/2004 (controls for food and feed law, animal health and animal welfare rules)	--	Yes (art.3.1)	--	Without prior warning + on an ad hoc basis (art. 3.2)	Appropriate training of the staff performing official controls	Regularly (art. 3.1.)			Indicates that controls are carried out at any stage of production, processing and distribution, which is also a relevant consideration for REACH. Lists the physical elements to be controlled.

2.3 Conclusions

From the above review of other legislation, a number of criteria can be identified that could be relevant for REACH and CLP inspections. The criteria drawn from other environmental legislation is in roman, while the criteria found in non-environmental legislation is *italicised.*

Criteria that could be developed in the context of REACH/CLP inspections

- **Qualifications and powers of inspectors**
  - Legal right to access to sites and to information
  - Obligation of operators to provide assistance to authorities carrying out inspections
  - Sufficient staff with appropriate skills and qualifications
  - *Sufficient powers (for carrying out inspections and for taking enforcement measures)*
  - *Inspectors shall carry out their duties independently, impartially, and without bias*
  - *Sufficient knowledge for the proper performance of their tasks*
  - *Minimum criteria for inspectors (e.g. regarding the level of experience, education, training, past experience, knowledge of EU requirements)*

- **Frequency of inspections by site/ Overall number of inspections per year**
  - Given frequency for all types of duty holders and inspections (e.g., once a year)
  - Frequency varying based on risk analysis (e.g., once a year for high priority targets, every three years for less important targets, within six months after observing non-compliance)
  - Numbered objective over a certain period of time (e.g., one-third of registrants in one year)
  - *Percentage of inspections over a certain period of time (e.g., 25% of registrants in one year)*

- **Ratio of surprise**
  - General statement on ratio (e.g., 'an appropriate proportion ' of inspections without prior warning)
  - Percentage of inspections without warning

- **EU Commission's role in inspection procedures**
  - Implementation reports to the Commission (with more guidance concerning what needs to be reported)
  - Communication of the result of inspections to the Commission
  - Control of the infrastructure and operation of the national inspectorates by the Commission
  - Investigations by national authorities upon request from the Commission, direct access of the Commission to documents from operators.

- **Collaboration between Member States, between authorities and with stakeholders**
  - Possibility for one Member State to ask another Member State to carry out inspections or investigations.
  - *Communication and coordination between national authorities and between Member States*
  - *Information to relevant stakeholders down/up the supply chain in case of non-compliance*

- **Programme of inspections**
  - Exhaustive or indicative list of the elements to be checked during an inspection.
  - *List of physical elements to be checked during an inspection*
  - *Checks of certain elements (e.g., characteristics of a product) by certain means (documentary checks, physical and laboratory checks)*

- ***Scope of inspections***
  - *Requirement to cover all stages of production and manufacture*
  - *Level of detail of inspections depending on the target and the corresponding risk identified*

3. Enforcement policy at Member State level (country studies)

In order to fulfil the objective of identifying criteria and enforcement strategy for this study, six Member States were selected to provide a panel of enforcement practices at national level. These countries are Bulgaria, France, Germany, Slovenia, Sweden and the United Kingdom. They were chosen either because of their significant chemicals industries or in order to cover different types of legal cultures and systems of inspections. Most of these countries have already given considerable thought on how to organise efficient and effective chemicals inspections systems, and the review of their experience aims at drawing on best practices concerning the identification of criteria to target inspections and strategies for inspections.

The information contained in this section is based on a desk study carried out by legal experts at national level and interviews (or questionnaires) with relevant national authorities from the six countries analysed, and in the first place with the members of the Forum.[46]

Four main areas have been analysed for these country studies:

- ***National inspection strategies***, including the description of strategies, the context of their adoption, and more specific elements on the priorities defined in the strategies and for the coordination of enforcement services.

- ***Criteria for inspections,*** including information on procedural elements of inspections (*e.g.*, frequency of inspections, proactive versus reactive inspections, planned versus unplanned, etc.) and the prioritisation and targeting of inspections.

- ***Competencies of inspectors,*** *e.g.*, powers of inspectors, training, etc.

- ***Best practices*** with regard to enforcement and the most important elements to take into account to make an enforcement strategy efficient.

3.1. The strategies adopted in the selected countries

3.1.1. The context of adoption of the strategies

Strategies

Enforcement in Bulgaria is regulated in 'Guidelines for Performing Control for the Implementation of REACH' adopted by Order No RD – 250/08.04.2009. The Guidelines serve as a strategy for inspection of REACH and do not refer to the CLP Regulation. The strategy was prepared and is addressed to the Ministry of Environment and Water, the Ministry of Health and the General Labour Inspectorate Executive Agency at the Ministry of Labour and Social Policy. The industrial chambers were also involved in the preparation.

[46] The interviewees were:
Bulgaria: Nikolay Savov, representative of Bulgaria at the Forum, Ministry of Environment and Water of Bulgaria.
France: Luc Maurer, representative of France at the Forum, Ministry of Ecology, Sustainable Development, Transport and Housing; and Dominique Girault, Department of Security and alert network-Security and chemical products, General Directorate for Fair Trading, Consumer Affairs and Fraud Control, Ministry of Economy, Finance and Industry.
Germany: Rosemarie Greiwe, Ministry of Labour, Integration and Social affairs of North-Rhine Westphalia; and Dr. Axel Dorenbeck, Ministry of Labour, Social affairs, Family and Women of Bavaria.
Slovenia: Semira Hajrlahović Mehić, Senior Chemicals Inspector at the Slovenian Chemicals Office, also with the participation of Alojz Grabner, Director of the Chemicals Office.
Sweden: Agneta Westerberg, representative of Sweden at the Forum, Director of Enforcement Department at the Swedish Chemicals Agency.
United Kingdom: Mike Potts, representative of the UK at the Forum, UK REACH Competent Authority, Chemicals Regulation Directorate, Health and Safety Executive.

France has adopted in 2006 a Ministerial Communication on the management of risks from chemical products (hereinafter 'the 2006 Communication'), which lists, as one of the main actions for the enforcement and implementation of REACH, the enhancement and coordination of inspections. Furthermore, every year since 2009, a circular (*circulaire administrative*) is drafted to set priorities for the enforcement of REACH and CLP and other chemical legal texts. The yearly inter-ministerial circulars are prepared by the representatives of the General Directions (*Directions Générales*) of the Prevention of Risks, Health, Labour, Fair Trading, Consumer Affairs and Fraud Control, Customs, part of the inter-ministerial group, together with representatives of the Common Service of laboratories (*Service commun des laboratoires*). The circulars are addressed to inspection bodies.

The German Working Committee of the Federal Government and the States on Chemical Safety (BLAC) has adopted a general strategy and a specific strategy for market surveillance of chemicals, including REACH and CLP (*Konzept der Umsetzung der Verordnung EG Nr. 765/2008, Leitfaden für die Marktüberwachung von Chemikalien*). The BLAC also developed an overall concept for enforcing compliance with the REACH provisions which formed the basis for the REACH-EN-FORCE 1 project. The strategy was developed by a working subgroup composed of representatives of the federal states and the supreme federal authorities as well as the custom authority. It was then adopted by the conference of the federal ministers of environment.

A specific enforcement strategy for REACH or CLP Regulations does not exist in Slovenia. Instead, the Chemicals Office of the Republic of Slovenia has two general planning documents which govern its activities: a medium-term five year plan and annual plans of activities. Enforcement in the field of chemical safety (including REACH and CLP) is just part of these plans. The current "Five-year plan of activities of the Chemicals Office of the Republic of Slovenia for 2008 – 2012"[47] sets as one of its major medium-term goals the coordination of inspection control in the area of chemical safety. Every annual plan of activities of the Chemicals Office has a chapter about enforcement, and is more an operational document setting the types and number of facilities to be inspected. It should be noted that no inter-sector strategy of enforcement exists. Both the Five-year plan of activities and annual plans of activities are prepared by the officials of the Chemicals Office, and for enforcement, more specifically by the officials working at the Chemicals Inspection. The five-year plan and annual plans of activities are adopted by the Head of the Chemicals Office.

Sweden does not have a specific strategy for enforcement of REACH and CLP. Instead, a general strategy for enforcement is implemented through a quality and environmental management system (ISO 9001 and ISO 14001). The Swedish Chemicals Agency (KemI) maintains a register of chemical products placed on the national market. Any company intending to start an operation in Sweden involving manufacture or import of chemicals is obliged to report the operation to the Products Register, and any company manufacturing, importing or changing names of chemical products to the minimum amount of 100 kg must file a product report. The register contains data on approximately 145,000 chemical products and biotechnological organisms, submitted by some 2,500 notifying companies. Information contained in the register is used to support supervisory activities and to make it possible to gain an overview of the chemical products used in Sweden. KemI inspectors call on companies manufacturing and importing chemical products, biotechnological organisms and other articles in order to check that the companies comply with rules and regulations. When starting new projects, the Products Register is always used to find companies in different regions and specific chemicals and chemical products. The information is used for e.g. checking the classification, labelling and safety data sheets, content of prohibited substances in chemical products, etc.

A UK REACH Enforcement Strategy has been adopted by the UK REACH Enforcement Liaison Group, which took into account the already existing Enforcement Policy Statement of the Health and Safety Executive. The strategy aims to create and operate enforcement processes that make best use of the skills of enforcing authorities' staff to secure compliance, using two principal approaches:

- the provision of education, advice and help to duty holders, and the promotion of REACH, as increased awareness and understanding will lead to increased levels of compliance; and

[47] Available at http://www.uk.gov.si/fileadmin/uk.gov.si/pageuploads/pdf/petletni_nacrt_URSK_11.9.08_dr.pdf.

- the use of a range of interventions (both proactive and reactive), backed up by formal enforcement where necessary.

Depending on the content of the strategy, the document is made publicly available or can only be consulted by its addressees. In Bulgaria and the UK, the strategies are published and available online. In France, though the circulars themselves are published, their annexes setting more specific details on the targets of inspections are not. In Germany, the national strategy (and also in the case of North Rhine Westphalia) is for internal use only. In Slovenia, while the five-year plan is public, the annual plans of activities are internal documents of the Office and are not publicly available.

Monitoring and evolution of the strategies

Most countries regularly update the strategies. This is the opportunity to adapt and improve the strategies' elements based on past experience, and to address specific difficulties identified in the practical implementation of the strategies. The Bulgarian Guidelines have been specifically prepared for an initial period 2009/2010. An update was prepared in 2011. In France, each year the inter-ministerial group in charge of the enforcement of REACH and CLP issues a detailed review of the controls related to chemical products and substances, which summarises the main actions of the strategy and how these actions were applied by the relevant inspection bodies. In Slovenia, the actual work of the Chemicals Office is evaluated at the end of each year in an annual report about the realisation of the annual plan of activities and in the annual financial report. In the UK, the Strategy is monitored by the compliance team and the Enforcement Liaison Group, which is among others in charge of identifying lessons learnt and best practice; proposing amendments to guidance, based on practical experience; and determining priority substances and/or issues.

As a good practice, it should be noted that several of the countries under study have set in place structures to monitor the implementation of the strategy or more generally of enforcement. For instance, Bulgaria has formed a permanent working group to discuss REACH implementation and enforcement where all relevant issues are discussed including compliance with the requirements of the Guidelines. Practical problems in implementing the Guidelines are also discussed at the regular training workshops on REACH enforcement organised for the inspectors at national and regional level.

In France, the General Directions drafting the yearly strategies organise meetings with their respective affiliated inspection bodies three times per year. Meetings and working networks of these inspection bodies are also set-up in the regions. The information gathered during these meetings (e.g. feedback on the enforcement of REACH) is then used by the General Directions for the elaboration of this inter-ministerial circular. Specific topics of the REACH and CLP enforcement strategy can be tested in pilot regions. For example, the French 2011 Circular recommends the setting of a pilot enforcement strategy in certain pilot regions for the control of conformity of certain REACH provisions on restrictions (Annex XVII) by inspectors of classified installations.

3.1.2. The priorities for enforcement

The national strategies are based on the setting of priorities for enforcement. The criteria used to set these priorities have similarities from a country to another. France, Germany, Bulgaria and Slovenia indicated that the priorities in the enforcement of REACH and CLP follow the REACH and CLP deadlines for enforcement of specific requirements. France also mentioned the priorities set in the Forum (REACH-EN-FORCE-1 and 2) as sources of information. Bulgaria and Slovenia, in addition to the enforcement calendar, set priorities according to the general objectives of protection of health and environment. Bulgaria also mentioned the risk presented by the infringement of certain obligations.

The studies have identified the following priorities in the strategies adopted by some of the Member States analysed:[48]

[48] Slovenia and Sweden did not provide information on that point.

Priorities in national enforcement strategies

Bulgaria

- Checking compliance with the requirements for (pre-)registration of manufacturers and importers ;
- Checking availability and quality of the SDS's within the supply chains, including information for the workers
- Identification of companies which produce, place on the market or use SVHCs
- Implementation of the safety measures as identified in the safety data sheets.
- Provision of information in accordance with chapter IV of REACH

Other important elements in the national guidelines are: 1) the clear distribution of the competences between the enforcement authorities and 2) the mechanisms for cooperation and joint actions between them.

France

In 2009 the main priorities were the control of conformity of the safety data sheets (2000 inspections) and the control of compliance with the pre-registration requirements to be done before December 2008 (300 inspections).

The 2011 Circular sets the following enforcement priorities for REACH and CLP inspections:

- The application of the REACH registration and pre-registration requirements;
- The application of Article 35 of REACH on access for workers to information in the Safety Data Sheets (SDS);
- The application of the SDS new formats;
- The application of REACH Title IV requirements on information in the supply chain by downstream users;
- The application by downstream users of the obligation to submit the safety data sheets to the other downstream users in the supply chain;
- The application of the CLP classification and notification requirements.

It also focuses on the application of the concentration limit for certain chemical substances set under Annex XVII of REACH on restrictions, in products falling under technical norms such as toys, tyres and adhesives.

These priorities of enforcement are shared or commonly held between the different inspection bodies.

Germany

In addition to obligations coming into force and training of inspectors, the focus is on reactive market surveillance (imminent danger), active market surveillance being risk based regarding health.

UK

The principal focus of interventions should be on those provisions which are most important to enforce in order to make REACH work effectively (such provisions are listed in the Strategy document).

3.1.3. Coordination of enforcement services

Almost all countries under study have several bodies playing a role in the enforcement of REACH and CLP. This makes the coordination between those crucial for an efficient control of the application of these acts.

Most strategies stress the importance of coordination and cooperation between enforcement bodies. For instance, in France, the coordination of inspectors constitutes a major objective of the strategy. The 2006 Communication provides recommendations for the coordination of inspection programmes, puts in place control campaigns involving the different inspection bodies inspecting chemical products, and set as an objective the coordination of the different inspection programmes of inspection bodies by 2009. The inter-ministerial circulars also provide recommendations for the coordination of inspection programmes. Finally, the French Environmental Code was amended to include a new common procedure to be applied by inspection bodies involved in the enforcement of chemical laws (including REACH and CLP). Similarly, the Bulgarian interviewee considered that the establishment of mechanisms ensuring best possible coordination and cooperation between enforcement authorities was the most important element of an efficient enforcement strategy.

Bodies involved in inspections

In Bulgaria, the competent authorities for implementation and enforcement of REACH are the Ministry of Environment and Water, the Ministry of Health, and General Labour Inspectorate Executive Agency at the Ministry of Labour and Social Policy. The inspections are carried out respectively by the regional authorities of Regional Inspectorate of Environment and Water, Regional Health Inspectorates and Labour inspectorates.

In France, the 2006 Communication established an inter-ministerial group gathering five General Directions (Prevention of risks, Health, Labour, Fair Trading, consumer affairs and fraud control, and Customs) to ensure the coordination of the government policies for the management of the risks related to chemicals. In addition, it identified the main four inspection bodies in the field of chemicals (Customs, Inspectorate of the General Directorate for Fair Trading, Consumer Affairs and Fraud Control, Labour Inspectorate and Inspectorate of classified installations). The Environmental Code also lists the different inspection bodies in charge to enforcing the CLP and REACH Regulations within their domain of competence. In addition to the four main inspection bodies already mentioned, it lists inspectors belonging to other State Services with a less important role in the enforcement of REACH and CLP (agriculture and transport, health, plant protection, defence, nuclear safety, maritime affairs, etc.).

In Germany, the legislative and executive competences to enforce REACH are divided between the Federal Republic (Bund) and the sixteen states of Germany (Länder). Whereas the competence to legislate on chemical safety is distributed to the Bund, the main responsibility to carry out REACH enforcement is vested in the Länder. The main national actors to enforce REACH are the enforcement authorities of the Länder, the Federal Institute for Occupational Safety and Health (BAuA) and the Bund/Länder working group on chemical safety (BLAC). The competent authorities of the Länder are responsible for enforcing REACH in practice. They carry out inspections and take measures to enforce compliance. It should be noted that in several Länder, the competence for chemical safety and the competence for workers health in within the same federal authority.

In Bavaria, the overall responsibility for REACH enforcement falls in the jurisdiction of the Bavarian Ministry of Labour and Social Affairs, Family, and Women. Surveillance measures and inspections are carried out by the seven trade supervisory authorities, each of which is subordinated to one of the seven Bavarian district governments. The REACH inspection system is independent from that for worker health and safety, but coordination and communication is ensured in several working groups. In North-Rhine Westphalia (NRW), the Ministry of Labour, Integration and Social Issues has the main responsibility for REACH enforcement and the five district governments can take enforcement measures. Two different groups of inspectors are responsible for REACH inspection. One group is mainly responsible for market surveillance (especially provisions of restrictions (Annex XVII)) and another group is responsible for manufacturers, importers and their facilities. These inspectors are also inspectors for occupational safety and health.

In Slovenia, the competent authority for the implementation of REACH and CLP is the Chemicals Office of the Republic of Slovenia (the Chemicals Office) at the Ministry of Health. Within the Chemicals Office, the Chemicals Inspection has been established. The Chemicals Inspection is the competent authority for the enforcement of the CLP, and has a shared competence for the enforcement of REACH. It is responsible for the enforcement of all aspects of REACH except for restrictions on the marketing and use of certain dangerous substances in toys and childcare articles, enforced by the Health Inspectorate, and the enforcement of the access to information for workers (Article 35 of REACH) and the use of substances and preparations in accordance with Article 37(5) and (7) of REACH, enforced by the Labour Inspectorate together with the Chemicals Inspectors.

The responsibility for enforcement of REACH in Sweden is mainly placed on the Swedish Chemicals Agency (KemI), except for enforcement of the REACH provisions concerning safety for workers which are placed on the Swedish Work Environment Authority.

The authorities given enforcement responsibility in the UK by the REACH Enforcement Regulations 2008 are the Health and Safety Executive (HSE); the Health and Safety Executive for Northern Ireland (HSENI); the Environment Agency (EA); the Scottish Environment Protection Agency (SEPA); the Northern Ireland Environment Agency (NIEA); the Department of Energy and Climate Change (DECC); and local authorities (LAs), as regards occupational health and safety and consumer protection (trading standards) issues. The enforcement of CLP is undertaken by local HSE inspectors (from within regional Product Safety Teams).

Coordination of intervention of different enforcement services

In Bulgaria, enforcement authorities coordinate on the basis of the mechanisms set in the Guidelines. The Guidelines require the enforcement services to exchange information and notify each other in cases of found infringements within the competence of other enforcement authority.

The French inter-ministerial group ensures the coordination of the government policies for the management of the risks related to chemicals, under which the different inspection bodies exchange on their actions. To implement the strategy, a specific department was created within this inter-ministerial group to coordinate the inspection programmes of the various bodies in charge of REACH enforcement. Based on the work of the inter-ministerial group, the 2011 Circular distributes tasks and actions between the different inspection bodies. It suggests, for instance, that Labour Inspectors control the compliance of the Safety Data Sheet requirements and labelling of chemical products, while inspectors from the General Directorate for Fair Trading, Consumer Affairs and Fraud Control look at the application of the REACH restrictions relating to certain substances. Inspection bodies dealing with the application of REACH and CLP are authorised by law, within the framework of their mission, to exchange all documents and information with regard to chemical substances, mixtures and articles held or collected in the course of their missions. The 2011 Circular encourages the exchange of information between inspection bodies within this legal framework. It provides for instance that Custom Services should submit information on importation of chemical substances to identify importers of chemical products falling under REACH. According to one interviewee, the coordination for the enforcement of REACH and CLP is working very well, and allows sharing experiences and knowledge between inspection bodies.

