Draft Final Report

Chemicals Management in the European Union

March 2013

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ENVIRONMENTAL LAW & POLICY

This Draft Final Report has been prepared by Milieu Ltd for the Ministry of Environment, Brazil, under Contract No.MD7401B/1 between Milieu Ltd and CESO CI Internacional SA. The primary authors were Dr Catherine Ganzleben and Ms Paola Banfi. Dr Catherine Ganzleben was responsible for overall editing of the report.

This report has been generated within the context of the Sectoral Dialogue on the control and regulation of chemicals between Brazil and EU, funded by the EU under the Sectoral Dialogue Programme. Further details are available at: http://www.dialogossetoriais.org/

The views expressed herein are those of the consultants alone and do not necessarily represent the official views of the Ministry of the Environment, Brazil or of CESO CI Internacional SA.

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Acronyms

BAT	Best Available Techniques
BPC	Biocidal Products
CARACAL	Competent Authorities for REACH and CLP
Chesar	Chemical safety assessment and reporting tool
CLP Regulation	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures
CMR	Carcinogenic, mutagenic and reprotoxic substances
CoRAP	Community Rolling Action Plan
CSA	Chemical safety assessment
CSR	Chemical safety report
DD	Draft Decision
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
eMSCA	Evaluating Member State Competent Authority
ENES	Exchange Network on Exposure Scenarios
EU	European Union
EU-OSHA	European Agency for Safety and Health at Work
GDP	Gross domestic product
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
IED	Industrial Emissions Directive
IPPC	Pollution Prevention and Control Directive
IUCLID	International Uniform ChemicaL Information Database
MSC	Member State Committee
MSCA	Member State Competent Authority
MSC-S	Member State Committee Secretariat
OEL	Occupational Exposure Limit Values
PBT	Persistent, Bioaccumulative and Toxic
PIC Convention	Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
PPORD	Substances manufactured in the Community or imported for the purpose of product and process orientated research and development
RAC	Risk Assessment Committee
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RIPoN	REACH Implementation Project on Nano
SEAC	Committee for Socio-economic Analysis
SEV	Substance Evaluation
SEVT	Substance Evaluation Team: Team from Directorate E composed of: •Team Leader(s) (TLs - Evaluation Units). •The Substance Managers (SMs - Evaluation Units). •The Evaluation Assistants (EAs - Evaluation Units).

SIEF	Substance Information Exchange Forum
SVHC	Substances of Very High Concern
vPvB	very Persistent and very Bioaccumulative

1. Introduction

This Draft Final Report has been prepared by Milieu Ltd for the Brazilian Ministry of Environment with the aim of describing the European Union (EU) model for chemicals management. As such, the report provides detailed descriptions of EU chemicals legislation and focusses on the procedural aspects involved in administering the legislation. In doing so, the key infrastructures for administering chemicals management legislation in the EU are described in section 2.

In the past fifteen years, nearly all the rules in the EU regarding chemical products have been revised. This includes the procedures for chemical risk assessment the substance classification system and notification to authorities of placement on the market. The most significant change has come with the introduction of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals[1] (REACH), complemented by the Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures[2] (CLP Regulation). REACH is considered in section 3 of this report, with CLP then considered in section 4. EU legislation to implement the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (PIC Convention) is described in section 5. The European Chemicals Agency (ECHA) has a key role to play in supporting the implementation of these three regulations, with their support activities described in section

There has also been evolution in legislation covering chemicals for particular uses, such as pesticides, biocides, and medicinal and veterinary products (considered in section 7 to 9 of this report). In addition, legislation regulating the use of chemicals in specific products, such as cosmetics, toys and electronic and electrical equipment, has received attention (considered in section 10 of this report). There have therefore been considerable changes in legislation with the aim of keeping pace with developments in the understanding of chemical risk.

Workers in the EU receive protection from exposure to chemicals in the workplace under occupational health and safety legislation, and the relevant body of legislation is briefly reviewed in

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 396, 30.12.2006, p. 1–849

[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ LJ353, 31.12.2008, pp.1-1355

section 11. Actions on specific groups of chemicals are then considered, namely mercury under section 12 and endocrine disruptors in section 13. The application of the precautionary principles to chemicals management in the EU is briefly discussed under section 14, before some conclusions are provided in section 15.

In section 1.1 below, we briefly consider the situation pre-REACH, before introducing REACH and CLP Regulation. Section 1.2 then provides a brief overview of the chemicals industry in the EU, in order to provide context to the discussion of the legislation.

1.1. Pre-REACH Chemicals Management in the EU

Prior to the introduction of REACH, chemical substances were treated differently depending on when they were introduced on the market. New substances (introduced after 1981) had to be tested and notified before marketing in volumes above 10 kg. For higher volumes more in-depth testing focusing on long-term and chronic effects has to be provided. On the basis of the information, they are assessed on their risks to human health and the environment. The legal basis was laid out in Directive 67/548/EEC on Dangerous Substances (Dangerous Substances Directive).

With regards to substances that were on the market prior to 1981, the EU had in place Council Regulation (EEC) 793/93 on existing substances and Commission Regulation (EC) 1488/94 on risk assessment, which laid down principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No 793/93. Four Priority List Regulations served to identify priority substances, which were then require to undergo an in-depth risk assessment by the Member States following a set methodology and coordinated by the European Chemicals Bureau (now replaced by ECHA). In addition, there were a number of Commission recommendations and conclusions that outline the results of risk evaluations and set risk reduction measure for specific groups of chemical substances. Finally, a number of regulations set out requirements for information and testing for manufacturers and importers of existing and priority substances.

An amended to the Dangerous Substances Directive in 1979 introduced a notification system for "new" substances and a listing of "existing" substances. EINECS, the European Inventory of Existing Commercial Chemical Substances, lists all substances that were reported to be on the market on or before 18 September 1981. "New" substances were added to ELINCS. ELINCS is the European List of Notified Chemical Substances.

In 2001, approximately 100,000 different substances were registered in the EU market of which 10,000 were marketed in volumes of more than 10 tonnes, and a further 20,000 were marketed at 1-10 tonnes. In managing the risks from chemicals on the market, the Dangerous Substances Directive distinguished between "existing substances" i.e. all chemicals declared to be on the market in September 1981, and "new substances" i.e. those placed on the market after that date of which there were some 2,700 substances in 2002. For new substances, testing and risk assessment were required before marketing in volumes above 10 kg and for higher volume new substances more in-depth testing focussing on long-term and chronic effects had to be provided. However, existing substances, which represented nearly 99% of the total volume of substances in circulation, were not subject to testing. This included an estimated 30,000 existing substances on the market at over 1 tonne. As such there was a severe lack of information regarding the hazards and uses of existing substances on the market. In addition, the risk assessment process for new substances was conducted by authorities, not by industry, and was slow and resource-intensive, so impeding innovation and competitiveness in the chemicals sector.[3] In addition, the legislative framework created a disincentive for the chemicals industry to conduct testing on their products.[4]

While public concern regarding the impacts of chemicals on human health and the environment was growing, there was insufficient information available to regulators on the hazards that chemicals on the EU market posed to human health and the environment. In addition, in recent incidences of serious damage to human health from chemical exposure (for example from DDT, benzene and asbestos), controls measures were not taken because information about the adverse impacts of these chemicals was not available before they were used in high volumes.

Recognising these gaps and in response to concerns that the existing system did not provide sufficient protection, in 2001 the European Commission adopted a White Paper[5] setting out the Strategy for a future Community Policy for Chemicals. Key objectives included ensuring a high level of protection for human health and the environment, while ensuring the efficient functioning of the internal market and stimulating innovation and competitiveness in the chemical industry. Key elements of the Strategy include, *inter alia*:

- implementing a single system for new and existing chemicals, with existing chemicals (phase in substances) to be phased in under a common system by 2012;
- making industry responsible for chemical safety;
- extending responsibility down the manufacturing chain;

[3] European Commission (2001) White Paper on the strategy for a future chemicals policy, COM(2001)88,
[4] Hansson SO and Ruden C (2003) Improving the incentives for toxicity testing, Journal of Risk Research, Vol.6(1): 3-12
[5] European Commission (2001) White Paper on the strategy for a future chemicals policy, COM(2001)88,

- establishing authorisation for substances of very high concern; and
- substituting hazardous chemicals.

In addition, the White Paper specifically mentions the chemicals goals set out in Agenda 21, identifies the lack of data on existing chemicals as a matter of global concern and notes that the recommendations "*will feed into the international programmes and make a major contribution to achieving safe use of chemicals at a global level*".

1.2. REACH

The main legislative tool for delivering chemical risk assessment in the EU is Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals[6] (REACH), as foreseen under the 2001 Strategy for a Future Community Policy for Chemicals. The Regulation entered into force on 1 June 2007 and replaced and repealed the Dangerous Substances Directive and the Dangerous Preparations Directive. Article 135 of REACH sets transitional measures regarding substances notified under Directive 67/548/EEC.

Under REACH, manufacturers and importers of substances are required to submit a registration to the ECHA for each substance manufactured or imported in quantities of 1 tonne or above per year, with the registration dossiers to the hazard information and, where relevant, an assessment of the risks that the use of the substance may pose and how these risks should be controlled. The registration dossier represents the key tool through which crucial data on the hazards associated with substances, and where relevant exposure assessment and risk assessment, are generated by industry and then channelled from industry to regulators. ECHA manages the technical, scientific and administrative aspects of the REACH and CLP systems at Community level, ensuring proper implementation and managing information availability.

In 2012, various aspects of REACH were reviewed in a process known as the REACH Review, including a number of studies on various aspects of REACH. The Commission published the conclusions of this process on 5th February 2013, in a report known as the "General REACH Review"[7] and accompanies by a Commission Staff Working Document[8]. The report notes that

[6] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 396, 30.12.2006, p. 1–849

[7] European Commission (2013) General REACH Review, General Report on REACH Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Brussels, XXX XXX […](2013) XXX draft, Commission, Brussels, Belgium

"*REACH is a key element of the EU's commitment towards the implementation plan adopted at the 2002 World Summit on sustainable development which aims to ensure that, by 2020, chemicals are produced and used in ways that lead to minimisation of significant adverse effects on human health and the environment*".

The report concludes that REACH functions well and delivers on all the objectives that can be assessed at this early stage of implementation. While the report identifies some needs for adjustment, in the interest of ensuring legislative stability and predictability the Commission decided not to propose any changes to the enacting terms of REACH. Nevertheless, time-bound goals are established in the report for the review of specific aspects of REACH. The report on the REACH Review also identifies the need to reduce the costs of REACH for SMEs and sets out measures that will contribute to this goal. In addition, the report sets out opportunities for optimizing REACH implementation.

While REACH provides the main framework for chemical risk assessment in the EU, some uses of substances are exempt from REACH, as they are regulated under other EU legislation with specific risk assessment requirements. The mechanisms of REACH are described in detail in section 3.

1.3. Classification and Labelling

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures[9] (CLP Regulation) ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the EU through classification and labelling of chemicals. The CLP Regulation is the legislative tool in the EU for implementation of the United Nations Globally Harmonised System of Classification and Labelling of Chemicals (GHS). CLP mechanisms are described in detail in section 4.

[8] European Commission (2013) Commission Staff Working Document Accompanying the document General Report on REACH, Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Brussels, 5 February 2013, SWD(2013)25, European Commission, Brussels, Belgium

[9] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ LJ353, 31.12.2008, pp.1-1355

1.4. Chemicals Industry in the EU

In this section we provide a brief overview of the EU chemicals industry, including data on the sales of chemicals, the EU contribution to global trade flows in chemicals and chemical sales by Member State. In addition, we consider the breakdown of sales by chemical industry sub-sector and the contribution made be the chemicals industry to the EU economy. A brief summary of key points is provided in box 1 below.

Box 1: EU chemicals industry in a nutshell

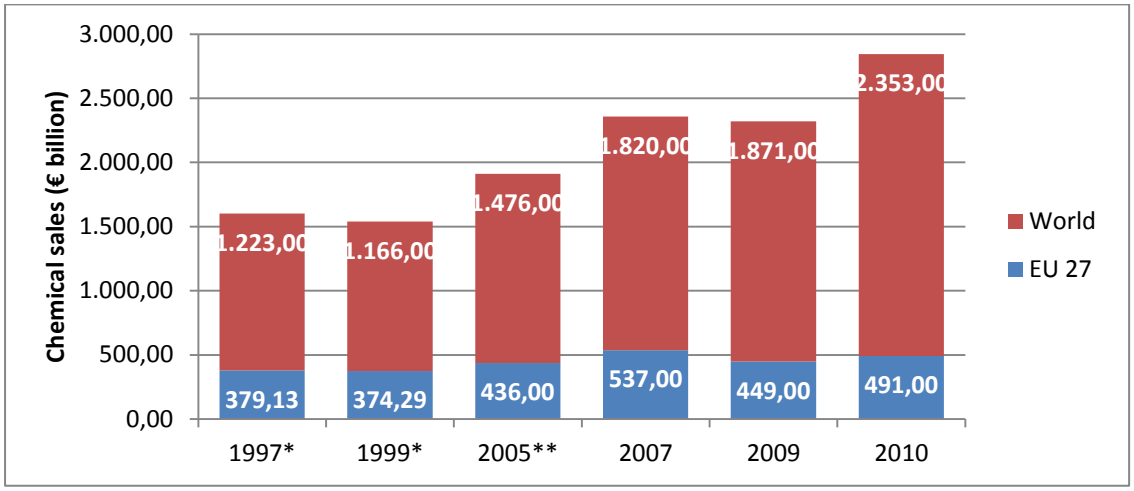
- Industrial chemicals are used as basic elements to convert many raw materials into other industrial products, thus the chemical industry has such an important role in modern world economy.
- Today, European Union is the second largest producer in chemicals industry, right after China, with an estimated € 491 billion in sales in 2010 – more than twice the size of the EU market for food products and beverages – and it accounts for 1,1% of EU income and of 44% of world chemical exports.
- Consumption of chemicals is far higher in EU countries than in the rest of the world.
- Similarly trade in chemicals is currently dominated by EU countries which have a nearly equilibrated trade balances with one another and register trade surpluses with virtually all the other regions of the world.
- The industry is a major employer accounting for 5,4 per cent of the total number of employees generated by EU manufacturing in 2007 and traditionally a high-tech industry with a heavy reliance on research and development due to the constant need for innovation. EU companies allot € 8.1 billion of their annual sales for R&D although the percentage of revenue spent on research varies from one branch to another.
- In line with the huge growth in the manufacture of synthetic organic polymers used in plastics, fibres and elastomeric products, the chemical industry in EU has accounted for 11% of the manufacturing industry's added value.
- The industry will continue to expand over the next 10 years, with faster growth rates in developing economies, such as China, Brazil and India. Chemical companies in EU countries will shift production to life science and speciality chemicals, and more companies will merge to form large and fewer multinationals.[10]

1.4.1. EU chemicals sales

According to a CEFIC report entitled the European Chemical Industry in a Worldwide Perspective Report[11], the European chemicals industry reached sales of €491 billion in 2010, accounting for 20.9% of the total world chemical sales in value terms (€2,353 billion). In 2005, world chemical sales were estimated at €1,476 billion, of which €436 billion were accounted for by Europe (around 30%), while in 1997, world chemical sales were estimated at €1,223 billion, of which the EU 12 accounted for €379,13 billion (around 31%). Figure 1 provides an overview of the value of global and EU chemical sales from 2007 to 2010.

[10] OECD (2001), Environmental Outlook for the Chemicals Industry, Paris, France
[11] CEFIC (2011), Facts and Figures 2011, The European chemical industry in a worldwide perspective

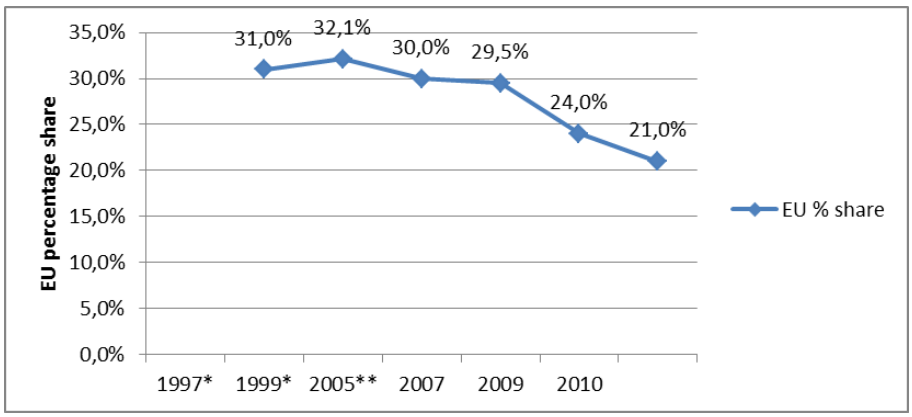
Figure 1: World chemical sales and EU proportion in Billion Euros, 1997 – 2010



*EU12, **EU25
Source: CEFIC, Facts and Figures. Series 1998 – 2011

The European chemical industry can thus still be portrayed as vibrant and strong despite the fierce worldwide competition. The industry has in fact lost its first place in the ranking to Asia, mainly due to the rise of Chine and India. Developments in the last 10 years show that the EU was the leader in world chemicals sales but has continuously lost ground to Asia. Chemical sales in Asia are more than double that of the European Union. The European contribution to world chemicals sales declined in 2010 by 10 percentage points compared with 1997, as shown in figure 2 below. In fact, the total value of sales in the European Union has been growing continuously, but overall world chemicals sales are growing at an even faster rate.

Figure 2: EU percentage share of world chemical sales, 1997 – 2010



*EU12, **EU25
Source: CEFIC, Facts and Figures. Series 1998 – 2011

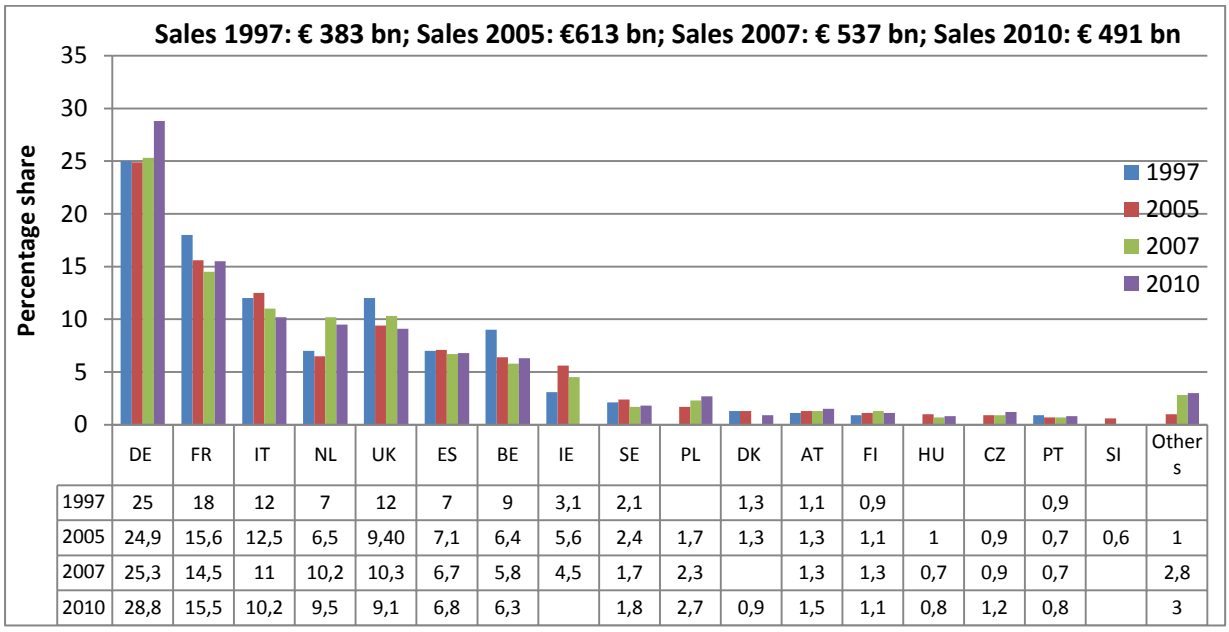
1.4.2. Chemical Trade flows

The key trading regions for the EU in 1997 were intra-EU trade and North America. In the following decade, despite a slight decrease EU share in world import, the EU continued to be the world's leading exporter and importer of chemicals in 2010, accounting for 41% of global trade, defined as the total value of exports plus imports. [12]

1.4.3. Chemicals Sales by Member State

In 2010, the 30 largest chemical-producing countries had a combined turnover of €2,103 billion. Eleven of the top 30 major countries are European, generating chemicals sales of €506 billion. Germany is at the fourth place after China, US and Japan with €141.6 billion of chemicals sales in 2010, followed by France (€76.1 billion) and Italy (€50.2 billion).[13] Germany is the largest chemicals producer in EU, followed by France, Italy and the Netherlands. Together, these four countries generated 64% of EU chemicals sales in 2010, valued at 315 billion Euros. The breakdown by Member State of EU chemical sales in provided in figure 3 below.

Figure 3: Breakdown by Member State of EU chemical industry sales



	DE	FR	IT	NL	UK	ES	BE	IE	SE	PL	DK	AT	FI	HU	CZ	PT	SI	Others
1997	25	18	12	7	12	7	9	3,1	2,1		1,3	1,1	0,9			0,9		
2005	24,9	15,6	12,5	6,5	9,40	7,1	6,4	5,6	2,4	1,7	1,3	1,3	1,1	1	0,9	0,7	0,6	1
2007	25,3	14,5	11	10,2	10,3	6,7	5,8	4,5	1,7	2,3		1,3	1,3	0,7	0,9	0,7		2,8
2010	28,8	15,5	10,2	9,5	9,1	6,8	6,3		1,8	2,7	0,9	1,5	1,1	0,8	1,2	0,8		3

Source: CEFIC, Facts and Figures. Series 1998 – 2011

[12] CEFIC (1998), Facts and Figures 1997, The European chemical industry in a worldwide perspective
[13] CEFIC (2011), Facts and Figures 2011, The European chemical industry in a worldwide perspective

1.4.4. Sectoral Breakdown of EU Chemical Industry Sales

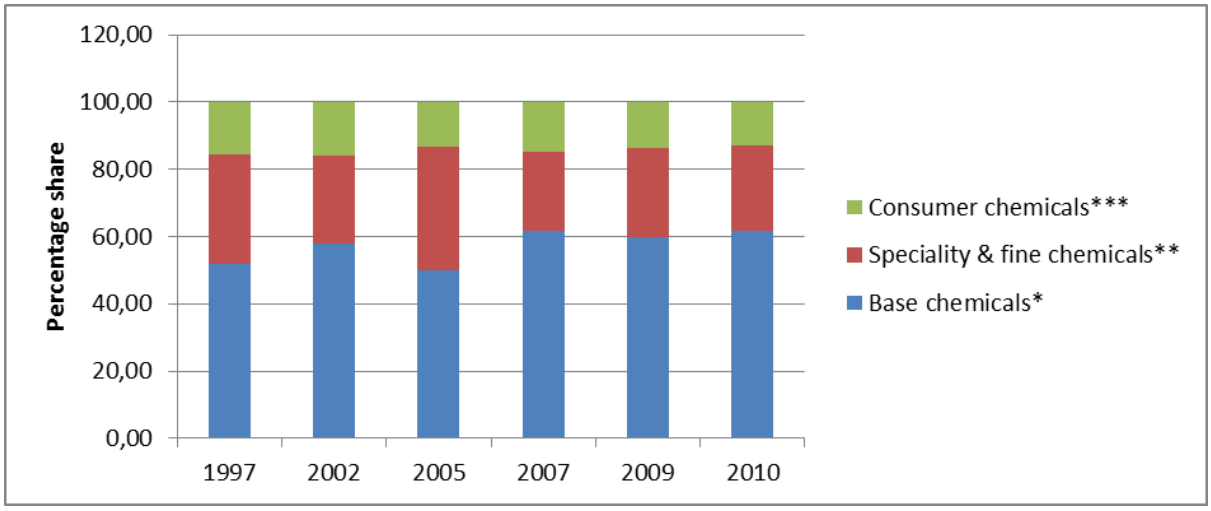
The output of the chemical industry covers three wide ranges of products: base chemicals, speciality and fine chemicals, and consumer chemicals.

Base chemicals cover petrochemicals and derivatives and basic inorganics. They are produced in large volumes, and are sold to the chemical industry itself or to other industries. In 2010, they reported an increase of nearly 10% of total EU chemicals sales from 1997.

Specialties cover the auxiliaries for industry, dyes & pigments, oleochemicals, crop protection, and paints & inks. Fine chemicals represent pharma-, agro-, and chemical intermediates. Specialty and fine chemicals are produced in small volumes but nevertheless represent 25.6 % of total EU chemicals sales compared to a share of 36.7 % in 2005 and 32.5% in 1997.

Finally, consumer chemicals are sold to final consumers: soaps and detergents, perfumes and cosmetics. They represent approximately 12.8 % of total EU chemicals sale with a decrease of nearly 3% from 1997. Figure 4 below provide a graphical representation of the sectoral breakdown of EU chemical sales.

Figure 4: Sectoral breakdown of EU chemical industry sales



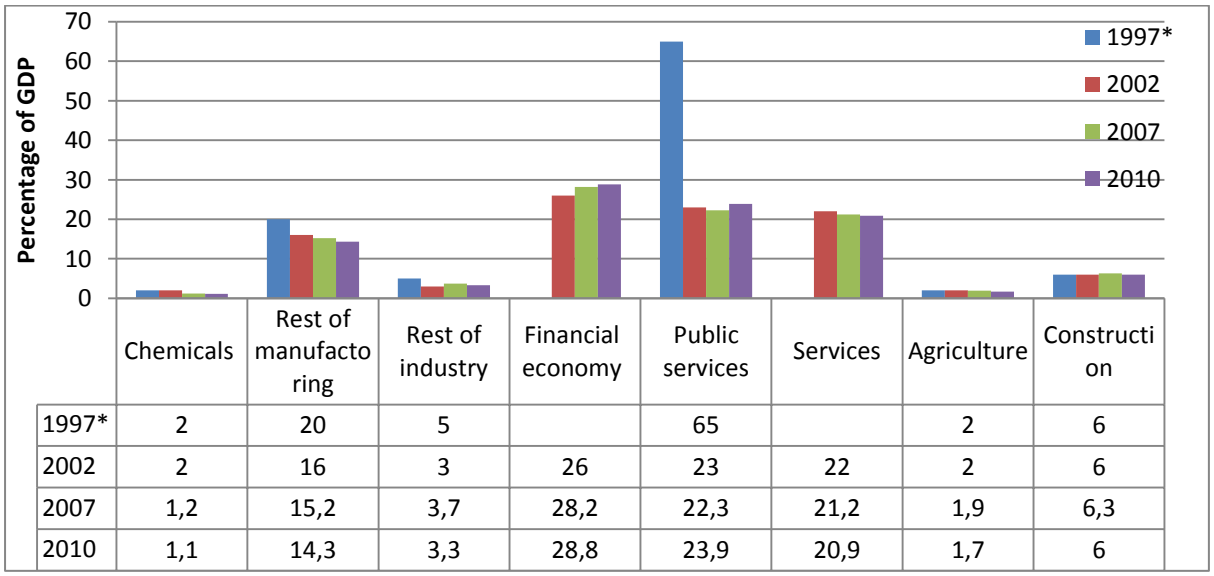
*Petrochemicals, plastics & syntetic rubber, man-made fibres, other basic inorganics, industrial gases, fertilisers
** Fine chemicals, other speciality chemicals, paints & inks, crop protection
*** Perfumes & cosmetics, soaps and detergents
Source: CEFIC, Facts and Figures. Series 1998 – 2011

1.4.5. Contribution of the chemical industry to the EU economy

In 2010, the chemical industry's contribution to the EU's GDP amounted to 1.1%, down from 2% in 2005. This can be interpreted in the light of the shrinking contribution of industry as a whole to GDP in advanced economies (21% in 2005 and 18.7% in 2010 in the EU) together with a rise in services. Figure 5 below shows trends in the contribution of the chemicals industry to the EU economy from 1997 to 2010.

There is a wide contribution of chemicals products that are present in all branches of the economy. For example, the chemicals industry in Germany is the most important supplier of innovative materials for manufacturing. Chemicals represent 10% of the supply of input and intermediary products, with the industry demonstrating an above average level of research and development.

Figure 5: Contribution of the chemicals industry to the EU economy, percentage of GDP 1997 – 2010



	Chemicals	Rest of manufacturing	Rest of industry	Financial economy	Public services	Services	Agriculture	Construction
1997*	2	20	5		65		2	6
2002	2	16	3	26	23	22	2	6
2007	1,2	15,2	3,7	28,2	22,3	21,2	1,9	6,3
2010	1,1	14,3	3,3	28,8	23,9	20,9	1,7	6

*In 1997, public services and services are measured together
Source: CEFIC (2011) Facts and Figures, CEFIC (2006), Facts and Figures

2. Chemicals Management Infrastructures

2.1. European Commission

The European Commission has a key role to play in proposing legislation, as well as supporting implementation.

2.2. Member State Competent Authorities

The Competent Authorities for REACH and CLP (CARACAL) is an expert group which advises the European Commission and ECHA on questions related to REACH and CLP. CARACAL is composed of representatives of Member States competent authorities for REACH and CLP, representatives from competent authorities of EEA-EFTA countries as well as a number of observers from non-EU countries, international organisations and stakeholders. Member State competent authority are defined under Article 45(2) of REACH. CARACAL meeting minutes available on the Commission website.

2.3. ECHA

Established in June 2007 in Helsinki, Finland, the European Chemical Agency (ECHA) is the key agency responsible for chemicals management legislation in the EU. ECHA helps companies to comply with relevant legislation, in particular REACH and CLP, advances the safe use of chemicals, provides information on chemicals and addresses chemicals of concern. In addition to EU-level organisations, ECHA cooperates closely with the Member States Competent Authorities in many of its processes, exchanging information, providing support and training to the Member States.

The main activities of ECHA are:

- Coordination of information exchange on chemicals
- Promotion collaboration between a range of governmental and non-governmental actors
- Overseeing risk assessment
- Implementing and enforcing legislation
- advance the safe use of chemicals
- address chemicals of concern
- provide information on chemicals

ECHA structures for delivering on these responsibilities are described below.

2.3.1. Structure

ECHA is comprised of a number of structures, including both core staff of the Agency and bodies that includes representatives from the Member States, the European Commission and the European Parliament, as well as stakeholders from industry and NGOs. ECHA bodies are presented in box 2 below.

Box 2: ECHA bodies

Management Board, responsible for a range of organisational matters, including for example adopting the financial planning, work programme, and annual reporting of the Agency.
Executive Director: the legal representative of the Agency, responsible for the day to day management and administration of the Agency, including responsibility over its finances. The Executive Director reports to the Management Board.
Member State Committee, to resolve differences of opinion on draft decisions proposed by the Agency or Member States and to make proposals for identification of substances of very high concern.
Risk Assessment Committee, to prepare opinions on evaluation, on applications for authorisation, on proposals for restrictions and on classification and labelling.
Committee for Socio-economic Analysis, to prepare opinions on applications for authorisation, on proposals for restrictions and on questions relating to the socio-economic impact of proposed legislative action.
Forum on enforcement matters, to coordinate a network of Member State competent authorities responsible for enforcement.
Secretariat, under the leadership of the Executive Director, to support the Committees and Forum, and to undertake work on registration and evaluation processes as well as the preparation of guidance, maintenance of databases and provision of information.
Board of Appeal, to decide on appeals against decisions taken by the Agency.

The ECHA Committees also provide scientific support to improve the cooperation between the Community, its Member States, international organisations and third countries relating to the safety of substances, as well as active participation in technical assistance and capacity building activities on the sound management of chemicals in developing countries.

The list of Members of the ECHA Management Board and Committees are available online, together with their CVs and declarations of interest. In the sections below the composition, roles and responsibilities of the different bodies are described.

Management Board

The Management Board is the governing body of the Agency. It has a supervisory role with general responsibility for budgetary and planning matters; the appointment of the Executive Director, the members and the Chair of the Board of Appeal and the reporting of ECHA's activities to EU institutions. The Board is composed of:

- 27 members from the EU Member States
- Six representatives of the Commission, including 3 members without voting rights appointed to represent interested parties
- Two representatives of the European Parliament

All Management Board members are appointed on the basis of their experience and expertise in the field of chemical safety or the regulation of chemicals. Their term of office is four years and can be renewed once. In addition to the members, the Management Board has invited one observer each from Iceland, Liechtenstein, Norway and Croatia. The representatives of the Member States are appointed by the Council. The members from European Commission and European Parliament are directly appointed by the institution concerned. Apart from the three members with voting rights, the Commission also appoints three members without voting rights to represent interested parties.

The Management Board is currently chaired by Ms Nina Cromnier, the Swedish Board member, while the deputy-chair, Mr. Martin Lynch, is the Irish member. Both the chair and the deputy-chair are appointed for two years. The Executive Director is responsible for providing the Secretariat for the Management Board. The Executive Office of the Agency carries out the practical work.

The Management Board usually meets four times a year. To facilitate decision-making, a number of working groups have been established (e.g. Working Group on Planning and Reporting, Working Group on Transfer of fees).

The rules of procedure of the Management Board, the Policy on conflicts of interest and Code of conduct are published on the ECHA website. Management board documents, including administrative documents, preliminary conclusions of board meetings and minutes of Board Meetings are available on the ECHA website.

Member State Committee

The Member State Committee (MSC) plays a key role in a number of REACH processes. In terms of its composition, each Member State appoints one member to the MSC for a renewable term of three years. The Committee may appoint up to five additional members chosen for their specific competencies. The current chairperson of the MSC is Anna-Liisa Sundquist. As specified by the rules of procedure of the MSC, the meetings of the Committee may be open to advisers, invited experts, case owners and observers at the request of the Committee members or ECHA's Management Board. The list of agreed observers is published online.

The MSC participates in several REACH processes such as evaluation and authorisation. Their roles under different REACH processes are summarised in box 3 below, with hyperlinks to relevant documents on procedural aspects included.

Box 3: Roles of the Member States Committee

Dossier evaluation: When amendments are proposed by Member States, the MSC seeks unanimous agreement on ECHA's draft decisions on testing proposals and compliance checks. Working procedures for the MSC to process draft decisions under dossier evaluation are available online.

Substance evaluation: The MSC seeks unanimous agreement on Member State draft decisions on substance evaluation when amendments are proposed on them by other Member States or ECHA. The MSC takes into account the comments of the registrants on the proposed amendments to the draft decisions based on dossier and substance evaluations. Once agreed by the MSC, ECHA finalises the decision and provides it to the registrant. The MSC Working Procedure for processing of Substance Evaluation draft decisions is available online. In addition, the MSC provides opinions on: the draft Community Rolling Action Plan (CoRAP); and proposals from any Member State to add substances on CoRAP outside the annual updates. Working procedures for the MSC in providing the opinion on the draft Community Rolling Action are available online. On the basis of these MSC opinions, ECHA adopts the final CoRAP for substance evaluation. The MSC also seeks agreement on cases where two or more Member States have expressed an interest in evaluating the same substance.

Authorisation: The MSC is responsible for resolving divergences of opinions among Member States and on proposals for the identification of Substances of Very High Concern (SVHCs). Working procedures of the MSC in the identification of substances of very high concern (SVHC) are available online. The Committee provides opinions on ECHA's draft recommendation for the authorisation list (Annex XIV). If an agreement is not reached within the MSC, the matter is referred to the European Commission for decision-making. Working procedures for the MSC in providing the opinion on the Draft Recommendation of priority substances to be included in Annex XIV are available online.

Requests of the Executive Director: On request of the Executive Director of ECHA, the MSC issues opinions relating to risks to human health and the environment on any other aspects concerning the safety of substances on their own, in preparations or in articles.

Risk Assessment Committee

The members of the Committee for Risk Assessment (RAC) are appointed by ECHA's Management Board based on candidates nominated by the Members States for a renewable term of three years. As specified by the RAC rules of procedure, the meetings of the Committee may be open to advisers, invited experts and observers at the request of the Committee members or ECHA's Management Board. A list of agreed observers is available online, together with the procedures for their admission. The current chairperson of the RAC is Tim Bowmer. The RAC meets between four and six times and year, with meeting agendas and minutes available online.

The RAC prepares the opinions of ECHA related to the risks of substances to human health and the environment in a number of REACH and CLP processes. Their roles under different REACH processes are summarised in box 4 below, with hyperlinks to relevant documents on procedural aspects and outputs in the form of opinions included.

Box 4: Roles of the Risk Assessment Committee

Harmonised classification and labelling: RAC examines the proposals for harmonised classification and labelling and gives an opinion on the proposed harmonised classification of substances as carcinogenic, mutagenic, toxic for reproduction or as a respiratory sensitiser, as well as other effects on a case-by-case basis. The Framework for RAC opinion development on substances for harmonised classification & labelling and the RAC Working Procedure on accordance check of a CLH dossier are available online. Opinions on the RAC on proposals for harmonised classification and labelling are published online.

Restriction: The Committee evaluates whether the proposed restriction on manufacture, placing on the market or use of a substance is appropriate in reducing the risk to human health and the environment. This includes the assessment of comments submitted by third parties. RAC working procedure on processing of Annex XV restriction dossiers and RAC working procedure on the conformity check of Annex XV restriction dossiers are published online.

Authorisation: RAC assesses the risk of a substance arising from the uses of a substance when an application for authorisation is submitted. This includes an assessment of the appropriateness and effectiveness of the risk management measures as described in the authorisation application, and if relevant, of the risks of possible alternatives. Third party contributions linked to the application will also be assessed. The RAC working procedure for developing opinions on authorisation applications and the RAC working procedure for conformity check of authorisation applications are available online.

Requests of the Executive Director: RAC gives an opinion on request from the Executive Director of ECHA relating to risks to human health and the environment on any other aspects concerning the safety of substances on their own, in preparations or in articles. The Framework for dealing with Article 77(3) requests is provided online. Opinions adopted under specific ECHA's Executive Director requests are published online.

Committee for Socio-economic Analysis

The members of the Committee for Socio-economic Analysis (SEAC) are appointed by ECHA's Management Board based on candidates nominated by the Members States for a renewable term of three years. As specified by the SEAC rules of procedure, the meetings of the Committee may be open to advisers, invited experts and observers at the request of the Committee members or ECHA's Management Board. A list of observers is available online.

The Committee for Socio-economic Analysis (SEAC) prepares the opinions of ECHA related to the socio-economic impact of possible legislative actions on chemicals in a number of REACH processes. Their roles under different REACH processes are summarised in box 5 below, with hyperlinks to relevant documents on procedural aspects and outputs in the form of opinions included.

Box 5: Roles of the Committee for socio-economic analysis

Restriction: The Committee evaluates the socio-economic impact of the proposed restriction on manufacture, placing on the market or use of a substance. This includes the assessment of comments and socio-economic analyses submitted by third parties. SEAC working procedure on the conformity check of Annex XV restriction dossiers and SEAC working procedure on processing of Annex XV restriction dossiers are available online. Opinions of the SEAC on restrictions under consideration are available online, together with those for past consultations.

Authorisation: SEAC assesses the socio-economic factors and the availability, suitability and technical feasibility of the alternatives associated with the uses of a substance when an application for authorisation is submitted. Third party contributions linked to the application will also be assessed. SEAC working procedure for conformity check of authorisation applications and SEAC working procedure for developing opinions on authorisation applications are available online.

ECHA's Executive Director's requests, REACH Article 77(3): SEAC issues opinions, on request of the Executive Director of ECHA, relating to socio-economic issues on any other aspects concerning the safety of substances on their own, in preparations or in articles. The Framework for dealing with Article 77(3) requests is provided online.

Details of SEAC meetings are available online, together with the agendas and meeting minutes.

The Biocidal Products Committee

The Biocidal Products Committee (BPC) prepares the opinions of ECHA related to several processes under the Biocidal Products Regulation (EU) 528/2012, as presented in box 6 below. Each Member State is entitled to appoint one member to the BPC for a renewable term of three years, as well as an alternate member. Details of meetings of the BCP are available online, together with the agendas and meeting minutes.

Box 6: Roles of the Biocidal Products Committee

- Applications for approval and renewal of approval of active substances
- Review of approval of active substances
- Applications for inclusion in Annex I of active substances meeting the conditions laid down in Article 28 and review of the inclusion of such active substances in Annex I
- Identification of active substances which are candidates for substitution
- Applications for Union authorisation of biocidal products and for renewal, cancellation and amendments of Union authorisations, except where the applications are for administrative changes
- Scientific and technical matters concerning mutual recognition in accordance with Article 38
- At the request of the Commission or of the Member States, the BPC is also responsible for preparing an opinion on any other questions that may arise from the operation of the BPR relating to risks to human or animal health or the environment, or to technical guidance.

Forum for Exchange of Information on Enforcement

The Forum for Exchange of Information on Enforcement (Forum) coordinates a network of Member State authorities responsible for enforcement. The Forum is composed of Members appointed by Member States, chosen for their experience in enforcement of chemicals legislation, as well as up to five co-opted members chosen on the basis of their specific competence. Members are appointed for a renewable term of three years. Stakeholders may be invited to attend meetings as observers, as appropriate, at the request of the Forum members, or the Management Board. The Forum shall appoint its own Chairman, and may choose to establish working groups. The main tasks of the Forum are presented in the box 7 below.

Box 7: Roles of the Forum

- Spread good practice and highlight problems at Community level
- Propose, coordinate and evaluate harmonised enforcement projects and joint inspections
- Coordinate exchange of inspectors
- Identify enforcement strategies, as well as best practice in enforcement
- Develop working methods and tools of use to local inspectors
- Develop an electronic information exchange procedure
- Liaise with industry, taking particular account of the specific needs of SMEs, and other stakeholders, including relevant international organisations, as necessary
- Examine proposals for restrictions with a view to advising on enforceability (Art.77(4))
- Agree common issues to be covered in the annual reports from the Member States in relation to enforcement (Art. 127).

The rules of procedure and work programme of the Forum are published online, with the current work programme serving from 2011 to 2013, together with details of Forum meetings.

The Forum has publishes non-binding guidance materials on enforcement, including Strategies for Enforcement of REACH and CLP, Minimum Criteria for REACH and CLP Inspections and Guidance for handling complaints under article 33.2.

Board of Appeal

The Board of Appeal was created by the REACH Regulation to decide on appeals against certain decisions taken by ECHA. The appeals process offers affected parties the possibility to request an independent review of certain ECHA decisions. Although the Board of Appeal is part of ECHA, it takes its decisions independently.

The Board of Appeal consists of a Chairman and two other members. While they are employees of ECHA, they are independent and not be bound by any instructions. They do not perform any other duties at ECHA, and serve for five years. Members are appointed by the Management Board of ECHA on the basis of a list of candidates proposed by the Commission. The qualifications of the members of the Board of Appeal are defined in Commission Regulation (EC) No 1238/2007 on laying down rules on the qualifications of the members of the Board of Appeal of the European Chemicals Agency. The Management Board also appoints alternate and additional members following the Rules on the designation of alternate and additional members. They are not employees of the Agency but are called upon by the Board of Appeal to deal with cases in the absence of the members or, if necessary, to ensure that the appeals can be processed at a satisfactory rate. The Board of Appeal is assisted in the performance of its functions by the Registry.

ECHA decisions against which an appeal can be introduced can concern:

- Exemptions from the general obligation to register for product and process orientated research and development;
- Rejections of registrations;
- Sharing of existing data in the case of registered substances;
- Sharing of data involving tests;
- Examination of testing proposals;
- Compliance check of registrations;
- Substance evaluation.

The Board of Appeal is also competent to decide on appeals against certain ECHA decisions taken under the Biocidal Products Regulation.

Each case is decided by a Chairman, a technically qualified member and a legally qualified member. Rules and procedures of the Board of Appeal are published online. The Board of Appeal's aim is to

consider all appeals as effectively and efficiently as possible based on a Code of Conduct. This includes, for example, ensuring that:

- the rights of all parties involved in an appeal are fully respected;
- exemplary standards of integrity, impartiality and independence are applied in the Board of Appeal's decision making process; and
- appeals are fully considered from both a legal and a scientific perspective.

The rules applicable to appeal proceedings are set out in the Rules of Procedure. To help parties prepare their appeals in the most effective way the Board of Appeal has laid down Practice Directions, as well as special forms and a supporting check list.

In terms of who may appeal, any natural or legal person may appeal against a decision addressed to that person. Any natural or legal person may also appeal against a decision which, although addressed to another person, is of direct and individual concern to the person lodging the appeal. The appeal must be lodged within three months of the notification of the decision to the person concerned. If the appellant is not the addressee of the decision, the appeal has to be lodged within three months of the day on which the decision became known to the appellant.

An appeal fee must be paid pursuant to Article 10 of the Fee Regulation (EC) No 340/2008. Fees range from €1,800 to €6,600 depending on the type of decision being appealed and the size of the company. An appeal will not be considered to be received if the appeal fee is not paid before the expiry of the time limit for bringing an appeal. Where appeals are decided in favour of the appellant, fees are refunded.

The Board of Appeal may exercise any power which lies within the competence of the Agency or remit the case to the competent body of the Agency for further action. Decisions of the Board of Appeal can be appealed before the General Court of the European Union.

An explanatory leaflet entitled "The Board of Appeal of the European Chemicals Agency: An independent review of ECHA decisions" is published on the ECAH website.

2.3.2. Budget

Details of ECHA's financial management and accounting are reported on the ECHA website Table 1 below provides a summary overview of ECHA's revenues and expenditure for 2012 and 2013, in terms of figures recorded for 2012 and anticipated for 2013 (amended budget (AMBU)).

