ECHA
EUROPEAN CHEMICALS AGENCY

enterprise europe network
Business Support on Your Doorstep

Guide for SME Advisers on REACH, CLP and the BPR

EU chemicals management rules and your clients' business

What every adviser from Enterprise Europe Network needs to know and check

Guide for SME Advisers on REACH, CLP and the BPR
EU chemicals management rules and your clients' business

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Table of Contents

About us

THE EUROPEAN CHEMICALS AGENCY

Established on 1 June 2007, the European Chemicals Agency (ECHA) is at the centre of the regulatory system for chemicals in the European Union (EU), which has changed in recent years with the introduction of four new regulations that ensure the free movement of chemicals in the EU and a high level of protection for human health and the environment:

- REACH - Registration, Evaluation, Authorisation and restriction of Chemicals;
- CLP – Classification, Labelling and Packaging of substances and mixtures;
- BPR – Biocidal Products Regulation;
- PIC – Prior Informed Consent in the international trade of hazardous chemicals and pesticides.

These legislative acts are applicable in all EU Member States without the need for transposition into national law.

ECHA ensures the consistent implementation of these regulations across the European Union and the countries in the European Economic Area – Iceland, Liechtenstein and Norway.

ECHA'S MISSION

ECHA is the driving force among regulatory authorities in implementing the EU's ground-breaking chemicals legislation for the benefit of human health and the environment as well as for innovation and competitiveness.

ECHA helps companies to comply with the legislation, advances the safe use of chemicals, provides information on chemicals and addresses chemicals of concern.

ECHA'S VISION

ECHA aspires to become the world's leading regulatory authority on the safety of chemicals.

THE ENTERPRISE EUROPE NETWORK

The Enterprise Europe Network is a key instrument in the EU strategy to boost growth and jobs. Bringing together around 600 business support organisations from across Europe and beyond, we help small companies seize unparalleled business opportunities in the EU Single Market.

Our member organisations include chambers of commerce and industry, technology centres, research institutes and development agencies. Most of them have been supporting local businesses for a long time. They know their clients' strengths and needs – and they know Europe.

As members of the Enterprise Europe Network they are linked up through powerful databases, sharing their knowledge and sourcing technologies and business partners across all Network countries. They are also closely linked with the European Commission, which enables them to keep abreast of EU policies and to feed small companies' views on them back to Brussels.

SERVICES TAILORED TO SMALL COMPANIES

Supporting small business is a cornerstone of the EU's drive for growth and jobs. As 99% of all EU companies are small and medium-sized enterprises (SMEs), accounting for 67% of jobs, what is good for SMEs is good for Europe's economy.

The Network is co-financed through COSME - the EU programme for the Competitiveness of Enterprises and Small and Medium-sized Enterprises (SMEs) running from 2014 to 2020. Our services are tailored to SMEs but are also available to all other businesses, universities and research centres.

STRONG FOUNDATIONS

The Enterprise Europe Network was launched in February 2008 by the Commission's Directorate-General for Enterprise and Industry. It is a true one-stop shop for small businesses, with around 4500 local experts providing practical answers to specific questions in your language.

Did you know?

The EU regulations for the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), for the Classification, Labelling and Packaging of substances and mixtures (CLP) and the Biocidal Products Regulation (BPR) have an impact on the business of most companies in the EU and in Iceland, Liechtenstein and Norway, which are part of the European Economic Area (EEA).

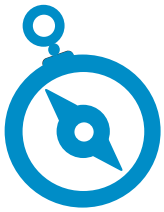
Recent surveys and inspections in 30 countries show that nearly 70% of the Small and Medium-sized Enterprises (SMEs) outside the chemical sector are not aware that e.g. REACH and CLP have a direct impact on their business. Smaller companies by their turnover are least likely to believe that they have to comply with REACH.

Such companies risk placing non-compliant, unsafe chemical products on the market. Some of them may be your clients and may need help to comply or business support to review their portfolio and reposition their business offer as a result of REACH, CLP and the BPR. If their business partners are based outside the EU, they may have to make them aware of the rules for importing chemical products into the EU.

Furthermore, surveys of SMEs and manufacturing companies show that when SMEs are aware of these EU regulations and know how they affect their business, they are the most active in re-designing their manufacturing process. Companies of all sizes are also involved in replacing the most hazardous chemical products with safer alternatives.

Complying with the EU chemicals legislation can trigger business decisions which can be beneficial for companies and enhance their brand. Not all SMEs can do this alone and may need your help.

This guide - how can you use it?



The Enterprise Europe Network (EEN) acts as the link between EU policies and SMEs. In your daily work you meet companies from many industrial sectors who may not be aware of EU chemicals legislation and that it can help make things better for them. You may also be getting questions from companies that are aware they have to comply, but do not know where to start or what to do next.

This guide was developed on request by Network partners who took part in the first training for Enterprise Europe Network on "EU chemicals legislation – why is it the business of non-chemical companies". It was organised in 2013 jointly by ECHA, the Executive Agency for Small and Medium Sized Enterprises (EASME) and Enterprise Europe Network-Finland.

Network partners have been directly involved in developing and drafting this guide. National helpdesks supporting companies to comply with the legislation have also provided input to the guide. Its aim is to enable both newcomers to the Enterprise Europe Network and experienced partners to gain knowledge or improve their understanding of the main EU regulations on the marketing and safe use of chemicals. This can help you make SMEs aware of their rights and responsibilities, to encourage them to take action to comply and help forward-looking companies to seize the business opportunities of eco-innovation and sustainable chemicals management.

This guide can be useful to all Network partners:

- **Advisers on legal issues** can use it to find out new sources of information and reach out to more companies that need to act;
- **Technology and business advisers** can integrate the regulation driven demand for safer chemicals and technologies into their services;
- **Consortium leaders** and sector group chairs are encouraged to consider structured cooperation with the national helpdesks in their countries and with ECHA.

You can also find examples of good practice from the Network that could be relevant for your own activities in this guide.

1. Introducing EU chemical safety law

The general rules for the marketing of chemicals in the EU are set in REACH and CLP. These two horizontal chemical safety laws are complemented by the BPR, which is a sector specific piece of legislation.

REACH, CLP and the BPR have a common aim to ensure a high level of protection for human health and the environment by making industry responsible for the safety of chemicals placed on the EU market. The regulations respond to important business and societal needs for sound chemicals management and their safe use. They apply to the European Economic Area (EEA), i.e. the 28 EU Member States and Iceland, Liechtenstein and Norway.

SMEs have the same responsibilities as large companies and cannot be exempt from any of the requirements for chemical safety. The only SME specific provisions are to pay reduced fees and charges.

REACH

Registration, Evaluation, Authorisation and Restriction of chemicals
(EC) No 1907/2006

REACH is the regulation for the Registration, Evaluation, Authorisation and Restriction of chemicals (EC) No 1907/2006. It is the main EU law on chemicals, covering in principle all substances on their own or in mixtures or in articles for industrial, professional or consumer use. Therefore, REACH has an impact on most industrial sectors and applies to most companies in the EU.

REACH sets the most ambitious chemical safety standards worldwide. Manufacturers and importers have to demonstrate how a substance they place on the market can be used safely and communicate the risk management measures to their customers. Communication in the supply chain is required by all actors to ensure the safe use. If the risks cannot be managed, authorities can restrict the use of a substance or make it subject to prior authorisation.

The REACH requirements for chemical stewardship put pressure on companies to review their portfolio of chemicals and to replace the most hazardous ones with safer alternatives. One of the aims of the regulation is to stimulate innovation and enhance the competitiveness of European brands on international markets.

CLP

Classification, Labelling and Packaging of substances and mixtures
(EC) No 1272/2008

CLP is the regulation for the Classification, Labelling and Packaging of substances and mixtures (EC) No 1272/2008. It complements the REACH Regulation and ensures that the hazards of chemicals are clearly communicated to workers and consumers through labels with standardised statements and pictograms.

Before placing chemical products on the EU market, industry must classify them in line with the identified hazards and then label and package them according to the CLP system. This makes the hazard characteristics of the product easier to understand in the EU and worldwide and facilitates global trade as the CLP implements the United Nations' Globally Harmonised System (GHS) of Classification and Labelling of Chemicals.

The CLP regulation replaces the Dangerous Substances Directive (67/548/EEC) and the Dangerous Preparations Directive (1999/45/EC). Substances have had to be classified and labelled according to the CLP system since 1 December 2010, while for mixtures the deadline to switch to to CLP is 1 June 2015.

CLP deals with the majority of the chemicals placed on the industrial, professional and consumer markets in the EU, including those supplied free of charge.

More than 20 EU laws refer to the classifying and labelling of chemicals, meaning that once a substance is classified as hazardous, other legal requirements kick-in to control their use, such as the requirement to undertake chemical safety assessment within the workplace. When substances cannot be placed on the market for certain uses because of their classification, companies need to find alternatives. For example, substances which are classified as carcinogenic, mutagenic or toxic for reproduction cannot be used in consumer products above certain concentration levels.

The **BPR** is the Biocidal Products Regulation (EU) 528/2012. It concerns the making available on the market and use of biocidal products, which have the purpose of protecting humans, animals, materials or articles against harmful organisms like pests or bacteria, by the action of the active substances contained in the biocidal product. The BPR repeals and replaces the Biocidal Products Directive 98/8/EC. The aim of the regulation is to improve the functioning of the biocidal products market in the EU, while ensuring a high level of protection for humans and the environment.

BPR

Biocidal Products Regulation (EU) 528/2012

All biocidal products require an authorisation before they can be made available on the market, and the active substances contained in that biocidal product must be previously approved with the exception of those that are undergoing review.

Small and medium-sized enterprises (SMEs) have the same responsibilities as large companies and cannot be exempt from any of the requirements for chemical safety.

The **European Chemicals Agency** (ECHA) ensures the consistent implementation of REACH, CLP and the BPR. It provides information, guidance and IT tools for companies to prepare and submit the required information, and a helpdesk service to support them in complying with the law. Key information for SMEs is published in 23 EU languages on ECHA's website.

1.1 WHY ARE CHEMICAL SAFETY RULES IMPORTANT FOR COMPANIES?

Applying the EU chemical safety rules can bring direct benefits for the users of chemicals who are, as a majority, SMEs from most sectors in the economy.

Chemical safety is a business asset. Complying with REACH, CLP and the BPR can help your clients to meet their business needs to:

- Be legally on the EU market;
- Ensure the safe supply, use and management of chemicals;
- Make the working environment safer;
- Save costs by preventing accidents as well as reducing impact on health and the environment;
- Improve their reputation towards customers, consumers, investors and the community who are getting more sensitive to the responsible care of chemicals and to sustainability;
- Find new markets if they have developed safer alternatives to very hazardous chemicals, for example, those that will have to be phased out due to the high concern for human health and the environment;
- Be more competitive on international markets.

Chemical safety is a business asset.

1.2 WHICH CHEMICALS ARE COVERED?

REACH, CLP and the BPR apply to a great variety of products supplied and used in the form of chemical substances, mixtures and articles.

REACH and CLP define a substance, mixture and article as follows:

REACH
CLP

Substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

> **EXAMPLES:** metals (aluminium, zinc, iron, chromium, etc.), acetone, phthalates, ethanol.

Mixture means a mixture or solution composed of two or more substances.

> **EXAMPLES:** cement, paint, glue, ink, metal alloys, household cleaners.

Article means an object given a special shape, surface or design that determines its function to a greater degree than its chemical composition does.

> **EXAMPLES:** clothing, furniture, electronics and practically all objects of modern life.

Attention: If the main purpose of the product is to release the substance, as in the case of a pen, perfume, ink cartridge, it is not considered as an article under REACH. It is a combination of a container (for example, a perfume flask) and its content (the perfume). Therefore, the container will be considered as an article, and the perfume – as a mixture.

