FORUM FOR EXCHANGE OF INFORMATION ON ENFORCEMENT
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“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)”

Disclaimer:

This paper describes enforcement strategies identified and agreed upon initially by the Forum for Exchange of Information on Enforcement at its meeting of 2-4 December 2008, and amended at Forum-9 on 1-3 March 2011. It contains elements that should be considered in developing effective strategies for enforcement of the REACH and CLP Regulations. It provides a framework and general recommendations for developing the national REACH and CLP enforcement strategies within the States concerned. The document is not legally binding on national enforcement authorities. The States concerned may develop their national enforcement strategies and establish their enforcement priorities according to the national circumstances (e.g., the type and scale of the industry with obligations under the REACH and CLP Regulations, division of competencies and responsibilities of the enforcing authorities), within the framework developed in this document.

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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)

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Introduction

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) entered into force on 1 June 2007. Its requirements will be gradually implemented through a phased approach, with a timeline that extends beyond 2020. The new chemicals legislation will signal fundamental changes in both European and national legislation in respect of the import, manufacture, use and trading in chemicals, mixtures and articles and in the rights and obligations of companies who manufacture, import, use or trade in these chemicals, shifting the responsibility from the competent authorities to industry. The aims of REACH are to improve the protection of human health and the environment from the risks that can be posed by chemicals; enhance the competitiveness of the EU chemicals industry; promote alternative methods for the assessment of the hazards of substances; and ensure the free circulation of substances on the internal market of the EU.


The CLP Regulation implements the United Nations Globally Harmonised System of Classification and Labelling of Chemicals (UN GHS) into European domestic law. UN GHS provides a basis for globally uniform physical, environmental, health and safety information on hazardous chemicals through the harmonization of the criteria for their classification and labelling. By means of the CLP Regulation, the EU aimed at lowering the barriers to trade which were caused by the re-classification and re-labeling of chemical products.

REACH and CLP are Regulations and therefore directly applicable. As they enter into force, they will automatically form part of Member States’ national laws. In order to enable REACH and CLP to operate effectively in practice, Member States are obliged to establish the necessary arrangements for their implementation. It should be noted, that the Regulations have EEA relevance, i.e. they are binding also for Norway, Iceland and Lichtenstein. As the EEA agreement is allowing for free movement of goods, it is important that EEA countries have the same approach in enforcing REACH and CLP as Member States, thus ensuring level playing field for their industry and high level of protection for both man and environment.
REACH and CLP are intended to exhaustively regulate all matters to which they relate. To do so some legal instrument is required at national level, which will define the administrative framework of their implementation and which will establish or define the State bodies in a Member State which will be responsible for the implementation and the enforcement of the Regulations.

Since the REACH and CLP Regulations set a complex set of requirements for the management of chemicals, their successful implementation will require good cooperation, coordination and exchange of information between the competent and enforcement authorities in the Member States, the European Chemicals Agency and the Commission in all matters regarding implementation and enforcement. The REACH and CLP regulations provide new challenges for enforcers due the shift from the pre-marketing to the pre-manufacturing model and the introduction of a new system for classification, packaging and labelling. Before REACH, chemical enforcement was primarily focused on the placing of the market of substances, now enforcers must also enforce the manufacturing of substances. For classification, packaging and labelling, there is a legislative system that has been in force for many years. CLP does not change this system fundamentally, but the enforcers have to deal with both systems for many years ahead according to the transitional provisions. Nevertheless, the majority of countries have experience already in the enforcement of similar requirements, based on particular national chemical as well as environmental and occupational health and safety legislations. In order to ensure compliance with these Regulations, Member States are required to apply effective monitoring and control measures. These measures should be planned, carried out and their results should be reported and if necessary, followed up. The Member States are also required to set up an appropriate framework for penalties with a view to imposing effective, proportionate and dissuasive penalties for non-compliance, as non-compliance can result in increased risk for the human health, occupational safety and the environment.

A valuable tool for exchange of information on, and coordination of the activities related to, the enforcement of chemicals legislation is the Forum for Exchange of Information on Enforcement (‘the Forum’) which is aimed to coordinate a network of Member States’ authorities responsible for the enforcement of these Regulations. The main tasks of the Forum are:

- to spread good practice and highlight problems at Community level;
- to propose, coordinate and evaluate harmonised enforcement projects and joint inspections;
- to coordinate exchange of inspectors;
- to identify enforcement strategies, as well as best practice in enforcement;
- to develop working methods and tools of use to local inspectors;
- to develop an electronic information exchange procedure;
- to liaise with industry, taking particular account of the specific needs of SMEs, and other stakeholders, including relevant international organisations, as necessary;

- to examine proposals for restrictions (under REACH) with a view to advising on their enforceability.

**Scope of the document**

Both the REACH and the CLP Regulations require Member States to have a system for compliance monitoring and control, including planning, performance and reporting of inspections.

Since the Regulations require actions to control and manage different requirements in the area of environmental protection, occupational health and safety, consumer protection, customs and the protection of the public from environmental or work-related hazards a number of different enforcing authorities are likely to be appointed throughout the EU, mostly including health and safety inspectorates, environmental inspectorates, consumer protection authorities and custom authorities. These authorities have to control and monitor compliance with the requirements of the Regulations throughout different supply chains, with a wide variety of stakeholders – manufacturers, importers, distributors, downstream users and the correspondent workforce. Each authority is also likely to have different priorities and resources.

However, the complexity of target groups, enforcement goals and techniques require the Member States to apply some strategic/programmatic approach in order to ensure the effective enforcement of the Regulations, coordinated actions and the best possible allocation of the resources of the enforcement authorities.

In order to be able to have a structured, harmonised and transparent approach to REACH and CLP enforcement, each of the Member States should develop working enforcement strategies. The strategies in different Member States and in different enforcement authorities should aim to advance the overall objectives of the REACH and CLP Regulations and should have a compatible philosophy, structure and approach.

Since there is a big difference between Member States in their administrative systems, the type and scale of the industry concerned, the division of competencies and responsibilities of the enforcing authorities, etc., the elaboration of a single, detailed EU wide enforcement strategy for REACH and CLP has not yet been developed. The Forum’s tasks may, over time, define and promote a degree of common EU wide activity.

Meanwhile, the most efficient approach is to elaborate general minimum criteria on the policy, implementation, monitoring and review of the REACH and CLP enforcement strategies of the Member States. The purpose of this document is to propose such framework for the elaboration of national REACH and CLP enforcement strategies. Each Member State and each
responsible enforcement authority on the national level can use the general framework described in this document to develop their own detailed strategy. Since the framework described here is general, the resulting strategies should be compatible and allow for achieving the overall EU policy goals in the field of chemicals management.