Table 1: ECHA revenues and expenditures recorded for 2012 and anticipated for 2013

Heading	2012	1st AMBU 2013
REVENUE		
Revenue from fees and charges		
Revenue from fees and charges under REACH		
Fees and charges from registration	24,000,000.00	35,127,000.00
Fees and charges from authorisation	180,000.00	600,000.00
Fees and charges from appeals	50,000.00	134,640.00
Fees and charges from CLP	68,000.00	510,000.00
Other fees and charges	2,000,000.00	2,000,000.00
Total fees and charges under REACH	26,298,000.00	38,371,640.00
Revenue from fees and charges under biocidal products regulation		
Fees relating to active substances	0.00	
Fees for Union authorisation of biocidal products	0.00	50,000.00
Miscellaneous fees	0.00	100,000.00
Total fees and charges under Biocides	0.00	150,000.00
ECHA accumulated budget surplus results from fees and charges	230,198,366.61	164,658,136.61
Total revenue from fees and charges	**256,496,366.61**	**203,179,776.61**
European Community Contribution		
European Community Contribution	0.0	p.m.
European Community Contribution	2 728 440.00	6 070 500.00
European Community Contribution	1 455 600.00	1 561 500.00
Biocides programme (earmarked)	500 000.00	p.m.
Total European Community Contribution	4,684,040.00	7,632,000.00
Total revenue from administrative operations (sales of publications, investments etc.)	1,745,000.00	3,425,000.00
Total revenue from contributions under specific agreements	185,676.00	1,114,324.00

Heading	2012	1st AMBU 2013
Total revenue from administrative operations		
TOTAL REVENUE	**263,111,082.61**	**215,351,100.61**
EXPENDITURE		
Total Expenditure on staff	**59,818,679.22**	**75,015,000.00**
Operational expenditure REACH		
Expenditure on REACH activities		
Registration, datasharing and dissemination	815,000.00	1,247,000.00
Evaluation	2,239,950.00	2,191,000.00
Authorisations and restrictions	462,500.00	834,800.00
Classification and labelling	162,500.00	178,000.00
Advice and assistance through guidance and helpdesk	234,360.00	277,800.00
Scientific IT tools	8,579,450.00	10,268,800.00
Scientific and technical advice to EU institutions and bodies	330,500.00	230,800.00
Total operational expenditure on REACH	12,824,260.00	15,228,200.00
ECHA bodies and cross-cutting activities		
Committees and Forum	1,370,920.00	1,563,400.00
Board of Appeal	80,000.00	105,000.00
Communications, including translation	4,959,080.00	4,053,800.00
International cooperation	0.0	p.m.
Total for ECHA bodies and cross cutting activities	6,410,000.00	5,722,200.00
Management Board and management of ECHA	**882,500.00**	**1,516,600.00**
Horizontal activities (training & missions)	**20,766,760.00**	**23,117,000.00**
International activities (cooperation with OECD)	**622,440.00**	**790,830.00**
Earmarked operations	**169,426.11**	**47,324.00**
Total operational expenditure on REACH	**21,558,626.11**	**23 955 154.00**
Operational expenditure Biocides		
Expenditure on biocides activities		
Substances, products and technical equivalence	0.0	p.m.
Submission, datasharing and dissemination	0.0	15,900.00
Advice and assistance through guidance and helpdesk	0.0	67,500.00
Scientific and technical advice to EU institutions and bodies	10,000.00	17,900.00
Scientific IT tools	1,426,336.00	1,278,700.00
Total expenditure on biocide activities	1,380,000.00	1,380,000.00
ECHA bodies and cross-cutting activities		

Heading	2012	1st AMBU 2013
Biocidal Products Committee and Rapporteurs	p.m.	224,500.00
Board of Appeal	p.m.	14,300.00
Communications, including translation	62,404.00	404,500.00
Total for ECHA bodies and cross cutting activities	62,404.00	643,300.00
Management Board and management of ECHA	**24,953.00**	**92,500.00**
Horizontal activities (training & missions)	**28,950.00**	**85,500.00**
International activities (cooperation with OECD)	**10,900.00**	**39,900.00**
Earmarked operations	**500,000.00**	**p.m.**
Total operating expenditure on biocides	**2,063,543.00**	**2,241,200.00**
Operating expenditure PIC		
Expenditure on PIC activities		
Studies and consultants	0.0	100,000.00
Advice and assistance through guidance and helpdesk	p.m.	20,000.00
Scientific IT tools	1,349,082.00	657,600.00
Total expenditure on PIC activities	1,349,082.00	777,600.00
ECHA bodies and cross-cutting activities		
Meetings with the DNAs and expert groups on PIC implementation	5,700.00	57,100.00
Communications including Translations	18,333.00	70,400.00
Total for ECHA bodies and cross cutting activities	24,033.00	127,500.00
Horizontal activities (training & missions)	1,343.18	30,000.00
Total operating expenditure on PIC	**1,374,458.18**	**935,100.00**

Table 2 below provides an overview of ECHA's planned expenditure for 2013.

Table 2: Overview of 2013 budget in €

Flows	Amount in €
TOTAL REVENUE	214,351,101
Title 1 - STAFF	64,108,000
Title 2 - BUILDING, EQUIPMENT AND MISCELLANEOUS OPERATING EXPENDITURE	15,857,800
Title 3 - OPERATING EXPENDITURE - REACH	23,955,154
Title 4 - OPERATING EXPENDITURE - BIOCIDES	1,726,000
Title 5 - OPERATING EXPENDITURE - PIC	935,100
Title 9 -RESERVE	107,769,047
TOTAL EXPENDITURE	214,351,101

2.3.3. ECHA's Performance

A PWC report[14] published in March 2012 and reviewing ECHA's performance finds that Agency should be more transparent in reporting on its contribution to most of the objectives of REACH and CLP. The report notes that ECHA should explicitly set goals on each objective and report on progress, noting that the quality of ECHA's goal setting has improved. The evaluation recommends that this information be included in the Agency's publically available annual Work Programmes and General Reports in future years. In general, stakeholders report satisfaction with ECHA's the achievements of ECHA during the review period and the amount of work achieved in a relatively short time. While, unforeseen circumstances and complementary activities reduced overall efficiency, ECHA is seen as responding flexibly to challenges. Finally, the report concludes that the perceived independence of the Agency could be improved, noting that intensive collaboration with industry results in costs for the Agency's credibility as an independent agency.

A 2012 NGO report[15] is considerably more critical, arguing that ECHA has taken a number of decisions that have seriously undermined its own ability to achieve REACH objectives. The report argues that ECHA has chosen to effectively support industry efforts to withhold data and to limit the transparency of REACH processes, making it more difficult for NGOs to participate in the implementation of REACH and reinforcing the perception of an Agency lacking independence from the chemical industry.

[14] PWC, (2012), Final Report the Review of the European Chemicals Agency Main report

[15] EEB and Client Earth (2012) identifying the bottlenecks in REACH: the role of ECHA in REACH's failing implementation, EEB and Client Earth, Brussels

Regarding the performance of ECHA's governance bodies and committees, the Client Earth/EEB report argues that the Risk Assessment Committee (RAC) and to a limited extent the Committee for Socio Economic Assessment (SEAC) have ignored REACH 's mandate to apply a precautionary approach in protecting human health and the environment and become entrenched in "paralysis by analysis" non-decision-making, so serving the less responsible elements in the chemical industry. They notes that while stakeholder participation has been guaranteed in all bodies to a certain extent, decisions on what meetings and documents are of a confidential nature has often been arbitrary.

Another concern raised in late 2012 is whether ECHA will have sufficient budget to deliver on its responsibilities in the face of budget cuts for 2013. The agreed EU budget leaves the agency with a shortfall of at least €1m.[16]

2.4. EFSA

The European Food Safety Authority (EFSA) is the keystone of European Union (EU) risk assessment regarding food and feed safety. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides independent scientific advice and clear communication on existing and emerging risks.

2.5. EU-OSHA

The European Agency for Safety and Health at Work (EU-OSHA) works to improve chemical safety in the workplace, through chemical risk assessment and risk management measures, including substitution.

[16] ENDs Europe (2012) 2013 budget deal leave ECHA underfunded, 14 December 2012, Ends Europe, Brussels

3. REACH

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals[17] (REACH) is the main legislative tool for delivering chemical risk assessment in the EU. The Regulation entered into force on 1 June 2007 and replaced and repealed the Dangerous Substances Directive and the Dangerous Preparations Directive. Article 135 of REACH sets transitional measures regarding substances notified under Directive 67/548/EEC. ECHA manages the technical, scientific and administrative aspects of the REACH and CLP systems at Community level, ensuring proper implementation and managing information availability.

3.1. Registration

REACH reference: Title II, Registration of substances, Article 5-24, Annexes III-X

3.1.1. Introduction

Under REACH, manufacturers and importers of substances are required to submit a registration to the ECHA for each substance manufactured or imported in quantities of 1 tonne or above per year, with the registration dossiers to the hazard information and, where relevant, an assessment of the risks that the use of the substance may pose and how these risks should be controlled. The registration dossier represents the key tool through which crucial data on the hazards associated with substances, and where relevant exposure assessment and risk assessment, are generated by industry and then channelled from industry to regulators. If a company fails to register a substance it means that this company is no longer allowed to manufacture or import this substance. Registration applies to substances on their own, substances in mixtures and certain cases of substances in articles. Manufacturers and importers are required to submit:

- a technical dossier, for substances in quantities of 1 tonne or more, and
- a chemical safety report, for substances in quantities of 10 tonnes or more.

3.1.2. Scope

REACH is very wide in its scope covering all substances whether manufactured, imported, used as intermediates or placed on the market, on their own, in preparations or in articles. At the same time,

[17] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 396, 30.12.2006, p. 1–849

some uses of substances are exempt from REACH, as they are regulated under other EU legislation with specific requirements (REACH Articles 15 and 16). Exemptions are reviewed in section 3.1.3 below.

The following actors in the supply chain must comply with the registration process:

- EU manufacturers and importers of substances on their own or in a mixture;
- EU producers and importers of articles meeting the criteria explained in the Guidance for Substances in articles; and
- "Only representatives" established in the EU and appointed by a manufacturer, formulator or article producer established outside the EU to fulfil the registration obligations of importers.

REACH creates a single system for both “existing” or phase in substances and “new” or non-phase in substances (i.e. those not produced or marketed prior to the entry into force of REACH).

Phase- in Substances

There is a special transitional regime for substances which, under certain conditions, were already manufactured or placed on the market before REACH's entry into force. Such substances are called phase-in substances. Companies can benefit from the transitional regime if they pre-registered their substances by 1 December 2008. Substances fulfilling at least one of the following criteria may be considered as phase-in substances in accordance with REACH (Article 3(20)):

- Substances listed in the European Inventory of Existing Commercial Chemical Substances (EINECS)
- Substances that have been manufactured in the EU (including the countries that joined on 1 January 2007) but have not been placed on the EU market after 1 June 1992
- Substances that qualify as "no-longer polymer"

Phase-in substances (existing substances) enjoy benefits of extended registration deadlines if pre-registered before Dec 2008 (REACH Article 28). The principle is that the higher the tonnage, the earlier the registration deadline, with priority given to substances on the basis of hazard.

Non phase-in substances

All substances that do not fulfil any of the criteria for phase-in substances are considered as non-phase-in substances. Normally, non-phase-in substances have not been manufactured, placed on the market or used in the EU before 1 June 2008, unless they were notified under Directive 67/548/EEC.

Non phase-in substances (new substances) need to be registered immediately before being placed on the EU market.

Following REACH Article 26, potential manufacturers and importers of non-phase-in substances have to submit an inquiry to ECHA and subsequently register the substance in accordance with REACH before they can manufacture or import the substance. For details of the inquiry process, see section 3.1.11 below.

NONS

All substances notified under Directive 67/548/EEC (also called NONS) are considered to be registered under REACH and ECHA has assigned registration numbers to all the notifications. The owner of the notification can claim the registration number from ECHA. ECHA distributes notifications via REACH-IT, upon request of the notification's owner.

In guiding industry, ECHA has published the Industry User Manual - Part 10: Claim of a registration number for a notified substance and Questions and Answers for the registrants of previously Notified Substances.

3.1.3. Exemptions and Reduced Requirements

REACH reference: Article 2, 6, 15-18

Some substances are specifically excluded from REACH, including:

- Radioactive substances
- Substances under customs supervision
- The transport of substances
- Non-isolated intermediates
- Waste
- Some naturally occurring low-hazard substances

In addition, REACH sets up specific exemptions to the obligation to register for substances used in medicinal products for human or veterinary use, active substances used in plant protection and biocidal products and in food or feedstuffs, as these substances are registered under other processes (REACH Articles 15 and 16). The distinct authorisation procedures under specific EU legislation for these uses are considered in sections 7 (pesticides), 8 (biocides) and 9 (medicinal and veterinary products) below.

A range of low risk and naturally occurring substances (in Annexes IV and V), and under certain conditions, substances registered and exported and re-imported in the EU or recovered in the EU and on-site isolated intermediates and transported isolated intermediates are also exempted from re-registration. There are specific conditions for substances use in research and for polymers, and these are discussed below.

PPORD

Substances manufactured in the Community or imported for the purpose of product and process orientated research and development (PPORD) can be exempted from the obligation of registration for a period of five years.

Companies that wish to benefit from this exemption must submit a PPORD notification to ECHA. This is done in the form of an electronic notification, including information on substance identity, its classification, information related to the PPORD programme, and the quantity of the substance expected to be manufactured or imported during the five-year period of exemption.

ECHA has produced "Guidance on Scientific Research and Development (SR&D) and Product and Process Oriented Research and Development (PPORD)" which describes specific provisions under REACH for substances manufactured, imported or used in Scientific Research and Development (SR&D) and Product and Process Oriented Research and Development (PPORD). The guidance clarifies the definition of PPORD and describes the steps for PPORD notification.

A PPORD notification dossier can be prepared either on-line through the Agency web-site (REACH IT) or using IUCLID 5. Specific guidance regarding PPORD notifications is provided on the ECHA website, as well as in Data Submission Manual 1: How to prepare and submit a PPORD notification, and Data Submission Manual 5: How to complete a Technical Dossier for Registrations and PPORD Notifications.

ECHA performs the assessment of the received information and may impose conditions to the PPORD exemption. The manufacturer or importer of the substance has to comply with the imposed conditions and must inform relevant customers involved in the PPORD.

Polymers

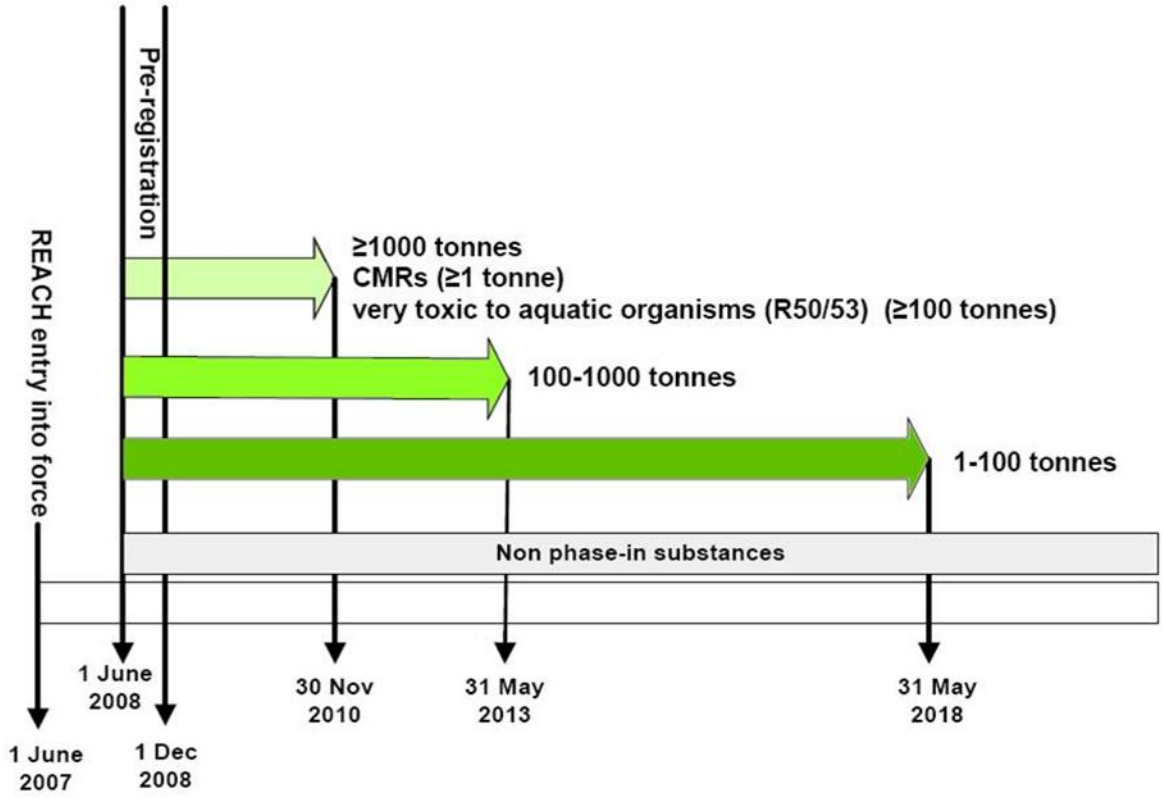
Polymers are also exempt from the requirement to register, (since they considered to usually not be very hazardous), but in certain circumstances monomers in polymers have to be registered. Here it

should be noted that a range of policy options for information requirements for polymers under REACH have been assessed in a RPA study[18] as part of the 2012 REACH Review. The aim of the project was to review possible ways of selecting polymers for registration in a practicable and cost-efficient way and on the basis of sound technical and valid scientific criteria.[19]

3.1.4. Registration Deadlines

The deadlines for REACH registration depends on the tonnage band of a substance and the classification of a substance. As explained above, substances are categorized into two groups under REACH: phase-in substances and non phase-in substances. Each group has different REACH registration deadlines, presented in figure 6 below.

Figure 6: REACH registration deadlines



Source: Website of the Chemical Inspection and Regulation Service

[18] RPA, Milieu, GNOSYS and ARCHE, 2013, Review of REACH with regards to the registration requirements for polymers and 1-10 tonnes substances, RPA, UK

[19] For further details see: http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review2012/registration_requirements_en.htm

Phase-in substances (existing substances) enjoy benefits of extended registration deadlines if pre-registered before Dec 2008. The principle is that the higher the tonnage, the earlier the registration deadline, with priority given to substances on the basis of hazard. Registration requirements for phase-in substances are staggered by tonnage to make the process manageable for both industry and regulators, with the deadlines for submission of registrations presented in box 8 below.

Box 8: Deadlines for the registration of phase-in substances

1 December 2008 for pre-registration of phase-in substances
Pre-registration was a requisite to benefit from the extended registration deadlines foreseen for these substances. Potential registrants who, for the first time after 1 December 2008, manufacture or import a phase-in substance in quantities of one tonne per year or more can still submit certain information to ECHA (late pre-registration) and benefit from the extended deadlines.

30 November 2010
- Substances produced or imported in quantities of ≥ 1,000 t/yr
- Substances classified as CMR1/2 produced or imported in quantities ≥1t/yr
- Substances classified as dangerous to aquatic organisms or the environment (R50/53) produced or imported in quantities ≥100 t/y

31 May 2013
Substances produced or imported in quantities of ≥ 100-<1,000 t/yr

31 May 2018
Substances produced or imported in quantities of ≥ 1-<100 t/yr

The annual tonnage refers to metric tons per manufacturer or importer, not to the total volume manufactured or imported.

Non phase-in substances (new substances) need to be registered immediately before being placed in the EU market.

In order to assist companies (manufacturers, importers and downstream users) who want to check whether their substance is planned to be registered by 31 May 2013, on its website ECHA provides a list of substances that that companies have told ECHA they intend to register by the 2013 REACH registration deadline. The list is based on the results of a survey conducted by ECHA. It also shows where lead registrants have been nominated and identified to ECHA.

3.1.5. Pre-Registration

The pre-registration period, between 1 June and 1 December 2008, allowed potential registrants of the same phase-in substance to get together and submit a registration dossier jointly (see section 4.3.10 on joint registration below). Pre-registration was a requisite to benefit from the extended registration deadlines foreseen for these substances.

Late Pre-Registrations

Potential registrants who, for the first time after 1 December 2008, manufacture or import a phase-in substance in quantities of one tonne per year or more can still submit certain information to ECHA (late pre-registration) and benefit from the extended deadlines. Producers and importers of articles with an intended release of a substance can also submit a late pre-registration.

Late pre-registrations have to be submitted within six months after the manufacturing or importing of the substance that exceeds the one-tonne threshold and no later than twelve months before the relevant registration deadline. Therefore, the late pre-registration period ends on 31 May 2012 for substances to be registered by 31 May 2013, and 31 May 2017 for substances to be registered by 31 May 2018. Late pre-registration is only obligatory if companies want to benefit from the extended registration deadlines. Companies can also decide to register their phase-in substances immediately, but in this case it is necessary to first submit an inquiry.

3.1.6. Substance Identity

Unambiguous substance identification is a pre-requisite to most of the REACH processes, not least registration. Actors in the supply chain must have sufficient information on the identity of their substance. The following information on the manufactured or imported substance shall be included in the dossier in order to unambiguously identify the substance:

- Substance name and related identifiers, molecular and structural formulae, if applicable;
- Information on the composition and purity of the substance;
- Spectral data and analytical information to verify the identity and composition of the substance; and
- Clear and concise description of the analytical methods.

In 2012, ECHA published "Guidance on the identification and naming of substances under REACH and CLP". The guidance document aims to assist manufacturers and importers in recording and reporting the identity of a substance within the context of REACH and CLP, including how to name the substance. It also gives guidance on whether substances may be regarded as the same in the context of REACH and CLP. Identifying the same substances is important for the process of (late) pre-registration of phase-in substances, for inquiries, for data sharing, for Joint Submission of data, for notification to the Classification and Labelling inventory and for Harmonisation of Classification and Labelling. In addition, ECHA has published a document entitled "Questions and answers on

substance identification" and "Data Submission Manual 18: How to report the substance identity in IUCLID 5 for registration under REACH".

3.1.7. Registration Dossiers

REACH reference: Article 10-14, Annexes I-X

The registrant of a substance needs to compile all the required information in a registration dossier, which consists of two main components:

- A technical dossier, respecting the information requirements tiered by tonnage; and
- If the registrant manufactures or imports a substance in quantities of ten tonnes or more per year; a chemical safety report.

The registration dossier has to be prepared using the IUCLID 5 software application. IUCLID 5 implements the Harmonised Templates developed by the OECD and it is compatible with other chemical legislations around the world. Once the dossier has been created with IUCLID 5, it has to be submitted to ECHA through REACH-IT.

In assisting registrants, ECHA has developed Guidance on registration.

3.1.8. Information Requirements for Registration Dossiers

REACH reference: Annexes VI to XI

The specific information requirements of the technical dossier are tiered according to the tonnage volumes of a substance placed on the market. The higher the tonnage, the more information on the intrinsic properties of the substance is required. At a minimum, this includes information on substance identity, physicochemical properties and any available (eco)toxicity data, and, depending on tonnage, may include data on: mammalian toxicity; ecotoxicity; environmental fate, including abiotic and biotic degradation; information on manufacture and uses as well as risk management measures.

The information requirements under REACH by tonnage band are presented in table 3 below.

Table 3: Information requirements by tonnage band

Tonnage band	Information Requirements
≥1-10 tonnes	Phase in non-Annex III*: information on physicochemical properties including state at 20°C and 101.3 kPa, melting/freezing point, boiling point, relative density, vapour pressure, surface tension, water solubility, octanol/water partition coefficient, flash point, flammability, explosive properties, self-ignition temperature, oxidizing properties, and granulometry.
	Non-Phase in & phase in meeting Annex III criteria: information on physicochemical properties as above AND acute (oral) toxicity, in vivo skin sensitization, one in vitro test for gene mutations in bacteria (further mutagenicity tests can be required in case of a positive result), acute toxicity to algae and Daphnia, and biotic degradation (ready biodegradability) (REACH annex VII), results from in vitro testing of eye and skin irritation
≥10 tonnes	Requirements for lower tonnage bands AND REACH annex VIII: in vivo skin and eye irritation, acute mammalian toxicity (second route in addition to oral route), acute toxicity to fish and microorganisms (activated sludge respiration inhibition), data on hydrolysis, an adsorption/desorption screening study, and an in vitro cytogenicity test using mammalian cells or an in vitro micronucleus test. If the mutagenicity tests performed are negative, then an in vitro gene mutation study using mammalian cells is also required. If a positive result is obtained in any of the tests, then further in vivo mutagenicity studies "shall be considered". In addition to these tests, a 28-day repeated-dose mammalian toxicity test and screening for reproductive toxicity can be required, but these tests are not mandatory and testing can be waived based on, for instance, the magnitude and nature of human exposures.
≥100-1000 tonnes	Requirements for lower tonnage bands AND REACH Annex IX: fate and behavior (bioaccumulation, simulation testing, and identification of degradation products), long-term toxicity to fish (OECD test guidelines 210, 212, or 215; OECD 1992, 1998, 2000), and Daphnia, short-term toxicity to terrestrial organisms and plants, subchronic toxicity to mammals (90 days of exposure), developmental toxicity (OECD test guideline 414; OECD 2001a), and a two-generation reproductive toxicity study (OECD test guideline 416; OECD 2001b)
≥1000 tonnes +	Requirements for lower tonnage bands AND REACH annex X: additional (long-term) effect data on sediment living organisms, terrestrial organisms, and plants can be required, as well as additional data on bird reproduction and a carcinogenicity study

* Phase-in substances are substances that were regulated under DSD. Substances meeting the REACH Annex III criteria are subject to stricter data requirements. REACH Annex III criteria are a) Substances that are predicted by the application of (quantitative) structure–activity relationships [(Q)SAR] or other evidence to be likely to meet the criteria for category 1A or 1B classification for carcinogenicity, mutagenicity, or reproductive toxicity (under DSD) or the criteria for persistent, bioaccumulating, and toxic substances (PBT), or the criteria for very persistent and very bioaccumulating (vPvB) substances (under REACH Annex VIII) b) Substances that both i) have dispersive or diffuse (consumer) use(s) and ii) are predicted [by the application of (Q)SAR or other evidence] to be likely to meet the classification criteria for any human health or environmental effects end points under DSD

3.1.9. Chemical Safety Report

REACH reference: Article 14, Annex I

A chemical safety report (CSR) is required for substances manufactured or imported in quantities starting at 10 tonnes and must be submitted as part of the registration dossier. The CSR documents the results of the chemical safety assessment (CSA), the main tool for delivering chemical risk assessment under REACH.

The CSA is carried out to demonstrate that the risks from the exposure to a substance, during its manufacture and use, are controlled when specific operational conditions and risk management measures are applied. These conditions of use of a substance constitute the exposure scenario, which

is an essential component of the chemical safety report. The aim of the CSA is to define the conditions of use under which the risks posed by a specific substance can be controlled.

The CSR is the key source from which the registrant provides information to all users of chemicals through the exposure scenarios. It also forms a basis for other REACH processes including substance evaluation, authorisation and restriction. It should be readily understandable in all its parts as a stand-alone document and it should include all the relevant information for the chemical safety assessment. The elements to be included in the chemical safety report are listed in Annex I, section 7 of REACH.

Key Steps in the Chemical Safety Assessment

The CSA includes the following steps:

- Collection and generation of information on intrinsic properties of the substance;
- Human health hazard assessment;[20]
- Physicochemical hazard assessment;
- Environmental hazard assessment; and
- Persistent, Bioaccumulative and Toxic (PBT) and very Persistent and very Bioaccumulative (vPvB) assessment.

If, after these steps, the conclusion is that the substance is PBT or vPvB, or meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC, the following steps are also needed:

- Exposure assessment
- Risk characterisation

Exposure Scenarios

Exposure assessment includes the development of exposure scenarios and exposure estimation. Exposure scenarios are sets of conditions that describe how substances are manufactured or used during their life-cycle and how the manufacturer or importer controls, or recommends to control, exposures of humans and the environment. The exposure scenarios must include the appropriate risk management measures and operational conditions that, when properly implemented, ensure that the risks from the uses of the substance are adequately controlled. Exposure scenarios need to be developed to cover all "identified uses" which are the manufacturers' or importers' own uses, and

[20] In the case of uses in cosmetic products and food contact materials, the CSA need not considering risks to human health as this is already completed under other legislation.

uses which are made known to the manufacturer or importer by his downstream users and which the manufacturer or importer includes in his assessment.

The final exposure scenario defines the operational conditions and risk management measures required to ensure the safe use of the substance for each exposed population during all the lifecycle stages of the substance, including the waste stage and the article service life, where applicable. It is achieved through refinement of the operational conditions and risk management measures until the risks for humans and the environment are shown to be controlled.

The final exposure scenario should be documented in a standardised way to accurately describe the conditions of use to promote adequate and achievable risk management measures. Relevant exposure scenarios will need to be annexed to the safety data sheets (SDS) that will be supplied to downstream users and distributors and ensure the dissemination of information on how to safely use chemicals. Importantly, under the human health hazard assessment, registrants will identify Derived No-Effect levels (DNELs), concentration thresholds above which human should not be exposed to the substance.

Support for the Chemical Safety Assessment

ECHA provides a range of support materials to assist registrants in undertaking their chemical safety assessment and documenting it in the chemical safety report. Available guidance includes the Guidance on information requirements and chemical safety assessment, which describes the information requirements under REACH with regard to substance properties, exposure, use and risk management measures, in the context of the chemical safety assessment.

Registrants are encouraged to use the online Chesar application when carrying out their chemical safety assessments (CSAs) and prepare their chemical safety reports (CSRs) and exposure scenarios (ES) for communication in the supply chain.

In addition, ECHA has made available on its website, practical examples of exposure scenarios, and provides an illustrative example of a chemical safety report.

Finally, ECHA has established the Exchange Network on Exposure Scenarios (ENES), a collaborative network aiming to identify good practices on preparing and implementing exposure scenarios, and to develop an effective communication exchange between supply chain actors to improve the protection of human health and the environment. The network meets twice a year and includes sector organisations Cefic, Concawe, Eurometaux, Fecc, A.I.S.E and DUCC.

3.1.10. Joint Registration

REACH reference: Article 11

Multiple registrants of the same substance are required by the REACH Regulation to jointly submit information on the intrinsic properties of the substance. In order to facilitate joint registration and associated data sharing, all potential registrants that have pre-registered the same phase-in substance are part of a Substance Information Exchange Forum (SIEF). The formation of a SIEF aims to facilitate the exchange of information on (robust) study summaries between potential registrants, and create a forum for agreeing on the classification and labelling where there is a difference between potential registrants.

The preparation of the joint registration dossier is usually coordinated by an elected SIEF member, but can also be entrusted to any person appointed by the SIEF members. SIEF members must also nominate the lead registrant for the joint submission of the dossier once it is complete. Joint registration dossiers shall be submitted first by the lead registrant, well before the registration deadline. It is recommended to submit the joint dossier at least two months before the deadline, in order to give sufficient time for other registrants to submit their own registrations. The other registrants then only have to submit their specific information, as part of their member dossier.

Lead registrants are advised to inform ECHA of their nomination. This will allow them to benefit from specific support and can help ECHA to direct other potential registrants of the same substance to the right SIEF. ECHA does not confirm or reject any lead registrant's notification. The nominations should be submitted using the "lead registrant notification" web form available on the ECHA REACH 2013 web section.

Substance Information Exchange Forum

Joining a SIEF is a legal obligation for all registrants of pre-registered phase-in substances. The work of a SIEF leads to one joint submission for each substance, therefore reducing costs and avoiding unnecessary animal testing.

Through the REACH-IT system, registrants have used the same substance name or numerical chemical identifier(s) such as EINECS or CAS numbers for pre-registering their substance are able to identify one another in a pre-SIEF, decide whether their substance is the same, and if so form a SIEF. Guidance on SIEF formation is provided in "Industry User Manual Part 5 - Pre-SIEF".

Members of a SIEF have to share existing studies, react to requests for information and work collectively to identify and carry out additional studies or submit testing proposals when needed. In addition to potential registrants, downstream users and any person or organisation holding data relevant to a phase-in substance can participate in the SIEF if they have identified themselves as a data holder and are willing to share their information.

SIEFs have no prescribed legal form and they are independently managed by industry. ECHA does not participate in the discussions between the potential registrants in the SIEF and members are free to choose how to organise their cooperation under REACH. ECHA provides a fact sheet on SIEF formation and data sharing, which advises registrants on how to form a SIEF and operate effectively.

Lead Registrants

SIEF members need to appoint a lead registrant who must act with the agreement of the other co-registrants and submit the lead dossier of the joint submission. REACH does not specify rules on how the lead registrant should be selected. For example, the lead registrant may be the registrant who plans to submit their registration dossier by the earliest registration deadline. The lead registrant also usually coordinates the activities within the SIEF. Lead registrants are advised to inform ECHA of their nomination via an online Lead Notification Webform.

A lead dossier is a complete dossier that includes the classification and labelling of the substance, (robust) study summaries and proposals for further testing, if applicable. The registrants can decide if they submit the guidance on the safe use of the substance and the chemical safety report, jointly or separately.

Member Registrants

Member registrants submit dossiers containing only information specific to their company and their substance. For example, this may include information about substance identity, their identified uses and their production volumes. These submissions do not need to include the information already provided by the lead registrant.

Data Sharing

The REACH Regulation requires multiple registrants of the same substance to share data and to jointly submit their registration dossier. Data sharing is required for:

- Data from tests on substances registered less than 12 years previously (Article 27); and
- Data from tests to meet the information requirements (Article 30(2); and

- Data involving tests on vertebrate animals in order to meet their information requirements (Article 30(5)).

By doing this, registrants of the same substance can reduce costs and avoid unnecessary testing on vertebrate animals. Sharing data also precedes joint registration when a substance is manufactured or imported by more than one company. Registrants must make every effort to ensure that the cost of sharing the information required for joint registration is determined in a fair, transparent and non-discriminatory way. All parties must fulfil their data sharing obligations in a timely manner.

Data Sharing through the SIEF

SIEF members need to assess the studies available among the SIEF members and agree on the need to generate new test data when information is missing. Before conducting any new study involving testing on vertebrate animals, SIEF members shall request whether the study is already available from other participants within the SIEF. If the owner of an existing study refuses to provide either the proof of costs for the study or the study itself, ECHA has a role in settling such data sharing disputes (see below).

Before conducting any new study not involving testing on vertebrate animals, SIEF members may ask other participants whether they already have those studies.

- If the owner of a study refuses to provide either the proof of costs for the study or the study itself, the other SIEF member(s) proceed with registration as if no relevant study is available within the SIEF.
- If a study is not available within a SIEF, only one study per information requirement shall be conducted by a SIEF member acting on behalf of the others.
- If the missing study is listed in Annexes IX (and X) of the REACH Regulation (information requirements for tonnage bands > 100 tonnes per annum), the SIEF members cannot proceed with the testing directly but have to first submit a testing proposal in their joint registration dossier.

Cost sharing between SIEF members must be determined in a fair, transparent and non-discriminatory way. Registrants are only required to share the costs of information that they are required to submit to fulfil the registration requirements according to their tonnage band.

Disputes on Data Sharing and ECHA's Role

Where dispute arise between existing and potential registrants, ECHA can assist in the resolution of data sharing disputes. ECHA provides potential registrants with the opportunity to inform ECHA of the failure to reach an agreement on data sharing through webforms tailored for data sharing under Article 27(5), Article 30(2) and Article 30(3). The registrant submitting the webform must provide documentary evidence demonstrating the efforts made by all the parties compelled to reach an agreement on the sharing. ECHA's decision will be based on an assessment of the parties' respective efforts to reach an agreement on the sharing of the data and its costs in a fair, transparent and non-discriminatory way.

In 2012, ECHA published "Guidance on Data Sharing", complemented by "Questions and answers on data sharing and disputes".

3.1.11. Inquiry

For non-phase-in substances and for phase-in substances that have not been pre-registered, **inquiry** is used to identify other potential registrants and share data. Potential registrants have to inquire from ECHA whether a registration has previously been submitted for the same substance, and inform ECHA of their information needs so that the available data can be shared among the registrants of the same substance. Registrants must also inform ECHA of the additional information that they would require for an update of a registration due to a tonnage band increase. The inquiry dossier must include enough information to allow the correct identification of the substance so that ECHA can determine whether the same substance has previously been registered or whether there are other inquirers for the same substance. The information submitted for the purposes of inquiry will not be published.

After assessment of an inquiry, ECHA connects the potential registrant and the previous registrants in order to allow for data sharing. ECHA also provides potential registrants with a list of available (robust) study summaries. Potential registrants need to wait for the result of the inquiry before submitting the registration dossiers or starting any tests on vertebrate animals. The result of the inquiry may trigger legal obligations to submit a joint registration and share data. ECHA provides a document entitled "Questions and answers on inquiry".

3.1.12. Dossier Receipt by ECHA

Dossier submission is done via REACH-IT (see section 6.2). Upon receipt, ECHA assigns a submission number to each received dossier. This number is used as a reference in all correspondence relating to this registration until a registration number is assigned.

All dossiers undergo administrative checks called **‘‘Business Rules"** checks to ensure that the dossiers fulfil the pre-requisites for ECHA to handle them. ECHA verifies that the dossiers are in the appropriate IUCLID format and that certain administrative information is consistent with the submission type. Passing the business rules only confirms that the dossier is accepted for processing, and does not mean that the registration is finalised yet. If there is a business rules failure, the registrant would need to correct the dossier and submit it again.

The next step is the **technical completeness check**. At this stage, the dossier is checked to certify that all the required information is included. This completeness check involves an automated technical completeness check which verifies whether data fields have been filled out, without assessing the quality or relevance of the information. If there is any missing information, the registrant will be given a reasonable deadline to re-submit a complete dossier. Only one additional submission attempt is allowed in this case.

Once the technical completeness check is successful and the invoice is paid, the dossier is considered complete and a registration number is assigned. The registration date is the date of the registration dossier's submission. If there is a second completeness check failure or a failure in paying the relevant fee, the dossier is rejected. All correspondence between ECHA and the registrant is via REACH-IT.

3.1.13. Updating Registrations

Registrants have a responsibility to keep their dossiers updated. Possible reasons to update a registration include:

- a change of the substance composition,
- the increase of the tonnage band or
- the availability of additional information, for example, related to classification and labelling.

The company information and other administrative information also need to be updated and new information has to be submitted to ECHA without undue delay. For some types of update a fee is charged.

3.1.14. Publication of Dossiers by ECHA

ECHA publishes information included in the registrations dossiers on its website to be freely available for all European citizens so they can be informed of any potential risks of the chemicals that they are using. The information published covers:

- the identity of the substance,
- the results of studies on its intrinsic properties and hazard profiles,
- the levels where no adverse effects are expected for human health or the environment,
- its classification and labelling, as well as
- guidance on its safe use.

If not claimed confidential, ECHA will also publish on the substance degree of purity essential for classification and labelling, total tonnage band, (robust) study summaries, information in the safety data sheet and the trade name. Under certain circumstances, the IUPAC name can be claimed confidential. In these cases, the registrant must provide a public name that the ECHA can use for dissemination purposes.

Before submitting their dossiers, registrants have the opportunity to request that certain data be kept confidential and to check what information will be publicly available. Requesting confidentiality applies only to a limited set of data and requires a justification, which will be evaluated by ECHA.

3.1.15. Nanomaterials in REACH Registration Dossiers

There has been considerable discussion in the EU regarding the application of the REACH registration requirements to nanomaterials, particularly since the REACH text does not specifically mentioned nanomaterials or nanoforms of substances. In co-operation with the Competent Authorities for REACH and CLP (CARACAL) subgroup on nanomaterials[21] the Commission clarified in a 2008 paper[22] the coverage of nanomaterials under REACH, stating specifically that nanomaterials (i.e. substances at the nanoscale) are covered by REACH, and that nanomaterials include aggregates and agglomerates. In addition, in 2011 the Commission provided a definition of nanomaterials[23], to be used in the adoption and implementation of legislation and policy. The definition is provided in box 9 below.

[21] "CASG Nano", composed of Member States and stakeholder experts
[22] European Commission (2008) Nanomaterials in REACH, CA/59/2008 rev.1, Brussels
[23] Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial, OJ L 275 , 20/10/2011 pp. 38-40

Box 9: Commission Definition of Nanomaterial following Recommendation 2011/696/EU

- 'Nanomaterial' means a material containing particles where for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm
- Includes aggregates and agglomerates
- In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50%

In determining whether their dossier covers nanomaterials following the definition, REACH registrants will need to characterise the nanoform using data on particle size distribution and/or surface area. While a range of methods are available to characterise nanomaterials they yield different results, meaning that data reporting must refer to methods.

A 2009 study[24] completed by the JRC under the ENRHES Project: Engineered Nanoparticles: Review of Health and Environmental Safety sough to undertake a REACH CSA following the 2008 ECHA Guidance for four classes of NM, namely metals, metal oxides, fullerenes and CNT. The study found that the currently available database for both hazard and exposure for nanomaterials is severely limited, generating high uncertainties in any conclusion on possible risks. They supported a case by case assessment for nanoforms of nanomaterials. The study concludes that the main risk to the environment is expected from metals and metal oxides, especially for algae and Daphnia, due to exposure to both particles and ions. At the same time, the authors highlight considerable uncertainties in any conclusion on risk, due to data limitation, and urge that the results should not be used for regulatory decision-making.

The European Commission's Scientific Committee for Emerging and Newly Identified Health Risks (SCENIHR) have pointed out that amendments have to be made to the 2003 Technical Guidance for risk assessment of chemicals "*due to the physico-chemical properties of nanoparticles, their behaviour and their potential adverse effects are not solely dependent on exposure in terms of the mass concentration*"[25].

In recognition of limitations in applying the 2008 ECHA Guidance to nanomaterials and in order to drawn in work from scientific research, in 2009 the Commission launched a REACH Implementation Project on Nano (RIPoN). This resulted in the generation of targeted guidance on Information

[24] Stone et al. 2009. Engineered nanoparticles: review of health and environmental strategy" ENRHES, JRC, also summarised in Aschberger K, Micheletti C, Sokull-Klüttgen B, Frans M. Christensen FM. 2011. Analysis of currently available data for characterising the risk of engineered nanomaterials to the environment and human health — Lessons learned from four case studies, Environment International, 37(6): 1143-1156

[25] Scientific Committee for Emerging and Newly-Identified Health Risks, The appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents for new and existing substances for assessing the risks of nanomaterials, European Commission, Brussels, Belgium, 2007

Requirements[26] and Chemical Safety Assessment[27] for nanomaterials under REACH. In April 2012, ECHA drew on these outputs to update the 2008 guidance with appendices on nanomaterials, specifically updating Chapters R.7a, R.7b and R.7c of the Guidance on Information Requirements and Chemical Safety Assessment. The recommendations cover endpoint specific guidance, dose-response for human health and the environment and occupational exposure estimation. At this point (November 2012), there is no NM-specific guidance for environmental exposure estimation. In addition, a recent study by the Joint Research Centre provides an overview of available measurement techniques for characterising nanomaterials.[28]

In a recent Communication on "Second Regulatory Review on Nanomaterials",[29] the Commission noted that these findings can partly be explained by the absence of detailed guidance to registrants on registration for nanomaterials and the general wording of the REACH annexes. The Communication identified REACH as the best framework for addressing nanomaterials, stated that current risk assessment approaches are applicable and called for a case by case approach to risk assessment for nanomaterials. The accompanying Commission Staff Working Paper on the "Types and uses of nanomaterials, including safety aspects"[30] notes that "*mainly as a result of the lack of exposure data, risk characterisation and combining hazard and exposure data necessarily remains at a very preliminary and qualitative level*." The Commission committed to reviewing regulatory options in the context of the REACH Review, in particular possible amendments of REACH annexes, to ensure clarity on how nanomaterials are addressed and safety demonstrated in registrations.

In addressing data gaps in the short term, the Commission Communication indicates that the Commission will create a web platform with references to all relevant information sources on nanomaterials, including existing registries on a national or sector level. The work towards a harmonized European web platform will draw on the recommendations of a 2010 RIVM project[31]. The Commission is to establish a first version mainly based on links to available information as soon as possible, and will assist in the development of harmonised data formats in order to facilitate information exchange.

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[26] Hankin SM, Peters SAK, Poland CA, Hansen SF, Holmqvist J, Ross BL, Varet J and Aitken RJ (2011) Specific Advice on Fulfilling Information Requirements for Nanomaterials under REACH (RIP-oN 2) – Final Project Report, RNC/RIP-oN2/FPR/1/FINAL, BSI, UK

[27] Aitken RJ, Bassan A, Friedrichs S, Hankin SM, Hansen SF, Holmqvist J, Peters SAK, Poland CA and Tran CL (2011) "Specific Advice on Exposure Assessment and Hazard/Risk Characterisation for Nanomaterials under REACH (RIP-oN 3)" Final Project Report, RNC/RIP-oN3/FPR/1/FINAL, BSI, UK

[28]

[29] European Commission (2012) Communication from the Commission to the European Parliament, the Council and the Economic and Social Committee on the Second Regulatory Review on Nanomaterials, COM(2012) 572 final, 3/10/2012, Brussels

[30] European Commission (2012) Commission Staff Working Paper on the types and uses of nanomaterials, including safety aspects, SWD(2012) 288 final, 3/10/2012, Brussels

[31] RIVM (2010) "Nanomaterials in consumer products: Update of products on the European market in 2010" RIVM Report 340370003/2010, the Netherlands

In April 2013, the Commission will be launching an impact assessment "*to identify and develop the most adequate means to increase transparency and ensure regulatory oversight, including an in-depth analysis of the data gathering needs for such purpose*". The Communication notes that this analysis will include those nanomaterials currently falling outside existing notification, registration or authorisation schemes. Work on data gathering for nanomaterials in the form of an EU Registry is due to commence in the second half of 2013, with finalization foreseen for 2014 or early 2015.