BPR

The BPR defines a biocidal product, an active substance and a treated article as follows:

Biocidal product means:

Any substance or mixture, in the form supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

Any substance or mixture, generated from substances or mixtures that do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

A treated article that has a primary biocidal function shall be considered a biocidal product.

EXAMPLES: Biocidal products are classified in 22 product types (listed in Title V of the BPR) grouped in four main application areas:

- disinfectants, for home and industrial use;
- preservatives, for manufactured and natural products;
- pest control products;
- other specialist biocidal products, e.g. antifouling products.

Annex II provides descriptions of each product type.

Active substance means a substance or a micro-organism that has an action on or against harmful organisms.

The BPR also includes specific provisions for nanomaterials, both in active substances and in biocidal products.

Treated article means any substance, mixture or article treated with, or intentionally incorporating, one or more biocidal products.

EXAMPLES: leather items, wooden furniture, bathroom products, kitchenware – practically any non-food consumer product manufactured or imported into the EU market, when it has been treated with or intentionally incorporates one or more biocidal products.

The BPR also includes specific provisions for nanomaterials, both in active substances and in biocidal products.

1.3 WHO HAS TO COMPLY?

All actors in the supply chain of a chemical product have an important role to control the risks and ensure the safe use of chemicals. Therefore, the requirements of REACH, CLP and the BPR apply to all of them.

The actors in the supply chain are defined by REACH and CLP as follows:

REACH
CLP
Legal definitions

Manufacturer means any natural or legal person established within the EU who manufactures a substance within the EU.

Importer means any natural or legal person established within the EU who is responsible for import.

Distributor means any natural or legal person established within the EU, including a retailer, who only stores and places on the market a substance, on its own or in a mixture for third parties.

Downstream user means any natural or legal person established within the EU, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of their industrial or professional activities.

Downstream users can be found in many industries and occupations and represent in their majority SMEs. Examples in the context of the REACH and CLP regulations include:

Formulators: Produce mixtures, which are usually supplied further downstream. This includes, for example, paints, adhesives, detergents and diagnostic kits.

End-users: Use chemical products but do not supply them further downstream. Examples include users of adhesives, paints, coatings and inks, lubricants, cleaning agents, solvents and chemical reagents like bleaching products.

Producers of articles: Incorporate substances or mixtures into or onto materials to form an article. Examples include textiles, industrial equipment, household appliances and vehicles (both components and finished goods).

Re-fillers: Transfer substances or mixtures from one container to another, generally in the course of repackaging or rebranding.

Re-importers: Import a substance, on its own or in a mixture, which has originally been produced in the EU, and registered by someone in the same supply chain.

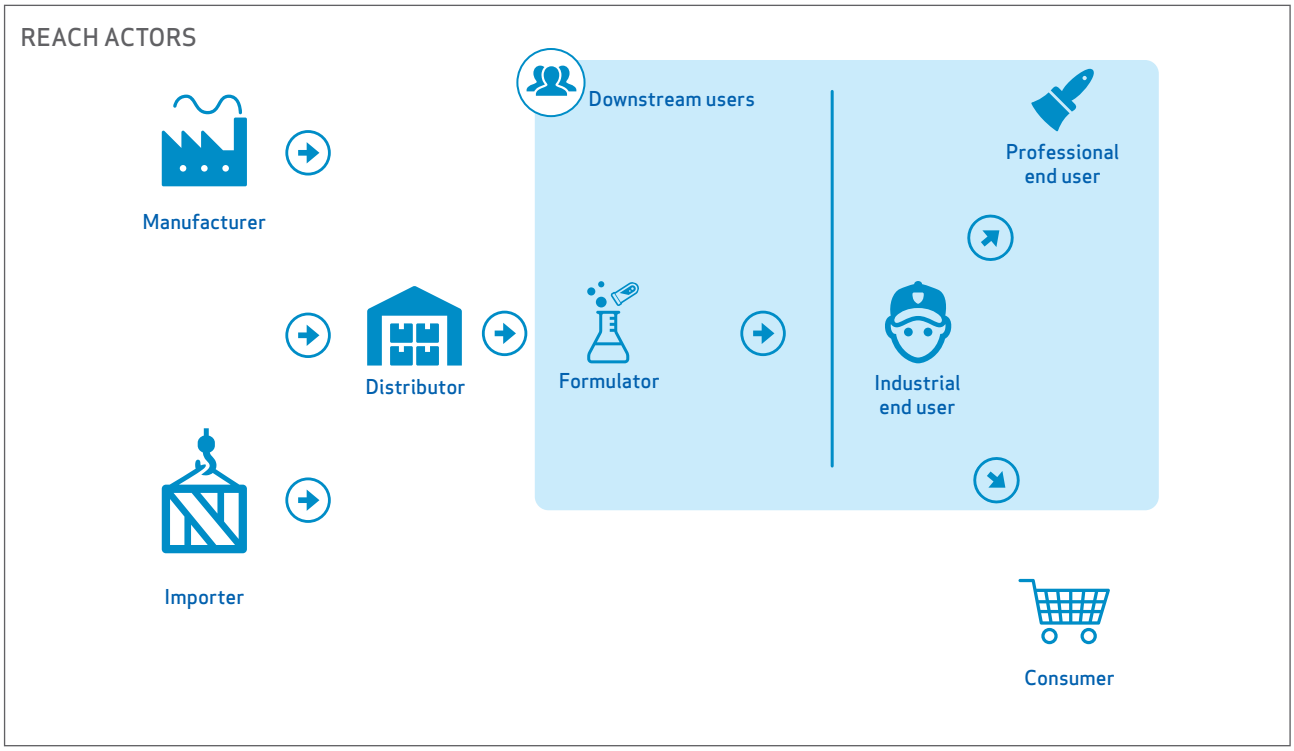
Importer with an only representative: Importers are downstream users when their non-EU supplier has nominated an only representative for the purpose of acting as a registrant established in the Union.

All actors in the supply chain of a chemical product have an important role to control the risks and ensure the safe use of chemicals.

Downstream users are:

Industrial users: Workers who use chemical products in an industrial site, which can be small or large.

Professional users: Workers who use chemical products outside an industrial setting, for example, in a workshop, a client site, or an educational or healthcare establishment. Other typical examples of small businesses with professional use include construction and mobile cleaning companies or professional painters.



BPR
Legal definitions

The Biocidal Products Regulation defines the actors as follows:

Substance supplier is a person established in the Union who manufactures or imports a relevant substance, on its own or in biocidal products.

Product supplier is a person who manufactures or makes available on the market a biocidal product consisting of, containing or generating a relevant substance.

1.4 THE REACH REGULATION – HOW DOES IT WORK?

REACH is based on four main procedures to ensure the safe manufacture, distribution and use of chemical substances and products containing them: registration, evaluation, authorisation and restriction.

REGISTRATION

» http://echa.europa.eu/regulations/reach/registration

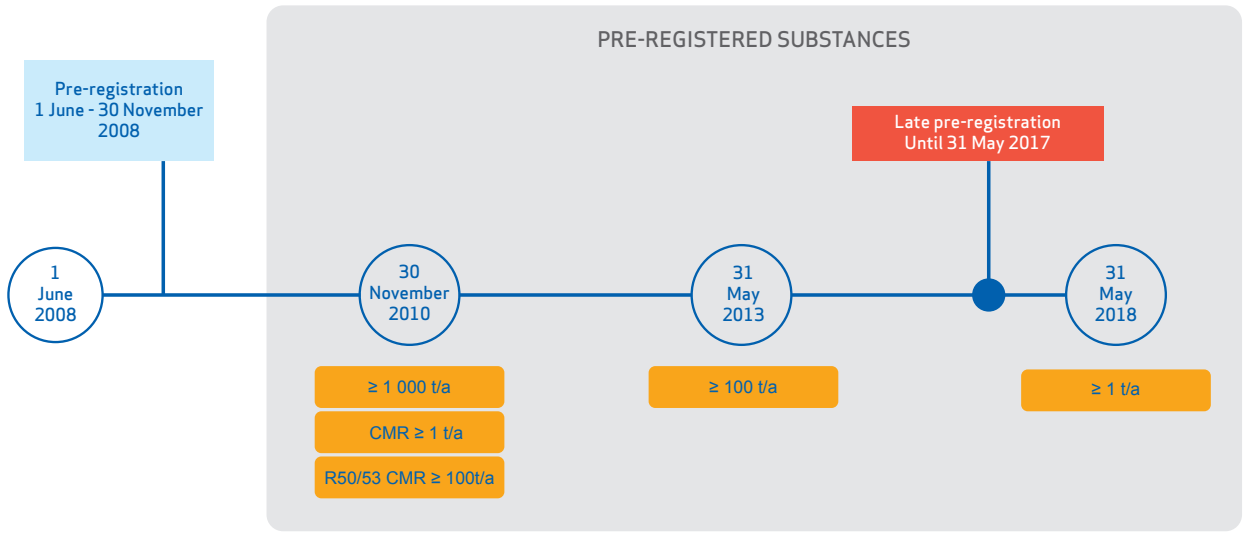
Registration
Title II of REACH
Each company that manufactures or imports a substance on its own, in mixtures or in articles over one tonne per year, regardless if it is hazardous or not, has to register the substance with ECHA, otherwise it cannot place it on the EU market: "No data, no market" principle.

There are exemptions from registration, listed in Article 2 of REACH.

In 2008 pre-registration allowed, under certain conditions, different transitional periods for registration, in 2010, 2013 and 2018 for substances currently on the market, depending on their tonnage and hazards. For companies that manufacture or import pre-registered substances for the first time late pre-registration is still possible before 31st May 2017 where the 2018 deadline applies. Companies that intend to register the same substance have to work together in a substance information exchange forum (SIEF) to share information and to avoid unnecessary tests.

New and not pre-registered substances need to be registered before they are placed on the market.

TIMELINES FOR REGISTRATION



Legend:
CMR – carcinogenic, mutagenic, reproductive toxicant
R50/53 – toxic for the aquatic environment
t/a - tonnes per year

Evaluation
Title VI of REACH
ECHA checks the compliance of information in the registration dossiers and examines all testing proposals in them to ensure that unnecessary testing on animals is avoided. Member States evaluate substances for specific concerns regarding human health and the environment.

EVALUATION

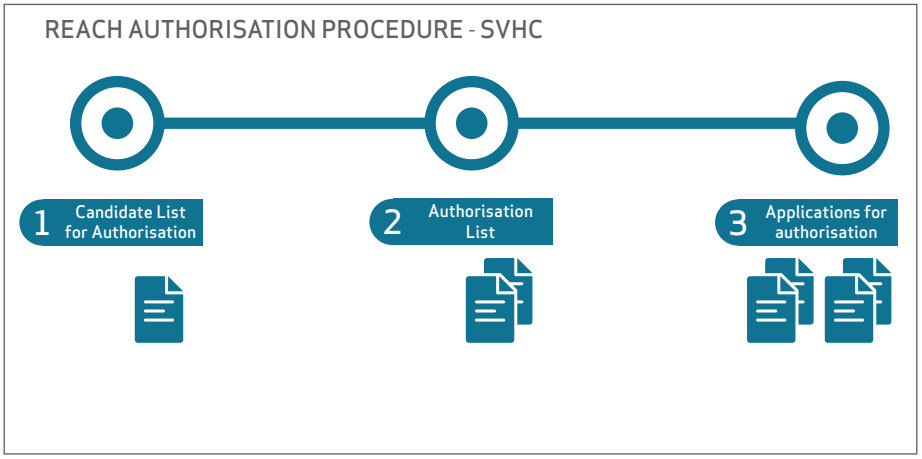
» http://echa.europa.eu/regulations/reach/evaluation

Authorisation
Title VII of REACH
This procedure is introduced to ensure that the risks from the chemicals on the market with the highest concerns are adequately controlled. The aim is to replace chemicals of high concern with safer alternatives when technically and economically viable.

