

Strategies and minimum criteria for enforcement of Chemical Regulations

Adopted at 06/12/2017



FORUM FOR EXCHANGE OF INFORMATION ON ENFORCEMENT

“Strategies and minimum criteria for enforcement of Chemical Regulations”

(EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH),

(EC) No. 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP),

(EU) No. 649/2012 concerning the export and import of hazardous chemicals (PIC) and

(EU) No. 528/2012 concerning the making available on the market and use of biocidal products (BPR)

Developments of this document

- First version of the document “Strategies for the enforcement of REACH”, including only REACH, was adopted at the Forum-3 meeting of 2-4 December 2008.
- First version of the document “Minimum Criteria for REACH And CLP inspections” was adopted by the Forum on its 6th meeting of 8-10 December 2009.
- The second version of the document “Strategies for the enforcement of REACH” was amended to include CLP, with the title “Strategies for the enforcement of REACH and CLP”. This second version and the second version of the “Minimum Criteria for REACH And CLP inspections” were adopted at Forum-9 on 1-3 March 2011.
- The third version of these documents was created by a working group mandated to revise the Forum’s “Strategies for the enforcement of REACH and CLP” and “Minimum Criteria for REACH and CLP Inspections”. The documents were combined into one and this new document “Strategies and minimum criteria for enforcement of Chemical Regulations” was adopted on 06/12/2017 by the Forum and BPR Subgroup to include PIC, BPR, the Commission REACH review and developments in the Forum.

Disclaimer:

This paper describes enforcement strategies identified and agreed upon by the Forum for Exchange of Information on Enforcement and the BPR Subgroup. It contains elements that should be considered in developing effective strategies for enforcement of the REACH, CLP, PIC and BP Regulations. It provides a framework and general recommendations for developing the national REACH, CLP, PIC and BPR enforcement strategies within the Member States concerned. The document is not legally binding on national enforcement authorities. The Member States 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, CLP, PIC and BP Regulations, division of competencies and responsibilities of the enforcing authorities), within the framework developed in this document.

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1. Introduction

This high level document provides a framework for developing national strategies for provisions set out under the chemical legislation whose enforcement activities are coordinated by the Forum for Exchange of Information on Enforcement (Forum), namely Regulations (EC) No. 1907/2006 (REACH), (EC) No. 1272/2008 (CLP), (EU) No. 649/2012 (PIC) and (EU) No. 528/2012 (BPR) as detailed below.

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 are being gradually implemented through a phased approach, with a timeline that extends beyond 2020. This piece of legislation regulates the import, manufacture, use and trading of substances, mixtures and articles as well as sets out the rights and obligations of companies who manufacture, import, use or supply these chemicals. 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 and innovation of the European Union (EU) 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.

Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 concerning the classification, labelling and packaging of substances and mixtures (CLP) entered into force on 20 January 2009. Similar to REACH, the requirements in CLP have been implemented gradually, and it has replaced the Council Directive 67/548/EEC as well as Directive 1999/45/EC.

The CLP Regulation implements the United Nations Globally Harmonised System of Classification and Labelling of Chemicals (UN GHS) into European law. UN GHS provides a basis for global uniform physical, environmental, health and safety information on hazardous chemicals through the harmonisation of the criteria for their classification, labelling and packaging.

CLP aims to provide a high level of protection of human health and the environment whilst allowing for the free movement of substances, mixtures and articles to be achieved through *inter alia* the harmonisation of classification criteria for hazardous chemicals and obligations on manufacturers, importers, producers of articles, downstream users and distributors regarding classification, labelling and packaging.

The Prior Informed Consent (PIC) Regulation (Regulation (EU) No. 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals) administers the export of certain hazardous chemicals and places obligations on companies who wish to export these chemicals to non-EU countries. It implements, within the EU, the Rotterdam Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade. Through a system of reference identification numbers that allows for identification of individual exports, the Regulation facilitates efficient control of compliance with legal requirements by designated national authorities (DNAs).

Regulation (EU) No 528/2012 of the European Parliament and of the council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR) is applicable since 1 September 2013. BPR replaced Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market. The aim of the legislation is to improve free movement of biocidal products within the Union while ensuring a high level of protection of human and animal health and the environment.

REACH, CLP, PIC and BPR¹ are direct-acting EU Regulations. As they and changes/adaptations made to them enter into force, they automatically form part of legislation in force in the Member States. In order to enable the Regulations to operate effectively in practice, Member States are obliged to establish the necessary arrangements for their implementation and enforcement. It should be noted, that the Regulations also have European Economic Area (EEA) relevance, *i.e.* they are binding for Norway, Iceland and Lichtenstein. As the EEA agreement allows for free movement of goods, it is important that EEA countries have the same approach in enforcing the Regulations as Member States have, thus ensuring that the objectives of these Regulations are achieved.

Since the Regulations lay out a complex set of requirements for the management of chemicals, their successful implementation requires 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.

In order to confirm that duty holders comply 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 to avoid compromising the objectives of these Regulations.

Therefore, a strategy is required at a national level, which defines the administrative framework for their implementation and the Member State bodies which are responsible for that implementation and the enforcement of the Regulations.

Forum provides for exchange of information on, and coordination of the activities related to the enforcement of the Regulations detailed above. It coordinates a network of Member States' authorities responsible for the enforcement of these Regulations.

Forum, as a body of ECHA, shares the four strategic objectives of ECHA which are set out in the Agency's Multi-Annual Work Programme (MAWP) 2014-2018². These include maximising the availability of high quality information to enable the safe manufacture and use of chemicals through the coordination of enforcement actions, mobilising authorities to use information intelligently to identify and address chemicals of concern through exchanging information on enforcement and through further developing the interlinks between ECHA and national authorities and using its expertise to maximise the benefits of enforcement activities.

Forum follows the enforcement practices described in this strategy document and its work is relevant in aiding enforcement authorities developing their enforcement strategies.

In practice, Forum has mandated a Working Group to prioritise and select relevant REACH/CLP/PIC enforcement (REF³) and pilot projects to ensure that annually there

¹ REACH, CLP, PIC and BPR shall be hereinafter referred collectively as "the Regulations".

² [ECHA's MAWP 2014-2018.](#)

³ REACH-EN-FORCE (REF) projects are enforcement projects designed to harmonise enforcement in each Member State and check the current level of compliance with regard to particular obligations imposed on industry by the REACH, CLP and PIC regulations.

are coordinated enforcement activities working towards continued cooperation between Member States and harmonisation of enforcement approaches.

Further to this, in 2017, the Forum has also mandated a Working Group on the Characterisation of Risk to define approaches to categorise risks related to non-compliance of legal requirements of the Regulations at Forum, national enforcement authority and inspector levels.

Additionally, the Forum developed an Interlinks document that serves as a guide for inspectors explaining the process for cooperation between ECHA, the European Commission, Member State Competent Authorities (MSCA) and national enforcement authorities relating to selected enforcement cases.

All documents relating to Forums work outputs as well as the Rules of Procedure and multi-annual work programme can be found on ECHA's website⁴.

The legislative mandate for Forum to carry out its tasks is set out in Article 76(1)(f) of REACH and Article 46(3) of CLP. Article 18(2) of the PIC Regulation and Article 76(1)(h) and 76(1)(l) of the BPR Regulation allow for the use of the Forum to coordinate a network of Member States authorities for enforcement of these Regulations.

The main tasks of the Forum are set out in Article 77(4) of REACH and referred to in CLP (Article 46(3)) as follows:

- 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.

One of the tasks of Forum is to coordinate enforcement strategies and best practices in enforcement and how this is achieved is set out in each of the Forum's activity work programmes.

Under its mandate to identify enforcement strategies, the Forum has compiled this document for Member States to aid in their development of national strategies and to work towards harmonising enforcement approaches across the EU.

2. 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. The PIC Regulation requires the Member States to control the export and import of certain chemicals, to monitor exporters' compliance and to report on the operation of the Regulation. BPR requires the Member States to

⁴ <https://echa.europa.eu/about-us/who-we-are/enforcement-forum>

make the necessary arrangements for the monitoring of biocidal products and treated articles which have been placed on the market to establish whether they comply with the Regulation. They shall also make necessary arrangements for official controls to be carried out in order to enforce compliance with the BPR.

Since the Regulations require actions to control and manage different requirements in the areas of environmental protection, occupational health and safety, consumer protection, market surveillance, 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. These authorities include health and safety inspectorates, environmental inspectorates, consumer protection authorities, agriculture and food authorities and custom authorities. They are required 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 and exporters. Each authority is also likely to have different priorities and resources.

The complexity of target groups, enforcement goals and techniques require the Member States to apply a 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 have a structured, harmonised and transparent approach to REACH, CLP, PIC and BPR 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 Regulations and should have a compatible philosophy, structure and approach.

Although there are differences 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., this strategy document and the description of minimum criteria for inspections (see [Annex I](#)) is a step towards the elaboration of a single, detailed EU wide enforcement strategy for REACH, CLP, PIC and BPR.

The Forum's tasks over the past 10 years since the implementation of REACH have helped to define and promote a degree of common EU wide activity working towards a harmonised enforcement approach under the Regulations.