**Elements of an enforcement strategy for REACH and CLP**

A number of Member States have elaborated enforcement strategies in order to ensure planned, structured, coordinated and consistent enforcement action involving all inspection bodies concerned. In general such a strategy should be based on a cyclic approach, which contains five principal elements:

1. Defining clear **policy objectives** and priorities, based on analysis of the desired behaviour and assessment of the risks of non-compliance and prioritization of the target groups.

2. Creating the necessary **organization** in order to be able to achieve effective, efficient, transparent and systematic enforcement of the Regulations. This includes the elaboration of an appropriate regulatory regime, which ensures equal treatment of all the dutyholders regulated by the REACH and CLP Regulations, development of a clear enforcement programme, which includes all the areas of enforcement (environment, occupational health and safety, consumer protection, customs, etc), formal and unambiguous provisions or arrangements for cooperation, communication and coordination amongst the enforcement authorities on regional and national level as well as considerations for cooperation, communication and coordination with enforcement authorities in other MS, including an implementation of a network for exchange of information on chemicals, nationally and in the EU and EEA. Other critical components of this element of the regulatory cycle are the provision of resources (regulatory powers of the inspectors, manpower, monetary, administrative and expert capacity, including training of inspectors), development of appropriate standards for enforcement and compliance tools and the establishment of effective communication and guidance on REACH and CLP issues with the industry and other stakeholders).

When strengthening the administrative and expert capacity of the REACH and CLP enforcement authorities, some actions have to be undertaken in order to ensure these authorities have all that is needed to perform their duties. Some examples of such action is the developing and distribution of suitable inspection tools, enabling access to the enforcement relevant REACH-IT information, creation of means of information exchange amongst inspectors, such as “inspectors’ helpdesks”, web-based information exchange platforms, establishments of regional and national REACH and CLP enforcement networks, etc.

A crucial element of the national enforcement is securing the necessary coordination and cooperation with the national customs. The customs
authorities are key players for a substantial proportion of the target groups – importers of substances of their own, in preparations and articles.

In order to make full use of the specific competencies and expertise of the customs authorities, a decision on the information exchange and the involvement of the Customs authorities should be taken. Since the area of the customs control is quite specific and sensitive, such action is preferably to be planned and accepted on EU level, which would involve coordinated action by the relevant Commission services, ECHA and the Forum. The already applied practise for controlling the imports/exports of certain dangerous chemicals in the framework of Regulation (EC) no. 689/2008 may give some insight into this specific matter.

Until an agreed framework exists, appropriate mechanisms should be in place to ensure the participation of these authorities in both proactive (compliance check with the REACH and CLP requirements when performing routine customs control) and reactive (supplying information during investigations and performing follow-up action) components of the enforcement process, with or without request of the competent and/or enforcement authorities. These mechanisms should preferably be based on some legal/formal documents, such as legislation, bylaws and orders or memorandums of understanding/cooperation agreements. A simple and fast solution would be to integrate custom authorities in REACH and CLP enforcement by making available to them data from REACH-IT, on the same conditions as they will be made available to the other REACH and CLP enforcers, but since cooperation with the customs can be developed in different ways in the MS, it will be up to the Member States to decide on this subject. In this way, the customs officers would be able to engage in REACH and CLP enforcement at the border. The main challenge will be to develop working procedures, enabling the customs authorities to use REACH-IT in a way that allows them to apply their “barrier approach”.

3. Performing actual enforcement measures, including compliance promotion, compliance enforcement and if needed, carrying out administrative or criminal proceedings, predefined for the various offences against the requirements of the Regulations.

4. Development and implementation of procedures for periodic progress monitoring and measurement, whereby attention is paid to such management aspects such as level of compliance, resources spent, information and organisation.

5. Development and implementation of procedures for review, evaluation and update of the enforcement strategy, based on the monitoring procedures.

This systematic approach offers direct relationship between the policy objectives and the enforcement efforts required to achieve the objectives. It also takes into account the behaviour of each identified target group, and uses risk assessment (what are important standards, what is the enforcement
level and what is the desired compliance level) and management (via setting intervention priorities) for the target groups in order to minimise risks.

The enforcement process should be an iterative process graphically depicted on Picture 1.

Diagram 1. Enforcement process for the REACH and CLP Regulation

Policy objectives

Since the policy objectives are defined in the Regulations themselves, the Member States’ enforcement strategies should be designed to advance those objectives. Article 1 of both REACH and CLP defines their purpose as ensuring a high level of protection of human health and the environment as well as the free circulation of substances on the internal market. Another emphasis is the precautionary principle which should be used any time doubts appear, since the REACH Regulation is based on the principle that
manufacturers, importers and downstream users have to ensure that they manufacture, place on the market or use such a substance that do not adversely affect human health and the environment. The Member States should follow these guiding principles and set appropriate priorities and enforcement measures in order to achieve compliance with the Regulations and when appropriate, to link them with the workplace, environmental and other relevant legislation.

**Setting of priorities for national enforcement strategies**

After the policy goals, compliance vision and mission for REACH and CLP enforcement have been defined at the national level, more detailed enforcement goals should be set. To enforce the Regulations efficiently, the Member State should set priorities considering:

- The particular industry/economic activities in the Member State
- Traditional behaviour and expectations regarding target groups compliance with legal requirements
- The legal and administrative prerequisites in the particular MS
- The vulnerability and severity of potential consequences for the people, the environment and the socio-economic situation in the country

The overall administrative capacity and expertise available for enforcement as well as coordination and cooperation issues are factors which also may have an impact on the national strategies.

Priorities for enforcement activities should be based upon an analysis of the risk of non-compliance. Such a risk analysis should be distinguished from risk assessment carried out with respect to substances. To perform this risk analysis the following inputs and preconditions have to be considered:

- The target groups: manufactures, distributors, downstream users and importers. These target groups, within the Member State may be further divided in subgroups, dependent on the legal obligations and the duties they have to comply with, e.g. subgroups like formulators.

- The legal obligations and the duties to fulfil should be listed. Annex 1 describes the Articles of REACH and Annex 2 those of CLP, which are considered to be essential requirements and should at least be considered. From these priorities follow the obligations and required behaviour i.e. the specific tasks of the different target groups in the MS.

- The effect of non-compliance, an estimation of the consequences of non-compliance for human health and the environment (risk recipients). Risk is the effect multiplied by the probability, so the risk of non-compliance is the
effect multiplied by the probability that non-compliance will occur. It is also important to consider the effects on the socio-economic situation in the particular MS and effects for industry and specific policies. For example the risk for unfair competition or the risk those particular policies of the MS are unable to succeed.