3.1.16. Registrations to Date

While registration requirements entered into force on 1 June 2007, registration is being phased in until 1 June 2018 for existing substances. To qualify for the phase-in provisions, companies had to pre-register their substances by 1 December 2008. ECHA received 2.7 million **pre-registrations** with respect to 146,000 phase-in substances, including 41,000 substances without an EC number. Also, 14,500 substances were submitted as multi-constituent substances. The number of preregistrations was 15-times higher than had been estimated.

The first phase-in deadline of 1 December 2008 has now passed and all substances manufactured/imported in quantities equal to or greater than 1,000 tonnes should have been registered, as should all potential Substances of Very High Concern (SVHCs) with CMR/PBT/vPvB properties and non-phase-in substances subject to registration.

According the website of ECHA, which provides summary data on REACH registrations, 27,684 new registration numbers have been granted by ECHA following submission of a registration dossier from 1 June 2008 up until 31 October 2012, representing a total of 4,734 unique substances. Table 4 below provides a breakdown by phase in and non-phase in substances.

Table 4: New registrations granted by ECHA and number of unique substances registered

	Registrations	Unique substances
TOTAL	**27,684**	**4,734**
Phase-in	26,131	4,004
Non phase-in	1,553	730

Substances notified under Directive 67/548/EEC (NONS) are considered as registered under REACH. ECHA granted 9,962 NONS a registration number, representing 5,292 unique substances. Table 5 provides an overview of the situation with regards to NONS.

Table 5: Notified substances (NONS) registrations under REACH and number of unique NONS

	Registrations	Unique substances
NONS granted a registration number by ECHA	9,962	5,292
NONS claimed by the notifier	5,091	3,715
NONS for which an update has been submitted under REACH	1,475	1,305

However, in order to have a picture of the nature of the data generated by these registrations, it is important to consider the tonnage bands, since this will determine the information requirements for the registration dossier. In terms of the number of unique substances registered by total tonnage band (i.e. sum of the most recent annual tonnage in all registrations), this is provided in table 6 below. Unfortunately, this data does not accurately reflect the tonnage per registration and is therefore only indicative of resulting information.

Table 6: Registered substances by total tonnage band

Total tonnage Band	Number of Substances
100,000,000 - 1 000,000,000 tonnes per annum	5
10,000,000 – 100,000,000 tonnes per annum	45
1,000,000 – 10,000,000 tonnes per annum	156
100,000 – 1,000,000 tonnes per annum	325
10,000 – 100,000 tonnes per annum	594
1,000 – 10,000 tonnes per annum	938
100 – 1,000 tonnes per annum	323
10 - 100 tonnes per annum	173
1 - 10 tonnes per annum	237
Intermediate Use Only	1,938
TOTAL	**4,734**

Total Tonnage Band is calculated by summing the latest year values for actual tonnages in all full registrations (i.e. not including intermediates) for a given substance and converting it to a band.

3.2. Evaluation

REACH References: Title VI Evaluation, Articles 40-54

ECHA and the Member States evaluate the information submitted by companies to examine the quality of the registration dossiers and the testing proposals and to clarify if a given substance constitutes a risk to human health or the environment. Evaluation under REACH focuses on three different areas:

- examination of testing proposals submitted by registrants;
- compliance check of the dossiers submitted by registrants; and
- Substance evaluation

Once the evaluation is complete, registrants may be required to submit further information on the substance through a decision. The main actors in the evaluation process are presented in table 7 below.

Table 7: Main actors in the evaluation process

Registrants	A natural or legal person established within the European Economic Area (EEA), manufacturing or importing a substance into the EEA at quantities of one tonne or more per year or who has been appointed as an only representative according to Article 8 of the REACH Regulation, can act as a registrant. REACH requires registrants to provide information on the intrinsic properties of a substance. The information required for each substance depends on the tonnage manufactured or imported; the higher the tonnage, the more information needs to be submitted. Submission includes a technical dossier and, for substances manufactured or imported in quantities of 10 tonnes per year or above, a chemical safety report.
Third parties	Third parties are citizens, organisations, academics, companies or authorities other than a registrant. They may provide information on testing proposals involving vertebrate animals.
ECHA	Secretariat The ECHA Secretariat supports the Committees and the Forum by providing the best possible scientific, technical and regulatory services in an efficient and transparent way. Member State Committee (MSC) The task of the Member State Committee is to seek unanimous agreement on the draft evaluation decisions of ECHA to which Member States have proposed amendments. These draft decisions are discussed and agreed upon by the Member State Committee in its meetings, or alternatively, agreement may be sought via written procedure. Once agreed by the Member State Committee, ECHA finalises the decision and provides it to the registrant. If unanimous agreement cannot be reached, the matter is referred to the European Commission for it to make a decision.
Member States	The Member State competent authorities can comment on and propose amendments to ECHA's draft decisions. They can also propose substances for substance evaluation. Member States will carry out this evaluation to clarify any potential risk to human health or the environment that the substance may cause. Further information may be requested through an ECHA decision. Member States can also impose national actions on substances or registrants, or initiate the adoption of EU-wide risk management measures (e.g. occupational exposure limits, EU-wide restriction, EU-harmonised classification and labelling).
European Commission	All evaluation decisions made by ECHA must be unanimously supported by the Member States. If unanimous agreement cannot be reached, the European Commission has to prepare the draft decision to be taken according to the comitology procedure.

3.2.1. Dossier Evaluation

REACH References: Articles 41-42

Dossier evaluations are subdivided into Compliance Checks of registration dossiers (REACH Article 41) and Examination of Testing Proposals (REACH Article 40). Specific issue related to the

examination of testing proposals are considered under section 3.2.2 below, while the description below focussed on the general procedures for dossier evaluation.

Information in the registration dossiers is assessed by ECHA firstly with regards to completeness and secondly with regards to compliance with the legal requirements for submitting information for the relevant tonnage band. The Member State Competent Authorities takes part in the decision making process and are informed regarding outcomes at specific stages in the procedures.

ECHA may examine any registration dossier to verify if the information submitted by registrants is in compliance with the legal requirements. Compliance checks evaluate the substance identity description, the safety information in the dossier including the chemical safety report or specific parts of the dossier, for example the information related to the protection of human health. Following REACH, ECHA is obliged to check at least 5% of the registration dossiers per tonnage band.

Procedures for Dossier Evaluation

Dossier evaluation is undertaken by ECHA, specifically by a Dossier Evaluation Group of the Evaluation Unit. The group includes scientific experts on specific endpoints, substance identify and chemical profiling and legal advisors, and may request input from ECHA's Risk Management and Classification Units. A quality check is conducted by a separate Dossier Evaluation Group. The results of the evaluation are summarised in an outcome document, which is provided to the MSCAs and the Commission.

ECHA has published procedures on dossier evaluation that cover both the compliance check and the examination of testing procedures. Dossier evaluation is divided into four stages, presented in box 10 below.

Box 10: Procedures for dossier evaluation

- Pre-processing:
  - selecting dossiers and preparing them for evaluation;
  - assigning dossiers to Dossier Evaluation Group;
  - obtaining chemical identity and profiling information; and
  - where a testing proposal includes vertebrate testing, third parties are invited to submit information.
- Scientific and legal processing
  - Scientific and legal analysis of dossier and any information from third parties;
  - Quality check that the correct proceedings for scientific and legal dossier evaluation were followed;
  - Dossier Evaluation Group recommends appropriate options;
  - Evaluation Director decides upon final option, which may include:
    - Production of a Quality Observation Letter; or
    - a Draft Decision; or
    - a conclusion document (procedure is then terminated).
- Processing of the draft decision (see section 4.5.4 for further details)
- Follow-up
  - Registrant to deliver an updated dossier by a set deadline;
  - Monitor receipt of updated dossier and inform MSCAs;
  - Targeted re-evaluation of the dossier;
  - Internal review of how to proceed; and
  - Prepare and approve outcome document, notify to the MSCAs and the Commission.

To be selected for a compliance check, a dossier must have been registered successfully and stored in the production IUCLID database. Dossier selection for compliance check is either random or concern based (targeted). The concern driven selection combines the likelihood of non-compliance based on the characteristics of the dossier, with the likelihood that a non-compliance will impact on safe use of the substance. In the targeted compliance check, ECHA evaluates only a specific part of the registration dossier (e.g. either specific endpoints in IUCLID or in the CSR) based on a specified concern. This allows ECHA to target endpoints which are identified as relevant for the safe use of substances. A dossier may be updated at any point during the process by the registrant, in which case ECHA takes a decision on how to proceed.

Possible Outcomes of a Compliance Check

In follow up to a compliance check, ECHA may:

- Decide to take no action towards the registrant;
- Identify shortcomings and send a Quality Observation Letter (QOBL); or
- Decide to request additional information from the registrant, though a draft decision.

ECHA may combine issuing a draft decision with the sending of a QOBL. The options for the draft decision are:

- a decision accepting the testing proposal;

- a decision accepting the testing proposal with modifications of the testing conditions;
- a decision accepting or rejecting the testing proposal but requiring one or more additional tests;
- a decision rejecting the testing proposal; or
- a decision covering any of the three first options.

For a decision covering any of the first three options, where several proposals are submitted for the same substance and the same tests are proposed, an agreement as to who carries out the tests must be reached.

Progress so Far with Dossier Evaluation

To meet the 5 % target for compliance checks for the dossiers submitted for the 2010 deadline, up to 1000 dossiers will be selected by ECHA for compliance checks to be concluded by the end of 2013. ECHA has reported that so far, these initial checks have indicated that a significant proportion of dossiers have shortcomings and still need to be improved with further information.

Based on the annual ECHA reports on progress with evaluation from 2008-2011[32], table 8 provides an overview of the numbers of dossiers subject to compliance checks and the resulting actions. The outcome of 2011 compliance checks suggests that the quality of the evaluated dossiers is poor, since 72% of the checks were concluded with a final decision and another 13% with a QOBL. The annual evaluation reports provide recommendations to industry on how to improve their dossiers.

Table 8: Numbers of dossiers checked for compliance and resulting actions, 2008-2011

Year	Compliance checks completed	Decision requesting additional information	Recommendations through QOBL	No action
2008	1			
2009	14		7	7
2010	70	12	22	25
2011	146	105	19	12

The 2012 EEB report[33] on REACH implementation is critical of ECHA's efforts in evaluating dossiers, arguing that a substance could therefore be on the market for years without complying with the REACH information requirements and states that "by granting a registration number, the

[32] ECHA (2009-2012) Evaluation under REACH: Progress Reports, ECHA, Helsinki, Finland
[33] EEB and Client Earth (2012) identifying the bottlenecks in REACH: the role of ECHA in REACH's failing implementation, EEB and Client Earth, Brussels

marketing and use of a substance for which part of the basic hazard information and the risk management measures are missing, or clearly irrelevant, is in breach of the basic principle of REACH of "*no data, no market*"". The report notes that in many cases ECHA has restricted its own powers to require registrants to update their dossiers to requesting voluntary improvement of the dossiers through Quality Observation Letters. The report argues that ECHA should exercise the full powers provided to it by REACH and require companies to bring their dossiers into compliance through corrections. In addition, the report argues that in the interest of transparency ECHA should publish all draft decisions and Quality Observation Letters, or at least a list including the names of the substances and the identity of the companies. In addition, the report notes that many dossiers that were subject to a compliance check have not yet been made public.

Screening for Intermediates

In 2010, ECHA also screened 303 dossiers for on-site and transported intermediates to check if the registrations fulfilled the requirements to be considered as intermediates, or whether they should have been a normal registration. Eleven dossiers for transported isolated intermediates were compliance checked and in all cases, Article 36 letters were sent to the registrants requesting further information. In 2011 under the verification of intermediate status process, ECHA screen 400 dossiers and sent 40 letters to registrants requesting further information in order to verify the intermediate status. For 17 substances screening of the lead registrant dossier revealed concerns on the intermediate status and strictly controlled conditions. ECHA's Evaluation Progress Report for 2011[34] indicates that after analysing the information received ECHA will consider the need for further action on intermediates, where necessary in coordination with the enforcement authorities.

EEB has argued that chemicals manufacturers and importers are abusing the intermediate status in order to avoid the costs of complying with REACH registration, and calls on ECHA to require proof that substances comply with the definition of intermediate used in "strictly controlled conditions"[35] as clarified in ECHA's Guidance.

3.2.2. Examination of Testing Proposals

REACH References: Article 40

When testing is needed to fulfil information requirements in dossiers for ≥100-<1000 tonne (Annex IX) and ≥1000 tonne (Annex X) substances, the registrants are obliged to submit a proposal as part of

[34] ECHA (2012) Evaluation under REACH: Progress Report 2011, ECHA, Helsinki, Finland
[35] REACH Article 18(4) sets out a list of cumulative conditions that must be fulfilled in order to consider the substance as "strictly controlled"

the registration, describing the planned test. Following REACH Article 40, all such testing proposals have to be examined by ECHA prior to testing, aiming is to ensure that tests are tailored to the information needs and that unnecessary testing, especially involving the use of vertebrate animals, is avoided.

Title III of REACH addresses data sharing and the avoidance of unnecessary testing and states that testing on vertebrate animals is the last resort for obtaining missing information on a substance in order to meet the information requirements of REACH, and that the duplication of other tests should be limited. Requirements for sharing test data through Substance Information Exchange Forums are reviewed under section 3.1.10 on joint registration. Here we consider the procedures undertaken by ECHA to examine testing methods, as laid down in Article 40 of REACH.

Publication of Testing Proposals and Consultation of Third Parties

ECHA publishes every testing proposal that involves vertebrate animals on its website for endpoints specified in Annexes IX and X under REACH before the testing is carried out. Both current testing proposals can be viewed, and the outcomes of previous testing proposals that have already been subject to review. Following publication, third parties have 45 days to submit "*scientifically valid information and studies that address the relevant substance and hazard endpoint, relating to the testing proposal*" that could be taken into account by ECHA in preparing its decision on the testing proposal (REACH, Article 40 (2)). This consultation is not for the registrant but it is reserved exclusively for third parties, namely anybody not directly and individually concerned by the dossier. Other specific procedures are available for registrants to provide additional information or modify a testing proposal.

The online tables for current and previous consultations present the substances, hazard endpoints, deadlines for submitting information and links to the submission format for which ECHA is currently requesting input from third parties. Third parties use the links in the current testing proposals table on the website to submit information by the deadline indicated, preferably in English. Third parties must provide a non-confidential version of the information, which ECHA may make available to the public. There is also an opportunity to submit confidential details to support the non-confidential information, with a relevant justification.

Evaluation of Testing Procedures

Any scientifically valid information and studies that address the relevant substance and hazard endpoint, relating to the testing proposal, will be taken into account by ECHA in preparing its

decision. As mentioned above, ECHA has published procedures on dossier evaluation that cover both the compliance check and the examination of testing procedures.

Draft Decisions on Testing Proposals

Possible options for the draft decision include:

- Acceptance of the testing proposal;
- Acceptance of the testing proposal with modifications of the testing conditions;
- Acceptance or rejection of the testing proposal but requiring one or more additional tests; or
- Rejection of the testing proposal.

Once a draft decision has been issued, registrants will have 30 days to submit their comments. ECHA adopts the decision based on the proposal and the information submitted by third parties. When the decision covers any of the first three options and several test proposals have been submitted for the same substance, registrants must then agree on who carries out the test.

In the interest of transparency, ECHA publishes non-confidential versions of its dossier evaluation decisions on its website after they have been sent to the registrants to get their feedback on the non-confidential version it intends to publish. These decisions will also address ECHA's conclusions drawn from the information provided by third parties. Decisions can be searched by evaluation process, decision number, the date of the issue and optionally the search can be based on the substance name, EC or CAS number when these data are public.

Testing Proposals Checked by ECHA, 2009-2011

The number of testing proposals that have been check by ECHA are presented in table 8 below, showing a significant increase in 2011.

Table 8: Numbers of testing proposals checked by ECHA and resulting decisions, 2009-2011

Year	Examination of testing proposals	Final decisions	Final decisions requesting tests	Final decisions modifying tests	Draft decisions	Cases closed
2009	8	1				
2010	123	4	3	1	11	
2011	472	22	18	4	165	58

The 2012 ECHA report[36] on evaluation indicates that during 2011, ECHA focused most of its efforts on the examination of proposals to test substances on vertebrate animals. This was necessary, because all testing proposals on phase-in substances from the first registration deadline of 1 December 2010 for Annex IX and X information requirements have to be examined by 1 December 2012.

3.2.3. Substance Evaluation

REACH References: Articles 44-48

Substance evaluation aims at verifying whether a substance subject to registration under REACH constitutes a risk for human health or the environment. Substance evaluation can be useful for substances that trigger initial concerns for human health or the environment. Such substances will be prioritised for substance evaluation if it is expected that by requesting and receiving further information the initial concern will be confirmed, or eliminated so that a conclusion can be drawn as to whether further action is necessary. Prioritised substances are then listed in a dynamic list of substances to be evaluated, known as the Community Rolling Action Plan (CoRAP).

The legal requirements regarding substance evaluation are contained in Articles 44 to 48 of REACH. Key actors in substance evaluation include ECHA's Directorate E and Member State Committee, the European Commission (DG Enterprise and DG Environment), the Member State Competent Authorities and registrants of chemical substances under REACH. According to Article 45(1) of the REACH Regulation, ECHA is responsible for coordinating the substance evaluation process and ensuring that substances on the CoRAP are evaluated. ECHA relies on the Competent Authorities of the Member States to undertaken evaluations. ECHA has developed a useful fact sheet on substance evaluation, available on their website.

Each **substance evaluation is undertaken by a Member State competent authority**[37], either acting alone or in cooperation with another Member State competent authority. The substance evaluation process may result in a **decision** to request additional information from the registrants or from the downstream users of the substances in order to clarify the suspected risk. Alternatively, it may be concluded that the substance does not constitute a risk and that no further data is needed. The evaluation may conclude that the risks are sufficiently under control with the measures already in place, or it may ultimately lead to the proposal of EU-wide risk management measures such as restrictions, identification of substances of very high concern, harmonised classification, or indeed other actions outside the scope of REACH.

[36] ECHA (2012) Evaluation under REACH: Progress Report, ECHA, Helsinki
[37] As defined under Article 45(2) of REACH

In implementing substance valuation, ECHA has held three workshops to establish a common approach and review lessons learned. Workshops were held in October 2010, May 2011 and June 2012, with proceedings for the latter two workshops available on the ECHA website.

Key steps in substance evaluation include the selection of substances for evaluation; their inclusion in the CoRAP; the evaluation process and possible follow up actions. These steps are reviewed below, together with a description of the administrative procedures for their implementation and the roles of key actors.

Criteria to Prioritise Substances for Substance Evaluation

Substances to be evaluated are identified by ECHA, in cooperation with the EU Member States, on the basis of risk-based criteria, or in the case of Member States, risk-based grounds of concern founded on national priorities. The **selection criteria** used to prioritise substances for evaluation are laid down in Article 44(1) of the REACH Regulation and are presented in box 11 below.

Box 11: Selection criteria under REACH Article 44 (1) with which to prioritise substances for substance evaluation

Article 44(1) of the REACH Regulation provides the general criteria for substances to be selected for substance evaluation. Furthermore, the legal text defines that prioritisation shall be on a risk-based approach.
Article 44(1) reads:
"(...) The criteria shall consider:
(a) hazard information, for instance structural similarity of the substance with known substances of concern or with substances which are persistent and liable to bio-accumulate, suggesting that the substance or one or more of its transformation products has properties of concern or is persistent and liable to bio-accumulate;
(b) exposure information;
(c) tonnage, including aggregated tonnage from the registrations submitted by several registrants."

The above-mentioned general selection criteria in the legal text cover hazard information (intrinsic properties), exposure information and tonnage of substances, including the aggregated tonnage of the same substance from multiple registrations. As such, the hazard and exposure related criteria are not used independently, but in combination to provide a risk-based approach. For example, a hazardous substance with controlled exposure can be of less priority than a less hazardous substance with widespread exposure.

It is expected that over time on the basis of experience, the criteria will be further developed and refined, with the possibility of a shift towards a different emphasis on certain groups of substances, hazard properties or exposure patterns. This is also foreseen by Article 44(1) as a task of ECHA in cooperation with the Member States.

In 2011, the general criteria were further developed by ECHA in cooperation with the Member States to give the "2011 CoRAP selection criteria", with progress summarised in a document published on the ECHA website. For this first set of the criteria ECHA consulted the Member States in two workshops organised by ECHA, in ECHA Member State Committee meetings and through a written procedure.[38]

Community Rolling Action Plan

The selected substances are listed by ECHA in the Community Rolling Action Plan (CoRAP), available on the ECHA website. The CoRAP includes:

- Names of the substances to be evaluated;
- An indication of the initial concern about the substances;
- Names of the Member States responsible for the evaluation of each substance; and
- The year of evaluation.

In addition, the ECHA website provides details on the status of evaluations of individual substances.

The CoRAP is a dynamic plan that indicates substances for evaluation by the Member States over the next three years, and is updated each year in March in order to respond to the regulatory need for substance evaluation. The rolling nature of the plan means that the list of prioritised substances included for evaluation during the second and the third year may change when the plan is annually updated.

The procedures for establishing updates of the CoRAP are laid down in a document published on the ECHA website, and provided in detail in box 13 below. In brief, ECHA compiles the draft CoRAP and submits it to the Member State Committee for their opinion in March of each year. The Committee then reviews ECHA's draft CoRAP in the light of the selection criteria used to prioritise substances for substance evaluation, and any further information provided upon each substance suggested for evaluation. Following specific working procedures, the Member State Committee appoints a rapporteur, a co-rapporteur and a working group (when needed) to develop an opinion on the draft CoRAP. The draft opinion is then finalised and adopted by the MSC. This opinion is the basis for ECHA to adopt the final CoRAP update. The opinions of the Member State Committee are available online on the ECHA website.

[38] At a workshop on prioritisation criteria held in October 2010, ECHA presented a proposal for criteria to be used for the establishment of the first CoRAP in accordance with REACH Art. 44. The initial ECHA proposal was amended according to the recommendations made during the October 2010 workshop and based on written comments provided by the Member States. At a second workshop in May 2011, participants supported the use of the refined criteria. Following the workshop, the selection criteria were adopted as a decision by ECHA's Executive Director and published on the ECHA website.

In October/November of each year, ECHA has committed to submitting a draft update[39] on the annual CoRAP to the Member States and to the Member State Committee for opinion, forming the basis for the formal update in March of the following year. The draft is published on the ECHA website, with the aim of informing stakeholders of progress made with substance evaluation process and helping the involved registrants to communicate with the relevant evaluating Member State. Finally, Member States may also make proposals to add substances to the CoRAP outside of the annual updates. The MSC provides opinions on such proposals.

Box 12: Steps for updating the CoRAP

Step 1: Identification of possible CoRAP candidate substances from the pool of registered substances by ECHA and the Member States

Step 1a – Receipt of MSCAs' notifications of candidate CoRAP substances

Based on Articles 44(1) and 45(5), at any time, the evaluating MSCAs can propose to ECHA, new substances as CoRAP candidates, through notification via a web form attaching a detailed justification for the selection by completing the template "Justification for the selection of a candidate CoRAP substance". If the notification from the MSCA is based on Article 45(5) and is indicated by the MSCA as an urgent case, the procedure continues with step 4. If the notification from the MSCA is based on Article 45(5), but is not indicated as an urgent case, it is processed together with the normal annual update system described in step 2 and onwards. ECHA puts all notified substances in the preliminary draft CoRAP and allocates the substances provisionally to the notifying Member States.

Step 1b – Preparation of a SEV pre-candidate list (in collaboration with MSCA and based on IT tools and Manual screening)

ECHA asks at least annually, from MSCAs, how many substances in the CoRAP they want to evaluate each year. SEVT in cooperation with the MSCAs and Directorates C and D, is responsible for identifying substances as potential candidates for substance evaluation. Substances can either be identified during the dossier evaluation processes or by selection through IT-screening of the IUCLID database based on the application of the CoRAP selection/prioritisation criteria. The results of the IT-screening are verified by manual screening of the potential dossiers by volunteering Member States and SEVT. The body performing the screening prepares a draft justification document for each substance that is considered to be a potential candidate for the CoRAP update. Later the ownership of the justification document is taken by the Member State that is designated as the eMSCA (see step 3). For each potential CoRAP candidate substance information is also collected to find out if a substance is subject to other ongoing or finished (ECHA/MS/other international) processes.

Step 2: Preparation of the preliminary draft (updated) CoRAP, and submission to MSCAs for comments

SEVT prepares a preliminary draft CoRAP containing substances identified in step 1. SEVT checks from the justification documents that all substances included in the preliminary draft CoRAP fulfil the prioritised selection criteria, or other equivalent risk based criteria (Article 45(5)), and that there are grounds for considering that the substances may constitute a risk to the human health or the environment. SEVT also analyses the regulatory efficiency of including the substance in the substance evaluation process. The information collected in step 1b and information in the justification documents help to assess if, despite of other ongoing or ended processes, it can be anticipated that substance evaluation provides added value, e.g. by potentially making a request for further information for the substance(s), instead of directly proposing risk management measures. If more candidate substances are available than can potentially be evaluated by the Member States, SEVT will consider which substances to propose for the current CoRAP update and which ones for the next year's update. This decision is based on the initial grounds of concern and interests from MSCAs to evaluate the substances. SEVT may tentatively propose allocation of the substances to eMSCA on the basis of their direct notifications and interests indicated by the Member States during or after the manual screening step taking also into account plans of the Member State to assess certain number of substances per year. ECHA (Dir C) performs a substance identity screening on the candidate substances to find out if a targeted compliance check on an unclear substance identity should be started. SEVT submits the preliminary draft CoRAP to the MSCAs for comments and expression of interest for evaluating the substances.

Step 3: Receipt of comments and expressions of interest by the MSCAs to evaluate substances

MSCAs shall confirm in writing or in a meeting with ECHA how they agree to distribute the candidate substances among themselves for evaluation. In cases where two or more Member States have expressed an interest in evaluating the same substance and they cannot agree on who should evaluate the substance, ECHA secretariat refers the matter to MSC, see step 6. In

[39] REACH requires ECHA to submit a draft of the update to the Member States by 28 February each year. However, ECHA has stated that it plans to adopt the updated CoRAP by the end of February and submit the relevant draft in October/November of the previous year.

all cases where the MSCAs express commitment for a substance, they take ownership of the justification document prepared so far. If relevant, MSCAs may review and update the justification document. If no MSCA is volunteering to evaluate a substance on the preliminary list, the substance could potentially be included in update CoRAP for the next year.

Step 4 – Preparation and submission of the draft (updated) CoRAP to the MSCAs and referral to the MSC for preparation of opinion. Publication on the ECHA web
A draft for an annual update shall be prepared at the latest by the end of February each year (Article 44(2)), but, if possible, ECHA will try to prepare the draft CoRAP well in advance to allow for adoption of updated CoRAP by end March each year. SEVT prepares and submits the draft CoRAP to the MSCAs. At the same time, the draft CoRAP is also referred to the Member State Committee for preparation of its opinion. In the draft CoRAP, each substance is allocated to one Member State. If a substance(s) has been referred to MSC to seek agreement on eMSCA, this is also indicated in the draft CoRAP (cf. step 6). The preparation of MSC opinion on whether the substances in the draft CoRAP should be included in the CoRAP, can go in parallel with step 6, when this step is needed, regarding who shall evaluate the agreed substances. If an urgent Article 45(5) notification is submitted, ECHA informs the other MSCAs about the proposal, and refers the case to the MSC as soon as possible. When the draft CoRAP is sent to the MSCA and MSC, the public version of this draft is published on ECHA's web site to inform the stakeholders of the intention to include the listed substances in the CoRAP.

Step 5 Management of Service contracts with the evaluating MSCAs
Provided that there is no disagreement of the evaluating Member State, the Evaluation Directorate and the Finance Unit, prepare service contracts, between ECHA and the evaluating MSCA and/or Mandated Institution. The purpose of the contract is to transfer a proportion of the fees collected by ECHA, as partial compensation for the provision of substance evaluation services, for the substances listed for evaluation within the first year covered by the draft CoRAP. The aim is that ECHA and evaluating Member States have signed the service contracts before the final adoption of the CoRAP in step 7. Director of Evaluation signs the service contacts on behalf of ECHA. Then the contracts are sent to Member State Competent Authorities and, where applicable, Mandated Institution(s) for signature. After receiving the signed service contracts from the evaluating Member States, SEVT confirms that the substances in the draft CoRAP are also in the final CoRAP. If a substance is left out from the final CoRAP, the related service contract becomes obsolete. The documents are filed and for the final CoRAP substances the appropriate transfer of funds are processed further in the course of the evaluation upon receipt of an invoice or comparable note from the evaluating Member State.

Step 6 – Referral to MSC to seek agreement on evaluating MSCA(s)
In cases where two or more Member States express an interest in evaluating the same substance and they cannot agree on who should be the competent authority, ECHA secretariat (MSC-Chair) refers the substances with disagreement to the Member State Committee, and the issue is to be solved according to Article 45(3). If MSC reaches unanimous agreement in 60 days, the MS authorities concerned become the responsible competent authorities for evaluation of substances, according to the agreement of MSC.

Step 6a – Referral to the Commission (Article 45(3))
If the MSC fails to reach a unanimous agreement, ECHA secretariat (Director of Regulatory Affairs) shall submit the conflicting opinions to the Commission, which shall decide in a Committee procedure which authority shall be the competent authority for the evaluation of this/these substance(s).

Step 7 - Adoption and publication of the final (updated) CoRAP
ECHA adopts the CoRAP update on the basis of the results of steps 4, 6 and 6a. The aimed timeline for adoption is annually before 31 March. As soon as the CoRAP is adopted, it is published on ECHA website. In case a Commission decision is needed, according to step 6a, the substance will be moved to a later CoRAP update as timing of the decision making in the Commission may not be in alignment with the timetable for adoption of the CoRAP update in question. A justification document for the selection of the substance is also published on ECHA website (starting from the CoRAP update in 2013). From the publication date of the CoRAP, the designated MSCAs have 12 months to carry out the evaluation of the substances listed in the first year of the CoRAP.

Source: Adapted from ECHA, 2012, PRO-0022.01 Substance Evaluation-Establishing updates of the Community Rolling Action Plan (CoRAP)

The first CoRAP was published in February 2012[40], and updated in October 2012[41], to include 116 substances, tentatively divided for evaluation in years 2013, 2014 and 2015. In 2012, Member States evaluated 36 substances and any draft decisions for asking further information had to be submitted to ECHA by 28 February 2013 at the latest.

[40] ECHA (2012) Community Rolling Action Plan, 29 February 2012, ECHA, Helsinki
[41] ECHA (2012) Community Rolling Action Plan update for years 2013-2015, 23 October 2012, ECHA, Helsinki

The annual update of the CoRAP for 2013-2015 contains 115 substances of which 62 are newly allocated and 53 come from the 2012 CoRAP. The Member States will evaluate those substances under the substance evaluation process of the REACH Regulation in 2013, 2014, and 2015. In 2013, there are 46 substances subject to evaluation, and for those cases the deadline for submitting any draft decisions to ECHA is 19 March 2014. In light of the capacity of the Member States for undertaking evaluations, ECHA foresees on average 50 substance evaluations carried out per year under the CoRAP.

The evaluation aims to clarify whether the manufacture and/or use of these substances could pose a risk to human health or the environment. In many cases, these initial concerns are related to potential persistency, bioaccumulation and toxicity (PBT), endocrine disruption, or carcinogenicity, mutagenicity and toxicity to reproduction (CMR); in combination with wide dispersive use or consumer uses. In general, the uses of these substances cover a range of areas and do not focus on any particular industrial, professional or consumer uses. The CoRAP includes a short description of the initial concern for each substance. Member States may focus their assessment on the area of initial concern, but this does not limit the scope of evaluation.

Evaluation Process

For each substance, a Member State is designated in the CoRAP as responsible for performing the evaluation. During the selection process, Member States may express an interest in undertaking the evaluation of a specific substance. In cases where two or more Member States have expressed an interest in evaluating the same substance, the Member States Committee seeks to find an agreement. In some cases, two Member States may jointly evaluation a substance, with one taking the lead. The contact information of the Member State competent authorities responsible for each substances are also been provided for each substance to facilitate interaction between the registrants and the evaluating Member State. ECHA encourages the Member States and registrants to communicate with each other in order to clarify any concerns related to the substances.

Following Article 45 of REACH, update the respective Member States have twelve months from publication of the CoRAP to evaluate substances and, where justified, to prepare a draft decision requesting the registrants to submit further information to clarify any possible risk. The Member State assesses all registration dossiers specific to that substance in order to take into account the combined exposure. Other available information is also considered. The initial reason for selecting a substance for the CoRAP does not limit the scope of the evaluation. During the evaluation, the Member State may identify other concerns that need clarification in order to conclude whether a substance is of

concern or not. However, the Member State may choose to focus the evaluation more upon certain aspects of the substance.

The substance evaluation process is described in an ECHA document that outlines procedures for the coordination of Substance Evaluation by MSCAs, the processing of draft decisions and the follow-up to substance evaluation. Procedures are to be reviewed in September 2013. The substance evaluation process can be divided into three stages, summarised below.

1. Coordination of Substance Evaluation

The evaluating MSCA shall submit to ECHA a SEV IUCLID dossier that contains a draft decision (if necessary), a (interim) substance evaluation report and a time recording sheet.

If received at least two months before the end of the 12-month evaluation period from the evaluating Member State, ECHA aims at performing a scientific and legal consistency screening on the draft decision to ensure that the substance evaluation is based on sound and consistent judgement, and that requests for further information are consistent, scientifically robust and legally accurate.

2. Processing of substance evaluation draft decisions

ECHA is responsible for notifying any draft decision issued by the evaluating MSCA to the relevant Registrant(s). The final decision shall be taken following involvement of the Registrant(s), consultation of the other MSCAs and ECHA, and possibly the MSC and the Commission following the procedure described by Articles 50 and 52.

3. Evaluation of obtained information

At this stage an updated dossier, referring to the initial substance evaluation decision with a set deadline, is expected from the Registrant(s). The updated dossier will be re-evaluated by the responsible MSCA that shall inform ECHA of its conclusions concerning the suitability and application of the information obtained. Subsequently, ECHA shall inform the Commission, the Registrant(s) and other MSCAs of the conclusions in a timely manner.

Key steps in the three stages of substance evaluation are described in boxes 14, 15 and 16 below. Further guidance on the technical aspects of the evaluation process is provided in the 2007 ECHA "Guidance for the Implementation of REACH: Guidance on Dossier and Substance Evaluation".

Box 13: Stage 1 of Substance Evaluation: Coordination of Substance Evaluation

Step 1 – Preparation and submission to evaluating MSCAs of aggregated IUCLID files for each substance to be evaluated
Following the establishment and respective updates of the CoRAP, ECHA will generate and submit via REACH-IT to the evaluating MSCAs an aggregated IUCLID file for each substance to be evaluated containing all information available in the latest version of registration dossiers for that substance. This will take place once at the beginning of the process. Upon request, ECHA may provide information on other substances relevant for the evaluation process to the evaluating MSCA.

Step 2 – Receipt of substance evaluation IUCLID dossiers submitted by the evaluating MSCAs
According to Article 45 the evaluating MSCAs have 12 months from the publication of the (updated) CoRAP to either: a) prepare a draft decision requesting further information or b) conclude that no further information to clarify the suspected initial concern is needed and notify ECHA accordingly. ECHA receives the results of the evaluation via REACH-IT or according to a temporary submission procedure, in the form of a SEV IUCLID dossier that contains: the technical dossier, a (interim) substance evaluation report and, if appropriate, a draft decision. The submission date, as indicated in REACH-IT (or during the temporary submission procedure), will be the reference date used for the 12-month deadline starting from the CoRAP publication.

Step 3 - Scientific and legal consistency screening (if requested) of outgoing documents
If received at least two months before the end of the 12-months evaluation period from the evaluating Member State, ECHA aims at performing a scientific and legal consistency screening of the draft decision on the basis of the interim substance evaluation report to ensure that the substance evaluation is based upon sound and consistent judgement and that requests for further information are consistent, scientifically robust and legally accurate. At such time, the Substance Manager, after coordination with Legal Advisors and SEV team, may suggest changes to the draft decision prepared by the evaluating MSCA. The SEV Team invites the MSCA to consider the suggestions made by ECHA, to modify the draft decision if appropriate and submit, via an updated SEV IUCLID dossier, the revised draft decision for further processing still within the 12-month evaluation period. When the conclusion of a substance evaluation is that no further information to clarify the concern is necessary, i.e. the evaluating MSCA is not preparing a draft decision on substance evaluation, the procedure continues with step 4. When the outcome of a substance evaluation is that an information request to clarify the suspected concern is deemed necessary, i.e. the evaluating MSCA is preparing a draft decision on substance evaluation, the procedure continues with step 5.

Step 4 – Information to the Registrant(s), MSCAs and Commission that the evaluation is completed
A conclusion document to inform the Registrant(s), MSCAs and Commission that the evaluation is completed and no further information to clarify the concern is needed shall be prepared by the evaluating MSCA and submitted to ECHA. ECHA, without undue delay, will share this information with the Commission, the Registrant(s) and the Competent Authorities of the other Member States. At the same time, or shortly after, the non-confidential version of the SEV report prepared by the evaluating MSCA will be published on the ECHA website. In this case the procedure is terminated.

Step 5 – Sign the notification letter to be sent with the draft decision to the Registrant(s)
When the outcome of a substance evaluation is a conclusion that further information from the Registrant(s) is needed in order to clarify the concern, a draft decision shall be prepared by the evaluating MSCA within the 12-month evaluation period. At this point of time ECHA is not modifying the content of the draft decision. The Director of Evaluation signs the notification letter accompanying the draft decision issued by the evaluating MSCA. In this case the procedure continues to step 6.

Box 14: Stage 2 of Substance Evaluation: Processing of substance evaluation draft decision

Step 6 – Notification of the draft decision to the Registrant(s)
ECHA notifies via REACH-IT without undue delay3 the draft decision to the Registrant(s) of the substance. The Registrant(s) is/are informed in the notification letter of their right to comment on the draft decision within 30 calendar days of receipt of the draft decision.

Step 7 – Information to the evaluating MSCA of the Registrant(s) comments
ECHA informs, via CIRCABC, the evaluating MSCA of any comments submitted by the Registrant(s) without undue delay. The evaluating MSCA shall take the comments of the Registrant(s) into account and record a response to each comment. The evaluating MSCA shall decide whether the draft decision needs to be amended on the basis of the comments/additional information provided by the Registrant(s) (Article 50(1)). Comments should be reflected in an appropriate manner in the draft decision or its supporting documentation. If no comments are received from the Registrant(s) within the 30-day commenting period, the draft decision is not amended by the evaluating MSCA. The registrant(s) may thus receive the draft decision after the end of the 12-month evaluation period.

Step 8 – Receipt of the (amended) draft decision.
ECHA and other MSCAs receive notification of the (amended) draft decision from the evaluating MSCA (Article 52(1)). The draft decision and additional documents including the original comments from the Registrant(s) and the responses provided by the evaluating MSCAs to these comments shall also be available via CIRCABC. Subsequently, ECHA (and the other MSCAs) may submit proposals for amendment to the draft decision within 30 calendar days starting from the date they were notified of the (amended) draft decision (Article 51(2)). ECHA proposals for amendment are prepared by the Substance Manager, signed by the Director of Evaluation and submitted to the evaluating MSCA via CIRCABC. If the evaluating MSCA does not receive proposals for amendment, the procedure continues in step 12b. If the evaluating MSCA receives proposals for amendment, the procedure

continues in step 9. In such cases, a response to each proposal for amendment shall be provided by the evaluating MSCA. The evaluating MSCA may modify the draft decision and provide the amended draft decision to ECHA (Article 51(4)), or communicate to ECHA that it does not consider that there are sufficient grounds to amend the draft decision, within 13 days from the deadline for ECHA/other MSCAs to make proposals for amendment.

Step 9 - Referral to the Member State Committee
MSC secretariat on behalf of MSC receives a notification from the evaluating Member State that because of proposals for amendment the draft decision is referred to the MSC. MSC-S refers the (amended) draft decision, together with any comments and proposed amendments, to MSC within 15 calendar days of the end of the 30-day commenting period in step 8. Within 60 days of referral, MSC shall seek agreement on the draft decision (Article 51(6)).

Step 10 – Communication of proposals for amendments (if any) to the Registrant(s)
ECHA communicates to the Registrant(s) after the end of the 30-day commenting period in step 8 the draft decision as notified to the other MSCAs and ECHA, the received proposals for amendment and a cover letter signed by the Substance Manager. The cover letter notifies the Registrant(s) of their right to comment on the proposals for amendment within a 30-day of receipt (Article 51(5)).

Step 11 – Forwarding of the Registrant(s) comments on the proposals for amendment to the evaluating MSCA
ECHA informs the evaluating MSCA and the MSC of the Registrant's comments, if any, on the proposals for amendment. According to Article 51(5), the Member State Committee shall take any comments received into account and record each relevant comment in the supporting documentation.
Step 12a - Referral to the Commission
When MSC fails to reach unanimous agreement, MSC-S refers the case to the Commission. Such a letter with accompanying documents is signed by the Director of Regulatory Affairs. ECHA also informs the Registrant that the case has been referred to the Commission.
Step 12b – Adoption of the final decision
If no proposals for amendment to the draft decision are submitted by ECHA/other MSCAs or if MSC reached unanimous agreement, the (amended) draft decision is adopted by ECHA and it becomes the final decision (Articles 51(3) and 51(6) respectively).

Step 13 – Notification of the final decision to the Registrant(s)
The final decision signed by the Director of the Regulatory Affairs is notified to the Registrant(s) by ECHA. ECHA informs also the other MSCAs of the final decision. The final decision will request further information to be provided by the Registrant(s) in the form of an updated dossier by a specified deadline. ECHA publishes on the ECHA website final decisions without confidential business information.
Step 13a – Decision on who shall perform studies
When Registrant(s) are required to perform a test as a result of a final decision, according to Article 53 those Registrant(s) shall make every effort to reach an agreement as to who is to carry it out on behalf of the other registrants and to inform the Agency accordingly within 90 days. If ECHA is not informed of an agreement of the registrants within 90 days of taking the final decision, it shall designate one of the registrants to perform the test(s) on behalf of all of them and issue a decision on this matter. Also in cases where registrants indicate who will perform the test(s), ECHA will confirm this agreement by issuing a decision on who shall perform the test(s).This decision shall be signed by the Director of Regulatory Affairs.

Box 15: Stage 3 of Substance Evaluation: Evaluation of obtained information

The Registrant(s) shall, within the timelines specified in the decision, submit the requested information to ECHA by updating the registration dossier(s) with that new data. If no Registrant(s) update addressing the requested information is received within the timeline specified in the decision, the procedure continues at step 17. If a Registrant(s) update addressing the requested information is received within the timeline specified in the decision, the procedure continues at step 14.

Step 14 – Communication of Registrant(s) update addressing the requested information to the evaluating MSCA
After receiving Registrant(s) update addressing the requested information, ECHA informs via CIRCABC the evaluating MSCA of the updated dossier(s) without undue delay. [From the date of receipt the evaluating MSCA has 12 months to evaluate the new information (Article 46(3)).

Step 15 – Receipt of updated SEV IUCLID dossier submitted by the evaluating MSCA
ECHA receives via REACH-IT, after the evaluating MSCA has carried out the evaluation of new obtained information, an updated SEV IUCLID dossier including a revised substance evaluation report and, if applicable, a new draft decision. Without undue delay, ECHA takes note of the conclusions from this new evaluation. If the evaluating MSCA considers that the information submitted meets the requests in the decision and no further information is needed to clarify the concern, the process can be finalised by continuing to step 16. In case no or only part of the requested information is provided in the Registrant(s) update, ECHA considers sending a letter to the evaluating MSCA (with the Registrant and the other MSCAs in copy). In such case, continue to step 17. If the evaluating MSCA considers that further information is still needed to clarify the concern, due to a change of circumstances or acquired knowledge, the SEV IUCLID dossier shall include a new draft decision and the process is repeated from step 3 under the same service contract as signed before between ECHA and the evaluating MSCA.

Step 16 – Notification of conclusions to the Registrant(s)/other MSCAs/Commission
If the evaluating MSCA concludes that the information is sufficient to clarify the concern, it shall notify ECHA accordingly, and provide an (updated) SEV IUCLID dossier with a final substance evaluation report and a conclusion document. Once the substance evaluation has been completed, the evaluating MSCA shall in accordance with Article 48 consider how to use the information obtained (e.g. for the purpose of authorisation, restriction, harmonised classification and labelling) and inform ECHA of its conclusions. ECHA will share this information with the Commission, the Registrant(s) and the Competent Authorities of the other Member States. At the same time, the SEV report prepared by the evaluating MSCA will be published on the ECHA website.

Step 17 – Informing that no update addressing the requested information was received after the deadline
When no update from the Registrant(s) is received within the timeline specified in the decision, ECHA sends a letter of failure to comply with the SEV decision to the evaluating MSCA (with the Registrant and the other MSCAs in copy) informing that Registrant(s) are in breach of their obligations following from the SEV decision and informs the evaluating MSCA and Forum, which shall consider making recommendations for enforcement actions towards the Registrant(s). The notification of a similar letter can be sent to the evaluating MSCA (with the Registrant and the other MSCAs in copy) also in the case where only part of the requested information is provided in the Registrant(s) update. These letters are signed by Director of Evaluation.