There are several steps in the procedure and each of them includes a public consultation:

AUTHORISATION

» http://echa.europa.eu/regulations/reach/authorisation



1 CANDIDATE LIST OF SUBSTANCES OF VERY HIGH CONCERN (SVHCs) – includes substances that have concerns with serious consequences for human health and the environment:

- Carcinogenic, mutagenic or toxic to reproduction, (CMR) with known or presumed effect on humans;
- Persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB);
- Substances giving rise to an equivalent level of concern, e.g. endocrine disruptors.

SVHCs are identified on an ongoing basis according to the criteria established in Article 57 of REACH and added to the Candidate List twice a year – in June and in December. This triggers obligations for companies supplying and using them to pass on safety information in the supply chain.

For more information:
» http://echa.europa.eu/regulations/reach/authorisation/the-candidate-list

2 **INCLUSION IN THE AUTHORISATION LIST** (Annex XIV to REACH) of substances from the Candidate List which are of highest concern due to their hazardous properties and use pattern. The use of these substances is forbidden after a certain date ("sunset date"), unless an authorisation is granted to individual companies for their specific use, or the use is exempted from authorisation. The aim of including a substance on the Authorisation List is to promote substitution and innovation.

3 **APPLICATION FOR AUTHORISATION**: manufacturers, importers and downstream users have the possibility to apply for authorisation to continue manufacturing and/or using substances included in the Authorisation List. They pay a (non-refundable) fee and have to demonstrate that the risks from using the substance are adequately controlled. If not, then authorisation can be granted if it is proven that the socio-economic benefits outweigh the risks and there are no suitable alternative substances or technologies.

There are few exemptions from authorisation, listed in Article 56.

Authorisation is not linked to the procedures of registration nor to restrictions.

RESTRICTION

» http://echa.europa.eu/regulations/reach/restriction

Restriction
Title VIII of REACH
Some substances or mixtures which pose unacceptable risks can be totally banned on the EU market (e.g. asbestos), have restrictions on specific uses (e.g. phthalates in toys and childcare articles), or have limits on the concentration of the substance (e.g. in consumer products such as tyres, clothing or jewellery). When certain uses are restricted or the substance is banned on the EU market, substitution is a must.

Restrictions are not linked to the procedures of registration nor to authorisation.

There are also restrictions in the product safety and sector specific legislation, for example, on detergents, cosmetics, toys, electronics.

WHAT IS REQUIRED BY THE DIFFERENT ACTORS TO COMPLY WITH REACH?

REACH sets different requirements for the different actors, depending on their position in the supply chain and the product considered.

Communication in the supply chain on chemical safety is required by all actors.

Requirements for each actor:

MANUFACTURERS OF SUBSTANCES

- **Register** the substance if the substance is manufactured in amounts equal to or above one tonne per year for each manufacturer, and if the substance is not exempted from registration.
  If the substance has been pre-registered, the deadline for registration is 31 May 2018 for substances placed on the EU market between 1 and 100 tonnes per year. Substances supplied in a higher volume and the most hazardous ones, e.g. those that are carcinogenic, should already have been registered in 2010 and 2013. Manufacturers and importers placing new substances and substances which have not been pre-registered on the market must register them before manufacture or import.
- **Carry out a chemical safety assessment** to identify and describe the conditions under which the manufacturing and use of a substance is considered to be safe and submit a chemical safety report (CSR). This is required when a substance is manufactured above 10 tonnes per year.
- **Communicate** safety information in the supply chain providing a safety data sheet for hazardous substances as required. The safety data sheet, which is governed by REACH (Article 31 and Annex II), is the main tool for communication in the supply chain to ensure better management of the risks from hazardous substances.
- **Check** if any substance is included in the Authorisation List (Annex XIV) or in the Restriction List (Annex XVII). In these cases it cannot be placed on the market without prior authorisation or used in the conditions described in the restriction.

MIXTURE FORMULATORS

As mixture formulators are using substances and/or mixtures:

- If the supplier of a substance or mixture is located inside the EU, the substances on their own or contained in the mixture should have already been (pre-) registered by their manufacturers. In this case, the mixture formulator is considered as a **downstream user** and does not have to register the substance, but has to comply with all other requirements for downstream users.
- If the supplier of the substance or mixture is located outside the EU and does not have an only representative in the EU, the mixture formulator is considered as an **importer**. In this case, they have to comply with the requirements for importers and has to register the substances used on their own or contained in the mixture.

When the formulator supplies the mixture downstream, they have the duty to communicate information on safe use and prepare a safety data sheet when required.

For more information:
» http://echa.europa.eu/regulations/reach/downstream-users/who-is-a-downstream-user/formulators

! In the raw material for a single product, which is a mixture, it is possible to have both cases. The supplier of one substance/mixture can be based within the EU and the supplier of another substance/mixture – outside the EU.

PRODUCERS OF ARTICLES

A producer of articles has the role of a downstream user and has to comply with the respective requirements. In addition, an article producer may have one or more of the following obligations:

- **Register** a substance intentionally released from articles, if more than one tonne/year of that substance is placed on the market and if it has not been registered for this use by its manufacturer. This is, for example, the substance released from a scented toy.
- **Notify** ECHA of a substance on the Candidate List in the composition of the article in a concentration above 0.1% weight by weight and in a quantity above one tonne/year.
- **Communicate** information on safe use to customers if a substance on the Candidate List is contained in an article in a concentration above 0.1% weight by weight. At least the name of the substance has to be transmitted to the professional clients, and on demand to consumers.
- **Check** and make sure that no substance contained in the article is restricted for this use.

Safety data sheets are not required for articles.

For more information:
Guidance in a Nutshell on Requirements for Substances in Articles
» http://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/guidance-in-a-nutshell

Communication in the supply chain on chemical safety is required by all actors.

IMPORTERS OF SUBSTANCES AND/OR MIXTURES

The importer of a substance has the same obligations as a manufacturer.

The importer of a mixture has to register all the substances in the mixtures if they are supplied in a quantity above one tonne/year per substance.

The importer should, however, check if the manufacturer located outside the EU has designated an only representative in the EU to fulfil the obligations of importers of substances, mixtures and/or articles (Article 8). In this case, importers are regarded as downstream users.

IMPORTERS OF ARTICLES

The importer of articles has to comply with the same requirements as the producer of articles. However, it can be more difficult for importers to gather the information on the substances released during use and on any SVHCs contained in an article.

You can help by advising your clients who are importers to inform their non-EU suppliers of the REACH requirements. You can also suggest to them to choose their suppliers carefully.

DOWNSTREAM USERS

Downstream users do not have the obligation to register.

To ensure the safe use of chemicals they are all required to:

Identify and apply appropriate measures in the safety data sheet
A downstream user has to follow the instructions of the safety data sheets provided by the supplier if a hazardous substance or mixture. If the hazardous substance is registered, the safety data sheet may include exposure scenarios, which describe how to manage the risks for each identified use.

When a downstream user receives a safety data sheet, they must identify and apply appropriate measures to control the risks on their site. This must be done within 12 months after receiving a safety data sheet for a registered substance.

Communicate safety information to suppliers and customers

- **RESPONSIBILITY TO INFORM SUPPLIERS**: A downstream user has to inform the supplier if the risk management measures are not appropriate or if they have new information on hazard identification or classification. These actions must be taken without delay.
- **OPPORTUNITY TO MAKE A USE AS AN IDENTIFIED USE** when the substance is not registered: This is an option, which can make it easier and cheaper

for a downstream user to have the risks for their uses assessed, as it is done by the manufacturer or importer that registers the substance. To make it possible to have his use(s) included in a registration dossier, the downstream user has to inform his supplier how he uses the substance at the latest 12 months before the registration deadline on 31 May 2018. If for business reasons a downstream user decides not to make their uses known, they may opt to make their own chemical safety report.

- **RESPONSIBILITY TO INFORM CUSTOMERS**: A company supplying hazardous substances or mixtures must provide information to its customers on their safe use, in the form of a safety data sheet. This information should be updated without delay if:
  - new information which may affect the risk management measures or new information on hazards becomes available;
  - once an authorisation is granted or refused;
  - a restriction has been imposed.

Comply with the authorisation conditions
If a downstream user uses a substance in the list of substances subject to authorisation, then they must comply with the conditions specified in the authorisation granted to an actor further up their supply chain and notify ECHA within three months of the first supply of the substance.

The downstream user also has the possibility to apply for authorisation if the substance is critical for their business. If no authorisation is granted to them or to a company up in their supply chain, they have to stop using the substance and look for safer alternatives.

Comply with any restrictions of use
If a restriction applies to a substance that a downstream user uses, they may only continue to use it if they comply with the conditions of the restriction.

For further information:
ECHA web pages for downstream users
» http://echa.europa.eu/downstream

Guidance in a Nutshell for Downstream Users
» http://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/guidance-in-a-nutshell

DISTRIBUTORS

The main priority for distributors is to ensure that the chemicals which they supply, comply with the registration, authorisation and restriction requirements of REACH.

Two situations can change the role of a distributor:

- when they supply a chemical product directly from outside the EU they are importers
- when they re-package a chemical product or re-label it to include their brand, they are considered as downstream users.

Communicate safety information to suppliers and customers
Distributors are the communication link between manufacturers and their customers and play an important role to ensure the safe use of chemicals. They have to pass safety information up and down the supply chain. This could include information on the safe handling of chemicals received from the manufacturer and passed down to the customer in a safety data sheet as required or information from the customer on the use of the chemical passed up to the manufacturer or importer.

Suppliers of articles must provide advice on the safe use of an article to industrial and professional users if the article contains a substance on the Candidate List in a concentration of 0.1% weight by weight. Similarly, they are obliged to respond within 45 days and free of charge to such requests from consumers. This can lead to additional pressure on industry to respond to consumer demands for safer products by replacing substances of very high concern with safer alternatives.

All actors
REACH requires manufacturers, importers, downstream users and distributors to keep information for 10 years from the date of the last supply of chemicals.

! Distributors, including retailers, are not downstream users and do not have to register substances or apply for authorisation.


Gas under pressure
Paineenalainen kaasu
Gas under tryck
Explosive
Räjähde
Explosiv
Oxidising
Hapettava
Oxiderande

1.5 THE CLP REGULATION – HOW DOES IT WORK?

Knowing the potential of a chemical to cause harm to people or the environment that can lead to its classification as hazardous is the starting point for safe chemical management.

All substances and mixtures have to be classified and the hazardous ones have to be labelled and packaged according to CLP (set out in Titles II, III and IV) before being placed on the market, regardless of the amounts in which they are supplied and used. CLP applies also to hazardous substances and mixtures used in research and development, or as intermediates in the production process when they are imported or supplied to third parties.

Manufacturers, importers and downstream users of substances and mixtures have to:

- Classify both substances and mixtures according to the CLP criteria,
- Apply the labelling and packaging requirements for hazardous chemical products.

To comply with CLP manufacturers and importers of substances and mixtures must submit a classification and labelling notification to ECHA for each substance which meets the criteria to be classified as hazardous and is placed on the market on its own or in a mixture. Notification is also required for each substance that has to be registered under REACH. If the substance has already been registered under REACH it is considered to be notified for the purposes of CLP.

Article producers and importers have obligations under CLP only for specific articles, such as explosive articles (as described in section 2.1 of Annex I to CLP).

Distributors have to make sure that the substances and mixtures they store and sell are labelled and packaged according to the CLP requirements before placing them on the market.