Drawing on Member State authorities and Forums experiences to date, this document aims to elaborate minimum criteria on the policy, implementation, monitoring and review of the Regulations' enforcement strategies of the Member States.

Therefore, the purpose of this document is to propose a framework to aid the development of national enforcement strategies as well as national enforcement policy relevant for REACH, CLP, PIC and BPR for use by each responsible national enforcement authority. The framework described in this document is broad, so as to allow for national authorities to develop their national strategies as per their priorities while following a harmonised approach towards enforcement and achieving the overall EU policy goals in the field of chemicals management.

3. Elements of an enforcement strategy for the Regulations

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 the following principal elements:

Table 1: Elements of an enforcement strategy

#	Elements of an enforcement strategy
1	Defining clear <u>policy objectives and priorities</u> , 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 <u>organisation</u> in order to be able to achieve effective, efficient, transparent and systematic enforcement of the Regulations
3	<u>Planning</u> enforcement activities
4	<u>Performing</u> actual enforcement measures, including compliance promotion, compliance control and if needed, carrying out formal enforcement such as administrative or criminal proceedings, predefined for the various offences against the requirements of the Regulations
5	Development and implementation of procedures for periodic progress <u>monitoring and measurement</u> , whereby attention is paid to management aspects such as level of compliance, resources spent, information and organisation
6	Development and implementation of procedures for <u>review, evaluation and update</u> of the enforcement strategy, based on the monitoring procedures
7	<u>Reporting on enforcement</u>

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



Diagram 1. Enforcement process for the Regulations

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.

3.1 Policy objectives and priorities

Since the main **policy objectives** are defined in the Regulations themselves, the Member States' enforcement strategies as well as the Forum's activity work programme should be designed to advance those objectives. Articles 1 of the Regulations define their purpose. An effective policy sets a clear direction for an organisation to follow, and highlights a demonstrable commitment to continuous improvement.

In determining how best to implement the minimum criteria for inspections as set out in [Annex I](#) of this document, enforcing authorities should have regard to the following general principles:

- a) The Regulations should be effectively enforced, but in ways which minimise the burden of checking compliance for both duty holders and for enforcing authorities.
- b) Comprehensive risk analysis should be used to ensure that enforcing authorities concentrate their resources on the areas that need them the most. Risk analysis in this context should follow the principles laid down in section [3.1.1](#) of this document. In particular, risk analysis should be based on all available relevant and good-quality data.
- c) Enforcing authorities should respond proportionately to identify contraventions with the Regulations, and within the framework of their enforcement policies, in order to deliver desirable regulatory outcomes.
- d) Duty holders should be helped and encouraged to understand and meet their obligations derived from the Regulations more easily. This includes the provision of readily accessible advice and guidance.
- e) Enforcing authorities shall carry out their duties independently, impartially and without bias.

3.1.1 Analysis of the risk of non-compliance

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 analysis of risk of non-compliance the following inputs and preconditions have to be considered:

a) The effect of non-compliance

An estimation of the consequences of the specific non-compliance for human health and the environment (risk recipients) should be performed.

Risk is the effect multiplied by the probability, so the risk to human health and the environment is the hazard of the chemical multiplied by the exposure to it. In general, chemicals or articles with severe inherent hazard properties and supplied for wide and divergent use could be looked as causing high risk and thus a priority from a risk perspective.

Risk of non-compliance is the effect multiplied by the probability that non-compliance will occur. Probability could be assumed as a function of the level of awareness and knowledge with the Regulations by the target groups, combined with the ambition of the companies to be in compliance, the estimation of their

economic implications of complying, the probability of being found in non-compliance, the probability and effectiveness of formal enforcement, and the possibility of adverse public reaction.

It is also important to consider the effects on the socio-economic situation in the particular Member State and effects for industry and specific policies specifically with regard to the single market, competitiveness and innovation. For example, the risk of unfair competition or the risk that particular policies of the Member States are unsuccessful in achieving their aims.

b) The target groups

Target groups for the enforcement are specified in the Regulations (manufacturers, importers, distributors, downstream users, only representatives, producers of an articles). These target groups, within the Member State, may be further divided in subgroups for the purposes of enforcement, dependent on the legal obligations and the duties they have to comply with. Some examples of subgroups of duty holders that can be used when prioritising enforcement activities are:

- NACE codes (sometimes aggregated to e.g. manufacture of chemicals, manufacture of non-chemicals, wholesale, retail, etc.);
- REACH role (M,I,OR, DU,D);
- Other company roles (e.g. Retailer, wholesaler, formulator, re-importer, re-filler, re-packager);
- Type of product (substance, mixture, article but also more specific (e.g. cleaning products, tyres, oils);
- Size of the company (non-SME, SME, micro);
- ECHA information (registration, classification).

c) The legal obligations and tasks

The legal obligations and the duties to fulfil should be listed. Annexes II to V of this document describe the Articles of the Regulations 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 Member State.

The risk analysis is a start to perform a further assessment of the compliance behaviour of the target groups. It allows assessing the impact of the non-compliance including environmental, occupational health and safety, public health, consumer protection and economic aspects. On the basis of knowledge in the Member State (including intelligence gathered at Forum level or other international projects) concerning traditional behaviour and expectations, the expected non-compliance of the target groups can be estimated.

Insight should be given 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.

Another emphasis is on the precautionary principle which should be used any time doubts appear, since for example the REACH Regulation is strongly 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 does not adversely affect the objectives of the Regulation. 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 other relevant legislation (e.g. market surveillance, workplace, environmental).

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

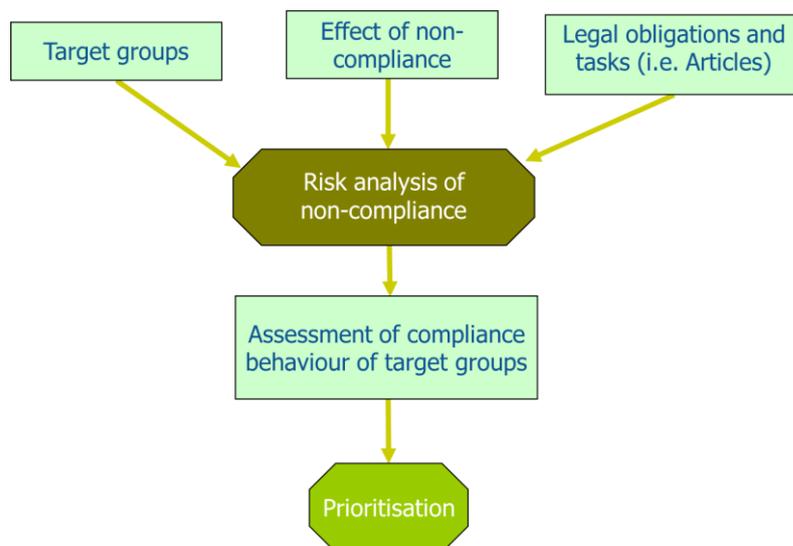


Diagram 2. Non-compliance risk analysis scheme for setting priorities for national enforcement strategies

3.1.2 Priority criteria

In order to prioritise its work based on risk, the enforcement authorities require a method to aid in prioritisation of cases of non-compliance. Particularly, the risk aspect should be kept in mind when planning proactive enforcement projects.

When deciding on how to handle reactive enforcement cases there can also be a need to prioritise those non-compliance cases that can cause more severe effects. The manner in which an enforcement authority reacts to each specific case is solved nationally but discussion on common understanding of risk of non-compliance is also ongoing in the Forum (*e.g.* Working Group on Characterisation of Risk).

To enforce the Regulations efficiently, the Member State should set priorities considering:

- The vulnerability and severity of potential consequences of the non-compliance for the human health and the environment;
- The particular industry/economic activities and the socio-economic situation in the country;
- Traditional behaviour and expectations regarding target groups compliance with legal requirements (including results of Forum enforcement projects);
- The legal and administrative prerequisites in the particular Member State;
- The Forum's work programmes developed by the Forum and the activities emanating from its implementation;
- 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.

As matter of example, the following table provides the ranking of priorities in REACH and CLP controls that the Member States provided in the last reporting exercise (REACH Article 117(1) and CLP Article 46) in 2015.