Source: Adapted from ECHA, 2012, PRO-0023.01, Substance Evaluation

Possible Outcomes of Substance Evaluation

The outcome of substance evaluation may be:

- A decision requesting further information from the Registrant(s), in order to clarify the concern. This request can address intrinsic properties or exposure and can go beyond the standard information requirements listed in Annexes VII – X of the REACH Regulation.

Or

- If the evaluation is finalised without a draft decision (implying that no further information is needed), the evaluating Member State also needs to notify ECHA of that outcome within 12 months. The notification should include a report on the analysis performed and the conclusions of the evaluation.

Role of the Registrants

Registrants of substances included in the CoRAP can actively prepare and participate in the substance evaluation process. An ECHA publication entitled "Substance evaluation under REACH: Tips for registrants and downstream users" provides practical advice for registrants who hold a registration for a substance included in the CoRAP and for downstream users of such substances. Keys steps that the registrant may undertake in response to the inclusion of their substance in the CoRAP are presented in box 17 below.

Box 16: Steps for registrants of substances prioritised for evaluation in the CoRAP to follow

Step 1: Check substances in the updated CoRAP

Step 2: Prepare for participation in substance evaluation

Make early contact with the evaluating Member State: Registrants should contact the evaluating Member State competent authority (eMSCA) early in the process to clarify the initial concern identified.

Coordinate with other registrants: There may be many registrants of a substance on the CoRAP so it is important that they start communicating with each other as soon as possible to coordinate involvement in the substance evaluation.

Update the registration dossier early, if needed: A registration dossier should always reflect all available and relevant information. ECHA recommends that registrants discuss any planned dossier updates which are relevant for substance evaluation with the eMSCA, especially for the first year substances.

Registrants should discuss any planned testing with the evaluating Member State: Registrants should inform the eMSCA of any need for further testing for first year substances.

Downstream users should share any relevant information: Downstream users may hold useful information relevant to the concern, such as exposure information. They should provide the information to the relevant registrant for them to include in their registration dossier or update their own downstream user report. Information should be shared as early as possible, even when the draft CoRAP is published.

Communicating with the evaluating Member State: Member States have agreed a common approach on interaction with registrants during substance evaluation. If the dialogue has not already started, the eMSCA will usually contact the lead registrant and offer the opportunity to meet to discuss technical issues related to substance evaluation. Registrants should consider nominating one representative for interacting with the evaluating Member State. For example, the lead registrant may take on this role, with agreement between registrants on how to deal with confidentiality and competition issues.

Step 3: Coordinate comments in the formal decision-making process

Coordinated response: Draft decisions requesting further information are normally addressed to all registrants of the substance, but in some specific cases, the decision may be addressed to only certain registrants or to certain downstream users of the substance. Addressees have 30 days to comment on a substance evaluation draft decision and then 30 days to comment on any subsequent proposals for amendment from the authorities and/or ECHA. If proposals for amendment are received, the draft decision is referred to the Member State Committee for agreement. Otherwise, the draft decision becomes a final decision and is issued by ECHA.

Comment on the draft decision: Instructions on how to submit comments on the draft decision are provided within the notification letter accompanying the draft decision. If a registrant has data that may change or make the request in the draft decision obsolete, this should be communicated in a dossier update with the new information within the first 30 days consultation period. The eMSCA will consider all comments and may consequently modify the draft decision. Comments submitted after the deadlines will not be considered.

Representation at the Member State Committee (MSC): The MSC will only discuss those aspects of the draft decision for which proposals for amendment have been submitted by the authorities. If a case is referred to the MSC for agreement, there may be an opportunity for registrants to send a representative to the Committee meeting. For organisational reasons, the number of participants in the meeting is limited. Normally, ECHA would invite the coordinator who has submitted comments.

Step 4: Provide the information requested

Following a final decision taken by ECHA as an outcome of the substance evaluation, the addressees of the decision must decide who is best placed to obtain the information requested.

Agree within 90 days of receipt of the decision on who will perform requested studies

If ECHA is not informed of such an agreement, it will designate one of the addressees to perform the study on behalf of all of them.

Agree on cost- and data- sharing

The registrant (or downstream user) who performs the test should provide the others concerned with a copy of the full study report.

Update registration dossiers: Registrants should update their registration dossiers with the requested information by the deadline indicated in the final decision.

Step 5: Follow the conclusion of substance evaluation

When information requested in a final decision is submitted to ECHA, the eMSCA will examine it within 12 months. If needed, the eMSCA may initiate a further request for information by a second decision. The advice provided under Step 3 above would again apply.

Right to appeal: All addressees of a final decision issued under substance evaluation have the right to appeal.

Source: Adapted from ECHA, Substance evaluation under REACH: Tips for registrants and downstream users

Follow up to Substance Evaluation

In many cases, substance evaluation is expected to result in a request for further information from the registrants of the substance. The registrants must submit the required information within the deadline specified in the final decision (see section 3.2.5 below).

Once the newly-provided information has been assessed, the responsible Member State completes the evaluation and considers whether and how to use the information obtained for the purposes of Community level risk management measures. The evaluating Member State may, if needed, draft a new decision to request more information within a further 12 months if the concern is still not clarified or new information raises further concerns. The conclusion can also be that the risks are sufficiently under control with the measures already in place. ECHA informs the Commission, the registrants and the other Member States about the conclusions.

If the evaluating Member State considers that the use of the substance poses a risk, it may then proceed with **follow-up actions** to substance evaluation. The following options may address the concern:

- A proposal for harmonised classification and labelling for carcinogenic, mutagenic or toxic to reproductions, respiratory sensitisers or other effects; or
- A proposal to identify the substance as a substance of very high concern (SVHC) (see section 4.6 below); or
- A proposal to restrict the substance; or
- Actions outside the scope of REACH such as a proposal for EU-wide occupational exposure limits, national measures or voluntary industry actions.

Alternatively, the Member State may choose to pursue risk management actions at the national level.

Funding Substance Evaluation

Substance evaluation is funding partly by the Member States, and partly by the registration fees collected by ECHA from industry. In terms of administrative procedures, ECHA's Evaluation Directorate and Finance Unit prepare service contracts between ECHA and the evaluating MSCA and/or Mandated Institution, on the basis of substances listed in the draft CoRAP. The contract enable a transfer of a proportion of the fees collected by ECHA, as partial compensation for the provision of substance evaluation services.

The Director of Evaluation signs the service contacts on behalf of ECHA, before they are sent to Member State Competent Authorities and, where applicable, Mandated Institution(s) for signature. ECHA and evaluating Member States aim to sign the service contracts prior to the final adoption of the CoRAP. After receiving the signed service contracts from the evaluating Member States, SEVT confirms that the substances in the draft CoRAP are also in the final CoRAP. If a substance is left out from the final CoRAP, the related service contract becomes obsolete. The documents are filed and for the final CoRAP substances, transfer of funds takes place during the course of the evaluation, upon receipt of an invoice or comparable note from the evaluating Member State.

3.2.4. Decision-Making Procedure for Generating Draft Decisions

REACH Reference: Articles 51 and 52

The decision-making procedure for reviewing draft decisions and ultimately generating decisions under the evaluation process are essentially common for dossier and substance evaluation and are set out under Articles 51 and 52 of REACH respectively, and it is therefore useful to summarise them here. The point of departure differs, in that Draft decisions are generated by ECHA for dossier evaluation and by the evaluating Member State Competent Authority for substance evaluation. Draft decisions are notified to the registrant, who may provide comments, as well as to the other Member States and ECHA, who may propose amendments. If proposals for amendments are made, the Member State Committee will also be involved before the decision becomes effective. The MSC seeks unanimous agreement on Member State draft decisions on substance evaluation when amendments are proposed on them by other Member States or ECHA, taking into account the comments of the registrants. Once agreed by the MSC, ECHA finalises the decision and provides it to the registrant. If there is no unanimity at the Member State Committee, the final decision is taken by the European Commission. Key steps in the process are outlined in box 18 below.

Box 17: Key steps in decision-making procedures for generating draft decisions

- First, the draft decision is sent to the registrant(s) for comments, within a 30 day time limit. Registrants can also update their dossiers with information relevant to the concern or fill the data gaps detailed within the draft decision
- The evaluating Member State or ECHA will take the comments and updated dossiers into account and may amend the draft decision accordingly. It may also consider that no additional information is required and the evaluation process may finish.
- Then the updated draft decision and comments are sent to the other Member States and ECHA who may propose possible amendments over a 30 day period.
- In cases where Member States and ECHA do not propose any amendments, ECHA takes the decision as notified to the Member States without the involvement of the Member State Committee.
- In cases where proposals for amendment are made to the draft decision, ECHA forwards the draft decision to the Member State Committee and to the registrants for comments.
- The Member State Committee will examine the draft decision, the registrants' comments, and any proposals for amendments from the other Member States and ECHA. It will then try to reach an agreement on the final decision. An involved registrant or a representative of a group of affected registrants may be admitted to the meeting as an observer when their specific case is addressed by the Committee. The Committee must seek agreement on the draft decision within 60 days.
- If the Member State Committee reaches a unanimous agreement, ECHA takes the decision accordingly.
- If a unanimous agreement cannot be reached in the Committee, the matter is referred to the European Commission and the decision will be made under the comitology procedure.
- After the adoption of the decision, the registrants shall, within the timelines specified in the decision, submit the requested information by updating their registration dossiers.

3.2.5. ECHA's Decisions

In **compliance check and testing proposal cases**, ECHA will examine the information provided by the registrant in the dossier update and consider whether the information complies with the REACH requirements and whether it is sufficient for the purposes of classification and labelling and risk assessment. If the information is deemed noncompliant or the new information causes further standard information needs, ECHA may prepare another draft decision to request for appropriate information.

For **substance evaluation**, the adopted ECHA decision requires registrants to submit the requested information by updating their registration dossiers within the specified deadlines. A decision requesting further information from the registrants to clarify the concern can go beyond the standard information requirements of REACH (Annexes VII to X) and it may pertain to the intrinsic properties of the substance or its exposure. For example, registrants may need to provide studies on mode of action or monitoring of concentration levels in organisms or the environment.

Registrants can appeal against this decision to ECHA's Board of Appeal within three months of receiving the notification of the decision. The non-confidential versions of ECHA decisions originating from compliance checks and examination of testing proposals are published on the ECHA website on the Evaluation decisions page.

3.3. Authorisation

REACH References: Title VII Authorisation, Articles 55-66, Annexes XIV XV and XVI

REACH provides for the identification of certain substances that may have serious and often irreversible effects on human health and the environment as Substances of Very High Concern (SVHCs). SVHC are prioritised for action by their inclusion on the Candidate List. The authorisation procedure aims to assure that the risks from SVHC are properly controlled and that these substances are progressively replaced by suitable alternatives while ensuring the good functioning of the EU internal market. ECHA must regularly submit proposals for substances that should be subject to authorisation to the European Commission. In doing so, ECHA prioritises substances from the Candidate List to determine which ones should be included in the Authorisation List (Annex XIV).

After a two-step regulatory process, SVHCs may be included in the Authorisation List and become subject to authorisation. These steps involve firstly the identification of SVHC and their inclusion on the Candidate List and secondly the generation of a recommendation for inclusion in the Authorisation List.

Substances subject to authorisation cannot be placed on the market or used after a given date, known as the **sunset date** unless an authorisation is granted for their specific use, or the use is exempted from authorisation. Manufacturers, importers or downstream users of a substance on the Authorisation List can apply for authorisation, and must do so before the **application date** if they wish to continue to use the substance for a specific use. These dates, known as transitional arrangements, are included in the Authorisation List. In addition, the list may include **review periods** for certain uses and **exemptions** for uses or categories of uses.

In section 3.3.1 below the procedures for identifying SVHC and including them on the Candidate List are described, together with legal obligations arising for the inclusion of substances on the Candidate List. Section 3.3.2 describes the procedures by which ECHA prepares recommendation for inclusion in the Authorisation List, while section 3.3.3 describe the process by which industry can apply for an authorisation for a specific use.

3.3.1. Substances of Very High Concern and the Candidate List

REACH reference: Articles 57 and 59

The identification of a substance as Substance of Very High Concern and its inclusion in the Candidate List is the first step of the authorisation procedure. The Candidate List is published on

ECHA's website, and updated following decisions on SVHC. The table includes links to the IUCLID 5 substance dataset, as well as details specific to the substances, including the reason for concern.

Criteria for Identifying SVHC

A Member State, or ECHA (on request of the Commission), may propose a substance to be identified as a SVHC through the preparation of a dossier according to REACH Annex XV. Following Article 57 of REACH, substances proposed as SVHC must meet the criteria set out in the box 19 below.

Box 18: Criteria for SVHC, REACH Article 57

a) Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction category 1A or 1B in accordance with Commission Regulation (EC) No 1272/2008 (CMR substances); or
b) Substances which are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH (Annex XIII); or
c) Substances, such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria above but for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in the above points and which are identified on a case-by-case basis (in accordance with the procedure set out in REACH Article 59)

The elements to include in an Annex XV dossier for the identification of a substance as a CMR, PBT, vPvB or a substance of equivalent concern according to Article 59 are presented in box 20 below.

Box 19: Elements to include in an Annex XV dossier for the identification of Article 57 substances

Proposal
The proposal shall include the identity of substance(s) concerned and whether it is proposed to be identified as a CMR according to Article 57(a), (b) or (c), a PBT according to Article 57(d), a VPVB according to Article 57(e), or a substance of equivalent concern according to Article 57(f).

Justification
A comparison of the available information with the criteria in Annex XIII for PBTaccording to Article 57(d), and vPvBs according to Article 57(e), or an assessment of the hazards and a comparison with Article 57(f), according to the relevant parts of Section 1 to 4 of Annex I shall be completed. This shall be documented in the format set out in Part B of the Chemical Safety Report in Annex I.

Information on exposures, alternative substances and risks
The available use and exposure information and information on alternative substances and techniques shall be provided.

In 2013, the Commission presented a Roadmap on SVHC[42] including a commitment to have all currently known SVHC on the Candidate List by 2020. In addition, the Roadmap sets out a process for the identification and assessment of substances meeting the criteria of Article 57 (a) to (f). The

[42] European Commission (2013) Roadmap for SVHCs identification and implementation of REACH Risk Management measures from now to 2020, European Commission, Brussels

process includes a screening of registration dossiers and a Risk Management Options (RMO) assessment.

Screening is performed against two criteria: substances registered under REACH; and substances not used only as intermediates. The Commission notes that potential SVHCs excluded by the application of these criteria could still be considered after 2020 on a case-by-case basis.

The RMO then identifies the best regulatory option to manage risk, either through REACH mechanisms (authorisation, restriction or substance evaluation) or through other legislation. In particular, the RMO should consider whether based on available information the substance poses a risk that is not adequately controlled and needs to be addressed at EU level. For those uses that have a demonstrated risk, according to Articles 69(1) and 69(4), a restriction process should be started. In addition, the RMO should assess whether known uses of the substance are not exempted from the authorisation requirement, and are not already regulated by specific EU legislation that provides a pressure for substitution, leading to the conclusion that no further regulatory action is needed under REACH. For substances falling under Articles 57(d) or (e) (PBTs and vPvBs) and substances under Article 57(f) for a hazard property without harmonised criteria in Annex I of CLP (for example, endocrine disruptors), the Commission notes that an official SVHC identification may be foreseen regardless of the RMO assessment, unless the RMO concludes that no further regulatory actions is necessary. With regards to endocrine disruptors, the Commission notes that it may be relevant to establish an ad-hoc working group to manage the screening and RMO process for these substances.

Procedures for the identification of substances are set out in Article 59 of REACH. Once an Annex XV dossier is complete, ECHA makes it available to the other Member States. If the dossier is prepared by a Member State, ECHA must make it available within 30 days of receipt from the submitting Member State.

Public Consultation

On its website, ECHA publishes a list of both current consultations and past consultations. The Annex XV Reports prepared by either the submitting Member State or by ECHA are available for download.

A public consultation on the proposal last for 45 days from the date of publication, during which time anyone can comment or add further information related to the use, exposure, alternatives and risks of a proposed substance. Those most likely to be interested are companies, organisations representing industry or civil society, individual citizens, as well as public authorities. Comments are welcomed from the EU or beyond.

Within 60 days of circulation of the Annex XV dossier, other Member States or ECAH may comment on the identification of the substances in relation to the Article 57 criteria.

The submitting Member State or ECHA will respond to any comments and forward them to the Member State Committee, who will agree on the identification of the substance as an SVHC. A substance is only included in the Candidate List without involvement of the Member State Committee, if no comments on the identification are received in the public consultation.

Role of the Member State Committee in the Identification of SVHC

If comments are received in public consultation on proposals, then the Member State Committee needs to seek a unanimous agreement within 30 days on the identification of substances as SVHC in accordance with the REACH Article 57 criteria. Following the agreement on the substance identification as a SVHC the substances will be included in the Candidate List. The Member State Committee may also unanimously agree (see other agreements) that there is not sufficient information available for the identification of the substance as a SVHC, or that the information indicates that the substance is not a SVHC. In these cases the substance will not be included in the Candidate List.

If the Member State Committee does not reach an agreement, the proposal will be referred to the European Commission with an opinion of the Member State Committee reflecting majority and minority views of the members. The final decision on the identification of the substance will then be taken by the Commission.

Progress with the Candidate List

There are currently 138 substances on the Candidate List, with the most recent addition being on 17 December 2012. This means the European Commission has met its goal of identifying 136 SVHCs by the end of 2012.

As mentioned above, the Roadmap on SVHC commits to have all currently known SVHC on the Candidate List by 2020. Although the Commission states that no numerical goal should be set, a preliminary, worst case estimation for planning purposes suggests that 440 substances to will need to be RMO assessed between 2013 and 2020. This would require developing around 55 RMOs per year. The Commission notes that the involvement of a range of actors will be essential for implementation of the Roadmap, including the Member States REACH Competent Authorities, the Commission and

ECHA. The Roadmap is expected to contribute to progress in other areas of REACH, in particular restrictions.

ECHA is currently consulting on ten potential additions to the REACH candidate list, which could lead to the chemicals being classified as SVHCs. If approved after consultation, the new chemicals would be listed as SVHCs under the EU's REACH regulation for chemicals.

Legal Obligations Regarding Candidate List Substances

Companies may have legal obligations resulting from the inclusion of substances in the Candidate List. These obligations refer not only to the listed substances on their own or in mixtures but also to their presence in articles. Obligations are summarised in box 21 below.

Box 20: Legal obligations regarding Candidate List substances

Information on Substances in Articles, REACH Article 33
From the date of inclusion in the Candidate List: EU or EEA suppliers of articles which contain substances on the Candidate List in a concentration above 0.1% (w/w) have to provide sufficient information to allow safe use of the article to their customers or upon request, to a consumer within 45 days of the receipt of the request. This information must contain as a minimum the name of the substance.

Notification of Substances in Articles, REACH Article 7
From 2011, EU and EEA producers or importers of articles have to notify ECHA if their article contains a substance on the Candidate List. This obligation applies if the substance is present in those articles in quantities totalling over one tonne per producer or importer per year and if the substance is present in those articles above a concentration of 0.1% (w/w). For substances included in the Candidate List before 1 December 2010, the notifications have to be submitted not later than 1 June 2011.
For substances included in the Candidate List on or after 1 December 2010, relevant notifications have to be submitted no later than 6 months after the inclusion. A notification is not required when:
- The producer or importer of an article can exclude exposure of humans and the environment during the use and disposal of the article. In such cases, the producer or importer shall however supply appropriate instructions to the recipient of the article.
- The substance has already been registered for that use.

Safety Data Sheets, REACH Article 31.1
From the date of inclusion in the Candidate List, EU and EEA suppliers of substances on the Candidate List have to provide their customers with a safety data sheet.
From the date of inclusion in the Candidate List, EU and EEA suppliers of mixtures not classified as dangerous according to Directive 1999/45/EC have to provide the recipients, at their request, with a safety data sheet if the mixture contains at least one substance on the Candidate List and the individual concentration of this substance in the mixture is ≥ 0.1% (w/w) for non-gaseous mixtures if the substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB). This is without prejudice to the general obligation for all EU and EEA suppliers of mixtures not classified as dangerous according to Directive 1999/45/EC to provide the recipients, at their request, with a safety data sheet if the mixture contains a substance with an individual concentration ≥ 1% (w/w) for non-gaseous mixtures and ≥ 0.2% by volume for gaseous mixtures where that substance poses human health or environmental hazards.

3.3.2. ECHA Recommendations for Inclusion in the Authorisation List

REACH reference: Article 58-59

Drawing on the Candidate List, ECHA recommends priority substances for inclusion in Annex XIV of REACH (the "Authorisation List"). ECHA drafts a proposal for recommendation of priority substances to be included in the Authorisation List at least every two years. In addition to identifying substances, ECHA proposes transitional arrangements and, where relevant, exemptions and review periods relating to the requirement for authorisation of each specific substance (Annex XIV entries).

Prioritisation of SVHC by ECHA for Inclusion in the Authorisation List

Substances are prioritised from the candidate list for inclusion in Annex XIV normally on the basis of PBT/vPvB properties, or, wide dispersive uses, or high volumes. The prioritisation approach used by ECHA has recently been revised to include a two tiered-process, described in the document General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation.

The first step delivers a ranked priority list on the basis of the Article 58(3) criteria. This includes consideration of the potential for releases to the environment, for worker exposure and for consumer exposure in all steps of the life-cycle.

In the next step, considerations regarding 'regulatory effectiveness and coherence' and any relevant further considerations are reviewed to produce a final selection of those substances on the Candidate List that should be prioritised for inclusion in the Authorisation List. Decisions are awarded scores and the resulting substances assigned final scores, with the aim of making the process more traceable and thus more transparent. The total score can be seen as a proxy for potential risk to human health or the environment, i.e. the higher the hazard, the volume used and the potential for release of a substance, the higher its potential risk and thereby its priority.

Approach to Generating Entries to the Authorisation List (Annex XIV)

Following REACH Article 58(1), the draft entries for substances recommended for inclusion in Annex XIV shall specify for each substance:

- The identity of the substance as specified in section 2 of Annex VI;
- The intrinsic property (properties) of the substance referred to in Article 57;
- Transitional arrangements,

    - The sunset date(s),
    - The application date(s);
- Review periods for certain uses, if appropriate;
- Uses or categories of uses exempted from the authorisation requirement, if any, and conditions for such exemptions, if any; and
- whether the authorisation requirement applies to product and process oriented research and development (PPORD) and if so, the maximum quantity exempted.

These elements are further described in box 22 below.

Box 21: Elements to be included in Annex XIV entries

Substance identity: All the available name(s) for the substance and its EC number(s) are taken from the Candidate List of Substances of Very High Concern for Authorisation. In addition, where available, CAS numbers are provided.
Intrinsic property: The intrinsic property (properties) referred to in Article 57 of REACH, which led to the identification of the substance as a substance of very high concern (SVHC), are taken from the Candidate List. The identity of the substance and the intrinsic properties referred to in Article 57 of REACH were confirmed and concluded in the earlier SVHC identification process in accordance with Article 59, which led to the inclusion of the substance in the Candidate List.
Transitional Arrangements
Sunset date: The date(s) from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted […] which should take into account, where appropriate, the production cycle specified for that use.
Application date: A date or dates at least 18 months before the sunset date(s) by which applications must be received if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date(s); these continued uses shall be allowed after sunset date until a decision on the application for authorisation is taken.
Review periods: According to Article 58(1) of REACH it is possible to set review periods for certain uses, if appropriate, in Annex XIV.
Exemptions: According to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses 'provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled'.

The procedures for establishing each of these elements under the current recommendation (ECHA's Fourth Annex XIV Recommendation) are set out in the General approach for defining the Annex XIV entries, which serves to explain how decisions were made on each of these elements based on information available at the time of drafting the Fourth Annex XIV Recommendation.

With regards to the number of substances included in the recommendation and the relevant sunset dates and application dates, Article 58(3) states that these should reflect the capacity of ECHA to handle applications in the time provided for.

Decision-Making Procedure for Recommendations for Inclusion in the Authorisation List

The results of the prioritisation process are published on the ECHA website. The draft is subject to a public consultation, during which stakeholders are able to comment on ECHA's proposals in a three-month public consultation period, in particular on uses which should be exempt from the authorisation requirement. ECHA shall then update the recommendation accordingly.

Following the public consultation the Member State Committee issues its opinion on the (updated) draft recommendation which takes into account the comments submitted during the public consultation. Opinions of the Member State Committee on the draft recommendation of the priority substances for Annex XIV entries are available on the ECHA website, together with substances specific information, including ECHA's responses to comments on specific substances.

ECHA will take into account the opinion of the Member State Committee when recommending to the priority substances that should be included in Annex XIV. This recommendation is made to the European Commission, taking into account the opinion of the Member State Committee. ECHA also provides the European Commission with background documents with details and justifications regarding the recommendation and, where relevant, the proposals for the Annex XIV entries. The European Commission finally decides, by "committee procedure" (with scrutiny), which substances will be included in Annex XIV and with which entries.

In January 2013, ECHA published its Fourth Annex XIV Recommendation. Consultations are currently on-going on ECHA's fourth recommendation of substances for the Authorisation list.

The Current Authorisation List

There are currently 14 substances on the Authorisation List.

3.3.3. The Authorisation Process

REACH reference: Article 60-64

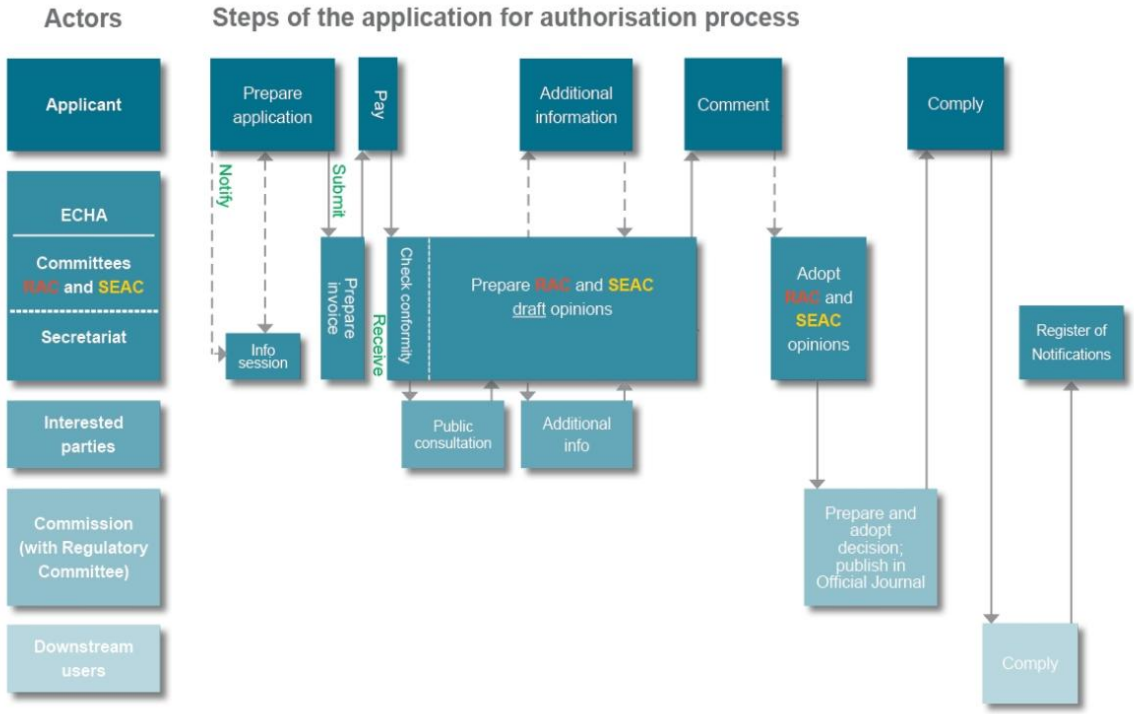
The placing on the market and use of Substances of Very High Concern included in the Authorisation List requires an authorisation. A manufacturer, an importer or a downstream user can apply for an authorisation. Applications for authorisation are submitted to ECHA. At the end of the authorisation process, which includes a public consultation and the development of opinions by ECHA's Committees on Risk Assessment and Socio-economic Analysis, the European Commission decides on

the granting or refusing of authorisations. Annex XIV substances are not subject to the authorisation requirements if used in:

- plant protection products within the scope of Directive 91/414/EEC;
- biocidal products within the scope of Directive 98/8/EC;
- motor fuels covered by Directive 98/70/EC;
- fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems;
- cosmetics; and
- food contact materials.

The authorisation process involves a number of actors, including the applicant from industry, ECHA, the RAC and MSC, interested parties and the Commission. Steps in the authorisation process are presented in figure 7 below.

Figure 7: Steps in the authorisation process



Source: ECHA website on the authorisation process

The main actors in the authorisation application process are presented in box 23, together with a brief description of their role.

Box 22: Actors in the authorisation process and their roles

Applicant
The applicant can be a manufacturer, an importer or a downstream user of a substance that requires authorisation (as listed in Annex XIV). The applicant may apply for authorisation in respect of his own use or uses for which he intends to place the substance on the market. An application may be made by one or several persons, for one or several substances that meet the definitions of a group of substances according to section 1.5 of Annex XI of the REACH Regulation, and for one or several uses.
If the Commission authorises the use of the substance the holders of authorisations must comply with the requirements of the authorisation when marketing and/or using the substance. The holders of authorisations need to update the Safety Data Sheet and include the authorisation number on the label before they place the substance or a mixture containing the substance on the market.

ECHA's Risk Assessment Committee (RAC)
RAC shall prepare an opinion on the application including an assessment of the risk to human health and/or the environment arising from the use(s) of the substance, including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives.

ECHA's Socio-Economic Analysis Committee (SEAC)
SEAC prepares an opinion on the application including an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application, and of any information on alternatives submitted by interested third parties.

ECHA Secretariat
The ECHA Secretariat provides guidance and tools to applicants for the preparation of their applications. The Secretariat also supports the ECHA Committees by providing scientific, technical and regulatory services in an efficient and transparent way.

Interested parties
Interested parties are citizens, organisations, companies as well as authorities. They can be from the EU or elsewhere. They may provide information on alternative substances or technologies during the consultation process for applications as well as for reviews of authorisations.

European Commission
The opinions of RAC and SEAC are sent to the European Commission. The Commission prepares a draft authorisation decision within three months of receipt of the opinions from the Agency. The Commission adopts the final decision granting or refusing the authorisation via the regulatory committee procedure. Summaries of the decision will be published in the Official Journal of the European Union and made publicly available through a database maintained by ECHA.

Downstream users
A Downstream user may use the substance if an authorisation for that use has been granted to an actor further up his supply chain. He must comply with the conditions set out in the authorisation and notify ECHA of his use of the substance.

Box 24 below outlines the main steps involved in the application for authorisation and the subsequent decision-making process on granting an authorisation for the placing on the market or use of a substance on the Authorisation List.

Box 23: Steps in the application for an authorisation

1. Prepare an application for authorisation
A manufacturer, an importer or a downstream user of the substance on the Authorisation list may prepare an application for authorisation for his own use(s) or for uses for which he intends to place the substance on the market.
2 Notification and pre-submission information sessions
Applicants are requested to notify ECHA well in advance of their intentions to submit an application.
When notifying or later, future applicants can request a pre-submission information session with ECHA to clarify regulatory and procedural issues related to the authorisation application process.
3. Submit the application
Applicants submit their applications for authorisation to ECHA.
4. Prepare the invoice
ECHA checks that the application is complete and can be processed so that it can prepare and send an invoice.
5. Pay the invoice
The applicants need to pay the invoice. Once ECHA has received the payment by the specified deadline the application is considered received and the Committees can start their work.
6. Check conformity
The Committees, supported by the Secretariat, check whether the application conforms with the information requirements of Article 62 of the REACH Regulation. The Committees may jointly require additional information to bring the application into conformity with the Regulation.
7. Public consultation on the uses applied for
ECHA will publish broad information on the uses applied for on its website inviting interested parties to submit information on possible alternative substances or techniques for these uses.
8. Require additional information on alternatives
SEAC may require the applicant or third parties to submit additional information on alternatives within a specified timeline.
9. Prepare draft opinions of RAC and SEAC
The Committees prepare and adopt their draft opinions for the application for authorisation within 10 months of receipt of the application. The opinions are based on the application, any information received during the public consultation, and any further information on alternatives that the applicant or interested parties have provided based on SEAC's request.
10. Comment draft opinions
The applicant has the possibility to comment on the draft opinions within two months of the receipt.
11. Adopt RAC and SEAC final opinions
RAC and SEAC adopt their final opinions taking into account the possible comments made by the applicant on the draft opinions. The Secretariat sends the opinions to the European Commission, the Member States and the applicant. Non-confidential versions of the opinions will be published on ECHA's website.
12. Prepare, adopt and publish the authorisation decision
Within three months of receipt of the Committees' opinions, the Commission prepares a draft decision as to whether or not the authorisation should be granted. Subsequently the Commission adopts the decision granting or refusing the authorisation under the regulatory committee procedure. A summary of the decision is published in the Official Journal of the European Union, and made publicly available through a database maintained by ECHA. The authorisation is subject to a time-limited review period.
13. Comply with the authorisation
Holders of an authorisation and downstream users using an authorised substance must comply with the requirements of the authorisation decision when marketing and/or using the substance.
Holders of an authorisation (i.e. manufacturers, importers and/or downstream users) need to include the authorisation number on the label before they place the substance or a mixture containing the substance on the market. This shall be done without delay once the authorisation number has been made publicly available (see step 12).
14. Register of the notifications of Downstream users
Downstream users of an authorised substance shall notify ECHA within three months of the first supply of the substance.
ECHA will keep a register of the Downstream User notifications (see step 13) and grant access to this register to the competent authorities of the Member States.

Source: ECHA website on authorisation process

In the sections below, key steps are described in greater detail.

Legal Basis for Authorisations

Authorisations will only be successful if applicants can demonstrate that the use of the authorised substance is necessary for their business and right for society as a whole. Under REACH Article 60 on the granting of authorisations, there are two principle routes through which authorisations can be granted, namely:

1. If risks to human health or the environment are adequately controlled (Article 60(2)); or
2. If the socio-economic benefits of the use outweigh the risk to human health or the environment (Article 60(4)).

The final decision as to whether to grant an authorisation is taken by the Commission. A decision to authorise a substance on the basis of adequate control, i.e. under Article 60(2), requires consideration of the following elements:

- whether the substances is adequately controlled in accordance with the exposure scenarios in the chemical safety assessment, as documented in the applicant's chemical safety report;
- the RAC opinion;
- all discharges, emissions and losses, including risks arising from diffuse or dispersive uses, known at the time of the decision.

Key elements for determining whether adequate control should be the legal basis for an authorisation include:

- Uses involving CMR substances for which thresholds are known (DNEL);
- Uses involving substances of equivalent concern for which thresholds are known (DNEL or PNEC);
- Evidence that risks are controlled by ensuring that exposure is below the thresholds;
- The absence of suitable alternatives; and
- The economic feasibility of a substitution plan over time, when suitable alternatives are available.

A decision to authorise a substance on the basis of socio-economic benefits, i.e. under Article 60(4), requires consideration of the following elements:

(a) the risk posed by the uses of the substance, including the appropriateness and effectiveness of the risk management measures proposed;

(b) the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise as demonstrated by the applicant or other interested parties;
(c) the analysis of the alternatives or any substitution plan, and any third party contributions submitted during the public consultation;
(d) available information on the risks to human health or the environment of any alternative substances or technologies; and
(e) the opinions of the RAC and the SEAC.

Key elements for determining whether socio-economic benefits should be the legal basis for an authorisation include:

- Uses involving non-thresholded CMRs;
- Uses involving non-threshold substances of equivalent concern;
- Uses involving PBTs and vPvB;
- Uses involving threshold substances without adequate control;
- Where no suitable alternatives are available; and
- Where the benefits of continued use outweigh the risks.

Procedures for Applying for Authorisation

When substances are included in the Authorisation List, a sunset date is set, together with a date for last applications for authorisations. The sunset date is the date after which placing on the market or use is prohibited, unless an authorisation is granted. A manufacturer, an importer or a downstream user can apply for an authorisation before the last application date.

Applications for authorisation are complex, time consuming and require expert input. The procedures for applying for an authorisation are laid out on the support pages of the ECHA website, and summarised below.

1. Firstly, ECHA establishes substance-specific windows for submitting applications for authorisation.

2. Applications are then required to notify ECHA in advance (i.e. 8 months) of the date they intend to submit an application for authorisation, using an online notification webform. At this stage, applicants may also request a pre-submission information session with ECHA representatives to ask case-specific questions regarding the application process.

3. Applicants then preparing an application, following specific steps and including the following documentation;
    a. Chemical safety report;
    b. Analysis of alternatives;
    c. Substitution plan, including a non-confidential summary;
    d. Socio-economic analysis, including a non-confidential summary;
    e. Argumentation for substance grouping;
    f. Justification for not considering certain risks; and
    g. Concordance table specifying where in the application dossier the important issues are for the formulation of the opinion on granting an authorisation.

    Templates and targeted guidance materials to assist in the preparation of these documents are provided online.

    Applications must use IUCLID 5 to submit the documentation, and must have a REACH-IT account. ECHA uses data in the REACH-IT account to calculate fees.

    In addition, ECHA provides Guidance on the preparation of an Application for Authorisation, Data Submission Manual Part 22 - How to Prepare and Submit an Application for Authorisation using IUCLID 5 and an ECHA Fee calculator, a tool for estimating the possible amount of a fee related to a given application for authorisation under REACH.

4. Applicants must then submit their application using online webforms.

ECHA has developed a range of materials that both support the application process and explain the decision-making procedures with regards to granting authorisations. These are listed in table 9 below.

Table 9: List of ECHA documents that support and explain the authorisation process

Document	Description
Participation of applicants, third parties and stakeholder observers in the application for authorisation process	This note defines ECHA's approach to the participation of applicants, third parties and stakeholder observers in the application for authorisation process
Submission of information on alternatives Non-confidential template Confidential template	Instructions of how interested third parties can submit information for the public consultation on alternatives for applications for authorisation.
How RAC and SEAC intend to evaluate the applications	Outline of the key principles in the development of RAC and SEAC opinions is provided. It focuses on issues where a common approach is needed in both RAC and SEAC.
Reporting format for the RAC and SEAC opinions	Format used by ECHA's Committees to write their opinions
Public sections of RAC and SEAC opinions	Parts of RAC and SEAC opinions which will be made publicly available are indicated.
Publication of information on applications during the opinion-making process	A description of information from applications for authorisations that will be made publicly available is outlined.
Working procedure for RAC and SEAC for developing opinions	Describes the main roles and tasks of the (co-)rapporteurs, the members of RAC and SEAC, and the ECHA secretariat as well as the timelines related to the opinion-making process.
Working procedure for RAC and SEAC on conformity check	Describes the main roles and tasks of the (co-)rapporteurs, the members of RAC and SEAC, and the ECHA secretariat as well as the timelines related to the conformity check of the applications.
Economic feasibility	How SEAC will evaluate economic feasibility

The number of received notifications of intentions to submit an application, held pre-submission information sessions and submitted applications are provided on the ECHA website. The names of substance(s) are to be made public once the application has been submitted.

Public Consultation

Upon receipt of the application, ECHA acknowledges the date of receipt of the application. ECHA publishes online broad information on uses for which applications have been received and for reviews of authorisations, with a deadline by which information on alternative substances or technologies may be submitted by interested third parties. The consultation lasts eight-weeks, during which anyone can comment on uses of the substance relevant to the authorisation using an online webform.

The term “broad information on uses” is contained within REACH Article 64(2) and has been interpreted by RAC and SEAC in a document entitled Public information in the process of applications for authorisation. The RAC and SEAC note that in order to provide meaningful information on alternatives during the public consultation, third parties need to have information on:

- Where the SVHC is used and/or ends-up (market sectors, life-cycle stages, service-lives).

- How the SVHC is used: conditions of use i) related to exposure as described in the exposure scenarios, and ii) related to the functional requirements as described in the analysis of alternatives.
- What function(s) is performed by the SVHC. A brief description of the function (softener, flame retardant, etc) can be provided with the use name and the descriptors. However, more detailed analysis of the SVHC's functional requirements (exact tasks, critical properties, critical process conditions under which these tasks are delivered, quality criteria for end-products, etc) will normally be documented in the analysis of alternatives.

ECHA therefore commits to publishing as part of "Broad Information on Uses" and additional supporting information:

- A summary using brief wording of:
  - Use name;
  - Key elements of conditions of use (exposure and functional requirements);
  - List of descriptors (codes, brief description of the function);
- Public version of the exposure scenarios (as provided in the application);
- Public version of the analysis of alternatives (as provided in the application);
- Public version of the substitution plan (if provided);
- Public version of the socio-economic analysis (if provided);
- The name of the applicant.

Opinions of the RAC and the SEAC

ECHA's Committees for Risk Assessment and Socio-economic Analysis are required to provide draft opinions on the authorisation application within ten months of the date of receipt of the application.

The opinions of RAC and SEAC are intended to add value by assuring that assessments presented in applications for authorisation are in accordance with appropriate technical and scientific standards. Consistency in the evaluations of RAC and SEAC is ensured through the application of common standards on how to carry out the evaluation guidelines, key principles, shared knowledge base, as summarised in a document on the Common approach of RAC and SEAC in opinion development on applications for authorisation.

RAC and SEAC evaluate and validate the evidence and assessment presented by the applicant in order to develop an independent opinion on the application. In particular, RAC and the SEAC aim to assess whether:

i) methods used are appropriate and applied consistently;

ii) conclusions are reached logically;

iii) evidence is robust and has the right scope;

iv) all relevant issues have been included and there are no omissions that would affect the outcome of the evaluation;

v) decisions not to include endpoints are justified; and

vi) effort in applicant's assessments is proportionate given the importance of the application.

As a first step, both committees check that the application conforms with the legal requirements for applications for authorisations, as set out in Article 62 of REACH. Procedures for conformity checking are published online for the RAC and the SEAC. The Committees may make a joint request for additional information if gaps are identified. In addition, the SEAC may request additional information on possible alternative substances or technologies. Information request should be made in the first four months of the evaluation of the application, and time bound.

Despite their adopting common procedures overall, the roles of the RAC and the SEAC are distinct:

- The role of the RAC is to provide an assessment of the risk to human health and/or the environment arising from the use(s) of the substance, including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives.
- The role of the SEAC is to provide an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application, and of any third party contributions submitted under the public consultation.

Information serving as the basis for the RAC and SEAC draft opinions includes:

- Application for authorisation;
- Any information on alternative substances and technologies submitted by third parties within the public consultation;
- Additional information provided by the applicant and/or by third parties on possible alternative substances or technologies as required and/or requested by SEAC (based on REACH Article 64(3));
- Any other information submitted by the applicant or third parties in response to requests by RAC and SEAC.
-

The working procedures of the RAC and the SEAC for developing opinions on authorisations describes the main roles and tasks of the (co-)rapporteurs, the members of RAC and SEAC, and the

ECHA Secretariat, as well as providing the timelines for different tasks. Table 10 below outlines the main steps in the development of the RAC and SEAC draft opinions starting from receipt of an authorisation application by RAC and SEAC until the adoption of the draft opinions by the Committees.