Before placing chemical substances or mixtures on the market, companies must:

- Establish the potential physical, health and environmental hazards and classify them in line with the CLP criteria;
- Label and package hazardous chemicals according to the standardised system set out in CLP so that workers and consumers know about their effects before they handle them.

HOW TO CLASSIFY?

Two obligations exist:

- **HARMONISED CLASSIFICATION** (as listed in Annex VI to CLP). It is agreed at EU level and legally binding for all suppliers of the respective substance placed on the market on its own or in mixtures. This type of classification

CLP

» Classify
» Label
» Package
» Notify

CLASSIFY

» http://echa.europa.eu/regulations/clp/classification

normally applies to the most hazardous substances such as carcinogenic, mutagenic, toxic for reproduction or respiratory sensitisers. Active substances for biocidal and plant protection products generally have harmonised classification.

The harmonised classification provides a level playing field for all businesses in the EU market. Companies can also propose to harmonise the classification and labelling of a substance (except for active substances of biocides and pesticides) and/or take part in the public consultations on the proposals for harmonising the classification of substances.

- **SELF-CLASSIFICATION** (set out in Annex I to CLP) applies to both substances and mixtures. It is required for substances when there is no harmonised classification for the given hazard class. If a mixture contains a substance with a harmonised classification, this information needs to be taken into account when classifying the mixture.

There are normally five basic steps to decide on the classification:

- Identify all available data on the substances and mixtures;
- Examine the reliability of this information;
- Evaluate the information against the classification criteria;
- Decide on the classification;
- Review when new information becomes available.

Companies can follow all these steps for classifying a mixture by using ECHA's website:
» http://echa.europa.eu/support/mixture-classification/where-do-i-start

LABEL

» http://echa.europa.eu/regulations/clp/labelling

HOW TO LABEL?

CLP defines the content of a hazard label and the organisation of the various elements in it (Article 17 of CLP). The general rules for the application of labels are provided in Article 31 of CLP.

A hazard label is made up of specific symbols (known as "pictograms") and warnings.

Under CLP, the pictograms have been re-designed and given a new shape from the orange square to a diamond with a red border (see Annex I). New signal words, hazard and precautionary statements along with supplemental information replace the indications of danger, risk and safety phrases to be used to help workers and consumers understand the hazards and potential risks before they use the chemical products.

The following example illustrates the requirements for the hazard label, including its dimensions and the position of the various elements.

HOW TO PACKAGE?

Special requirements for the packaging of hazardous substances and mixtures are set out in the CLP Regulation (Article 35). The packaging of products containing hazardous substances and mixtures must be designed and constructed in a way that its content cannot escape and the materials used cannot damage the content. The package design should not be attractive for children or mislead the consumer.

For example, all domestic cleaning products, detergents and other products for home swimming pools, pesticides and products for the garden should not have a similar presentation or design used for food or animal feed or medicinal or cosmetic products.

HOW TO NOTIFY TO THE C&L INVENTORY?

The procedure is straightforward and free of charge. Companies submit the required information on the classification and labelling (C&L) to ECHA (Article 40 of CLP). They can use an online tool designed to guide them through the process. Mixtures themselves do not have to be notified, but they will be illegally on the market if all the hazardous substances they contain are not notified by their manufacturers or importers.

Notification has to be done at the latest one month after placing the hazardous substance on its own or in a mixture on the EU market. For importers, the one month delay is counted from the day when the product is physically introduced into the EU customs territory. The non-confidential part of this information is published by ECHA in the C&L Inventory.

PACKAGE

» http://echa.europa.eu/regulations/clp/labelling

NOTIFY

» http://echa.europa.eu/regulations/clp/cl-inventory/notification-to-the-cl-inventory

CLP ROLES AND REQUIREMENTS AT A GLANCE

Role in the supply chain	Classify	Label	Package	Notify ECHA	Gather and keep the information for at least 10 years
Manufacturer	Yes	Yes	Yes	Yes	Yes
Importer	Yes	Yes	Yes	Yes	Yes
Producer/ Importer of explosive * articles	Yes	Yes	Yes	Yes	Yes
Downstream user**	Yes/No**	Yes	Yes	No	Yes
Distributor/ Retailer**	No**	Yes	Yes	No	Yes

* Explosive articles and articles producing a practical, explosive or pyrotechnic effect (part 2.1, Annex I to CLP)

**Downstream users and distributors have a possibility to take over the classification used by their supplier unless they change the product in any way (e.g. formulation of a new mixture).

1.6 THE BIOCIDAL PRODUCTS REGULATION – HOW DOES IT WORK?

A biocidal product cannot be made available on the market or used unless it is in compliance with the BPR. The legislation also applies to producers and importers of treated articles.

Access to the market is based on a two-step procedure:

- The active substances contained in the biocidal product must be approved at the EU level;
- All biocidal products intended to be made available on the market and used require an authorisation at national or EU level.

APPROVAL OF ACTIVE SUBSTANCES

A dossier for an approval of an active substance for specific product types must be submitted to ECHA. When an active substance has been approved, the European Commission includes it in the list of approved active substances.

AUTHORISATION OF BIOCIDAL PRODUCTS

Authorisation under the BPR is different from authorisation under REACH. BPR authorisation means national authorisation, Union authorisation or simplified authorisation as described in Article 3 of the BPR.

It is possible to choose between:

- **National authorisation** (Article 29) – when a company is planning to sell a product in one EU Member State, it is sufficient to apply for product authorisation in that country.
- **Mutual recognition –** if the product is intended to be placed on the market in several European countries, then the company has to opt for mutual recognition, either in sequence (Article 33) – by extending an already existing authorisation in one EU country, or in parallel (Article 34) – by starting the authorisation procedure for all intended countries in one go.
- **Union authorisation** (Article 41) – this new procedure, managed by ECHA, allows companies to get EU authorisation in one go, for certain products that will be used under similar conditions across all Member States.
- **Simplified authorisation** (Chapter V) – this new "fast track" procedure aims to encourage the use of biocidal products that are less harmful for the environment, human and animal health. To be eligible, the biocidal product must contain only active substances laid down in Annex I to the regulation. It cannot contain any substance of concern or any nanomaterials, it must be sufficiently effective for its purpose and the handling of the product must not require protective equipment. The simplification means faster processing times and access to the entire EU market without the need for mutual recognition.

BPR

» Approval of active substances
» Auhorisation of biocidal products
» Treated articles

APPROVAL OF ACTIVE SUBSTANCES

» http://echa.europa.eu/information-on-chemicals/biocidal-active-substances

AUTHORISATION OF BIOCIDAL PRODUCTS

» http://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products

For more information:
On the practical aspects of the BPR:
» http://echa.europa.eu/practical-guides/bpr-practical-guides

TREATED ARTICLES

» http://echa.europa.eu/regulations/biocidal-products-regulation/treated-articles

TREATED ARTICLES

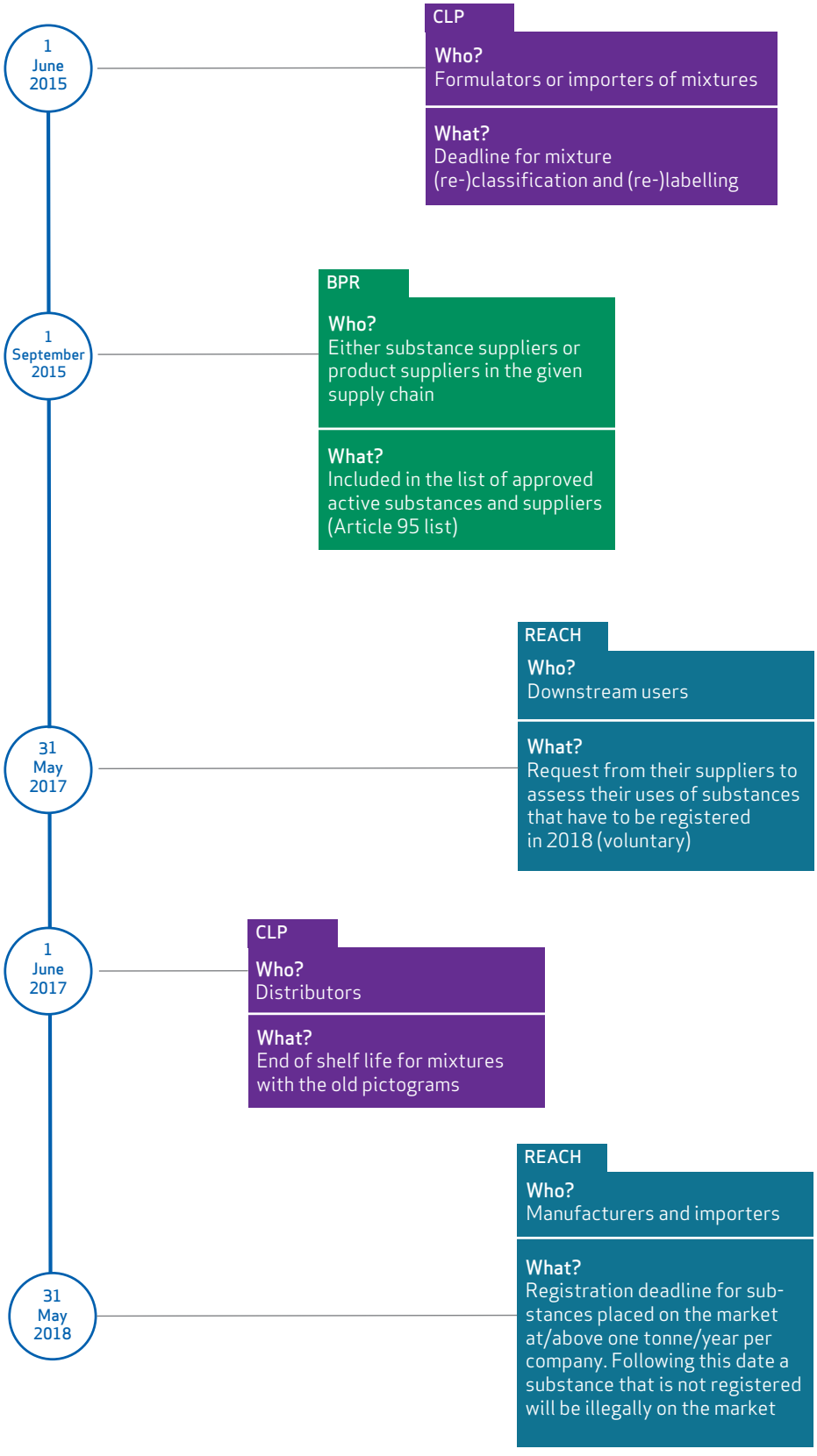
The BPR sets rules for the use of articles treated with, or intentionally incorporating, one or more biocidal products.

According to the regulation, articles can only be treated with biocidal products containing active substances approved in the EU. This is a change from the Biocidal Products Directive (repealed by the BPR from 1 September 2013), where articles imported from third countries could be treated with substances not approved in the EU – such as, wood treated with arsenic, and sofas and shoes containing Dimethyl fumarate (DMF).

Companies must also be ready to provide the consumers with information about the biocidal treatment of the article they are selling. If a consumer requests information about a treated article, the supplier must provide it free of charge within 45 days.

1.7 WHAT ARE THE DEADLINES?

The important dates to ensure access to the market:



OTHER DEADLINES

REACH

Who?
Manufacturers, importers and downstream users

What?
Apply for an authorisation if they wish to continue placing on the market for a use or use themselves a substance on the Authorisation List after its sunset date.

CLP

Who?
Manufacturers and importers

Notification to the C&L Inventory within one month after placing on the market a hazardous substance.

REACH

Who?
Downstream users

What?
Downstream users relying on an authorisation granted to an actor up their supply chain must comply with the conditions specified in the authorisation and notify ECHA within three months of the first supply of the substance.