Table 2: Ranking of prioritisation of controls based on REACH and CLP duties provided by the Member States

	Ranking of priorities in REACH controls during 2010-2014 report ¹	Ranking of priorities in CLP controls during 2010-2014 report ¹
1	Information in the supply chain	Hazard communication in the form of labelling
2	Restrictions	Packaging
3	Registration	Hazard classification
4	Imported goods	Harmonisation of classification and labelling of substances
5	Authorisation	Notification to the classification and labelling inventory according to Article 40
6	Duty to communicate information on substances in articles	Other common provisions, such as the obligation to maintain information and requests for information
7	Registration and notification of substances in articles	Imported goods
8	-----	Other CLP obligations
¹ Controls per obligations for all Member States that have reported (between 26 – 17 Member States)		

3.2 Organisation of enforcement

This refers to putting in place an effective management structure and arrangements so that the policy objectives set previously can be delivered. This includes the:

- a) Elaboration of an appropriate regulatory regime, which ensures equal treatment of all the duty holders. In this case, as the Regulations apply directly to all the EU and EEA countries, it is guaranteed that the regulatory regime is the same. The Forum tasks are also set by the Regulations. A regulatory regime is needed also for defining the powers for the enforcement authorities.
- b) Development of a clear enforcement programme, which includes all the areas of enforcement (environment, occupational health and safety, consumer protection, customs, market surveillance, etc.), formal and unambiguous provisions or arrangements for cooperation, communication and coordination amongst the enforcement authorities on regional and national levels as well as considerations for cooperation, communication and coordination with enforcement authorities in other Member States. This includes the implementation of a network for exchange of information on chemicals, nationally and in the EU and EEA (the Forum).
- c) 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 issues with the duty holders, industry and other stakeholders. 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.

When strengthening the administrative and expert capacity of the national 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 actions are the development and distribution of suitable inspection tools, enabling access to the enforcement relevant REACH-IT information (PD-NEA⁵) and respective BPR information, creation of means of information exchange amongst inspectors, such as “inspectors’ helpdesks”, web-based information exchange platforms, establishments of regional and national enforcement networks, etc.

- d) A crucial element of the national enforcement is securing the necessary coordination and cooperation with national customs authorities. The customs authorities are key players for a substantial proportion of the target groups, i.e. importers and exporters of substances on their own, in mixtures and articles.

In order to make full use of the specific competencies and expertise of the customs authorities, a decision on the level of 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 preferable to be planned and accepted on an EU level, which would involve coordinated action by the relevant Commission services, ECHA and the Forum.

The Forum had already addressed the cooperation with Customs authorities at the beginning of its establishment and more recently via the Working Group Customs 2⁶. This working group was established in 2016 with the objective to discuss with the European Commission DG TAXUD and the Customs Authorities the possible involvement of Customs in the control of REACH and CLP (and possibly aspects of PIC and BPR).

Appropriate mechanisms should be in place to ensure the participation of customs authorities in both proactive (compliance check with the REACH, CLP, PIC and BPR 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, by-laws and orders or memorandums of understanding/cooperation agreements. A solution would be to integrate custom authorities in enforcement of the Regulations by making data from REACH-IT/PD-NEA or other relevant IT systems available to them on the same conditions as they will be made available to the other REACH, CLP, PIC and BPR enforcers. Development of factsheets, guidance documents, check-lists or tailored-made training may also contribute to facilitate the integration of customs authorities in some tasks of enforcing of these Regulations. In the context of PIC, customs and national enforcement authorities (NEAs) already have access to an IT system that provides information on the legal status of exports of chemicals subject to that Regulation (ePIC).

Additional information on the minimum criteria for the organisation of enforcement can be found in [Annex I](#), section A.

⁵ Portal Dashboard for national enforcement authorities

⁶ <https://echa.europa.eu/about-us/who-we-are/enforcement-forum/working-groups>

3.3 Planning for national enforcement strategies

After the policy goals, compliance vision and mission for chemicals' enforcement have been defined at the national level, more detailed enforcement goals should be set.

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.

Further information on the minimum criteria concerning the planning of enforcement strategies can be found in [Annex I](#), section B.

3.4 Enforcement process

Once the enforcement priorities are set, the authorities 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 activities such as:

- a) inspections;
- b) Investigations;
- c) formal enforcement action (such as issuing enforcement notices or instituting legal proceedings);
- d) compliance promotion;
- e) communication with all the relevant stakeholders.

The most important aspect in the enforcement process is to take actions that help in avoiding the risks caused by non-compliance of the duty holder. Enforcement aims at effectively ensuring the compliance of the target groups and to maximise the achievement of all objectives of these Regulations. 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.

3.4.1 Enforcement programmes

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 with regard to checking the compliance with the main duties (Annexes II to V of this document).

3.4.2 Communication

Communication is a fundamental element of the enforcement process. Proper communication amongst all relevant stakeholders – enforcement authorities, target groups, workers, interested communities (for example Non-Governmental Organisations (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 achieve the objectives of these Regulations.

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. However, 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.

Systems for communicating information on enforcement related activities have been set up by Forum in collaboration with ECHA and the European Commission, namely PD-NEA and ICSMS⁷ (see Table 3 below). These provide a secure means of exchanging relevant information between national enforcement authorities, for example, referrals from one country to another on non-compliant products, and for sharing of information between ECHA and authorities.

In order to communicate to actors in the supply chain and to the general public, information on outcomes from Forum coordinated REF and pilot projects are published on ECHA's website⁸. In addition, the RAPEX alert system provides information on hazardous products as reported by national authorities in order to prevent or restrict their marketing or use. The system enables a quick exchange of information between all Member States and the European Commission relating to hazardous non-food products, including chemicals, posing a risk to health and safety of consumers.

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 of not achieving the objectives of these Regulations.

The communication on enforcement should be subject and target specific (*e.g.* to target groups, NGOs, workers, general public) and be submitted by appropriate channels in order to achieve the desired effect.

In addition, also general communication on upcoming enforcement projects and lessons learned from past projects is useful and enables more companies than just those inspected to benefit from the information. Such information is published on ECHAs website as relevant.

"Name and shame" and "Name and fame"-type communication campaigns are effective and influential as they stimulate target groups for better compliance and cooperation. National legislations may however vary in respect of publishing the names of companies and/or products inspected.

3.4.3 Compliance promotion and monitoring

Compliance promotion is necessary because enforcement alone is often not effective, especially in the context of these Regulations, where the size of the regulated targets far exceeds the resources for enforcement. One of the main problems the enforcers face is the general lack of knowledge of the target groups (especially small and medium enterprises (SME) 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

⁷ Information and Communication System for Market Surveillance

⁸ <https://echa.europa.eu/about-us/who-we-are/enforcement-forum/forum-enforcement-projects>

assistance, building public support and building expert and administrative/managerial capacity within the regulated community. Compliance promotion is also a task of other bodies than enforcing authorities (like national REACH/CLP/BPR Helpdesks etc.)

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.

3.4.4 Enforcement actions

The following factors may assist inspectors when deciding what type of action to take when non-compliance is found:

- the hazards presented by the substance, the mixture or the substance in article in question and the risks resulting from the non-compliant 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 or would arise 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 and level of cooperation of the duty holder;
- the potential competitive advantage by not complying with the Regulation;
- avoiding the correct functioning of the single market.

In addition, judgements 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 or how they address particular hazardous chemicals 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.

The choice of enforcement action is clearly a matter for the inspector/enforcing authority 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 and in general they can be information exchange, administrative offences and criminal offences as explained in more detail in the following table (Table 3):

Table 3: Formal enforcement measures and actions

Formal enforcement measures/actions¹		Monetary actions²
Information exchange	<ul style="list-style-type: none"> • RAPEX, ICSMS • Ad-hoc information to another MS(s) 	
Administrative offences	<ul style="list-style-type: none"> • Verbal advice • Written advice • Legal proceedings • Administrative measures/orders • Legal convictions • (Temporary) confiscation, seizure • Destroy non-compliant products • Withdrawal of products from the market, possibly combined with requirement for the company to publish the non-compliance • (Temporary) ban of sale/ban of use • (Temporary) prohibition of activities e.g. by suspension of business licence • Withdrawal of the activity permit 	Fines Sanctions Penalties
Criminal offences	<ul style="list-style-type: none"> • Convictions • Imprisonment 	Fines Sanctions Penalties
<p>¹ Some of these actions may be interlinked as some of them cannot occur without others have happened before (e.g. legal conviction are typically preceded by legal proceedings). ² Sanctions and penalties are typically linked to certain types of enforcement actions. Information about the national penalties relating to REACH can be found in the Commission report from 2010: http://ec.europa.eu/environment/chemicals/reach/pdf/report_reach_penalties.pdf</p>		

Where non-compliance with the Regulations 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.

Enforcing authorities should ensure that products which present a serious risk requiring rapid intervention, including a serious risk where the effects are not immediate, are treated in accordance with the requirements of Articles 20 and 29 of the Accreditation and Market Surveillance (AMS) Regulation (*inter alia*, recalling, withdrawing or destroying such products or prohibiting them from being made available on the market).

As the AMS Regulation stipulates in Article 41 and as the REACH, CLP, PIC and BP 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 economic situation (e.g. Gross Domestic Product (GDP) as an indicator), the size of the enterprises, the compliance culture amongst the target groups, the legal systems, etc., a fully harmonised penalty system in the Union is not possible, but some minimum level and some common elements should be integrated in the corresponding national provisions.

Enforcement measures vary significantly from country to country and are a challenge to the pursuit of level playing field in chemical risk management throughout the EU. Minimum powers for sanctions for enforcement authorities are stipulated in the AMS Regulation. Further information on the different measures and actions (pecuniary fines, confiscation of economic gains from non-compliant activities, deprivation or suspension of rights (e.g. business license), name and shame, court injunctions, etc.) and availability of these measures in Member States, can be found in the Commission report on penalties (see footnote 2 of the Table 3).