The risk analysis is a start to perform a further assessment of the compliance behaviour of the target groups. On the basis of knowledge in the Member State concerning traditional behaviour and expectations, the expected compliance of the target groups can be estimated. Distinction can be made between for example expected non-compliance due to lack of awareness or ambiguity of the legislation and intentional non-compliance due to cost benefits, which gives insight in the compliance behaviour of target groups, thus offering a better possibility to prioritise enforcement activities and a method to identify the effect of different enforcement tools.

The prioritised and supplementary enforcement goals can be established based upon this process as is shown in the diagram below.

Diagram 2. Non-compliance risk analysis scheme for setting priorities for national REACH and CLP enforcement strategies
Enforcement process

Once the enforcement priorities are set, the authorities of the Member States should plan and implement activities designed to ensure target groups achieve compliance with the requirements of the Regulations and take preventive or corrective measures. Generally enforcement includes inspections, investigations, formal enforcement action (such as issuing enforcement notices or instituting legal proceedings) and compliance promotion as well as communication with all the relevant stakeholders.

Enforcement should be planned, carried out and that the results should be reported and if necessary, followed up. This structured approach is especially important in order to ensure a harmonised approach to enforcement, to avoid duplication of work and to manage the enforcement capacities. The requirements of the Regulations should be met by the preparation and implementation of enforcement programmes which define the action for a certain predefined time period. The enforcement programmes should include both activities to promote and enforce the requirements of the Regulations. The effective blend of both approaches (compliance promotion and enforcement response) should be predefined in certain limits by the risk assessment and prioritisation phase of the enforcement strategy. The enforcement programme should clearly indicate the enforcement authorities’ competencies and duties in regard of checking the compliance with the main duties, defined in the REACH Regulation (registration, information in the supply chain and use related duties, and also authorisation and restriction duties) and in the CLP Regulation (duties to classify, label and package substances and mixtures, notify classifications to ECHA).

The most important aspect in the enforcement process is to effectively ensure the compliance of the target groups and to achieve high level of protection of the human health and the environment. The particular inspection and investigation methodologies employed by enforcing authorities could differ, but this should not be a problem if effective outcome in terms of compliance of the duty holders is achieved.

Communication is a fundamental element of the enforcement process. Proper communication amongst all relevant stakeholders – enforcement authorities, target groups, workers, interested communities (for example NGOs) and general public allows for better understanding of the Regulations and the connected duties and rights, to attain acceptance for the enforcement, to promote the level of compliance and as end effect to raise the level of protection for workers, general public and the environment. “Name and shame” and “Name and fame”-type communication campaigns are effective and influential as they stimulate target groups for better compliance and cooperation. Information should be actively disseminated, with or without request from the relevant target groups and should be regularly updated, for example when new data is available or new legal requirements enter into force, etc. Risk information and communication to the relevant risk recipients and competent/enforcement authorities, submitted via appropriate channels is essential if non-compliance results in enhanced risk for human health or environment. The communication on enforcement should be subject and
target specific (e.g. to target groups, NGOs, workers, general public) and to be submitted by appropriate channels in order to achieve the desired effect. Since much of the information, received by the enforcers could be sensitive and/or confidential, special attention has to be paid as to which part should be communicated.

Compliance promotion is necessary because enforcement alone is often not effective, especially in the context of REACH and CLP, where the size of the regulated targets far exceeds the resources for enforcement. One of the main problems the REACH and CLP enforcers will face is the general acquaintance of the target groups (especially SMEs and previously non-regulated target groups) with the legal requirements. Compliance promotion should in the broader sense be understood as actions for providing education and technical assistance, building public support and building expert and administrative/managerial capacity within the regulated community.

The compliance promotion should be complemented with appropriate compliance monitoring (e.g. inspections and investigations). The compliance monitoring should be carried out based on an inspection programme/plan. This inspection plan should take into account the known target groups within the plan’s area, the legal requirements these target groups have to comply with, the available resources, data on and from previous inspection activities, etc. They have to include procedures for both planned, proactive inspections, as well as reactive, *ad hoc* investigations in case of complaints, need for follow-up action and occurrence of incidents/accidents.

As both the REACH and CLP Regulations stipulate, Member States are required to set up an appropriate framework for penalties with a view to imposing effective, proportionate and dissuasive penalties for non-compliance. This area is once again more or less up to the Member States to explore, plan and apply. Given the difference in the GDP, the size of the enterprises, the compliance culture amongst the target groups, the legal systems, etc., a fully harmonised penalty system is not possible, but some common elements should be integrated in the corresponding national provisions. The most important point is that the authorities should be given enough powers to effectively enforce the Regulations. This means that they have to have the authority to require preventive and remedial measures (which should range up to prohibition of the activities), to impose sanctions or seek sanctions through the legal system, and to prosecute offenders or to report violators to the public prosecutor. The availability of these tools varies significantly from country to country and is a serious challenge to the pursuit of level playing field in chemical risk management throughout the EU.

The choice of enforcement action is clearly a matter for the inspector at the time, guided by the legal requirements and the enforcement authority’s enforcement policy and procedures. Enforcement decisions are always taken on a case by case basis. The following factors may assist inspectors when deciding what type of to take:
- the hazards presented by the substance or the mixtures 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.

In addition, judgments as to risk can be assisted by the Regulations themselves. That is, the Regulations have risk assessment "built in" to a certain degree, by setting thresholds based on tonnage, hazardous properties of a substance etc. It follows that failure to comply for certain substances/quantities may often be judged to represent more serious breaches. Intuitively this is not the case for every contravention and so enforcement guidance will be developed and discussed with enforcing authorities at national level.

A common approach towards the philosophy of imposing sanctions would be invaluable in creating level playing field for the target groups throughout the EU. The issue should be discussed in the near future, when the enforcement authorities have more data on the compliance level and the relevance of the different penalty means.

**Progress monitoring, measurement and reviewing performance**

Information on the progress achieved is vital for successful enforcement. This demonstrates that enforcement authorities are consistent and fair in the application of the established strategy. With its help, the enforcement strategy could be further refined and lessons learned could be incorporated as the enforcement strategy is further developed.

Periodic evaluations on the effectiveness and the efficiency of the enforcement activities and results serve many purposes, like evaluation of the suitability of the enforcement strategy, internal and public accountability, awareness raising, etc.
In order to ensure that the goals set are met and the overall policy objectives are achieved, the enforcement strategy has to identify the procedural and management tools which will allow for periodical monitoring and measurement of the progress achieved. These tools should be compatible in order to allow the reporting on the implementation and enforcement as required by Article 117 of the REACH Regulation and by Article 46 of the CLP Regulation.