REACH

Who?
Downstream users

What?
12 months after receiving a safety data sheet for a registered substance to identify and implement risk management measures.

If any of these deadlines concern your clients, advise them to start preparing now. They will have to take first important business decisions and to have a good strategy in place.

Make sure you advise companies to:

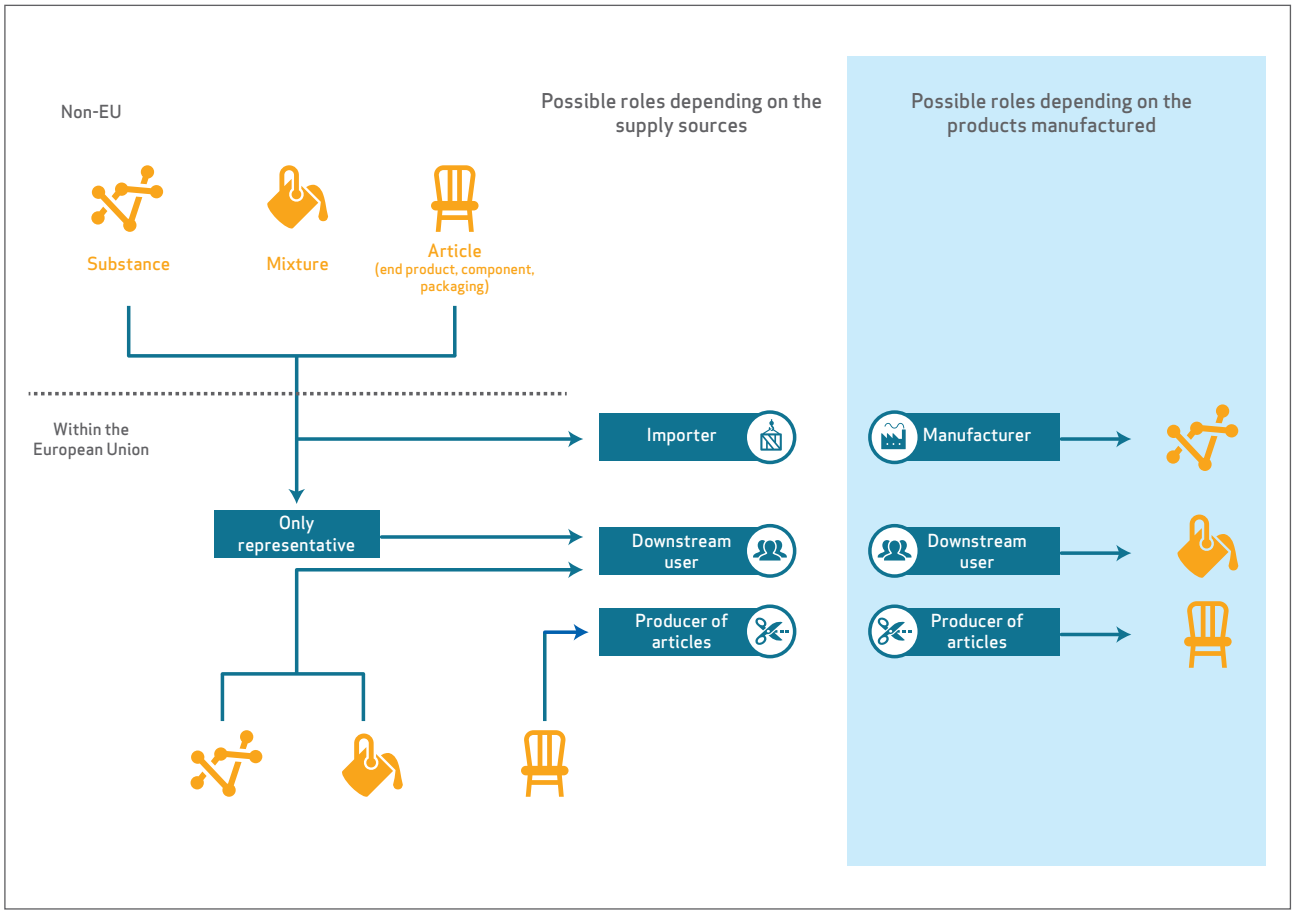
- Identify their role under REACH, CLP and the BPR for each substance and be proactive – to communicate in the supply chain
- Monitor the volume of the substances they manufacture, import or use
- Keep up-to-date with the legal developments and constantly monitor on ECHA's website or via ECHA news, the regulatory status of their substances for harmonised classification under CLP, inclusion of new substances on the REACH Candidate List, Authorisation List or Restriction List, or identifying biocidal active substances as candidates for substitution.

2. How to integrate EU chemicals legislation in the Enterprise Europe Network activities

Enterprise Europe Network can provide a range of services to support both SMEs which have legal obligations and those that are developing or can provide safer alternatives. You can play an important role in helping companies to turn legal obligations into business opportunities.

2.1 IDENTIFY WHICH COMPANIES NEED TO COMPLY

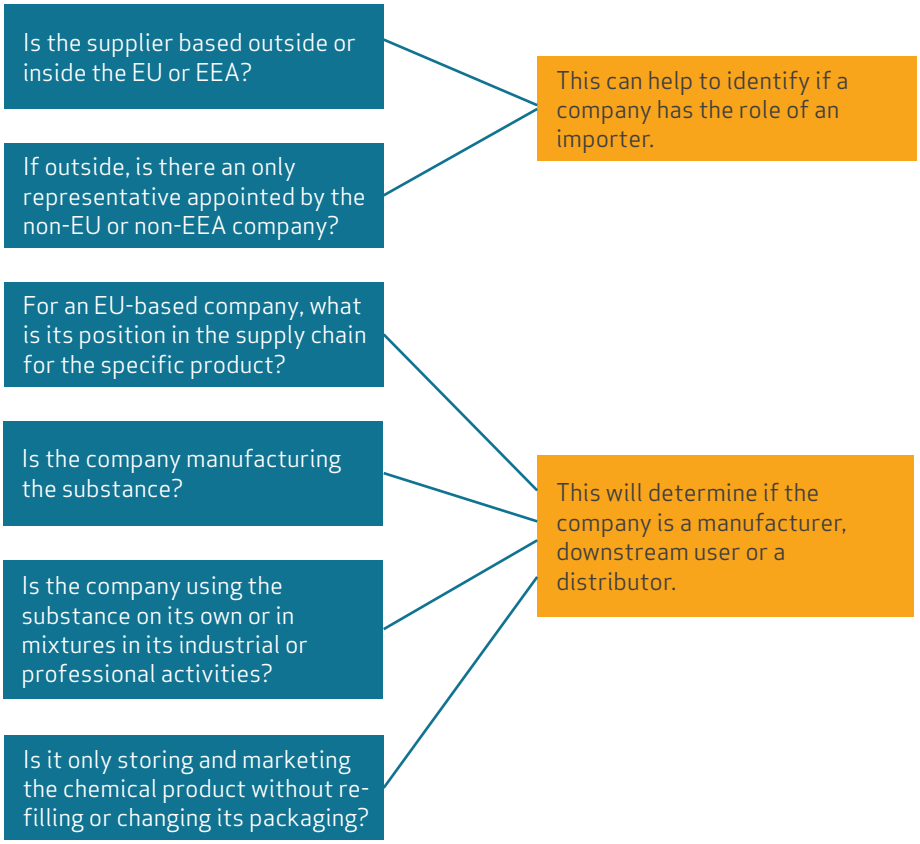
The case of REACH and CLP.



When a company is not aware or not convinced that REACH and CLP applies to its business, you can check and motivate it to act according to the following three steps:

1 STEP 1: IDENTIFY THE ROLE/ACTIVITY OF THE COMPANY

The main roles of companies under REACH and CLP are: manufacturer, importer, downstream user or distributor of a substance on its own, in mixtures or in articles.

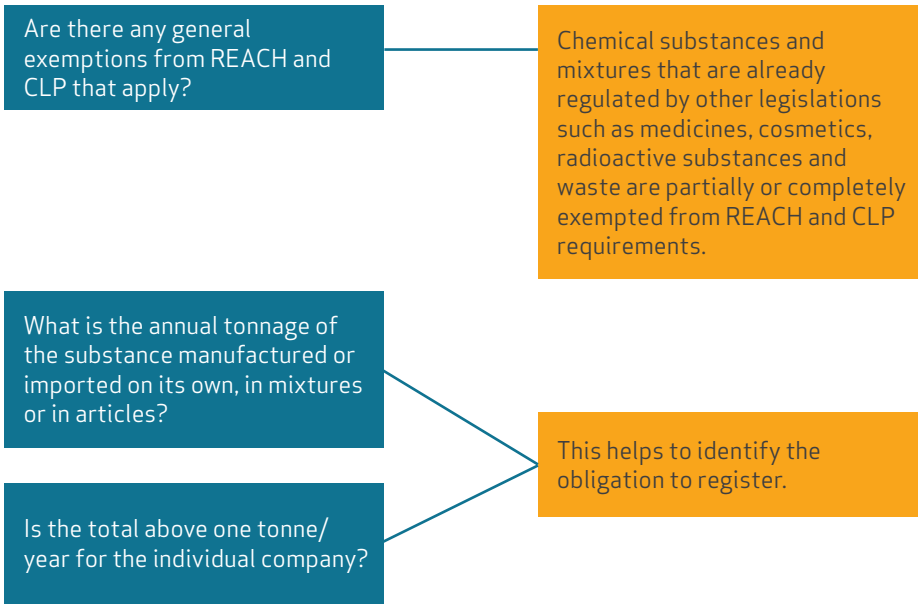


For specific scenarios which can help identify if the company is a downstream user or has another role in the supply chain under REACH, use ECHA Guidance for Downstream Users:

» http://echa.europa.eu/documents/10162/13634/du_en.pdf

2 STEP 2: IDENTIFY THE PRODUCT THE COMPANY MANUFACTURES, BUYS, SELLS OR USES

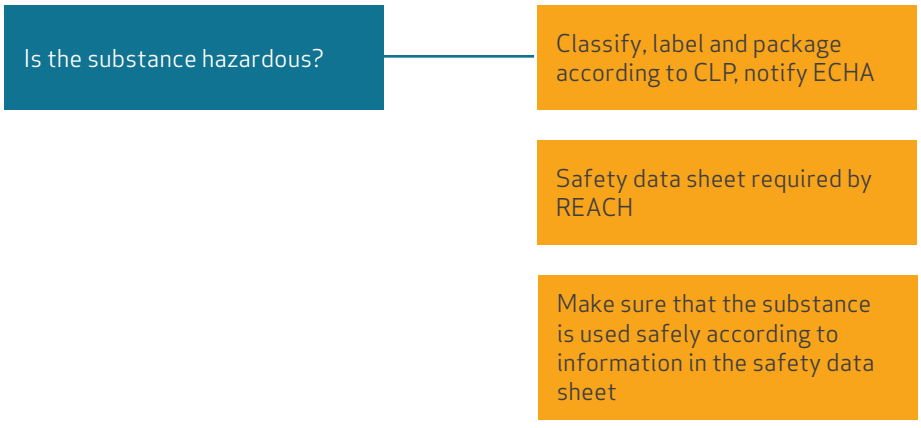
A chemical product can be a substance (e.g. formaldehyde), a mixture (e.g. lubricant) or an article for professional use (e.g. window frame) or for consumers (e.g. a mobile phone, a leather item).

