

CLP Regulation and REACH Regulation: links, implementation and control in Italy

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Summary. In the last years the European policy for the management of chemicals is deeply changed after entering into force of the European Regulations (EC) no. 1907/2006 and (EC) no. 1272/2008. The implementation of the two Regulations requests a strong effort both from the enterprises and from national and regional institutions. The activities already realised or that are planned for the implementation of one of them could support the implementation of the other one. The crucial point is the creation of the surveillance coordination through a network that involves also the professional figures currently present in the border areas in order to check the compliance with the European legislation of substances on their own, in mixtures or in articles before they are put on European market.

Key words: REACH, CLP, enforcement, substances, implementation.

Riassunto (*Regolamento CLP e Regolamento REACH: collegamenti, attuazione e controllo in Italia*).

Negli ultimi anni la politica europea di gestione delle sostanze chimiche è profondamente cambiata con l'entrata in vigore dei Regolamenti europei (CE) no. 1907/2006 e (CE) no. 1272/2008. L'attuazione dei due Regolamenti richiede un grande sforzo sia da parte delle imprese che delle istituzioni nazionali e regionali. In particolare, si sottolinea che alcune attività poste in essere per l'attuazione di uno di essi sono a sostegno anche dell'implementazione dell'altro. Punto cruciale è la realizzazione del coordinamento in materia di vigilanza per mezzo della rete di controlli che coinvolga anche le figure professionali attualmente presenti nell'area di frontiera, al fine di verificare la conformità alle norme europee delle sostanze in quanto tali o contenute in miscele o articoli prima della loro immissione sul mercato europeo.

Parole chiave: REACH, CLP, attuazione, sostanze chimiche, controllo.

INTRODUCTION

In recent years the European politic management of chemicals is deeply changed. From one side the new European Regulation (EC) no. 1907/2006 [1] concerning the registration, the evaluation and the authorisation of chemicals (REACH), has created a new European system of chemical management that has the main target to increase the knowledge of the risks linked to the majority of substances already put on the market. The registration system created by REACH asks the same information both for a substance already on the market at June 2008 (called phase-in substance) and for a new substance at June 2008 (called non-phase-in substance), anyway it is foreseen a transitional period for the registration of phase-in substances. The REACH Regulation introduces an authorisation procedure for the substances of very high concern that are listed in Annex XIV to REACH and it collects in its Annex XVII the restriction measures already foreseen from the previous directive on this matter (Directive 76/769/EEC [2]). On the other side the European Community is committed to contribute to the global harmonisation of the criteria for classification and labelling of

substances and mixtures within the United Nations [3]. This commitment has requested a regulatory activity aiming at transferring the new criteria defined at the United Nations level to the European existing system on classification and labelling. The European Regulation (EC) no. 1272/2008 [4] concerning the new criteria of classification, labelling and packaging of substances and mixtures, called CLP Regulation, indicates in the transitional provisions that the new rules are applied to substances from 1 December 2010 and then to mixtures from 1 June 2015.

LINKS BETWEEN THE REACH AND CLP REGULATIONS

There are several links between the REACH and the CLP Regulations because some dispositions under REACH are applied whether or not the substance is classified and how it is classified.

These common points are described below:

- the first registration deadline was the 1 December 2010 for manufactures and importers of the substances manufactured or imported above 1

tonne/year and classified according to the CLP Regulation as carcinogenic, mutagenic or toxic to reproduction (CMR Cat. 1A&1B). The 1 December was also the deadline for manufacturers and importers of the substances manufactured or imported above 100 tonne/year and very toxic for aquatic environmental;