In Germany, the BAuA is responsible for the information exchange of the enforcement authorities of the Länder, while the BLAC serves as an information exchange forum among the Länder and between the Bund and the Länder. The BLAC guidance on market surveillance of chemicals emphasises the importance of the information exchange between the competent authorities, and recommends carrying out the information exchange via ICSMS (Internet-supported Information and Communication System).[49]

In Slovenia, since the Chemicals Office is responsible for enforcement of all aspects of CLP and almost all aspects of REACH, very little coordination is required between different authorities. The coordination of enforcement between different inspection authorities is formally regulated in the Inspection Act. The Inspection Act provides that an Inspection Council must be established as a permanent cross-sector working body. Its tasks include the coordination of plans of activities between different inspectorates and the coordination of work of different inspection authorities where such coordination is necessary. They may also propose the formation of cross-sector team of inspectors to the Government. The Inspection Council provides a common information system, within which the different inspection authorities exchange data and information about their work. The Inspection Council has also proposed the formation of joint information system for all misdemeanours procedures (which has not yet been put into action).

[49]ICSMS is an interactive secured database for providing and sharing information on non compliant products and chemicals in Europe via the internet. This programme is used by Austria, Belgium, Cyprus, Estonia, Germany, Luxembourg, Malta, the Netherlands, Slovenia, Sweden, Switzerland and the UK. See https://www.icsms.org/icsms/App/blankPublic.jsp#scr

In Sweden, there is no formal cooperation or information exchange with other authorities concerning REACH enforcement. However, activities such as training and information to authorities at central, regional and local level have been carried out. Concerning other chemicals legislation, the inspectors at the Swedish Chemicals Agency (KemI) co-operate with regional and local enforcement authorities, the Swedish Rescue Services Agency and the Swedish Work Environment Authority. Local inspectors are contacted by KemI before inspections are carried out. Co-operation is also carried out with other EU enforcement authorities in different inspection projects within the network CLEEN (Chemical Legislation European Enforcement Network) and with the Nordic countries. Cooperation, coordination and exchange of information are under development.

In the UK, the legislation implementing the REACH enforcement regime – the REACH Enforcement Regulations 2008 – requires enforcing authorities to co-operate and share information with each other. The Regulations also give enforcing authorities the power to agree arrangements with each other to allow the carrying out of an enforcement duty by another authority. This means that there is flexibility for the most suitable enforcing authority to carry out enforcement in any particular case. A Memorandum of Understanding (MoU) on REACH enforcement has been agreed between the UK REACH enforcing authorities. The MoU details the administrative procedures and working arrangements between the enforcing authorities. It contains provisions as to joint working arrangements where enforcement responsibility overlaps, the sharing of information between enforcers and notification of matters of concern regarding duty holders. To further strengthen cooperation and coordination, the MoU sets up the UK REACH Enforcement Liaison Group already mentioned above. This Group is composed of representatives from all UK REACH enforcing authorities and meets at least twice a year. Its functions include proposing and coordinating enforcement activity on these where possible.

Joint inspections

In Bulgaria, joint inspections are set out as a legal option in the Guidelines and carried out in practice, with each enforcement authority drawing a separate report for the joint inspections in accordance with its competence.

In France, the 2011 Circular recommends the implementation of joint inspections between labour inspectors and inspectors of classified installations depending on the local context. This circular also mentions that a pilot inspection campaign to control the application of certain restrictions on substances under Annex XVII to REACH should be held jointly by the classified installations inspection body, custom services and the General Directorate for Fair Trading, Consumer Affairs and Fraud Control. In addition, as already mentioned, the Environmental Code sets a common inspection procedure that can be followed by inspection bodies involved in controls related to chemical products. In practice, inspection bodies may follow the inspection procedure they use in their respective domain of competence. For instance when controlling the application of REACH and CLP inspectors of the General Directorate for Fair Trading, Consumer Affairs and Fraud Control are more likely to use the inspection procedure under the Consumer Code *(Code de la consommation).* However inspectors are not allowed to mix different inspection procedures.

In Germany, joint inspections are carried out depending on the federal states. The interviewee for NRW indicated that environmental inspectors and "REACH/CLP"/ occupational health and safety inspectors belong to the same authority and are working closely together.

In Slovenia, up to now, no joint inspections were organised in the field of REACH or CLP Regulations; the reason being that such joint inspections are mostly not necessary because the Chemicals Inspection is almost completely responsible for the enforcement of both Regulations.

The UK indicated that no joint inspection has been carried out until now.

Sharing of information with decision makers setting national enforcement policy and with ECHA

In Bulgaria, the results of the enforcement activities are reported on a regular basis to the decision makers. The working group on REACH implementation and enforcement is informed on the inspection activities and the enforcement measures taken. Information on inspections and enforcement is sent to ECHA through the Forum in the required format for exchange of information.

In France, most of the inspection bodies have established a mechanism to collect information on the REACH and CLP inspections. For instance the Inspectorate of classified installations has set-up an information system GIDIC (*Gestion informatique des Données des Installation Classées*) which includes a section on REACH and CLP Inspections. Information on REACH and CLP inspections are sent to ECHA following the schedule of the Forum.

Germany mentioned that it has an extensive information exchange up and down the chain and is trying to improve the conditions for enforcement. As far as possible information, best practices and problems are communicated to ECHA via the Forum or CARACAL. It is a 'hit-and-miss' communication. One interviewee indicated that, to ensure an efficient enforcement, access to the information available at ECHA (in particular on registration, classification and labelling notifications and notifications according to Article 7) was needed.

The UK indicated that the REACH Compliance team is in regular contact with the Competent Authority and Defra (as the Government Department with policy lead for REACH in the UK). The interviewee also indicated that issues of interest are presented to the Forum, and that RAPEX is also used (for instance it was used to notify other Member State enforcers of the issue of asbestos in sky lanterns).[50]

3.2. The criteria for inspections

3.2.1. Procedural elements [51]

Frequency of inspections

The countries under study did not have legal requirements regarding the frequency of inspections. However, France and Slovenia mentioned indications for frequency in their annual strategic planning of inspections. For instance, the French 2011 Circular set some objectives for the number of inspections per year for inspectors on classified installations, with 400 inspections to be carried out on all the French territory.[52] In Slovenia, the annual plan of the Chemicals Office also provides a minimum number of inspections to be carried out per year. As a rule, the same facility is visited every one year and a half to five years, depending mainly on previous experience with the facility (known issues about compliance, non-compliance), the volume of substance imported/produced/used, the hazardous nature of the substances produced/used (e.g. SVHCs) and the type of activity.

In Bulgaria, even though there is no minimum number of inspections to be carried out per year, and no specific criteria formulated for deciding how often to check a particular facility, usually the same facility is checked at least once per year, either by a site visit or via a desktop inspection, a desktop check being preferred for reasons of time and cost effectiveness when checking documentation.

Germany and the UK do not have a minimum number of inspections per year. For Germany, both Lands indicated that the inspectors for REACH and CLP also enforce other legislation (e.g., enforcement of the Seveso Directive and occupational health and safety legislation), which renders the obligation to set a minimum number of inspections impossible. It was hover mentioned that for certain

[50] Sweden and the UK also mentioned the exchange of information between Member States, through referrals, notably through REACH-IT.

[51] This section does not include information on Sweden, as data could not be obtained through the case study for that aspect.

[52] Among these 400 inspections, 150 should be dedicated to the application of the registration requirements, 150 to the control of downstream users, 100 should be based on desk research by comparing data and written requests.

enforcement projects, a fixed number of inspections must be carried out by one authority. The number is set by the Ministry in the annual planning according to the capacity for inspection of the authority in question.

Proactive vs reactive

In Bulgaria, all pro-active inspections are carried out according to the annual inspection plan. The reactive inspections are based only on information provided to the competent authorities either by the other authorities or the public. It is a legal requirement to check all officially registered complaints, and the Ministry of Environment and Water and the Regional Inspectorates try to make as much information as possible available to the public in order to reduce erroneous complaints. The number of reactive inspections is variable. Normally about 15 to 20 % of the inspections are reactive, which was considered by the person interviewed to be a good ratio.

In France, according to one of the interviewees around 10% of the inspections are reactive. They are mainly initiated through complaints or based on decisions taken by ECHA (incomplete or not conform registration dossiers). Inspectors of the General Directorate for Fair Trading, Consumer Affairs and Fraud Control also launch reactive inspections based on information from the Community alert network (RAPEX).

In Germany, at the Federal level, the BLAC guidance on market surveillance of chemicals recommends proactive and reactive inspections. Reactive inspections may be triggered by different elements, such as surveillance activities or information from other authorities, commercial users and customers. In Bavaria, proactive inspections predominate. The interviewee nevertheless raised concerns as to the possibility to see reactive inspections, triggered by complaints from companies and consumers, increase and dominate on a longer term. In NRW, reactive inspection can stem from the market surveillance of chemicals, accidents or incidents (resulting in inspections focused on occupational safety and health), or information from non-governmental organisations, companies or consumer organizations (for the latter especially non-compliance to the requirements of Article 33 and placing on the market of a restricted chemical). The interviewee mentioned that the results of the market surveillance and the follow-up of proactive inspection trigger too often reactive inspections, and that proactive inspections on the sites of manufacturers and downstream users for the enforcement of REACH and CLP are at the moment very seldom and have been carried out on a regular basis in the past only in the context of specific inspection projects. This was explained by the need for more personnel to perform more proactive inspections.

In Slovenia, of all inspection procedures led by the Chemicals Inspection, 70 % are proactive and 30% reactive. With regard to REACH and CLP inspections, the percentage of proactive inspection is even greater – approximately 85% of all inspections are proactive. This ratio was considered adequate by the interviewee, as proactive inspections are considered easier to perform, because they can be planned in advance, and can be a part of a wider enforcement campaign. The reactive inspections are usually triggered by information by "whistle-blowers" to the Chemicals Inspection (which are often other operators), official transfer of inspection case from another inspection authority (which proclaimed itself not responsible), incidental information received while performing inspection control in another unconnected matter, and self-request from operators to perform the inspection of their own facilities.

The UK did not provide a ratio of reactive versus proactive inspections, but has developed a specific approach of this matter. The Health and Safety Executive uses a model developed by the Environment Agency for conducting proactive REACH inspections. A campaign-based approach has been developed, centred on particular substances or topics. This involves gathering much pre-campaign intelligence to identify supply chain activity surrounding the subject matter of the inspections. This intelligence can then be compared to existing records (e.g. of companies that have submitted a (pre-) registration), to effectively target those companies that appear to be in breach of core requirements in REACH. The approach also presents authorities with opportunities to assess compliance with other REACH duties. The UK believes such an approach strikes the best balance between effective enforcement of REACH while ensuring minimal regulatory burden on compliant companies. It also reduces the burden on enforcing authorities – for example, much work is undertaken remotely from

duty holders, and visits are only paid to those already suspected to be non-compliant, it also aims to remove the need for visits by multiple enforcing bodies. UK REACH enforcing authorities have also established 'reactive' processes with a view to securing compliance. These typically involve a REACH-specific contact point (separate to the UK REACH Helpdesk), to handle approaches from: - duty holders who believe or know that they might now be in contravention of REACH (e.g. having missed the pre-registration period); - those who wish to contact us to raise their concerns about the compliance of others (i.e. "complaints"); and - other UK enforcing authorities, EU Member States and the European Chemicals Agency (ECHA) who need to refer enforcement issues across.

Planned vs unplanned

In almost all countries, inspections are usually planned, with surprise visits being the exception. Bulgaria, Slovenia argued that informing the operators about the inspection in advance is more efficient, as it ensures the availability of the complete documentation to be checked. In the UK, the inspection body has so far only undertaken planned visits, as most of the investigations were focused on registration issues, which also require extensive documentation.

In Germany, Bavaria indicated that the possibility to inform a company of an upcoming inspection depends on the type of inspection planned. Inspections concerning Annex XVII are mostly surprise inspections, while an inspection on registration requirements may be announced by the inspector to ensure the availability of the documentation. NRW stated that the operators are usually not informed in advance about an inspection.[53]

In Bulgaria, usually surprise inspections are not carried out unless there is a specific notification by other authorities or the public. In Slovenia, surprise visits are mainly used in case of prior non-compliance or when operators were given a deadline to rectify the non-compliance.

In France, there is no legal obligation for inspectors to inform operators of on-site inspections in advance, meaning that unplanned inspections are allowed. In practice, unplanned inspections are mainly done by the Customs Services and inspectors of the Fair Trading, Consumer Affairs and Fraud Control, but are hardly used for the inspection of classified installations.

Monitoring and follow-up of inspections

All countries keep record of the inspections. In Bulgaria, the findings of the inspections are recorded in inspections reports which are available to all enforcement authorities. In France, after each inspection, inspectors must send to duty holders an official record summarizing the inspection if they identified infringements to the legislation. In Slovenia, the findings of inspections are kept in the procedural minutes, which are prepared and kept for each inspection. They are exchanged between different responsible authorities – the exchange is not formally prescribed but carried out on an unofficial basis when an inspector judges that to be necessary.

Several countries mentioned the use of electronic systems for the monitoring of inspections. In Germany, in Bavaria, inspections are reported in an internal database.[54] In NRW, the inspection authorities also use an IT tool for reporting and storing all enforcement related information and results concerning a facility, and the interviewee mentioned another electronic tool in used internally to record chemical products-related information (findings of the market surveillance). In the UK, a computer based system records all contacts and correspondence (paper and electronic) with a company. Checking this database is one of the first steps in any desk-top study. Follow up where appropriate is managed by the electronic systems used by the enforcement authorities. Electronic systems are foreseen, even though not yet implemented, in Bulgaria and Slovenia. In Bulgaria,

[53] Even though in the course of the REACH-EN-FORCE 1 and REACH-EN-FORCE 1follow-up, the operators were informed in advance, because the inspectors needed a fair amount of documentation and information from the companies.

[54] The representative of Bavaria also mentioned the possibility to exchange information between authorities via ICSMS.

questionnaires in electronic format are developed and are expected to be used. The Slovenian Inspection Council endeavours to establish a common information system, within which the different inspection authorities should exchange data and information about their work. However, this system has not been put into action.

As part of the follow-up of inspections, several countries described the procedure that follow the observation of a breach. In Bulgaria, in principle, if the inspection reveals breaches, another inspection is planned and carried out to check if compliance is achieved. Depending on the nature of the breach, a desktop check may be carried out. In France, when an inspection reveals a case of non-compliance, inspectors must report it to the relevant administrative authority, which must issue a letter of formal notice to the duty holder requesting him to comply with the legislation within a specific time period. At the end of this time period, an inspection is planned to verify whether duty holders comply with the legislation. In NRW, planning follow-up inspections after an inspection revealing breaches is part of the regular follow-up after an inspection. In addition, it frequently happens that an on-site inspection results in an inspection of another operator (for example if an inspection of a downstream user reveals a faulty SDS, the manufacturer of the substance will be informed or inspected to ensure that the SDS is corrected).

3.2.2. Prioritisation

In Bulgaria, so far, the hazard and/or risk have been taken into the account to target inspections, in combination with the priorities for enforcement decided according to the deadlines for the implementation of the different requirements of REACH and CLP. In Germany, Bavaria also indicated that the inspections are first of all risk-based, concerning the hazard of worker or of consumer. Then, the focus is on one specific obligation of REACH/CLP at a certain point in time. On the other hand, inspections in France and Slovenia are not targeted based on potential risks, with the exception in France of inspections regarding REACH restrictions on certain substances.

Rather, in France, REACH and CLP inspections are mainly targeted based on the rating of past inspections, volume of substances produced/ used, known issues (e.g. REACH dossier rejected, pre-registration indicating a particular deadline but no registration, accident) and the type of industrial activity, by geographical areas. Similarly, inspections in Slovenia are prioritised based on the rating of past inspections, the volume of substance(s) produced or used, the hazardous nature of the substances used (e.g. SVHCs), known issues (e.g. REACH dossier rejected, pre-registration indicating a particular deadline but no registration, accident), and the type of industrial activity. The prioritisation in Slovenia is also based on specific obligations under REACH/CLP, especially the production, handling or use of SVHC, classification and labelling notifications, compliance with authorisation provisions, within restriction constraints, and compliance of SDS. These elements are also taken into account for targeting inspections in Bavaria, together with the results of past inspections and information received from external sources.[55]

The German Land of NRW explained that the process to select a facility involves looking at the results of the market surveillance of chemicals products, information received *inter alia* from ECHA, or gathered from other inspections (for example environmental inspections). It also takes into account the focus of the annual planning.[56] The selection can also be based on specific projects, such as the Forum's enforcement projects.

In Sweden, inspections are focused on risk reduction. Companies are selected in those areas where there is a potential for improvement, e.g.:

- companies that import/manufacture products which contain substances of high concern,
- when new regulations start to apply
- information regarding poor compliance of a specific piece of legislation,
- information on companies or sectors of industry with poor compliance,

[55] For instance via ICSMS, see ibid.

[56] The main focuses of the annual planning for the market surveillance of chemical products are often certain entries of Annex XVII (restrictions).

- companies having high-volume products with a wide circulation,
- products containing hazardous substances which are used by sensitive groups (e.g. children) etc.

Inspections concerning chemical products and/or pesticides are focused on classification, labelling and safety data sheets, while inspections concerning articles mostly focus on prohibited substances or substances of high concern in articles.

In the UK, companies who meet certain criteria are selected for desktop studies or inspection in terms of a campaign. They are chosen because of potential registration requirements. The substances selected for campaigns are chosen on the basis of hazard (e.g. CMR), UK's own priorities (e.g. sensitisation and cancer), timing of obligations (e.g. recent registration deadline) and intelligence. Additionally sectors were targeted following the identification of non-compliance within their area. For example, a project looked at the presence of asbestos in sky lanterns following the identification of a non-compliant sky lantern containing asbestos being imported into the UK.

3.3. Competencies of inspectors

Qualifications of REACH and CLP inspectors

In Bulgaria, the legal requirements for taking the position of inspector in the enforcement authorities are a bachelor degree and 2 years of professional experience. The preferred qualification for a REACH/CLP inspector is a bachelor in chemical engineering. In the UK, inspectors competent for REACH/CLP are also recruited as graduates (no specified degree necessary) with normally some years of industrial experience. In the case of Slovenia, the requirements are set in the Inspections Act, which states that every inspector has to have at least a higher technical educational degree, at least five years of practical experience, and has to pass an inspection examination. For Germany, Bavaria indicated that inspectors require basic chemical knowledge and that every inspector (for all duties) has a two-year qualification training concluded with a final examination.

NRW mentioned that a full range of qualifications can be asked depending on the tasks of the inspectors. Whereas certain tasks require holding a master degree in chemistry with additional knowledge in toxicology, others (in particular on-site inspections) are carried out by inspectors with a bachelor degree in chemical engineering or environmental engineering, with experience in administrational processes and a detailed knowledge of the relevant laws and regulations. In practice, in some cases, inspectors are master craftsmen or technicians with additional vocational training in administrative and enforcement law. For instance, future inspectors for occupational health and safety need a bachelor degree or a master craftsman and have to complete a 2 year-training closed by a final examination. Inspectors specialised in market surveillance of chemicals are required to complete an apprenticeship.

Training of inspectors

In France, inspectors have to undertake a basic course on chemicals legislation and REACH during their studies.[57] Then continuous training on REACH is set by the different inspection bodies. Inspectors that are more specialised in the control of chemicals (around one by region) receive more in-depth courses on REACH and CLP. The trainings on REACH can differ from one inspection body to another (*e.g.*, trainings to labour inspectors will tend to focus on workers issues in REACH). This is very similar in Germany. In Bavaria, in addition to the training followed during their studies, inspectors have the possibility to take part in a general training once a year and, according their needs, designed advance trainings. NRW mentioned that all inspectors get regular in service-training.[58] Inspectors which receive an initial training as part of their studies (health and safety inspectors and market surveillance inspectors) are also provided additional in-service training on certain aspects (respectively on REACH and CLP and on enforcement). Also in the UK, there is a combination of

[57] In the case of REACH, the course is considered as a very simple initiation to the Regulation.

[58] The current main focus of training is the development of special skills concerning REACH, SDS and classification and labelling.

training during the studies and 'on the job'. Inspectors receive formal training in terms of a post graduate diploma in Health and Safety, formal training courses, including coverage of REACH and CLP, and in-service training from senior inspectors.