Table 10: Main steps in the development of RAC and SEAC draft opinions on authorisation applications

Step		Deliverables	Timeline in weeks
A	RAC and SEAC members are informed that the Secretariat has published on the ECHA website broad information on uses for which the application has been received and has invited interested third parties to submit information on alternative substances or technologies (within an 8 week period).	Information	1
B	Newsgroups are initiated in CIRCA allowing RAC and SEAC members to submit initial comments on the application (within an 8 week period).	Initial comments	1
C	If necessary, the SEAC (co-)rapporteurs compile questions to the applicant on alternative substances or technologies (in co-operation with the RAC (co-)rapporteurs). If necessary, the RAC and SEAC (co-)rapporteurs jointly compile questions to the applicant related to the content of the application. They should also decide on the deadline for submission of this information.	Questions to the applicant on Alternatives and content related questions	4
D	Information submitted by third parties within the public consultation and additional information on alternatives submitted by the applicant (if required by SEAC) as well as the applicant's responses to the content related questions (if asked by RAC and SEAC) are made available to RAC and SEAC.	Information	9
E	First dialogue between the RAC and SEAC (co-)rapporteurs is convened for the first exchange of views on the submitted application and any additional information available as well as on any comments received by RAC and SEAC members within the initial commenting round.	Exchange of views	11-12
F	The RAC/SEAC (co-)rapporteurs prepare the first outline of the RAC/SEAC draft opinion. The (co-)rapporteurs may ask the applicant to comment on information obtained through the public consultation. The documents prepared by the (co-) rapporteurs are distributed to RAC and SEAC.	(Co-)rapporteurs' first outline of the RAC/SEAC draft opinion	14
G	First RAC/SEAC plenary discussion. The application, information received through the public consultation, additional information received from the applicant, and the (co-) rapporteurs' first outline of the RAC/SEAC draft opinion are discussed.	RAC/SEAC plenary discussion	16-17
H	The RAC/SEAC (co-)rapporteurs prepare the 1st version of the RAC/SEAC draft opinion. The documents prepared by the (co-) rapporteurs are distributed to RAC and SEAC.	1st version of The RAC/SEAC draft opinion	20
I	The Secretariat, together with the RAC and SEAC (co-) rapporteurs, prepare the Supporting Annexes (SA)9 to the (co-) rapporteurs' 1st versions of the RAC and SEAC draft opinions. The SA are distributed to RAC and SEAC.	Supporting Annexes	20
J	The RAC/SEAC members provide written comments on the (co-)rapporteurs' 1st version of the RAC/SEAC draft opinion and the RAC/SEAC-related parts of the SA within 28 calendar days.	Written comments	20-23
K	Second dialogue between the RAC and SEAC (co-)rapporteurs is convened for exchange of views on additional information on alternatives received from third parties (if requested by SEAC) and to agree on the 2nd versions of the RAC and SEAC draft opinions.	Exchange of views	25-26
L	The RAC/SEAC (co-)rapporteurs respond to comments received from other RAC/SEAC members within the written commenting round (in the form of an ORCOM10) and send the 2nd version of	ORCOM; 2nd version of the AC/SEAC draft opinion	27

Step		Deliverables	Timeline in weeks
	the RAC/SEAC draft opinion within 21 calendar days. The documents prepared by the (co-)rapporteurs are distributed to RAC and SEAC.		
M	The Secretariat, together with the RAC and SEAC (co-) rapporteurs, revise the SA to be in line with the (co-) rapporteurs' 2nd versions of the RAC and SEAC draft opinions. The revised SA are distributed to RAC and SEAC.	Revised supporting Annexes	27
N	Second RAC/SEAC plenary discussion takes place where the 2nd version of the RAC/SEAC draft opinion is discussed.	RAC/SEAC plenary discussion	29-30
O	Third dialogue between the RAC and SEAC (co-)rapporteurs is convened to agree on the 3rd versions of the RAC and SEAC draft opinions.	Exchange of views	39-39
P	The RAC/SEAC (co-)rapporteurs prepare the 3rd version of the RAC/SEAC draft opinion taking into account comments received from other RAC/SEAC members in the previous plenary meeting. The documents prepared by the (co-) rapporteurs are distributed to RAC and SEAC.	3rd version of The RAC/SEAC draft opinion	41
Q	The Secretariat, together with the RAC and SEAC (co-) rapporteurs, revise the SA to be in line with the (co-) rapporteurs' 3rd versions of the RAC and SEAC draft opinions. The revised SA are distributed to RAC and SEAC.	Revised supporting Annexes	41
R	Following the discussion at the RAC/SEAC plenary meeting, RAC/SEAC adopts its draft opinion (and the RAC/SEAC-related parts of the SA).	RAC/SEAC plenary discussion	43-44

ECHA sends the draft opinions of the Committees to the applicant by the end of the ten months deadline. The applicant then has a possibility to comment on the RAC and SEAC draft opinions, and must indicate their intent to comment within a one month period from receipt of the draft opinions.

If the applicant does not wish to comment, the Secretariat shall send these opinions to the Commission, the Member States (MSs) and the applicant, within 15 days of the end of the comment period or receipt of notice from the applicants that she/he does not intend to comment.

If the applicant wishes to comment, written comments must be sent to the ECHA Secretariat within two months of the receipt of the draft opinions. RAC and SEAC consider the comments and adopt their final opinions within two months of receipt of the comments, taking them into account where appropriate. The final opinions of the Committees are sent to the Commission, the Member States and the applicant.

Table 11 below describes the main steps in the preparation of the RAC/SEAC final opinion starting from the receipt of the applicant's comments on the RAC/SEAC draft opinion until the adoption of the RAC/SEAC final opinion.

Table 11: Main steps in the development of RAC and SEAC final opinions on authorisation applications

Step		Deliverables	Timeline starting from the date of receipt of the applicant's comments
S	Comments received from the applicant on the RAC/SEAC draft opinion are distributed to RAC and SEAC.	Applicant's comments on the RAC/SEAC draft opinion	Day 1
T	The RAC/SEAC (co-)rapporteurs prepare a draft version of the RAC/SEAC final opinion taking into account the applicant's comments on the RAC/SEAC draft opinion. The documents prepared by the (co-) rapporteurs are distributed to RAC and SEAC.	Draft version of the RAC/SEAC final opinion	Week 4
U	The RAC/SEAC members provide written comments on the (co-)rapporteurs' draft version of the RAC/SEAC final opinion within 10 calendar days.	Written commenting	Weeks 4-6
V	The RAC and SEAC (co-)rapporteurs respond to comments received from other RAC/SEAC members within the written commenting round (in the form of an ORCOM) and revise the draft version of the final opinion. The Secretariat, together with the RAC and SEAC (co-)rapporteurs, revise the SA to be in line with the revised draft versions of the RAC and SEAC final opinions. The documents are distributed to RAC and SEAC.	ORCOM; revised draft version of the RAC/SEAC final opinion; revised SA	Weeks 6
W	Following the discussion at the RAC/SEAC plenary meeting, RAC/SEAC adopts its final opinion (and the RAC/SEAC-related parts of the final SA). OR (in case plenary meetings are not foreseen that time) The Secretariat launches a written procedure in RAC/SEAC to adopt the RAC/SEAC final opinion and the RAC/SEAC-related parts of the final SA. The Secretariat informs RAC and SEAC about the outcome of the written procedures.	RAC/SEAC PLENARY DISCUSSION OR WRITTEN PROCEDURE	Weeks 8-9

Source: adapted from the working procedures of the RAC and the SEAC for developing opinions on authorisations

Within a further 15 days the Secretariat will send the RAC and SEAC final opinions, with the applicant's written argumentation attached, to the Commission, the MSs and the applicant. Further supporting documentation (ORCOMs, minutes of the RAC and SEAC plenary meetings and written procedure reports, if any) can be forwarded to the Commission on request.

Trialogue Discussions During the Authorisation Process

In December 2012, ECHA established an approach to the participation of applicants and representatives of stakeholder organisations in the authorisation process. Currently, applicants for authorisation may contribute to the authorisation process through their responses to Committees' requests for additional information through the Rapporteurs and by commenting on the draft opinions. However, Committees do not currently have the opportunity to discuss issues raised by an application with applicants in an interactive and discursive way. In addition, the public consultation could generate additional information on possible alternatives, and Committees need to understand the significance of this information within the specific context of the application.

To meet this possible need for additional discussion, an application 'trialogue' between the applicant and the RAC and SEAC rapporteurs is to be established in the opinion-making procedure. This

trialogue will allow rapporteurs to discuss with applicants any information on alternatives generated through public consultation or any other technical or scientific issues with the application. The trialogue should be held after the conclusion of the public consultation so that rapporteurs can explore with applicants (and third parties) the significance of any relevant information received. It should be held sufficiently in advance of the second Committee plenaries as to allow good time for the likely role of confidential business information (CBI) in Committee deliberations to be assessed (see Figure 1).

Rapporteurs will also be able to invite those third parties who submitted information to the public consultation which is of particular interest and relevance to the application. Stakeholder observers of RAC and SEAC will be invited to attend the trialogue to provide scrutiny and transparency, although applicants and third parties will have the opportunity to argue that information to be discussed is confidential and that observers should be excluded from any parts of the meeting when that information might be discussed.

The ECHA Secretariat has committed to developing general, experience-based criteria for indicating when a trialogue is normally expected, leaving enough flexibility for rapporteurs, in consultation with with the ECHA Secretariat and Committee Chairs, to decide on a case-by–case basis. The format of the trialogue should be flexible to the opinion-making needs of the application and the complexities involved, as well as to logistical and financial concerns. It may therefore take place in person, or through video- or teleconference. No trialogue need be held if there are no open questions and no issues have been raised during the public consultation.

Preparation and Publication of the Authorisation Decision

Within three months of receipt of the Committees' opinions, the Commission prepares a draft decision as to whether or not the authorisation should be granted. Subsequently the Commission adopts the decision granting or refusing the authorisation under the regulatory committee procedure.

A summary of the decision is published in the Official Journal (OJ) of the European Union, and made publicly available through a database maintained by ECHA. The authorisation is subject to a time-limited review period (see Review of the authorisation).

Review of Authorisations

Authorisations are valid until the Commission decides to withdraw or amend the authorisation in the context of a review. All authorisation decisions will define a time-limited review period. Holders of authorisations must submit a review report at least 18 months before the expiry of the time-limited review period.

In addition, an authorisation may be reviewed at any time if:

- the circumstances have changed so as to affect the risk to human health or the environment, or the socio-economic impact; or
- new information on possible substitutes becomes available.

3.4. Restrictions

REACH reference: Title VII Authorisation, Articles 67-73, Annexes XV, XVI and XVII

If a chemical poses an unacceptable risk that needs to be addressed on an EU-wide basis, a Member State or ECHA (on request of the Commission) may propose a restriction on the manufacturing, placing on the market or the use of that chemical of concern. Restrictions limit or ban the manufacture, placing on the market or use of certain substances that pose an unacceptable risk to human health and the environment.

A substance on its own, in a preparation or in an article that is classified as CMR 1A or 1B may be subject to restrictions for any consumer use more easily than other substances, as Annex XVII can be amended in a simplified manner for these substances. The provisions on restrictions do not apply to the use of substances in cosmetic products.

A REACH restriction sets conditions for the prohibition of or concerning, the manufacture, use or placing on the market of a substance, preparations and/or articles. As such, restrictions enable harmonized EU-level risk management measures beyond those already implemented by manufacturers, importers and downstream users. Restrictions apply to all manufacturers, importers, downstream users and distributors of a substance if the manufacture, use or placing on the market (activity) of this substance is included in Annex XVII.

The level of restriction can be divided into two main categories:

- Restrict the use or existence in certain products (e.g. the mass fraction of benzene should not exceed 5mg/kg in toys or toys parts; PBB cannot be used in textiles such as underwear, blankets, clothing and the skin contact items); or
- Restrict all uses (ie, total prohibition on use as for example on asbestos, ichloro[(dichlorophenyl)methyl]methylbenzene, UGILEC121 Monomethyldibromodiphenyl -methane).

Currently, there are 59 categories of restricted substances in the Annex XVII List of Restrictions, involving more than 1000 substances. REACH took on the pre-existing provisions under the Dangerous Substances Directive relating to restrictions on the marketing and use of certain dangerous substances and preparations, as well as subsequent modifications.

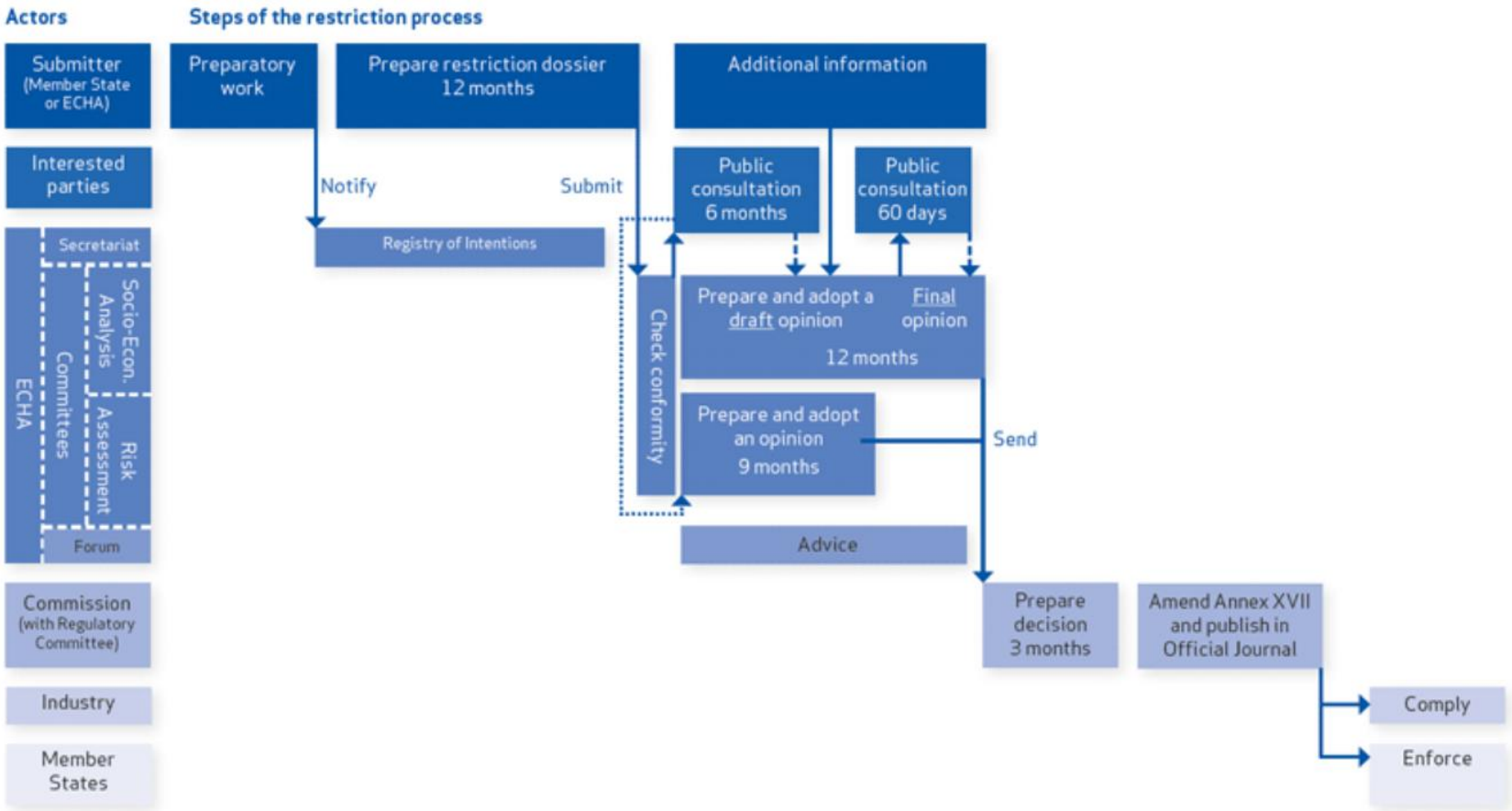
The procedure for establishing restrictions is described in section 3.6.1 below.

3.4.1. Restrictions Procedure

REACH reference: Articles 67-73, Annexes XV, XVI and XVII

The authorisation process involves a number of actors, including the Member States, ECHA, in particular the Risk Management Implementation Unit, the RAC and MSC, interested parties, industry and the Commission. Steps in the authorisation process are presented in figure 8 below.

Figure 8: Overview of the restrictions process



Source: ECHA website on restrictions process

The main actors in the process and their roles are described in box 25 below.

Box 24: Actors in the restrictions process

Submitter (Member State or ECHA)
The submitter of a restriction dossier can be either a Member State or ECHA, if asked by the Commission. Only they can initiate a restriction process.

Interested parties
Interested parties are citizens, organisations, companies as well as authorities other than the submitter. They can be from the EU or elsewhere. They may provide comments and information during public consultation.

ECHA Secretariat
The ECHA Secretariat supports the Committees and the Forum by providing the best possible scientific, technical and regulatory services in an efficient and transparent way.

ECHA Risk Assessment Committee (RAC)
RAC formulates an opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment based on its consideration of the relevant parts of the restriction dossier and the comments submitted by interested parties.

ECHA Socio-Economic Analysis Committee (SEAC)
SEAC formulates an opinion on the suggested restriction and its socio-economic impact, based on its consideration of the relevant parts of the restriction dossier and the socio-economic impacts. When formulating its opinion, SEAC also takes into account the comments and socio-economic analyses submitted by interested parties.
ECHA Forum for the Exchange of Information on Enforcement (the Forum)
The Forum may provide advice on the enforceability of the restriction proposal.

European Commission
The opinions of RAC and SEAC are sent to the European Commission. The Commission prepares a draft amendment to the list of restrictions, which are contained in Annex XVII of the REACH Regulation.
If the Council or the European Parliament do not oppose the amendment (using a process called "Regulatory committee with scrutiny"), the Commission adopts the decision and adds the restriction to Annex XVII.

Industry
Once the substance restriction has been adopted industry needs to comply with it. By industry we mean anyone addressed in the restriction, such as manufacturers, importers, distributors, downstream users or retailers.

Member States
Member State Competent Authorities are responsible for enforcing the restrictions.

The adoption of a new restriction on the manufacturing, placing on the market or use of substances involves the steps set out in box 26 below.

ECHA provides Questions and Answers on restrictions.

Box 25: Steps in the restrictions process

1. Preparatory work
A Member State or the European Commission may have a concern that a certain substance poses a risk to human health or the environment. If so, it would undertake preparatory work to investigate the problem further.

2. Notify the intention to prepare a restriction dossier
If the Member State or the Commission concludes that a restriction appears to be the best way forward, it has to notify its intention to prepare a restriction dossier. ECHA maintains a Registry of Intentions (RoI) which is publicly available on ECHA's website. It enables the stakeholders to prepare their contributions to the process.

3. Prepare the restriction dossier
The restriction dossier shall include information on hazards and risks, available information on alternatives and a justification for restrictions at EU-wide level. The dossier needs to demonstrate that the restriction is the most appropriate risk management instrument to address the identified risk or risks. The restriction dossier may also include an analysis of the socio-economic impacts. The proposal needs to be prepared according to the requirements given in Annex XV of REACH. The dossier needs to be submitted within 12 months of the notification in the Registry of Intentions.

4. Submit the restriction dossier
Currently Member States can submit restriction proposals by e-mail or via CIRCA. Submission of Annex XV restriction dossiers through REACH-IT is under development.

5. Check conformity
The Committees check whether the submitted restriction dossier conforms with the requirements of Annex XV of the REACH Regulation.

6. Public consultation on the restriction report
Conforming restriction reports will be published on ECHA's website, excluding any confidential information. Interested parties may submit comments on the restriction report and supporting documentation within six months of the date of their publication.

7. Advice from the Forum
The Forum may provide advice to RAC and SEAC on the enforceability of the proposed restriction.

8. Prepare and adopt the opinion of RAC
Within nine months of the date of the publication of the restriction report, RAC prepares and adopts an opinion based on the restriction dossier and comments received during the public consultation.

9. Prepare and agree the draft opinion of SEAC
Within nine months of the date of the publication of the restriction report, SEAC prepares and agrees a draft opinion based on the restriction dossier, the socio-economic impacts, and the comments and socio-economic information received during the public consultation

10. Public consultation on SEAC draft opinion
The draft opinion of SEAC and the final opinion of RAC will be placed on ECHA's website. Interested parties may submit comments on the SEAC draft opinion within 60 days from publication.

11. Prepare and adopt the opinion of SEAC
SEAC prepares and adopts the final opinion taking into account the comments on its draft opinion.

12. Send the opinions to the Commission
ECHA sends the opinions of RAC and SEAC along with relevant background documents to the European Commission. These are also published on ECHA's website.

13. Prepare and adopt the restriction decision
Within three months of receipt of the Committees' opinion, the Commission prepares a draft amendment of the list of restrictions. If the Council or the European Parliament do not oppose to the restriction, the Commission adopts it. The decision to restrict is published in the Official Journal as an amendment Annex XVII of the REACH.

14. Comply with restriction
Once the substance restriction has been adopted industry needs to comply with it. By industry we mean anyone addressed in the restriction, such as manufacturers, importers, distributors, downstream users or retailers.

15. Enforce the restriction
Member State Competent Authorities are responsible for enforcing the restriction.

Preparing an Annex XV Dossier

A Member State, or ECHA on request of the European Commission, can start the restriction procedure when they have a concern that a certain substance poses an unacceptable risk to human health or the environment. The intention to prepare a restriction proposal is made public in the registry of intentions before the proposal file itself is prepared so as to give advance warning.

The dossier proposing the restriction contains background information such as the identity of the substance and justifications for the proposed restrictions. It includes the identified risks, any information on alternatives to the substance and the costs, as well as the environmental and human health benefits, resulting from the restriction. The dossier needs to be prepared according to the REACH Regulation (Annex XV), with elements to include presented in box 27 below.

Box 26: Requirement for an Annex XV restrictions dossier

Proposal
The proposal shall include the identity of the substance and the restriction(s) proposed for the manufacture, placing on the market or use(s) and a summary of the justification.

Information on hazard and risk
The risks to be addressed with the restriction shall be described based on an assessment of the hazard and risks according to the relevant parts of Annex I and shall be documented in the format set out in Part B of that Annex for the Chemical Safety Report. Evidence shall be provided that implemented risk management measures (including those identified in registrations under Articles 10 to 14) are not sufficient.

Information on alternatives
Available information on alternative substances and techniques shall be provided, including:
– information on the risks to human health and the environment related to the manufacture or use of the alternatives,
– availability, including the time scale,
– technical and economical feasibility.

Justification for Restrictions at Community Level
Justification shall be provided that:
– action is required on a Community-wide basis,
– a restriction is the most appropriate Community wide measure which shall be assessed using the following criteria:
(i) effectiveness: the restriction must be targeted to the effects or exposures that cause the risks identified, capable of reducing these risks to an acceptable level within a reasonable period of time and proportional to the risk;
(ii) practicality: the restriction must be implementable, enforceable and manageable;
(iii) monitorability: it must be possible to monitor the result of the implementation of the proposed restriction.

Socio-economic assessment
The socio-economic impacts of the proposed restriction may be analysed with reference to Annex XVI. To this end, the net benefits to human health and the environment of the proposed restriction may be compared to its net costs to manufacturers, importers, downstream users, distributors, consumers and society as a whole.
Information on stakeholder consultation Information on any consultation of stakeholders and how their views have been taken into account shall be included in the dossier.

ECHA provides Guidance for the preparation of an Annex XV dossier for restrictions, as well as Guidance on the socio-economic analysis for restrictions, and an Addendum to the Guidance on Socio-Economic Analysis: Calculation of Compliance costs. Reporting formats are also provided for Annex XV dossiers.

Any relevant information from registration dossiers can be considered, as well as other available information may be used. For hazard information which has not been previously submitted to the Agency, a robust study summary shall be included in the dossier.

The dossier must be submitted to ECHA within twelve months after the intention to prepare the proposal was notified. Upon receiving the dossier the ECHA Committees check whether the proposal conforms to the requirements of Annex XV, following a template for checking conformity. Working procedures for the compliance check by the RAC and the SEAC are published online. If it does, the dossier will be made publicly available for consultation (excluding any commercially confidential information).

Public Consultation

An Annex XV proposal dossier to restrict a substance is published and followed by a six-month public consultation. Anyone can comment on a proposal to restrict a substance. Those most likely to be interested are companies, organisations representing industry or civil society, individual citizens, as well as public authorities. Comments are welcomed from the EU or beyond.

Third parties submit comments on on-going consultations online, and are encouraged to comment within the first three months of the consultation period to ensure that comments are taken into account when the rapporteurs of RAC and SEAC meet three months after the publication of the proposal. Details of previous consultations are also available online.

Opinions of the RAC and the SEAC

Rapporteurs of RAC and SEAC meet three months after the publication of the proposal in order to generate two draft opinions. The roles of the RAC and the SEAC are distinct:

- RAC evaluates whether the suggested restriction is the appropriate measure to reduce the risk to human health and the environment. Within nine months of the publication of the proposal,

RAC will adopt its opinion. RAC working procedure on processing of Annex XV restriction dossiers

- SEAC balances the pros and cons of the restriction for society, based on the information provided by proposals and the comments received. The committee analyses the health and environmental benefits, the associated costs and other socio-economic impacts of the restriction. The draft opinion of SEAC is subject to a public consultation.

The working procedures of the RAC and the SEAC for developing opinions on restrictions describe the main roles and tasks of the (co-)rapporteurs, the members of RAC and SEAC, and the ECHA Secretariat, as well as giving the timelines for different tasks. Table 12 below outlines the main steps in the development of the RAC final opinion and the SEAC draft opinion, starting from the publication of an Annex XV restriction dossier on the ECHA website.

Table 12: Main steps in the development of RAC final opinion and SEAC draft opinion on restrictions

	Step	Deliverables and milestones	Timeframe
Start of public consultation on Annex XV dossier			
A	RAC & SEAC members are informed via e-mail about the start of the public consultation on an Annex XV restriction proposal with the Member States, the Forum and interested parties.	Information	Date of publication on ECHA website week 1
B	A Newsgroup to the full Annex XV dossier will be created in the RAC CIRCA IG and the SEAC CIRCA IG with deadline for initial comments by the end of the month 2.	Initial comments	Date of publication on ECHA website week 1
C	First dialogue between RAC & SEAC (co-) rapporteurs will be convened for first preliminary exchange of views on the proposed restriction. Dossier submitter, Chair of the Forum working group on restrictions and other participants to be invited on request of rapporteurs.	Exchange of views	Week 2-6
D	The preliminary draft Forum advice will be made available to the (co-)rapporteurs.	Information	Week 7-8
E	SEAC & RAC deliver the 1st version of draft opinions (and rapporteurs questions) to the Secretariat, taking into account the preliminary draft Forum advice and any SEAC comments.	1st versions of RAC & SEAC opinions	By week 10
F	1st version of the SEAC draft opinion will be made available to RAC for information via the CIRCA IGs after their submission to the Secretariat. 1st version of RAC opinion will be made available to SEAC for information via the Circa IG after its submission to the Secretariat.	Information	By end of week 10
G	Draft Forum advice will be made available to SEAC via the SEAC Circa IG as soon as it becomes available.	Information	By end of week 12
H	RAC provides written comments on Rapporteur's 1st version of the RAC opinion and rapporteur's questions, if any, within 21 days. SEAC provides written comments on Rapporteur's 1st version of the SEAC opinion and rapporteur's questions, if any, within 21 days.	Written comments	By week 13
I	Comments submitted by MSCAs and interested parties by 14th week, as well as the first Forum advice will be compiled in a table by the Secretariat and made available to RAC and SEAC via the CIRCA IGs.	Information	By week 14
J	Dossier submitter will be asked by the Secretariat to prepare within 21 days a response to the comments (early RCOM) and to the first Forum advice and to provide a Background Document (BD) based on the original Annex XV report. This early RCOM and the BD7 prepared by the dossier submitter will be forwarded to the RAC and SEAC members via CIRCA IGs.	Information	By week 17

	Step	Deliverables and milestones	Timeframe
K	Second dialogue between SEAC & RAC (co-) rapporteurs for exchange of views on the comments received, early RCOM and impact on the opinions. Dossier submitter, the lead member of the Forum Working Group on Enforceability of Restrictions and any other relevant participants to be invited on request of rapporteurs.	Exchange of views on the comments	Week 18-19
L	The rapporteurs & co-rapporteurs of both the RAC and the SEAC prepare a response to the comments of their respective committees on their 1st version of their respective opinions in a table format (ORCOM9 table) and, if necessary, a 2nd version of the opinion (based on Committee comments and the early RCOM) within 21 days and send both documents to the ECHA Secretariat for distribution to RAC and SEAC members via CIRCA. RAC & SEAC rapporteur & co-rapporteur also review and make comments to early RCOM (if relevant) and send it to the ECHA Secretariat for distribution to RAC and SEAC members via CIRCA.	2nd version of RAC & SEAC opinions and ORCOM, revised RCOM	By end of week 22
M	Drafting group consisting of the Secretariat, RAC & SEAC rapporteurs and co-rapporteurs and dossier submitter will revise the BD to be in line with the rapporteur`s 2nd version of RAC opinion.	Revised BD	By end of week 22
N	First plenary discussion on the 2nd version of RAC opinion will take place leading to rapporteur's 3rd version of the opinion at the plenary, if necessary. First plenary discussion on the 2nd version of SEAC draft opinion will take place leading to rapporteur's 3rd version of SEAC draft opinion at the plenary, if necessary.	Discussion at RAC & SEAC Plenary meetings, 3rd versions of RAC & SEAC opinions	Week 24-25
O	3rd versions of the RAC and SEAC opinions will be made available to Forum and, following request, for Forum advice on enforceability of the proposal made in the opinion.	Information	By end of week 24-25
	End of public consultation		
P	Final comments submitted by interested parties and MSCAs will be compiled by the Secretariat and made available to RAC, SEAC and Forum via CIRCA IGs.	Information	By week 27
Q	Second Forum advice (if relevant10) will be made available to RAC and SEAC via the CIRCA IGs.	Information	By week 29
R	Dossier submitter will be asked by the Secretariat to prepare the response to the final comments (final RCOM) within 21 days This final RCOM prepared by the dossier submitter will be forwarded to the RAC and SEAC members via CIRCA.	Information	By end of week 30
S	Third dialogue between SEAC & RAC (co-) rapporteurs will be convened for third exchange of views on the comments received and consultation on possible further amendments in the draft opinions and in BD. Dossier submitter, the lead member of the Forum Working Group and any other relevant participants to be invited on request of rapporteurs.	Exchange of views and consultation on draft opinions	By end of week 31
T	The final Forum advice will be made available to SEAC and RAC via the Circa IGs.	Information	By end of week 33
U	RAC & SEAC rapporteurs & co-rapporteurs will prepare 4th versions of the RAC & SEAC opinions if necessary on the basis of the final comments and second Forum advice (when given) within 21 days after receiving them and send it to the ECHA Secretariat for distribution to RAC and SEAC members via CIRCA. RAC & SEAC rapporteurs & co-rapporteurs will also review and make comments to the final RCOM (if relevant), respond to the second Forum advice (when given) in the final RCOM and send the revised final RCOM to the ECHA Secretariat for distribution to RAC and SEAC members via CIRCA.	4th versions of RAC & SEAC opinions revised RCOM	By end of week 33
V	Drafting group consisting of the Secretariat, RAC & SEAC rapporteurs and co-rapporteurs and dossier submitter will revise the BD to be in line with the rapporteur`s 4th version of RAC & SEAC opinions.	Revised BD	By end of week 33
W	4th version of RAC opinion will be made available to SEAC for information via the CIRCA IG after it has been sent to the Secretariat. 4th version of the SEAC draft opinion will be made available to RAC for information via the CIRCA IGs after it has been sent to the Secretariat.	Information	By end of week 33
X	SEAC members provide written comments on rapporteur´s 4th version of SEAC draft opinion and BD, and reviewed RCOM (including response to the final Forum advice where relevant), within 14 days of posting of the draft opinion on the SEAC Circa Newsgroup. RAC members provide written comments on rapporteur's 4th version of the RAC	Written commenting	By end of week 35

Step		Deliverables and milestones	Timeframe
	opinion and BD and reviewed RCOM within 14 days of posting of the draft opinion on the RAC CIRCA Newsgroup		
Y	SEAC rapporteur & co-rapporteur prepare their oral responses to be given at the forthcoming SEAC plenary meeting to the comments received from SEAC members on the 4th version of SEAC draft opinion. RAC rapporteur & co-rapporteur prepare their oral responses to be given at the forthcoming RAC plenary meeting to the comments received from the RAC members on the 4th version of RAC opinion.	Oral response	By week 37-38
Z	Following the discussion at a SEAC meeting, SEAC may agree on its draft opinion on the proposed restriction either by a) agreeing on an unchanged version of the rapporteur's 4th version of the draft opinion; or b) agreeing on an opinion modified by the rapporteur during the meeting in line with the outcome of the discussion. Following the discussion at a RAC meeting, RAC may adopt its opinion and RAC-related parts of the BD on the proposed restriction either by a) adopting an unchanged version of the Rapporteur's 4th version of the opinion; or b) adopting an opinion modified by the rapporteur during the meeting in line with the outcome of the discussion. In all cases the RAC – related parts of the BD will be modified at the meeting, as necessary, to support the opinion. The opinion may be adopted either by consensus or by simple majority. In the latter case the minority positions will also be recorded and published with the opinion. When RAC does not formulate an opinion, the reasons would be documented in the minutes. Final RAC opinion is published on the ECHA website and RAC CIRCA IG.	SEAC plenary discussion RAC Plenary discussion, Final RAC opinion	Week 38-39
End of the procedures for the RAC – month 9			

ORCOM - document compiling RAC members' comments on the rapporteur's version of the opinion and the rapporteur's response to them.
RCOM - document compiling comments received during the public consultation and dossier submitter's response to them
CIRCA – online information storage and share-point for the EU institutions
BD – background document

Source: SEAC and RAC working procedures for the processing of Annex XV dossiers

Public Consultation on the SEAC Opinion

After publishing the draft opinion of SEAC, ECHA organises another public consultation where all interested parties may comment only on the SEAC draft opinion. Other comments cannot be taken into account. Comments are welcomed from the EU or beyond. The consultation lasts for 60 days after the publication of SEAC's draft opinion, with third parties able to enter comments online on the on-going consultations webpage.

The procedures for the SEAC during and following the public consultation on their draft opinion are set out in table 13 below.

Table 13: Steps for SEAC during the public consultation on the SEAC draft opinion on an Annex XV restriction

	Step	Deliverables and milestones	Timeframe
Start of public consultation on SEAC draft opinion			
A	SEAC members are informed via e-mail about the start of the public consultation on a SEAC draft opinion with the Member States, the Forum and interested parties.	Information	Week 40
B	The lead member of the Forum Working Group, in cooperation with the Working Group, provides support on enforcement related issues to the SEAC (co-)rapporteurs in the elaboration of the SEAC final opinion..	Support	Month 10-12
C	Comments submitted by MSCAs and interested parties by end of week 44 will be compiled in a table by the Secretariat and made available to SEAC via the Circa IG.	Information	End of week 44
End of the public consultation on the SEAC draft opinion			
D	Final comments submitted by MSCAs and interested parties will be compiled by the Secretariat and made available to SEAC via the Circa IG.	Information	Week 49
E	SEAC rapporteur & co-rapporteur will prepare a response to final comments received within the public consultation on SEAC draft opinion (external ORCOM) and the 1st version of SEAC final opinion within 1 week after receiving them and send both documents to the Secretariat for distribution to SEAC and RAC members via Circa.	External ORCOM, 1st version of SEAC final opinion	Week 50
F	Drafting group consisting of the Secretariat, SEAC rapporteur and co-rapporteur and dossier submitter will revise the BD to be in line with the rapporteur´s 1st version of SEAC final opinion. The Secretariat will be leading and co-ordinating the work of the drafting group.	Revised BD	Week 50
G	SEAC rapporteur & co-rapporteur give their oral responses to the comments received from SEAC members on the 1st version of SEAC final opinion and if relevant, modify the opinion at the plenary.	Oral response	Week 51-52
H	Following the discussion at a SEAC plenary meeting, SEAC may adopt its final opinion on the proposed restriction either by a) adopting an unchanged version of the rapporteur´s 1st version of SEAC final opinion, or b) adopting an opinion modified by the rapporteur during the meeting in line with the outcome of the discussion. The opinion may be adopted either by consensus or by simple majority. In the latter case the minority positions will also be recorded and published with the opinion.	SEAC plenary session	Week 51-52
I	When SEAC does not formulate an opinion, the reasons would be documented in the minutes.	Reasons documented	Week 51-52
J	SEAC final opinion (compiled with RAC opinion) and the final BD are published on the ECHA website, SEAC and RAC Circa IGs and forwarded to the Commission.	SEAC final opinion, final BD	Week 52
End of the procedure for the SEAC - End of month 12			

Publication by the European Commission

ECHA forwards the two opinions of the scientific committees to the European Commission, who drafts an amendment to the list of restrictions (Annex XVII of REACH) within three months. A new restriction or a revision of an existing restriction will be adopted if the European Council of Ministers or the European Parliament do not oppose to the restriction.

List of Restrictions

The list of restrictions contains those substances (on its own, in a mixture or in an article) for which manufacture, placing on the market or use is limited or banned in the European Union. This list is Annex XVII to REACH and includes all the restrictions adopted in the framework of REACH and the previous legislation, Directive 76/769/EEC. Each entry shows the substance or group of substances or the mixture, and the conditions of their restriction. The latest consolidated version of REACH presents the restrictions adopted until that date. Subsequent changes are included in the amending Commission regulations.

3.5. Information in the Supply Chain

REACH Reference: Title IV, Information in the supply chain, Articles 31-36

3.5.1. Safety Data Sheets

REACH Reference: Article 31, Annex II

Safety data sheets are the main tool for ensuring that manufacturers and importers communicate enough information along the supply chain to allow safe use of their substances and mixtures. Safety data sheets include information about the properties of the substance, its hazards and instructions for handling, disposal and transport and also first-aid, fire-fighting and exposure control measures.

Suppliers of a substance or a mixture shall provide the recipient of the substances or mixture with a Safety Data Sheet in the following cases:

- A substance (and from 1 June 2015 a mixture) classified as hazardous according to CLP.
- A mixture classified as dangerous according to the Dangerous Preparations Directive (until 1 June 2015).
- A substance that is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), as defined in REACH (Annex XIII), or
- A substance is included in the Candidate List of substances of very high concern.

Under certain conditions some mixtures, which do not meet the criteria for classification as dangerous or hazardous, also require a safety data sheet.

Safety Data Sheets must be complied in accordance with REACH Annex II, with ECHA having provided Guidance on the compilation of safety data sheets. The safety data sheet shall be dated and shall contain the following headings:

1. identification of the substance/preparation and of the company/undertaking;
2. hazards identification;
3. composition/information on ingredients;
4. first-aid measures;
5. fire-fighting measures;
6. accidental release measures;
7. handling and storage;
8. exposure controls/personal protection;
9. physical and chemical properties;
10. stability and reactivity;
11. toxicological information;
12. ecological information;
13. disposal considerations;
14. transport information;
15. regulatory information;
16. other information.

Where any actor in the supply chain has carried out a Chemical Safety Assessment (under REACH Article 14 or 37) for a specific substance or mixture, the information in the Safety Data Sheet for that substance or mixture must be consistent with this assessment. Relevant exposure scenarios must be included in an annex to the Safety Data Sheet covering identified uses and including specific conditions. The Safety Data Sheet must be provided in the official languages of the Member States where the substance or mixture is placed on the market, free of charge on paper electronically no later than the date on which the substance or mixture is first supplied.

Safety data sheet must be updated and re-issued:

- as soon as new hazard information or information that may affect the risk management measures becomes available;
- once an authorisation under REACH has been granted or refused; or
- once a restriction under REACH has been imposed.

Suppliers must then re-issue the updated safety data sheets to all the recipients that they have supplied the substance or mixture to within the preceding 12 months, free of charge.

3.5.2. Duty to Communicate on Substances in Articles

REACH Reference: Article 7(2), Article 33

The identification of a substance as a SVHC and its inclusion in the Candidate List creates certain legal obligations for the importers, producers and suppliers of an article that contains such a substance. REACH defines an article as an object which during production is given a special shape, surface or design that determines its function to a greater degree than its chemical composition. According to REACH, articles are for example; t-shirts, flooring and plastic packaging.

In supporting suppliers of articles in fulfilling these obligations, ECHA has published Guidance on requirements for substances in articles, Guidance in a Nutshell: Requirements for substances in articles and Guidance Fact Sheet: Requirements for substances in articles.

Notifications to ECHA of Candidate Substances in Articles

Following Article 7(2), importers and producers of articles must submit a notification to ECHA if a Candidate List substance is present in their articles above one tonne per year and in a concentration above 0.1% weight by weight. Notifications must be submitted online through a REACH-IT webform no later than six months following the inclusion of the substance in the Candidate List.

In some cases, in particular for articles produced in the EU, the use of the SVHC in articles will already have been covered in the registration dossier for the substance. In such cases, no separate notification by the article producer needs to be made to ECHA.

In support of this notification process, ECHA provides a webpage with Questions and Answers on the notification procedure, as well as a Data Submission Manual Part 20 for substances in articles and an Information leaflet on substances in articles notifications.

ECHA then collates the data from the notifications and publishes data on Candidate List substances in articles on their website, based on notification received. ECHA notes that the data does not provide a comprehensive picture of the presence of Candidate List substances in articles on the EU market, as ECHA has only received a limited number of notifications. In addition, the information on the article type and the use in articles in registration dossiers is usually not very specific. Consequently, it is possible that also other articles contain Candidate List substances than those mentioned in on the website.

Duty to Communicated Information on Substances in Articles

Following REACH Article 33, suppliers of articles that contain SVHCs that are on the Candidate List above a concentration of 0.1% (w/w), the supplier must inform the recipient of such an article of the presence of the substance in the article and provided the recipient with enough information to allow safe handling. This obligation applies even in cases, where the total quantity of substance in the produced / imported articles is below 1 tonne per year. Such information should consider the entire life cycle of the article.

The same information requirements exist also in cases of consumer or supplier requests, in which case this information should be provided, free of charge, within 45 days of receipt of the request.

3.5.3. Duty to Communicate for Substances and Mixtures for which no Safety Data Sheet is Required

REACH reference: Article 32

REACH also sets a duty to communicate information down the supply chain for substances on their own or in preparations for which a safety data sheet is not required. Following Article 32, any supplier of a substance on its own or in a preparation who does not have to supply a safety data sheet in accordance with Article 31 shall provide the recipient with:

- the substance registration number
- details of any authorisation granted or denied;
- details of any restrictions; and
- any other available and relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied.

The information shall be provided free of charge on paper electronically no later than the date on which the substance or mixture is first supplied. Requirements for updating the information are common to those for Safety Data Sheets, namely:

- as soon as new hazard information or information that may affect the risk management measures becomes available;
- once an authorisation under REACH has been granted or refused; or
- once a restriction under REACH has been imposed.

3.6. Downstream Users

REACH reference: Title V, Downstream users, Articles 37-39

Downstream users are companies or individuals who use a chemical substance, either on its own or in a mixture, in the course of their industrial or professional activities. Downstream users have a key role to play in advancing the safe use of chemicals by implementing safe use at their own site and communicating relevant information both to their suppliers and their customers. Downstream users can be found in many industries and occupations, with examples presented in box 28 below.

Box 27: Examples of downstream users

Formulators: Produce mixtures, which are usually supplied further downstream. This includes, for example, paints, adhesives, detergents and diagnostic kits.
End-users: Use substances or mixtures but do not supply them further downstream. Examples include users of adhesives, 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-Community supplier has nominated an "only representative" for the purpose of acting as a registrant established in the Community.

When downstream users are based at an industrial site, which can be small or large, they are termed industrial users. When workers use substances or mixtures outside an industrial setting, they are termed professional users. Professional users may be based, for example, in a workshop, a client site, or an educational or healthcare establishment. The distinction between industrial and professional users is made to reflect the typical conditions of use. A worker undertaking spray painting in an automotive plant is termed an industrial user, but a construction worker spray painting a bridge is termed a professional user.

3.6.1. Roles and Obligations

REACH reference: Articles 31(9), 34, 37-39

The main roles and obligations of downstream users are:

- to provide information regarding their uses to suppliers of substances, enabling registrants to include these uses in the chemical safety assessment;

- to implement measures specified by their supplier to ensure the safe use of the substance, or to establish safe conditions of use and document these in a downstream user chemical safety report;
- to inform their supplier if they have new information on the hazards of the substance or the risk management advice is not appropriate;
- to comply with the conditions of any restriction which may apply to that substance; and
- to communicate with their supplier if using a substance included in the Authorisation List.

Box 29 below provides a summary of the main obligations of downstream users and associated timelines. To support implementation of these obligations, ECHA has provided Guidance for downstream users and a Practical guide for downstream users, providing examples of what downstream users should do when they receive exposure scenarios. In addition, ECHA has produced a fact sheets on Safety Data Sheets and Exposure Scenarios: Key information for Downstream Users.

Box 28: Obligations of downstream users

Inform supplier of a use when the substance is not yet registered
The downstream user needs to make a request twelve months before the registration deadline, and the supplier needs to assess the risk of that use.
- 31 May 2012 for 2013 registration, for quantities at or above 100 tonnes per year
- 31 May 2017 for 2018 registration, for quantities at or above one tonne per year
This is a voluntary action.

Inform supplier of a use not covered in the safety data sheet of registered substance
Suppliers need to comply with their obligations before the next supply. However, if the next supply is within one month of receiving the downstream user request, suppliers have one month to comply. Downstream users need to ensure full details are provided. This is an optional action, based on the downstream user review of the safety data sheet.

Implement the measures communicated in the safety data sheet or take alternative actions
Downstream users need to implement the conditions of use within twelve months of receipt of the safety data sheet for a registered substance. Alternatively, downstream users can take other actions:
- Prepare a downstream user chemical safety report
- Determine whether exemptions to preparing a chemical safety report apply
- Change supplier, if feasible
- Stop using the substance or substitute it

Communicate information to suppliers
Downstream users need to inform suppliers if the suggested risk management measures are inappropriate and whenever new information on hazards becomes available. This obligation is laid down in Article 34 of REACH. If it is necessary, this should be undertaken without delay.

Communicate information regarding safe use to own customers
Downstream users have to communicate information regarding the safe use of their own customers within twelve months of receipt of the safety data sheet for a registered substance. Downstream users need to update the safety data sheet without delay if:
- New information on risk management measures or hazards becomes available
- An authorisation was granted or refused
- A restriction has been imposed
This obligation is laid down in Article 31(9) of REACH.

Preparing a downstream user chemical safety report
Downstream users may choose to carry out a chemical safety assessment if they use a substance outside the conditions described in the exposure scenario provided by the supplier, or if the use is advised against by the supplier. The chemical safety assessment is documented in a chemical safety report, which should be kept up to date and available. A downstream user chemical safety assessment needs to address only the uses that are not covered in the received exposure scenarios. There is no requirement to undertake a hazard assessment if the downstream user considers the hazard assessment reported in the safety data sheet to be appropriate. If downstream users need to prepare a downstream user chemical safety report, this has to be done within twelve months of receipt of the safety data sheet for a registered substance. They have to inform ECHA that they intend preparing a chemical safety report within six months. However, downstream users do not submit the chemical safety report themselves to ECHA.
There are a number of cases where downstream users do not need to carry out a chemical safety assessment. These are:
- A safety data sheet is not required for the substance. For example, because it is not classified as hazardous.
- A chemical safety report is not required for the substance. For example, because the registered tonnage is below 10 tonnes).
- The substance is present in a mixture in a concentration lower than any of the concentrations set out in Article 14 (2) of REACH.
- Downstream users use the substance or mixture in a total quantity of less than one tonne per year.
- Downstream users use the substance for process oriented research and development (PPORD).