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.

A common approach towards the philosophy of imposing sanctions and administrative orders would be invaluable in creating a level playing field for the target groups throughout the EU.

Further information can be found in [Annex I](#), section C "Carrying out inspections".

3.4.5 Reporting on enforcement activities to the duty holder

Following enforcement activities under the Regulations, inspectors should report findings from each of those activities, for example, inspections or investigations, to the duty holder. This should be done in accordance with the information provided in section D of [Annex I](#).

Additionally, records of such reports should be kept by the enforcement authority for use in collating enforcement related data (see section [3.5.1](#) and [3.7](#) for further details).

3.5 Progress monitoring and measurement of 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 the different Regulations (see section [3.7](#)).

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

3.5.1 Enforcement reports

All reports related to enforcement activities under the Regulations should be recorded as per details in section [3.4.5](#) and section D of [Annex I](#). Enforcement authorities may wish to collate this information for communication on enforcement activities to other national authorities and/or to the public, for example to inform the public about actions taken in relation to non-compliances.

Collection of such information allows for authorities to analyse the findings of enforcement activities and review the outcomes. Evaluation of the performance such as compliance levels, duty holders and chemicals involved and results of the activities should help in devising future plans, goals and strategies.

Collation of this information is also necessary in order for Member States to gather data for the purposes of reporting on enforcement related actions to the Commission (see section [3.7](#) below).

When considering data relevant for gathering, Member States may find it useful to consider the enforcement indicators (see section [3.5.2](#) and [Annex VII](#)) which have been developed to capture all significant enforcement elements at a Member State level.

3.5.2 Performance indicators

Performance should 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. This could be done through the means of a set of performance indicators, measuring the above-mentioned elements of the enforcement process.

A set of enforcement indicators for REACH and CLP was developed following a study from the Commission with contributions from Forum. The results of the study are publically available⁹. The study proposes a set of indicators to measure and monitor the enforcement of two key Regulations on chemicals: REACH and CLP. These indicators should help:

- in gaining a better knowledge of the state-of-play of the implementation and enforcement of these Regulations;
- the Forum to measure the performance of their activities and towards improved fulfilment of their objectives;
- to achieve a more harmonised and systematic approach concerning the collection of enforcement information and reporting at EU and national level;
- Member States to use similar data to evaluate their own enforcement activities.

⁹ http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8280

The study proposes to set three levels of enforcement indicators, at the level of the individual Member States, the Forum and the EU as a whole. The Forum has selected 13 indicators and the Commission is using 12 EU level indicators to monitor enforcement at EU level. The study proposed 16 enforcement indicators at Member State level that are summarised in [Annex VII](#).

3.6 Reviewing performance

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.

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.

Enforcing authorities should regularly check and review the success of their arrangements for inspections, including the elements of organisation, planning and carrying out, using appropriate performance indicators. If necessary, the arrangements should be updated in order to further the effectiveness of chemical inspections.

3.7 External Reporting

As detailed in [3.5.1](#), enforcement authorities should ensure that appropriate systems are in place to facilitate the collection and collation of relevant information on enforcement activities.

For these purposes, 'relevant information' means – as a minimum – the enforcement-related information that is required to be submitted to the European Commission for the purposes of reporting under the different Regulations (*i.e.* Article 117(1) of REACH (with reference to Article 127), under Article 46 of CLP, under Article 22 of PIC, and Article 65 of BPR. This would include results of official controls such as inspections, investigations and monitoring as well as any other enforcement measures taken.

4. Co-operation and co-ordination between enforcing authorities

The enforcement of the requirements of the 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 all enforcement authorities, both nationally and EU-wide as well as between Forum/ECHA and the relevant authorities, to ensure effective and efficient enforcement of the Regulations. 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 should represent an enforcement authority with a specific competence and the tasks for Forum stretches over several competencies, the Forum member should ensure that there is appropriate co-ordination between

relevant enforcement authorities nationally. The member should encourage cooperation between the responsible authorities and also relay any problems encountered by the different enforcement authorities at the European level, for example, hold regular national authorities meetings to discuss priorities, Forum outcomes, planned campaigns etc.

4.1 Co-operation and co-ordination between national enforcement authorities

When defining national 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 are divided in the legislation and how possible common duties should in practise 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 non-governmental resources, especially in relation to communication;
- 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 on minimum standards of co-operation. Joint inspections between different enforcing authorities are also encouraged;
- If joint inspections between different enforcing authorities are completed, 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 on a national level;
- The communication mechanisms needed between the Competent Authority and the enforcement authorities such as notification between enforcing authorities of identified matters of concern regarding duty holders. This should include the use of Helpdesk and information from REACH-IT, PD-NEA and ICSMS.
- 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;
- The communication mechanisms needed to co-ordinate the information to and from the Forum to relevant enforcement authorities, for example, through PD-NEA;
- Participation in Forum co-ordinated projects can lead to the establishment of co-operation procedures;
- Mutual support between enforcement authorities, and where appropriate the provision of specialist advice;

- Establishment of national, regional and/or local networks or fora for enforcement liaison;
- How to record enforcement activities to fulfil the national obligations and the obligations in reporting to the Commission according to Article 117 in REACH, Article 46 in CLP, Article 22 of PIC and Article 65 in BPR.

The above-mentioned issues are meant to assist when developing provisions on the division of the competencies and responsibilities amongst the national enforcing authorities and on the co-operation and co-ordination between them. These provisions could form a part of the enforcement strategy or be a stand-alone 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.

4.2 Co-operation and co-ordination between EU enforcement authorities, Forum and Commission

In addition to national coordination activities, Member States must ensure that they work closely with other EU/EEA authorities to provide a uniform approach towards enforcement and enhance cross border cooperation. The Forum coordinates enforcement activities for Member States, *e.g.* REF projects, and supports them in carrying out their duties, for example by providing information on areas of non-compliance through screening exercises and by facilitating means of exchanging information *e.g.* PD-NEA and ICSMS. Member States should therefore consider the following when developing their strategies:

- Exchange of inspectors to facilitate cooperation between authorities on an EU level;
- Co-operation between different Members States enforcement authorities;
- Communication means between enforcement authorities across the EU and Forum. An internal Forum document on Interlinks prepared for NEA's use serves as a useful guide for inspectors and focal points as it describes the process for cooperation between ECHA, the European Commission, MSCAs and NEAs relating to selected enforcement cases. Those cases are mostly related to the follow-up of ECHA's regulatory decisions and can be found in PD-NEA.
- Each Member State should assign a focal point who coordinates and handles communication related to interlinks cases from and to ECHA, Member State Competent Authorities, national enforcement authorities and/or the Commission.

For details on how enforcement authorities cooperate and coordinate activities, see [Annex I](#), section A.

5. Member State approaches to develop enforcement strategies

For reference and harmonisation purposes, Forum members are continuously invited to submit the examples of their national enforcement strategies to the ECHA Forum Secretariat. Such national enforcement strategies will be made available as examples on the Forum S-CIRCABC website. The sharing of enforcement projects, experiences, plans, etc. is a standing agenda item for every Forum plenary meeting

which the Forum members can use to contribute to the harmonisation of enforcement.

In the Commission document on Member State reporting under Article 117 REACH and Article 46 of CLP¹⁰, the majority of EU/EEA countries indicated that they have implemented an enforcement strategy for REACH and that they have implemented a strategy for the CLP Regulation all in line with the Forum strategy. In addition, many countries stated that they have a formal planning document for REACH and CLP inspections and that their inspection strategy took into account the enforcement strategy developed and activities carried out by the Forum.

6. Review of this document

This paper shall be reviewed by the Forum at least once every five years. The present review was undertaken in 2017. 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 ECHA Forum 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, CLP, PIC and BPR enforcement, in line with the tasks of Forum, as specified by Article 77(4) of the REACH Regulation.

7. Conclusions

The enforcement of the Regulations is vital to ensure 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 chemical producers, importers, exporters, downstream users and distributors, and the enhanced competitiveness and innovation of EU industry.

The Forum for Exchange of Information on Enforcement is a valuable body for exchanging information on, and coordinating, activities relating to the enforcement of chemicals legislation. One of its principal tasks is to identify enforcement strategies and best practices.

In order to ensure structured, harmonised and transparent enforcement of the Regulations, each Member State should elaborate a working enforcement strategy, based on the framework presented in this document and its Annexes.

The enforcement strategy should set out:

- a) clear policy objectives and priorities;
- b) suitable organisational provisions, development of a clear enforcement programme, provisions for cooperation, communication and coordination amongst enforcement authorities at regional, national and EU level, appropriate standards for enforcement and compliance tools and effective

¹⁰ Service contract for technical assistance to review the existing Member State reporting questionnaire under Article 117 REACH, including the evaluation and configuration of an appropriate IT tool for the reporting

- communication and guidance on REACH, CLP, PIC and BPR issues with industry and other stakeholders;
- c) actual enforcement measures, including compliance promotion, monitoring, sanctions (including, if needed, administrative or criminal proceedings);
 - d) procedures for periodic progress monitoring and measurement;
 - e) procedures for the review, evaluation and updating of the enforcement strategy, based on the monitoring procedures.