For the other countries, different practices were mentioned. In Slovenia, inspectors attend courses and have to pass tests on the functioning of public administration, on inspections and an examination which authorises them to manage the procedures for misdemeanours and to issue penalties. Bulgaria trains inspectors extensively via projects and programmes, with a strong focus on legal requirements and their enforcement and on inspection techniques. In Sweden, it was mentioned that seminars have been held to inform authorities concerned at central, regional and local level. In addition, inspectors meet once a year to exchange experience and present reports on inspection activities in the context of a meeting of the Nordic countries and in the context of the CLEEN network.

Powers of inspections

The table below summarises the most important powers of inspectors by country.

Table 12 Powers of inspectors in the selected countries

	Enter premises	Take samples	Seizure	Other powers
Bulgaria[59]	✓	✓ (laboratory testing in relation to production, placing on the market, use, storage and export of chemical substances)	✓ (of goods for Customs authorities [60]and of substances and mixtures for the Health protection inspectorate[61])	• Require information and documentations
France[62]	✓ (premises and vehicles, vessels and aircrafts used for professional transport of substances and mixtures)	✓ (with very detailed requirements set by law for the sampling procedure)	No, except under specific circumstances in application of the Consumer Code	• Enforcement powers (can issue formal record to the Public Prosecutor or the relevant administrative body)
Germany[63]	✓	✓	✓ (in accordance with the Lander police and regulatory law)	• Require information from all natural and legal persons subject to obligations under national law and REACH • Require documents on application, notification, registration and authorisation under REACH • Examine working tools and protective work equipment • Examine manufacturing and application processes and measure the level of hazardous substances and mixtures • May require external expertise, and to transfer imported substances, mixtures or articles not in compliance back to the country of origin
Slovenia	✓	✓		• Stop the production or use of forbidden materials or substances • Temporary halt the manufacture or use of materials or substances which use or manufacture

[59] Article 28 of the Law on Protection against the Harmful Impact of the Chemical Substances and Preparations.
[60] in case of doubt for breaching the bans or restrictions for import of certain substances and/or preparations until the decision of the environmental competent authorities is received
[61] found to non-compliant with the legal requirements and are considered risky for the human health and safety from the market and users.
[62] Article L.521-13 s. and R521-2 s. of the Environmental Code.
[63] § 21 of the Federal Chemicals Act.

	Enter premises	Take samples	Seizure	Other powers
				has not been authorised. • Impose monetary and other penalties in misdemeanours procedure
Sweden	No information	No information	No information	• Enforcement powers (can issue an injunction with or without a fine)
UK[64]	✓	✓	✓	• Enforcement powers (can issue an enforcement notice, prosecution)

The interviewees of the different countries analysed generally considered the powers of inspectors sufficient to carry out their duties efficiently. The NRW interviewee nevertheless pointed out a potential lack of knowledge on the part of inspectors regarding the range of their powers.

Tools used by enforcement bodies to encourage compliance

Most countries (Bulgaria, France, Slovenia, UK) mentioned as primary tools for enforcement training, information campaigns and cooperation with industry associations. Bulgaria and Germany mentioned the use of their helpdesk for the dissemination of information and communication with duty holders. NRW uses, in addition to information leaflets and information events targeting specific provisions, co-operation with industry associations via notably a database for knowledge management on REACH.[65] In Slovenia, it was noted that the cooperation with industry associations, especially with the Chamber of Commerce and the Chamber of the Economy is excellent, so that information campaigns and other actions take place at least twice a year. UK stated that training and information campaigns were preferred as they could potentially target the most people.

Formal notices and on the spot sanctions are usually used as complementary tools to information to ensure a higher rate of compliance (for instance in France, Bavaria, Slovenia and the UK). NRW stated that in principle they use all tools (from information campaign to sanctions) at their disposal under administrative law, and that the optimal results were obtained through a 'combination of all options adapted to the specific regional and economic situation and adjusted to the on-going process'. The Slovenian interviewee observed that the "soft approach" used in Slovenia, i.e., to issue formal notices to operators which are in breach of REACH or CLP, and give them additional time for the rectification of these violations has a very high rate of success.

3.4. Minimum requirements on inspections

As part of the case-studies, the authorities of the countries analysed were asked about their opinion on minimum requirements for REACH and CLP inspections. The Bulgarian and German federate authorities replied to this question with two different approaches.

The Bulgarian interviewee considered that inspections should target all duty holder groups, taking into account relevant deadlines, the risk for human health and environment (size of establishment, risk recipients, compliance history) and the state of the local industry in the Member State. Annual inspections should be carried out for a maximum percentage of duty holders subject to particular deadlines, and those with bad compliance record should be checked. An inspection should be carried every year to every three years. He stated that surprise visits are useful to avoid duty holders preparing to pretend compliance with the legal requirement after receiving an announcement, but that such visits should nevertheless concentrate on checking known problematic issues and/or industries with proven compliance deficits.

The Bavarian interviewee mentioned that, with regard to other legislations, it could be useful to introduce an indicative number of inspections to be carried out, potentially based on the number of inhabitants (especially for registration, authorization and restriction related requirements). This would allow adjusting the number of inspectors and ensuring a certain level of enforcement. He considered

[64] REACH Enforcement Regulations 2008.
[65] See http://www.reach-net.com/1.htm.

that a minimum requirement for the frequency of inspections, a percentage between surprise and non-surprise visits, the size of the organisation and the percentage duty holders inspected would not be manageable, and do not correspond to the reality. Rather, inspections should be decided by the inspectors on a case-by-case basis and according to their experience and to the facts. Along the same line, the NRW interviewee indicated that, in general, duty holders have to be inspected regardless of the size of their organisation, and that the timing of inspections should be based on planned priorities. She considered that minimum criteria for inspections, such as a fixed rate of enforcement activities would not be appropriate to ensure effectiveness, and that flexibility should be ensured when using inspections and all other enforcement tools to adapt to each specific situation.

3.5. Best Practices

The interviewees were asked to give best practices in their countries. These are reflected in the box below, along with a discussion on the broader relevance to REACH and CLP inspection:

Country	*Best practices in the countries under stud*	*Relevance to REACH & CLP*
Bulgaria	The coordination between the enforcement authorities in Bulgaria is considered as an example of best practice.	REACH and CLP both require Member States to maintain a system of official controls and other activities as appropriate to the circumstances. However, these do not have to be undertaken by the same organisation, even different parts of the same legislation may be enforced by different organisations, so good co-ordination is important.
France	The institutional structure set in place for the coordination between Ministries and between inspection bodies for the enforcement of REACH can be considered as an example of 'best practice'.	
Germany	Bavaria and NRW both pointed out a lack of exchange of information between inspectors of different Member States. Bavaria mentioned the use of ICSMS as a good practice, and a solution to this problem. ICSMS uses the internet to facilitate a comprehensive exchange of information between enforcement authorities across borders. It enables wide-scale market intervention in cases where non-compliant products and chemicals are identified and can help to avoid duplicate or multiple inspections and testing. Using the information in ICSMS, unsafe or non-compliant products and chemicals can be removed from the market simultaneously in all Member States. Currently the EU-Commission and ICSMS-AISBL are negotiating to make ICSMS the European IT-tool under the Market Surveillance Regulation. It would be very useful to use the same system for REACH enforcement as for the AMS Regulation, since parallel systems would result in an increase of administrative efforts.	The use of ICSMS would allow Member States to easily exchange information about chemicals placed on the market across the European market and allow better inspection results.
Slovenia	The preventive approach adopted by Slovenia is considered a good practice. The inspection authority aims at in providing timely information to duty holders about their duties with regard to REACH and CLP, in particular before the end of transition periods.	REACH and CLP are complicated regulations to comply with, especially for smaller duty holders and so such timely information may help such companies to comply.

Country	*Best practices in the countries under stud*	*Relevance to REACH & CLP*
Sweden	The products register maintained by the Swedish Chemicals Agency contains information on 145,000 chemical products and biotechnological organisms, submitted by some 2,500 notifying companies. The information provides an overview of chemical products used in Sweden and helps in locating companies in different regions and substances in chemical products.	The register is used to support supervisory activities, including checking compliance with e.g. classification, restrictions on certain substances in products, etc.
United Kingdom	Desktop studies and the campaign approach have proved to be very useful tools in REACH enforcement.	These best practices can optimise time spent on inspection and focus efforts on key issues.

4. Developing a strategic approach to inspections

The Technical Specifications for this project call for the elaboration of 'the simplest, broadest, practice oriented and most effective strategy for inspections by which, using the same resources, the inspectors would achieve the greatest output in checking compliance.' They also call for a list of specific criteria and requirements for REACH and CLP inspections which would be appropriate to apply in order to ensure the optimal effectiveness of the enforcement of REACH and CLP.

Both of these tasks are aimed at supporting inspectorates in setting priorities. The first type of prioritisation needed is strategic: which of the many obligations set forth in REACH and CLP are the keystone obligations, i.e., the most fundamental for ensuring adequate control of risks to human health and the environment and therefore should be checked and enforced first. The second type of prioritisation is also aimed at efficiency and effectiveness, in considering how best to target the actual inspection activities.

This section first looks at criteria for setting priorities in the enforcement strategy. In doing so it introduces the draft Enforcement Strategy developed in the course of the project in response to the challenge set forth in the Technical Specifications, which is found in Annex I of this Report. It then reviews various criteria for targeting inspections, with the aim of selecting the optimum mix for possible legislative action.

4.1. Criteria for selecting priority REACH & CLP provisions for checking compliance (Enforcement Strategy)

Section 1.3 of this Report reviews the REACH and CLP legal requirements, with the aim of identifying the priority requirements that are the most fundamental for ensuring adequate control of risks to human health and the environment from the manufacture, import and use of the substances subject to those requirements, including substances in mixtures as well as in articles. It selects, from a long list of enforceable Articles, those considered particularly important in terms of the obligations they impose on the duty holders, and groups them into 1) registration related duties, including the basic CLP obligation of classification, 2) supply chain related duties, including REACH Titles VII (authorisation) and VIII (restrictions) and CLP requirements to label and package substances, and mixtures according to hazard and 3) use related duties, including REACH Title V.

After additional analysis and from a practical point of view, the draft Enforcement Strategy selects the following obligations under REACH & CLP as those with the potential to give the best indication of a duty holder's status of compliance. These are therefore proposed as priority inspection topics for focusing limited inspection resources. They are:

- Exposure Scenarios
- Safety Data Sheets
- Information on Substances in Articles.

These three elements, in combination, are considered as key in helping to deliver the different objectives of REACH and CLP. The Enforcement Strategy discusses how these three elements can serve as the basis for an effective, practice-oriented strategy for checking compliance with REACH and CLP. It suggests ways to enhance the interplay between the information in the registration dossier and the SDS, and what is happening at the site where the inspection takes place. It also considers how enforcement of REACH can enhance the implementation of other EU requirements related to the protection of human health and the environment. However, it should be understood the key topics will not cover all eventualities.

In addition, criteria related to timing are built into the Enforcement Strategy. The REACH and CLP obligations are phased in over a number of years. In the case of REACH, the obligation to pre-register

all substances in order for take advantage of the staggered requirements for phase-in substances came first, followed by the first deadline of December 2010 for submission of registration dossiers for all substances manufactured or imported over the 10,000 tonnage threshold. Moreover, implementation of such elements as the REACH Title VII authorisation provisions require additional time to start up, before applications for specific uses can be accepted and processed.

With respect to timing, therefore, the Enforcement Strategy proposes a structured approach covering those obligations which are applicable today, to be extended over time to the other obligations that will come due under the expanding REACH & CLP requirements.

4.2. Criteria for carrying out strategic planning (targeting) of inspections

In addition to these criteria for selecting priority REACH & CLP provisions for enforcement, a number of other criteria are important for strategic planning of inspections. In this regard, the Technical Specifications mentioned the possibility of reinforcing the current enforcement requirements of REACH and CLP, giving as examples such aspects as minimum frequency of inspections, minimum requirements of inspections, a minimum level of availability of control capacity and staff allocation, and a minimum level of training requirements for inspectors.

In addressing this task, the *Minimum Criteria for REACH and CLP Inspections* developed by the Forum were analysed. As already noted, these build on the RMCEI developed by the IMPEL network. While the Forum *Minimum Criteria* are more specific to the context of REACH and CLP in that they take human health into account, they follow a similar approach to the RMCEI in focusing on the procedural aspects of planning environmental inspections. They stress the importance of developing an appropriate enforcement strategy or strategies, and list criteria for such a strategy under the following headings:

- Organisation (e.g., the need for cooperation and exchange of information)
- Planning (including objectives, targets, routine and non-routine inspection)
- Carrying out the REACH/CLP inspection (compliance checking according to the role of the duty holder, consideration of risks to human health and the environment)
- Action following the REACH/CLP inspection (preparing inspection reports, follow-up measures taken if further action needed by the enforcing authority and/or by the duty holder)
- Checking and review of arrangements for REACH/CLP inspection

Given the work carried out by the Forum to date on this, the task of developing further criteria for REACH/CLP inspection becomes one of considering what additional criteria might be useful. On the one hand, there may be **procedural** criteria additional to those in the Forum's *Minimum Criteria* that could be considered. On the other hand, additional types of criteria, such as **phasing** criteria, **risk-based** criteria and '**holistic**' criteria, might be useful for targeting of inspections, as elaborated further below. The criteria identified below as particularly relevant in the context of REACH and CLP inspections are based on the analysis of other EU acts in Section 2 and of the enforcement practices in a selection of Member States presented in Section 3.

Procedural criteria

The review of inspection criteria in other EU legislation has identified some additional procedural elements that might generate new criteria to be considered in the context of REACH and CLP enforcement. These include:

- frequency of inspections
- overall number of inspections per year (e.g. a set % of total premises per year),
- initiation of inspections (proactive/reactive/follow-up/new scientific or technical knowledge),
- a ratio of surprise to arranged visits or specific topics or general inspections
- what could be covered (assess relevant documents held by the duty holder/interview people/observe site conditions,

- how to publish outcomes and keep records,
- how inspectors should be trained to carry out such inspections
- feedback loop to ensure inspection results shared with ECHA and the Forum
- methods to ensure follow-up if enforcement action is needed.

Concerning *frequency of inspections*, the approach that is usually followed is based on a risk analysis. For example, the proposal for a Seveso III Directive sets frequency of inspection requirements on the basis of level of risk, with annual inspection for the most dangerous installations and inspections every three years for the less dangerous ones.

With respect to the *overall number of inspections* per year, this will clearly vary depending on the number of duty holders within a particular Member State's jurisdiction. An example of a provision in this area is Article 34 of Directive 2010/63/EU on testing of animals which requires inspection of one-third of the users each year in accordance with the specified risk analysis, as well as inspection of breeders, suppliers and users of non- human primates at least once a year.

Criteria concerning *initiation of inspections* can range widely. A frequent criterion is to require inspections of new (or significantly changed) facilities prior to commencement of operations. An example of this is Article 17 of the Mining Waste Directive, which requires the competent authority to inspect extractive waste facilities prior to the commencement of deposit operations and at regular intervals thereafter, to ensure compliance with permit conditions.

Other criteria could require inspections in response to complaints or accidents (reactive inspections), as follow-up to previous inspections where non-compliance had been identified, or in the event of new scientific or technical knowledge indicating an increase in risk. For example, the Industrial Emissions Directive provides that non-routine environmental inspections are to be carried out to investigate serious environmental complaints, serious environmental accidents, incidents and occurrences of non-compliance as soon as possible and, where appropriate, before the granting, reconsideration or update of a permit.

Criteria on *ratio of surprise to arranged visits* or specific topics or general inspections can also range widely. Article 34(4) of Directive 2010/63/EU on testing of animals simply provides that an "appropriate proportion of the inspections shall be carried out without prior warning."

The next procedural element is related to *what could be covered*. Criteria could cover the types of documents held by the duty holder that should be checked, such as the safety data sheets for substances classified as hazardous that should be passed down the supply chain. They might also require interviews with enterprise representatives or to record certain specifics concerning site conditions. For example, the Waste Shipment Regulation specifies that checks on shipments shall include the inspection of documents, the confirmation of identity and, where appropriate, physical checking of the waste.

How to publish outcomes and keep records can also be the focus of inspection criteria. For example, the Industrial Emissions Directive requires each site visit to be followed by preparation of a report describing the findings regarding the installation's compliance with the permit conditions and whether any further action is necessary. This report is to be notified to the operator concerned within two months of the site visit, and then made publicly available by the competent authority within four months of the site visit. REACH/CLP could similarly provide that information on inspections and investigations be made available to the public, e.g., through a publicly accessible register recording all desk and physical inspections carried out with regard to REACH, along with any follow-up actions taken.

Other criteria could address *how inspectors should be trained* to carry out such inspections. The criteria can be quite detailed. For example, Regulation (EC) No 882/2003 on controls for food and feed law provides that all staff performing official controls should receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to carry out

official controls in a consistent manner. The Regulation's Annex II lists the areas that should be covered by such training.

The *feedback loop* to ensure inspection results shared with ECHA and the Forum is a criterion discussed in the Enforcement Strategy. Finally, procedural criteria could also cover *methods to ensure follow-up* if enforcement action is needed. The Industrial Emissions Directive, for example, provides that if an inspection has identified an important case of non-compliance with the permit conditions, an additional site visit must be carried out within 6 months of that inspection.

Phase-in criteria

These criteria focus on when particular obligations come into force and therefore when the respective duty holders should be held responsible for compliance. This aspect is used for setting priorities in most of the countries analysed for the case studies.

A timeline for checking specific obligations would be structured according to which obligations are now in force and which will come into force sometime in the future. This would be comparable to the structured approach set forth in the Enforcement Strategy, which first covers those obligations applicable today, and then phases in the other obligations that will come due under the expanding REACH & CLP requirements.

Risk-related criteria

In addition to its procedural elements, the Forum *Strategies for enforcement* document discusses the need to define national-level policy goals for REACH and CLP enforcement as part of setting priorities for efficient enforcement. It suggests that analysis of the risk of non-compliance is a key to setting priorities for enforcement and that this type of risk analysis requires consideration of

- The target groups or duty holders, i.e., manufacturers, distributors, downstream users and importers.
- The legal obligations and the specific behavior required of the different target groups.
- The effect of non-compliance, i.e., an estimation of the consequences of noncompliance for human health and the environment (risk recipients).

The risk-based prioritisation was mentioned by the authorities interviewed for the case studies as being widely used to target inspections.

A risk analysis of the target groups could consider the particular industries and economic activities carried out in the Member State's territory and the possibilities for workers and the environment to be exposed to any chemicals of concern used in particular industrial processes. Coordination with other enforcement authorities could be particularly useful here. For example, inspectors checking compliance with integrated permits under the Industrial Emissions Directive would potentially have information on chemical uses in industrial processes, particularly if the inspections are coordinated to also check compliance with the Seveso II Directive's requirements, which require facilities to provide information sufficient to identify the dangerous substances involved, the quantity of such substances and their physical form, and the activity or proposed activity of the installation or storage facility. Similarly, labour inspectors would be a good source of information on workplaces where exposure to chemicals is a concern.

With regard to the second aspect, the risk analysis would consider the legal obligations to be fulfilled by the different duty holders, keeping in mind the three basic elements identified in the draft Enforcement Strategy: exposure scenarios, information in the supply chain and substances in articles. These cover some of the most difficult obligations to implement and therefore pose a strong risk of non-compliance. Duty holders' obligations related to exposure scenarios are, as already noted, useful in checking compliance with other EU requirements related to workers' protection and industrial pollution control.

This aspect of the risk analysis would also consider the historical records, i.e., the various target groups and economic sectors have behaved with respect to chemical safety in the past, as well as their current records of compliance with legal requirements concerning protection of workers, consumers and the environment. It would also consider the societal expectations concerning such behavior, including how the inspection process could be used to encourage compliance and when targeted enforcement action such as sanctions should be rigorously applied.

The third aspect concerning the impact of non-compliance would consider the degree of hazard presented by the substances in question and the risks presented by particular activities. Particularly hazardous substances such as CMR would thus form one element to be considered. The other key element would be the possibilities for exposure during particular activities, such as manufacturing, importing, supplying or using particular substances, and the potential consequences for people likely to be exposed and the environment, including the severity of the consequences.

Other risk-based criteria to be used in setting priorities include:

- the overall volume (tonnage) of a substance or number of substances being manufactured, imported, supplied or used (this would link to Seveso II requirements);
- the size of the duty holder and its position and influence in the supply chain, i.e., where in the supply chain the greatest enforcement effect could be achieved, particularly where the duty holder could influence a range of other duty holders;
- the inspection history of the duty holder, including whether they have received previous relevant advice and failed to take on board such advice.[66]

Additional risk-related criteria may be possible based on information in registration dossiers, including:

- Where exposure scenarios indicate considerable exposure to certain populations, including environment
- Where exposure scenarios do not seem plausible (e.g., some claims of zero emissions)
- Where information on sector-specific uses seem particularly weak

Finally, as already noted, risk analysis could be linked to procedural criteria. For example, the *frequency of inspections* could be based on a measure of risk for a certain type of duty holder, with large manufacturers inspected on a set frequency, e.g., at least every 3 years. The risk measure could be based on findings from past inspections, tonnage levels, hazardous substances used (e.g. SVHCs), known issues (e.g. REACH dossier rejected, accident), or type of industrial activity.