- a Member State or the European Commission can begin the formal identification process of a substance as very high concern (SVHC) if it is classified as carcinogenic, mutagenic, or toxic for reproduction;
- some restrictions in Annex XVII are related to substances having a specific classification. For example substances or mixtures classified can not be used in tricks and jokes (point 3 of Annex XVII), or the carcinogenic substances on their own and in mixtures can not be placed on the market for sale to the general public in individual concentration equal to or greater in quantity 0.1% w/w;
- when a substance is manufactured or imported above 10 tonne/year the registrant has to conduct a risk assessment. The first step of this assessment is to evaluate whether or not the substance meets the CLP criteria;
- the obligation to supply a safety data sheet (SDS) set forth in the Article 31 of REACH Regulation is linked to the substance and mixture classification;
- a Member State until 2015 or the European Chemical Agency (ECHA) from 2015 can permit the use of an alternative name of a substance present in a mixture upon request of a company which indicates that an economic damage could occur if known the chemical name of the substance. When the authorisation is granted the supplier of the mixture can use the alternative name instead of the chemical name in the mixture SDS as well as on the mixture label. This permission can be granted only if the substance is classified in specific categories and classes set forth in Article 24 of CLP Regulation;
- in the "hazard identification" and "composition" sections of a SDS the information have to be reported on the basis of the legislation concerning the classification currently in force. The Annex II of the REACH Regulation was modified recently by the Regulation (EC) no. 453/2010 [5], in particular this latter regulation specifies that in the "hazard identification" section the substance classification has to be indicated with the rules set forth both in CLP Regulation and in the Directive (EEC) no. 67/548 Dangerous Substance Directive - (DSD) [6] since 1 December 2010, instead the mixture classification has to be reported in the SDS with the rules set forth in Directive (EC) no. 1999/45 [7] (Dangerous Preparation Directive - DPD) until 2015. However a ingredient of a mixture has to be reported in the "composition" section with the rules set forth both in the DPD and in the CLP Regulation unless derogations. This

double indication has to be applied for five years (1 December 2010 - 1 June 2015) and it is necessary in order to pass gradually from the rules of the DPD to the CLP ones.

On the other way round, in the CLP Regulation there are some mandatory requests based on what it is the substance or mixture status under REACH. Below some examples are reported:

- it is mandatory to notify to the ECHA's Inventory on the classification and labelling the substances that have to be registered under the REACH Regulation. Therefore even if the substance does not meet the criteria set forth in the CLP the notification has to be submitted together with the justification why the eco-toxicological, toxicological or chemical-physical data do not match the CLP criteria;
- where during the REACH registration process the ECHA has permitted the use of a "alternative designation" for a substance because the company indicated that an economic damage would occur if known the chemical name, the alternative designation can be used in the SDS and in the label, without submitting the specific request set forth in Article 24 of CLP (see Article 24, paragraph 6).

IMPLEMENTATION OF THE REACH AND CLP REGULATIONS IN ITALY

As mentioned above the two REACH and CLP Regulations are linked each other and they both modify the European chemical management policy, therefore both the national activities and the industries actions already realised or planned to be carried out in the future for the implementation of one of them could support the implementation of the other.

The implementation of the two Regulations needs a huge effort from the enterprises because, in particular, the REACH is based on the principle that industry should manufacture, import, use or place on the market substances ensuring that, under reasonably foreseeable conditions, the human health and the environment are not adversely affected. Instead the new CLP criteria of the classification and labelling require the enterprises to update in a short time for example the software used to determinate classification, labelling or to the safety signs on the workplace. In addition the enterprises should respect the provisions of other pieces of legislation linked with the classification criteria and that now can have an impact on some substances or mixtures that before were out of the scope.

On the other hand also the national institutions are called to do a strong effort related to the implementation of the two regulations. Indeed, even if a European Regulation does not need a national application law the Member State has to create specific instruments to assure the implementation of the new European rules, and it has to evaluate whether some economic resources are needed.

The Italian institutions are committed for the

REACH implementation since 2007. The instruments that were created to implement the REACH will be useful also for the CLP Regulation. With the law no. 46/2007 [8] the Ministry of Health was designated as Competent Authority (CA) for REACH Regulation instead the legal basis for designation of CLP Competent Authority does not exist yet. The REACH CA cooperates with the Ministry of Environmental and the Ministry of Economic Development and receives the technical support from the National Centre for Chemical Substances (CSC) located within the National Institute of Health in Italy (ISS) and from the National Institute of Environmental Protection and Research (ISPRA). It is important to underline that the CSC was instituted in order to have a national reference point which give scientific support in the framework of REACH implementation. Other than the above mentioned national institutions, also the Regional level supports the REACH implementation. These different administrations are coordinated by a co-ordination technical committee, formally defined [9, 10]. The Committee meetings are planned at least three time per year and the Committee has 6 working groups:

- surveillance network;
- support to ECHA committees activities;
- meet with enterprises;
- nanomaterials;
- support to Committee procedure set forth in REACH Article 133;
- information and trainings.

In order to support activities concerning the inspections the Regions have as focal point a technical groups within inter-regional prevention management (CIP).