This would guarantee that Member States' 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.

As can be seen from the Member States reporting under CLP and REACH in the Commission document on Member State under Article 117 REACH, Article 46 of CLP, Article 22 of PIC and Article 65 of BPR, Member States are using the present strategy to develop their own national REACH, CLP, PIC and BPR enforcement strategies.

Co-operation and co-ordination of enforcement is reported both between NEAs nationally and between Member States, especially through participation in Forum coordinated projects.

Such harmonisation of approaches in the enforcement of REACH, CLP, PIC, BPR and cooperation between responsible authorities meets the aim of achieving the overall EU policy goals in the field of chemicals management.

8. List of Annexes

This document contains seven Annexes.

The first annex contains the **minimum criteria for chemical inspections** and provides a set of criteria that are considered sufficient to have a more harmonised enforcement in the EU and as consequence a better level playing field.

The following four Annexes (II-V) include the **essential legal requirements** for the four Regulations under the remit of the Forum.

Clarification on the definitions used in this document and the Member State enforcement indicators can be found in Annex VI and VII, respectively.

Annex I. Minimum criteria for chemical inspections

Annex II. Essential legal requirements for the enforcement of REACH

Annex III. Essential legal requirements for the enforcement of CLP

Annex IV. Essential legal requirements for the enforcement of PIC

Annex V. Essential legal requirements for the enforcement of BPR

Annex VI. Definitions

Annex VII. Member State enforcement indicators

Annex I - Minimum criteria for chemical inspections

REACH, CLP, PIC and BPR Regulations (hereinafter referred to as “the Regulations”) inspection activities should be carried out in Member States following minimum criteria to be applied in the effective organisation, planning, implementation, carrying out and review of such tasks, thereby strengthening duty holder compliance with the Regulations, as well as contributing to more harmonised enforcement. These are key factors in realising the objectives of REACH and CLP to ensure a high level of protection of human health and the environment as well as the free movement of substances while enhancing competitiveness and innovation.

The information in this Annex is addressed to enforcing authorities (and other public authorities as appropriate) in Member States with responsibilities under the Regulations and compliments the information provided in the main body of this document.

A. Organisation

1. Appropriate provisions should be made to ensure, as far as is reasonably practicable, that enforcing authorities cooperate and exchange information (as mentioned in Article 122 of REACH and, Article 43 (2) of CLP, Article 18 of PIC and recital 60 of BPR with:
 - a) other enforcing authorities within their Member State;
 - b) their Competent Authority or Authorities;
 - c) enforcing authorities or Competent Authorities in other Member States; and
 - d) the European Chemicals Agency;

where this will facilitate compliance with, or the effective enforcement of the Regulations (with reference to the requirements of the Accreditation and Market Surveillance (AMS) Regulation, insofar as there are no specific provisions with the same objective, nature or effect in these Regulations) in the Member States.

2. Where not already provided for by national law, formal arrangements should be devised and implemented as appropriate that provide for clear and effective co-operation and information exchange between enforcing authorities within a Member State (where there is more than one enforcing authority responsible for the enforcement of the Regulations). Details of what national enforcement authorities should consider which would facilitate good co-operation and co-ordination are listed in section 4 of this Strategy document.

In practice, the cooperation between national 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.

In the Commission document on Member State reporting questionnaire under Article 117 REACH¹¹, the majority of countries indicated that they have more than one authority involved in the enforcement of REACH.

Most countries reported that they have established formal or informal coordination mechanisms for exchanging information on enforcement-related issues, for example, establishment of a forum or working group involving NEAs, which meets between 1-3 times annually. In a number of countries where co-ordination of activities involves numerous regional actors, co-ordination takes the form of a network of established contact points.

Additionally, countries reported that REACH joint inspections involving several national authorities have taken place mostly as part of Forum coordinated REF projects and that in some cases participation in REF projects has led to the establishment of cooperation procedures. Member States reported that they considered the Forum's coordinated REF and pilot projects as the most effective cooperation activities and mentioned specifically that the REF-3 project on registration duties was particularly productive and strengthened the cooperation with customs authorities.

The majority of countries reported that they have similar coordination activities for CLP as under REACH. Member States indicated that exchanges in relation to CLP enforcement activities are mainly mediated through Forum activities and the PD-NEA IT system.

Outside the remit of the Forum, Member States also participate in CLEEN¹² and PROSAFE¹³ projects and co-operate with other networks such as IMPEL¹⁴ and SLIC¹⁵. Furthermore, the Regional group of Nordic countries (Denmark, Finland, Iceland, Norway, Sweden) meets annually to discuss enforcement of chemicals legislation e.g. CLP, Biocides, Restriction of Hazardous Substances Directive, etc. Other countries report on joint training initiatives and bilateral capacity building projects.

3. Information about the enforcing authorities, their tasks and responsibilities and how they may be contacted should be publicly available in all Member States.
4. Matters of concern identified through REACH and/or CLP and/or PIC and/or BPR inspection activity that relate to the compliance of duty holders based in other Member States, or that appear to raise significant cross-border issues, should be communicated as soon as possible via the electronic information exchange system adopted by the Forum for the purposes of enforcement of the Regulations. Details on communication are outlined in section [3.4.2](#) of this strategy document. Information on general enforcement issues with Community Union-wide interest should be exchanged via the Forum.
5. Enforcing authorities should disclose to the bodies referred to in paragraph (1) information they hold in relation to compliance with, or the enforcement of, the Regulations where they believe:
 - a) it is reasonable to make that disclosure;

¹¹ Service contract for technical assistance to review the existing Member State reporting questionnaire under Article 117 REACH, including the evaluation and configuration of an appropriate IT tool for the reporting"

¹² Chemicals Legislation European Enforcement Network

¹³ Product Safety Forum of Europe

¹⁴ European Union Network for the Implementation and Enforcement of Environmental Law

¹⁵ Senior Labour Inspectors Committee

- b) such disclosure is lawfully allowed by national legislation; and
 - c) the disclosure will facilitate compliance with, or the effective enforcement of the Regulations in Member States.
6. Enforcing authorities should ensure that they make appropriate resources available for inspection of the Regulations, and that inspectors (and other relevant staff as may be necessary) have suitable qualifications and have been given the necessary powers to enforce those parts of the Regulations for which they have enforcement responsibility. Suitable training and up to date support materials should be provided to those involved in inspection of the Regulations.

B. Planning

1. Enforcing authorities should ensure that their inspection activities under the Regulations are planned in advance, by having at all times an inspection plan or plans, collectively taking into account all the territory of the Member State and of the known target groups.
2. Such plan or plans may be established at national, regional or local levels, but enforcing authorities should ensure that the plan or plans apply to all of their REACH, CLP, PIC and BPR inspections and that the plans have regard to the strategy or strategies developed in this document.
3. Plans for REACH, CLP, PIC and BPR inspections should be produced on the basis of the following:
 - a) the enforcing authorities' objectives and targets, their overall statutory responsibilities and competencies, and the provisions of the Regulations that 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 and the single market 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) an analysis of risks to the effective functioning of the single market or to competitiveness, taking into account relevant socio-economic factors;
 - f) a general appraisal of the likelihood of non-compliance by the duty holders/target groups with the Regulations' requirements, taking into account factors such as previous inspection records and potential future risks.
 - g) information at EU level e.g. EU enforcement indicators, Commission reports, Member States reports and guidance such as Good Practice for Market Surveillance¹⁶, the OECD Best Practice Principles for Regulatory Policy: Regulatory Enforcement and Inspections¹⁷, which provides a framework to support improving regulatory enforcement through inspections,
 - h) take into account planned Forum coordinated projects e.g. REF and pilot projects.

¹⁶ <http://ec.europa.eu/DocsRoom/documents/23041>

¹⁷ <http://www.oecd.org/gov/regulatory-policy/enforcement-inspections.htm>
<http://www.oecd.org/gov/regulatory-enforcement-and-inspections-9789264208117-en.htm>

4. Plans for inspection of the Regulations should:
- a) be appropriate to the inspection tasks/competencies of the relevant enforcing authorities;
 - b) take into account the number and size of the different duty holders/target groups concerned, products concerned;
 - c) take into account relevant existing information in relation to specific duty holders, such as safety data sheets, chemical safety reports, information used for the purposes of classification and labelling, other information available from the electronic information exchange system (as adopted by the Forum) or from REACH-IT, PD-NEA or ICSMS, results of previous inspections, or information kept and made available by the duty holders according to Article 36 of REACH, Article 49 of CLP or article 68 of BPR;
 - d) consider the amount and suitability of existing information available to the enforcing authority, and the need for further work to better identify duty holders/target groups and gather intelligence on supply chain information, so as to provide for more effective risk analysis, and targeting and use of resource; and
 - e) give priority to measures that are designed to achieve an effective outcome in terms of compliance, based on risk analysis.
5. Each planned inspection should, as a minimum:
- a) define the geographical area which it covers, which may be for all or part of the territory of a Member State;
 - b) cover a defined time period, for example one year;
 - c) provide for co-ordination, co-operation, communication and information exchange in accordance with section A (Organisation) above;
 - d) provide for routine (proactive) inspections, which identifies the specific duty holders / target groups covered and which describes the scope and, if possible, the frequency of the inspection;
 - e) provide and outline the procedures for non-routine (reactive) inspections, ensuring that appropriate resources can be set aside as necessary; and
 - f) include specific provisions for its revision.