'Holistic' criteria (links with other areas of EU legislation)

A further type of criteria would help to target those duty holders also subject to other EU legislative requirements in such areas as worker health and safety, industrial pollution control and accident prevention, and product requirements. For example, a risk analysis for targeting REACH & CLP inspections could be cross-checked against risk analyses carried out by other inspectors. This would build on the systems of risk classification or risk analysis used by a number of Member State labour inspectorates in targeting enterprises for inspection of safety and health at work.[67] These include:

[66] Other factors for considering what enforcement action to take are not appropriate for setting of priorities, e.g., "the extent of the contravention, i.e. how far away from the required standards the duty holder is judged to be; where a contravention is shown to be due (in part or in full) to the acts or omissions of another person, whether the duty holder took all reasonable precautions and exercised all due diligence to avoid the contravention; the intention of the duty holder in non-compliance, e.g. whether noncompliance is deliberate in order to gain commercial advantage; the standard of general conditions and the attitude of the duty holder."

[67] See *Labour inspectorates' strategic planning on safety and health at work*, European Risk Observatory Working Paper, European Agency for Safety and Health at Work, 2009, available at: http://osha.europa.eu/en/publications/reports/TE-80-09-641-EN-N_labour_inspectorates .

- the existence of particular hazards (also based on information from previous inspections)
- the sector or size
- the existence or incidence of complaints or accidents.

This would serve to facilitate the use of the exposure scenarios etc. under REACH in other enforcement efforts, including health and safety at work inspections, industrial emissions controls, and inspections/investigations following environmental pollution events.

4.3. Criteria for developing options for legislative changes

The Technical Specifications also called for examination of the options and benefits for potential new legislative requirements relating to REACH and CLP inspections. The development of such options started with consideration of three main elements:

- Harmonisation across the EU versus individual Member State actions
- Voluntary actions versus binding legal requirements
- The basis for the enforcement action

Harmonisation across the EU versus individual Member State actions:

Under the principle of subsidiarity, in the areas where competence is shared between the EU and the Member States, the choice of whether action should be taken at European, national or local levels should consider where the intervention will be most effective. The EU should only intervene if it is able to act more effectively than the Member States.

Implementation and enforcement of the REACH and CLP Regulations is an area of shared competence. The two Regulations have been adopted at EU level. The Member States are responsible for implementing, monitoring and enforcing the REACH and CLP Regulations within their territories, while the European Commission – as guardian of the Treaties – is responsible for ensuring that the Member States meet their obligations in this regard.

The legal basis for both REACH and CLP is Article 95 TEC, now Article 114 TFEU. Both acts are aimed at approximation of the laws or administrative actions taken by the Member States with the objective of establishing a well-functioning internal market. In addition, Article 114 TFEU requires that the acts as proposed by the European Commission and adopted by the European Parliament and the Council are based on a high level of protection for health, safety, environmental protection and consumer protection. Thus harmonisation across the EU is an important objective of the REACH and CLP regimes.

Both REACH and CLP already have mechanisms aimed at bringing about consistency across the EU Member States with respect to implementation and enforcement. These include the European Chemicals Agency, established "for the purposes of managing and some cases carrying out the technical, scientific and administrative aspects of this Regulation and *to ensure consistency at Community level* in relation to these aspects" (REACH Article 75) [emphasis added].

The need for a consistent approach means that individual Member States cannot carry out their activities with respect to monitoring and inspection of REACH and CLP in isolation from that of other Member States and the Commission -- hence the importance of the ECHA's Forum for Exchange of Information on Enforcement, charged with coordinating the network of Member States authorities responsible for enforcing REACH. It is therefore important to consider whether national-level monitoring and inspection of REACH and CLP has been sufficiently consistent across all Member States to achieve the objective of establishing a well-functioning internal market.

Voluntary actions versus binding legal requirements

As already noted, the Forum is the primary vehicle for coordinating REACH and CLP monitoring and inspection activities across the Member States. To date, these activities have been voluntary, including development of the "Minimum Criteria for Inspection" and the "Strategies for enforcement" document, and managing the REACH-EN-FORCE-1 and EN-FORCE-2 projects. Forum members have indicated the possibility of further development of these documents, and have mentioned that some of the ideas set forth in the strategy document prepared for this study and included as Annex I could be considered.[68]

Of course, uptake at Member State level of these voluntary standard-setting efforts depends on the capacity of the Member State inspectorate, including the individual efforts of the Member State official participating in Forum activities. Individual Member States can promote consistency, e.g., by sharing their own experiences with other Member States at conferences, by supporting exchanges of officials in order to provide a first-hand view of national inspection practices, or by inviting outside audits of their national enforcement/inspection practices (IMPEL has had some success with this).

In addition, voluntary uptake of non-binding EU-level instruments can be enhanced through various means, such as provision of more detailed guidance – particularly on technical aspects of REACH implementation, such as additional Exposure Scenarios for specific industrial processes[69] -- or availability of financial support.

However, the ten-year effort to upgrade Member State inspection and enforcement practices with respect to industrial installations through the RMCEI has had only limited results. As a consequence, some of the voluntary recommendations set forth in the RMCEI are now incorporated into the 2010 Industrial Emissions Directive as **binding** provisions.

Given that the REACH and CLP Regulations are still not yet completely implemented, it may well be too soon to determine whether binding provisions on monitoring and inspection are required to achieve the necessary degree of harmonisation and consistency to ensure the internal market. However, the issue should be kept in mind over the next few years, and a more ambitious study on REACH and CLP inspection and enforcement carried out in the future to determine whether binding requirements are in fact needed.

The basis for the enforcement action

As already discussed, and as set forth in the "Minimum Criteria for REACH and CLP inspection" adopted by the Forum, a number of bases for an enforcement activity are possible. These include:

- Frequency of inspections (ad-hoc, reactive, fixed time interval, based on prioritisation);
- Level of pro-active inspection/enforcement;
- Level of re-active inspection/enforcement;
- Use of prioritisation based on hazard/risk (e.g. based on rating of past inspections, tonnage levels, hazardous substances used (e.g. SVHCs), known issues (e.g. REACH dossier rejected, pre-registration but no registration, accident), volume of substance(s) used, type of industrial activity (c.f. IPPC) or risk assessment on site-by-site or area basis); and
- Use of prioritisation based on specific issue (e.g. SVHC, SVHCs in articles, C&L notification, compliance with authorisation provisions, within restriction constraints, compliance of SDS).

To be used in practice, the Member States will have to accept these criteria into their inspection programmes with a possible cost, including diversion of resources from other priorities. Some MS may approach the integration with more enthusiasm than others so how the criteria are implemented

[68] Comments on the Draft Final Report received from Austria and Norway.

[69] E.g., the ECHA Guidance mainly for Industry Use document on *Exposure Scenarios for the Semiconductor Industry Examples*, available at http://echa.europa.eu/documents/10162/17234/es_project_document_v5.pdfl

will have an effect on their success. This implementation could take several forms from voluntary implementation to incorporation of criteria into one form of legislation or another.

In developing the options for legislative changes discussed in the next section, care was taken to identify those aspects of inspection where criteria could be developed to show a range of ambition levels. This was considered fundamental to carrying out a meaningful impact assessment. The following criteria were therefore selected for further analysis:

- Frequency of inspection
- Surprise visits;
- Programme of inspections; and
- Training.

Each of these criteria could be considered procedural in nature, though risk analysis would clearly be useful in determining frequency of inspection, whether desk-based or site-based, and in developing the programme of inspections.

The impact assessment provided in the next section of the Report provides more details concerning the specific criteria used for the three levels of ambition assessed, Option 1 being the low ambition proposal, Option 2 being the medium ambition proposal, and Option 3 representing the high ambition proposal.

5. Options for new legislative requirements and assessment of their benefits

5.1. Introduction

5.1.1. Introduction to the impact assessment

In August 2010, the Forum published the Project Report of REACH-EN-FORCE-1[70] containing the results of inspections that had taken place in 1,600 companies in 25 Member States of the EEA in the period May-December 2009. The goal of the project was to verify the compliance of manufacturers and importers of substances with REACH obligations on the (pre)registration and Safety Data Sheets (SDSs)[71].

Non-compliance with REACH obligations was observed in 24% (378) of the inspected companies with the majority of such cases concerning SDS provisions (293).[72] The study also concluded that 'it is unlikely that especially SMEs will be able to comply with the registration obligations, mainly due to the lack of material resources and information'.

Although the above figures are not discouraging, the onus is on inspecting activities to prove that they can deliver the benefits on increased compliance. This impact assessment examines different legislative options in order to improve compliance with the REACH and CLP Regulations and examines the costs and benefits of these options.

5.1.2. Objectives for the impact assessment

The following list of key objectives with respect to future policy in relation to REACH and CLP enforcement provides the framework against which to assess the options in terms of effectiveness and efficiency:

1) To secure and strengthen proper implementation and enforcement of the Regulations;
2) To ensure a level playing field within the internal market, including an equivalent and consistent level of enforcement activities across Member States;
3) To ensure the protection of human health and the environment;
4) To minimise the operating cost and administrative burden of REACH enforcement activities on Member State authorities and industry commensurate with the need to ensure protection of health and the environment;
5) To ensure the effective coordination of enforcement activities within Member State authorities and then across Member State authorities.

Following the principles of the Smart Regulation,[73] the aim will be to make recommendations as to the policy option that generates the greatest benefits without disproportionate costs.

5.1.3. Options for new legislative requirements

For the purpose of the impact assessment, three levels of inspections-related legislative requirements were developed, covering the following broad categories:

- Frequency of inspection (by operator type and by type of inspection, i.e. desk-based versus site-based);
- Surprise visits;

[70] REACH-EN-FORCE-1, Results of the Forum coordinated REACH enforcement project on registration, pre-registration and safety data sheets, August 2010 (REACH-EN-FORCE-1).
[71] *Ibid*, p. 3.
[72] *Ibid*, p.2 and 6.
[73] From Better to Smart Regulation in the European Union: http://ec.europa.eu/governance/better_regulation/key_docs_en.htm. .

- Programme of inspections; and
- Training.

Other categories were considered for inclusion, such as "sufficient powers of the inspectors" (namely legal rights to access the site unannounced, to take samples etc.), and "sufficient staff and resources", however, these categories were not taken further in the assessment. The reasons for this were that, from the information gathered, it appears that in the case study countries inspectors already have sufficient powers to perform a full inspection and investigation process.[74] With regard to the second category (i.e. requiring Member States to have sufficient staff and resources), it was considered that having sufficient staff and resources is inextricably linked to the proportion of duty holders inspected: having a requirement to inspect a certain proportion of duty holders would automatically require a certain number of staff and resources, in order to ensure that the targets are met.

The options selected for the assessment are within the scope of the minimum criteria developed by the Forum. As mentioned in Section 4.3, they are based on three different levels of ambition: low, medium and high. These are designed to be consistent and coherent, with criteria becoming increasingly stringent from the low ambition to the high ambition proposal. For example, the proportion of duty holders subject to inspection is greater in option 3 than in option 2 and greater in option 2 than in option 1. The key assumption is that increasing the frequency of the inspections and their coverage will result in significantly higher levels of compliance. The low ambition option is designed not to place too much pressure on the duty holders and to leave a higher level of discretion to the Member States Competent Authorities. The medium and high ambition options aim to ensure a strong and effective enforcement system throughout Europe, making it uniform to guarantee a fair playing field within the internal market to the actors across the different Member States, including an equivalent level of enforcement.

Option 1: Low Ambition Proposal

The table below sets out the different requirements under option 1.

Table 13: Low Ambition Proposal

Proportion of manufacturers and importers inspected per year (desk based and on-site)	10% overall but Member State discretion concerning ratio of site-visits to desk-based inspections.
Proportion of formulators inspected per year (desk based and on-site)	5% overall but Member State discretion concerning ratio of site-visits to desk-based inspections.
Proportion of distributors inspected per year (desk based and on-site)	5% overall but Member State discretion concerning ratio of site-visits to desk-based inspections.
Frequency of inspection if non-compliance suspected	100% (100% of which to be site-visits)
Surprise visits	50% (100% of which to be site-visits)
Programme of inspections	Member State discretion concerning programme of inspection
Training	Initial training and email updating

Option 1 requires 10% of manufacturers and importers and 5% of distributers and formulators[75] to be inspected on an annual basis. Member States are given discretion regarding the programme of inspection and the ratio of site-visits to desk-based inspections. However, of the site-based inspections that take place, option 1 requires 50% to be surprise visits. In all instances where non-compliance is suspected, option 1 requires a site-based inspection to be carried out.

[74] See Section 3.3, p.44.

[75] As providing an estimate of industrial and professional end users of chemicals as defined by REACH would be very difficult, and given that formulators are the downstream users holding major duties in this first phase of REACH, objectives were set up just for formulators.

Training is required under option 1 but only on uptake of the post, with email updating at regular intervals thereafter.

Option 2: Medium Ambition Proposal

The table next page sets out the requirements under option 2.

Table 14: Medium Ambition Proposal

Proportion of manufacturers and importers inspected per year	Site-based	2%
	Desk-based	18%
Proportion of formulators inspected per year.	Site-based	0.5%
	Desk-based	9.5%
Proportion of distributors inspected per year.	Site-based	0.5%
	Desk-based	9.5%
Frequency of inspection if non-compliance found		100% (100% of which to be site-visits)
Surprise visits		50% (100% of which to be site-visits)
Programme of inspections		In-depth assessment of prioritized sites plus 5% of other companies.
Training		Initial training with annual refreshment

Option 2 requires 20% of manufacturers and importers to be inspected on an annual basis. Of the 20% of manufacturers and importers that are inspected, 10% should be site-based inspections and 90% should be desk-based

Under option 2, 10% of formulators would be inspected each year with 10% of inspections on formulators being site-based. The remaining 90% of inspections on formulators would be desk-based.

As with option 1, a site-based inspection should be carried out in all cases where non-compliance is found. Of the site-based inspections that take place, option 2 requires 50% to be surprise visits.

Under option 2, Member States would be required to perform an in-depth inspection of the prioritised sites (in terms of risk, history of compliance, etc.) plus 5% of the other companies. An in-depth inspection would comprise a full assessment of the quality, correct nature and completeness of the documentation, going beyond a formal check of the requirements. For instance, an in-depth inspection would look at the accuracy of the exposure scenarios, including:

1) Where exposure scenarios indicate considerable exposure to certain populations, including environment
2) Where exposure scenarios do not seem plausible (e.g., some claims of zero emissions);
3) Where information on sector-specific uses seem particularly weak.

It would also include a general appraisal of the likelihood of non-compliance by the duty holders/ target groups with REACH and/or CLP requirements, taking into account factors such as previous inspection records and potential future risks.

Under option 2, non-routine site-based inspections would need to be carried out following serious environmental complaints, serious environmental accidents, incidents and occurrences of non-compliance, as well as when issuing first authorisations, permits and licences, and when these are reissued, renewed or modified.

Option 2 also requires inspectors to participate in a more rigorous training regime than option 1. Under Option 2, training would be required on uptake of the post and then on an annual basis thereafter.

Option 3: High Ambition Proposal

The table next page sets out the requirements under Option 3.

Table 15: High Ambition Proposal

Proportion of manufacturers and importers inspected per year	Site-based	4%
	Desk-based	26%
Proportion of formulators inspected per year.	Site-based	1.5%
	Desk-based	13.5%
Proportion of distributors inspected per year.	Site-based	1.5%
	Desk-based	13.5%
Frequency of inspection if non-compliance found		100% (100% of which to be site-visits)
Surprise visits		50% (100% of which to be site-visits)
Programme of inspections		In-depth assessment of prioritized sites plus 10% of other companies.
Training		Initial training with continual professional development (CPD)

Option 3 requires 30% of manufacturers and importers and 15% of formulators to be inspected on an annual basis.

Of the 30% of manufacturers and importers that are inspected, 20% of inspections would be site-based. Ten percent of inspections on formulators should be site-based. As with the previous options, a site-based inspection is required in all cases of non-compliance. Of the site-visits that take place, 50% should be unannounced.

Under option 3, Member States would be required to perform in-depth inspection of the prioritized sites plus a further 10% of other companies.

Formal training would be required on uptake of the post with Continual Professional Development (CPD) undertaken thereafter. In this context, CPD would consist of formal educational activities aimed at maintaining, developing and increasing the professional performance of inspectors.

5.2. Approach to the Impact Assessment

5.2.1. Overview

This Impact Assessment follows the European Commission's Impact Assessment Guidelines, as revised in 2009, and is based on a case study approach. As already mentioned in Section 3, the different countries chosen as case studies were selected in agreement with the Commission services and are expected to reflect the spectrum of compliance levels across the EU.

For each of the case study countries, and for each of the policy options, an initial screening exercise has been carried out to qualitatively assess the performance of each option relative to 'the baseline'. For the purposes of this study, the baseline describes the current inspection and enforcement activities in the case study countries and assumes that current practice in each of the Member States will continue. It has been established based on the following sources of information:

- Data from the Member States reports on the current implementation of REACH;[76]
- Consultation with the Competent Authorities within the Member States (case studies interviews and questionnaires);
- A review of national level legislation pertaining to REACH and CLP enforcement and inspections;
- Information gathered through literature review.

While the Member States reports data are available for the years 2007, 2008 and 2009, there is considerable variability in the data between years. Given this variability, it was decided by the consultant to take 2009 as the baseline year for the impact assessment, rather than average data. In some cases, data from the Member States reports have been supplemented or replaced by information provided by the country experts specifically for this study (as this information was deemed to be more reliable). The data used for the impact assessment can be found in Annex IV to the Report.

For the initial screening exercise, a simple rating system has been used to record the likely impacts, with ratings defined as shown in Table 16.

Table 16: Rating system used for initial screening exercise

++ :	Very significant increase/positive change/benefit
+ :	Slightly significant increase/positive change/benefit
0 :	No change/no benefit
+/- :	Positive and negative impacts balance out or are uncertain
- :	Slightly significant decrease/negative change/damage
-- :	Very significant decrease/negative change/damage
N/A :	Impact type not relevant to this option

Following an initial screening exercise (and where data were available), the potential impacts of each option have been quantitatively assessed. Again, data from the Member States reports, information provided in the country fiches and information gathered through literature review were used to carry out this exercise. Where data were not available, assumptions have been made to try to assess the likely impacts of the policy options. The consultant's key assumptions are outlined fully in Section 5.2.4.

5.2.2. Groups affected

The initial screening exercise has identified the following as the main groups affected by the proposed options:

- Member States competent authorities and enforcement bodies who will be responsible for carrying out inspections;
- REACH/CLP duty holders (i.e. manufacturers, importers, distributers and downstream users of chemical substances) who will be inspected;
- The public who may benefit from greater industry compliance with REACH/CLP in terms of human health and the environment; and
- The environment which may benefit from a reduction in emissions of harmful substances due to greater industry compliance with REACH/CLP.

[76] REACH Art.117 reports

5.2.3. Impacts considered

The table below sets out the main impacts considered under this impact assessment. They are further described in points a) to d).

Table 17: Main impacts by stakeholder

Economic Impacts	Environmental Impacts	Social Impacts
- For Member States Competent authorities • Administrative Costs from changes in number and level of inspections, including reporting requirements; • Policy costs from developing strategies; • Legal costs from non-compliance; • Changes in revenues from increased/reduced fines. **- For REACH duty holders:** • Administrative costs for inspection preparation; • Legal costs from non-compliance; • Reduced /increase level of fines. **- Competition in the internal market;** **- Competitiveness.**	Benefits from increased compliance (controlled emissions and waste management).	• Occupational health benefits from increased compliance; • Public health benefits from reduced exposure through the environment and consumer product (also through C&L); • Impact on employment.

a. Member States competent authorities and enforcement bodies

In terms of costs, the most significant impact on Member States competent authorities and enforcement bodies will be direct administrative costs associated with carrying out inspections.

Administrative costs will include:

- Costs associated with carrying out desktop studies;
- Costs associated with carrying out site-visits;
- Costs of reporting;
- Costs associated with creating new posts in the enforcing authorities, when needed; and
- Training costs.