Furthermore the Italian Law no. 46/2007 assigned for each year the financial resources to every Ministries and Institutes above mentioned.

Another instrument defined in order to implement the REACH Regulation is the creation of a surveillance network. This network is based on the coordination between the Ministry of Health and the Regions and it is based on the State-Regions Agreement [11]. According to this Agreement every Region or autonomous Province has to implement the Agreement in his legal organisation. At the moment, 13 Regions and 1 autonomous Province have already done this step and they have individuated the "control authority" that will be dedicated to the inspections in his own territory. As interesting element, most of these Regions have underlined that the REACH control authorities it is also the control authorities implementing the CLP Regulation.

A key element of the surveillance network creation is to clarify the involvement of the different border authorities in the REACH implementation.

Another specific instrument necessary to implement the two regulations at national level is an appropriate penalties system which has to ensure transparency, impartiality and consistency of the single Member State enforcement activities, with a

view to imposing effective, proportionate and dissuasive penalties for REACH and CLP non-compliances. In Italy the national Decree no. 133/2009 [12] sets up the penalties system for the REACH non-compliances. The Decree establishing the penalties for CLP non-compliances has not been emanated yet, however the legislative process is ongoing.

The penalties for the non-compliance with REACH provisions are both administrative and criminal and this is foreseen also for the CLP penalties system. The maximum level of the REACH sanctions is related to non-compliance with the authorisation and restriction provisions as it is foreseen the prison until three months. Different administrative sanction levels are foreseen in the Decree no. 133/2009 for others REACH non-compliances. Some examples are reported below:

- when a company manufactures, imports or puts on the market a substance not registered, the penalties level is set up in the range 15 000 – 90 000 €, while whether the substance without registration is an intermediate the level goes down to 10 000 – 60 000 €;
- the highest penalties level (15 000 – 90 000 €) is set up for the absence of the communication concerning the updating on tonnage of a notified substance under Directive EEC no. 67/548 (DSD);
- in the Decree no. 133/2009 the penalties are in the range 15 000 – 90 000 € foreseen for the violation to the obligations detailed in the REACH article 14, concerning the chemical safety report and duty to apply and recommend risk reduction measures;
- unless it constitutes a criminal offence, the registrant who carries out tests on vertebrate animals that are not absolutely necessary and fails to introduce measures for limiting the useless repetition of other tests, in accordance with REACH Article 25 paragraph 1, shall incur a fine within the range 10 000 – 60 000 €;
- also the violation of the obligations detailed in Articles 7, 31, 32, 33, 34, 35 and 36 of the REACH, in respect with the information in the supply chain is sanctioned at different levels, from 3000 – 18 000 € if the SDS is not in Italian language up to 10 000 – 60 000 € if a supplier of a substance or a mixture does not supply SDS in accordance with Articles 31 and 32.

In the context of the adaptation of the previous national legislation on chemicals according to the new REACH provisions, it has been necessary to modify the national Decree no. 52/97 that implemented the Directive (EEC) 67/548. The main change was the deletion of the national notification unit, because the registrations of chemicals are now collected by ECHA. The modification has been done through the Decree no. 145/2008 which also introduced a new element useful for both the REACH and the CLP inspections. This element indicates the need to establish a fee to be applied to the inspected company. This choice has the following justification: in the past the inspections were conducted by the Ministry of Health and the ISS to verify the compliance with

the rules of the substances and mixture classification and the labelling and with the notification duty under Directive (EEC) no. 67/548 and the financial coverage was assured by the notification fees. With the entering into force of the REACH Regulation the registration fees are managed by ECHA, thus the future inspections concerning the respect of the CLP and REACH provisions are not foreseen to be financed. The Italian Decree no. 145/2008 introduces the fees application concept on inspections. The fees are now established in a default amount of 2000 €, but a future Ministerial Decree will specify the criteria to apply the fees.