C. Carrying out inspections

Enforcing authorities should apply the following criteria in respect of all inspections under the Regulations:

- a) identify correctly the role of the duty holder in terms of which of the target groups they belong to;
- b) check compliance with the Regulations requirements relevant to the particular scope of the inspection and according to the role of the duty holder (*i.e.* to the different obligations of the target groups – registration, information in the supply chain, use, authorisation, restriction, classification, labelling, notification or other duty as appropriate);
- c) consider the risks to, and impact on, human health, the environment, single market and competitiveness are considered;

- d) exchange information on activities and co-ordinate site visits and other inspection work under the Regulations where site visits are to be carried out by more than one enforcing authority;
- e) report the findings of the inspections ensuring that the reports provide the information needed by the Member State for the purposes of reporting under Article 117(1) of REACH (with reference to Article 127), under Article 46 of CLP, Article 22 of PIC and under Article 65 of the BPR;
- f) examine the essential requirements of the Regulations as prioritised in the national enforcement strategies, relevant for the given duty holder / target group, in accordance with the Regulations requirements, the inspection plan(s) and the enforcing authorities' responsibilities and competencies;
- g) promote duty holders' knowledge and understanding of their duties under the Regulations during inspection activities and ensure duty holder compliance (using formal enforcement where appropriate);
- h) investigate complaints received by enforcing authorities and made by third parties relating to the compliance of a particular duty holder or duty holders as soon as possible after such complaints are received, in line with any relevant selection criteria that enforcing authorities may apply;
- i) investigate serious accidents or incidents without undue delay after these come to the notice of the relevant enforcing authorities, in line with any relevant accident or incident selection criteria they may apply;
- j) treat products identified during inspection activities which present a serious risk requiring rapid intervention, including a serious risk where the effects are not immediate in accordance with the requirements of Articles 20 and 29 of the AMS Regulation;
- k) take measures to alert users to hazards identified where relevant by using the appropriate procedures as required by Article 19(2) of the AMS Regulation;
- l) ensure that recall or withdrawal of products, or prohibitions on making products available on the market is carried out according to the provisions of Articles 19 to 29 of the AMS Regulation;
- m) preserve confidentiality where necessary in order to protect commercial secrets or to preserve personal data pursuant to national legislation, although this shall not prevent the dissemination of relevant information to relevant enforcing authorities and to the public as necessary, in order to protect the interests of users in the Community.

D. Actions following inspections under the Regulations

Enforcing authorities should ensure that after every inspection relevant inspection reports are produced without unnecessary delay and stored, which as a minimum contain:

- a) basic data on the inspection (for example, the date, name of the inspector(s), scope of the inspection, details of the duty holder, etc.);
- b) the significant findings of the REACH and/or CLP and/or PIC and/or BPR inspection;
- c) a comparison of the findings with the legal requirements, relevant to the duty holder / target group concerned;

- d) an evaluation thereof, identification of any non-compliance, and a conclusion on whether any further action should follow, such as formal enforcement or further inspections; and
- e) the measures taken pursuant to the REACH and/or CLP and/or PIC and/or BPR inspection, by the enforcing authority and/or by the duty holder.

The inspection reports should be properly recorded in writing or in electronic format and kept in an accessible and retrievable format. The reports should be communicated to duty holders promptly with clear explanations of what action they are required to take.

The enforcing authorities should ensure that if a duty holder is required to take action in response to an inspection, then appropriate checks are made where necessary to ascertain that the required action has been taken, and as soon as possible, after the expiry of any deadline given to the duty holder. The failure of the duty holder to complete the activities required should result in further enforcement action to ensure compliance.

Information on reviewing inspection activities is detailed in section [3.6](#). Section [3.7](#) of the document deals with reporting on enforcement activities under Article 117(1) of REACH, Article 46 of CLP, Article 22 of PIC and Article 65 of BPR.

Annex II – Essential legal requirements related to the enforcement of REACH

REACH was fundamentally a new approach to chemical management. Under REACH, each manufacturer or importer into the EU of chemicals in volumes of 1 tonne or more per year – around 30,000 substances – has to register them with the European Chemicals Agency, submitting information on their properties, their 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 manufacture, placing on the market and use of certain dangerous substances, and for other substances of very high concern, use-specific authorisation is required.

REACH imposes a range of duties on essentially four *target groups*:

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

Though 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 objectives of REACH are met.

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.

Article	Description	Target group
<p>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.</p>		
5	<p>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.</p>	<p>Manufacturers, importers (Only Representatives)</p>
6 & 7	<p>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.</p>	<p>Manufacturers, importers</p>
8	<p>Article 8 describes the specific obligations of an only representative.</p>	<p>Only representatives</p>
10, 11, 12, 14 & 19	<p>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.</p>	<p>Manufacturers, importers</p>
12(2) & 24(2)	<p>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.</p>	<p>Manufacturers, importers</p>
22(1) & 22(2)	<p>These Articles require registrants to update their registration information as appropriate.</p>	<p>Manufacturers, importers</p>
40(4), 41(4) & 46(2)	<p>These articles contain requirements to submit information to ECHA regarding dossier and substance evaluation</p>	<p>Manufacturers, importers</p>

<p>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.</p>		
31	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 scenarios consistent with the information in the CSA/CSR (if required). This is the key provision to ensure information is provided through the supply chain.	Manufacturers, importers, distributors, downstream users
32(1)	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.	Manufacturers, importers, distributors, downstream users
33(1) & 33(2)	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.	Manufacturers, importers, distributors, downstream users
34	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.	Distributors, downstream users
35	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.	Manufacturers, importers, distributors, downstream users
36(1)	Obligation to keep available all the information required to carry out duties under REACH for a period of at least 10 years after last manufacture, import supply or use of a substance or mixture.	Manufacturers, importers, distributors, downstream users
56(1)	This requires manufacturers, importers or downstream users not to place substances on the market if they are included in Annex XIV after the substance's sunset date (<i>i.e.</i> subject to authorisation).	Manufacturers, importers, downstream users
65	This requires the holder of an authorisation to include the authorisation number on the label	Manufacturers, importers, downstream users

	<p>before placing the substance on the market for an authorised use.</p> <p>This is important information for the downstream user when checking if his use is within the authorisation for that substance. It applies once the authorisation number is available in the Commission's authorisation decision.</p>	
67(1)	<p>This states that substances subject to restriction shall not be manufactured or placed on the market unless they comply with the conditions of that restriction.</p>	Manufacturers, importers, distributors, downstream users
<p>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.</p>		
14(6)	<p>This requires registrants to identify and apply appropriate measures to adequately control risks identified in their chemical safety assessments.</p>	Manufacturers, importers
37(3)	<p>This requires the manufacturer, importer or downstream user to comply with Art. 14 requirements for registered substances before he next supplies the substance to a downstream user making a request to have his use identified.</p> <p>Where the manufacturer, importer or downstream user is not able to include the use as an identified use, he must provide ECHA and the downstream user with the reasons for that decision in writing.</p>	Manufacturers, importers, downstream users
<p>37(5), with refer- ence to 37(2), 37(4), 37(6), 38(1) & 39</p>	<p>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.</p> <p>This is one of the most important of all REACH Articles for enforcing authorities.</p> <p>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.</p> <p>This will mean choosing one of the following options:</p> <p>a) changing their use to bring it within the exposure scenario;</p>	Downstream users

	<p>b) finding another supplier who is able to support the use;</p> <p>c) replacing the substance or process with an alternative substance or process;</p> <p>d) making the use known to the supplier, with the aim that this becomes an identified use (Article 37(2));</p> <p>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)).</p> <p>Where the downstream user uses less than one tonne per year of the substance or mixture and does not require a chemical safety report, he must consider the use and identify risk management measures and where relevant include in the SDS (Art. 37(6)).</p>	
37(7)	Downstream users must keep their chemical safety report up to date and available.	Downstream users
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.	Manufacturers, importers, downstream users
56(1) & 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.	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.	Manufacturers, importers, downstream users
66(1)	This requires a downstream user, using a 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.	Downstream users

67(1)	This states that substances, mixtures or articles for which Annex XVII contains a restriction shall not be used unless they comply with the conditions of that restriction.	Downstream users
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Annex III – Essential legal requirements for the enforcement of CLP

Regulation (EC) No. 1272/2008 on classification, labelling and packaging (CLP) entered into force on 20 January 2009. 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.

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.

Manufacturers and/or importers 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 take regard of 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 manufacturers / 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.