The progress monitoring and measurement activities should cover all the elements of the regulatory cycle and should allow for an assessment of its main concepts, such as:

- the enforceability of the legislations
- the effectiveness and efficiency of:
  - the planning and organisation of the enforcement process
  - the enforcement activities
  - the review and update provisions
- the level of compliance for both specific duties (registration, information in the supply chain, use, notification C & L classification, labelling etc.) and specific target groups

This could be done through the means of a set of performance indicators, measuring the abovementioned elements of the enforcement process. The development of such tools for progress monitoring and measurement represent a serious challenge for the Member States, because some of the enforcement aspects, and especially the outcome of the enforcement process are not easily quantifiable and therefore not really measurable, and this can be a subject for a discussion within the Forum. When establishing performance indicators, particular elements and sub-elements of the regulatory cycle should be analysed and appropriate questions should be asked (for example when analysing the enforcement, questions like “Is the enforcement action covering all of the priorities defined?”, “Does the enforcement process contribute to the compliance with the requirements?”, etc. should be asked) and proper indicators should be derived. Depending on the enforcement aspects, input, output, and outcome indicators should be formulated and some benchmarks should be defined, on which the progress towards the desired level of compliance with the REACH and CLP requirements could be measured. Such core benchmarks could also be used for an EU wide evaluation for the progress made and could also be part of the periodic report, required by Member States according to Article 117 of the REACH Regulation and Article 46 of the CLP Regulation.

Based on the progress monitoring and measurement, an appropriate review, and if appropriate an update, of the enforcement strategy should be undertaken. The enforcement strategy must have a certain degree of freedom
and flexibility, which gives ground for such actions without allowing substantial downstream changes.

Co-operation and co-ordination between enforcing authorities

The enforcement of the requirements of the REACH and CLP Regulations involves many different enforcement authorities and other bodies. There is a need for a national strategy defining the needs for co-operation and co-ordination between these enforcement authorities to ensure effective and efficient enforcement of REACH and CLP. A key element in any strategy is to define the roles and responsibilities of the various groups involved. This would allow for an efficient enforcement process, avoiding gaps and dealing with any overlaps in the enforcement competencies and responsibilities.

According to Article 86.1 of REACH each Member State shall appoint a member to the Forum. As this member probably represents an enforcement authority with a specific competence and the tasks for Forum stretches over several competences, a national strategy, the Forum member should ensure that there is appropriate co-ordination between the different enforcement authorities. The member could encourage cooperation between the responsible authorities and also relay any problems encountered by the different enforcement authorities at the European level.

When defining the co-operation and co-ordination needed it could be useful to, among many things, consider:

- Which authorities will be involved, e.g., environmental agencies, labour inspectorates, health agencies, consumer agencies, customs authorities.

- How responsibilities for enforcement should be divided nationally among the enforcement authorities, based on their expertise, mission, priorities and resources available, and on which level (national, regional, local).

- If there should be separate enforcement strategies and/or programmes for different aspects of the Regulations (e.g., registration, information in the supply chain, classification, labelling etc.).

- If, and to what extent, the enforcement strategy shall make use of trade associations and other nongovernmental resources.

- If, and to what extent, expert staff and legal advisors shall be integrated within an enforcement authority.

- The mechanisms needed to ensure effective co-ordination between the enforcing authorities where there are joint enforcement responsibilities and if there is a need to agree of minimum standards of co-operation.
Joint inspections between different enforcing authorities are also a possibility.

- If joint inspections between different enforcing authorities are realised, it will be necessary to ensure the jurisdictional validity of the procedure and the joint outcome.

- Exchange of inspectors, in order to facilitate cooperation between inspectors both on national as well as on EU level.

- The communication mechanisms needed between Competent Authority and the enforcement authorities. This should include the use of Helpdesk and information from REACH IT.

- The need for the national enforcement authorities to give feedback to the national member of Forum, to participate as national experts to the meetings of Forum and in Forum WG’s.

- Cooperation between different Members States enforcement authorities.

- The communication mechanisms needed between the different enforcement authorities. As this connects to the Forum task to develop an electronic information exchange procedure (WG established), there is also a need to co-ordinate the information to and from the Forum to relevant enforcement authorities.

- How to record the enforcement to fulfil the national obligations and the obligations in reporting to the Commission according to Article 117 in REACH and Article 46 in CLP.

The above-mentioned issues are meant to assist when developing provisions on the division of the competencies and responsibilities amongst the enforcing authorities and on the co-operation and co-ordination between them. These provisions could form a part of the enforcement strategy or be an alone standing document, which nevertheless should be compatible with the overall enforcement philosophy. The list is non-exhaustive and should of course be customised and complemented when applied for an individual Member State as the local factors varies.

In practice the cooperation between enforcement authorities can be formalised through official memoranda of understanding signed between different authorities defining the scope and way of cooperation. Forum members are invited to submit the examples of such memoranda and other documents describing the cooperation on national level to the Forum Secretariat. Such national memoranda of understanding will be made available as examples on the Forum CIRCA website.
Member State approaches to developing enforcement strategies

For reference and harmonisation purposes, Forum members are invited to submit the examples of their national enforcement strategies to the Forum Secretariat. Such national enforcement strategies will be made available as examples on the Forum CIRCA website.

Review

This paper shall be reviewed by the Forum no later than the end of 2010 and after that at least once every five years. The Forum shall, in plenary meetings, decide upon the manner in which the review shall be carried out, for example, by a working group, general discussion at plenary meetings etc. The Chair and/or the Secretariat shall ensure that review of this paper is included as an agenda item in the meeting prior to the review date.

The Forum may review this document more frequently than the minimum timescales set out above if it so chooses.

The review may also include a review of all, or a selection of, Member States’ enforcement strategies in order to identify and spread best practice for REACH and CLP enforcement, in line with the tasks of Forum, as specified by Article 77(4) of the REACH Regulation.

Conclusions

The enforcement of the REACH and CLP Regulations is vital for ensuring a high level of protection of human health and the environment, free circulation of substances on the internal market, a level playing field for all chemicals’ producers and/or importers, downstream users, distributors and the enhanced competitiveness and innovation of the EU industry. In particular, the REACH Regulation is a groundbreaking piece of legislation, which applies a totally new approach in chemical risk management and is a huge challenge to both regulators and industry.

The Forum for Exchange of Information on Enforcement is a valuable body for exchange of information on, and coordination of, the activities related to the enforcement of chemicals legislation. The Forum is coordinating a network of Member States’ authorities responsible for the enforcement of both the REACH and CLP Regulations. One of its principal tasks is to identify enforcement strategies, as well as best practice in enforcement.