Downstream user report to ECHA
Downstream users need to report unsupported uses to ECHA within six months of receipt of the safety data sheet for a registered substance. This requirement applies if:
- They prepare a downstream user chemical safety report.
- They claim exemptions due to the use of a substance or mixture in a quantity of less than one tonne per year, or they use the substance for process oriented research and development (PPORD).
- They have a different classification of a substance to their supplier.
Downstream user reports are submitted online either via a webform available on the ECHA website, or via REACH-IT.
There is one exception to this requirement. Downstream users do no need to report to ECHA if the quantity of the substance for that particular use is less than one tonne. However, the chemical safety report must still be prepared, if the total use by the downstream user is greater than one tonne per year.

Where substances used by downstream users are subject to authorisation under REACH, a downstream user may apply for an authorisation or have their use included in an authorisation applied for by a supplier or manufacturer.

Downstream uses that are formulators must provide their customers with appropriate information on hazards and conditions of safe use for their mixture. Formulators need to communicate relevant safety information further down the supply chain to their own customers. This information can be communicated in any of the following ways:

- Include the information in the main body of the safety data sheet provided to customers.
- Generate exposure scenarios for customer uses and attach these to the safety data sheet.
- Forward the exposure scenarios received from suppliers to the customers.

3.7. REACH Fees

ECHA fees are laid down in Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to ECHA and are subject to regular reviews.

Specifically, the REACH Regulation requires that fees or charges are paid for:

- registration of chemicals;
- request (in a registration submission) that certain information is kept confidential;
- certain updates of registration submissions;
- notification to the Agency of product and process orientated research and development activities with a view to obtain an exemption from the obligation to register;
- an extension of the exemption indicated above;
- application for an authorisation for chemicals included in Annex XIV of REACH;
- review of an authorisation; and
- appeals to the Board of Appeal of the Agency.

Fees for REACH Registration Dossiers

Fees are charged for the submission of registration dossiers. In addition, confidentiality claims are chargeable. After a REACH submission has been received by ECHA, ECHA sends out invoices to registrants electronically, via REACH-IT. This electronic invoice can be downloaded from the REACH-IT account in PDF format.

In case of fees for registrations submitted, as well as in the case of updates of a registration, the initial payment due date of the fee is set to 14 calendar days from the date on which the invoice was notified. However, in the case of fees for registration of pre-registered substances, the initial payment due date of the fee is set to 30 calendar days from the date on which the invoice was notified.

It is important to note that in case the payment has not been made within the prescribed period (by the initial payment due date), ECHA will set a second deadline for payment. This second deadline (extended payment due date) is usually up to 60 calendar days from the initial payment due date.

The late payment of a REACH registration fee renders the dossier incomplete and will lead to a rejection of the registration. The registration fee is not be reimbursed in such cases.

Fees for PPORD Notification

Fees invoiced for notification of an exemption for product and process oriented research and development (PPORD), as well as charges for requests to extend this exemption. In case of fees for notification of PPORD exemptions, the initial payment due date of the fee is 7 calendar days from the date on which the invoice was notified. In case of requests to extend a PPORD exemption, the initial payment due date of the fee is set to 30 calendar days from the date on which the invoice was notified.

In case the payment has not been made by the initial payment due date, ECHA will set a second deadline. This second deadline (extended payment due date) is usually up to 60 calendar days from the initial payment due date. Where the payment is not made by expiry of the second deadline, the notification or the request for an extension will be rejected.

Making Payments

Bank transfer is the only payment method accepted. ECHA's full bank details are given in the invoice, and every payment must indicate the invoice number.

Amendment to the Fee Regulation

In 2013, the Commission amended the REACH fee regulation through Fee Regulation (EC) No 254/2013.with the aim of benefiting SMEs. The reduction awarded to micro, small and medium-sized enterprises in registration and authorisation fees will be increased by 5 percentage points. This is to lessen the impact of complying with REACH obligations on SMEs.

In order to avoid any negative effect on ECHA's revenues, the standard registration fees and charges will be increased by 4 per cent and the standard authorisation fees by 3.5 per cent. Moreover, all fees will for the first time be adjusted for the inflation that was recorded in the EU in 2011, which was 3.1 per cent. REACH fees have not been updated in the four consecutive years (from 2009 to 2012).

The new fees entered into force on 22 March 2013, one day after the amendment of the fee regulation has been published in the Official Journal of the European Union.

Further changes were made to the fee regulation. In particular, companies can now ask for an extension to the payment deadlines in two specific cases: invoices concerning confidentiality claims in updated dossiers and invoices concerning legal entity changes. To benefit from these extensions, companies are requested to contact the ECHA helpdesk.

Tool for Fee Calculation

In order to assist industry in calculating their fees under REACH, ECHA provides a REACH fee calculator plug-in and a dossier submission manual. In addition ECHA provides frequently asked questions on fees.

3.8. Enforcement of REACH

The actual implementation and enforcement of REACH is the responsibility of the Member States. REACH requires the Member States to maintain systems of official controls, to monitor compliance, and to report on the results of the controls and other enforcement measures taken. The harmonisation of enforcement amongst Member States was a key issue during the development of REACH and led to the development of the European Chemicals Agency Forum for Exchange of Information on Enforcement (the FORUM). The FORUM, according to Regulation (EC) 1907/2006, coordinates a network of enforcement authorities responsible for the following tasks:

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

- Examine proposals for restrictions with a view to advising on enforceability (Art.77(4)); and
- Agree common issues to be covered in the annual reports from the Member States in relation to enforcement (Art. 127).

The Forum has adopted a set of minimum inspection criteria for REACH and CLP, which should be utilised primarily in the context of the Market Surveillance Regulation. The REACH Minimum Criteria propose an inspection regime based on coordinating the work of the various enforcement and customs authorities whose mandates include REACH; advance planning of inspection activities; recording and reporting results; and communicating clearly with REACH dutyholders. The inspections themselves should consider risks to and impact on health and the environment, and should respond promptly to complaints or incidents. They should also "promote dutyholders' knowledge and understanding of their duties under REACH," and "preserve confidentiality where necessary."

These criteria operate alongside the Forum's "Strategies for enforcement of [REACH] of March 2009," which provides a framework and general recommendations for developing national REACH and CLP enforcement strategies within the Member States, who may develop their national enforcement strategies and establish their enforcement priorities according to the national circumstances within the framework developed in the document. The document includes essential requirements for REACH, which includes Article 67(1) within the list of supply chain related duties and use related duties, which should be considered when setting priorities for enforcement activities. The Strategy concludes that coordinating REACH/CLP inspection activities with other enforcement authorities such as labour inspectorates, industrial pollution control inspectorates, and market surveillance authorities is important for achieving the maximum benefit from the REACH/CLP regime. It acknowledges this to be a medium to long-term effort and recognises that additional policy and guidance may be needed at EU-level to achieve these potential gains.

3.8.1. Enforcement of Restrictions

Article 67(1) of REACH states that substances subject to restriction, shall not be manufactured or placed on the market unless they comply with the condition of that restriction. A 2011 Milieu report[43] assessed the level of implementation and enforcement of the restrictions under Annex XVII of REACH, with a focus on 10 selected restrictions. The report found that the degree of implementation and enforcement varies both by substance and across the Member States. The report found that the majority of Member States having taken some sort of action, such as reactive enforcement, non-

[43] Milieu (2012) Implementation and Enforcement of Restrictions under Title VIII and Annex XVII to REACH in the Member States, Final Report, Milieu, Brussels

official product checks, checks on products notified under RAPEX, preliminary investigations or information campaigns, rather than actual enforcement campaigns. The majority of non-compliant products were found to be imported products from outside EU, suggesting an important role for customs officials.

3.9. Advantages, Challenges and Disadvantages of REACH

3.9.1. Advantages

Role for Industry in Providing Data and Testing Chemicals

REACH Article 1 states that "*the Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment."* REACH requires that the manufacturers and importers of substances obtain information on the substances they manufacture or import and use this information to assess the risks arising from the uses and to ensure that risks are properly managed. This process is documented in the registration dossier that manufacturers and importers of substances are required to submit to ECHA for each substance manufactured or imported in quantities of 1 tonne or above per year.

Importantly, the costs of ensuring that chemicals placed on the market are safe, in terms of data gathering, and where required, testing, are carried by industry and not by the regulator.

However, a recent publication entitled "*Identifying the Bottlenecks in REACH Implementation*"[44] by Client Earth and the European Environmental Bureau (EEB) accuses industry of attempting to undermine the REACH system in a number of ways, including:

- giving an unclear identification to a substance so that several substances can be registered under one dossier (with a considerable saving in costs);
- unduly claiming that the substance is an intermediate (as the information requirements are simplified); and
- submitting very poor quality dossiers including irrelevant information or empty fields.

[44] EEB and Client Earth (2012) identifying the bottlenecks in REACH: the role of ECHA in REACH's failing implementation, EEB and Client Earth, Brussels

The report argues that this had led to missing information for substance on the market and has impeded decision making on restrictions and authorisations. This suggests implementation issues exist and enforcement of requirements is needed.

Increased Information on Chemicals on the EU Market

REACH Registration requirements are contributing to the expansion and acceleration of international assessment of chemical risks, and significantly increasing the availability of information on the hazards and risks associated with the different uses of chemical substances.

A 2012 RPA report[45] found that information generated under REACH is resulting in changes in classification, with the majority of these being more restrictive classifications, in particular endpoints such as acute toxicity, sensitisation, reproductive toxicity and aquatic toxicity (acute and chronic). They found that the percentages classified after registration increased across all of the endpoints being considered, and suggest that the reliability of classifications is improving with increased information on substances properties. Since classifications then drive the need for a CSA (at 10 + tonnes) including exposure scenarios and recommended risk management measures in their extended Safety Data Sheets (eSDS), this will increase available information on safe chemicals management.

Improved Risk Management

The 2012 RPA report on the health and environmental benefits of REACH supported the hypothesis that CSA should lead to safer use as new or more stringent risk management measures than those currently in place are recommended by registrants to their downstream supply chains. They argue that this should lead to benefits for workers, to the environment (through reduced emissions) and to the general public through reductions in exposures. Elements of REACH found to enhance the benefit drivers are the provision of guidance, evaluation, inspections and enforcement activities. Key benefits include:

- an increase in the available information on chemicals resulting in changes in classification, the majority being to more stringent classifications;
- increased information in the supply chain and the use of safety data sheets leading to better risk management and risk reduction; and
- moves towards the substitution of SVHC in the supply chain.

[45] RPA, 2012, Assessment of health and environmental benefits of REACH, ENV.D.3/SER/2011/0027r, available at: http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review2012/health_env_benefits_en.htm

The 2013 General Report on REACH therefore concludes that "*progress towards meeting the human health and environment objective of REACH is therefore materialising*" and anticipates that this trend will accelerate. The report does identify a number of shortcomings which may reduce benefits, including:

- many registration dossiers have been found to be non-compliant, including with regard to substance identity;
- insufficient assessments by registrants of persistent, bioaccumulative and toxic (PBT) and very persistent, and very bioaccumulative (vPvB) properties;
- problems with regard to the content and format of the extended safety data sheets.

Substitution

In terms of the market withdrawal of substances in response to REACH requirements, the 2012 RPA report found qualitative evidence that substances have been "dropped" from the market or otherwise not registered due to their properties (in particular CMRs) and the potential costs of supporting them through authorisation as well as registration. However, it was not clear that withdrawn substances were consistently replaced with less hazardous substances, rather in some cases, manufacturers are offering alternative substances of a similar hazard profile.

3.9.2. Challenges and Disadvantages

Costs on Industry, Impacts on SMEs

The implementation of REACH has significant cost implications for industry, in particular SMEs. The General Report on REACH notes that the cost of REACH registration has discouraged some companies from competing on certain substances' markets, which has increased market concentration and prices for these substances.

The registration has impacted also downstream users who are, in general, less aware of their role in REACH. The Commission has committed to further monitoring the situation, especially in the context of future registration deadlines. In particular, attention has to be paid to the situation of article producers and to the costs related to the administration of REACH. Given that great majority of downstream users are SMEs, they should be a focus in improving the implementation of REACH

Evidence suggests that a significant number of SMEs are unaware about their role and obligations related to REACH, and those who are aware, may have a false impression of the exact scope of their duties, which calls for further action to support and guide these types of companies. The

Commission's concern over the impact of REACH on SMEs is reinforced by the recent survey showing that REACH is considered by SMEs as one of the 10 most burdensome pieces of EU legislation[46].

In the General Report on REACH, the Commission made a number of commitments, including to:

- reduce the financial impact of the Regulation, in particular for SMEs, inter alia, by reviewing the distribution of registration fees to grant greater reductions to SMEs and by asking ECHA to provide more specific guidance on transparency, non-discrimination and fair cost sharing;
- address concerns about transparency, communication and cost sharing in the Substance Information Exchange Forum (SIEF), to intensify collaboration on streamlining procedures and to develop user-focused guidance, all with special attention to the SMEs and costs;
- continue to promote REACH-compatible legislation internationally;
- monitor the preparedness of the industry ahead of the next registration deadlines and encourage Member States and ECHA to strengthen efforts in relation to prepare the industry for these crucial milestones.

The Commission has subsequently reduced fees for SMEs to spread the financial impact of registration more evenly.

Limitations in the Scope

As mentioned above, the requirement for REACH registration applies to all substances manufactured or imported in quantities at the threshold of one tonne per year or more. It has been noted that highly toxic or ecotoxic substances produced or imported at below 1 tonne may cause more problems than a less toxic substance produced or imported in much larger volumes and the exclusion from REACH of substances in this tonnage band is seen as one of the compromises that were made in order to facilitate implementation of the legislation.[47]

Limitations in the Information Requirements

The information requirements for 1-10 tonne substances are quite limited, in particular for phase in substances that do not meet the REACH Annex III criteria. Even for those substances that do meet these criteria, the information provided may be insufficient to allow for effective classification of

[46] Public Consultation: "Which are the TOP10 most burdensome EU legislative acts for SMEs?" held by the European Commission from 28.09.2012 to 21.12.2012.

[47] Rudén C and Hansson SO (2010) Registration, Evaluation, and Authorization of Chemicals (REACH) Is but the First Step–How Far Will It Take Us? Six Further Steps to Improve the European Chemicals Legislation, Environmental Health Perspectives, Vol. 118(1): 6–10

these substances under CLP Regulation. In turn, risk management measures under environment, consumer and occupational health and safety legislation may not be implemented in full. The lower data requirements for these substances are based on the assumption that human (occupational, consumer and via the environment) and environmental exposure to 1 to 10 tonne substances will be lower than for high production volume substances. It is of note that the possibility to extend the information requirements for substances manufactured or imported at 1 tonne and below 10 tonnes has been assessed under an RPA study[48] as part of the 2012 REACH Review, with particular consideration of the latest developments in alternative hazard information generation methodologies.

Generating Data for Classification

It is one of the purposes of REACH to generate data on the toxicity and ecotoxicity of substances in order to feed into hazard assessment and substance classification. CLP sets the criteria by which available hazard data should be assessed and specifies the corresponding hazard classification categories and the warning labels that apply to each classification. In addition, CLP also specifies standardized test methods for different end points. The connection between REACH and CLP and the subsequent effect that hazard classification has on the application to substances of downstream legislation aimed at protecting the environment, workers and consumers from exposure to chemicals makes it important to compare the data required by REACH with the data that are required for hazard assessment of different end points.

Rudén and Hansson (2010)[49] undertook an analysis of the data yields delivered under REACH against the data requirements for classification under different endpoints. The analysis is based on hazard criteria as specified according to the Dangerous Substances Directive. It suggests that data for effective hazard assessment will be lacking, in particular for substances produced and on the market at <10 tonnes. The results of the analysis are summarised in table 14 below, where a + indicates that the data requirements for classification under an endpoint are met and – indicates that they are not met.

[48] RPA, Milieu, GNOSYS and ARCHE, 2013, Review of REACH with regards to the registration requirements for polymers and 1-10 tonnes substances, RPA, UK

[49] Rudén C and Hansson SO (2010) Registration, Evaluation, and Authorization of Chemicals (REACH) Is but the First Step–How Far Will It Take Us? Six Further Steps to Improve the European Chemicals Legislation, Environmental Health Perspectives, Vol. 118(1): 6–10

Table 14: Summary of REACH data yields by tonnage against data demands of classification criteria

Endpoint	Tonnage band			
	1-<10tonnes	10-<100tonnes	100-<1000 tonnes	≤1000 tonnes
Acute toxicity	+ - for non Annex III phase in	+	+	+
Sub-acute toxicity	-	+	+	+
Mutagenicity	Test requirements determined in a stepwise procedure based on initial testing			
Carcinogenicity	-	-	-	+
Reproductive toxicity	-	-	+	+
Ecotoxicity	+ - for non Annex III phase in	+	+	+
PBT and vPvB	-	-	+	+

CLP classifications are based on available data, which in many instances may be limited to that generated under REACH. It should be noted that Article 5 (1) of the CLP Regulation provides a list of other data sources, which may include pre-existing data, and/or data generated under independent studies or under other EU legislation (i.e. Biocides, PPPR, Cosmetics, Food Contact Materials Regulation). With the exception of data on physico-chemical properties, there is no requirement under CLP for the generation of additional information solely for the purposes of classification, although it cannot be excluded that companies may choose to generate new data to inform classification. However, for the majority of chemical substances manufactured or imported into the EU, REACH represents the main tool for generating data. The analysis reported above suggests that data will be lacking for some endpoints to allow classification under CLP.

Exposure versus Hazard as Criteria for Testing Requirements

Under REACH, production volume is the main priority-setting criterion for testing requirements, and not hazard criteria. This system for priority setting has been criticised as a severe weakness in REACH.[50] The requirement to undertake a full risk assessment within the context of the CSA is triggered by a combination of tonnage (i.e. 10 tonnes +) and hazard criteria (i.e. PBT, vPvB, dangerous).

Failure to Consider Combination Effects

It is important to note that the risk assessment under REACH essentially considers the risks of single substances in isolation, and does not consider the effects of substances acting in combination. This overlooks the normal situation whereby chemicals interact and present combined exposure to the

[50] Hansson SO and Rudén C (2006) Priority setting in the REACH system, Toxicological Sciences Vol.90(2): 304-308

environment and to humans. Indeed, 90-95% of all chemicals on the European market are preparations, i.e. mixtures of chemical substances. They include: industrial chemicals, such as solvents and coatings; petrochemicals, such as fuels and lubricants; agricultural chemicals such as pesticides; consumer products, such as detergents and disinfectants; and many others.[51] Considering that there are 30,000 to 50,000 chemicals marketed in the EU, and an estimated 50 000 chemicals present in surface waters[52], the potential for mixture effects is considerable.

The combination effect undermines the traditional risk assessment paradigm of a threshold dose below which a chemical fails to produce effects, since every similarly acting chemical in a combination contributes to the overall mixture effect, in proportion to its potency and dose. Whether the individual doses are also effective on their own becomes immaterial, and even doses below thresholds are of relevance. In particular, robust evidence exists of the combination effect for EDCs.[53]

In 2009, Sweden initiated a discussion on chemical combination effects in the European Council, following which the Council adopted conclusions on the combination effects of chemicals[54]. The conclusions invite the Commission to assess how and whether existing legislation addresses this problem and to suggest appropriate modifications and guidelines. In 2010, KEMI followed up with a report entitled "Hazard and risk assessment of chemical mixtures under REACH"[55]. The report notes that "*independent of the specific chemical composition of a particular mixture, the exposed organism or biological endpoint under observation: the joint toxicity of a chemical mixture is always higher than the individual toxic effect of even the most potent compound present*". It further states that REACH does not currently provide a mandate for considering the toxicity of so-called "coincidental" mixtures of industrial chemicals – multicomponent cocktails that are found in the environment or the human body as a result from the concurrent use of different chemicals in a given area. The report considers two options for the risk assessment of "coincidental mixtures" within the context of REACH, namely (a) a default mixture assessment factor (MAF) and (b) scenario specific cumulative risk assessments. The actual implementation of these options is currently hampered by substantial knowledge gaps, mainly data limitations. In particular, data on "typical" exposure scenarios involving

[51] European Commission, DG Enterprise website at: http://ec.europa.eu/enterprise/sectors/chemicals/classification/dangerous-preparations/index_en.htm
[52] Matthiessen P and Johnson I (2006) Implications of research on endocrine disruption for the environmental risk assessment, regulation and monitoring of chemicals in the European Union, *Environmental Pollution,* 146(1) 9–18
[53] EEA (2013) The impacts of endocrine disrupters on wildlife, people and their environments, The Weybridge+15 (1996–2011) report, EEA Technical Report No 2/2012, EEA, Copenhagen
[54] Council of Europe (2009) Combination effects of chemicals, Council Conclusions, 17820/09, 23 December 2009, Brussels
[55] Backhaus T, Blanck H and Faust M (2010) Hazard and risk assessment of chemical mixtures under REACH: State of the art, gaps and options for improvement, 3/10, KEMI, Gothenburg, Sweden

REACH-chemicals is missing. KEMI reiterated the call for an enhanced and harmonised methodology for dealing with combination effects in risk assessment in a 2012 report[56].

A 2010 Special Issues of DG Environment's New Alert Service[57] looked specifically at Combination effects of chemicals, noting that living organisms face an intricate array of physical, chemical and biological environmental stressors that vary in space and time. The issue reports on a biology-based method developed under the NoMiracle Project for assessing combination effects, whereby the interaction of mixtures with biological processes is assessed. This receptor-oriented approach puts the exposed individual, population or ecosystem at the heart of assessment, recognising that the physiology and behaviour of the receptor are important drivers of cumulative risks. In addition, an article within the issue entitled 'Integrating chemical mixture assessments into REACH and the WFD' suggests steps to limit the mixtures to be assessed based on the 'PEC/PNEC' ratio, e.g. for compounds with ratios larger than 0.1. It recommends using Concentration Addition as a default assessment method of mixtures within REACH, a method based on the concentrations and properties of individual chemicals within the mixtures.

In May 2012, the Commission published a Communication from the Commission on Combination effects of Chemicals (Chemical mixtures)[58], committing to launching a new process to ensure that risks associated with chemical mixtures are properly understood and assessed. Under the new approach, the Commission will identify priority mixtures to be assessed and ensure that the different strands of EU legislation deliver consistent risk assessments for such priority mixtures. The Commission will also tackle some of the data and knowledge gaps to improve understanding of the mixtures to which people and the environment are exposed.

Challenges in Identifying SVHC

The preparation of Annex XV dossiers for the identification of SVHC under REACH is time and resource consuming. Given the current economic climate in Europe where government budgets are restricted, MSCAs suffer from a lack of resources for the preparation of dossiers and struggle with the identification of suitable substances for further work. This has slowed down the process of identifying SVHC and the evolution of the CoRAP.

A 2012 EEB report on REACH implementation suggest that given the limited resources of most of Member States to submit Annex XV dossiers, a simplified procedure for the identification of SVHC

[56] KEMI (2012) Improved EU rules for a non-toxic environment, KEMI Report 1/12, Gothenburg, Sweden
[57] European Commission (2010) Combination effects of chemicals, June 2010, issue 21, DG Environment, Brussels
[58] Communication from the Commission to the Council on the combination effects of chemicals Chemical mixtures, /* COM/2012/0252 final

should be considered. In addition, they propose that the RMO analysis should be moved to the prioritisation phase only, where substances with high volumes, wide dispersive use or PBT /vPvB properties would normally be prioritised for listing within Annex XIV.

With the aim of fast-tracking chemicals of urgent concern for substitution, ChemSec, in collaboration with other NGO s in the EU and US, presented the first SIN List in 2008. [59] The SIN List identifies Substances of Very High Concern according to REACH criteria through the combined efforts of public interest groups, scientists, and technical experts. The list is based on credible, publicly available information from existing databases, scientific studies, and new research. The aim of the SIN List is to put pressure on legislators to move forward with speed and urgency. In addition, it aims to provide progressive retail companies with a helpful list of hazardous chemicals to avoid as they aim for a sustainable future.

A 2012 NGO publication[60] criticises the CoRAP as being insufficiently ambitious. It notes that the original target was to have 950 substances evaluated by 2021[61], implying that an average of 95 substances per year would need to be evaluated. ECHA has subsequently lowered its expectations regarding the number of substance evaluations that are feasible to 50 per year.[62] However, given that the programme was only launched in 2012 it remains too early to draw fixed conclusions. Certainly the evaluation will need to accelerate to meet the target of evaluating 951 substances by 2021.

Quality of the Registration Dossiers

The 2013 General Report on REACH recognises the need to improve the quality of registration dossiers.

A 2012 NGO report[63] on REACH implementation is critical of ECHA's efforts in evaluating dossiers. The report notes that in many cases ECHA has restricted its own powers to require registrants to update their dossiers to requesting voluntary improvement of the dossiers through Quality Observation Letters. The report argues that ECHA should exercise the full powers provided to it by REACH and require companies to bring their dossiers into compliance through corrections. In addition, the report argues that in the interest of transparency ECHA should publish all draft decisions

[59] See the ChemSec Website at: http://www.chemsec.org/publications/sin-list
[60] EEB and Client Earth (2012) identifying the bottlenecks in REACH: the role of ECHA in REACH's failing implementation, EEB and Client Earth, Brussels
[61] As reported by ChemicalWatch (2011) ECHA publishes list of 91 substances for evaluation, 21 October 2012, available with subscription at: http://chemicalwatch.com/8803/echa-publishes-list-of-91-substances-for-evaluation
[62] ENDS Europe (2012) ECHA expands REACH evaluation list, 24 October 2012, Brussels
[63] EEB and Client Earth (2012) identifying the bottlenecks in REACH: the role of ECHA in REACH's failing implementation, EEB and Client Earth, Brussels

and Quality Observation Letters, or at least a list including the names of the substances and the identity of the companies. In addition, the report notes that many dossiers that were subject to a compliance check have not yet been made public.

Alternative to Animal Testing

Under REACH, animal testing is to be avoided in favour of alternative methods and registrants can only carry out tests involving the use of animals as a last resort. However, significant challenges remain in identifying alternative testing methods for specific endpoints. REACH registration requirements include reproductive and developmental toxicity testing in experimental animals for 10 tonne + substances. While, alternative methods are encouraged, ECHA's technical guidance indicates that in vitro and QSARs are not adequate to replace reproductive and developmental toxicity testing in whole animals. A 2012 article suggests that the most practical opportunity for the avoidance of whole animal testing for these endpoints may be `read-across,' a process in which gaps are filled using data from related compounds. A method called `weight of evidence' may also replace whole animal reproductive and developmental toxicity testing, based on existing data in regulation and non-regulation studies and based on factors such as chemical structure and anticipated exposure. It is also possible that thresholds of toxicological concerns will be accepted as a method to avoid vertebrate animal testing. Further clarification is required in the ECHA guidance regarding the acceptability of these alternatives.[64]

Challenges with Implementation

Given the fairly recent enactment of REACH, data on approaches towards implementation and actual impacts on the ground remains limited. A 2013 survey[65] by the British trade association EEF of REACH implementation amongst manufacturers in the UK suggest that awareness of REACH requirements remains low and throws some of the benefits into doubt. The survey of 250 firms found that one fifth of respondents thought that REACH did not apply to them at all, while a further 30% said REACH was not important to their business. On a more positive note, the EEF survey found that where there is awareness of REACH, firms are taking action. Nearly four fifths of those aware of REACH had substituted or considered substituting chemicals (in particular, SVHC) as a result, it found. More than half of those aware of REACH were changing work practices and redesigning processes in response. This suggests that information being conveyed through the Safety Data Sheets is having a positive effect. The results indicate that a significant amount of work remains to raise awareness of REACH, provide clarify of requirements and make guidance user-friendly.

[64] Scialli AR and Guikema AJ (2012) REACH and developmental and reproductive toxicology: still questions, Systems Biology in Reproductive Medicine Vol.58(1): 63-69

[65] EEF (2012) REACH: Awareness, activity and perceptions, EEF, UK

4. CLP Regulation

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures[66] ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the EU through classification and labelling of chemicals. Before placing chemicals on the market, manufacturers and importers of substances, downstream users, including formulators of mixtures and re-importers of substances or mixtures must establish the potential risks to human health and the environment of such substances and mixtures, classifying them in line with the identified hazards. The hazardous chemicals also have to be labelled and packaged according to a standardised system so that workers and consumers know about their effects before they handle them. Distributors (including retailers) of substances and mixtures also need to label and package in accordance with CLP.

Manufacturers and importers (or groups of manufacturers or importers) who place a hazardous substance on the market, will also have to **notify** certain information, in particular the substance identity and the classification and labelling of that substance to ECHA, unless this information has already been submitted as part of a registration under REACH. ECHA will then include the notified information in the Classification & Labelling Inventory.

Hazards are communicated through standard statements and pictograms on labels and safety data sheets, with the method for classifying and labelling chemicals based on the United Nations' Globally Harmonised System (GHS). The GHS provides a harmonised basis for globally uniform physical, environmental and health and safety information on hazardous chemical substances and mixtures. It establishes a system to classify hazardous chemicals, to inform uses about hazards through standardised symbols (pictograms) and phrases on the packaging and to provide additional information regarding safe use in Safety Data Sheets (SDS). GHS provides for a building block approach, whereby countries of regions can adapt the system to suit their needs. CLP goes beyond GHS in some areas, by including one additional hazard class, namely hazardous to the ozone layer, and by including additional hazard phrases, EUH014 (reacts violently with water) and EUH066 (in use may form flammable/explosive vapour/air mixture).

CLP entered into force on 20 January 2009 and repeals and replaces, with transitional periods, the Dangerous Substances Directive and the Dangerous Preparations Directive. For substances,

[66] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ LJ353, 31.12.2008, pp.1-1355

classification and labelling had to be consistent with the CLP rules from 1 December 2010, while for mixture the deadline is 1 June 2015.

The applicability of the CLP rules by the aforementioned dates and their relationship to the REACH registration deadlines for phase-in substances are illustrated in figure 9 below.

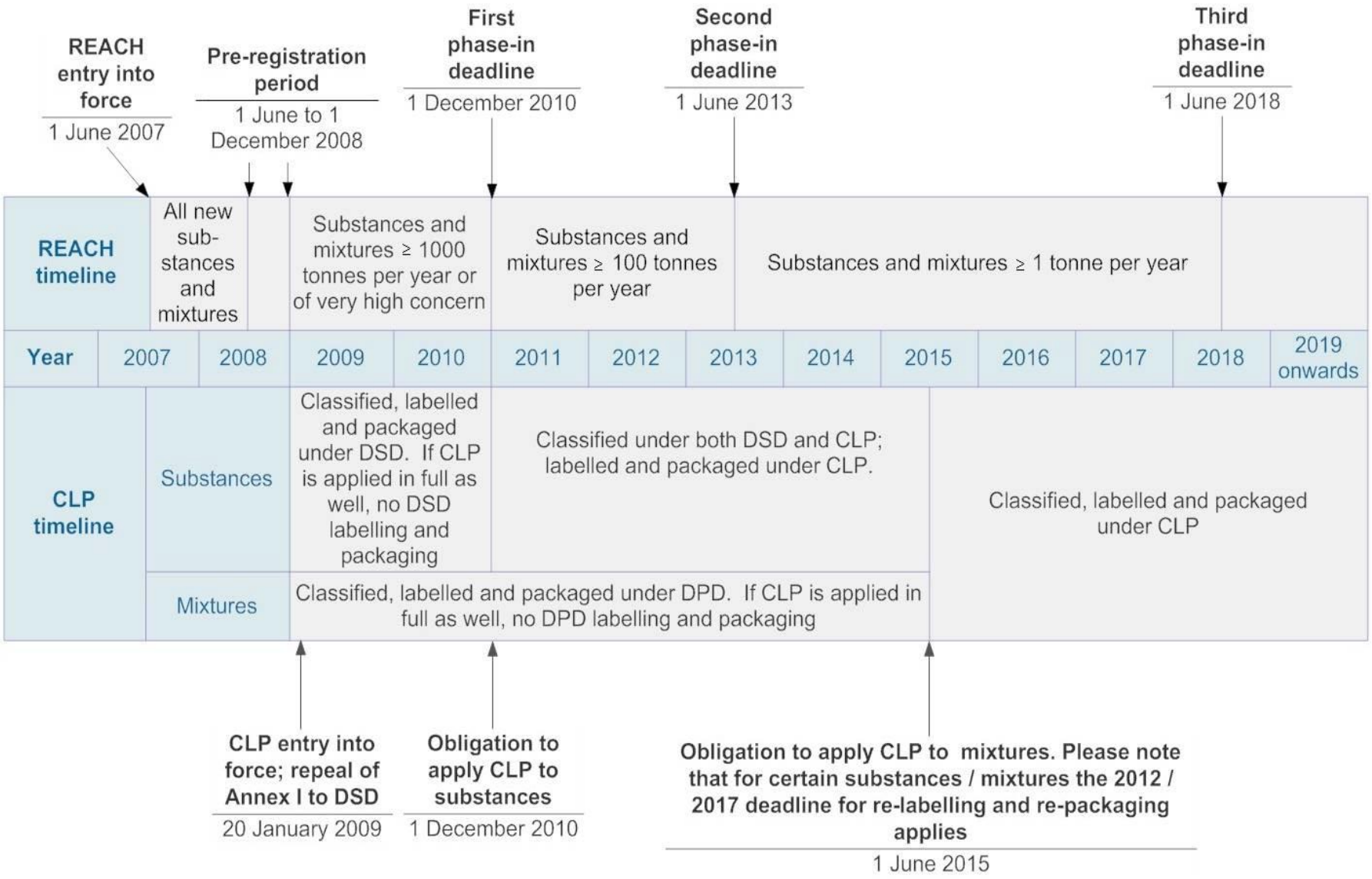


Figure 9: Phase in of CLP Regulation

4.1. Impact on Companies

Suppliers of chemicals must classify, label and package their substances and mixtures in accordance with the CLP Regulation. Suppliers may have one or more of these roles:

- Manufacturer of substances or mixtures
- Importer of substances or mixtures
- Producer of specific articles
- Downstream user, including formulator and re-importer
- Distributor, including retailer

Suppliers placing a hazardous substance on the market must notify ECHA of its classification and labelling within one month of placing the substance on the market for the first time. For importers, the one month is counted from the day when a substance, on its own or contained in a mixture, is physically introduced in the customs territory of the EU.

4.2. Classification

Under CLP there are two parallel systems for classification, harmonised classifications of substances that are agreed at EU level and, in their absence, self classification. These classification systems are described below.

4.2.1. Self Classification

Under CLP, manufacturers, importers and downstream users are generally obliged to classify the substance or mixture that they place on the market on the basis of hazard, through a process called self-classification. There are four basic steps to self-classify a substance or a mixture:

- Collection of available information;
- Evaluation of the adequacy and reliability of the information;
- Review of the information against the classification criteria; and
- Decision on classification.

As such, the hazard classification generally does not generated new data, but rather relies upon relevant available information. This is very likely to include data generated under REACH, and may also include publically available scientific research and research undertaken independently (and

voluntarily) by the private sector. For the purpose of determining whether a substance or a mixture entails a health, physical or environmental hazard, the supplier may be required to undertake additional testing on physico-chemical properties. As such, data generation under CLP is restricted to data on physico-chemical properties in cases where adequate data is not available.

The information gathered and generated must then be evaluated by the duty holders for the purpose of self-classification of substances against the criteria for hazard classification as set out in Annex I to CLP. ECHA has published Guidance on the application of the CLP criteria.

If required by REACH, manufacturers and importers also need to classify substances which are not placed on the market, such as on-site isolated intermediates, transported intermediates or substances for product and process-orientated research and development (PPORD).

Manufacturers, importers and downstream users need to follow new scientific or technical developments and estimate whether a re-evaluation of the classification of the substance or mixture they place on the market should be done.

4.2.2. Harmonised classification and labelling

CLP reference: Annex VI

In addition to self-classification, CLP provides a procedure for legally-binding EU harmonisation. It is then mandatory for the suppliers of the respective substance or mixture to apply this harmonised classification and labelling. The harmonisation of the classifications aims at protecting human health and the environment while enhancing competitiveness and innovation. This could happen in three situations:

- Where the substance is either carcinogenic, mutagenic, toxic for reproduction or a respiratory sensitiser.
- When the substance is an active substance in biocidal or plant protection products.
- When it is justified that a classification at EU level is needed.

All previously harmonised substances classifications under the previous legislation (Dangerous Substances Directive) have been converted into CLP harmonised classifications. CLP has been subject to three Adaptations to Technical Progress (ATP), with the aim revising classification criteria and introducing new hazard categories and sub-categories, as well as updating the list of substances with harmonised classifications. There are currently 4,472 substances on the list of harmonised classification and labelling.

Harmonised classifications are based on proposals to ECHA submitted by competent authorities or duty holders. ECHA assesses the proposal and forwards its opinion to the Commission who may draft a decision on harmonised classification and labelling for inclusion in Annex VI of CLP. The process for developing harmonised classification and labelling is described below.

4.2.3. Harmonised Classification and Labelling Process

CLP reference: Articles 37(1) and 37(2), Annex VI

Member State Competent Authorities or manufacturers, importers and downstream users can submit a proposal for harmonised classification and labelling of substances to ECHA as defined by CLP Articles 37(1) and Art 37(2), respectively. Proposals can only be submitted for substances, and not for mixtures.

The CLH dossier submitted to ECHA shall follow the format set out in Part B of the Chemical Safety Report (CLP Annex VI, Part 2) and contain the relevant information provided for in Part 1 of the CLP Annex VI. This is further defined by the ECHA 'Guidance on the preparation of dossiers for harmonised classification and labelling' and 'CLH report format'.

Key steps in the submission of a CLH dossier by a dossier submitter (DS) with a proposal to harmonise the classification and labelling (C&L) for a substance are described in box 30 below. The intention to prepare a harmonised classification and labelling proposal is made public on the registry of Intentions to allow interested parties to prepare their contribution to the process.

The harmonised classification dossier includes information on the manufacture and uses of the substances, its hazards and a justification that action is needed at Community level. The report must contain sufficient information to make an independent assessment of various physical, toxicological and ecotoxicological hazards based on the information presented.

Box 29: Steps in the submission of a CLH dossier

Preparatory work
Member State competent authorities as well as manufacturers, importers or downstream users may submit proposals for harmonised classification and labelling of substances to the European Chemicals Agency (ECHA).

Before submitting a CLH proposal
Before a CLH proposal is submitted, it is recommended to check the Registry of Intentions, which contains information from the parties who intend to submit a CLH dossier to the Agency. This would avoid having two parties submitting a CLH dossier for the same substance.

Preparing a CLH dossier
The CLH dossier shall contain a proposal with the identity of the substance and the proposed classification, including a scientific justification for this proposal. The dossier needs also to contain a justification that action is needed at European Community level for other hazard classes than CMR (carcinogenicity, mutagenicity and reproductive toxicity) and respiratory sensitisers, unless the substance is an active substance in Pesticides or Biocides.

Submitting the CLH dossier
Currently Member States can submit CLH proposals by e-mail or via CIRCA. Industry can submit either by e-mail or by sending their dossier in a CD format.

The DS has the burden of proof on the original proposal and as such is responsible for collecting and presenting the administrative, scientific and technical information for the proposed classification in the CLH dossier, and is requested to respond to any comments received during the PC. The role of the DS is thus to ensure not only the compliance of the CLH dossier with the legal requirements but also that the dossier contains all relevant scientific information.

An accordance check is undertaken by ECHA with the aim of ensuring that a CLH dossier is prepared in accordance with the requirements. In addition, the RAC (co-) rapporteurs are given the opportunity to provide their view on whether the dossier appears to have sufficient information and argumentation for RAC to formulate an opinion and/or specific comments and suggestions for improving the dossier within three weeks.

Public Consultation

After receiving the proposal, ECHA organises a public consultation period for 45 days, where third parties are invited to submit comments to the proposed harmonised classification and labelling (CLH) of the substance using an online webform. Current consultations and previous consultations are published on the ECHA website. The comments received will be published regularly on the ECHA website during the consultation period. ECHA may need to contact parties concerned in order to discuss specific issues related to the CLH of the substance.

All parties concerned may provide further information relevant to the substance under consideration. The information submitted includes, but is not limited to, published or non-published study results not

included in the CLH report, alternative interpretation of the data in the CLH report, or any comment on the CLH report.

All non-confidential information submitted during the consultation will be made available to MSCAs, dossier submitters, RAC members, accredited stakeholders and the RAC and ECHA Secretariats. The non-confidential comments and attachments will appear on the ECHA website after the adoption of the opinion. Confidential information will be available only to ECHA, its Committees, and the dossier submitter. Third parties are asked to submit a non-confidential version of the information so that, if needed, this can be made publicly available.

After this time, ECHA forwards all comments received to the Member State or those companies who had submitted the proposal and invites them to provide their view on the comments. The DS is requested to provide responses to public consultation comments in a response to comments document (RCOM). RAC will also provide its view in the same RCOM document, which is then published as an annex to the RAC opinion.

RAC Opinion

The proposal, the comments and the views of the dossier submitters will be forwarded to the RAC. After the consultation period the RAC will prepare a scientific opinion on the proposal taking into account the received comments. RAC will adopt an opinion on any CLH proposal within 18 months of receipt of the proposal.

Following the RAC Working Procedure on accordance check of a CLH dossier, RAC will examine the available evidence for all hazard classes proposed and may consider another category more appropriate for the classification of the substance after having examined the available information.

The parties concerned are encouraged to coordinate their involvement in the RAC opinion-making process with the regular and sector-specific stakeholder observers. RAC observers from stakeholder organisations act as conduits between RAC and the parties concerned for information about RAC deliberations. Their main role in the CLH process is transfer information from ECHA and RAC to the stakeholders. The procedure for involvement of stakeholder organisations in the work of RAC on CLH substances follows the general RAC procedure for admission of stakeholder organisations. The list of these stakeholders, the working procedure for their participation in the RAC meeting as well as the RAC meeting agendas and minutes are available on the ECHA website.

The RAC opinion has annexed a background document and a response to comments table based on the comments from the public consultation. Opinions of the RAC on proposals for harmonised classification and labelling are published on ECHA's website together with the background document and the response to comments.

Flexibility

It is vital for the efficiency of the overall process that ECHA maintains the flexibility to adapt the process on a case-by-case basis depending on the complexity of issues within a proposal. The need for flexibility also applies to situations where data or compelling arguments are submitted under the public consultation. Since ECHA is responsible for administering the opinion development process, ECHA is able to exercise discretion and tailor the process. Crucial, complex or potentially contentious issues may be identified in the dossier by the RAC (co-)rapporteur in collaboration with the ECHA Secretariat. The need to involve the DS to resolve these is decided case-by-case. Subsequent actions may involve targeted consultation with parties concerned with the dossier or withdrawal of the dossier (and possible resubmission) by the DS.

Commission Decision

ECHA will forward this opinion and any comments to the Commission. If the Commission finds that the proposed harmonised classification and labelling is appropriate, it will submit a draft decision concerning the inclusion of that substance in Part 3 of Annex VI to CLP.

After its inclusion, all manufacturers, importers and users of the substance in the EU should classify the substance accordingly, enabling the users to be better informed about the substance, its potential effects and how best to make use of it safely.

4.3. Notification

4.3.1. Who has to notify

Industry actors must notify a substance to the Classification & Labelling (C&L) Inventory established at ECHA in cases where they are placing the substance on the market and either:

- Manufacture the substance and it is subject to registration under the REACH Regulation; or
- Import the substance and it is subject to registration under the REACH Regulation; or

- Manufacture or import the substance and it is classified as hazardous, irrespective of the quantity; or
- Import a mixture which contains the substance that is **classified as hazardous** and is present above the relevant concentration limit, which results in the classification of the mixture as hazardous according to the CLP Regulation; or
- Import an article containing substances which are subject to registration under Article 7 of the REACH Regulation.

Actors are supported by Practical guide 7: How to Notify Substances to the Classification & Labelling Inventory.

4.3.2. How to notify

Actors are required to prepare a notification a classification and labelling notification using IUCLID, with ECHA providing a practical guide. Information to be included in the notification is listed in box 31 below.

Box 30: Information to be included in a CLP notification

Name and contact details of the notifier;
Identity of the substance, including name and other identifiers, information related to molecular and structural formula, composition, nature and amount of additives;
Classification of the substance according to the CLP criteria;
Reason for "no classification" in case the substance is classified in some but not all hazard classes or differentiations indicating whether this is due to
- lack of data,
- inconclusive data, or
- data which is conclusive for non-classification;
Specific concentration limits or M-factors, where relevant, including a justification for setting them; and
Label elements, including hazard pictograms, signal words, hazard statements and any supplemental hazard statements.

Companies may, under certain conditions, keep the IUPAC name of a substance confidential when notifying it to the C&L Inventory. The IUPAC name can be considered confidential and therefore not published in the C&L inventory in the following cases:

- non-phase-in substances;

- substances only used as one or more of the following:
- as intermediates;
- in scientific research and development; or
- in product and process orientated research and development.

To keep the IUPAC name confidential, companies need to provide in their IUCLID dossier:

- **A justification** including a clear indication whether the substance concerned is a non-phase-in substance, a substance used as a chemical intermediate, in scientific research and development or in product and process orientated research and development.
- **An alternative name** for dissemination by ECHA.

The notification can only be submitted electronically via the REACH-IT portal on the ECHA website. Actors must sign-up in REACH-IT and create an account to be able to submit their notification. ECHA provides guidance on how to submit a notification on their website. An in-built mechanism avoids double regulation by exempting from notification to the inventory information already submitted as part of registration under REACH.