Article	Description	Target group
Title I – General Issues. General obligations to classify, label and package		
4 (1)	Manufacturers, importers and downstream users <u>shall classify</u> substances or mixtures in accordance with Title II before placing them on the market.	Manufacturers, importers, downstream users
4 (4)	Where a substance or mixture is classified as hazardous, suppliers shall ensure that the substance or mixture is <u>labelled and packaged</u> in accordance with Titles III and IV, before placing it on the market.	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.	Suppliers
Title II – Hazard Classification		
Chapter I – Identification and examination of information		
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.	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 a hazard and to ascertain this information is adequate, reliable and scientifically valid for the purpose of the evaluation.	Manufacturers, importers, downstream users
7	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	Entities performing tests for the purposed of the CLP Regulation?

Title II – Hazard Classification		
Chapter II – Evaluation of hazard information and decision on classification		
9	This requires the evaluation of the information identified by applying the criteria for hazard class classification or differentiation so as to ascertain the hazards associated with the substance or mixture.	Manufacturers, importers, downstream users
10	This requires setting, if appropriate, specific concentration limits and M-factors for substances for classification of substances and mixtures.	Manufacturers, importers, downstream users
11	This requires determination of and respecting cut-off values when classifying a substance or a mixture containing a substance classified as hazardous.	Manufacturers, importers, downstream user
12	This requires the carrying out of further evaluation of hazard information in specific cases.	Manufacturers, importers, downstream users
13	This requires deciding on the classification of a substance or a mixture on the basis of the evaluation of the relevant information.	Manufacturers, importers, downstream users
14	This provides specific rules for the classification of mixtures.	Manufacturers, importers, downstream users
15 (1)	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.	Manufacturers, importers, downstream users
15 (2)	This requires the carrying out a new evaluation in certain cases where a change in the composition is introduced to a mixture that has been classified as hazardous.	Manufacturers, importers, downstream users
Title V – Harmonisation of classification and labelling of substances and the classification and labelling inventory		
Chapter II – Classification and labelling inventory		
40	This requires a notification to ECHA of the identity and classification of substances classified as hazardous.	Manufacturers and importers
Title VII – Common and Final Provisions		
49	Obligation to keep available all information used by a supplier for the purposes of classification and labelling for a period of at least 10 years after last supply of a substance or mixture.	Suppliers: Manufacturers, importers, downstream users, distributors

Annex IV – Essential legal requirements for the enforcement of PIC

The Prior Informed Consent Regulation (PIC, Regulation (EU) No 649/2012) regulates the export and import of certain hazardous chemicals and places obligations on companies who wish to export those chemicals to non-EU countries. It aims to promote shared responsibility and cooperation in the international trade of hazardous chemicals, and to protect human health and the environment by providing in particular developing countries with information on the safe handling of hazardous chemicals.

The PIC Regulation implements, within the European Union, the Rotterdam Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade. The date of the PIC Regulation's entry into operation was 1 March 2014. From this date, ECHA is responsible for some administrative and technical tasks related to the new Regulation.

The PIC regulation provides for two main requirements for the export of chemicals, the export notification and the explicit consent of the importing country. The export notification has to be done by the exporter for all chemicals listed in Annex I prior to the export by introducing it in the database available on the website of ECHA. The notification is checked and validated by the designated national authority (DNA) of the exporter and subsequently sent to the importing country by ECHA. For some chemicals, explicit consent of the importing country is required before the export can proceed. That consent has to be sought by the DNA of the exporter or is available through the import response given by the importing country under the Rotterdam Convention.

To facilitate handling and control of requirements, the PIC Regulation continues with the use of Reference Identification Numbers (RIN), introduced by Regulation (EC) No 689/2008. The RIN is assigned by the database to each export notification and has to be provided by the exporter in his customs declaration (box 44 of the SAD). The RIN is activated by ECHA as soon as all requirements are met and, therefore, allows customs to check the status when clearing the export.

More information on the enforcement of PIC can be found in the Forum document "The description of enforcement of the PIC Regulation on the national level and Forum activities related to the PIC Regulation"¹⁸.

¹⁸ https://echa.europa.eu/documents/10162/13577/forum_pic_enforcement_en.pdf/aaa8856f-46b7-405b-afbd-1ffb05e4e4e3

Article	Description	Target group
2(3)	Exporters are requested to get a RIN and to provide that RIN in their export declaration.	Exporter
8	Exporters are requested to notify the export of chemicals listed in Part 1 of Annex I and to provide information pursuant to Annex II in that notification.	Exporter
10	To provide information on quantities of chemicals listed in Annex I that were exported or imported.	Exporter and importer
11(4)	To provide the available information about chemicals qualifying for PIC notification on request by the Commission within a deadline	Exporter and importer
14	To seek explicit consent from the importing country prior to export.	Exporter
15(1)	To notify the export of certain articles.	Exporter
15(2)	To refrain from exporting chemicals listed in Annex V.	Exporter
16(2)	To provide certain information to specified countries in case of transit movements of chemicals listed in Part 3 of Annex I.	Exporter
17 (1)	To package and label chemicals when exported pursuant to Regulation (EC) No 1107/2009, Directive 98/8/EC and Regulation (EC) No 1272/2008, or any other relevant Union legislation.	Exporter
17(2)	Where appropriate, to provide information on the expiry date (together with climatic zone) and production date on the label of exported chemicals.	Exporters
17(3)	To add a safety data sheet in accordance with Regulation (EC) No 1907/2006 to chemicals when exported.	Exporter
17(4)	This requires that information provided on the label or in an SDS of exported chemicals complies with certain rules on language.	Exporters
19	To get a reference identification number and provide it in the export declaration.	Exporter

Annex V – Essential legal requirements for the enforcement of BPR

Regulation (EU) No 528/2012 of the European Parliament and of the council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR) is applicable since 1 September 2013.

The aim of the legislation is to improve free movement of biocidal products within the Union while ensuring a high level of protection of human and animal health and the environment. It is underpinned the precautionary principle to ensure that active substances and biocidal products that are manufactured and made available on the market should not result in harmful effects in human or animal health or unacceptable effects on the environment.

The BPR aims to harmonise the market at Union level, simplify the approval of active substances and authorisation of biocidal products and introduce timelines for Member State evaluations, opinion-forming and decision-making. It also promotes the reduction of animal testing by introducing mandatory data sharing obligations and encouraging the use of alternative testing methods.

The legislation regulates the approval of active substances and the authorisation of biocidal products, the making available on the market and use of biocidal products and the placing on the market of treated articles. A strong impact on enforcement comes from the ongoing existing active substance Review Programme resulting in active substances being approved or non-approved and affecting existing biocidal products on the market.

The approval of active substances takes place at Union level and the subsequent authorisation of the biocidal products at Member State level. This authorisation can be extended to other Member States by mutual recognition. However, the regulation also provides applicants with the possibility of a new type of authorisation at Union level (Union authorisation).

In addition, any supplier of an active substance as such or in a biocidal product is required to be listed at ECHA's Article 95 list.

The list of essential legal requirements of the BPR is not an inventory of all enforceable obligations. It depends, to a large extent, on the national transitional provisions of each Member State covering biocidal products with active substances still in the Review Programme, to which extent entries in the list of essential legal requirements of the BPR are relevant for the enforcement authorities in a Member States. In Member States with national transitional provisions requiring a transitional national authorisation, it is the national authorisation bodies that ensure that the transitional provisions for biocidal products with active substances still in the Review Programme are properly observed by duty holders.

Article	Description	Target group
17 (1)	Requirement not to make biocidal products available on the market or to use them unless authorised (see for details of different authorisation provisions in the Articles 17 to 51 of the BPR).	Any supplier or user
17(5) first sub-paragraph	Requirement that biocidal products shall be used in compliance with the terms and conditions of the authorisation.	User
17 (6)	Requirement for authorisation holder to notify additional products for inclusion in a biocidal product family.	Authorisation holder
23(3), (7)	The making available or use of biocidal products that contain substances that are candidates for substitution are prohibited or restricted where acceptable alternatives exist.	Any supplier or user
27(1)	Requirement to notify a MS (30 days before) and use official language(s) of that Member State (unless it provides otherwise) in the product's labelling when placing a biocidal product on the market authorised in accordance with a simplified authorisation procedure.	Any supplier
41	Union authorisation.	Authorisation holder
47(1)	Obligation for notification of unexpected or adverse effects.	Authorisation holder
52	Period of grace for supply and use of biocidal products where authorisation has been cancelled, not renewed or amended.	Any supplier or user
53 (1)	Permit required for parallel trade.	Any supplier
55 (1), (2)	Derogation from authorisation.	Any supplier or user
56	Conditions for experiments and tests for research and development of BP without authorisation.	Any supplier or user
58 (2)	Prohibition on placing on market a treated article unless all active substances contained in biocidal products that it was treated with or incorporates are approved and conditions of approval complied with.	Person responsible for placing on the market
58 (3)	Requirement to label certain treated articles placed on the market.	Person responsible for placing on the market
58 (4)	Requirement to label certain treated articles placed on the market with the relevant instructions for use.	Person responsible for placing on the market
58 (5)	Requirement to provide a consumer with information on the biocidal treatment of a treated article within 45 days on request.	Any supplier
58 (6)	Details of labelling requirements for treated articles.	Manufacturer Person responsible for placing on the market