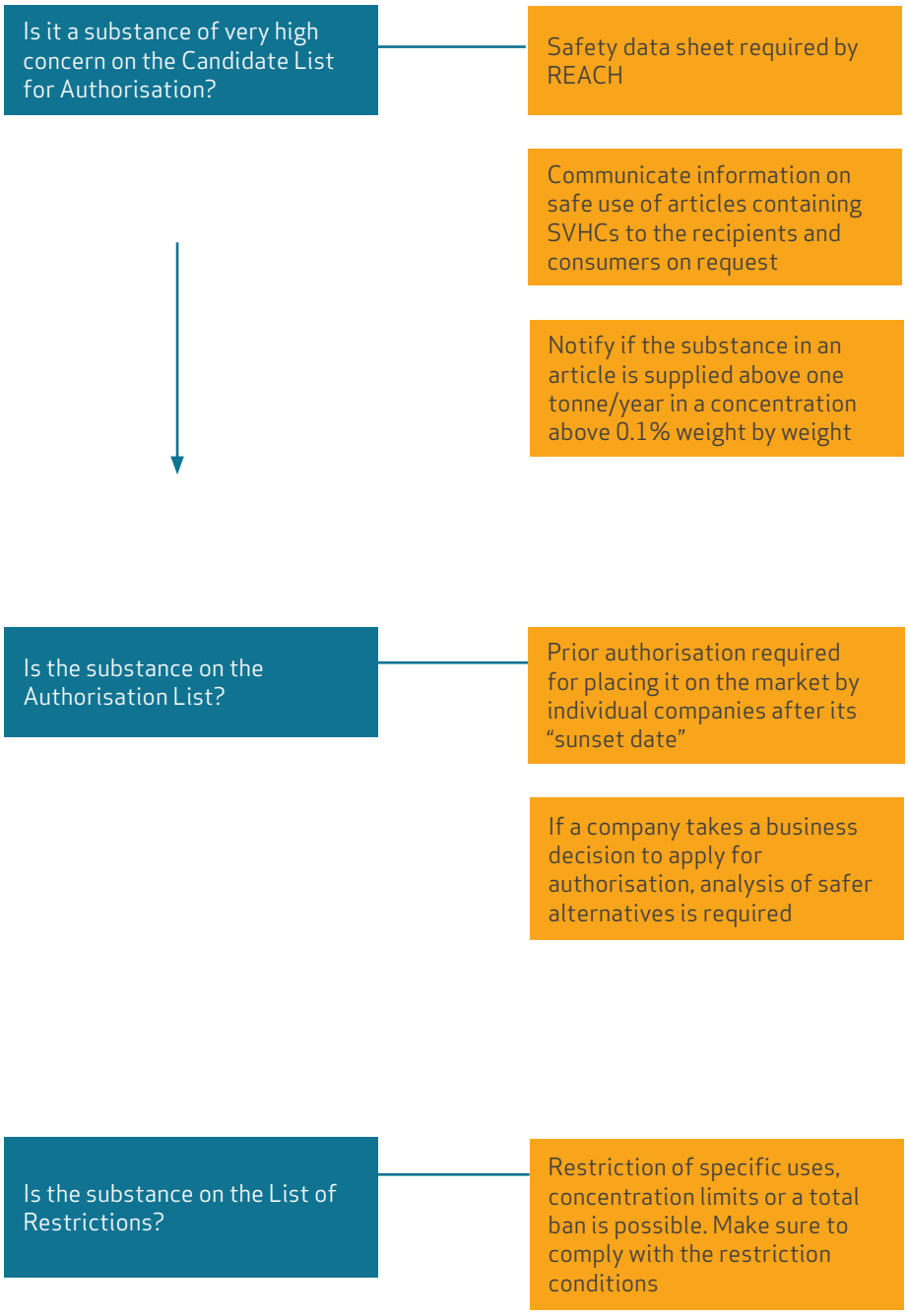


3 STEP 3: IDENTIFY THE MAIN REQUIREMENTS

To ensure a high level of protection for human health and the environment, the more hazardous the substances are, the more is required by suppliers and users to comply with the REACH and CLP requirements for chemical safety.

This can trigger decisions by companies to review their portfolio and to replace (the most) hazardous substances with safer ones.





! The requirements are established for every individual substance and there may be several requirements for a single product.


ECHA

ONLINE RESOURCES TO IDENTIFY AND CLARIFY INDIVIDUAL OBLIGATIONS

Advise companies to:

- Use ECHA's Navigator tool to identify their individual obligations for each specific substance and access directly the relevant guidance documents. Navigating REACH is possible in 23 EU languages:
  - » http://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/identify-your-obligations

- Check how a substance is regulated under REACH and CLP (e.g. if it is on the Candidate or Authorisation List) using the "Search for Chemicals" box on ECHA's homepage:
  - » http://echa.europa.eu

- Find answers to frequently asked questions on ECHA's website or on the website of your national helpdesk.
  The links to follow:
  - » http://echa.europa.eu/support/qas-support/qas
  - » http://echa.europa.eu/support/helpdesks

2.2 TELL COMPANIES THAT THEY ARE NOT ALONE

They can contact:

- Their suppliers – for information on the substances they use
- Industry associations – for sector-specific information and advice, for sharing experience
- National helpdesks – for questions on compliance
- ECHA Helpdesk – for support with the IT tools that have to be used to submit information required by the law
- Professional consultants, when individual tailor made support is needed.

2.3 HELP SMEs TO REDUCE THEIR COSTS

REACH and the BPR, and in some cases also CLP, require the payment of fees and charges to ECHA – the smaller the company, the lower the fees and charges.

A company can benefit from reduced fees and charges only if it is a micro, small or medium-sized enterprise according to EU law: Commission Recommendation 2003/361/EC.

The main factors determining whether your client is an SME are the staff headcount ceiling and one (or both) of the financial limits in the following table:

Enterprise category	Headcount	Turnover	or	Balance sheet total
medium-sized	< 250	≤ 50 million euro	≤ 43 million euro	
small	< 50	≤ 10 million euro	≤ 10 million euro	
micro	< 10	≤ 2 million euro	≤ 2 million euro	

These ceilings apply to the figures for individual firms only.

A company which is part of larger grouping may also need to include employee/turnover/balance sheet data from that grouping.

ECHA's website gives five clear steps and an online calculator to help companies determine their company size category:
» http://echa.europa.eu/support/small-and-medium-sized-enterprises-smes/how-to-determine-the-company-size-category

Advise companies to follow these steps which can help them to know if they qualify for the reduced fees and avoid administrative charges if they wrongly declare their company size.

Other costs often exceed the fees. These will depend on the specific company obligations, the need to generate or buy data, the choice of using consultants or the need/decision to find safer alternatives in place of hazardous chemicals.

YOU CAN HELP COMPANIES TO REDUCE THEIR COSTS IN DIFFERENT WAYS

- Advise SMEs to make the best use of the free support provided by ECHA, national helpdesks, industry associations, the Enterprise Europe Network advisers on law and standards. This can help them to understand their duties, to identify tools and resources that are provided free of charge and relevant to a specific substance or sector.
- Guide companies through the relevant information and services that can help them gain practical knowledge of what they have to do to comply.

In annex III, you can find useful online information and services with SMEs in mind.

- Suggest to your clients to take part in ECHA's annual stakeholders' days. These events are free of charge and provide an opportunity to have one-to-one consultations with ECHA staff on practical aspects and processes of the legislation. Online participation is also possible and video recordings are published on the website:
  » http://echa.europa.eu/news-and-events/events/

- **Advise SMEs to select private consultants wisely** and provide them with a checklist. SMEs may need to use private consultants to comply with REACH, CLP and the BPR, but sometimes they tend to pay for more than they actually need. To help such companies save unnecessary costs, industry associations working with ECHA have prepared a checklist for selecting a good consultant for complying with REACH, available in 23 EU languages:
  » http://echa.europa.eu/about-us/partners-and-networks/directors-contact-group

2.4 ASSIST COMPANIES TO FIND SAFER ALTERNATIVES

This may be needed when the substance used by a company is not registered or is included in the Authorisation List or restricted for that use. It could also be a voluntary action by this company to replace a substance of very high concern.

To help such companies you can use the **Partnership Opportunity Database of Enterprise Europe Network**. You can search for alternative substances and technologies and provide this information to SMEs. When there are no entries in the database, which can meet the needs of the company, you can introduce a request on its behalf.

A link to the Partnership Opportunity Database is available on the Enterprise Europe Network Intranet.

2.5 SUPPORT INNOVATORS

Inform companies of the legal incentives to go green
REACH, CLP and the BPR promote substitution of the most hazardous chemicals. There are also direct provisions to support research and innovation in chemicals:

RESEARCH AND DEVELOPMENT

Substances used for scientific research and development are exempt from REACH registration, authorisation and restriction provisions. There are reduced labelling requirements for the inner packaging of substances and mixtures below 10 ml under CLP.

Substances used for product and process oriented research and development, such as development and testing a new process when changing raw materials, or testing of new applications for a substance, are exempt from REACH registration for five years. Notification is required instead.

To encourage research and development in active substances and biocidal products, the BPR contains specific provisions for experiments and tests involving an unauthorised biocidal product or non-approved active substance (Article 56 of the BPR). Furthermore, provisional national or Union authorisation for up to three years may be issued for biocidal products containing new active substances when certain conditions are met (Article 55(2) of the BPR). Longer periods for data protection (from 10 to 15 years) are granted to new active substances (and their products) as an incentive for developing new and safer products.

SAFER ALTERNATIVES

The availability of suitable alternatives is considered in the decisions on REACH authorisations and restrictions. All companies applying for REACH authorisations have to analyse the availability of alternatives and consider the technical and economic feasibility of substitution.

Biocidal products containing an active substance that is a candidate for substitution, for example, carcinogenic, toxic to reproduction or to the environment, will undergo a comparative assessment before authorisation. This is done to find out whether there are safer alternatives on the market. If safer alternatives are available and they are effective, the use of the biocidal product can be prohibited or restricted.

FUNDING

Consider if your client SMEs can apply for EU or national funding, help them to find partners and build up new projects
REACH and CLP implementation and the provisions of the new Biocidal Products Regulation create a demand for safer alternatives and technologies to replace the most hazardous chemicals on the EU market today. These substances are identified on an ongoing basis as candidates for substitution under the BPR and to be included in the REACH Candidate List, the Authorisation and Restriction List. These growing lists could be used as a reference where further research and innovation is needed.

Some of the EU Programmes in which the Enterprise Europe Network is involved can support the development of new solutions for substitution and eco-innovation.

For further information, see Annex III.

Promote safer alternatives and technology solutions developed by your client SMEs

This could be a win-win for them and for companies which need such solutions in order to meet the requirements of REACH and the BPR to phase out hazardous substances and to change their process or portfolio in order to stay on the market. Beyond the legal requirements, the increasing consumer pressure for safer chemicals and products is an additional strong incentive to develop greener solutions. Furthermore, using substances of very high concern can entail high costs for companies due to the need to apply stringent risk management measures and, in many cases, monitoring.

PUBLIC CONSULTATIONS

ECHA's public consultations on the REACH authorisation and restrictions and on the biocides that are candidates for substitution seek information on safer alternatives. Innovative companies should take advantage of these opportunities to provide information on their alternative solutions if these are relevant to the case under consultation.

Information on a new or a not well known alternative, which appears to be particularly suitable for a certain use, will be of high interest for ECHA and the concerned companies. The Agency is also building up a partner service which can be used by companies to inform others about an alternative or to look for such alternatives. Other initiatives such as the Substitution Support Portal also aim to promote alternative solutions.

For more information

ECHA's public consultations on addressing chemicals of concern under REACH, CLP and the candidates for substitution under the BPR:
» http://echa.europa.eu/addressing-chemicals-of-concern

Overview of the public consultations for REACH authorisation:
» http://echa.europa.eu/fr/addressing-chemicals-of-concern/authorisation/public-consultation-in-the-authorisation-process

ECHA's Partner Service on REACH authorisation:
» http://echa.europa.eu/applying-for-authorisation/partners-service-for-applicants

The Substitution Support Portal:
» http://www.subsport.eu/

3. Get involved – work with national helpdesks and ECHA

National helpdesks established by the competent authorities in each of the 28 EU Member States and the three EEA countries give advice on the provisions of REACH, CLP and the BPR. They are also part of a network, known as HelpNet and made up of ECHA and the national REACH, CLP and BPR helpdesks. One of its main objectives is to promote harmonisation of the advice given to companies, which covers their responsibilities under each of the three regulations.