In order to implement the two regulations other activities have been done with the cooperation among the different institutions indicated in the national Decree of the 22 November 2007. Below these activities are briefly described:

- official communications to clear some interpretation of the two regulations;
- organising conferences and workshops;
- organising trainings for inspectors and public administrators;
- management of the national helpdesk. The Ministry of the Economic Development is responsible of the REACH helpdesk;
- support to enterprises by collecting practical issues and sharing views on possible solutions with category associations;
- the Ministry of the Economic Development has promoted by national Decree of the 19 March 2009 [13] economic incentives to the industries having a project of research and development in order to substitute the substances that meet the criteria set forth in Article 57 of REACH;
- the REACH CA and the Ministry of environment have invested financial resources to improve the knowledge on substance having endocrine disrupting properties;
- evaluation of ECHA's draft decisions concerning the completeness check of a registration dossier and the testing proposal. The Centro Nazionale Sostanze Chimiche (CSC) and ISPRA support the REACH CA in this task through a defined procedure;
- creation and management of the database of models for substance SDSs. The CA offers a

free support to elaborate a substance SDS. The SDS models are available in the web site of the Ministry of Health, in the "chemicals safety" section (www.salute.gov.it/sicurezzaChimica/sicurezzaChimica.jsp). Obviously the supplier of a substance or a mixture remains responsible of the SDS but the database helps to elaborate the SDS;

- activities concerning the dissemination of the information by on-line magazines. For example the magazine edited since 2007 by the Ministry of Economic Development "REACH-on digit" contains useful topics to support the enterprises. Since 2009 the Ministry of Environment has been publishing a magazine *Bollettino di informazione sostanze chimiche – ambiente e salute* which has as main target the general public;
- promoting master on REACH. The Ministry of Health as CA collaborated with Ministry of Research and University in order to establish common topics in the different Master projects [14]. Few masters have already been hold and other universities are planning to start new ones. Until now the masters have offered a high level education in the risk assessment field, anyway it is important to disseminate information about the socio-economic analysis criteria. The REACH CA supports these initiatives with some economic resources;
- furthermore, some REACH and CLP implementation activities have involved also the school world. Promoting the curiosity in the young students could be a way to obtain in the future an higher number of experts in risk management of chemicals or experts in socio-economic analysis. On the other hand the promotion of the knowledge of the key points concerning the hazard and risk of the chemicals or the knowledge of the rights to have more information about articles could create citizens more aware that their behaviour influences the status of their own health and the quality of the environment. A training for teachers from every Region of Italy has been hold on December 2010. Thus they will disseminate the key information about the REACH and CLP Regulations. Also for this project financial resources have been given by REACH CA.

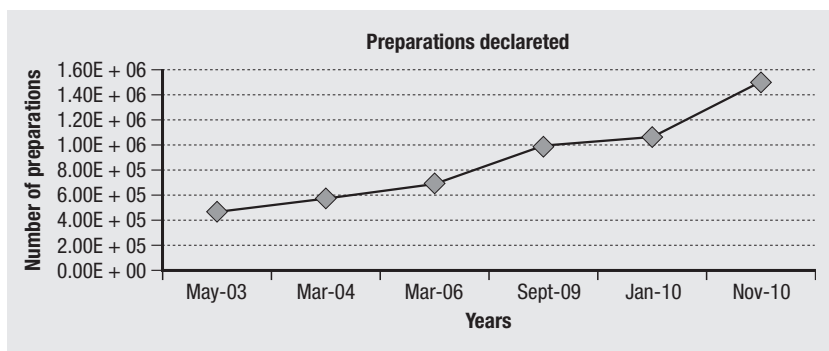


Fig. 1 | In the graph the mixtures declared up to November 2010 in the archive are reported.

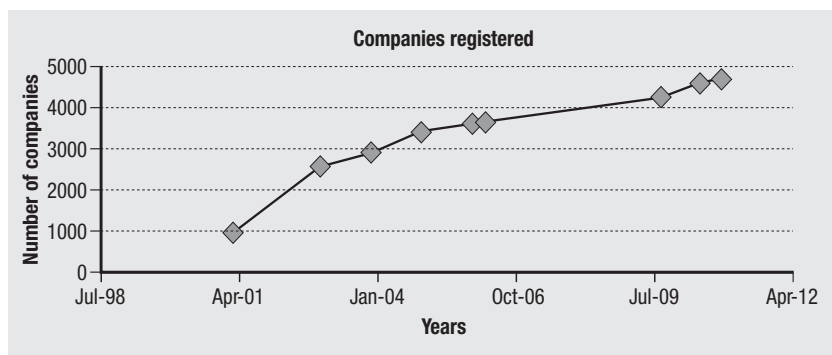


Fig. 2 | The figure shows the number of companies that have submitted the notifications until now.