In order to ensure a structured, harmonised and transparent enforcement of REACH and CLP, each of the Member States should elaborate a working enforcement strategy, based on the framework presented in this document and its Annexes. In such an enforcement strategy clear policy objectives and
priorities are defined and suitable organisational provisions are developed, including the elaboration of an appropriate regulatory regime, development of a clear enforcement programme, provisions for cooperation, communication and coordination amongst the enforcement authorities on regional, national and EU level, development of appropriate standards for enforcement and compliance tools and the establishment of effective communication and guidance on REACH and CLP issues with the industry and other stakeholders. Other important elements are the actual enforcement measures, including compliance promotion, compliance enforcement and if needed, carrying out administrative or criminal proceedings, the development of procedures for periodic progress monitoring and measurement, and the development and implementation of procedures for review, evaluation and update of the enforcement strategy, based on the monitoring procedures. This would guarantee that their efforts to fully implement the requirements of the Regulations are on the right track, that their enforcement approach is compatible with those applied by the other Member States and that they are progressing towards achieving the overall EU policy goals in the field of chemicals management.
Annex 1 – Essential requirements for REACH

REACH creates a fundamentally new approach to chemicals’ control. Under REACH, each manufacturer or importer into the EU of chemicals in volumes of 1 tonne or more per year – around 30,000 substances – will have to register them with the European Chemicals Agency (ECHA), submitting information on the properties, uses and safe ways of handling them. Suppliers must pass safety information down the supply chain to ‘downstream users’ so that they know how to use the substances. REACH restricts the use of certain dangerous substances, and for other substances of very high concern, use-specific authorisation is required.

The system that REACH imposes is achieved by it placing a wide range of duties on essentially four target groups:

- manufacturers;
- importers;
- only representatives;
- distributors; and
- downstream users.

Though REACH places many requirements on these target groups, enforcement effort should be focussed on the essential requirements, that is, on those duties that are the most significant in ensuring that risks to human health and the environment are adequately controlled. For the purposes of enforcement, the requirements imposed by REACH can be divided up into three general areas, in terms of the nature of the duties that are placed on the target groups:

- registration related duties, imposed on manufacturers and importers;
- supply chain related duties, applicable to all target groups where appropriate; and
- use related duties, applicable to all target groups where appropriate.

Details of these essential requirements of REACH are provided below. Member States are strongly encouraged to have regard to these requirements when devising and implementing their own REACH enforcement strategies, and when setting priorities for REACH enforcement. Naturally there may be local considerations that influence this process, e.g. if a Member State has a higher proportion of suppliers manufacturers and importers).

The list below should not be seen as an inventory of all enforceable obligations, but only those that are considered to have the most significant impact on the objectives of the REACH Regulation and as such could be seen as priority for REACH enforcement. For the complete list of obligations subject to enforcement, please refer to Annex I of the Forum report on REACH IT.
### Registration related duties

Registration is fundamental to the operation of REACH. Without it, insufficient information will be prepared to improve product data and to identify hazards and risks, as well as to give information on how to adequately control the risks during use, and the intentions of REACH will not be fulfilled. ‘Evaluation’ is also considered under this heading, as evaluation can result in requirements on registrants to provide complementary registration information where appropriate.

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<tr>
<th>Article</th>
<th>Description</th>
<th>Entry into force</th>
<th>Target group</th>
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<tr>
<td>5</td>
<td>This contains the ‘no data, no market’ principle and states that substances on their own, or in articles or preparations, shall not be manufactured or placed on the market unless they have been registered in accordance with Title II where this is required. Articles 6, 7, 17 and 18 contain the specific duties to register, and Articles 10 and 12 build on these provisions and specify what information has to be provided with a registration.</td>
<td>1 June 2008</td>
<td>Manufacturers, importers (Only Representatives)</td>
</tr>
<tr>
<td>6 &amp; 7</td>
<td>Articles 6 and 7 contain the principal requirements for registration of substances on their own, in preparations or in articles, and for monomers in polymers. Article 7 also contains requirements for notification of ECHA of SVHCs in articles.</td>
<td>1 June 2008</td>
<td>Manufacturers, importers</td>
</tr>
<tr>
<td>10, 11, 12, 14 &amp; 19</td>
<td>These Articles contain the requirements for information that must be submitted with a registration, including requirements to prepare a chemical safety report (CSR), and a chemical safety assessment (CSA) where required.</td>
<td>1 June 2008</td>
<td>Manufacturers, importers</td>
</tr>
<tr>
<td>12(2) &amp; 24(2)</td>
<td>These provisions contain a requirement on manufacturers and importers to notify ECHA with additional information where the quantity manufactured / imported reaches the next tonnage threshold.</td>
<td>1 June 2008</td>
<td>Manufacturers, importers</td>
</tr>
<tr>
<td>22(1) &amp; 22(2)</td>
<td>These Articles require registrants to update their registration information as appropriate.</td>
<td>1 June 2008</td>
<td>Manufacturers, importers</td>
</tr>
<tr>
<td>40(4), 41(4) &amp; 46(2)</td>
<td>These articles contain requirements to submit information to ECHA regarding dossier and substance evaluation</td>
<td>1 June 2008</td>
<td>Manufacturers, importers</td>
</tr>
</tbody>
</table>

### Supply chain related duties

Information provision both down and back up supply chains is again critical to the successful operation of REACH. Inspection of safety data sheets has been carried out for many years, so this is not a new task for enforcing authorities. What is new are the requirements concerning exposure scenarios that have to be annexed to safety data sheets, information requirements when a safety data sheet is not needed, information about substances of very high concern in articles, and requirements to pass information back up the supply chain in certain circumstances.

<table>
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<tr>
<th>Article</th>
<th>Description</th>
<th>Entry into force</th>
<th>Target group</th>
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<tbody>
<tr>
<td>31</td>
<td>This contains a variety of duties aimed at ensuring recipients of substances and preparations classified as hazardous/dangerous are provided with a safety data sheet, which will contain exposure</td>
<td>1 June 2007</td>
<td>Manufacturers, importers, distributors, downstream users</td>
</tr>
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</table>
### Article Description

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<tr>
<th>Article</th>
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<th>Entry into force</th>
<th>Target group</th>
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<tbody>
<tr>
<td>32(1)</td>
<td>This requires suppliers of substances or preparations who do not have to supply safety data sheets under Article 31 to provide the recipient with certain information.</td>
<td>1 June 2007</td>
<td>Manufacturers, importers, distributors, downstream users</td>
</tr>
<tr>
<td>33(1) &amp; 33(2)</td>
<td>This requires suppliers to communicate information on substances in articles to recipients and, on demand, also to consumers. This is important information for the recipients to receive, so that they can ensure that the article can be handled safely.</td>
<td>1 June 2007</td>
<td>Manufacturers, importers, distributors, downstream users</td>
</tr>
<tr>
<td>34</td>
<td>This requires new information on hazardous properties, or any other information that might call into question the appropriateness of the risk management measures on a safety data sheet, to be passed up the supply chain.</td>
<td>1 June 2007</td>
<td>Distributors, downstream users</td>
</tr>
<tr>
<td>35</td>
<td>This requires that workers and their representatives be granted access by their employer to safety data sheets and other information provided under articles 31 and 32 in relation to substances or preparations they use or that they may be exposed to at work.</td>
<td>1 June 2007</td>
<td>Manufacturers, importers, distributors, downstream users</td>
</tr>
<tr>
<td>56(1)</td>
<td>This requires manufacturers, importers or downstream users not to place substances on the market if they are included in Annex XIV (i.e. subject to authorisation).</td>
<td>“Sunset date” for each substance (Annex XIV)</td>
<td>Manufacturers, importers, downstream users</td>
</tr>
<tr>
<td>65</td>
<td>This requires the holder of an authorisation to include the authorisation number on the label before placing the substance on the market for an authorised use. This is important information for the downstream user when checking if his use is within the authorisation for that substance.</td>
<td>Once authorisation number is made publically available</td>
<td>Manufacturers, importers, downstream users</td>
</tr>
<tr>
<td>67(1)</td>
<td>This states that substances subject to restriction shall not be manufactured or placed on the market unless it complies with the condition of that restriction.</td>
<td>1 June 2009</td>
<td>Manufacturers, importers, distributors, downstream users</td>
</tr>
</tbody>
</table>