It is difficult to make generalisations regarding the cost of an 'average' inspection as the time taken to carry out an inspection will vary considerably depending on individual circumstances. The cost of an inspection may also vary according to the level of non-compliance found (for example, Defra 2008 have stated that registration and supply-chain related enforcement costs more on a case-by-case basis than use related enforcement). Equally, there are likely to be differences in the cost of a desk-based inspection compared to a site-visit, with site-visits likely to cost relatively more due to the additional time and resources needed to visit a duty holder (e.g. cost of travel) compared to carrying out an inspection remotely.

Usually REACH related inspections are carried out alongside other enforcement activities with this removing the need for a separate inspection regime. For example, in the UK, REACH inspections are carried out alongside wider enforcement of Health and Safety at Work and Consumer Safety legislation. As a result, the cost of a REACH inspection is embedded within the cost of other inspections and so the marginal cost of a REACH inspection is relatively small.

In terms of training costs, there will be time and resources costs associated with the training of inspectors as well as costs associated with the preparation and dissemination of training materials. There will also be an opportunity cost associated with the time for inspectors to undertake training.

Under option 1, Member States competent authorities and enforcement bodies will also carry the burden of compliance costs associated with developing a strategy for visits (although it is likely that they will continue to follow the strategy of the Forum where they are already doing so, or continue to use their own strategy where they are not).

Given the concentration of duty holders in some Member States, administrative burdens may vary considerably across Member States. For example, the administrative burden on Germany is likely to be considerably higher than on Slovenia. As an aside, it may be important to consider that administrative burdens could vary across regions within a Member States, given the concentration of duty holders in some areas. For example, in the UK, the administrative burden might be greater in the North West and East, as both regions account for more than 20% of UK total turnover from the manufacture of chemicals, chemical products and man-made fibres.[77]

Other indirect costs and benefits will include those related to the legal costs and fines associated with non-compliance. For example, Member States may face a change in legal costs associated with punishing non-compliance. Legal costs may increase if more cases of non-compliance are found due to an increase in the frequency of inspection; conversely legal costs may decrease if the threat of inspections encourages more firms to become compliant (reduced cost associated with court cases for infringement). The impact of a change to the REACH/CLP inspection regime on legal costs is therefore uncertain. Similarly, the impacts of the level of fines and lost revenue are difficult to estimate with accuracy. As a result, it has not been possible to quantify such costs here.

In terms of benefits, EU-wide inspection standards could level the playing field between Member States, thereby making conditions of competition more equal. This may have benefits in terms of the functioning of the internal market.

b. REACH duty holders

The costs of a regulation are usually divided into two types:

- Policy costs are the costs stemming from the substantive requirements of the legislation, the costs incurred by businesses in meeting the aims of the regulation; for instance, the costs deriving from testing the substances to collect data about their safety are policy costs;
- Administrative costs are those costs incurred by enterprises in meeting legal obligations to provide information on their activities, either to public or private parties *(CEC, 2011).*[78]

Furthermore, it is important to distinguish between administrative costs and administrative burdens, the latter being the costs generated by the collection of information that would not been collected by an entity in the absence of the legislation: for instance, the costs in terms of time or money spent filling in a form for a desktop based inspection or showing an inspector around a facility during a site visit is an administrative burden.

The administrative burden to business associated with a REACH/CLP inspection will include both the cost of preparing for the inspection (e.g. gathering relevant documents, checking systems are up to date) as well as the cost of the inspection itself. This will take into account the time taken for a business to show the inspector(s) that the chemicals being used by the business have been registered (where this is required by the Regulation), that safety datasheets have been issued or received where required, or that chemicals are not being used outside the conditions of a restriction or authorisation. At the level of the individual firm, the time taken to prepare for an inspection will vary according to business type and individual circumstances.[79] However, it can be assumed that a desktop inspection will require only minimal input in terms of time and resources from a company and that a site-based

[77] Defra 2008.
[78] Definition from CEC Better Regulation, available at: http://ec.europa.eu/governance/better_regulation/glossary_en.htm#_g_admin_costs.
[79] Defra 2008.

inspection will only take-up a couple of days of time for a manager or skilled employee to prepare documentation and show the inspector around the facility/site.

It could be expected that the time taken to prepare for an inspection and the length of the inspection itself is likely to reduce over time as businesses become increasingly familiar with the process. As a result, the administrative burden on businesses is likely to reduce over time.

It is important to recognise, however, that any increase in compliance costs or information obligations is likely to have a disproportionate impact on SMEs. SMEs will have a smaller number of employees and, as a consequence, a higher level of human resources may be required to prepare for or deal with an inspection. Given the large number of SMEs within the chemicals sector, this distributional impact should be an important consideration.

Firms have an incentive to comply with REACH (and CLP) due to the risk of punitive measures, criminal sanctions and the risk of damage to their corporate reputation.[80] Should a company be found to be non-compliant, they are likely to be subject to more rigorous investigation in the future, due to the risk-based approach to inspections used in most Member States. As a result, it is likely that they would face additional administrative costs associated with further dealings with the enforcing authority (potentially including further inspections) and potentially prosecution. The fear that they may be inspected may also increase compliance levels. The impact on the cost of prosecution and related legal expenses is thus difficult to estimate with accuracy.

In terms of the costs/benefits of a surprise visit versus an announced inspection, although surprise inspections could act as a greater deterrent against non-compliance, it has been commented by the country expert for the UK that the nature of REACH inspections does not allow non-compliant operators to achieve compliance within the short time period of the notice. Thus, the benefit of carrying out a surprise inspection may not be any greater than that of carrying out an announced inspection. It is likely therefore that an announced inspection would be relatively less costly (both for a company and for an enforcing authority) as the company would have time in advance to ensure that the necessary documentation is available, complete and ready to be checked.

Assuming that a higher frequency of inspection leads to a greater level of compliance, duty holders might benefit from an improvement in the chemical industry's reputation and an improvement in public attitudes (and attached values) about chemicals and the chemicals industry (linked to a perceived higher degree of safety).[81] This impact is difficult to estimate with accuracy.

c. The public and the environment

Industry compliance with REACH and CLP should bring about benefits to workers and the public more generally in terms of health benefits. Health benefits (and associated economic benefits) accruing to an increase in the frequency of REACH inspections can be broadly divided into two:

- Occupational impacts: Reduced occupational exposure to harmful substances and fewer instances of occupational disease; and
- Public Impacts: Reduced risk to / exposure of the general public to harmful substances via the environment (e.g. through inhalation of air, consumption of food, or through drinking water); from use of consumer products and/or increase control on waste management activities.

In addition, there could be benefits to the environment in term of increased compliance and reduction of emissions of harmful substances (from production processes or from the use or disposal of chemical substances) and waste control. Examples of environmental impacts associated with emissions of harmful substances are numerous and include:

- Impacts on water quality (including surface and groundwater);

[80] Ibid.
[81] Ibid.

- Impacts on soil quality; and
- Impacts on biodiversity, flora and fauna.

The benefit to the environment and human health from a change to the REACH/CLP inspection regime will depend on current levels of non-compliance in each Member State. In countries where all duty holders are already fully compliant with REACH and CLP, the benefits of an increase in the frequency of inspection would be negligible. In countries where non-compliance remains, the benefits will be greater. The human health and environmental impacts arising from changes to the inspection regime are difficult to quantify however. Ideally, an approach to assess the human health and environmental benefits under options 1, 2 and 3 would require:

- Estimation of the extent of chemicals-related damage subject to control under REACH/CLP;
- Development of assumptions regarding the impact of REACH/CLP in preventing that damage and of proportion of such impact from inspection and enforcement activities under each Option;
- Compilation of damage costs – for example, based on a combination of actual costs (e.g. costs already incurred, costs of curing disease or of remediating the environment), assumed average costs (e.g. monetised costs of lost productivity resulting from a physically impaired workers) and other derived (virtual) costs (e.g. willingness to pay values, QALYs and DALYs to assign value to individual damage to health or environment);
- Multiplication of damage prevented with damage costs; and
- Extrapolations to the EU level from individual cases or substances to all chemicals on the market or all chemicals-related damage subject to control under REACH and/or CLP.

The level of benefits will depend on the type of non-compliance prevented, i.e. provision of SDS. However, data are not available to quantitatively assess the environmental and human health benefits of a change to the REACH/CLP inspection regime. For example, data are not available in many cases to assess the cause-effect relationship between exposure to harmful substances and impact on the environment or human health and quantification of damage costs in monetary terms is extremely difficult.

d. Other social elements

In addition to environmental and human health benefits, there are also likely to be wider social impacts associated with the implementation of the three options described above. These include:

- Employment effects – job creation/loss/redistribution within Member States competent authorities and enforcement bodies. In relation to the three Options described above, the impacts on employment are highly uncertain;
- A change in standards and rights related to job quality associated with training. Again the impacts in relation to the three Options described above are highly uncertain;

Finally, given that duty holders are concentrated in particular Member States or particular areas within Member States, there may be distributional (geographic) implications associated with implementing any of the options described above. This will be investigated through the case study countries.

5.2.4. Key Assumptions and Limitations

The main assumption here concerns the Member States response to an option less stringent than the current baseline. It is important to recognise that there is a risk that by implementing an option that is less stringent than the baseline, that Member States will scale-back their efforts with regard to REACH and CLP inspections. This could lead to an increase in cases of non-compliance with implications for the environment and for human health. The impact assessment undertaken for this study assumes that Member States will not respond in this manner. Instead, it is assumed that Member States will continue 'business-as-usual' in response to the new requirements introduced by the EU when these are less stringent that current practices in the Member States.

In addition, because the benefits of inspections alone are difficult to estimate with accuracy based on current data, the costs of the option are compared against the benefits of REACH as reviewed in the literature (see Section 5.3.5).

Administrative burden (enforcers and duty holders)

Following EC (2009) guidelines, baseline administrative costs have been assessed by multiplying the average cost of an inspection (P) by the total number of inspections performed per year (Q). Where the cost of an inspection is not known but where an indication has been given of the number of person-days required to undertake an inspection, the average cost per inspection has been estimated by multiplying a daily tariff (based on the standard hourly tariffs as specified by the EU for the calculation of administrative costs in the context of the Action Programme for reducing administrative burdens 2008-2009) by the number of person-days required to undertake the inspection. For this calculation, the assumption has been made that a working day constitutes 7.5 hours.

> Σ P x Q (Price = daily tariff x person-days; Q: Quantity = number of inspections carried out each year).

Given that the hourly tariff specified for the calculation of administrative costs in the context of the Action Programme for reducing administrative burdens 2008-2009 is the same for a REACH/CLP inspector as it is for other 'professionals', and given that inspectors and duty holders are likely to spend approximately the same amount of time preparing for and participating in an inspection, it is assumed that the total cost of inspections is the same for enforcing authorities as it is for duty holders.

Compliance

The main aim of a REACH/CLP inspection is to ensure that companies are complying with the Regulations in order to ensure that the negative impacts of harmful substances are avoided. The main benefit of an inspection is that it makes a company more likely to comply with REACH and CLP either due to actual enforcement, or due to the threat of enforcement (with inspections, particularly surprise inspections, acting as a deterrent).[82]

A key assumption in this assessment is that a higher inspection frequency will lead to a greater level of compliance. This assumption is supported by evidence from the literature which shows that significant increases in compliance rates can be achieved as a result of an effective enforcement regime.[83] However, it is difficult to say the level of increase in compliance with accuracy. Baseline levels are a good indicator of current compliance and the potential for increase. This is likely to change across the Member States but quantification is unlikely to be possible.

Environmental and Human Health Impacts

Although it is not possible to value the environmental and human health impacts associated with a change to the REACH and CLP inspection regime, it is assumed that a greater level of compliance with both the REACH and CLP Regulations would lead to reduced risk to the environment and human health. In countries where all duty holders are already fully compliant with REACH and CLP, the benefits of an increase in the frequency of inspection would be negligible. In countries where the level of compliance is more limited, the benefits will be greater but still difficult to estimate with accuracy.

Number of duty holders

For the analysis of the baseline in each one of the six Member States selected for the study, different datasets were compared and combined:

[82] Defra 2008
[83] Ibid.

- EUROSTAT Structural Business Statistics[84];
- Figures and estimates from experts in the different Member States Competent Authorities;
- Data from the Member States reports on the current implementation of REACH.

To setup an objective in terms of frequency/proportion of duty holders to be inspected every year, it is essential to know the number of duty holders in the different countries. The main problem is to avoid the double counting of the different actors playing a role during the life-cycle of a substance (manufacturers and/or importers, downstream users (formulators, industrial end-users, professional end-users), distributors and consumers). It is common for a manufacturer of basic chemicals to also be importing other substances, distributing as a distributor and producing chemical products as a formulator. Data on the number of such duty holders are not available at national level and so a set of assumption is needed to proceed with an estimate.

To estimate the number of manufacturers who are likely to be registrants of substances, the NACE codes showed in the table below were selected.

Table 18: Rev. 2 NACE codes considered to estimate the number of manufacturers

C19.20: Manufacture of refined petroleum products
C20.11: Manufacture of industrial gases
C20.12: Manufacture of dyes and pigments
C20.13: Manufacture of other inorganic basic chemicals
C20.14: Manufacture of other organic basic chemicals
C21.10: Manufacture of basic pharmaceutical products
C23.14: Manufacture of glass fibres
C23.20: Manufacture of refractory products
C23.5: Manufacture of cement, lime and plaster
C23.9: Manufacture of abrasive products and non-metallic mineral products n.e.c.
C24.10: Manufacture of basic iron and steel and of ferro-alloys
C24.41: Precious metals production
C24.43:Lead, zinc and tin production
C24.44: Copper production
C24.45: Other non-ferrous metal production

There are other NACE codes where it is possible that some companies will have to register some substances resulting from their manufacturing process (for example: C10 Manufacture of food products, C11.01 Manufacture of distilling, rectifying and blending of spirits) but in order to be conservative in the estimates, they were not considered here. Registrants could also be manufacturers of articles containing substances in quantities totalling over 1 tonne per producer per year, but no data were found to provide a basis for an estimate.

The table below shows the NACE codes considered to estimate the number of distributors.

Table 19: NACE codes considered to estimate the number of distributors

G46.71 Wholesale of solid, liquid and gaseous fules and related products
G46.72 Wholesale of metals and metal ores
G46.73 Wholesale of wood, construction materials and sanitary equipment
G46.75 Wholesale of chemical products
G46.76 Wholesale of other intermediate products
G46.77 Wholesale of waste and scrap

[84] http://epp.eurostat.ec.europa.eu/portal/page/portal/statistics/search_database

Also for the distributors, there are other NACE codes where companies will have duties under REACH or CLP, so that the figure used here will be an underestimate.

The number of only representatives in relation to imported substances is assumed to be 6% of the sum of number of manufacturers and number of companies in the wholesale of chemical products based on information from REACH-EN-FORCE-1.[85]

To estimate the number of downstream users, the assumption is that the inspections and investigations in this first phase of the implementation of REACH and CLP have been addressed to the formulators and not to the industrial and professional end-users. The formulators have in fact major duties regarding information up and down the supply chain, providing the manufacturers and the importers with exposure scenarios for some uses of the substances and providing the industrial and professional end-users with the Safety Data Sheets. Industrial and professional end-users will have to check the Safety Data Sheets and implement the recommended Risk Reduction Measures.

Table 20: NACE codes considered to estimate the number of formulators

C20.15 Manufacture of fertilisers and nitrogen compounds
C20.16 Manufacture of plastics in primary forms
C20.17 Manufacture of synthetic rubber in primary forms
C20.20 Manufacture of pesticides and other agrochemical products
C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics
C20.41 Manufacture of soap and detergents, cleaning and polishing preparations
C20.42 Manufacture of perfumes and toilet preparations
C20.51 Manufacture of explosives
C20.52 Manufacture of glues
C20.53 Manufacture of essential oils
C20.59 Manufacture of other chemical products n.e.c.
C20.60 Manufacture of man-made fibres
C21.20 Manufacture of pharmaceutical preparations

The table above shows the NACE codes considered for the (conservative) estimate of the number of formulators.

To provide a figure for the number of industrial and professional end-users would be a very difficult exercise, since all the companies in the manufacturing and construction sectors are likely to belong to those categories.

Table 21 shows the number of duty holders in the different countries, estimated by summing the number of enterprises classified by NACE codes in 2009 from the Eurostat database. Where data for 2009 were no available, 2008 data were considered[86].

Table 21: Estimated number of duty-holders in the case study countries

	BG	FR	DE	SL	SE	UK
No. of duty-holders[87]	7,240	20,341	19,636	1,014	9,153	17,482
No. of manufacturers	433	1,291	2,593	107	438	1,506
No. of importers	77	228	275	14	68	187

[85] 6% is the percentage of "pure" importers on the total number of visited companies that was found during the REACH-EN-FORCE-1 project. ECHA (2010): *Results of the Forum coordinated REACH enforcement project on registration, pre-registration andsafety data sheets*, Forum for the Exchange of Information on Enforcement, 2010, pag.6

[86] This is especially the case of France, where most of the data were available for 2008. This could lead to an overestimate of the number of duty-holders in comparison for example with Germany, considering that between 2008-2009 the crisis was reflected by a decreasing in the number of companies across all the sectors.

[87] These numbers do not consider industrial and professional end users.

No. of formulators	499	2,966	3,219	147	761	2,725
No. of distributors	6,231	15,856	13,549	746	7,886	13,064

As already stated, a unit may perform one or more economic activities described in one or more categories of NACE. The principal activity of a unit is the activity which contributes most to the total value added of that unit. Setting an objective in terms of frequency for manufacturers, for example, will catch exclusively the units classified as manufacturers of basic chemicals (and of the other categories identified) but will leave out those units where the principal activity is, for example, the manufacture of other chemical products, even if part of their activity is the manufacturing of basic chemicals. This is a limitation of setting up frequency of inspections by categories. It has to be noted however, that where a formulator is also a manufacturer of basic chemicals, the inspection should look at the requirements for registration and the other duties for manufacturers. Regarding the limitations of the classification by activity we refer to the Eurostat document about the methodology of NACE Rev. 2[88].

Number of inspections

The Member States Reports for each case study countries provide information on the total number of inspections and investigations carried out by enforcing authorities in which REACH was discussed and/or enforced in 2009. The data provided in the Member States Reports are likely to overestimate the total number of REACH and CLP inspections however, as a discussion on REACH/CLP during an inspection could have lasted only a couple of minutes, rather than being the sole focus or main focus of the inspection.

In order to provide a more accurate estimate of the total number of inspections/investigations carried out in each of the case study countries, data were taken on the total number of manufacturers/importers, distributors and downstream users subject to inspection/investigation in 2009 and it was assumed that each duty holder was inspected only once. It should be recognised that some duty holders may have been subject to inspection/investigation on more than one occasion (for example, where non-compliance was detected on the first inspection) however it is assumed that it is more common for a duty holder to be only inspected once in any given year.

To estimate the total number of inspections/investigations on manufacturers and importers in 2009, the consultant has added the total number (i.e. 100%) of manufacturers subject to inspection/investigation in 2009 to 6% of the total number of importers subject to inspection/investigation in 2009. The reason for this being that REACH-EN-FORCE-1 found that 6% of importers are only representatives[89].

5.3. Impacts of the options

5.3.1. Baseline

As a starting point for the impact assessment, national legislation pertaining to REACH and CLP in each of the case study countries was assessed together with information provided in the countries case studies and data from the REACH Art. 117 Member States Reports. From these sources of information the baselines for each of the case study countries have been established. The baselines are outlined in Table 22. A full description of the data sources and assumptions used to complete this table can be found in Annex IV to this report.

http://circa.europa.eu/irc/dsis/nacecpacon/info/data/en/NACE%20Rev%202%20structure%20+%20explanatory%20notes%20-%20EN.pdf.

[89] 6% is the percentage of "pure" importers on the total number of visited companies that was found during the REACH-EN-FORCE-1 project. ECHA (2010): *Results of the Forum coordinated REACH enforcement project on registration, pre-registration andsafety data sheets*, Forum for the Exchange of Information on Enforcement, 2010, p.6.

As shown in Table 22, there is a significant degree of variability across the case study countries with regard to the percentage of duty holders subject to inspection each year. In Bulgaria, for example, the authorities reported that 100% of formulators were inspected in 2009, whereas in the UK, only 4% of formulators were inspected. Such difference could stem from the Member State reports on the current implementation of REACH, where Competent Authorities reported the number of inspections performed on downstream users, without any distinction between formulators, professional and industrial end users. In the lack of better data, the consultants assumed that 100% of those inspections were performed on formulators. The assumption is justified by the Work Programme 2011-2013 of the Forum[90], focusing now on formulators of mixtures and foreseeing the inspectors to raise awareness regarding the obligations of the downstream users with relation to the Extended Safety Data Sheets. Regarding the high figure for Bulgaria, it seems to be justified by the habit to check the same facility is at least once per year, either by a site visit or via a desktop inspection[91].