Find your national helpdesk at:
» http://echa.europa.eu/support/helpdesks/

The HelpNet is governed by a Steering Group, which includes the national helpdesks and ECHA, the European Commission and observers from candidate countries and/or stakeholder organisations accredited with ECHA. Cooperation between the Enterprise Europe Network and HelpNet can be of mutual benefit for the Network and for the national helpdesks, but most importantly – it can help to reach out to more SMEs and help improve the services provided to them:

- REACH, CLP and the BPR helpdesks are established at national level, Network partners provide services at regional level.
- National helpdesks are mostly hosted by the competent authorities, while Network partners represent business organisations – chambers of industry, science and technology parks, investment and regional development agencies, technology transfer organisations.
- REACH, CLP and the BPR helpdesks support companies to comply with the legal obligations, Network partners can also help them to find safer alternatives.
- At EU level, ECHA hosts the secretariat of HelpNet and cooperates with the Executive Agency for SMEs.

The most effective will be to focus on the national level, taking into account national specificities.

The HelpNet activities include:

- Information exchange on the implementation of REACH, CLP and the BPR;
- Consistent and harmonised advice to stakeholders by its members;
- Capacity building and training of national helpdesks;
- Communication and awareness raising activities with a particular emphasis on SMEs.

3.1 COOPERATION AT NATIONAL LEVEL – WORKING WITH NATIONAL HELPDESKS /AUTHORITIES

Cooperation between Network partners and national helpdesks and/or national authorities can be structured, to clarify objectives, scope, activities, organisation, confidentiality issues and any other aspect of the collaboration. This could eventually take the form of a formal cooperation agreement.

Key issues are:

3.1.1 Decide how to organise the cooperation:

Network partners and the national helpdesks/authorities decide at national level which is the best organisation model to carry out cooperation activities.

EXAMPLES OF DIFFERENT APPROACHES:

- Designating a contact point in the national consortium of the Network to liaise with the national helpdesk/authority in order to channel company questions and act as a communication channel to ensure that relevant information is provided and promoted to all national Enterprise Europe Network partners and where relevant, they get involved in the national helpdesk activities;
- Direct communication between the individual Enterprise Europe Network partners and the national helpdesks/authorities, while appointing a unique contact point responsible for representing the Network when one voice is requested (important events, events abroad, defining the cooperation agreement with the national helpdesks/authorities, relationships with ECHA, etc.).

3.1.2 Define collaboration activities

EXAMPLES OF SUPPORTING COMPLIANCE:

- Network partners signpost questions on compliance from client companies to national/ECHA helpdesks; national helpdesk refers to Enterprise Europe Network companies seeking assistance to replace hazardous substances;
- Identify and promote "how to" examples of good practice from SMEs;
- Enterprise Europe Network information days on eco-innovation could integrate REACH/substitution information;
- Activities supporting REACH and CLP campaigns on the forthcoming deadlines on CLP 2015 and REACH 2018;
- Awareness days, one-stop-shop events for small companies.

EXAMPLES OF INFORMATION EXCHANGE:

- Mutual promotion of the collaboration in the web pages of the organisations involved in the Network and the national helpdesks;

- Distribution of relevant information on REACH, CLP and the BPR from the national helpdesks/authorities to the Enterprise Europe Network and from the Network to companies at local level;
- Dissemination of relevant information in the Enterprise Europe Network newsletters and social media.

The Enterprise Europe Network promotes national helpdesk/authority events, ECHA webinars, stakeholder days to companies, and national helpdesks/authorities promote relevant events organised by the Network Joint events represent another opportunity to strengthen co-operation.

Cooperation agreement
This forms the basis for sustained collaboration in the long run and does not have to involve additional resources, either for Network partners or for the national helpdesks. In the launch phase, it can integrate capacity building for the local Enterprise Europe Network staff, and should include the organisation of regular coordination meetings and monitoring activities.

3.1.3 Successful cooperation examples

Italy – cooperation agreement
The cooperation is based on the national REACH strategy. It was launched in 2011 by signing an agreement between the national REACH helpdesk, hosted by the Ministry for Economic Development, and seven Network partners representing all Italian regions. The agreement sets the collaboration framework for the establishment of territorial information desks. One Network partner is appointed as contact point only on those cases where "one voice" is needed (important events, events abroad, etc.), while in the day-to-day activities each partner manages the collaboration with the national helpdesk.

The Enterprise Europe Network staff has been initially trained by the REACH national helpdesk and the Italian institutions involved in the REACH implementation. The collaboration is based on a regular exchange of information, on the organisation of events, on providing answers to company enquiries, monitoring the impact and periodic reports to the national helpdesk. The local contact points from Enterprise Europe Network organised 15 events between 2011 and 2013 to support the national REACH 2013 registration campaign and assisted nearly 300 companies.

From 2015, it is planned to extend the scope of the agreement with the new Network to include business support services aimed at fostering substitution and eco-innovation.

For more information:
ECHA Newsletter edition February 2013
» http://newsletter.echa.europa.eu

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France – SME working group
Network partners from the regional chambers of commerce played an active role in the national campaign for the REACH 2013 registration deadline. A special working group to identify areas of support for SMEs was set up at national level. This working group chaired and hosted by the French REACH competent authority (Ministry for the Environment) involves the national helpdesk, national and regional representatives of chambers of commerce, and a few professional federations, the Ministry of Labour, the Ministry of Industry and the national institute for occupational health and safety (INRS).

The action plan established by the working group included the production of a simple brochure explaining REACH in a non-technical language, which featured examples of SMEs from the non-chemical sector and promoted the services of the national helpdesk. 15 000 copies of the brochure were disseminated during the campaign using the channels of national Enterprise Europe Network partners. The chambers also organised regional and even some local information meetings for SMEs involving representatives of the Ministry or the national helpdesk. Some of the meetings were also attended by the local press which raised further awareness. Thanks to the involvement of the Network partners in the campaign, its webinar programme reached a wider SME audience beyond the chemical sector.

The Ministry is consulting the SME task force on a regular basis to adapt the action plan for SMEs for the 2015 CLP deadline and in preparation for the 2018 REACH registration deadline but also for other requirements of the legislation.

For more information:
ECHA Newsletter edition August 2012
» http://newsletter.echa.europa.eu

Contact:
Clio Brivois-Poupard, Enterprise Europe Network, CCI Alsace
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Ireland – joint events
Taking care of business is the annual one-stop-shop event for companies organised in cooperation between Enterprise Ireland and 19 authorities. The Health and Safety Authority, which hosts the national REACH and CLP helpdesk is closely involved.

For more information:
» https://www.takingcareofbusiness.ie/

Finland – joint events with ECHA
Enterprise Europe Network Finland organised a joint event with ECHA in 2012 to support the REACH 2013 registration campaign. ECHA provided the speakers and managed the programme, while Network partners ensured participation from companies representing all sectors affected by REACH. The national consortium supported a training event for the Network organised by ECHA and EASME in 2013. Cooperation with the national helpdesk includes the publication of articles on the EU chemicals legislation and promotion of events.[1]

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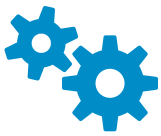
1 Examples from other countries will be included in the next edition of this guide



3.2 COOPERATION AT SECTOR GROUP LEVEL – WORKING WITH ECHA

Enterprise Europe Network sector groups cover areas of direct relevance to the EU chemicals legislation, such as biotech, environment, healthcare, textiles, sustainable construction and nano- and micro-technologies. Sector groups can play an active role in supporting substitution and promoting innovation.

Examples of sector group involvement:

- Designate a contact point in the sector group to keep interested members informed on the REACH developments and public consultation opportunities.
- Support sector-specific awareness raising campaigns on REACH.
- Promote/participate in ECHA's public consultations for safer alternatives to SVHCs under REACH and candidates for substitution under the BPR.
- Disseminate thematic information and publications.

Events:

- Topical presentations on REACH to the sector group.
- REACH information (stand/workshop) at trade fairs and brokerage events.
- Information about REACH at international company missions.
- Identify and promote "how to" examples of SMEs that have succeeded in turning legal obligations into business opportunities.

Examples of good practice:

The BioChemTech Sector Group has designated a contact person for REACH who keeps members up-to-date on the legal developments of relevance to them.

Contact:
Clio Brivois-Poupard, Chamber of Commerce and Industry, Alsace
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The Environment Sector Group has started cooperation with ECHA which includes guest presentations, participation in a brokerage event and a training package for the sector group members developed in cooperation with the national REACH and CLP helpdesk in Spain.

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ARE YOU READY FOR THE NEXT STEPS?

The information provided in this guide can help you to make companies aware of the EU chemical safety law. It can be useful to identify the actions they have to take to comply and/or to take business advantage of the increasing demand for safer alternatives for the most hazardous chemicals on the market today.

However, the complex and dynamic nature of the EU chemicals legislation requires capacity building. Ad hoc training activities and networking have already started. To achieve a critical mass and make visible impact a working group on the forthcoming REACH 2018 campaign and/or advisory services for substitution could be established.

Interested Network partners are invited to contact EASME and to follow the information on REACH, CLP and the BPR published on EASME's Intranet.

Annexes

ANNEX I
NEW CLP PICTOGRAMS
WHICH PICTOGRAMS ON WHICH PRODUCTS

CORROSIVE 	Examples of where we can find it: Drain cleaners, acetic acid, hydrochloric acid, ammonia Symbols that will be phased out:  
GAS UNDER PRESSURE 	Examples of where we can find it: Gas containers Symbol that will be phased out: There is no existing symbol for this hazard pictogram
HEALTH HAZARD 	Examples of where we can find it: Washing detergents, toilet cleaner, coolant fluid Symbol that will be phased out: 
EXPLOSIVE 	Examples of where we can find it: Fireworks, ammunition Symbol that will be phased out: 

FLAMMABLE 	Examples of where we can find it: Lamp oil, petrol, nail polish remover Symbol that will be phased out: 
HAZARDOUS FOR THE ENVIRONMENT 	Examples of where we can find it: Pesticides, biocides, petrol, turpentine Symbol that will be phased out: 
OXYDISING 	Examples of where we can find it: Bleach, oxygen for medical purposes Symbol that will be phased out: 
SERIOUS HEALTH HAZARD 	Examples of where we can find it: Turpentine, petrol, lamp oil Symbol that will be phased out:  
ACUTE TOXICITY 	Examples of where we can find it: Pesticide, biocide, methanol Symbol that will be phased out:  

Source :
» http://echa.europa.eu/chemicals-in-our-life/clp-pictograms

ANNEX II
BIOCIDAL PRODUCT-TYPES

In Annex V to the BPR the biocidal products are classified into 22 biocidal product-types, grouped in four main areas.

Number	Product-type	Description
Main group 1: Disinfectants These product types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.		
Product-type 1	Human hygiene	Products in this group are biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp.
Product-type 2	Disinfectants and algaecides not intended for direct application to humans or animals	Used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs. Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air conditioning systems; and walls and floors in private, public, and industrial areas and in other areas for professional activities. Used for disinfection of air, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil. Used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials. Used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties.