### Use related duties

REACH places the main responsibilities on manufacturers and importers, for instance to gather and assess data and, through use conditions and exposure scenarios, inform downstream users about uses. However, unlike earlier legislation, REACH requires downstream users to either stick to these use conditions or exposure scenarios, or to themselves take over the responsibility. This is primarily to ensure that the information gained through registration and evaluation, and passed down the supply chain, is effectively used to control risks.

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<tr>
<th>Article</th>
<th>Description</th>
<th>Entry into force</th>
<th>Target group</th>
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<tbody>
<tr>
<td>14(6)</td>
<td>This requires registrants to identify and apply appropriate measures to adequately control</td>
<td>1 June 2008</td>
<td>Manufacturers, importers</td>
</tr>
<tr>
<td>Article</td>
<td>Description</td>
<td>Entry into force</td>
<td>Target group</td>
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| 37(5), with reference to 37(2), 37(4), 38(1) & 39 | This requires downstream users to identify and apply the risk management measures recommended to them in the safety data sheet or other information sources available to them. This is one of the most important of all REACH Articles for enforcing authorities. If the downstream user does not keep within the exposure scenario, or uses a substance against the advice of their supplier, then they must take appropriate action. This will mean choosing one of the following options:  
   a) changing their use to bring it within the exposure scenario;  
   b) finding another supplier who is able to support the use;  
   c) replacing the substance or process with an alternative substance or process;  
   d) making the use known to the supplier, with the aim that this becomes an identified use (Article 37(2));  
   e) alternatively, should downstream users not wish to make their use known to their suppliers (e.g. for reasons of commercial confidentiality), or should the supplier not accept their use, downstream users may have to prepare a chemical safety assessment and report certain information to ECHA (Articles 37(4) and 38(1)). | 1 June 2008 | Downstream users |
<p>| 55 | A general requirement stating that all manufacturers, importers and downstream users applying for authorisation shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution. | 1 June 2008 | Manufacturers, importers, downstream users |
| 56(1) &amp; 56(2) | These provisions contain the core requirement that the use of substances of very high concern listed in Annex XIV is only allowed if an authorisation has been granted and the use is in accordance with the conditions in the authorisation, or that the use has been exempted from the authorisation requirement, or an application for authorisation has been submitted before the latest application date but an authorisation decision has not yet been adopted. | By &quot;sunset date&quot; | Manufacturers, importers, downstream users |
| 60(10) | This requires holders of authorisations to ensure that, notwithstanding any conditions of authorisation, exposure is reduced to as low a level as is technically and practically possible. | Date of entry into force of authorisation decision | Manufacturers, importers, downstream users |
| 66(1) | This requires a downstream user, using a | Date of entry | Downstream users |</p>
<table>
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<tr>
<th>Article</th>
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<th>Entry into force</th>
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<td></td>
<td>substance according to his supplier’s authorisation, to notify ECHA within three months of the first supply of the substance. This is important information for enforcing authorities, to enable them to check whether the conditions in authorisations are respected by the downstream user or not.</td>
<td>into force of authorisation decision</td>
<td></td>
</tr>
<tr>
<td>67(1)</td>
<td>This states that substances, mixtures or articles for which Annex XVII contains a restriction shall not be used unless it complies with the condition of that restriction.</td>
<td>1 June 2009</td>
<td>Downstream users</td>
</tr>
</tbody>
</table>
Annex 2 – Essential requirements for CLP


CLP is different from REACH, it does not create a new approach to chemicals’ control but replaces:

- Directive 1999/45 (Dangerous Preparations Directive)
- REACH, Title XI (Classification & Labelling).

The objective of CLP, as for the previous legislation, should be to determine which properties of substances and mixtures should lead to a classification as hazardous in order for the hazards of substances and mixtures to be properly identified and communicated.

The main responsibilities under CLP are that the manufacturers, importers and downstream users shall classify, label and package substances and mixtures before placing them on the market.

Distributors must pass the information down the supply chain to downstream users so they receive correct hazard information about the substances and/or mixtures used.

One of the challenging issues with respect to enforcement is the transitional period 2010 – 2015 for CLP is that both classification systems can to be used.

The classification and labelling for any registered or hazardous substance placed on the market should be notified to ECHA to be included in a classification and labelling inventory. Any manufacturer or importer will have to submit information about the classification and labelling elements.

Under CLP any manufacturer or importer will have to notify ECHA of the substance placed on the market, submitting information about the classification and labelling elements. However notification is not necessary if information has already been submitted as a part of a REACH registration.

In line with REACH, the system that CLP imposes is achieved by placing a wide range of duties on essentially four target groups:

- manufacturers;
- importers;
- distributors; and
- downstream users
Though CLP, as well as REACH, places many requirements on these target groups, enforcement effort should be focused on the essential requirements, that is, on those duties that are the most significant in ensuring that classification, labelling and packaging are correct such that information about risks to human health and the environment are adequately controlled. For the purposes of enforcement, the requirements imposed by CLP can be divided up into two general areas, in terms of the nature of the duties that are placed on the target groups:

- **notification**-related duties, imposed on manufacturers and importers;
- **supply chain**-related duties, applicable to all target groups where appropriate; as classifying, labelling and package duties

Details of these essential requirements of CLP are provided below. Member States are strongly encouraged to have regard to these requirements when devising and implementing their own CLP enforcement strategies, and when setting priorities for CLP enforcement. Naturally there may be local considerations that influence this process, e.g. if a Member State has many downstream users and distributors and few manufactures / importers.