The high difference between the number of inspections in Germany and United Kingdom stems from the different strategy they implemented: while the authorities in Germany, even without setting a minimum amount of inspections to be performed, proceed with an extensive enforcement campaign, the authorities in UK focus on particular substances or topics. In their view this approach strikes the best balance between effective enforcement of REACH while ensuring minimal regulatory burden on compliant companies.

In both the UK and in France all suspected cases of non-compliance are investigated and in France any complaint, accident or evidence of pollution is likely to lead to an inspection soon thereafter. For the UK, however, there is uncertainty as to whether a site-visit takes place in all cases where non-compliance is suspected, although it is assumed that this is likely to be the case.

To date, surprise visits have not been undertaken in the UK or in Sweden. The reason for this in the UK being that the nature of REACH inspections does not allow non-compliant operators to achieve compliance within the short time period of the notice and so the benefit of carrying out a surprise inspection may not be any greater than that of carrying out an announced inspection (although it could be argued that the threat of an unannounced inspection may lead to a greater level of compliance). In Slovenia, the country study has indicated that surprise inspections take place in around 5% of cases. There was not sufficient information to determine whether surprise inspections are carried out in the other case study countries.

In all six Member States, the programme of inspections is tailored according to risk, with all six Member States following the strategy devised by the Forum.[92]

The country studies indicated that inspectors regularly participate in training activities (e.g. projects, programmes, seminars etc). In the UK, Germany and France, it appears that training is carried out in conjunction with other training activities and training activities differ across the different inspection bodies (e.g. in France training for labour inspectors tends to focus on workers issues in REACH).

Table 22: Baseline

	BG	FR	DE	SL	SE	UK
No. of manufacturers and importers inspected	167	309	387	19	12	80
Percentage of manufacturers and importers inspected per year	33%	20%	13.5%	16%	2%	4.5%

[90] http://echa.europa.eu/doc/about/organisation/forum/forum_work_programme_2011-2013.pdf.
[91] As stated at page 38 of this report.
[92] Information from Member States Report.

	BG	FR	DE	SL	SE	UK
No. of formulators inspected per year	499	216	960	99	60	122
Percentage of formulators inspected per year	100%	7%	30%	63%	8%	4%
No. of distributors inspected per year	53	24	90	36	250	77
Percentage of distributors inspected per year	1%	0%	1%	5%	3%	1%
Frequency of inspection if non-compliance suspected	No data	Any complaint, accident or evidence of pollution is likely to lead to an inspection soon thereafter	No data	No data	No data.	All suspected cases of non-compliance are investigated
Surprise visits	No data	No data	No data	5%	0%	0%
Programme of inspections	Programme of inspection based on risk.	Programme of inspection based on risk.	Programme of inspection based on risk.	Programme of inspection based on risk.	Programme of inspection based on risk.	Programme of inspection based on risk.
Training	Inspectors extensively trained via projects and programmes.	Initial training with regular updating.	Inspectors have the possibility to undertake advance trainings according to their needs.	Formal training	Inspectors regularly attend seminars and meet to exchange experience	Formal training and regular 'on the job' training.

Table 24 shows the cost of an inspection in each of the case study countries, Table 25 shows the total number of dutyholder subject to inspection in 2009 and Table 26 gives an overview of the administrative burden on enforcers and businesses under the baseline. For the calculation of the administrative burden on businesses we applied the Standard Cost Methodology, estimating the resource cost, time, population and frequency of the inspection and multiplying these together.

As already stated, the "population" parameter is taken from the Eurostat Structural Business Statistics database. The frequency of inspections and investigations is taken from the Member States reports on the current implementation of REACH, and refers to the number of inspections in 2009. The frequency is likely to change every year, depending on the phase of REACH, the Strategy of the Forum and of the national Competent Authorities, number of non-compliances founded, the available resources and so on.

Regarding the "time" parameter, the different Member State Competent Authorities declared different time bands. In order to ensure comparability across the case country studies, we will assume the same time bands for every country:

- ½ day for an inspection on a distributor;
- 1 day for a desk based inspection on manufacturers, importers and formulators;
- 2 days for a site visit inspection on manufacturers, importers and formulators.

These times reflect the responses received from the country experts.

A key assumption is that the time spent by the businesses to deal with enforcement (i.e. preparing the documentation for an inspection etc) is the same as the amount of time spent by the Authorities to plan that inspection. As the enforcement of REACH and CLP takes place alongside existing regimes, no additional time has been allocated for site travel or reporting.

For the "resource cost" parameter, the tariffs/gross earnings per hour for "professional" figures across the different Member States were considered. Table 23 shows the different gross earnings per hour in the countries considered.

Table 23: Tariffs per hour for "Professionals" category[93]

Member State	Gross earnings per hour (euros)
Bulgaria	2.24
Germany	43.15
France	47.02
Slovenia	18.75
Sweden	40.47
United Kingdom	49.75

A full description of the methods and assumptions used to calculate the administrative burden for each country is given in Annex IV.

Table 24: Cost of an inspection in 2009 (Euros)

Member State	Cost of inspection on distributor (Euros)	Cost of desk based inspection on manufacturer, importer or formulator (Euros)	Cost of site based inspection on manufacturer, importer or formulator (Euros)
Bulgaria	8	17	34
Germany	162	324	647
France	176	353	705
Slovenia	70	141	281
Sweden	152	304	607
United Kingdom	187	373	746

Table 25: Total number of dutyholders subject to inspection in 2009

Member State	Distributors	Manufacturers, importers and DU (desk based)	Manufacturers, importers and DU (site based)
Bulgaria	53	133	533
Germany	90	1212	135
France	24	473	53
Slovenia	36	6	112
Sweden	250	65	7
United Kingdom	77	192	10

Table 26: Baseline administrative burden (Euros, 2009)

Member State	Total cost to enforcers	Total cost to businesses

[93] *Source: Tariffs used as a basis for the calculation of administrative costs in the context of the Action Programme for reducing administrative burdens in 2008-2009*

Bulgaria	21,000	21,000
Germany	494,000	494,000
France	208,000	208,000
Slovenia	35,000	35,000
Sweden	62,000	62,000
United Kingdom	94,000	94,000

As shown in Table 26, the average cost of an inspection is highest in Germany and France and lowest in Bulgaria.

From the information provided in Tables 24 and 25, we estimate that the overall cost to enforcers of carrying out inspections in 2009 in Germany was €494,000. This is due to the large number of inspections and high inspection costs in Germany relative to the other case study countries. The overall cost to enforcers was lowest in Bulgaria, where the administrative burden on enforcing authorities has been estimated as €21,000. This is largely because the cost of an inspection in Bulgaria is significantly lower than in the other countries.

5.3.2. Costs from Option 1: Low Ambition

This Section reviews the likely impacts of implementing option 1 in each of the case study countries. It presents a summary of the findings of the impact assessment, with a detailed review of the likely impacts described for each of the case study countries in the Annex IV to this report.

For each case study country, the main changes relative to the baseline introduced by option 1 are:

- Higher numerical targets on the proportion of manufacturers and importers to be inspected each year in Sweden and the UK;
- Higher numerical targets on the proportion of formulators to be inspected each year in the UK; and
- Higher numerical targets on the proportion of distributors to be inspected each year in Bulgaria, Sweden, Germany, France and the UK.

As shown in Table 23, the largest number of additional inspections (relative to the baseline) would be introduced in the UK. An additional 93 inspections on manufacturers and importers, 27 inspections on downstream users and an additional 523 inspections on distributors would be required in the UK to meet the targets under option 1. The consultant estimates that this would cost UK enforcing authorities and businesses around €289,600 (with almost €100,000 being the cost for additional inspections on distributors). In Slovenia, however, no additional inspections would be required to meet the targets under option 1 as the proportion of manufacturers and importers, distributors and downstream users subject to inspection each year is higher under the baseline than under option 1.

Under Option 1, Member States would be given discretion regarding the programme of inspection and it is assumed that each Member State would continue to pursue their current strategy. For this reason, Option 1 is unlikely to impose any additional costs, or deliver any additional benefits in any of the case study countries in this regard.

As outlined above, inspectors in the case study countries regularly participate in training activities and so participating in initial training with email updating (as specified under Option 1) is unlikely to impose any additional burden on enforcing authorities.
Surprise visits have not taken place in either Sweden or the UK and only 5% of inspections in Slovenia are unannounced. For this reason, the number of surprise inspections would need to increase in all three countries to meet the targets specified under Option 1. The impact of this is uncertain however. While the country expert for the UK has suggested that the benefit of carrying out a surprise inspection may not be any greater than that of carrying out an announced inspection (as companies would not have sufficient time to become compliant within the short period of the notice given), it

could be argued that the threat of an unannounced inspection may lead to greater incentive to become/remain compliant than the threat of an announced inspection. It should be further noted that the cost of a surprise inspection may be higher for both businesses and enforcing authorities than the cost of an announced inspection: giving businesses notice of an inspection would enable them to prepare documentation at a time when it is least costly to them, it would enable businesses and authorities to agree a mutually convenient time for an inspection and it would enable businesses to have all relevant documentation to hand when the inspector arrives.

Overall, it is estimated that the total cost of option 1 (relative to the baseline) would be highest in Germany and lowest in Slovenia, although it should be noted that this estimate is subject to considerable uncertainty.

Table 27: Number of additional inspections relative to the baseline introduced by option 1

	BG	FR	DE	SL	SE	UK
Manufacturers and importers	0	0	0	0	40	93
Formulators	0	0	0	0	0	27
Distributors	249	76	542	0	158	523
Total	249	76	542	0	198	643

Table 28: Costs from option 1 by Member State (relative to the baseline)

	BG	FR	DE	SL	SE	UK
Proportion of manufacturers & importers inspected per year	0	0	0	0	44,600 to 91,600	35,000 to 209,200
Proportion of formulators inspected per year.	0	0	0	0	0	10,000 to 60,800
Proportion of distributors inspected per year.	12,400 to 37,800	80,400	188,600 to 2,263,400	0	176,400 to 457,000	196,600 to 1,176,800
Frequency of inspection if non-compliance suspected	No data	0	No data	No data	No data	0
Surprise visits	No data	No data	No data	+/-	+/-	+/-
Programme of inspections	0	0	0	0	0	0
Training	0	0	No data	No data	0	0

Note: *All costs given in €2009. All impacts are relative to the baseline. Costs include those to businesses and enforcing authorities.*

5.3.3. Costs from Option 2: Medium Ambition

This Section presents a summary of the findings of the impact assessment with regard to the implementation of option 2. A detailed review of the likely impacts of implementing option 2 in each of the case study countries is given in Annex IV to this report.

For each of case study country, the main changes relative to the current regulatory baseline introduced by option 2 are:

- Higher numerical targets on the proportion of manufacturers and importers to be inspected each year in Sweden, Slovenia, Germany and the UK;
- Higher numerical targets on the proportion of downstream users to be inspected each year in Sweden, France and the UK; and
- Higher numerical targets on the proportion of distributors to be inspected each year in Bulgaria, Sweden, Slovenia, Germany, France and the UK.

As shown in Table 29 the largest number of additional inspections (relative to the baseline) would be introduced in the UK and the lowest number would be introduced in Slovenia. In the UK, 1601

additional inspections would need to be carried out to meet the requirements under option 2. It is estimated that this would cost enforcing authorities and businesses in the UK around €788,600 per year relative to the baseline (in 2009 prices). In Slovenia, only 42 additional inspections would need to be carried out each year to meet the inspection targets under option 2. Relative to the baseline, it is estimated that this would cost businesses and enforcing authorities approximately € 6,600 per year (in 2009 prices).

Overall, it is estimated that the costs of option 2 would be highest in Germany and lowest in Slovenia, although it should be noted that the estimates in Table 26 are subject to considerable uncertainty. Relative to the baseline, it is estimated that Option 2 would cost enforcing authorities and businesses in Germany around €847,000 per year (in 2009 prices) and enforcing authorities and businesses in Bulgaria around €11,000.

The cost estimates provided in Table 30 do not, however, take into account the likelihood that enforcing authorities would need to hire more staff and increase the amount of resources (e.g. office space, computers, training etc) available for them to meet these inspection targets.

As under option 1, the impact of requiring all site visits to be surprise inspections is uncertain. While the number of surprise inspections would need to increase in Sweden, the UK and Slovenia to meet the targets specified under option 2, the consultant does not know whether surprise inspections represent a net cost or a net benefit.

As outlined above, inspectors in Bulgaria, Sweden, France and the UK regularly participate in training activities and so participating in initial training with annual refreshment (as specified under Option 2) is unlikely to impose any additional burden on enforcing authorities.

Table 29: Number of additional inspections relative to the baseline introduced by option 2

	BG	**FR**	**DE**	**SL**	**SE**	**UK**
Manufacturers and importers	0	0	186	5	91	263
Downstream users	0	89	0	0	15	163
Distributors	561	1506	1219	37	552	1175
Total	561	1595	1405	42	658	1601

Table 30: Costs from option 2 by Member State (relative to the baseline)

		BG	**FR**	**DE**	**SL**	**SE**	**UK**
Proportion of manufacturers and importers inspected per year	Site-based	0	0	0	0	12,000	50,800
	Desk-based	2,000	0	316,200	1,400	49,200	170,800
Proportion of downstream users inspected per year	Site-based	0	12,700	0	0	0	12,000
	Desk-based	0	56,500	135,400	0	11,600	115,600
Proportion of distributors inspected per year Site-based		9,000	530,000	395,000	5,200	167,800	439,400
Frequency of inspection if non-compliance suspected		No data	0	No data	No data	No data	0
Surprise visits		No data	No data	No data	+/-	+/-	+/-
Programme of inspections		+27,000 €	No data	No data	No data	No data	No data
Training		0	0	No data	No data	0	0

Note: *All costs given in €2009. All impacts are relative to the baseline. Costs include those to businesses and enforcing authorities.*

5.3.4. Costs from Option 3: High Ambition

This Section presents a summary of the findings of the impact assessment with regard to the implementation of option 3. A detailed review of the likely impacts of implementing option 3 is given in Annex IV to this report

Table 27 gives an overview of the main changes relative to the baseline introduced by option 3 in each of the case study countries. In particular, option 3 introduces:

- Higher numerical targets on the proportion of manufacturers and importers to be inspected each year in Sweden, Slovenia, Germany, France and the UK;
- Higher numerical targets on the proportion of downstream users to be inspected each year in Sweden, France and the UK; and
- Higher numerical targets on the proportion of distributors to be inspected each year in Bulgaria, Sweden, Slovenia, Germany, France and the UK.

As shown in Table 31, the largest number of additional inspections (relative to the baseline) would be required in France and the lowest number would be required in Slovenia to meet the inspection targets under option 3. In France, an additional 3,709 inspections would need to be carried out each year to meet the inspection targets under option 3. It is estimated that this would cost enforcing authorities and businesses in France approximately €1.13 million per year (in 2009 prices). In Slovenia, however, only 129 additional inspections would need to be carried out each year to meet the inspection targets under option 3. It is estimated that this would cost enforcing authorities and businesses in Slovenia approximately €16,000 per year (in 2009 prices). The key reasons for this difference are the relative size of the chemical industry in France and Slovenia and the difference in the cost of an inspection in these two countries.

Overall, the consultant estimates that the total cost to businesses and to enforcing authorities of implementing option 3 would be highest in Germany and lowest in Slovenia; however it should be noted that the cost estimates are subject to considerable uncertainty. In order to meet the inspection targets under option 3, it is estimated that the cost to businesses and enforcing authorities in Germany would be around €1.3 million and the cost to businesses and enforcing authorities in Sloveniaaround €16,000. Note, however, that these costs do not take into account the fact that enforcing authorities would almost certainly need to hire more staff in order to meet these inspection targets.

As outlined above, inspectors in Bulgaria, Sweden, France and the UK regularly participate in training activities and so participating in CPD is unlikely to impose any additional burden on enforcing authorities.

As under Options 1 and 2, the impact of surprise inspections is uncertain.

Table 31: Number of additional inspections relative to the baseline introduced by option 3

	BG	FR	DE	SL	SE	UK
Manufacturers and importers	0	152	473	17	142	386
Downstream users	0	386	0	0	91	299
Distributors	1184	3171	2574	112	1341	1834
Total	1184	3709	3047	129	1574	2519

Table 32: Costs from option 3 by Member State (relative to the baseline)

		BG	FR	DE	SL	SE	UK
Proportion of manufacturers and importers inspected per	Site-based	0	21,200	0	1,200	24,200	32,800
	Desk-based	3,400	96,700	464,600	4,200	73,600	271,600

year							
Proportion of downstream users inspected per year	Site-based	0	33,800	0	0	4,800	52,200
	Desk-based	0	150,400	229,400	0	29,800	197,000
Proportion of distributors inspected per year Site-based		14,000	828,000	614,600	10,600	287,600	686,000
Frequency of inspection if non-compliance suspected		No data	0	No data	No data	No data	0
Surprise visits		No data	No data	No data	+/-	+/-	+/-
Programme of inspections		54,000 €	No data	No data	No data	No data	No data
Training		0	0	No data	0	No data	0

Note: *All costs given in €2009. All impacts are relative to baseline. Costs include those to businesses and enforcing authorities.*

5.3.5. Comparison of the costs of the options versus the benefits of REACH

There are several studies in the literature that tried to quantify the benefits that the implementation of REACH will deliver to the businesses on one side and to human health and the environment on the other, all of them dealing with high uncertainty and lack of information at different levels. In fact, data on chemical properties, dose-response relationships and exposures are needed to quantify the magnitude of the benefits, and one of the main objectives of REACH is to provide such information. As a result, the impact assessments conducted during the period prior to REACH introduction adopted reasonable assumptions about some of the key variables and parameters. The enforcement system to ensure the proper functioning of the legislation will assist to realise those benefits, but to apportion part of them to the system would be a misleading exercise.

Instead it could be helpful to compare the estimates of the costs for the enforcement system in the country case studies and the magnitude of the benefits expected from the implementation of REACH in those countries. To do so, it is considered that the estimate of the benefits delivered by REACH on occupational health calculated in RPA (2003) and quoted in the Extended Impact Assessment of REACH (2003).

In order to account for uncertainty as to the impacts of REACH, varying assumptions were made and benefits estimated under low to high scenarios. The main assumptions were made regarding the effectiveness of REACH: lower bound was defined as one third of the diseases caused by unknown chemicals could be avoided (2,167 cases of cancer); higher bound was defined as two third of the diseases caused by unknown chemicals can be avoided (4,333 cases of cancer). Other important assumption was made on the value of a human life: two figures were considered, a low and best value. For this assessment, the best "Value of a Statistical Life" (VOSL), equal to 1,230,000 euro (2009 value), based on human costs and some elements of medical costs and lost output, is considered.

Once the estimates of the number of disease cases avoided for worker populations were developed (using incidence rates for individual countries), the study then valued these in money terms. The result was that the benefits for occupational health were estimated to be between €33 billion and €67 billion, using the best VOSL. It has to be noted that these are not the total benefits of REACH, since the positive effects for the businesses, public health and the environment were not taken into account.

The figures presented in Table 33 assume that the benefits are realised over a 30-year time period. A 3% discount rate was assumed for consistency with the Business Impact Assessment carried out for REACH (RPA and Statistics Sweden, 2002).

Table 33: Discounted value of health impact reductions (1million €, 2009 prices[94], discounted over 30 years at 3%)

	Lower Bound	Upper Bound
Total including cancer (best VOSL)	33,500	67,100

Table 34 below shows the value of the benefits apportioned by the workforce in each of the country case studies and number of cases of cancer expected to be reduced by REACH over a period of 30 years.

Table 34: Estimate of REACH benefits on occupational health by country

	Percentage of the Chemical Industry workforce on the EU total (EU27)	Total Lower Bound (million €)	Total Upper Bound (million €)	Number of cases of cancer reduced under REACH	
				Lower bound	Upper bound
Bulgaria	1.62%	540	1,080	35	70
France	11.88%	3,980	7,970	258	515
Germany	23.42%	7,850	15,720	508	1015
Slovenia	0.69%	230	460	15	30
Sweden	2.19%	730	1,470	48	95
United Kingdom	8.69%	2,910	5,830	188	377

Considering the highest bound of the costs to inspect manufacturers, importers and formulators[95] over a period of 30 years under the baseline and the most ambitious option and comparing it with the lower bound of the occupational health benefits expected to be delivered by REACH in the same period, it is evident how the costs to run the enforcement system are fully justified. The main challenge is that with limited resources, the Member States will have to allocate these in the most cost-efficient manner. Increasing the requirements for minimum number of inspections may not deliver greater benefits than providing guidance to companies as to their obligations in order to increase compliance levels.