Number	Product-type	Description
Product-type 3	Veterinary hygiene	Used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with anti-microbial function. Used to disinfect the materials and surfaces associated with the housing or transportation of animals.
Product-type 4	Food and feed area	Used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals. Used to impregnate materials which may enter into contact with food.
Product-type 5	Drinking water	Used for the disinfection of drinking water for both humans and animals.
Main group 2: Preservatives Unless otherwise stated these product-types include only products to prevent microbial and algal development.		
Product-type 6	Preservatives for products during storage	Used for the preservation of manufactured products, other than foodstuffs, feeding stuffs, cosmetics or medicinal products or medical devices by the control of microbial deterioration to ensure their shelf life. Used as preservatives for the storage or use of rodenticide, insecticide or other baits.
Product-type 7	Film preservatives	Used for the preservation of films or coatings by the control of microbial deterioration or algal growth in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works.

Number	Product-type	Description
Product-type 8	Wood preservatives	Used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms, including insects. This product type includes both preventive and curative products.
Product-type 9	Fibre, leather, rubber and polymerised materials preservatives	Used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products by the control of microbiological deterioration. This product-type includes biocidal products which antagonise the settlement of micro-organisms on the surface of materials and therefore hamper or prevent the development of odour and/or offer other kinds of benefits.
Product-type 10	Construction material preservatives	Used for the preservation of masonry, composite materials, or other construction materials other than wood by the control of microbiological and algal attack.
Product-type 11	Preservatives for liquid-cooling and processing systems	Used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels. Products used for the disinfection of drinking water or of water for swimming pools are not included in this product-type.
Product-type 12	Slimicides	Used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction.
Product-type 13	Working or cutting fluid preservatives	Products to control microbial deterioration in fluids used for working or cutting metal, glass or other materials.
Main group 3: Pest control		
Product-type 14	Rodenticides	Used for the control of mice, rats or other rodents, by means other than repulsion or attraction.

Number	Product-type	Description
Product-type 15	Avicides	Used for the control of birds, by means other than repulsion or attraction.
Product-type 16	Molluscicides, vermicides and products to control other invertebrates	Used for the control of molluscs, worms and invertebrates not covered by other product types, by means other than repulsion or attraction.
Product-type 17	Piscicides	Used for the control of fish, by means other than repulsion or attraction.
Product-type 18	Insecticides, acaricides and products to control other arthropods	Used for the control of arthropods (e.g. insects, arachnids and crustaceans), by means other than repulsion or attraction.
Product-type 19	Repellents and attractants	Used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds, fish, rodents), by repelling or attracting, including those that are used for human or veterinary hygiene either directly on the skin or indirectly in the environment of humans or animals.
Product-type 20	Control of other vertebrates	Used for the control of vertebrates other than those already covered by the other product types of this main group, by means other than repulsion or attraction.
Main group 4: Other biocidal products		
Product-type 21	Antifouling products	Used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.
Product-type 22	Embalming and taxidermist fluids	Used for the disinfection and preservation of human or animal corpses, or parts thereof.

ANNEX III
USEFUL RESOURCES FOR SMEs

This is a non-exhaustive and constantly evolving list .

IN 23 EU LANGUAGES OR MULTILINGUAL

Navigator to identify companies' role and requirements under REACH and CLP
» http://echa.europa.eu/identify-your-obligations

ECHA-term – to get the language of REACH, CLP and the BPR explained
» http://echa.cdt.europa.eu/

Guidance in a Nutshell
» http://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/guidance-in-a-nutshell

ECHA SME web section
» http://echa.europa.eu/sme

REACH 2018 registration service
» http://echa.europa.eu/reach-2018

Leaflets
Chemical Safety and Your Business
Classifying and Labelling Chemicals - a brief guide
ECHA Services at a Glance
» http://echa.europa.eu/publications/leaflets

Checklist to hire a good consultant for REACH
» http://echa.europa.eu/about-us/partners-and-networks/directors-contact-group

ECHA web pages on the classification of mixtures
» http://echa.europa.eu/support/mixture-classification

ECHA web pages on using chemicals safely at work
» http://echa.europa.eu/use-chemicals-safely-at-work

EU-OSHA Napo series on Safety with a Smile
» http://www.napofilm.net

The Substitution Support Portal
» http://subsport.eu

For more information and useful resources in your language, check out the website of your national REACH, CLP and/or BPR helpdesk:

» http://echa.europa.eu/support/helpdesks/national-helpdesks/list-of-national-helpdesks

IN ENGLISH

Frequently asked questions on REACH, CLP and the BPR can be browsed by topic or searched on ECHA website
» http://echa.europa.eu/support/qas-support/qas

"How to" articles in ECHA's newsletter, featuring SMEs
» http://newsletter.echa.europa.eu

Practical examples and practical guides focusing on specific aspects of the legislation
» http://echa.europa.eu/publications

ECHA e-Guide on Safety Data Sheets and Exposure Scenarios
» http://view.pagetiger.com/ECHAeGuide1-1/Issue1

ECHA Guidance on Scientific Research and Development and on Product and Process Oriented Research and Development
» http://echa.europa.eu/support/guidance

Topical webinars
» http://echa.europa.eu/support/training-material/webinars

Topical information sheets
REACH - Production, Import and Supply of Articles
Safety in Contract Cleaning
Information for Retailers on Hazard Labelling and Packaging
Labelling and packaging Requirements for Detergents and Biocidal Detergents
» http://www.hsa.ie/eng/Publications_and_Forms/Publications

Subscribe to ECHA news to keep up-to-date with new information and material that could be useful to your and to your client companies.

» http://echa.europa.eu/subscribe

ANNEX IV
EU FUNDING OPPORTUNITIES FOR SMEs

EU programmes have already funded projects supporting REACH implementation and will continue to provide such support under the multi-annual financial framework of the EU (2014-2020).

The European Commission's regulatory fitness Programme REFIT highlighted in its first annual scoreboard published in June 2014[2] the need for "promoting the use of existing EU funding programmes, such as Horizon 2020 or of the LIFE Programme, to help SMEs find suitable alternatives to hazardous chemicals".

Access to finance could not only make it easier for SMEs to comply, but could also boost their capacity for innovation.

HORIZON 2020

Horizon 2020
European Union Funding
for Research & Innovation

The EU funding programme for research and innovation has a total budget of almost € 80 billion during the current financial period (2014-2020).

Two of its three pillars – Competitive Industries and Societal Challenges cover REACH.

Excellent Science	Industrial Leadership	Societal Challenge
European Research Council Frontier Research by the best individual teams **Future and Emerging Technologies** Collaborative research to open new fields of innovation **Marie Skłodowska -Curie Actions** Opportunities for training and development **Research Infrastructures** (including e-infrastructure) Ensuring access to world class facilities	**Leadership in enabling and industrial technologies** ICT Nanotechnologies, Advanced materials, Advanced manufacturing and processing and Biotechnologies Space **Access to risk finance** Leveraging private finance and venture capital for research and innovation **Innovation in SMEs** Fostering all forms of innovation in all types of SMEs	**Health, demographic change and wellbeing** **Food Security, Sustainable Agriculture and Forestry, Marine, Maritime and Inland Water Research and the Bioeconomy** **Secure, Clean and Efficient Energy** **Smart, Green and Integrated Transport** **Climate Action, Environment, Resource Efficiency and Raw Materials** **Europe in a changing world - Inclusive, innovative and reflective societies** **Secure societies – Protecting freedom and security of Europe and its citizens**

Website
» http://ec.europa.eu/programmes/horizon2020/en

2 Commission Regulatory Fitness and Performance Programme (REFIT): State of Play and Outlook, COM(2014) 368 final, p. 6 http://ec.europa.eu/smart-regulation/docs/scoreboard_en.pdf

The SME Instrument under the Industrial Leadership Pillar of Horizon 2020
The instrument provides full-cycle business innovation support from idea conception and planning to business plan execution and demonstration and finally commercialisation.

Participants can also get business innovation coaching for the duration of their project. This programme is managed by EASME and involves directly the Enterprise Europe Network in coaching the SMEs selected to go ahead with their research ideas.

Relevance to REACH
The first calls have already included the opportunity to apply for projects supporting REACH implementation.

More information
SME instrument web pages and SMEs in Horizon 2020
» http://ec.europa.eu/programmes/horizon2020/en/area/smes

Horizon 2020 Challenge 5
Climate Action, Resource Efficiency and Raw Materials under the Societal Challenges Pillar
This part of the programme is the successor of the previous Eco-innovation programme (2007-2013) which brought to market new technologies of SMEs for the substitution of hazardous chemicals.

Raw materials represent one of the main areas for financing projects under this "Challenge". The programme supports the European Raw Materials initiative.

Relevance to REACH and the BPR
An opportunity to finance substitution projects.

Project example
- SAMDOKAN – eco-friendly pre-treatment for plastic chrome plating.
- TiLeather – eco-friendly leather tanning with Titanium.

More information
Horizon 2020 website
The New Raw Materials Initiative
» http://ec.europa.eu/enterprise/policies/raw-materials/chemicals

ENVIRONMENT AND CLIMATE ACTION PROGRAMME - LIFE

LIFE is the EU's financial instrument supporting environmental and nature conservation projects throughout the EU. It has a budget of €3.4 billion until 2020 to finance projects which contribute to sustainable development and to the implementation of the Seventh Environment Action Programme.

Relevance to REACH, CLP and BPR
'Environment and Health' is one of the main themes of LIFE. Calls for proposals under this theme will cover support activities for the

implementation of REACH and the BPR to ensure safer, more sustainable or economical use of chemicals, including nanomaterials.

The programme can finance activities and services by SME support organisations.

LIFE is managed by EASME.

Project examples
- Life+ Extruclean, Life+ Textileather, Life+ Waleva, Life+ Ecodefatting, launched in 2014, as described in the European Commission press release:
  » http://europa.eu/rapid/press-release_MEMO-14-320_en.htm
- The Substitution Support Portal
  » http://subsport.eu

More information
The Life programme website
» http://ec.europa.eu/life

EUROSTARS PROGRAMME AND EUREKA INITIATIVE

This is a joint programme dedicated to R&D performing SMEs, and co-funded by the European Commission and 34 Eurostars countries. Eurostars supports the development of innovative products, processes and services, to help SMEs gain competitive advantage. Eurostars does this by providing funding for transnational innovative projects; the products of which are then rapidly commercialised.

Through this joint Programme, based on Art. 185 of the Lisbon Treaty, Eurostars combines a bottom-up approach, a central submission and evaluation process, and synchronised national funding.

Relevance to REACH, CLP and the BPR
Eurostars represents an opportunity to finance substitution projects, as well as training and support services.

Project example
- EuroStars TaniXing - a leather industry project

More information
» https://www.eurostars-eureka.eu/

EU STRUCTURAL FUNDS

Between 2014 and 2020, the reformed cohesion policy will make up to €351.8 billion available to invest in Europe's regions, cities and the real economy. It will be the EU's principal investment to achieve the goals of smart, sustainable and inclusive economic growth by 2020.

This will be helped through targeting the European Regional Development Fund at key priorities such as support for SMEs where the objective is to double the investments from €70 to €140 billion over seven years.

Funding will be used to support innovative start-ups; to tap into business know-how and advice; to mitigate entrepreneurial risk; to exploit new sources of growth, such as the green economy; and to train entrepreneurs, managers and workers to adapt to new challenges.

Relevance to REACH and the BPR
Depending on the national programmes and priorities, it is possible to get grants for purchasing equipment.
» http://ec.europa.eu/regional_policy/sources/docgener/informat/2014/fiche_sme_en.pdf

Example
- In Belgium, the VLARIP Business initiative for mentoring SMEs has been financed by the European Regional Development Fund
  » http://www.essenscia.be/en/vlarip

More information
Cohesion policy
» http://ec.europa.eu/regional_policy/index_en.cfm

Contacts of the managing authorities in the Member States
» http://ec.europa.eu/regional_policy/manage/authority/authority_en.cfm

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