Classification and Labelling Platform

The Classification and Labelling Platform is a web-based discussion forum which allows notifiers to discuss the classification and labelling of their substances and agree on appropriate classification. ECHA has established the C&L Platform to assist registrants and notifiers in fulfilling their legal obligations and to respond to the multiple different classifications that have been notified for many substances in the C&L Inventory.

Access to the platform is restricted to registrants and notifiers of the same substance and users have the option of discussing using an alias. The C&L Platform can only be accessed through the C&L Inventory. When two or more different classifications have been notified for the same substance, a discuss button becomes available in the summary page for that substance in the C&L Inventory. Upon clicking this button, the users are guided to a login page where they enter the platform discussion room for that substance using their REACH-IT credentials. Only those registrants and notifiers who have submitted a notification for this substance through REACH-IT can access the relevant discussion room. Discussion rooms for other substances are not available through the link and they need to be accessed through their relevant C&L Inventory summary pages.

4.4. Classification and Labelling Inventory

CLP reference: Article 42

CLP puts in place a Classification and Labelling Inventory (C&L Inventory), to include all substances notified under CLP and those subject to registration under REACH. Information submitted as part of a REACH registration or CLP notification is directly included in the C&L Inventory, which is maintained by ECHA in the form of a database. The database also includes the list of harmonised classifications (Table 3.1 of Annex VI to the CLP Regulation).

The following information is published:

- the name in the IUPAC Nomenclature for substances classified with certain hazard classes or categories set out in Article 119(1)(a), without prejudice to Article 119(2)(f) and (g) of REACH
- the name of the substance as given in EINECS, if applicable, and other numerical identifiers as appropriate and available
- the classification and labelling of the substance

The number of notifications and substances in the database will increase over time as companies submit more C&L notifications and registration dossiers. As such, the data in the public inventory itself is refreshed on a regular basis. The information in the inventory is publicly accessible and searchable. While ECHA maintains the Inventory, it does not review or verify the accuracy of the information.

4.1. Packaging and Labelling

Suppliers must label a substance or mixture contained in packaging according to CLP before placing it on the market either when:

- A substance is classified as hazardous.
- A mixture contains one or more substances classified as hazardous above a certain threshold.

CLP defines the content of the label and the organisation of the various labelling elements. The label includes:

- The name, address and telephone number of the supplier
- The nominal quantity of a substance or mixture in the packages made available to the general public (unless this quantity is specified elsewhere on the package)

- Product identifiers
- Where applicable, hazard pictograms, signal words, hazard statements, precautionary statements and supplemental information required by other legislation.

ECHA provides Guidance on Packaging and Labelling.

4.1.1. Small packaging exemptions

CLP provides certain exemptions for substances and mixtures contained in packaging that is small (typically less than 125ml) or is otherwise difficult to label. The exemptions allow the supplier to omit the hazard and/or precautionary statements or the pictograms from the label elements normally required under CLP.

4.1.2. Child-resistant fastening and tactile warnings

If substances or mixtures are supplied to the general public, then child-resistant fastenings and/or tactile warnings of danger have to be attached to their packaging in case these substances or mixtures display certain hazards or if the packaging contains methanol or dichloromethane. An overview of the different hazards that trigger this obligation is provided in an overview table on the ECHA website.

4.1.3. Outer packaging

As a general rule, the labelling or marking in accordance with transport legislation is sufficient when the outer packaging of a hazardous substance is subject to both the transport and the CLP rules. The CLP labelling does not need to appear. Similarly, when a hazard pictogram required by CLP relates to the same hazard as in the rules for the transport of dangerous goods, the CLP pictogram does not need to appear on the outer packaging.

4.1.4. Alternative Chemical Names

CLP reference: Article 24 and Annex I, 1.4.1

Suppliers who are concerned about disclosing the full composition of a mixture, on the label or in the safety data sheet, can request the use of an alternative chemical name for a substance to protect the confidential nature of their business, and in particular, their intellectual property rights.

Until 1 June 2015, suppliers should submit their requests to ECHA or to a Competent Authority depending on whether the mixture is classified and labelled according to CLP or the previous legislation (Dangerous Preparations Directive).

Requests that follow the classification criteria of CLP should be submitted to ECHA, not to a Competent Authority. Any requests for alternative chemical names approved by ECHA will be valid in all EU member states. This alternative chemical name can be used on the label and in the safety data sheet of the mixture instead of the substance name.

An alternative chemical name can only be approved in these cases:

- When the substance does not have a Community workplace exposure limit.
- The use of the alternative name meets the need to provide enough information to take necessary health and safety precautions at the workplace and that the risks from handling the mixture can be controlled.
- The substance is classified only in certain hazard classes (see 1.4.1 (III), Annex I, CLP Regulation).

Requests that follow the classification criteria of Dangerous Preparations Directive (DPD) should be submitted to the Competent Authority in one of the EU Member States where the mixture is placed on the market. If the alternative name is approved by the Competent Authority before 1 June 2015, it can be used in the mixtures specified in the approval also after 1 June 2015.

Requests for use of an alternative chemical name according to CLP are subject to a fee. In general, the fee depends on the company size and number of mixtures in a request.

4.2. Safety Data Sheets

See section 3.7.1 under REACH for a discussion of Safety Data Sheets.

4.3. Enforcement of CLP

According to the CLP Enforcement Strategies, once enforcement priorities are set, the enforcing authorities of Member States should adopt enforcement measures. Enforcement programs should comprise of compliance promotion activities complemented with appropriate, proactive and reactive,

compliance monitoring (inspections and investigations). As such, enforcement, including inspections to ensure compliance, is the responsibility of the Member State.

The enforcement of CLP is closely related to the enforcement of REACH, both facing similar challenges. Member States pursue their CLP inspections often as a part of REACH inspections. As noted by the General Report on REACH, a strong and harmonised approach towards enforcement of CLP and REACH throughout the EU is vital for delivering their objectives.

The first CLP implementation reports should cover enforcement and were submitted by the Member States in January 2012, however they were not found to be publically available. The 2013 General Report on REACH notes that overall 26 Member States submitted reports, with large variations in the level of detail and the issues addressed. The reports showed that most Member States co-operate, co-ordinate, and exchange information and have appropriate sanctions in place to enforce the CLP Regulation. Following CLP implementation, the total number of inspections concerning particular products and individual duty holders has steadily increased over the last three years. In terms of areas where further improvements are required, compliance with the legal requirements could be substantially improved (generally the compliance rates amounted to 70%), and the reporting by Member States needs further harmonisation.

Regular reporting on enforcement will allow Member States to target enforcement activities on problematic areas and to further develop joint enforcement strategies. However, Member States might have to dedicate additional resources to enforcement and to the regular reporting to fully profit from the experience gained across the EU.

ECHA's Forum for Exchange of Information on Enforcement (the Forum) is charged with coordinating REACH and CLP enforcement at the European level. The Forum has developed Strategies for enforcement of REACH and CLP, as well as Minimum criteria for REACH and CLP inspections. It is expected that further development of the enforcement strategy of the Forum in relation with CLP will also have a positive effect on the effectiveness of enforcement in improving the rate of compliance. The strategy should include harmonised and targeted enforcement projects, and an element of awareness-raising particularly focussed on SMEs.

4.4. Advantages, Challenges and Disadvantages of CLP

4.4.1. Advantages

Self Classification

The self-classification process should feed into the procedures for setting harmonised classifications, in particular since self-classification is resulting in many more substances being classified under specific endpoints. For example, in the C&L Inventory 3,535 substances are classified as R1A, 1B or 2, with only 661 of these having a harmonised classification[67]. It is too early to undertake a quantitative assessment of how self-classification is affecting the number of substances for which there are harmonised classifications.

The self-classification process has resulted in multiple self-classifications, which is giving rise to problems for formulators. However, it is expected that these should reduce over time as more substances go through registration.[68]

4.4.2. Challenges and Disadvantages

Low Public Recognition of Symbols

A 2012 Commission report[69] on the safe use of chemicals describes the outcomes of a 2010 Europe-wide Eurobarometer survey of European citizens' capacity to understand labels and hazard pictograms, together with a more targeted study on risk perception. Results show that recognition and understanding of the new hazard pictograms vary across Member States, with low public understanding of safety measures required when using chemical products. In particular, certain pictograms that are new under CLP had very low recognition and understanding rates (see figure 10 below).

[67] Data drawn from the C&L Inventory as updated on 4 January 2013
[68] RPA and Okopol (2012) Technical assistance to prepare the Commission Report on the Operation of REACH, Final Report under contract 70307/2010/584820/SER/D3, RPA, UK
[69] European Commission (2012) Report from the Commission to the European Parliament and the Council on communication on the safe use of chemicals, COM(2012) 630 final, Brussels

Figure 10: CLP pictogram for "Serious health harm" (left) had very low recognition rates (20%) and understanding rates (12%), while the CLP pictogram for "Acute Toxicity" has a 33% understanding rate

In addition, most respondents felt only moderately informed or not well informed about the hazards associated with chemical products. Regarding behaviour, in the EU, the most common means of understanding possible hazards associated with a product are to read the safety instruction, although this was more common for certain products (pesticides, insecticides) than for others (car care products, household detergents).

The report emphasised the need to increase public awareness and promote the understanding of hazard labels and associated safety measures through awareness raising activities and training. Such activities should take into account national hazard perception patterns and should be targeted at the general public, as well as at specific audiences such as families, single households and school children using a range of tools tailored to the audience. In addition, the report suggested that industry could undertake voluntary efforts to align product packaging with the hazard message in the label content, in order to raise awareness and improve safe use of chemicals. In addition, labels should be simplified with key messages promoted.

A new analysis of the impact of the CLP pictograms on EU citizens' behaviour and understanding will be undertaken after June 2015.

5. Regulation on Prior Informed Consent

5.1. Transposition of the Rotterdam Convention

The European Union was one of the signatories of the Rotterdam Convention in 1998 and ratified the Rotterdam Convention on 20 December 2012. In the EU, the Rotterdam Convention is now implemented through Regulation (EC) No 689/2008 was recast as Regulation (EU) No 649/2012, which entered into force on 16 July 2012 and is to be implemented by 1st March 2014.

Regulation (EU) No 649/2012 includes a number of provisions that go beyond the requirements of the Rotterdam Convention, in order to deliver a higher level of protection to human health and the environment. These are summarised in box 32 below.

Box 31: Provisions of Regulation (EU) No 649/2012 that go beyond the Rotterdam Convention

Firstly, the requirements for export notification extend to all countries, not only to Parties of the Convention, irrespective of use.

Secondly, the Regulation establishes an explicit consent procedure that requires the explicit consent of the importing party before export can proceed. The procedure applies to all chemicals that are BOSR in the EU in a convention use category (Annex I, Part 2), as well as all PIC chemicals (Annex I, Part 3) for which no import decision from the importing country is published. For chemicals in part 3 of the Annex, this requirement does not apply when a positive import response is published in the PIC circular of the Rotterdam Convention, and certain criteria are met. An explicit consent remains valid for subsequent exports during a period of three calendar years, unless otherwise specified in the conditions of the explicit consent itself. For those three years, any company in the EU may export the same chemical to the country that has granted the explicit consent, but still needs to meet the annual notification and reporting requirements.

Thirdly, the scope of the EU Regulation is not limited to chemicals that are BOSR under the Convention but also covers chemicals that are BOSR at EU level. Some chemicals might not qualify for PIC notification pursuant to Article 5 of the Convention, but the restrictions are such that the EU nevertheless alerts importing countries so as to ensure a higher level of protection.

Fourthly, the two Convention use categories have been divided into two subcategories: pesticides are divided in agricultural and non-agricultural pesticides, and industrial chemicals are separated in chemicals for professional use and chemicals for consumer use. Under the EU Regulation, the ban or severe restriction of a chemical at subcategory level but not at Convention use level can trigger export notification.

Fifthly, the EU makes export notifications irrespective of the intended use and whether or not that use is banned or severely restricted within the EU, recognising that it cannot be guaranteed that the intended use is identical to the final use in the importing country.

Finally, unless specified to the contrary, the Regulation's obligations extend to exports to all countries, irrespective of whether or not they eventually are Parties to the Convention.

5.2. Annex I of Regulation (EU) No 649/2012

The PIC Regulation applies to a list of entries (for individual chemicals or groups of chemicals), which are included in Annex I, and to mixtures containing such chemicals in a concentration that triggers labelling obligations under the CLP Regulation (EC) No 1272/2008 (irrespective of the presence of any other substance), as well as to articles containing these chemicals in an unreacted form.

This list is updated regularly as a result of regulatory actions under EU legislation, and developments under the Rotterdam Convention. It is divided into three parts that define the different obligations applied to the chemicals: (Part 1), chemicals subject to the explicit consent procedure (Part 2); and subject to the PIC procedure under the Rotterdam Convention (Part 3). These are described in box 33 below.

Box 32: The three parts of Annex I of the PIC Convention

Part 1
These entries are subject to the export notification procedure. This comprises all of the chemicals that are banned or severely restricted within the EU in at least one of the four use subcategories defined in the PIC Regulation:
Industrial chemicals for professional use
Industrial chemicals for consumer use
Pesticides used as plant protection products
Other pesticides such as biocidal products

Part 2
Apart from the export notification requirement, the entries in part 2 are subject to the additional requirement of ECHA receiving a statement from the authorities of the importing country to show that they agree to the import. This is called explicit consent.
These chemicals qualify for PIC notification under the Rotterdam Convention because they are banned or severely restricted within the EU in one of the two use categories defined by the Rotterdam Convention: pesticide or industrial chemical.

Part 3
The entries in part 3 are subject to the export notification requirement, and additionally to the explicit consent, except where a positive import response is published in the PIC circular of the Rotterdam Convention, and certain criteria are met. Part 3 also includes a number of substances identified in the Stockholm Convention as persistent organic pollutants, which are subject to a total export ban.
These are the chemicals subject to the PIC procedure as described in the Rotterdam Convention, and are listed in Annex III to the Convention itself.

5.3. Designated Competent Authorities

The contact details for the DNAs of the EU Member States are available on the JRC website, as well as on the website of the Rotterdam Secretariat.

The Commission acts as the single contact point for all Community interaction with the Secretariat and other Parties to the Rotterdam Convention. DG Environment has overall responsibility within the Commission and is supported by the Consumer Products Safety and Quality Unit (CPSQ) of the Joint Research Centre of the Commission in several tasks that are fundamental to the effective operation of the legislation.

This means that the Commission acts as a common designated authority on behalf of all Member State DNA and in close cooperation with them. As the single contact point for all Community interaction with respect to the Rotterdam Convention, the Commission carries out various administrative functions on behalf of the Member States. This includes:

- transmitting export notifications to Parties and other countries;
- submitting notifications of relevant EC or Member State regulatory actions banning or severely restricting a chemical;
- transmitting information about other final regulatory actions not qualifying for PIC notification;
- submitting decisions with respect to imports of PIC chemicals;
- receiving export notifications from third countries, informing the Member States and publishing them on EDEXIM; and
- receiving information from the Secretariat.

To ensure close coordination with the Member States, the Commission chairs biannual meetings of the DNAs. The Commission also represents the EU at COPs and at meetings of the CRC. Prior to sessions of the COP and the CRC, the Commission convenes preparatory meetings with Member States in order to coordinate common positions.

5.4. Responsibilities of Exporters

An "exporter" includes the person holding the export contract, or in the absence of a contract, the person having the power to determine export of the chemical from the customs territory of the Community. In the case where the exporter is not established in the Community, the contracting Party established in the Community must fulfil the obligations of the exporter

The main provisions of the Regulation regarding the exporters are as follows:

- To notify the DNA of the Member State concerned no later than 30 days prior to the first export of any chemical (either as substance itself or in preparation) listed in part 1 of Annex I and no later than 15 days prior to the first export in each subsequent calendar year.
- To provide the DNA of the Member State concerned each year before 31 March with an annual report for the preceding year on quantities of chemicals in Annex I exported (similar obligation imposed on importers as regards imports). Any additional necessary information shall be provided upon request.
- To ensure that all exported dangerous chemicals and preparations are packaged and labelled in accordance with the relevant EC legislation, as far as practicable in the official/principal language(s) of the importing country. Where appropriate, to indicate expiry and production dates on the label and provide safety data sheets.

5.5. Export Notifications

Exporters based in an EU Member State have to notify their intentions to export certain chemicals to a non-EU country. This applies to the chemicals listed in Annex I to the PIC Regulation. Exporters have to notify the designated national authority of the country from which the export will originate before the first yearly export takes place, as well as before the first export in each subsequent calendar year.

Each export notification is assigned a unique identifier, called a reference identification number. This is used, for example, to facilitate customs control of the exports of chemicals listed in Annex I.

5.5.1. Content of the notification

The main elements of the data requirements for an export notification include:

- Identity of the substance, mixture or article to be exported. Typically this is the EC number, CAS number and the chemical name as listed in the Regulation.
- Information on the export, such as country of origin, country of destination, expected date of first yearly export, estimated amount to be exported, intended use in the country of destination, name and address of exporter and importer
- Information on precautions to be taken
- Summary of physico-chemical, toxicological and ecotoxicological properties
- The uses of the chemical in the EU
- Summary of regulatory restrictions and reasons for them

The full set of data requirements can be found in Annex II to the PIC Regulation.

The intention to export a chemical listed in Annex I must be notified at the latest according to the following schedule:

- 35 days before the export is due to take place: Exporter must notify the designated national authority of the Member State from which the export will originate.
- 25 days before the export is due to take place: The designated national authority validates the notification and forwards it to ECHA.
- 15 days before the export is due to take place: ECHA sends the notification to the non-EU designated national authority in the importing country.

The notification process is currently administered by the European Commission's Joint Research Centre (JRC) via EDEXIM.

5.6. Explicit Consent Requirement

In addition to the notification requirement, the export of chemicals included in parts 2 and 3 of Annex I to the PIC Regulation are also subject to the existence of a valid explicit consent given by the designated national authority of the importing country outside the EU. A waiver might be granted only under exceptional circumstances. For chemicals in part 3 of the Annex, this requirement does not apply when a positive import response is published in the PIC circular of the Rotterdam Convention, and certain criteria are met.

An explicit consent remains valid for subsequent exports during a period of three calendar years, unless otherwise specified in the conditions of the explicit consent itself. For those three years, any company in the EU may export the same chemical to the country that has granted the explicit consent, but still needs to meet the annual notification and reporting requirements.

ECHA will maintain a database of all existing and new notifications and explicit consent responses. The Agency will make them available to designated national authorities for consultation if the conditions of the consent are broad enough to be reused for a subsequent export.

5.7. EDEXIM

The European Commission's Joint Research Centre (JRC) currently maintains the European Database of Export and Import of Dangerous Chemicals (EDEXIM). The legislation is published on EDEXIM, as well as details of Designated National Authorities in the EU, PIC import responses, notifications, including export and import notifications and the explicit consent list. Areas of the EDEXIM website are reserved for customs official and for exporters, with access by password.

5.8. Support for PIC Implementation

To date, the JRC has provided scientific and technical support for the implementation of the PIC Regulation and managed the European centralised database of export and import of certain hazardous chemicals and pesticides, EDEXIM. In accordance with the new Regulation, in 2014 the JRC will transfer these tasks to ECHA, which will then be responsible for transferring notifications to importing parties that are non-EU and for maintaining a database on the notifications. The database on the imported and exported hazardous chemicals will be made available of the ECHA website.

Technical Guidance Notes for the Implementation of the PIC Regulation are available online.

6. ECHA's Support for Implementation

ECHA provides a wide range of support for the implementation of REACH and CLP, including guidance materials, formats, online IT tools, practical guides, frequently asked questions, information toolkits. Support is available on the ECHA website.

6.1. Guidance

With the aim of providing industry with the relevant tools to meet commitments under REACH, ECHA has generated extensive guidance on REACH. The guidance documents were drafted and discussed within the REACH Implementation Projects (RIPs) led by the European Commission services, involving stakeholders from Member States, industry and non-governmental organisations. These guidance documents can be obtained via the ECHA website.

6.2. Dossier Submission Tools

ECHA has developed a number of IT tools to facilitate implementation of REACH and CLP and these are presented below.

6.2.1. REACH-IT

The online REACH-IT system provides for the implementation of the REACH and CLP Regulations. REACH-IT provides functions for:

- Pre-registration
- Inquiry
- Registration
- Joint Submission
- NONS
- PPORD
- Notifying substances in articles
- Downstream user report
- Notification to the C&L Inventory
- Requesting an alternative chemical name in mixtures

Manuals for data submission and for the use of REACH-IT are available online.

6.2.2. International Uniform Chemical Information Database (IUCLID)

IUCLID (International Uniform ChemicaL Information Database) is a software application to capture, store, maintain and exchange data on intrinsic and hazard properties of chemical substances. It is a key software application essential for chemical industry to comply with REACH and CLP. Industry stakeholders, EU Member States, ECHA, and any other interested party download the IUCLID installation kit for free from the IUCLID website. IUCLID software is then allows for the capture, storage, submission and exchange of data on chemical substances stored according the harmonised OECD format.

The IUCLID 5 project was initiated in 2003 when the European Commission decided to completely overhaul IUCLID 4 in order to propose a data submission tool that would support REACH, as well as other Chemical Evaluation Programmes, such as the OECD HPVC Programme. Data that can be stored and maintained with IUCLID 5 include the party running IUCLID 5 (production sites, contact persons, etc.), as well as data on the chemical substances, including:

- Composition
- Reference information, like CAS number, IUPAC name and other identifiers
- Classification and labelling
- Physical/chemical properties
- Toxicological properties
- Eco-toxicological properties
- Any report relevant to the substance (e.g. study result, assessment).

6.2.3. Chemical safety assessment and reporting tool (Chesar)

Chesar is an application developed by ECHA to help companies carry out their chemical safety assessments (CSAs) and prepare their chemical safety reports (CSRs) and exposure scenarios (ES) for communication in the supply chain. Chesar is available for download from the ECHA website. To support use of the tool, manuals and tutorials are also available on the website, together with frequently asked questions.

Chesar enables registrants to carry out their safety assessments in a structured, harmonised and efficient way. This includes the importing of substance-related data directly from IUCLID, describing the uses of the substance, identifying risk management measures if needed, carrying out exposure estimates and demonstrating control of risks. Based on this, Chesar automatically generates the CSR and exposure scenarios for communication in an electronic exchange format and as a text document. It also facilitates the re-use (or update) of assessment elements generated in a single Chesar instance or imported from external sources.

6.3. Practical Guides

ECHA has published online a number of practical guides providing practical information on REACH and CLP requirements and best practice on how to fulfil them. The list of practical guides is presented in box 34 below.

Box 33: Practical guides on REACH and CLP published by ECHA

Practical Guide 1: How to report in vitro data [PDF]
Practical Guide 2: How to report weight of evidence[PDF]
Practical Guide 3: How to report robust study summaries[PDF] (22/11/2012)
Practical Guide 4: How to report data waiving [PDF]
Practical Guide 5: How to report (Q)SARs [PDF]
Practical Guide 6: How to report read-across and categories [PDF]
Practical Guide 7: How to notify substances in the Classification and Labelling Inventory [PDF]
Practical Guide 8: How to report changes in identity of legal entities [PDF]
ECHA has temporarily withdrawn Practical Guide 9: How to do a registration as a member of a joint submission. The information on this document is outdated after the latest release of REACH-IT. Visit the joint submission member support page to find the relevant manuals for creating, checking and submitting IUCLID dossiers using REACH-IT as a member of a joint submission.
Practical Guide 10: How to avoid unnecessary testing on animals [PDF]
Practical Guide 12: How to communicate with ECHA in dossier evaluation [PDF]
Practical Guide 13: How downstream users can handle exposure scenarios [PDF]
Practical Guide 14: How to prepare toxicological summaries in IUCLID and how to derive DNELs [PDF]
Practical Guide 15: How to undertake a qualitative human health assessment and document it in a chemical safety report [PDF]
ECHA has withdrawn Practical Guide 11: How to address specific substance identification issues: evaluation of different crystalline forms. The decision was based on feedback that parts of it were open to misinterpretation and had caused confusion.

6.4. Information Toolkit

The information toolkit provides practical information and tools in relation to help in using of existing information and non-test methods (i.e. predictions) as a first step to meeting REACH information requirements. Website users are able to click on the coloured boxes in the flowchart to obtain more detail and to be guided to relevant resources and tools.

6.5. Help Desks

The ECHA Helpdesk provides administrative advice to those who have obligations under the REACH and CLP Regulations. This service also includes support to users of ECHA's IT tools (such as IUCLID, Chesar and REACH-IT), and assistance related to the processing of individual submissions.

The advice offered by the Agency through the ECHA Helpdesk is free of charge. As a service, it can provide information on the obligations of registrants under REACH and CLP, but it will not solve business-specific problems. The ECHA Helpdesk processes questions which have been submitted by the public through the dedicated ECHA Helpdesk contact form on the ECHA website.

According to the REACH and CLP Regulations (Article 124(2) of REACH and Article 44 of CLP), the countries of the European Union, in addition to Norway, Iceland and Liechtenstein, have

established national REACH and CLP helpdesks to provide advice and assistance on REACH and CLP obligations. Their national helpdesks are the first point of contact for companies.

ECHA supports a network of national helpdesks to foster cooperation among Member State REACH and CLP helpdesks and to harmonise replies they give to enquirers. To support the Member State REACH helpdesks, 'HelpNet' was established. HelpNet promotes a common understanding of REACH and CLP obligations through the harmonisation of feedback to the private sector. The HelpNet aims at harmonising replies to companies by providing up-to-date information on REACH and CLP implementation, discussing difficult questions in the HelpNet Exchange platform, which is a tool that allows HelpNet members to discuss difficult questions, to cooperate and to support one another on a daily basis to reach agreement on REACH and CLP FAQs to be published on ECHA's website.

6.6. Webinars

Webinars are information sessions hosted online by ECHA, and consisting of presentations, video and other interactive features such as questions and answers, desktop sharing and audio conferencing. Up to one thousand participants can remotely join a webinar at once. For open webinars a registration link will be available for each individual webinar closer to the event date. Webinars are recorded and later published on the ECHA website.

7. Pesticide Authorisation

Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market[70] (PPPR) has applied in the EU from 14 June 2011, and as such is very recent. The PPPR requires a risk assessment to be undertaken for relevant substances (active substances, safeners and synergists) and mixtures. With a few exceptions, active substances, safeners or synergists that are classified as CMR category 1A or 1B under CLP, or as having endocrine disrupting properties, or that are considered as a POP, PBT, or vPvB cannot be approved, the so called "cut off" criteria. As such, hazard-base criteria act as a gatekeeper for the placement of plant protection products on the market in the EU.

It is also important to note that Article 4 states that the residues of plant protection products "*shall not have any harmful effects on human health, including that of vulnerable groups, or animal health, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available*". This requires an assessment of the cumulative or cocktail effects of the substances, where methods are available.

The risk assessment looks at impacts, after the placing of the substance or product on the market, on the general population, including vulnerable groups. In addition, the assessment should determine the threshold above which the concentration of active substances in plant protection products in food products presents a risk for humans and animals, with the aim of informing EFSA who then issue opinions on maximum residue limits.

The risk assessment is carried out by the Member States competent authorities based on the information supplied by the applicant and summarises this assessment in a Draft Assessment Report (DAR), for which a common format is agreed between the EU and the OECD.[71] EFSA reviews the DAR and subsequently adopts conclusions as to whether or not the substance meets the requirements of the Regulation. The approval or non-approval of the substance is decided on the basis of the assessment report and the EFSA conclusions, by adopting an approval regulation or a non-approval decision upon proposal of the Commission. Substances that are approved for use are included on the EU Pesticides database, which provides updated information on the authorisations and withdrawal of plant protection products in the EU Member States.[72]

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[70] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309, 24.11.2009, p. 1.

[71] A range of guidance documents are available at: http://ec.europa.eu/food/plant/pesticides/approval_active_substances/guideline_documents_en.htm

[72] See: http://ec.europa.eu/sanco_pesticides/public/index.cfm

Authorisation for placing on the market is valid for 10 years and may be renewed. A Member State may review an authorisation at any time if it no longer complies with one of the pre-conditions for placing on the market and should this be the case, withdraw or amend the authorisation. Following the principle of mutual recognition established in PPPR, the holder of an authorisation is authorised to place the product on the market in another Member State insofar as the agricultural, plant health and environmental conditions are comparable. However, the relevant Member State may provisionally limit or ban the movement of a product on its territory if the product in question presents a risk to human or animal health, or to the environment.

There is currently controversy surrounding the impacts of uses of neonicotinoid pesticides on bee populations, with scientists calling for bans. In a recent report[73] for the European Parliament, researchers conclude that the risk to bees from neonicotinoids is such that the chemicals should be at least partially banned, following the "precautionary principle", as inscribed in the PPPR. In response, a 2013 industry-funded study[74] argued that a ban on neonicotinoids could cost €17bn over a five-year period and lead to the loss of over 60,000 jobs across the entire economy, with a drop in yields for crops such as maize, winter wheat, barley and sugar beet drop by 20-40%.[75] In January 2013, the European Food Safety Authority (EFSA) completed two review studies on neonicotinoids and bees, with a view to providing advice to the European Commission. EFSA recommended that three neonicotinoids (clothianidin, imidacloprid and thiamethoxam) should not be used on flowering crops attractive to honey bees, noting that exposure to these substances in dust and plant sap poses a hazard to the insects. EFSA acknowledged a number of uncertainties and data gaps, which must be resolved before a full risk assessment can be completed. In response, the European Commission has confirmed it will propose a two-year EU ban on the use of clothianidin, imidacloprid and thiamethoxam, which are believed to be harmful to bees, applying to four types of crops: sunflower, maize, rapeseed oil and cotton (cultivated in southern Europe).[76]

[73] Environment Agency Austria (2012) Existing Scientific Evidence of the Effects of Neonicotinoid Pesticides on Bees, European Parliament, Brussels

[74] Noleppa S and Hahn T, 2013, The value of Neonicotinoid seed treatment in the European Union, Humboldt Forum for Food and Agriculture (HFFA) Working Paper 01/2013, Germany

[75] ENDs Europe (2013) Most farm ministers back action on neonicotinoids, 29 January 2013, Ends Europe, Brussels

[76] ENDS Europe (2013) EC proposed restrictions on neonicitinoid pesticides, 31 January 2013, ENDs Europe, Brussels

8. Biocides Authorisation

On 22 May 2012 Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products[77] was adopted. The new Regulation simplifies and streamlines the requirements for approving biocides, by providing for the EU-level authorisation of certain biocidal products and by improving the functioning of national authorisation processes and mutual recognition.

The new biocidal product regulation provides for the authorisation at the Union level of certain biocidal products. It improves the functioning of national authorisations and mutual recognition by introducing binding deadlines and strengthening the system of mutual recognition dispute settlement. It reduces the number of animal tests by obligatory data sharing with respect to vertebrate animal studies; strengthens the rules on data waiving (i.e. not request data which is not necessary); extends the scope to cover articles and materials treated with biocidal products (e.g. furniture treated with wood preservatives), which are imported from third countries.

8.1. Approval of Active Substances

Persons placing biocidal products on the market must hold the data on active substances. Companies have to apply for the approval of an active substance by submitting a dossier to ECHA. After the validation check has been performed by the Agency, the evaluating competent authority carries out a completeness check and an evaluation. The result is forwarded to ECHA's Biocidal Products Committee, which prepares an opinion within 270 days. This is then submitted to the European Commission for decision-making.

8.1.1. Exclusion criteria

Active substances meeting the exclusion criteria will not be approved. This includes:

- carcinogens, mutagens and reprotoxic substances category 1A or 1B according to the CLP Regulation
- endocrine disruptors
- persistent, bioaccumulative and toxic (PBT) substances
- very persistent and very bioaccumulative (vPvB) substances

[77] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167, 27.06.12, pp. 1-128

Derogations are foreseen, in particular when the active substance might be needed on grounds of public health or of public interest when no alternatives are available.

8.1.2. Substitution criteria

Active substances meeting the substitution criteria will be designated as candidates for substitution during the approval procedure. The criteria are based on the intrinsic hazardous properties in combination with the use and potential exposure. During the evaluation for national or Union authorisation of a biocidal product that contains active substances considered as candidates for substitution, a comparative assessment will be performed to estimate whether less harmful products are available for the same use.

8.1.3. Technical Equivalence

In the assessment of the technical equivalence an active substance is compared to one already approved substance (reference active substance) to determine if both are equivalent. ECHA is responsible for this assessment and it is done in two tiers. The tier I is based on the assessment of analytical data. If it fails, a tier II assessment is performed based on the hazard profile using physico-chemical and (eco)toxicological data.

The technical equivalence of an active substance needs to be assessed when:

- The source of an active substance is different from the source of the already approved reference substance (technical material from a new or different manufacturer).
- The source of an active substance is the same as a reference one but there was a change in the manufacturing process (new or different method applied, or starting materials changed), or in the manufacturing location.
-

Companies have to submit an application to ECHA which, based on the assessment of technical equivalence, will take a decision within 90 days.

8.1.4. Alternative Suppliers

Alternative suppliers are manufacturers or importers of active substances who were not involved in the review programme for the active substances under the Biocidal Products Directive and did not

contribute to the approval of an active substance, but are benefitting from it by placing the active substance on the market.

Under the BPR, alternative suppliers have to submit to ECHA either a dossier, a letter of access, or if all data protection periods have expired, a reference to an existing dossier. ECHA will publish a list of those who submitted a file to ECHA. The participants in the review programme will also be added to the list.

From 1 September 2015, a biocidal product cannot be placed on the market if the manufacturer or importer of the active substances contained in the biocidal product, or where relevant the importer of the biocidal product, is not included in the list.

8.1.5. Renewal of Approval

A similar process takes place for the renewal of the approval of an active substance, where, depending on the amount of new studies available at the renewal, a distinction is made between a full evaluation and a limited evaluation. The application to ECHA has to be submitted 550 days before the expiry date of the approval.

8.2. Authorisation of Biocidal Products

The authorisation of biocidal products in the EU is based on a system of national authorisation and mutual recognition. After the approval of an active substance, companies wishing to place biocidal products on the market in a Member State have to apply for product authorisation. This is done by submitting a dossier to that Member State, which then has to evaluate and take a decision on the authorisation within 365 days.

Once a first authorisation is granted by a Member State, the applicant can ask for the recognition of that authorisation by other Member States, either in sequence or in parallel. This is called mutual recognition. Disagreements regarding mutual recognition will be referred to the Coordination Group, which has 60 days to seek agreement. ECHA will provide the secretariat for this group. If an agreement cannot be reached, the matter is referred to the Commission which may ask ECHA for an opinion on the scientific or technical aspects of the case.

8.2.1. Union Authorisation

One of the new elements of the BPR is the possibility to have certain biocidal products authorised at Union level. This will allow companies to place these biocidal products on the market in the entire Union, without the need to obtain a national authorisation followed by mutual recognition. This authorisation will give the same rights and obligations in all the Members States as those issued by the national authorisation.

Union authorisation will be granted to biocidal products with similar conditions of use across the Union, except those containing active substances meeting the exclusion criteria and certain product-types. The authorisation process starts with the submission of a dossier by a company to ECHA. The evaluating competent authority that has previously been chosen by the applicant, evaluates the dossier and forwards the result to ECHA's Biocidal Products Committee to prepare an opinion within 180 days. Finally, the European Commission takes a decision based upon ECHA's opinion.

8.3. Nanomaterials in Biocidal Products

Finally the Biocidal Products Regulation addresses nanomaterials. It requires that, where appropriate, articles that have been treated with biocides must list 'the name of all nanomaterials contained in the biocidal products, followed by the word 'nano' in brackets' on a label. Nanomaterials used in biocidal products must be assessed separately.

While the EU has legislation in place regarding the use of pesticides (plant protection products), there is no comparable legislation regarding the use of biocides. The Biocidal Products Regulation does, however, foresee that by 18 July 2015 the Commission shall review how the regulation is contributing to the sustainable use of biocidal products and consider the need for additional measures to reduce the risks posed to human health, animal health and the environment by biocidal products. On basis of that report, the Commission may, if appropriate, submit a proposal.

9. Medicinal Products and Veterinary Products

Directive 2001/83/EC[78] put in place a Community Code relating to the placing on the market, production, labelling, classification, distribution and advertising of medicinal products for human use. It sets a marketing authorisation procedure and the principle for mutual recognition of authorisations. This Directive sets several requirements with regard to the assessment of the environmental impacts of medicinal products for human use. The risk assessment must include any risk relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health but also any risk of undesirable effects on the environment, including risk connected with the release of medicinal products containing or consisting of GMOs. Applications for marketing authorisation must be accompanied by an evaluation of the potential environmental risks posed by the medicinal product, including reasons for any precautionary and safety measures to be taken for the disposal of waste products. The Directive sets specific information requirements for medicinal products are made from GMOs or contain GMOS, as well as regarding pharmacokintetics.

Directive 2001/82/EC[79] includes all the provisions relating to the production, placing on the market, distribution and use of veterinary medicinal products, as well as a marketing authorisation procedure. Application for authorisation can be made in several EU countries at the same time, and the holder of an authorisation in a Member State can also ask for its authorisation to be recognised in other EU countries. The definition of risks relating to use of the product also includes any risks of undesirable effects on the environment. Applications for marketing authorisation must contain tests assessing the potential risks posed by the medicinal product for the environment. The environmental risk assessments procedure differs depending on whether veterinary medicinal products are immunological and whether they contain or consist of GMOs.

[78] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67–128

[79] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, OJ L 311, 28.11.2001, p. 1–66

10. Chemicals in Products

There is a wide range of EU legislation specifically targeting chemicals in certain product groups, aim at achieving a high level of protection of human health and the environment. Product legislation aims to reduce consumer exposure, as well as reducing environmental exposure to chemicals along the product life cycle and resulting human exposure via the environment.

10.1. General Product Safety

Directive 2001/95/EC on general product safety aims to ensure a high level of product safety throughout the EU for consumer products that are not covered by specific sector legislation such as that on toys, chemicals, cosmetics and machinery. This Directive provides for an alert system, known as the Community Rapid Information System (RAPEX), which ensures that the relevant authorities are rapidly informed of dangerous products (e.g. containing unexpected hazardous substances). Where more serious product risks exist, temporary decisions may be taken on Community-wide measures, and in certain cases the Commission may adopt a formal Decision requiring the Member States to ban the marketing of an unsafe product, to withdraw it from the market or recall it from consumers.

In 2004, the Commission adopted specific guidance ("the RAPEX Guidelines") to ensure the efficient operation of RAPEX. With regard to chemicals the RAPEX Guidelines provides the following: *'When the measure notified pursuant to Article 11 or Article 12 seeks to limit the marketing or use of a chemical substance or preparation, the Member States must provide as soon as possible either a summary or the references of the relevant data relating to the substance or preparation considered and to known and available substitutes, where such information is available. They will also communicate the anticipated effects of the measure on consumer health and safety together with the assessment of the risk carried out in accordance with the general principles for the risk evaluation of chemical substances as referred to in Article 10(4) of Regulation (EEC) No 793/9311 in the case of an existing substance or in Article 3(2) of Directive 67/548/EEC12 in the case of a new substance.*'

In addition, on 17 March 2009, the Commission adopted Decision 2009/251/EC requiring Member States to ensure that, as of 1 May 2009, all consumer products containing dimethylfumarate (DMF) are banned (maximum limit: 0.1 mg DMF per kg of product or part of the product).

10.2. Detergents

Regulation (EC) No 648/2004 on detergents provides a definition of surfactants, with a clear and precise description of the relevant types of biodegradability. The primary biodegradability requirements are extended to all surfactants, in particular cationic and amphoteric. The Regulation imposed stricter testing methods for detergents to determine the ultimate rather than the initial biodegradability. Healthcare professionals can request manufacturers the full listing of ingredients in detergents to determine a causal link with allergies. A detergent can only be placed on the market if it complies with the requirements set forth in this Regulation. It sets restrictions based on biodegradability of surfactants. Surfactants that do not meet the Regulation's requirements in terms of biodegradability are listed in Annex VI (list of banned or restricted surfactants), which acts as a negative list. It should be noted that Annex VI is still empty.

Regulation (EU) No 259/2012 amended Regulation (EC) No 648/2004 to limit the content of phosphate and phosphorous compounds in detergents.

10.3. Toys

Under the new Toys Directive 2009/48/EC, CMR chemicals substances, are no longer allowed in accessible parts of toys. For certain substances like nickel tolerable limit values have been introduced and certain heavy metals which are particularly toxic, like lead, may no longer be intentionally used in those parts of toys that are accessible to children.

A 2010 EFSA report[80] on Lead in Food concluded that it is impossible to establish, for lead, a threshold below which no critical effect on health can be observed and recommended reducing lead exposure via both food and non-food products. The study shows that the level of protection of children against exposure to lead as established by the Toys Directive is not adequate and it is necessary to amend the current values for lead. A consultation on the revision of lead limit values in toys was undertaken in 2012.

10.4. Construction Products

Under Regulation (EU) No 305/2011 for the marketing of construction products, the declaration of performance of construction products made by a manufacturer must contain information referred to in

[80] EFSA Panel on Contaminants in the Food Chain (CONTAM). Scientific Opinion on Lead in Food. EFSA Journal 2010; 8(4):1570. [147 pp.]. doi:10.2903/j.efsa.2010.1570. Available online: www.efsa.europa.eu/efsajournal

the Safety Data Sheets or information on substances subject to Authorisation under REACH. The Commission as set in place a database on national regulations on construction products related to the emission/content of dangerous substances in these products.

10.5. Food Contact Materials

The core legislation covering all food contact materials and articles is Regulation (EC) No 1935/2004. It is a horizontal measure that applies across the board to all food contact materials and articles. It provides that specific measures for groups of materials and articles (active and intelligent materials and articles, adhesives, ceramics, cork, rubbers, glass, ion-exchange resins, metals and alloys, paper and board, plastics, printing inks, regenerated cellulose, silicones, textiles, varnishes and coatings, waxes, wood) must be amended or adopted by the Commission. This legislation sets criteria (e.g. migration limits) in order to ensure that constituents of material in contact with food do not endanger the health of consumers and adversely affect the nature or quality of the food. In comparison to Directive 89/109/EEC, this Regulation includes active and intelligent food contact materials and articles in its scope and the main requirements for their use.

Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food establishes specific requirements for the manufacture and marketing of plastic materials and articles intended to come into contact with food; or already in contact with food; or which can reasonably be expected to come into contact with food. Compared to the previous Directive 2002/72/EC and its amendments the scope of this Regulation has been enlarged and now also addresses plastic layers which are part of multimaterial multi-layer material and articles. This Regulation was recently amended to prohibit the use of Bisphenol A in plastic infant feeding bottles.

10.6. Packaging and Packaging Waste

Directive 94/62/EC on packaging and packaging waste requires that Member States must ensure that the sum of concentration levels of lead, cadmium mercury and hexavalent chromium present in packaging or packaging components must not exceed 100 ppm by 2001.

10.7. Restrictions on Hazardous Substances

The new RoHS Directive (RoHS 2) applies to new categories of products, medical devices (with the exclusion of active implantable medical devices) monitoring and control instruments as of 22 July 2014, in-vitro diagnostic medical devices as of 22 July 2016, industrial monitoring and control instruments as of 22 July 2017. All Electrical and Electronic Equipment (EEE) not listed in Annex I that are not excluded from the scope of the Directive must comply with it. The new Directive requires manufacturers to draw up technical documentation and a declaration of conformity and to affix the CE marking to a product if it complies with the Directive. Annex II of the Directive lists the maximum concentration values tolerated by weight in homogeneous materials (Lead 0.1%, Mercury 0.1%, Cadmium 0.01%, Hexavalent chromium 0.1%, Polybrominated biphenyls (PBB) 0.1%, Polybrominated diphenyl ethers (PBDE) 0.1%). The recitals of this Directive also explicitly refer to nanomaterials.

In 2013, the Commission launched the first of four consultations on new bans under the RoHS 2 directive. The consultation process is expected to end in November 2013 with the publication of a final report on a methodology to identify candidate substances and recommending new bans. A review of banned substances listed in annex II of the law is required by 22 July 2014. At a minimum, flame retardant HBCDD and phthalates DEHP, BBP and DBP will be included in the review.

10.8. Cosmetic Products

Regulation No 1223/2009 on cosmetic products aims at harmonising rules, simplifying procedures and strengthening the regulatory framework regarding cosmetic products and ensuring a high level of protection of human health. It reinforces the general product safety legislation in relation to cosmetic products, taking into consideration the possible use of nanomaterials. The major elements include:

- The obligation to set safety reports that provide an evaluation of cosmetic products (quantitative and qualitative composition of the product, information about impurities and information on packaging materials, toxicological profiles of the substances used)
- Product Information File (PIF) that the cosmetic product distributor must create and keep for a period of ten years from the last distribution.
- Provisions regulating nanomaterials in cosmetics
- EU-wide notification method
- Prohibition of the use of substances in cosmetic products classified as CMR Category 2;
- Prohibition use of CMR substances categorized as 1A or 1B exceptions possible in case of compliance with certain criteria (i.e. in compliance with EU food safety, no

alternatives, exposure known, substance found safe by the Scientific Committee for Consumer Safety

Risk assessment of cosmetics products involves a dual approach, whereby an individual safety evaluation is performed by product manufacturers on those ingredients with no regulatory restrictions and documented in the Cosmetic Product Safety Report (CPSR). Information to be listed in the CPSR includes the toxicological profiles of the ingredient substances, their physical and chemical characteristics, impurities, trace components, as well as their exposure criteria in use.

In addition, the Scientific Committee for Consumer Safety (SCCS) undertakes risk assessment of specific substances. The use in cosmetic products of substances classified as CMR 1A and 1B is prohibited. However, they may be used in cosmetic products where the substance has been evaluated by the SCCS and found safe for use in cosmetic products.