Table 35: Comparison between costs of the Enforcement System and value of benefits (million euro), and number of cases of cancer to be avoided and number of cases of cancer expected to be avoided

	Costs of the Enforcement system under the baseline for 30 years	Costs of the Enforcement system under Option 3 for 30 years	Benefits Value lower bound	Number of cases of cancer to be avoided to justify the costs		Cases of cancer avoided
				Baseline	Option 3	
Bulgaria	1.26	1.78	540	0.08	0.11	35
France	12.48	46.38	3,980	0.8	3	258
Germany	29.64	68.90	7,850	2	4	508
Slovenia	2.1	2.58	230	0.1	0.1	15
Sweden	3.72	16.32	730	0.2	1	48
United Kingdom	5.64	42.83	2,910	0.4	3	188

5.3.6. Conclusions

[94] Revalued applying the Harmonised Indices of Consumer Prices (HICP) for the Euro area (17 countries): http://epp.eurostat.ec.europa.eu/tgm/table.do?tab=table&language=en&pcode=tsieb060&tableSelection=1&footnotes=yes&labeling=labels&plugin=1

[95] The costs for distributors are not considered because overestimated, since an inspection would check the presence of the SDS and if the substances are properly labelled.

This impact assessment has calculated the costs of the different options in terms of the administrative burden that it will impose on the enforcing authorities and businesses. As expected, option 3 imposes the greatest costs (as it has more stringent requirements in terms of site visits and level of inspections). It has to be noted that the most significant cost burden is associated with inspection on distributors. The benefits of the option however are less than certain. This is because although site visits may help in developing an understanding of the levels of non-compliance, the benefits will accrue when non-compliance is identified as an issue (and not in cases where compliance currently takes place, imposing a disproportionate burden). Similarly, the benefits from surprise visits are uncertain. As a result, unplanned visits are not considered to be beneficial to any inspection regime. Desk-based inspections are considered to be more cost-effective. The increased number of inspections may result in greater levels of compliance, with environmental and human health benefits as a result. Other benefits accruing to business include the prevention of business risks related to liability claims and less costs from penalties related to environmental emissions. Because of the inability to estimate with accuracy the increase in the level of compliance such benefits have not been subject to quantification.

All three options will have additional benefits in terms of levelling the playing field across the Member States (as the current baseline has shown that the baseline situation is quite variable across the case study countries in terms of level of inspections) with positive impact of competition across the EU. Because it will apply to the importers of substances too, there could be impact on competitiveness but these are not expected to be significant as compared to the general requirements of REACH, namely registration and/or authorisation.

Other conclusions from this study are:

- Loss of flexibility would mean that inspectors would not necessarily target the duty holders that they should be targeting. Depending on levels of non-compliance, Member States might want to focus their efforts on particular sectors/duty holders at a particular time. Likewise, Member States may not think it is necessary to visit certain duty holders once it is clear that they are compliant. Thus, requirements on site-visits may be disproportionately costly. Moreover, setting requirements on the number of site-visits may deter from more efficient allocation of resources in terms of providing guidance to companies about their obligations. This may apply particularly to formulators as they are responsible for collection of data across complex supply chains;
- Minimum inspection rates may be given as best practice guidance based on number of duty holders and types of non-compliance suspected. It is still too early days to establish such minimum requirements and these may change as more information becomes available from the Member States on inspections and reporting.
- Need for harmonization of the criteria used to target inspection
- Unplanned site visits may not deliver so many benefits compared to their costs; this is especially the case for distributors.

Table 36, overleaf, summarises the conclusions of the Option evalution against REACH and CLP objectives. As shown, the benefits of Option 2 and Option 3 are more significant in relation to establishing a common high level playing field across the MS. On the other hand, the efficiency of these Options is highly uncertain in terms of increased level of compliance.

The case study countries have shown the different level of inspections in terms of numbers according to their priorities, although they all follow the Forum strategy. For example, the UK and Sweden have the lowest percentage of inspections on dutyholders (in all groups) in comparison with Germany, whereas Slovenia and Bulgaria show high percentages but the number of dutyholders are significantly lower. Increasing the number of inspections across the board can create an unnecessary administrative burden on businesses.

It is too early in the implementation and enforcement of REACH and CLP to set minimum requirements on number of inspections for specific groups of dutyholders, mainly formulators of

mixtures. The need for minimum requirements may become more evident once the CLP regulations are applied to mixtures, in 2015.

Thus it is the conclusion of this impact assessment that at the time of writing, resources may be more efficiently allocated by providing guidance to companies as to their obligation in order to increase the levels of compliance. In addition, future work is recommended on the following aspects:

- A more systematic way of collecting data on the number and type of duty holders to facilitate any impact assessment work in the future;
- Member States to record types of non-compliance;
- Guidance on in-depth assessment based on risk and type of non-compliance may be made available without excessive costs and significant benefits.
- Refreshment courses and training will offer significant benefits when regulatory changes take place or for specific sectors that Member States consider may be at greater risk of non-compliance – this could be undertaken at EU level or at Member State level, with EU funds assigned to this purpose.

Table 36: Evaluation of the impacts of the different options on the objectives of REACH and CLP

REACH/CLP Objectives	Baseline	Option 1	Option 2	Option 3
to ensure a high level of protection of human health and the environment **(REACH and CLP objective)**	Currently the Competent Authorities are ensuring that REACH and CLP are fully understood by the companies. This will assist the achievement of a high level of protection of both human health and the environment	+ Option 1 may deliver moderate benefits through the increased number of inspections and non-compliance cases detected but the link between increased inspection and increased compliance is unclear. Also inspections may help achieving compliance with other regulation, e.g. OHS or emission controls.	0/+ As Option 2 will include a programme of inspections with in-depth assessment of prioritised sites this is likely to deliver moderate to significant benefits, especially for cases of non-compliance. The level of benefits will depend on the type of non-compliance and number of cases of non-compliance however so the Option efficiency is uncertain. To set a minimum amount of inspections could however divertresources from targeted risk-based inspections or developing other on-going support to companies if not more resources are allocated to this end	0/+ As Option 3 will include a programme of inspections with in-depth assessment of prioritised sites this is likely to deliver moderate to significant benefits, especially for cases of non-compliance. To set a higher amount of inspections could however be too burdensome and diver resources from targeted risk-based inspections or developing other on-going support to companies if not more resources are allocated to this end
promotion of alternative methods for assessment of hazards of substances **(REACH objective)**	Inspections could just check that the companies have submitted proper testing proposals to ECHA	0 Option 1 is unlikely to impact on this as Member State will have discretion concerning the programme of inspections	0Option 2 is unlikely to deliver benefits in terms of promotion of alternative methods	0 Option 3 is unlikely to deliver benefits in terms of promotion of alternative methods
, [..] free circulation of substances on the internal market **(REACH and CLP objective)**	The harmonisation of the system through the initiatives of the Forum ensures the CAs that substances and articles imported from a MS were subject to a fair enforcement system	0/+ There may be some moderate positive impacts from setting some minimum inspection requirements and increased trust among players but this cause-effect link is highly uncertain	0/+ There may be some moderate positive impacts from setting some minimum inspection requirements and increased trust among players but this cause-effect link is highly uncertain	0/+ Similar to Option 1 and 2, there may be some positive impacts but link uncertain
enhancing competitiveness and innovation **(REACH objective)**	The enforcement system as it is implemented in the case country studies does not impact competitiveness and innovation alone	0 Few additional inspections would not impact competitiveness and innovation	-/0 May increase burden unnecessary on a number of companies which are not in the priority list and may impact competitiveness and	-/0 May increase burden unnecessary on a number of companies which are not in the priority list and may impact competitiveness and

REACH/CLP Objectives	Baseline	Option 1	Option 2	Option 3
			innovation negatively	innovation negatively
Other objectives (as in Section 5.1.2)				
To ensure and strengthen proper implementation and enforcement of the regulation	Currently the Competent Authorities are ensuring that REACH and CLP are fully understood by the companies.	+ Especially because of visits when non-compliance is found	+/++ Because of visits when non-compliance is found but also continuous training	+/++ Because of visits when non-compliance is found but also continuous training
To ensure a high level playing field within the internal market, including an equivalent and consistent level of enforcement activities across MS	Although all the National Strategies are based on the Forum Strategy and the MS are implementing the guidelines of the Forum, there is a high difference in the level of enforcement activities (see DE vs UK)	+ By setting minimum inspection requirements (including in-depth assessment)	+ By setting minimum inspection requirements (including in-depth assessment)	+ By setting minimum inspection requirements (including in-depth assessment)
To minimise the operating costs and administrative burden of REACH enforcement activities	The risk based approach ensures that just the needed inspections are undertaken	- Some moderate negative costs because of increased inspection requirements	-/-- Some negative costs because of increased inspection requirements	-- Higher costs implications because of in-depth assessment to 10% of companies that are not priority sites
To ensure the effective coordination of enforcement activities within MS authorities and then across MS authorities	This role is currently played by the Forum	-/? To set a minimum amount of inspections could affect the flexibility (and effectiveness) of the different enforcement systems	-/? To set a minimum amount of inspections could affect the flexibility (and effectiveness) of the different enforcement systems	-/? To set a minimum amount of inspections could affect the flexibility (and effectiveness) of the different enforcement systems

6. The potential role of the Commission in terms of monitoring and supervision of REACH & CLP inspections

In addition to the assessment of potential legislative changes in order to incorporate minimum requirements for inspections in EU law, the Technical Specifications for this project request an analysis of 'the potential role of the Commission in terms of monitoring and supervision' of the REACH and CLP inspections. While the Commission as the "guardian of the Treaty" already has the general role of ensuring that Member States fulfil their tasks related to REACH and CLP implementation and enforcement, some of the secondary legislation sets forth specific powers and responsibilities for the Commission in the area of monitoring implementation and enforcement.

This section first looks at what the REACH and CLP Regulations currently say about the role of the Commission in terms of enforcement, including inspections. It then reviews a number of options for an additional Commission role in this area, most of which can already be found in other EU legislation. The principle of subsidiarity, i.e., whether an intervention would be more effective at European, national or local levels, is a key consideration throughout the discussion.

The options identified below are presented in the order of increasing Commission involvement:

1. The current situation (baseline)
2. More detailed mandatory elements for Member State reporting on enforcement
3. Provision of technical guidance concerning proposed expanded role for REACH & CLP enforcement
4. A stronger role for the Commission within the Forum
5. Direct role for the Commission in trainings of Member State inspectors
6. Commission power to request specific investigations by national authorities, including direct access to documents of operators
7. Control of the infrastructure and operation of the national inspectorates by the Commission
8. Powers to undertake direct inspections

6.1. The current situation

The Commission holds the general duty under the Treaty to ensure that Member States meet their obligations under EU law by implementing and enforcing the obligations set forth in secondary law, such as REACH/CLP. The Commission's current role with respect to REACH inspections consists of two elements:

1. Entitlement, together with ECHA,[96] to attend the meetings of the Forum and its working groups (REACH Article 86(1) para. 4)), and
2. Receipt of Member State reports on the operation of REACH every five years (REACH Article 117(1)).

The Commission's role in attending Forum meetings is ambiguous. REACH Article 86(1) para. 1 provides for each Member State to appoint one "member" to the Forum chosen for their role and experience in enforcement of chemicals legislation. In addition, to ensure a broad range of relevant expertise, the Forum may co-opt up to five additional members. Article 86(1) para. 3 provides that Forum members may be accompanied by scientific and technical advisers. Finally, Article 86(1) para.4, in addition to entitling the Commission and ECHA to attend Forum meetings, also provides that Forum members and the ECHA Management Board may invite other stakeholders to attend these meetings, as appropriate, but as observers only.

Thus the Commission is neither a "member", "adviser" nor "observer," and it is not clear to what extent the Commission's entitlement to attend Forum meetings also entitles it to participate actively.

[96] According to REACH Article 76(1)(f), the Forum is an integral part of ECHA.

The Member State reports must include sections on evaluation and enforcement. The information received from the Member States is then to form part of the general report that the Commission must publish every five years, the first report to be published by 1 June 2012 (REACH Article 117(4)).

REACH Article 127 provides more details on what the Member State reports are required to include in relation to enforcement. The reports cover the results of the official inspections, the monitoring carried out, the penalties provided in the case of infringements and the other measures taken pursuant to Articles 125 (Member State obligation to maintain system of official controls) and Article 126 (Member State obligation to lay down penalties applicable for infringements). The common issues related to enforcement to be covered in the reports are to be agreed by the Forum.

The box below outlines the information that Member States were required to provide in the first round of reporting to the Commission concerning their enforcement activities.

REACH Reporting Questionnaire

General information (five-year reporting period)

- The enforcing authorities
- The enforcement strategy
- Explanation of the coordination, cooperation & exchange of information – between enforcing authorities, with Competent Authorities & internationally
- Level & extent of monitoring activities
- Sanctions available to enforcing authorities
- Referrals from ECHA & from other Member State

Specific information (actual year)

- Total no. of duty holders likely to have duties imposed under REACH (optional)
- Total no. of inspections & investigations carried out in which REACH was discussed or enforced
- No. of duty holders subject to inspections and investigations, & their size (in terms of range, e.g., small, small-medium, large)
    - Manufacturer duty holders
    - Importer duty holders
    - Distributors
    - Downstream users
- Number of inspections that addressed
    - Registration
    - Information in the supply chain
    - Downstream use
    - Authorisation
    - Restriction
    - Other REACH duties
- Number of investigations prompted by
    - Complaints & concerns raised
    - Incidents & dangerous occurrences
    - Monitoring
    - Results of inspection/follow up activities
- Number of inspections/investigations resulting in
    - No areas of non-compliance
    - Verbal or written advice
    - Formal enforcement short of legal proceedings
    - Initiation of legal proceedings
    - Convictions following legal proceedings (optional)
- Number of duty holders subject to formal enforcement
    - Manufacturers
    - Importers
    - Distributors

The equivalent provision on the Commission's role with respect to CLP inspections and enforcement is set forth in Article 46(2) of the CLP Regulation. It requires Member States to submit a report to ECHA also every five years, on the results of the official controls and other enforcement measures taken, with the first report to be submitted by 20 January 2012. ECHA is to then make these reports available to the Commission, which is to take them into account in preparing the report due every five years under REACH Article 117.

It is worth noting that the CLP Regulation has no provision equivalent to REACH Article 127, which explicitly states that 'the common issues to be covered in the reports shall be agreed by the Forum'. CLP Article 46(3) assigns the Forum the same tasks with respect to CLP as those specified in REACH Article 77(4)(a) to (g). However, these tasks do not include deciding on what will be reported.

In both REACH and CLP, however, the Commission's role with respect to determining the content of the periodic reports due from the Member States is not stipulated.

6.2. More detailed elements for Member State reporting on enforcement

The results of the first round of Member State reporting on REACH implementation and enforcement indicate a need for more attention to what Member States need to report. A number of figures provided by Member States in their REACH implementation reports appear to be either unavailable or inconsistent, making a comparative analysis difficult. For example, Member States were asked to provide an estimate of the total number of duty holders who are likely to have duties imposed on them by REACH. Germany, with total chemicals sales of €141.6 billion in 2010,[97] reported 206,760 duty holders, while France, with total chemicals sales of €76.1 billion in 2010, reported a total of only 3600 duty holders.[98] These widely varying figures indicate that such concepts as duty holder may be interpreted quite differently from one Member State to another.

The lack of consistent and comparable data will limit the Commission's ability to provide a meaningful analysis of the operation of REACH in the general report on REACH implementation due to be published in June 2012. The need for a more systematic way of collecting data on the number and type of duty holders in the future was also pointed out in the recommendations issued under Section 5.3.6 of this Report. If the first round of CLP Member State reports due on 20 January 2012 produces similarly inconsistent findings, the need for more attention to the reporting requirements of both REACH and CLP would appear to be confirmed.

This option therefore considers whether more detailed requirements are needed concerning what should be reported, as a mechanism to assist Member States to deliver more reliable and comparable information on enforcement in their Article 117 reports. These could be provided as non-binding guidance to the Member States through the Forum. Alternatively, they could be laid down in the REACH/CLP legislation directly. A third alternative would be for the REACH/CLP legislation to give the Commission a concrete role in determining what elements should be reported under REACH and CLP.

The first possibility would be to provide more detailed specifications in the form of non-binding guidance concerning what Member States should report. The guidance could for example provide working definitions of key terms such as those used for the different duty holders, including details on how to identify the various categories of duty holders, including different types of downstream users. The guidance could also give some general guidelines on how to count the number of inspections carried out, including whether desk or site inspections, the number of duty holders where follow-up measures required, number of formal enforcement actions taken, and so on. Guidance on other elements of inspection could also be considered, e.g., suggestions concerning percentages of various

[97] Chemicals sales figures from CEFIC, "Facts and figures brochure 2010".
[98] To overcome such obvious disparities, the impact assessment carried out under this contract used Eurostat data to estimate the number of duty holders, including manufacturers, importers, formulators and distributors.

types of duty holders to inspect each year as well as other elements corresponding to those analysed in the impact assessment (Section 5) for this project. As already noted, more detailed requirements could also be laid down in amendments to REACH and CLP.

A second possibility would be to give the Commission an expanded role in determining what elements should be reported under REACH and CLP. As already noted, under REACH Article 127 it is currently the Forum that agrees on the common issues related to enforcement to be covered in the reports submitted to the Commission every five years. This is at variance with other major EU acts related to environmental protection, where the Commission decides on the elements to be reported periodically, through a formal comitology procedure. For example, Article 72 in Directive 2010/75/EU on industrial emissions (IED) on reporting by Member States provides that the type, format and frequency of information to be reported, including determination of specific activities and pollutants, shall be established via the regulatory procedure referred to in the IED's Article 75(2).[99]

It may be possible for the Forum and the Commission to work more closely together on to ensure that Member States provide more consistent and comparable information on their REACH implementation and enforcement activities, without a formal comitology procedure in place. This could perhaps be achieved by reaching agreement through the Forum on how to interpret key concepts such as downstream user provision or through development of non-binding detailed guidance on what information to gather for the periodic reports.

6.3. Provision of technical guidance concerning proposed expanded role for REACH & CLP enforcement

The draft Strategy Document attached as Annex I to this Report highlights the links between REACH & CLP and other EU health and environment-related requirements, including in the area of health and safety of workers, industrial pollution control and product requirements. The Strategy Document proposes *inter alia* use of the exposure scenarios required under REACH to check compliance with these other requirements. It points out the potential for greater efficiencies to be gained by Member States in relation to the enforcement of the other legislation, but notes that some organisational or policy changes may be needed to implement this ambitious approach.

Under this option, the Commission would play an active role in developing technical guidance for Member State enforcement authorities on how to apply the exposure scenarios and other REACH/CLP elements in checking compliance with other EU requirements such as those on health and safety of workers, industrial pollution control and product safety. Precedence for such a role may be found in Article 13 of the Industrial Emissions Directive, which provides for the Commission to organise exchanges of information as needed to draw up, review and update reference documents concerning best available techniques (BAT).

Industrial Emissions Directive
Article 13: **BAT reference documents and exchange of information**

1. In order to draw up, review and, where necessary, update BAT reference documents, the Commission shall organise an exchange of information between Member States, the industries concerned, non-governmental organisations promoting environmental protection and the Commission.

2. The exchange of information shall, in particular, address the following
(a) the performance of installations and techniques in terms of emissions, expressed as short- and long-term averages, where appropriate, and the associated reference conditions, consumption and nature of raw materials, water consumption, use of energy and generation of waste;
(b) the techniques used, associated monitoring, cross-media effects, economic and technical

[99] See also Directive 91/692/EEC standardizing and rationalizing reports on the implementation of certain Directives relating to the environment, which provides that the reports are to be based on a questionnaire or outline drafted by the Commission in accordance with the specified comitology procedure.

viability and developments therein;
(c) best available techniques and emerging techniques identified after considering the issues mentioned in points (a) and (b).

As a starting point, the technical guidance could focus on specific industrial sectors where risk analysis has indicated health or environmental impacts from specific substances. It could review the exposure scenarios for those substances and their intended uses that have been developed in the course of the REACH chemical safety assessment, evaluate them in terms of feasibility of implementation and provide a number of concrete examples of potential areas for inspection.