The picture drawn above shows the infrastructure created at national level to support REACH implementation. Of course this infrastructure will work also to support the CLP implementation: for example the REACH technical committee of coordination could be the meeting point to discuss the management of the CLP issues and agree possible solutions. However, as anticipated previously, at while the REACH CA has been appointed (Ministry of Health), the CA for CLP has not been designated yet. For the sake of continuity, who managed the old classification and labelling legislation should continue to manage the same matter.

Even in absence of an official appointment, several activities related to CLP implementation have been already carried out in Italy. To give an example, the CLP helpdesk is managed by the CSC and is currently working.

The collection of useful information to support anti-poisoning centres activities set forth in Article 45 of the CLP Regulation is based on dangerous preparation archive created in the 2000 under the Directive 1999/45/EC [15]. Up to now, one million and half notifications on dangerous mixtures and detergents (independently from their classification) have been submitted by about five thousand companies (Figure 1 and Figure 2).

Furthermore the access to the database have been granted to 9 Italian anti-poisoning centres.

The information required for the notification are listed in the Table 1.

Table 1 | Information required for the notification to preparations archive

Information required	Mandatory (yes/no)
Name/address, Tel./Fax., e-mail of registrant	yes
Trade name of the products	yes
Intended uses	yes
Physical state	yes
Other physico-chemical properties	no
Full quali-quantitative chemical composition	yes
C&L	no
Packaging description	no

This database is going to be revised since the European Commission is working to define on harmonized core set data and a common format that the importers and downstream users will have to use.

A good example of collaboration between different levels that work to ensure safety of products on the market and the respect of the chemical legislation is the Italian activity on methanol.

In the 2007 after an accident occurred to a consumer after skin application of a mixture of unknown composition, the anti-poisoning centre of Milan (Niguarda Ca'Grande Hospital) communicated to the ISS and the Ministry of Health that this dangerous preparation was not in the archive. The effects that the patient showed were after attributed to the methanol action. Taking into consideration that other cases were later identified also by other anti-poisoning centres, that a national law of 1982 prohibits the presence of methanol in detergents, cosmetics and paints, Italy would like to promote a European action on the basis of a socio-economic and a risk management option analyses. Italy has just committed to submit a proposal for a new classification of the methanol as toxic for reproduction (development) Category 1B.

The CSC offers different implementation tools which are present in its website (www.iss.it/cnsc/):

- the 1st tool is a database which contains substances within the European inventories and gives information on the harmonised classification according to both the DPD and CLP criteria and, where present, the database gives information regarding the restrictions and/or authorisation set forth in REACH;
- the 2nd tool is a link to German converter from that can be used to establish a proposed "new" GHS-compliant classification based on the previous classification in line with the guideline relating to the relevant substance or mixture;
- the 3rd tool is a database that collects the most recent literature search about carcinogenic and sensitizer substances.

ITALIAN INSPECTION NETWORK FOR REACH AND CLP

The REACH and CLP inspections could be either carried out together or separately, thus the Italian en-

Table 2 | Regional/Provincial control Authorities for REACH and CLP Regulation

Regions / autonomous Province	Adoption	Legal act	Control Authority for REACH	Indication concerning Control Authority for CLP
Abruzzo [17]	yes	*DGR n. 242 del 22/03/2010	Direzione Politiche della Salute, Regione Abruzzo	yes
Basilicata	no			
Bolzano	no			
Calabria [18]	yes	DGR n. 26 del 28/01/2010	Dipartimento Regionale Tutela della Salute e Politiche Sanitarie, Regione Calabria	yes
Campania [19]	yes	DGR n. 372 del 23/03/2010	Settore Assistenza Sanitaria Igiene e Sanità Pubblica Igiene e Medicina del lavoro dell'Area di Coordinamento Assistenza Sanitaria dell'Assessorato alla Sanità, Regione Campania	yes
Friuli Venezia-Giulia	no			
Emilia Romagna [20]	yes	DGR n. 356 del 08/02/2010	Servizio Sanità Pubblica della Direzione Generale Sanità e Politiche Sociali, Regione Emilia Romagna	yes
Lazio [21]	yes	DGR n. 272 del 01/06/2010	Direzione Regionale Politiche della Prevenzione e dell'Assistenza Sanitaria Territoriale, Regione Lazio	yes
Liguria [22]	yes	DGR n. 397 del 05/03/2010	Dipartimento Salute e Servizi Sociali, Regione Liguria	-
Lombardia	no			
Marche [23]	yes	DGR n. 562 del 15/03/2010	Posizione di Funzione Sanità Pubblica del Servizio Salute, Regione Marche	yes
Molise	no			
Piemonte [24]	yes	DGR n. 30-13526 del 16/03/2010	Direzione Sanità, Regione Piemonte	yes
Puglia [25]	yes	DGR n. 729 del 15/03/2010	Servizio Programmazione Assistenza Territoriale Prevenzione dell'Assessorato alle Politiche per la Salute, Regione Puglia (Autorità Competente per i controlli) Direttore Generale dell'Azienda Sanitaria Locale (Autorità Sanitaria Locale)	yes
Sardegna	no			
Sicilia	Working in progress			
Toscana [26]	yes	DGR n. 346 del 22/03/2010	Direzione Generale Diritto alla Salute e Politiche di Solidarietà – Regione Toscana	yes
Trento [27]	yes	**DGP n. 848 del 16/04/2010	Direzione Igiene e Sanità Pubblica della Azienda Sanitaria Provinciale	-
Umbria [28]	yes	DGR n. 80 del 25/01/2010	Direzione regionale Sanità e Servizi Sociali Regione Umbria	-
Valle d'Aosta [29]	yes	DGR n. 1298 del 14/05/2010	Assessorato della Sanità salute e politiche sociali Servizio igiene e sanità pubblica, veterinaria e degli ambienti di lavoro	yes
Veneto [30]	yes	DGR n. 523 del 02/03/2010	Direzione Regionale Prevenzione Regione Veneto	-