The list below should not be seen as an inventory of all enforceable obligations but only those that have the most significant impact on the objectives of the CLP Regulation and as such could be seen as priority for CLP enforcement.
KEY ARTICLES OF CLP REGULATION TO BE ENFORCED

I. General obligations to classify, label and package

Article 4
- Art 4(1): requirement to classify substances and mixtures in accordance with Title II before placing them on the market;
- Art 4(4): requirement to label and package in accordance with Titles III and IV;
- Art 4(10): substances and mixtures shall not be placed on the market unless they comply with the Regulation.

II. Identification and examination of information

Articles 5-6 Requirement to identify and examine relevant available information on substances (Art 5) and mixtures (Art 6)

Article 7 Restrictions on animal and human testing
- tests on animals only allowed when no other alternative;
- tests on non-human primates prohibited;
- tests on humans shall not be performed for the purpose of CLP, data obtained from other sources such as clinical studies can be used.

III. Evaluation of hazard information and decision on classification

Article 9 Requirement to evaluate information identified so as to ascertain the hazards associated with substances and mixtures.

Articles 10-11 Requirements to set, if appropriate, specific concentration limits and M-factors for substances.
Requirement to respect cut-off values, concentration limits and M-factors when evaluating and classifying a substance or mixture.

Article 12 Requirement to carry out further evaluation of hazard information in specific cases.

Articles 13-14 Requirement to take the appropriate decision to classify substances and mixtures, on the basis of the evaluation of the relevant information.

Article 15 Requirement to carry out a new evaluation if new scientific or technical information becomes available and, in certain circumstances, in case of a change in the composition of a mixture that has been classified as hazardous.
### Essential requirements of CLP

2 (based on the list of key Articles of CLP Regulation to be enforced prepared by the Commission)

<table>
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<tr>
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</table>
| **Title I – General Issues**  
General obligations to classify, label and package | | | |
| 4 (1) | Manufacturers, importers and downstream users shall classify substances or mixtures in accordance with Title II before placing them on the market | Substances: 1 December 2010  
Mixtures: 1 June 2015 | Manufacturers, importers, downstream users |
| 4 (4) | Where a substance or mixture is classified as hazardous, suppliers shall ensure that the substance or mixture is labelled and packaged in accordance with Titles III and IV, before placing it on the market | Substances: 1 December 2010  
Mixtures: 1 June 2015 | Suppliers: Manufacturers, importers, downstream users, distributors, producers of articles |
| 4 (10) | Substances and mixtures shall not be placed on the market unless they comply with the Regulation | Substances: 1 December 2010  
Mixtures: 1 June 2015 | Suppliers? |

| **Title II – Hazard Classification**  
Chapter I – Identification and examination of information | | | |
<p>| 5 | This requires the identification and examination of relevant available information on substances for the purposes of determining whether the substance entails a hazard and to ascertain this information is adequate, reliable and scientifically valid for the purpose of the evaluation | 1 December 2010 | Manufacturers, importers, downstream users |
| 6 | This requires the identification and examination of relevant available information on mixtures or substances contained in mixtures for the purposes of determining whether the substance entails | 1 June 2015 | Manufacturers, importers, downstream users |</p>
<table>
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<tr>
<th>Article</th>
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<th>Target group</th>
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<tr>
<td>a hazard and to ascertain this information is adequate, reliable and scientifically valid for the purpose of the evaluation</td>
<td></td>
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</tr>
<tr>
<td>7</td>
<td>Restrictions are placed on animal and human testing where new tests are carried out: 7 (1) tests on animals undertaken only where no other alternatives are possible 7 (2) tests on non-human primates shall be prohibited 7 (3) tests on humans shall not be performed. Data obtained from other sources such as clinical studies can be used</td>
<td>Substances: 1 December 2010 Mixtures: 1 June 2015</td>
<td>Entities performing tests for the purpose of the CLP Regulation?</td>
</tr>
<tr>
<td>Title II – Hazard Classification</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Chapter II – Evaluation of hazard information and decision on classification</td>
<td></td>
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</tr>
<tr>
<td>9</td>
<td>This requires the evaluation of the information identified by applying to it the criteria for hazard class classification or differentiation so as to ascertain the hazards associated with the substance or mixture</td>
<td>Substances: 1 December 2010 Mixtures: 1 June 2015</td>
<td>Manufacturers, importers, downstream users</td>
</tr>
<tr>
<td>10</td>
<td>This requires to set, if appropriate, specific concentration limits and M-factors for substances for classification of substances and mixtures</td>
<td>Substances: 1 December 2010 Mixtures: 1 June 2015</td>
<td>Manufacturers, importers, downstream users</td>
</tr>
<tr>
<td>11</td>
<td>This requires to determine and respect cut-off values when classifying a substance or a mixture containing a substance classified as hazardous</td>
<td>Substances: 1 December 2010 Mixtures: 1 June 2015</td>
<td>Manufacturers, importers, downstream user</td>
</tr>
<tr>
<td>12</td>
<td>This requires to carry out further evaluation of hazard information in specific cases</td>
<td>Substances: 1 December 2010 Mixtures: 1 June 2015</td>
<td>Manufacturers, importers, downstream users</td>
</tr>
<tr>
<td>Article</td>
<td>Description</td>
<td>Entry into force</td>
<td>Target group</td>
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<tr>
<td>13</td>
<td>This requires to decide on the classification of a substance or a mixture on the basis of the evaluation of the relevant information</td>
<td>Substances: 1 December 2010</td>
<td>Manufacturers, importers, downstream users</td>
</tr>
<tr>
<td></td>
<td>Mixtures: 1 June 2015</td>
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<tr>
<td>14</td>
<td>This provides specific rules for the classification of mixtures</td>
<td>Substances: 1 December 2010</td>
<td>Manufacturers, importers, downstream users</td>
</tr>
<tr>
<td></td>
<td>Mixtures: 1 June 2015</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15 (1)</td>
<td>This requires manufacturers, importers and downstream users to take reasonable steps to make themselves aware of new scientific or technical information that may affect the classification of the substances or mixtures they place on the market and to carry out a new evaluation when this information becomes available and is considered to be adequate and reliable</td>
<td>Substances: 1 December 2010</td>
<td>Manufacturers, importers, downstream users</td>
</tr>
<tr>
<td></td>
<td>Mixtures: 1 June 2015</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15 (2)</td>
<td>This requires to carry out a new evaluation in certain cases where a change in the composition is introduced to a mixture that has been classified as hazardous</td>
<td></td>
<td>Manufacturers, importers, downstream users</td>
</tr>
<tr>
<td></td>
<td>Mixtures: 1 June 2015</td>
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Title V – Harmonisation of classification and labelling of substances and the classification and labelling inventory

Chapter II – Classification and labelling inventory

<table>
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<th>Target group</th>
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<tbody>
<tr>
<td>40</td>
<td>This requires a notification to ECHA of the identity and classification of substances classified as hazardous</td>
<td>Substances: 3 January 2011</td>
<td>Manufacturers and importers</td>
</tr>
</tbody>
</table>
Annex 3. Key elements of successful management system for compliance with REACH and CLP

Where non-compliance with REACH and CLP is found then, in addition to enforcing the essential requirements as set out above, inspectors may want to assess the suitability of a duty holder’s management systems to determine the underlying factors that allowed the contravention to happen. Unless weaknesses in those systems are identified and corrected, similar contraventions may re-occur.