The guidance could also set out options for appropriate risk management measures and associated management measures, e.g. frequency of maintenance of risk management measures, which could be checked during site inspections. These would need to holistically cover both worker protection and environmental protection issues. In addition, other issues that could be covered include appropriate monitoring techniques plus an indication of appropriate training that might be needed to take samples and interpret results. Finally, classification issues related to the targeted substances and any mixtures they would be used in could also be covered, particularly if the substances do not have a harmonised classification.

It should be noted here that REACH Article 77 already empowers ECHA to provide technical and scientific guidance on the risks and safe use of chemicals, and this -- combined with its close connection with the Forum – argues for a strong role for ECHA in preparing the guidance described above. However, given that the guidance referred to above would focus on links with other EU legislation including on health and safety at work and industrial pollution, it is logical for the Commission to take a strong principal role in the preparation of such guidance. Nonetheless, in order for such guidance to be used in practice in national inspection programmes, it would be important to secure the broad participation of the Member States through the Forum.

6.4. Stronger role for the Commission within the Forum

As noted above, while the Commission is entitled to attend all meetings of the Forum and its working groups, the extent of the Commission's role with respect to the Forum and its members is not defined. While a Commission representative might be able to suggest that the members of the Forum undertake certain activities, the Commission cannot oblige the Forum or its members to do anything specific concerning inspection and enforcement, other than the rather general obligations already placed on the Member States via Articles 125-127.

The Forum's specific tasks are set forth in REACH Article 77(4). The same tasks with respect to enforcement of CLP are assigned to the Forum in Article 46 of the CLP Regulation.

REACH Article 77(4)

4. The Forum shall undertake the following tasks:
(a) spreading good practice and highlighting problems at Community level;
(b) proposing, coordinating and evaluating harmonised enforcement projects and joint inspections;
(c) coordinating exchange of inspectors;
(d) identifying enforcement strategies, as well as best practice in enforcement;
(e) developing working methods and tools of use to local inspectors;
(f) developing an electronic information exchange procedure;
(g) liaising with industry, taking particular account of the specific needs of SMEs, and other stakeholders, including relevant international organisations, as necessary;
(h) examining proposals for restrictions with a view to advising on enforceability.

It seems possible for the Commission to take a more active role with respect to certain of these tasks, even if REACH or CLP do not specifically provide for this. For example, there is no restriction in

either REACH or CLP on the Commission's participation in Forum activities. The Commission should be able to actively participate in Forum meetings and make suggestions concerning what the Forum (or individual Member States) should be doing. Forum tasks listed in REACH Article 77(4) where Commission support might be usefully provided would include (b) proposing and evaluating harmonised enforcement projects and joint inspections, or (e) developing working methods and tools of use to local inspectors.

6.5. More active report-back role for the Commission

The remaining suggestions would probably require legislative changes to REACH and CLP. The first of these suggestions is to give the Commission a more active report-back role. At this point the Commission's reporting role consists of publishing a general report every five years on the experience acquired with the operation of REACH. Instead, or perhaps in addition to this general report, the Commission could be required to periodically report to the Council and the European Parliament on REACH and CLP implementation, including the monitoring and inspection activities of the Member States, as coordinated through the Forum.

A precedent for a more active role such as this may be found in the Industrial Emission Directive's Article 73, which requires the Commission to submit a report reviewing the IED's implementation every three years directly to the European Parliament and to the Council. This report could, amongst other issues, highlight relative contributions from Member States in Forum projects.

6.6. Commission powers to request specific investigations, including records of operators

Another option would be to include provisions in REACH and CLP to empower the Commission to request specific investigations by national authorities, including direct access to documents of operators, and to participate in such investigations. A precedent for empowering the Commission in this way can be found in Article 28(2) of Regulation (EC) No 1005/2009 on substances that deplete the ozone layer (ODS Regulation).

Ozone-Depleting Substances Regulation
Article 28: **Inspection**

1. Member States shall conduct inspections on the compliance of undertakings with this Regulation, following a risk-based approach, including inspections on imports and exports of controlled substances as well as of products and equipment containing or relying on those substances. The competent authorities of the Member States shall carry out the investigations which the Commission considers necessary under this Regulation.
2. Subject to the agreement of the Commission and of the competent authority of the Member State within the territory of which the investigations are to be made, the officials of the Commission shall assist the officials of that authority in the performance of their duties.
3. In carrying out the tasks assigned to it by this Regulation, the Commission may obtain all necessary information from the governments and competent authorities of the Member States and from undertakings. When requesting information from an undertaking the Commission shall at the same time forward a copy of the request to the competent authority of the Member State within the territory of which the undertaking's seat is situated.
4. The Commission shall take appropriate action to promote an adequate exchange of information and cooperation between national authorities and between national authorities and the Commission. The Commission shall take appropriate steps to protect the confidentiality of information obtained under this Article.
5. At the request of another Member State, a Member State may conduct inspections of undertakings or investigations of undertakings suspected of being engaged in the illegal movement of controlled substances and which are operating on the territory of that Member State

In addition, Article 23 of the ODS Regulation requires duty holders (undertakings) to take all precautionary measures practicable to prevent and minimise any leakages and emissions of controlled substances and to maintain certain records on, e.g., the quantity and type of controlled substances added and recovered during maintenance, servicing and final disposal. These records are to be made available on request to a Member State competent authority and to the Commission. While Member States are to define the minimum qualification requirements for personnel carrying out maintenance, servicing and final disposal of ODS, the Commission may adopt harmonising measures regarding those minimum qualification requirements, by way of comitology.

Under both of these provisions in the ODS Regulation, the Commission is required to coordinate and work closely with the Member State competent authority concerned, which reflects the fundamental role of the Member States to implement and enforce EU law within their territories. However, at the same time the Commission is given considerable investigative powers. The EU legislators apparently considered these powers justified given the importance of restricting and phasing out ozone-depleting substances and the continued involvement of organised crime in bringing illegal virgin ODS into EU territory.

Certain key parts of REACH such as Title VII on authorisation of SVHCs or Title VIII on restrictions provide for the possibility of similar restrictions and phase-outs of substances if the risks linked to those substances cannot be managed in less restrictive ways. The implementation of REACH authorisations or restrictions could similarly lead to a black market for those substances no longer easily available on the market. If this led to smuggling and/or illegal sales of restricted substances on a significant scale, there could be a need for the Commission and/or ECHA to have a more active coordinating and investigatory role in REACH/CLP enforcement.

Since REACH is still a relatively recent legislative act and since its focus is on making the duty holders responsible for compliance, it may be too early to determine whether the Commission should have direct investigative powers such as those set down in the ODS Regulation. However, if illegal distribution of restricted substances becomes a larger EU enforcement problem, the precedent of the ODS Regulation in giving the Commission specific investigative powers should be kept in mind.

6.7. Direct role in the training of national inspectorates

Another possibility would be for the Commission and/or ECHA to have a direct role in the training of the national enforcement authorities carrying out inspections concerning compliance with REACH and CLP. A number of the tasks for the Forum set forth in REACH Article 77(4) fit within a training scheme, including (b) proposing, coordinating and evaluating harmonised enforcement projects and joint inspections; (c) coordinating exchange of inspectors: and (e) developing working methods and tools of use to local inspectors. In this regard it should be noted that the Forum is already carrying out some of these training-related activities.

Precedence for the Commission or ECHA to have a direct role in the training of national enforcement officials can be found in the Regulation establishing Frontex.[100] The role of Frontex is considered as not replacing or superseding national training, but rather creating a harmonised pan-European training regime to enable representatives of the various Member States to work together effectively in joint operations. Elements of this training regime include social and communication skills, knowledge of human rights and the related legislation, security, fairness and incorruptibility among many others.

[100] Regulation (EC) No 2007/2004 establishing a European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union, OJ L 349, 25.11.2004, p. 1, as amended by Regulation (EC) No 863/2007 establishing a mechanism for the creation of Rapid Border Intervention Teams and regulating the tasks and powers of guest officers.

Regulation (EC) No 2007/2004 establishing the Frontex Agency
Article 2: **Main tasks**

1. The Agency shall perform the following tasks:
(a) coordinate operational cooperation between Member States in the field of management of external borders;
(b) **assist Member States on training of national border guards, including the establishment of common training standards**;
(c) carry out risk analyses;
(d) follow up on the development of research relevant for the control and surveillance of external borders;
(e) assist Member States in circumstances requiring increased technical and operational assistance at external borders;
(f) provide Member States with the necessary support in organising joint return operations…

It should be noted that the Forum is already involved in the training of national inspectorates. A more active role for the Commission in training of inspectorates would therefore seem appropriate, if in the context of the work carried out by the Forum. It is also worth noting that REACH Article 77(2)(l) provides for ECHA, at the Commission's request, to provide technical and scientific support for steps to improve cooperation between the EU, the Member States, international organisation as and third countries, including "active participation in technical assistance and capacity building activities on sound management of chemicals in developing countries." A training role for ECHA is thus already envisioned, albeit for developing countries. Expansion of this role for ECHA so that it also supports Member States in the training of their national inspectorates for monitoring compliance with REACH/CLP could therefore be considered, with support from the Commission.

6.8. Direct control of national inspectorates

In addition, the possibility of a Commission or ECHA audit of each Member State's inspection/enforcement activities if a problem has been identified could be considered. Under this option, the Commission would have the power to review and evaluate the adequacy of control of the infrastructure and operation of the national inspectorates.

Precedence for such a mechanism can be found in Directive 2010/63/EU on the protection of animals used for scientific purposes, which sets forth in its Article 34 a number of requirements for Member States' inspections. Its Article 35 then empowers the Commission to carry controls of the infrastructure and operation of national inspections, when there is due reason for concern.

Directive 2010/63/EU on the protection of animals used for scientific purposes
Article 35: **Controls of Member State inspections**

1. The Commission shall, when there is due reason for concern, taking into account, inter alia, the proportion of inspections carried out without prior warning, undertake controls of the infrastructure and operation of national inspections in Member States.

2. The Member State in the territory of which the control referred to in paragraph 1 is being carried out shall give all necessary assistance to the experts of the Commission in carrying out their duties. The Commission shall inform the competent authority of the Member State concerned of the results of the control.

3. The competent authority of the Member State concerned shall take measures to take account of the results of the control referred to in paragraph 1.

The Directive 2010/63/EU requirement for a showing of due reason for concern is an important proviso for the Commission being empowered in this way: it acts as a safeguard to prevent the Commission from using the power to control a Member State's inspection activities arbitrarily.

In the context of REACH and CLP monitoring and inspections, there is no evidence to date of any problems of the scale that would give rise to such concern. However, if at a later date a clear indication emerged that a Member State was systematically failing to take enforcement actions considered important in terms of protecting human health and the environment, the precedent of Directive 2010/63/EU in empowering the Commission to undertake audits of Member State enforcement authorities could be kept in mind.

6.9. Powers to undertake direct inspections

The area of EU law where the Commission is granted the most extensive investigative powers is EU competition legislation. These powers are enshrined in TFEU Article 105, which provides that the Commission shall ensure the application of the principles in TFEU Article 101 (former TEC Article 81 - prohibition against restrictive agreements between undertakings) and TFEU Article 102 (former TEC Article 82 - prohibition against abuse of dominant position). Under TFEU Article 105, the Commission has the power to conduct its own investigations of suspected infringements of these principles, either on the request of a Member State or on its own initiative, and in cooperation with the competent authorities in the Member States.

Article 20 of Regulation (EC) No 1/2003 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty explicitly gives the Commission the power to 'conduct all necessary inspections of undertakings and associations of undertakings'. Commission officials and other accompanying persons are empowered to enter any premises, to examine the books and other business records, to take copies or extracts from such books or records, to seal premises for the period and extent necessary for the inspection, and to ask for on-the-spot oral explanations about facts or documents related to the purpose of the inspection and to record the answers.

Regulation (EC) No 1/2003 on the implementation of the rules on competition
Article 20: **The Commission's powers of inspection**

1. In order to carry out the duties assigned to it by this Regulation, the Commission may conduct all necessary inspections of undertakings and associations of undertakings.
2. The officials and other accompanying persons authorised by the Commission to conduct an inspection are empowered:
(a) to enter any premises, land and means of transport of undertakings and associations of undertakings;
(b) to examine the books and other records related to the business, irrespective of the medium on which they are stored;
(c) to take or obtain in any form copies of or extracts from such books or records;
(d) to seal any business premises and books or records for the period and to the extent necessary for the inspection;
(e) to ask any representative or member of staff of the undertaking or association of undertakings for explanations on facts or documents relating to the subject-matter and purpose of the inspection and to record the answers.

At the request of the Commission or the Member State competition authority, officials of the Member State where the inspection is to be carried out are to actively assist Commission officials in carrying out the investigation, and in so doing have the same powers as specified above. If an undertaking opposes the inspection, the Member State concerned shall request where appropriate the assistance of the police or equivalent Enforcement authority. This is to include application for authorisation from a judicial authority according to national rules, if required.

These provisions empowering the Commission to carry out direct inspections with the assistance of Member State competition authorities are highly unusual for EU secondary legislation. Moreover, in practice, the resources available to DG Competition to carry out direct inspections of undertakings are quite limited, and it is current Commission policy to encourage decentralisation of the enforcement

process to the Member State competition authorities and national courts, so that the Commission can concentrate on major cases of EU interest.

Given that the EU legislator has already given the primary role for REACH and CLP monitoring and inspections to the Member States, albeit coordinated through the Forum, there does not seem to be a need for the Commission to be empowered to carry out direct inspections, unless illegal activities related to the marketing of restricted chemicals reached a significant level that posed threats to human health and the environment. Moreover, as in the case of DG Competition, the resources available to the Commission for direct inspections would most likely be quite limited. Option 6.6 above (granting the Commission the power to request specific investigations by national authorities) is thus considered a more reasonable and viable approach.

7. Conclusions

As mentioned in the introduction, this project had the overarching objective to secure and strengthen proper implementation and enforcement of the REACH and CLP Regulations. In addition, it had three specific objectives:

- to identify criteria and enforcement strategy for Member States (building on the work already performed by the Forum on enforcement) on how to effectively conduct REACH and CLP controls and inspections;
- to assess the potential benefits and options for further legislation on REACH and CLP inspections at EU level; and
- to assess whether the current requirements of the REACH and CLP Regulations could potentially be reinforced and how.

The three key outputs of the project correspond to these three specific objectives. The proposed **Enforcement Strategy** included as Annex I to this report is linked to the first specific objective of building on the work already performed by the Forum on REACH/CLP enforcement in order to identify further criteria and enforcement strategy for Member States on how to effectively conduct REACH/CLP controls and inspections. The section in the draft Final Report on the options for legislative analysis and benefits assessment corresponds to the second specific objective for the project. Finally, the third specific objective – to assess whether the current requirements of REACH/CLP concerning inspection could potentially be reinforced and how – is addressed by the Report's section concerning the role of the Commission in REACH/CLP inspections.

The Enforcement Strategy proposes a more focused and potentially more efficient approach in REACH/CLP inspections. It concludes that there is considerable scope for efficiency gains in REACH and CLP inspections, and suggests that virtually of the objectives of REACH/CLP can be delivered by focusing compliance checking on just three elements of REACH – the Exposure Scenarios, information in the supply chain and substances in articles. The Strategy also suggests a more ambitious agenda for REACH/CLP inspections. It points out that the information gathered in REACH/CLP is relevant in the enforcement of other EU legislation, including worker health and safety, industrial pollution control and product requirements. In particular, it proposes that enforcing authorities for other relevant legislation could use the Exposure Scenarios to check compliance with the obligations in this other legislation and if necessary organise joint inspections with the REACH/CLP authorities where doubts over compliance are raised.

The Strategy concludes that coordinating REACH/CLP inspection activities with other enforcement authorities such as labour inspectorates, industrial pollution control inspectorates, and market surveillance authorities is important for achieving the maximum benefit from the REACH/CLP regime. It acknowledges that this is a medium to long-term effort and that there may need to be additional policy and guidance support at EU-level to achieve these potential gains.

The **Options for legislative analysis** selected for the assessment of their potential benefits are based on several broad procedural categories (frequency of inspection (by operator type and by type of inspection, i.e. desk-based versus site-based); surprise visits; programme of inspections; and training) and then criteria developed to show a range of ambition levels (low, medium, high). The assessment found that .if setting a minimum number of inspections would ensure a level playing field within the European market, it could also result in a loss of flexibility at the national level. This could lead to the diversion of resources from more targeted inspections (based on risk assessment) or from the development and provision of support and guidelines to companies.

In general, desk-based inspections are considered to be more cost-effective, if appropriate follow-up measures are taken, than site inspections. Site inspections are however important when the desk-based inspection indicates non-compliance. The assessment also found that the benefits from surprise

(unscheduled) inspections are uncertain and may not provide enough additional value to become a major part of an inspection regime.

Finally, the study considers **the role of the Commission** in REACH and CLP inspections. Though the Commission's current situation with respect to the Forum and Member State REACH/CLP inspection activities is ambiguous and though neither REACH nor CLP spell out to what extent the Commission can participate actively in or exert some type of control over Forum activities, the study concludes that there is considerable scope for the Commission to play a stronger role within the Forum and to develop a more active cooperation on inspection and enforcement issues.

For example, while REACH gives the Forum the power to agree on the common elements to be covered related to enforcement, it does not restrict the Commission from taking a more active role in, e.g., suggesting more detailed elements in the templates used for Member State reporting on REACH/CLP enforcement Another option would be for the Commission to prepare detailed guidance documents on how to define and identify various categories of duty holders, with the aim of bringing about more harmonised approaches to reporting and more reliable information in the national reports on enforcement.

Another potentially important role for the Commission would be to develop technical guidance concerning the proposed expanded role for REACH and CLP inspectorates in checking compliance with other EU legislation, including in the areas of worker health and safety, industrial pollution control and product requirements. This would facilitate the ambitious agenda set forth in the draft Enforcement Strategy, and would find precedence in the BATREF documents prepared under the EU industrial pollution control legislation. As a starting point, the technical guidance could focus on industrial sectors where risk analysis has indicated health or environmental impacts from specific substances. It could review the exposure scenarios for those substances and their intended uses developed for REACH chemical safety assessments, evaluate them in terms of feasibility of implementation and provide a number of concrete examples of potential areas for inspection.

REACH Article 77 already empowers ECHA to provide technical and scientific guidance on the risks and safe use of chemicals. However, given that the guidance referred to above would focus on links with other EU legislation including on health and safety at work and industrial pollution, the Commission should also take a strong principal role in the preparation of such guidance. Nonetheless, in order for such guidance to be used in practice in national inspection programmes, it would be important to secure the broad participation of the Member States through the Forum. A stronger role for the Commission within the Forum could also include active report-backs to the Parliament and the Council on Member State enforcement experiences, and support for the Forum's activities with respect to training of national inspectorates.

Since REACH and CLP are still both relatively recent acts and since the focus is on making duty holders responsible for compliance, it may be too early to determine whether the Commission should have additional responsibilities and powers with respect to REACH and CLP inspections. However, certain key parts of REACH such as Title VII on authorisation of SVHCs or Title VIII on restrictions provide for the possibility of restrictions and phase-outs of substances if the risks linked to those substances cannot be managed in less restrictive ways, and this could lead to a black market for those substances no longer easily available on the market.

If the result was smuggling and/or illegal sales of restricted substances on a significant scale, there could be a need for the Commission and/or ECHA to have a more active coordinating and investigatory role in REACH/CLP enforcement. In such a case, the Commission could consider pursuing legislative changes to empower it to request specific investigations by national authorities, including access to records of operators (precedence is found in the Regulation on ozone-depleting substances). Another option would be to carry out direct audits of national REACH/CLP inspectorates in cases where there is due reason for concern, e.g., egregious pattern of failure to take enforcement action in cases where human health and the environment is at risk (precedence in the Animal Testing Directive).

However, even without legislative empowerment, the Commission can already take a stronger role in a number of areas relevant to REACH and CLP monitoring and inspection. Suggestions include :

- more detailed guidance on reporting key information on REACH and CLP monitoring and inspection activities, and
- additional sector-specific technical guidance on how the information available under REACH, including Exposure Scenarios, could be used to check compliance with other EU legislation, such as worker health and safety, industrial pollution control and product requirements.

This last suggestion could focus on development of guidance for a few pilot industrial sectors, either self-identified or suggested by other stakeholders because e.g. of particular concerns for the health and safety of workers and other exposed populations.