62	Requirement - that testing on vertebrates shall not be repeated; - to submit a request to the Agency to establish whether vertebrate testing has already been submitted; - to request from the data owner the vertebrate testing data and the right to refer to it, for data that has already been submitted.	Applicant, authorisation holder
65 (2)	Requirement to maintain documentation in relation to manufacturing process.	Manufacturer
68 (1)	Record keeping and reporting – requirement to keep records of biocidal products placed on the market for at least 10 years afterwards or 10 years after authorisation is expired or cancelled. Make available information in records to the Competent Authority on request.	Authorisation holder
69	Requirements of classification, labelling and packaging.	Authorisation holder
70	Requirement for safety data sheets.	According to the reach regulation Any supplier
72 (1)	Requirement for advertising to include sentences.	Any advertiser
72 (3)	Requirement for advertising to not refer to product in a manner misleading in the respect of the risks.	Any advertiser
89 (2), (3), (4)	Transitional measures for a member state to use national legislation.	Authorisation holder
93	Transitional measures concerning biocidal products not covered by the scope of Directive 98/8/EC.	Authorisation holder
94 (1), (2)	Transitional measures for treated articles – Provides deadlines at which the derogation from Article 58(2) ceases to apply in different circumstances.	Manufacturer, importer Person responsible for placing on the market
95 (1), (2), (3)	Requirement not to make available on the market any biocidal product unless either the substance supplier or product supplier is on the 'Article 95 list'.	Any supplier

Annex VI – Definitions

1. Legislations

- a) “**REACH**” means 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 (OJ L 396, 30.12.2006, p1) as amended.
- b) “**CLP**” means Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 concerning the classification, labelling and packaging of substances and mixtures (OJ L 353, 31.12.2008, p1) as amended.
- c) “**PIC**” means Regulation (EU) 649/2012 of the of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (OJ L 201, 27.7.2012, p60) as amended.
- d) “**BPR**” means Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p1) as amended.
- e) “**the AMS Regulation**” means 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 (OJ L 218, 13.8.2008, p30).

- 2. “**the Forum**” means the Forum for Exchange of Information on Enforcement, as established by Article 76(1)(f) of REACH.

3. Enforcement

- a) “**enforcement activities**” means the range of activities an enforcing authority may undertake in order to assess, secure or promote a duty holder’s compliance with the Regulations. Such activities may be routine (proactive) or non-routine (reactive), and include inspection, investigation, monitoring, formal enforcement and other measures taken in pursuance of Articles 125 and 126 of REACH, of Articles 46 and 47 of CLP, of Article 18 of PIC and of Article 65 of BPR. Rights available for national enforcement authorities for conducting controls differ between the different countries but include usually rights, for example, to entering the duty holder’s premises, taking samples and receiving information. Enforcement activities mean both market surveillance and controlling of the use and storage conditions. It can be defined as in the following sub-paragraphs:
 - (i) ‘**inspection**’ refers to a proactive (planned and/or 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 in question. Information may be obtained by reviewing relevant information and documents held by the duty holder

or available to the enforcing authority, and/or interviewing people, and/or monitoring, and/or observing site conditions, standards or practices where activities subject to the requirements of the Regulations are carried out under the duty holder's control. It follows that an inspection activity can occur at or away from the duty holder's premises.

- (ii) '**investigation**' refers to a reactive (non-routine) process which includes all those activities carried out in response to an accident, incident, complaint, referral from another enforcing authority or public body or from competitors, or an identified non-compliance, to gather and establish the facts, detect contraventions of duties according to the Regulations, identify immediate and underlying causes and the lessons to be learned, prevent recurrence, and take appropriate action, including formal enforcement.
 - (iii) '**monitoring**' means periodic or continuous surveillance, measurement, sampling, testing and/or analysis of various media, such as substances, mixtures and articles, to determine the level of compliance with legal requirements. Information from monitoring of chemicals in the environment (air, water, soil, vegetation, animals), humans (biomonitoring) or the workplace may also be used for enforcement purposes.
- b) '**enforcing authority**' means any public authority at national, regional or local level, which is established or designated by the Member State and is responsible for enforcement of the matters that are covered by this document.
 - c) '**enforcer**' or '**inspector**' a person duly authorised on behalf of the enforcing authority to perform any enforcement actions.
 - d) '**formal enforcement**' refers to a range of enforcement activities an enforcing authority is statutorily empowered to take, such as, issuing notices, formal cautions, orders or prohibitions, administrative penalties (such as undertakings or on-the-spot fines), bringing legal proceedings by criminal or civil means, and so on.
 - e) '**market surveillance**' shall mean the activities carried out and measures taken by enforcing authorities according to chapter III of the AMS Regulation.
 - f) '**other measures**' include advisory, educational, training and promotional activities, and refers to the activities enforcing authorities may undertake to assist duty holders to comply with the Regulations. 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 and/or the Article 65 report of BPR and/or the Article 22 report in PIC). It also excludes Helpdesk activity as this is covered in other sections of the Member States' Report to the Commission.

4. Risk management

- a) "**risk analysis**" means the determination of the impact and the probability of non-compliance with requirements of the Regulations in order to consider how this should influence the priorities of enforcing authorities.
- b) '**risk recipient**' is any person or environment feature that are endangered as a result of non-compliance of some of the duty holders with the requirements of the Regulations. Such risk recipients are for example workers, consumers, surface or groundwater, etc.

5. Other definitions

- a) '**activity**' is an operation or work process conducted by a target group member.
- b) '**compliance**' is the state of conformity with the obligations imposed by the Regulations.
- c) '**complaint**' – an accusation against a duty holder that they are in some way failing to meet one or more of the duties imposed upon them by the Regulations.
- d) "**duty holder**" means any person (whether natural or legal) with obligations under the Regulations covered by this document, other than enforcing authorities, Competent Authorities, the European Chemicals Agency (ECHA) or the European Commission.
- e) '**efficiency**' is 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.
- f) '**effectiveness**' is the degree to which the goals have been reached.
- g) "**non-compliance**" is any kind of violation of one or several provisions in the Regulations by the duty holder.
- h) '**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. (More information in Section [3.5.2](#)).
- i) '**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.

j) **'product'** shall have the meaning assigned to it under Article 15(4) of the AMS Regulation.

k) **'target group'** means a group of duty holders who exercise a particular activity and have a characteristic set of obligations according to the Regulations. Target groups under the Regulations are manufacturers, importers, producers of an article/treated article, distributors, only representatives (under REACH) and downstream users of substances, mixtures, articles or treated articles.

6. All references to Member States in this document should be read as including EEA-EFTA States unless otherwise provided.

7. Other expressions used in this document which are used in REACH, CLP, PIC and BPR have the same meaning that they bear in these Regulations.

Annex VII – Member State enforcement indicators

In the following table are stated the set of key Member States level enforcement indicators proposed by the Commission.

More information can be found on the 'Study on development of enforcement indicators for REACH and CLP'¹⁹.

Category	Label	Short name	Long name
Discovery of non-compliance	MS1	Controls prompted by complaints or concerns received	The number of official REACH and CLP controls prompted by complaints or concerns received as a share of the total number of official REACH and CLP controls
	MS2	Controls prompted by incidents	The number of official REACH and CLP controls prompted by incidents as a share of the total number of official REACH and CLP controls
	MS3	Controls prompted by monitoring activities	The number of official REACH and CLP controls prompted by monitoring activities as a share of the total number of official REACH and CLP controls
	MS4	Controls prompted by results of inspections	The number of official REACH and CLP controls prompted by results of inspections as a share of the total number of official REACH and CLP controls
	MS5	Controls prompted in relation to alleged contraventions	The number of official REACH and CLP controls prompted by enforcement authorities in relation to alleged contraventions of the REACH and CLP regulations as a share of the total number of official REACH and CLP controls
Official controls	MS6	REACH controls per duty-holder	The number of official REACH controls carried out as a share of the total the number of duty holders
	MS7	CLP controls per duty-holder	The number of official CLP controls carried out as a share of the total number of CLP duty holders
Training	MS8	Inspectors trained in REACH	The total number of inspectors that attended training on REACH
	MS9	Inspectors trained in CLP	The total number of inspectors that attended training on CLP

¹⁹ http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8280

Category	Label	Short name	Long name
Duties	MS10	Compliance with REACH duties	The percentage of overall compliance on REACH duties
	MS11	Compliance with CLP duties	The percentage of overall compliance on CLP duties
Enforcement actions	MS12	Enforcement decisions overturned (REACH)	The number of REACH enforcement decisions that were appealed and subsequently overturned
	MS13	Enforcement decisions overturned (CLP)	The number of CLP enforcement decisions that appealed and subsequently overturned
	MS14	Controls that resulted in verbal or written advice	The number of official controls that resulted in verbal or written advice as a share of the total number of official REACH and CLP controls
	MS15	Controls that resulted in legal proceedings	The number of official controls that resulted in legal proceedings as a share of the total number of official REACH and CLP controls
	MS16	Controls that resulted in convictions	The number of official controls that resulted in convictions as a share of the total number of official REACH and CLP controls