The key elements of a successful management system for REACH and CLP are as set out below:

- **Policy**: An effective policy sets a clear direction for an organisation to follow, and highlights a demonstrable commitment to continuous improvement.

- **Organising**: This refers to putting in place an effective management structure and arrangements so that the policy can be delivered. It should ensure that:
  - roles and responsibilities are clearly defined;
  - all relevant persons are involved and co-operation between them is promoted;
  - individuals are competent to carry out their duties; and
  - effective lines of communication are put in place.

- **Planning**: is essential for the implementation of the policy and ensuring legal compliance. It will identify the various duties with which the organisation must comply, and establish performance targets and allocate resources so they can be achieved.

- **Measuring performance**: Performance must be measured in order to identify when and where improvements are needed, and should occur both proactively and also in response to any identified failures or incidents.

- **Reviewing & auditing**: Reviewing is the process of making judgments about the adequacy of performance and taking decisions about the nature and timing of the actions necessary to remedy deficiencies. Auditing involves collecting independent information on the efficiency, effectiveness and reliability of the management system as a whole, and drawing up plans for corrective action.
Annex 4 – Glossary

- ‘Sanctions’ any adverse consequence imposed on the violator by an enforcing authority in case of non-compliance with the Regulation.

- ‘Target group’ is a group of entities which exercise a particular activity and have a characteristic set of obligations according to the REACH or the CLP Regulations. Target groups under REACH and/or CLP are manufacturers, importers, distributors, only representatives (under REACH) and downstream users of substances, mixtures or articles.

- ‘enforcer’ or ‘inspector’ a person duly authorised on behalf of the enforcing authority to perform any enforcement actions.

- ‘enforcing authority’ – any public authority at either national, regional or local level, which is established or designated by the Member State and responsible for the matters that are covered by this document.

- ‘enforcement’ refers to the range of actions an enforcing authority may take in order to secure a duty holder’s compliance with REACH and CLP. Enforcement should be given a wide interpretation, and includes not only formal enforcement but also inspection, investigation, monitoring and other measures taken.

- ‘inspection’ is a proactive (planned and routine) process that involves collecting information to make an assessment of a duty holder’s current level of compliance, by comparing their activities to the legal requirements and benchmark standards relevant to the activities in question. Information may be obtained by reviewing relevant documents held by the duty holder, and/or interviewing people, and/or monitoring, and/or observing site conditions, standards or practices where activities subject to the requirements of REACH and CLP are carried out under the duty holder’s control. It follows that REACH and CLP inspection activity can occur at or away from a duty holder’s premises.

- ‘investigation’ is a reactive (non-routine) process which includes all those activities carried out in response to an accident, incident, or an occurrences of non-compliance or an identified instance of non-compliance, to gather and establish the facts, detect contraventions of REACH and/or CLP duties, identify immediate and underlying causes and the lessons to be learned, prevent recurrence, and take appropriate action, including formal enforcement.

- ‘monitoring’ means periodic or continuous surveillance, measurement, sampling, testing and/or analysis of various media, such as substances, mixtures, articles, the environment (air, water, soil, vegetation, animals) and so on, to determine the level of compliance with statutory requirements.

- ‘formal enforcement’ refers to a range of enforcement activity an enforcing authority is statutorily empowered to take, such as bringing legal proceedings by criminal or civil means, serving enforcement notices or other such administrative penalties (such as undertakings or on-the-spot fines), issuing formal cautions, and so on.
- ‘other measures’ include advisory, educational, training and promotional activities, and refers to the activities enforcing authorities may undertake to assist dutyholders to comply with REACH and CLP. While this includes, for example, holding an educational event such as a seminar where the delegates can be identified, it does not include the writing and dissemination of general guidance publications where the recipients of such guidance cannot be identified (though such activities will, of course, be relevant to other parts of the Article 117 report in REACH and/or the Article 46 report in CLP). It also excludes Helpdesk activity as this is covered in other sections of the Member States’ Report to the Commission.

- ‘Performance indicators’ are instruments that measure results achieved by compliance and enforcement programmes. Performance indicators compare actual conditions with a specific set of reference conditions. They measure the ‘distance(s)’ between the current situation and the desired situation (target) and provide ‘distance to target’ assessment. Performance indicators could measure the input, output and outcome of the enforcement process. Examples of such performance indicators are the number of inspections performed, number of inspectors per known target groups, number of enforcement notices issued, etc.

- ‘Procedure’ a procedure defines and controls the work that should be done, and explains how it should be done, who should do it, and under what circumstances. In addition, it explains what authority and what responsibility has been allocated, which inputs should be used, and what outputs should be generated.

- ‘Activity’ - An operation or work process conducted by a target group member.

- ‘Efficiency’ - The degree to which the goals have been reached, in relation to the means that have been applied and the available resources. Efficiency reflects the degree to which the goals have been reached, given the initial restraints and limitations of the enforcement process.

- ‘Effectiveness’ - The degree to which the goals have been reached.

- ‘Compliance’ - The state of conformity with the obligations imposed by the REACH and CLP Regulations.

- ‘Complaint’ – An accusation against a dutyholder that they are in some way failing to meet one or more of the duties imposed upon them by the REACH and CLP Regulations.

- ‘Dutyholder’ - The generic term for a person (natural or legal) with responsibilities under the REACH and CLP Regulations. It is generally the equivalent of a member of one of the target groups.

- ‘Risk Analysis’ - Determination of the impact and the probability of non-compliance with the REACH and CLP requirements in order to consider how this should influence the priorities of enforcing authorities. Amongst the impacts, environmental, socio-political (including public health, occupational health and safety and consumer protection issues) and economic effects should be noted. Probability could be assumed as a function of the level of awareness and knowledge and the level of acceptance of the legislation by
the target groups, combined with their estimation on the economic implications when implementing REACH and CLP, the probability of being found in non-compliance, the probability of sanctions to be imposed by the enforcement authorities, and the possibility of adverse public reaction.

- ‘Risk Assessment’ – Estimation of the acceptability of the risk determined by the risk analysis. If the risk is unacceptable, preventive or correction measures have to be applied.

- ‘Risk Recipient’ – any person or environment feature that are endangered as a result of non-compliance of some of the dutyholders with the requirements of REACH and CLP. Such risk recipients are for example workers, consumers, surface or groundwater, etc.