*DGR (Delibera della Giunta Regionale): regional legal act.

**DGP (Delibera della Giunta Provinciale): provincial legal act.

enforcement authorities for REACH and CLP are not necessarily the same. In Italy while the controls on classification and labelling of substances and mixtures are a duty of the Regions since 1978 (Law 23 December 1978 no. 833) [16], it was necessary to establish an agreement between State and Regions in order to define the control Authorities for REACH. This agreement indicates that the Regions, as it was for the old legislation on chemicals enforcement, have a main role for REACH inspections.

Different legal steps are needed to define enforcement control authorities for REACH at regional level. At present 13 Regions and 1 Province autonomous have already been appointed it and in most cases this authority is also in charge of CLP controls (Table 2).

It is important the transparency of these appointments in order to make easy the improvement of the coordination promoted from the ECHA Forum with

respect to both the other EU Member States enforcement authorities and to the national ones, to the national CA and ultimately to the inspectors.

The Competent Authority (Ministry of Health) has supported Regions with financial resources for the establishment of regional inspectors accesses to the REACH-IT system of ECHA. Furthermore the CA has organized two trainings for trainers who will then in turn train REACH inspectors. After these national events three macro-regional events (north, south, centre of Italy) were held for inspectors, with a financial support of the CA.

To complete the picture, the inspections were also performed at central level, according to the ENFORCE 1 program of ECHA Forum and will continue to be conducted with the participation of the CA. In some of these central inspections regional inspectors can join the inspection team in order to make practical experience. In the future most part of the REACH and CLP inspections will be conducted by the regional authorities.

CONCLUSIONS

In light of the new system of management of chemicals as substance on their own, in mixtures or in articles a huge effort has been done at both institutional level and enterprise level. Industries need to be supported in order to make them aware of the new rules and the upcoming deadlines. It is important to underline that the Italian landscape is populated mainly by medium and small enterprises that more than ever need to be supported by new professional figures, category associations and public institutions in order to be competitive and correctly apply the new chemicals legislation. This is the main reason why the Ministry of Health as Competent Authority collaborates with the Ministry of Instruction in order to encourage training activities

at different levels. The introduction within the educational system, starting from secondary school up to post-graduate level, of specific courses will have an important impact on creating new resources for both the enterprises and the public institutions and will help to increase the general knowledge and awareness of the general public on this matter.

The coordination of inspections is a crucial point. The first step is to define clearly all inspection network by individuating in each Region and Province autonomous the local enforcement authority. It is important to define the annual inspections national programme according to the future programmes defined by ECHA Forum and taking into consideration the specific territorial needs.

In addition it is necessary to define procedures to involve the control authorities present at the border areas in order to improve the controls on substances, mixtures and articles before they enter the European market.

Finally it is desirable a strong cooperation and an effective management to make all different actors involved both in the implementation and in the enforcement of the REACH and CLP achieving a good functioning of "Italian system" within the European activity on new policy on chemicals management.

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