The Cosmetics Directive also addresses nanomaterials, whereby cosmetic products containing nanomaterials shall be notified to the Commission. Information to be included in the notification includes:

- the identification of the nanomaterial including its chemical name (IUPAC) and other descriptors;
- the specification of the nanomaterial including size of particles, physical and chemical properties;
- an estimate of the quantity of nanomaterial contained in cosmetic products intended to be placed on the market per year;
- the toxicological profile of the nanomaterial;
- the safety data of the nanomaterial relating to the category of cosmetic product, as used in such products; and
- the reasonably foreseeable exposure conditions.

11. Chemicals-related Occupational Health and Safety Legislation

The EU has a number of legislative acts in place to protect workers from chemical-related risks in the workplace. Framework Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work[81] establishes general principles that apply to risks arising from the use of chemical agents at work. These provisions are then complemented by a number of legislative acts on specific groups of chemicals, as well as targeting specific groups that are more vulnerable. These are briefly introduced below.

11.1. Chemical Agents Directive

Directive 98/24/EC on chemical agents[82] at work lays down minimum technical requirements for the protection of workers from risks arising from chemical agents that are present in the workplace, covering all hazardous substances including CMRs as classified according to the CLP Regulation.

The Directive requires that if there is a hazardous substance then the employer should assess any risk from the chemical to the safety and health of workers. There are four key steps in carrying out a risk assessment:

- What is the hazard (hazard identification)?
- What is the dose/exposure that causes the effect (e.g. is there an OEL or blood limit value for the chemical), through what route does it cause its effect (e.g. inhalation) and any conclusions from health surveillance (hazard characterisation)
- What is the the level, type and duration of exposure (exposure assessment)
- Given the above 3 steps, is there a risk (risk characterisation)?

The employer should work through each of these steps in developing his or her risk assessment, progressively refining the risk assessment as more or new information becomes available. If there are any risks then the necessary preventive measures must be put in place to eliminate or reduce them to a minimum, as described in the previous sections.

[81] Council Directive of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work, O.J. L 183/1, 29 June 1989.
[82] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC), O.J. L 131/11, 5 May 1998.

In addition, there is a focus on the protection of workers from the risk associated with exposure to endocrine disruptors in the workplace, an area that is not specifically addressed under EU law as yet. The Safety Data Sheets will include data on endocrine disruptors for which a Chemical Safety Assessment has been performed, i.e. on the market at 10 tonnes plus.

The CAD provides for the establishment by the Commission of indicative and/or binding occupational exposure limit values (OELs) based on an evaluation of the relationship between the health effects of hazardous chemicals and the level of occupational exposure. For any indicative OEL, Member States shall establish a national OEL, taking into account the Community limit value and in accordance with national legislation and practice. For any binding OEL, Member States shall establish a corresponding national OEL based on, but not exceeding, the Community limit value. The Commission may also draw up binding biological limit values, with Member States obliged to then establish corresponding and not less stringent national binding biological limit values.

To date, the Commission has only established binding OELs under the CAD for inorganic lead and its compounds, provided in table 16 below.

Table 15: Binding OELs for inorganic lead and its compounds under the CAD

Name of agent	Occupational exposure limit value 8 h (3)
	mg/m3 at 20 °C and 101,3 kPa
Inorganic lead and its compounds	0,15

Following Annex II of the CAD, biological monitoring must include measuring the blood-lead level (PbB) using absorption spectrometry or a method giving equivalent results. A biological limit value for lead in human blood is set at 70 μg Pb/100 ml blood. Medical surveillance is carried out if:

- exposure to a concentration of lead in air is greater than 0,075 mg/m3, calculated as a time-weighted average over 40 hours per week; or
- a blood-lead level greater than 40 μg Pb/100 ml blood is measured in individual workers.

Reflecting scientific advances in understanding of the impacts of lead, in 2002 the EU Scientific and Social Committee for Occupational Exposure Limits (SCOEL) reviewed the evidence regarding the impacts of lead exposure on human health against the requirement in the CAD. Regarding the reprotoxic effects of lead, SCOEL concluded that adverse signs of male reproductive toxicity appear consistently at lead blood levels above 40 g/dl. The adverse reproductive toxicity effects in females, which they argued to be of highest potential impact, included impairment of the cognitive development in newborns and infants. SCOEL concluded that a definite threshold for this effect could

not be derived from the available literature data. In conclusion, SCOEL recommended lowering the biological limit value for lead in blood to 30 µg/100ml.[83] They noted that the recommended blood limit value is not entirely protective of the offspring of working women, for which no threshold for potential central nervous system effects in new born and infants could be identified, arguing that the exposure of fertile women to lead should therefore be minimised. To date the Commission has not acted on this recommendation to revise the limits on lead under the CAD.

The Commission has adopted three Directives in response to the Chemical Agents Directive, with three lists of indicative occupational exposure limit values for chemical agents at work. Directives 2009/161/EC[84], 2006/15/EC[85] and 2000/39/EC[86] establishing lists of indicative occupational exposure limit values for chemical agents at work.

11.2. Carcinogens and Mutagens Directive

A key step was the adoption of Directive 2004/37/EC on carcinogens and mutagens at work[87] (CMD), which serves to provide additional protection from those chemical substances identified as posing more significant risks to human health. The more stringent requirements of the CMD reflect the view that the health risks associated with exposure to certain carcinogens and mutagens (genotoxic carcinogens) are not linked to a particular concentration or threshold, but may arise at any concentration. As such it is not possible to establish "no effect threshold levels". The control regime under CMD therefore permits occupational exposure only when there is no alternative substance/system available and with workers' exposure minimised.

The Commission is currently considering whether substances categorised as reprotoxic category 1A and 1B should be included under the CMD, with the aim of extending additional protecting to workers from these substances. In particular, pregnant women can be exposed to reprotoxic substances priori

[83] EU SCOEL, 2002, Recommendation from the SCOEL for lead and its inorganic compounds, SCOEL/SUM/83, January 2002, European Commission, available at: www.ec.europa.eu/social/BlobServlet?docId=6506&langId=en
[84] Commission Directive 2009/161/EU of 17 December 2009 establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC, OJ L 338, 19.12.2009, p. 87–89
[85] Commission Directive 2006/15/EC of 7 February 2006 establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC, OJ L 38, 9.2.2006, p. 36–39
[86] Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, OJ L 142, 16.6.2000, p. 47–50
[87] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC), O.J. L 158/50, 30 April 2004

to declaration of pregnancy in the critical early window of pregnancy, when resulting effects on the unborn child have the potential to be serious and irreversible.

11.3. Asbestos

Directive 2009/148/EC[88] requires that for activities in which workers are or may be exposed to dust arising from asbestos or materials containing asbestos, a risk assessment must be carried out including consultation with the workers. Any activity exposing workers to intentionally added asbestos fibres shall be prohibited, with the exception of the treatment and disposal of products resulting from demolition and asbestos removal. The Directive sets a single maximum limit value for airborne concentration of asbestos is 0.1 fibres per cm^3 as an eight-hour time-weighted average (TWA). In order to ensure compliance with the limit values, qualified personnel shall regularly measure asbestos-in-air concentrations, in an appropriate way. If the limit value is exceeded, the reasons must be identified and appropriate measures taken to remedy the situation. If limit values cannot be kept by technical measures, the employer shall implement protective measures, including: providing proper personal protective equipment, putting up warning signs and preventing the spread of asbestos dust. Employers must keep a register for 40 year indicating the nature and duration of the activity and the exposure and to be made available to workers and physicians.

11.4. Vulnerable Groups

Two pieces of legislation specifically target vulnerable groups. Directive 94/33/EC on young people at work[89] prohibits the employment of young people in activities involving harmful exposure to chemical agents, including reprotoxic substances. Directive 92/85/EEC on pregnant workers, workers who have recently given birth or are breastfeeding[90] recognizes the particular vulnerability of this specific group and extends additional protection from exposure to chemical agents, including a prohibition of work involving exposure to lead and its derivatives.

[88] Directive 2009/148/EC - exposure to asbestos at work of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work,

[89] Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work, O.J. L 216/12, 20 August 1994

[90] Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC), O.J. L 348/1, 28 November 1992

11.5. Use of Safety Data Sheets in OHS

When conducting a risk assessment in order to determine whether any hazardous chemical agents are present at the workplace, employers will draw on the information in safety data sheets provided by the suppliers of chemical substances. The safety data sheets will be used to develop an inventory of chemicals used or produced in a workplace and to gather basic information on the chemicals to determine if they are hazardous. Table 17 below provides a summary of the information in the safety data sheet that can feed into the risk assessment.

Under REACH, producers or supplies of chemicals that are sold in volumes of 10 tonnes per year or more are obliged to undertake a Chemical Safety Assessment, the results of which are must be included in the registration dossier. The Chemical Safety Assessment determines whether the risks from a particular use of a substance (on its own, in a mixture or in an article) are properly controlled. The assessment includes an assessment of the hazards of the substance, including establishing the level of exposure to a substance below which no ill-effects occur, or Derived No-Effect Level (DNEL)[91] or, in the case of substances where impacts are not linked to the concentration of exposure, the level at which the risk is deemed to be tolerable, or Derived Minimal Effect Level (DMEL)[92].

If the substance is classified as dangerous or is bioaccumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB), then an exposure assessment and risk characterisation must be performed to demonstrate that the risks are adequately controlled. This involves the development of exposure scenarios, an estimate of the exposure and a comparison of the exposure to the limits derived under the hazard assessment. If the exposure is lower than the DNEL/DMEL then the substance is properly controlled. Data generated by the REACH registrant under the chemical safety assessment should be included in the safety data sheet, and hence will be available to employers when conducting a risk assessment.

DNEL(s) shall be established for the substance, reflecting the likely route(s), duration and frequency of exposure. For some endpoints, especially mutagenicity and carcinogenicity, the available information may not enable a threshold, and therefore a DNEL, to be established. If justified by the exposure scenario(s), a single DNEL may be sufficient. However, taking into account the available information and the exposure scenario(s), it may be necessary to identify different DNELs for each

91 Derived No-Effect Level (DNEL): A DNEL is the level of exposure to the substance below which no adverse effects are expected to occur. It is therefore the level of exposure to the substance above which humans should not be exposed. DNEL is a derived level of exposure because it is normally calculated on the basis of available dose descriptors from animal studies such as No Observed Adverse Effect Levels (NOAELs) or benchmark doses (BMDs).

92 Derived Minimal Effect Level (DMEL): For non-threshold effects, the underlying assumption is that a no-effect-level cannot be established and a DMEL therefore expresses an exposure level corresponding to a low, possibly theoretical, risk, which should be seen as a tolerable risk.

relevant human population (e.g. workers, consumers and humans liable to exposure indirectly via the environment) and possibly for certain vulnerable sub-populations (e.g. children, pregnant women) and for different routes of exposure. Thus additional protection is foreseen for vulnerable groups.

Table 16: Information from the safety data sheet to feed into risk assessment

Section of the safety data sheet	Relevant information
SECTION 1: Identification of the substance/mixture and of the company/undertaking	This section contains information on the chemical including its REACH registration number (if there is one), plus the supplier details for further information.
SECTION 2: Hazards identification	This section contains the classification of the chemical (important for hazard identification), its label and hazards that don't lead to classification but that may still need to be assessed (e.g. dustiness).
SECTION 3: Composition/information on ingredients	This section gives information on ingredients of mixtures (along with their hazards) that might be useful for risk assessment if they have a higher volatility to the other components.
SECTION 4: First aid measures	This section will not normally have so much relevance to risk assessment
SECTION 5: Firefighting measures	This section gives some information on hazardous thermal decomposition products.
SECTION 6: Accidental release measures	This section contains useful information on spills and precautions for such situations.
SECTION 7: Handling and storage	This is one of the key sections that details safe handling and storage precautions that will guide the possible risk management measures for the chemical.
SECTION 8: Exposure controls/personal protection	Another key section that contains information on applicable national OELs and BLV for the chemical or its ingredients. Also contained here are details of risk management measures and Personal Protective Equipment relevant for uses of the chemical.
SECTION 9: Physical and chemical properties	This section contains information on properties that might give rise to physical hazards e.g. flammability and that influence exposure such as boiling point/volatility and granulometry.
SECTION 10: Stability and reactivity	This section contains information on the reactivity of a chemical, how stable it is, if there are any hazardous reactions and what conditions or materials to avoid.
SECTION 11: Toxicological information	This section contains information on the health effects of the chemical, such as its effects on reproduction.
SECTION 12: Ecological information	This section contains environmental information.
SECTION 13: Disposal considerations	This section contains information on how to dispose of the product and its packaging safely.
SECTION 14: Transport information	This section contains information on safe transport of the substance.
SECTION 15: Regulatory information	This section contains information on relevant safety and health regulations/legislation specific for the chemical.

The DNELs generated under REACH must be considered against existing Occupational Exposure Limit Values (OELs) under EU legislation, both indicative and binding. Guidance on deriving DNELs in cases when EU or national level OEL are available is provided in the ECHA Guidance on information requirements and the chemical safety assessment (Chapter R 8). In theory, compliance by industry with the DNEL should provide adequate protection, removing any need to consider

additional OELs. Ideally, only one DNEL would exist for a substance/exposure scenario. However, there are concerns that, in practise, several DNELs may be derived (e.g. by different suppliers) and it has been suggested that, at least during REACH phase-in, use of OELs will continue to be important, particularly where it is not feasible to address all possible exposure scenarios in a CSA. In particular, national level DNELs vary considerably, both in terms of the absolute values for any one substance and the number of substances for which DNELs are set. This suggests that the use of national OELs as a basis for deriving DNELs will increase variation in DNELs.

Where DNELs differ from OELs, this will obviously lead to short-term confusion, while industry and regulators adjust to the new information becoming available. Indeed, such differences are likely given the very different basis for their respective derivations. Importantly, OELs are intended as specific occupational health and safety instruments while DNELs primarily define a risk level and are then used to establish what risk management measures are necessary[93]. This is illustrated by a recent comparison of 88 OELs produced by SCOEL with their corresponding worker DNELs under REACH, which showed that the safety margins for DNELs were overall about six-times higher than for the OELS, although they ranged between 0.3 and 58.[94] This indicates that DNELs may not be more protective than OELs in every case, but generally are likely to be so. Thus, at least over the phase-in period for REACH and until such time as the apparent differences between OELs and DNELs can be clarified, it is likely that industry may be subject to some confusion and formal clarification from the Commission would be useful.

In the 2013 General Report on REACH, the Commission provides clarification regarding the relationship between OELs and DNELs, presented in box 35 below. The Commission takes the position that the lower of the two values should be complied with by the employer, and calls for additional guidance to be provided on how to consider two values, both in the ECHA guidance and in the SDS.

[93] Kayser M (2007): DNEL: multiple values for identical substances?. Lecture at Occupational Limit Values for Hazardous Substances – Health working conditions in a global economy. Comference under the German Presidency of the European Council, Germany, May 7-8, 2007.

[94] Schenk L and Johanson G (2011) A Quantitative comparison of the Safety Margins in the European Indicative Occupational Exposure Limits and the Derived No-effetc Levels for Workers under REACH.Toxicol. Sci, 121, 408-416

Box 34: Commission clarification of the relationship between OELs and DNELs

The Commission services are of the view that OELs and DNELs (for both the same duration and the same route of exposure) may co-exist, and in some circumstances may apply simultaneously to some work activities. In certain cases, where the guidance allows the registrant to use OEL instead of deriving DNEL, the problem of two different values would not arise. In other cases, it is the Commission's view that, in principle, the lowest level should be complied with by the employer. The binding OEL needs to be always complied with by the relevant employer. In cases when the DNEL is lower than the OEL, the compliance with DNEL is based on the premise that the registrant could not use OEL instead of deriving DNEL for the same exposure route and duration, as he has obtained new scientific information which indicated that the OEL does not provide the appropriate level of protection.

Annex II to REACH provides for an obligation to list the relevant applicable EU or national OELs in Section 8 of the SDS (exposure controls/personal protection). Therefore the Commission services consider that more guidance on the relationship between the DNEL and different OELs in the ECHA Guidance on the compilation of SDS would be helpful for duty holders to fulfil properly their obligation to compile a SDS to avoid confusion between the two systems. The SDS itself could contain some explanation how those two values should be considered by the downstream user as an employer.

11.6. Emerging Risks in the Working Environment

11.6.1. Nanomaterials

EU-OSHA published a series of expert forecasts on potential emerging risks in the world of work in which experts agreed that nanoparticles and ultrafine particles pose the strongest emerging risk. In particular, the lack of knowledge regarding the specific properties of the range of nanoforms that workers may be exposed to and concerns regarding the applicability of test protocols generate uncertainties in risk assessment and resulting risk management options.

Growing production and use of nanomaterials result in an increasing number of workers and consumers exposed to nanomaterials.[95] The potential for human exposure depends on the way the nanomaterial is being used and is likely to be greater for 'free' nanomaterials, i.e. in powder form, than for embedded nanomaterials. Techniques for measuring exposure to nanomaterials in working environments are under development, for example through a number of European Commission-funded projects. The major challenge is distinguishing the specific target nanoparticles from other ambient ultrafine particles. In controlling exposure to nanomaterials in the workplace, the most effective approach is to contain the processes involving the sources of the materials.[96]

[95] EU-OSHA (2009) Workplace exposure to nanomaterials, EU-OSHA, available at: https://osha.europa.eu/en/...reviews/workplace_exposure_to_nanoparticles

[96] EU-OSHA (2011) Risk perception and communication with regards to nanomaterials, European Risk Observatory, Luxembourg, available at: https://osha.europa.eu/...nanomaterials.../risk-perception-communication-on-nanotechnology.pptx

EU-OSHA continues to work on the issue of workers' protection from nanomaterials, having generated publications on workplace exposure to nanomaterials and risk communication. In addition, EU-OSHA has developed an on-line database of company Good Practice examples of good workplace management of manufactured nanomaterials which covers a variety of industries, such as textile, construction and medical applications.[97]

In their 2012 Staff Working Document Paper, the Commission notes that "*in general little or no information is currently available in the Safety Data Sheets (SDS), making it often difficult for employers and workers at the use stage to assess specific exposure to nanomaterials and to implement adequate prevention measures*". In addressing this, changes have been made to REACH Annex II[98], which is the legal framework for SDS, while guidance from ECHA provides advice on how to address characteristics of nanomaterials in SDS.[99]

In 2012, the Commission launched a study aiming to:

- check the extent to which the current EU OSH legal framework covers sufficiently and effectively nano-related risks in the workplace;
- delineate a series of possible scenarios that should help shed light on which options may be better suited to tackling nano-related workplace risks without undue demands on businesses; and
- draft a practical guidance document that may help tackle the mentioned workplace risks, pending development of a specific regulatory framework.

The study includes an in-depth characterisation of likely exposures of workers to nanomaterials, relevant risk assessment issues, types and effectiveness of risk management measures and relevant regulatory issues. The study is due for finalisation by early 2013. The 2012 Staff Working Paper concludes that "*where the application of current regulatory obligations such as from REACH registration or the Chemical Agents Directive may not be sufficiently effective, further regulatory action, including possible restrictions of use of certain nanomaterials may become necessary"*. [100]

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[97] See: http://osha.europa.eu/en/practical-solutions/case-studies/index_html/practicalsolution?SearchableText=&is_search_expanded=True&getRemoteLanguage=en&keywords%3Alist=nanotechnology&nace%3Adefault=&multilingual_thesaurus%3Adefault=&submit=Search

[98] Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 133, 31.5.2010, p. 1.

[99] See: http://echa.europa.eu/documents/10162/17235/sds_en.pdf

[100] European Commission (2012) Commission Staff Working Paper on the types and uses of nanomaterials, including safety aspects, SWD(2012) 288 final, 3/10/2012, Brussels

In responding to the recent 2012 Second Regulatory Review on Nanomaterials, the European Confederation of Trade Unions (ETUC) stated that the Communication "*does not provide new elements that could clarify the regulatory situation and that existing gaps are still unaddressed*". The ETUC calls for urgent modifications to REACH to ensure the potential high risks of nanomaterials are properly controlled and states that the precautionary principle needs to be applied to workers' protection from nanomaterials.[101]

11.6.2. Endocrine Disrupting Chemicals

Increasing information on the health risks associated with exposure to EDCs has raised concern regarding exposure in the workplace. The on-going consideration of whether to include reprotoxic substances under the CMD will goes some way towards addressing this issue, although not all EDCs operate through reproductive endpoints. Further action is required at EU level to address the risks of workers' exposure to EDCs in a comprehensive manner.

In terms of action on specific substances, following the recommendation of SCOEL, the Commission adopted an indicative occupational exposure limit value of 10 mg/m3 for Bisphenol-A from inhalable dust.

[101] ETUC website, Workers' protection lost in nano-space? ETUC reaction to the European Commission second regulatory review of nanomaterials, last accessed 21.02.13 at: http://www.etuc.org/a/10394

12. Mercury

In 2002, a Commission report[102] highlighted the fate of 12-15 thousand tonnes of surplus mercury resulting from chlor-alkali industry's conversion away from the mercury cell process. With the aim of addressing this issue and cutting EU uses and emissions of mercury through a coherent life cycle approach to protecting the environment and human health from mercury releases, the EU Mercury Strategy was launched in 2005. The Strategy includes actions to ban mercury exports, establish safe storage criteria for metallic mercury removed from decommissioned mercury cell chlor-alkali plants, restrict specific uses of mercury, promote alternatives in products and processes and control emissions, as well as OHS requirements that affect mercury. The strategy has the following objectives:

- Reducing mercury **emissions**.
- Reducing the entry into circulation of mercury in society by cutting **supply** and **demand**.
- Resolving the long-term fate of mercury **surpluses** and societal **reservoirs** (in products still in use or in storage).
- Protecting against mercury **exposure**.
- Improving **understanding** of the mercury problem and its solutions.
- Supporting and promoting **international action** on mercury.

A total of 20 specific actions were set, divided under each objective.

12.1. Progress on the 2005 Mercury Strategy

An independent 2010 report[103] reviewed the EU's progress in implementing the 20 actions foreseen under the Community Strategy Concerning Mercury and concluded that good progress had been achieved on twelve actions, moderate progress on six actions and little progress on two actions. The progress under the objectives are discussed below.

12.2. Reducing Mercury Emission

Point source emission of mercury include the chlo-alkali industry, cement production, coal combustion, crematoria (from combusted dental amalgam), metal smelters, steel production and waste incineration. Mercury emissions from industrial installations were regulated under the Industrial

[102] Report from the Commission to the Council concerning mercury from the chlor-alkali industry, COM(2002) 489 final, 06.09.2002, Brussels
[103] BioIntelligence Service (2010) Review of the Community Strategy Concerning Mercury, Paris, France

Pollution Prevention and Control Directive (IPPC), with local authorities granting permits with emission limit values based upon Best Available Techniques (BAT) listed in the BAT Reference Documents (BREF). The IPPC Directive states that existing installations - installations in operation before October 1999 - should operate in accordance with the requirements of the Directive by 30 October 2007. However, IPPC left considerable discretion to the local authorities and permits conditions in many cases did not reflect BAT.

In 2010, the IPPC was replaced by the Industrial Emissions Directive (IED), which entered into force on 6 January 2011 and has to be transposed into national legislation by Member States by 7 January 2013. Although the principle is the same as for IPPC, the role of the BREFs has now been strengthened. The possibility for permitting authorities to deviate from the AEL levels is more restricted and subject to justification according to strict criteria set out in the Directive.

With regards to the chlo-alkali industry, in their 2011 Communication on implementation of the Mercury Strategy, the Commission notes that "*it is expected that this will result in an accelerated replacement of mercury-based technologies and reduction of mercury emissions in a range of industrial sectors, in particular cement production, non-ferrous metal industries, large combustion plants, waste incineration and chlor-alkali manufacturing".*[104]

The first chlor-alkali BREF document was published at EU level in December 2001. According to the chlor-alkali BREF, the membrane (mercury free) process, and not the mercury-cell process, is regarded as BAT for the chlor-alkali industry. The revision of the BREF has started in 2010 and is expected to be finalised in 2012. The real effects in the chlor-alkali sector are expected to be seen however only in 2016-2017, so around 4 years after the revision of the chlor-alkali BREF.

According to a 2005 study[105], emission from small-scale coal combustion was estimated to contribute 16% of total EU mercury emissions. While the original Commission proposal for the IED suggested reducing the threshold for the application of the rules applying to large combustion plants from a total rated input of 50 MW to 20 MW, the 50 MW threshold was maintained in the final Directive. The Commission is required to review, by the end of 2012, the need to control emissions below the 50 MW threshold.

[104]COMM, 2010 "Communication from the Commission to the European Parliament and the Council on the review of the Community strategy concerning mercury" COM(2010) 723 final

[105] AEA Technology/NILU-Polska (2005) Costs and environmental effectiveness of options for reducing mercury emissions to air from small-scale combustion installations, AEA Technology/NILU-Polska

A 2006 Resolution[106] of the European Parliament recognised that coal burning is the main source of mercury emissions and asked the Commission to introduce emission limit values for mercury for all relevant process, and in particular for large and small-scale coal combustion processes under the IPPC Directive or in a separate legislative instrument. With regards to the chlo-alaki industry, it calls on the Commission to ensure strict implementation of the IPPC Directive, bearing in mind that the mercury-cell process in the chlor-alkali industry is not identified as BAT. The Resolution calls on the Commission to implement PARCOM Decision 90/3 and phase out the use of mercury-cell chlor-alkali plants as soon as practicable, with the objective that they should be phased out completely by 2010. Regarding mercury emissions from crematoria, it asks the Commission to take further measures, in the short term, to control mercury emissions, and in addressing the source of these emissions it asks the Commission to propose by the end of 2007 restrictions on the use of mercury in dental amalgam, to take measures regarding treatment of dental waste, and to investigate whether additional measures are prevent amalgam from entering the waste stream.

Dental amalgam is the second biggest use of mercury in the EU and generates considerable emissions in the form of hazardous waste. Commission Decision 2000/532/EC characterises amalgam waste from dental care as hazardous waste, making it subject to the provisions of the Waste Framework Directive that address hazardous wastes. The European Parliament resolution on the European Environment & Health Action Plan 2004-2010 - Article 6, declared that, consistent with the opinion of the relevant Scientific Committee, urgent consideration should be given to restricting the marketing and/or the use of mercury used in dental amalgams. In March 2012, the Commission requested the Scientific Committee for Emerging and Newly Identified Health Risks (SCENIHR), as well as the Scientific Committee for Health and Environmental Risks (SCHER) to update their opinions on dental amalgam issued in 2008 on the basis of new information made available.

12.3. Cutting Supply and Demand

Following Regulation (EC) No 1102/2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury[107], the export of metallic mercury is banned after 15 March 2011, and mercury from decommissioned chlor-alkali plants shall be safely stored.

[106] European Parliament resolution on the Community strategy concerning mercury (2005/2050(INI))
[107]

12.4. Restrictions on Uses of Mercury in Products

Following Directive 2007/51/EC relating to restrictions on the marketing of certain measuring devices containing mercury, fever thermometers as well as other mercury-containing measuring devices (e.g. manometers, barometers, sphygmomanometers, thermometers other than fever thermometers) intended for sale to the general public may no longer be placed on the market. The Directive includes a review clause for a possible extension of the existing restrictions to other measuring devices containing mercury.

A ban on the use of mercury in measuring devices will apply from April 2014 under REACH restrictions. In addition, REACH includes a restriction on the use of mercury substances in marine anti-fouling paints, wood preservatives, among others. In addition, the manufacture, sale and use of phenylmercury substances in concentrations over 0.01% will be banned from October 2017.

Directive 2006/66/EC[108] on batteries and accumulators and waste batteries and accumulators, in the EU, set maximum mercury limits for alkaline and button cell batteries, and prohibit the marketing of mercury oxide batteries, although there may still be significant quantities of the latter that transit the EU in trade flows. A study on the potential for reducing mercury emissions from batteries is on-going.

According to Regulation (EU) No 1233/2009 mercury and its compounds may not be present as ingredients in cosmetics, including soaps, lotions, shampoos, skin bleaching products, etc. (except for phenyl mercuric salts as a preservative in eye make-up, and in products for removal of eye make-up, in concentrations not exceeding 0.007 percent by weight) that are marketed within the European Community. Mercury in cosmetics is also covered through legislation implementing the Rotterdam Convention. The production for export in the EU of mercury containing cosmetics was banned in 2003 under Annex 5 of the EU Regulation 689/2008 implementing the Rotterdam Convention.

The EU has developed and passed two pieces of legislation regulating the content and disposition of electrical and electronic equipment (EEE). Directive 2002/96/EC (WEEE) mainly ensures separate collection and recycling of EEE, while Directive 2002/95/EC (RoHS) limits the use of certain hazardous chemicals – including mercury or any components containing mercury – to a maximum concentration by weight of Mercury 0.1% in new equipment marketed after 1 July 2006. At present, however, due to the lack of widely available energy-efficient alternatives, the EU has specifically permitted continued use of fluorescent lamps with a low mercury content, as well as all specialty

[108] DIRECTIVE 2006/66/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC

mercury lamps (more details on this are contained in the RoHS Directive). The content of mercury in energy efficient lighting has recently been revised under the relevant annex of the RoHS directive.

Mercury in lamps is also relevant to the EU Ecolabel. According to European Commission Decision 1999/568/EC (amended 9 September 2002), for a manufacturer to be allowed to use the European Ecolabel on a single-ended compact fluorescent lamp, the mercury content must not exceed 4 mg, and the life of the lamp must exceed 10,000 hours. This decision is under revision and mercury content maximum allowed level is expected to be further lowered.

12.5. Environmental Quality Standards for Mercury

In terms of quality standards for mercury in different environmental media, the relevant legislation addressing ambient air quality standards is Directive 2004/107/EC relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air. The Directive requires that mercury is measured at background sampling points with a spatial resolution of 100,000 km^2 in order to provide information on geographical variation and long-term trends. Monitoring of particulate and gaseous divalent mercury is also recommended.

With reference to water, mercury is classified as priority hazardous substance according to Annex X of the Water Framework Directive (WFD). Member States are obliged in the long term to take measures to cease or phase out the emissions, discharges and losses of this substance. In addition and reflecting the combined approach of the WFD, Directive 2008/105/EC establishes Environmental Quality Standards (EQS) in the field of water policy for certain priority substances, including mercury and its compounds. In case these standards are not met, Member States have to take measures to comply with them by 2015. The EQS for mercury are presented in table 18 below.

Table 17: EQS for mercury under Directive 2008/105/EC

Name of substance	CAS number	AA-EQS Inland surface waters	AA-EQS(i) Other surface waters	MAC-EQS Inland surface waters(ii)	MAC-EQS(iii) Other surface waters
Mercury and its compounds	7439-97-6	0.05(viii)	0.05(viii)	0.07	0.07

i This parameter is the EQS expressed as an annual average value (AA-EQS). Unless otherwise specified, it applies to the total concentration of all isomers.
ii Inland surface waters encompass rivers and lakes and related artificial or heavily modified water bodies.
iii This parameter is the Environmental Quality Standard expressed as a maximum allowable concentration (MAC-EQS). Where the MAC-EQS are marked as "not applicable", the AA-EQS values are considered protective against short-term pollution peaks in continuous discharges since they are significantly lower than the values derived on the basis of acute toxicity.
viii If Member States do not apply EQS for biota they shall introduce stricter EQS for water in order to achieve the same level of protection as the EQS for biota set out in Article 3(2). They shall notify the Commission and other Member States, through the Committee referred to in Article 21 of Directive 2000/60/EC, of the reasons and basis for using this approach,

the alternative EQS for water established, including the data and the methodology by which they were derived, and the categories of surface water to which they would apply.

12.6. Dietary Exposure to Mercury

A key dietary source of mercury intake is through the consumption of fish species that contain methymercury as a result of bioaccumulation in the food chain. Some of the highest human exposure is seen in native Arctic communities, due to the accumulation of mercury in fish and the high contribution of fish to the local diet.

In 2003, the Joint Expert Committee on Food Additives (JECFA) recommended a Provisional Tolerable Weekly Intake (PTWI) of methylmercury of 1.6 µg/kg/week, which the WHO adopted as the current international exposure guideline for methylmercury intake, which is about twice as high as the US Reference Dose, at 0.1 µg/kg/day. JECFA argued that the PTWI dose should produce an equilibrium maternal blood mercury level of about 8.7 µg/L, which is 1.5 times the equivalent US reference value.

Substantial new evidence published since 2003 shows that the limit is inadequate in protecting public health against methylmercury damage, with several studies reporting adverse effects at mercury doses below the JECFA PTWI.[109] A recent review of epidemiological evidence conducted by US-based Biodiversity Research Institute considers the health impacts of mercury in fish and suggests that 10% of pregnant women and young children in Europe are at risk of significant damage to the children's developing brains from the methylmercury in the ordinary amounts of fish they eat. They propose a new guideline of 0.025 µg/kg/day, noting that this dose level should be feasible to achieve for most people without restricting their overall seafood consumption, although women and parents would need to select low-mercury fish species.[110]

The EU sets maximum concentrations for heavy metals, including mercury, in fish. Maximum levels were already in place at the baseline in 2002, and have since been revised twice to reflect growing

[109] Debes F et al. (2006) Impact of prenatal methylmercury toxicity on neurobehavioral function at age 14 years, Neurotoxicology and Teratology 28:363-375; Oken E, Radesky JS, Wright RO, Bellinger DC, Amarasiriwardena CJ, Kleinman KP, et al. (2008) Maternal fish intake during pregnancy, blood mercury levels, and child cognition at age 3 years in a US cohort, Am. J. Epidemiol. 167, 1171-1181; Sagiv SK, Thurston SW et al (2012) Prenatal exposure to mercury and fish consumption during pregnancy and Attention Deficit/Hyperactivity Disorderrelated behavior in children. Archives of Pediatric and Adolescent Medicine. Published online: http://doi:10.1001/archpediatrics.2012.1286, Available at: http://archpedi.jamanetwork.com/article.aspx?articleid=1377487; Jedrychowski W, et al. (2006) Effects of prenatal exposure to mercury on cognitive and psychomotor function in one-year-old infants: Epidemiologic cohort study in Poland, Annals of Epidemiology 16(6): 439-447

[110] Groth E (2012) An overview of epidemiological evidence on the effects of methymercury on brain development and a rationale a lower definition of tolerable exposure, ZeroMercury Working Group, Brussels

concerns regarding human health impacts.[111] EFSA is currently reviewing existing safe levels, with an opinion to be published before the Christmas break 2012.

In terms of dietary exposure in the EU, the 2005 Mercury Strategy noted that most people in central and northern Europe showed bioindicators of exposure below the internationally accepted safe levels for methylmercury, the majority of the population in coastal areas of Mediterranean countries, and around 1-5% of the population in central and northern Europe, are around the internationally accepted safe levels. Importantly, large numbers among Mediterranean fishing communities and the Arctic population exceed them significantly. A 2012 publication[112] providing results from biomonitoring found levels of mercury were found to be relatively high around the Mediterranean, due to greater consumption of seafood. Finally, for 2010, OSPAR reported concentrations above EU dietary limits mainly around Denmark and in certain industrialized estuaries in the UK.[113]

Finally, the Drinking Water Directive 98/83/EC set limits on heavy metals in drinking water, including lead, cadmium, mercury and nickel.

12.7. Contribution to the Mercury International Negotiating Committee

On Saturday, 19 January 2013 Governments agreed to the text of the global legally binding instrument on mercury, the "Minamata Convention on Mercury". Following the conclusion of the negotiations at INC5, the text will be open for signature at a Diplomatic Conference (Conference of Plenipotentiaries), which will be held in Minamata and Kumamoto, Japan, from 9 to 11 October 2013. The convention was developed under the auspices of the Intergovernmental Negotiating Committee to Prepare a Global Legally-binding Instrument on Mercury, to which the EU made significant substantive contributions. The EU was awarded the Gold Certificate by UNEP's Mercury Club for its financial contributions to support the negotiating process on mercury.[114]

[111] Amended in 2002 by COMMISSION REGULATION (EC) No 221/2002 of 6 February 2002 amending Regulation (EC) No 466/2001 setting maximum levels for certain contaminants in foodstuffs, OJ L37, 7.2.2002, p 4-6; and amended in 2005 by Commission Regulation (EC) No 78/2005 of 19 January 2005 amending Regulation (EC) No 466/2001 as regards heavy metals, OJ L16, 20.01.2005, p 43-35

[112] Preliminary summary of the DEMOCOPHES results available at: http://www.health.belgium.be/eportal/Aboutus/relatedinstitutions/NEHAP/PROJECTSANDACTIONS/HumaneBiomonitoring/Results/index.htm

[113] OSPAR Commission (2010) Quality Status Report 2010, Status and trend in marine chemical pollution, OSPAR, UK

[114] See: http://www.unep.org/hazardoussubstances/Mercury/Negotiations/MercuryClub/tabid/29753/Default.aspx

13. Endocrine Disruptors

The Commission responded to growing concern regarding endocrine disrupting chemicals (EDC) in 1999, with the launch of the Community Strategy for Endocrine Disruptors[115]. With regards to the risk assessment of EDC, the Strategy highlighted the need for selection criteria for classifying EDC, as well as validated test methods for the identification of EDC to serve in hazard assessment. In addition, it recognised that risk assessment procedures may require re-evaluation in the light of the potential synergistic and low dose effects of EDC.

The EDC strategy outlined short, medium and long-term actions to be undertaken in order to address the potential impacts of EDCs on health and the environment. In particular, short-term actions included the establishment of a list of priority substances[116] on the basis of the current scientific data available and with the purpose of further evaluating the role of such substances in endocrine disruption.

The medium-term actions of the Commission's strategy focused on the development of practical and experimental activities needed to test the suspected EDCs and in particular to conduct hazard assessment. The on-going test development process is directed by the Organization for Economic Co-operation and Development (OECD) through a framework that is intended both for new and existing substances, with the Commission channelling input from Member States. In addition, under the Community Framework Programme on R&D, considerable resources have been allocated to research on risk assessment methods for EDC.

A 2009 report[117] commissioned by the Commission reviewed the state of the art in the assessment of EDCs, aiming to review evidence collected since 2002, analyse approaches to the identification of criteria in EU Member States or other countries, and draw conclusions regarding criteria identification. The report identified the two following critical areas:

- Definition of EDCs, with general acceptance of the definition for endocrine disrupting chemicals developed by the WHO International Programme on Chemical Safety [118]

[115] European Commission (1999) Communication from the Commission to the Council and the European Parliament on a Community Strategy for Endocrine Disruptors, Com(1999)706 final,
[116] Priority list: http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm#priority_list.
[117] Andreas Kortenkamp, Olwenn Martin, Michael Faust, Richard Evans, Rebecca McKinlay, Frances Orton and Erika Rosivatz. State of the Art Assessment of Endocrine Disrupters.
http://ec.europa.eu/environment/endocrine/documents/4_SOTA%20EDC%20Final%20Report%20V3%206%20Feb%2012.pdf.
[118] Definition from the WHO/IPCS report: An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations. A potential endocrine disruptor is an exogenous substance or mixture that possesses properties that

- Definition of endocrine system, low-dose effects, non-monotonic dose-response relationship.

The report also proposes four stages in the identification process: identification of mode of action; considering relevance; toxicological evaluation; and final decision. This methodology will serve with next steps regarding the EU Priority List.

In November 2012, DG Environment presented a discussion paper[119] to an ad-hoc group of officials from Member States, EU agencies and the European Commission. The paper suggests four classification categories – known, presumed, suspected and potential endocrine disruptors – based on the certainty of their effect on hormonal systems. This follows the format established under CLP, with a classification as a 'known' endocrine disruptor based on human studies and 'presumed' based on animal tests. The paper also suggests criteria for defining key terms such as 'endocrine system', 'adversity', 'route of exposure' and 'potency'. The paper is also being discussed by a separate group of experts, due to report conclusions in February 2013.[120]

The long-term actions concerned the updating, amending or adapting of the related legislative framework. Various pieces of legislation now require an assessment of the risks of chemicals with the potential for endocrine disruption, or set criteria to exclude them from products. Box 7 below provides an overview of the requirements for reviews of legislative requirements regarding risk assessment for EDC under EU legislation. The revised biocides regulation requires the Commission to define endocrine disruptors by mid-December next year and the PPPR sets a similar deadline for a draft definition. The Commission is also required to review how endocrine disruptors are controlled under the REACH regulation by June 2013.

In January 2013, the European Parliament adopted a resolution on EDCs calling on the Commission to conclude review of the strategy on endocrine disruptive chemicals (EDCs) and either amend exiting law or propose new rules by June 2015 to reduce human exposure to EDCs. Key elements of the resolution include the following:

- endocrine disrupting properties should be determined on the basis of comprehensive hazard assessments, then used to conduct risk assessments and to put in place risk management measures;

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might be expected to lead to endocrine disruption in an intact organism, or its progeny, or (sub)populations. (*http://www.who.int/ipcs/publications/en/ch1.pdf*)

[119] European Commission (2012) The Community Strategy for endocrine disruptors, the 5th Ad-Hoc meeting of Commission Services, EU Agencies and Member States, ED-AD-HOC-5/2012/04, 22 November 2012, Brussels

[120] ENDs Europe (2012) Commission weighs options for defining ECDs, 7 December 2012, ENDs

- EDCs should be regarded as "non-threshold" substances for which no limit value can be set to determine a safe exposure level since these chemicals are thought to be harmful even at low concentrations, unless a manufacturer "can show scientific proof" of a threshold; and
- the criteria for defining endocrine disruptors, which are under development, should be applied horizontally across all EU legislation rather than to specific legislation.[121]

[121] Ends Europe (2013) MEPs want action on EDCs by June 2015, 24 January 2013, ENDs Europe, Brussels

14. Application of the Precautionary Principle under EU Chemicals Management

14.1. The Precautionary Principle in EU Law

The precautionary principle is mentioned in the context of environmental protection in Article 191 (2) of the Treaty on the Functioning of the European Union[122] (ex Article 174 of the Treaty establishing the European Community), with the aim of ensuring a higher level of environmental protection through preventative decision-taking in the case of risk. However, in practice, the scope of this principle is far wider and also covers consumer policy, European legislation concerning food and human, animal and plant health.

In 2000, the Commission also issued a Communication on the precautionary principle[123], with the aim of outlining the Commission's approach to using the principle and establishing common guidelines on its application. The Communication does not deal specifically with application of the PP in the context of chemicals, but it does set out numerous guidelines that are of particular relevance for chemicals, notably because it places the PP within the realm of dealing with risks. The Communication calls for a structured approach to risks which comprises of three elements: risk assessment, risk management and risk communication. The PP is to be used especially in the risk management phase. Before deciding on taking action or not, the Communication underlines that it is necessary to complete as far as possible a risk assessment, consisting of four components: 1) hazard identification, 2) hazard characterization, 3) appraisal of exposure and 4) risk characterization.

According to the Commission, the precautionary principle may be invoked when a phenomenon, product or process may have a dangerous effect, identified by a scientific and objective evaluation, if this evaluation does not allow the risk to be determined with sufficient certainty. The Commission also emphasizes that the precautionary principle may only be invoked in the event of a potential risk and that it can never justify arbitrary decisions. In particular, the precautionary principle may only be used when three preliminary conditions are met:

- identification of potentially adverse effects;
- evaluation of the scientific data available;
- the extent of scientific uncertainty.

[122] Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, signed at Lisbon, 13 December 2007. OJ C 306, 17.12.2007, p. 1–271

[123] Communication from the Commission on the precautionary principle /* COM/2000/0001 final */

The Communication also states that if action is deemed necessary, measures based on the precautionary principle should be proportional to the chosen level of protection, non-discriminatory in their application, consistent with similar measures already taken, based on an examination of the potential benefits and costs of action or lack of action, subject to review in the light of new scientific data, and capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.

The burden of proof, i.e. the need to prove the absence of danger, may lie on consumers or on the business community depending on whether Community rules establish prior approval before the placing on the market of certain products, such as chemicals, drugs, pesticides or food additives.

Since the Commission Communication, the precautionary principle has been enshrined in relevant chemicals-related legislation at EU level. In particular, the legislative acts in box 36 below include a specific reference to the Precautionary Principle.

Box 35: Legislative acts on chemicals with reference to the precautionary principle

REACH: The REACH Regulation refers to the principle several times in its preamble and assures in Article 1(3) that the Regulation is "underpinned by the precautionary principle".

Pesticides: Regulation (EU) No 1107/2009 concerning the placing of plant protection products on the market contains a reference to the PP in Article 1(4): "The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory."

Biocides: Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products explicitly mentions in the preamble that the "Regulation should be underpinned by the precautionary principle to ensure that the manufacturing and making available on the market of active substances and biocidal products do not result in harmful effects on human or animal health or unacceptable effects on the environment." Also, Article 1.1 emphasizes that "The provisions of this Regulation are underpinned by the precautionary principle, the aim of which is to safeguard the health of humans, the health of animals and the environment. Particular attention shall be paid to the protection of vulnerable groups."

Water: Both the Water Framework Directive and Directive 2008/105/EC on environmental quality standards refer to the precautionary principle.

Waste: Directive 2008/98/EC on waste specifically mentions the precautionary principle: "In order to implement the precautionary principle and the principle of preventive action enshrined in Article 174(2) of the Treaty, it is necessary to set general environmental objectives for the management of waste within the Community. By virtue of those principles, it is for the Community and the Member States to establish a framework to prevent, reduce and, in so far as is possible, eliminate from the outset the sources of pollution or nuisance by adopting measures whereby recognised risks are eliminated".

As mentioned above, the 2000 Communication sets out that the PP should only be applied in the event of a potential risk, if it cannot be fully demonstrated or quantified or its effects determined because of the insufficiency or inconclusive nature of the scientific data. It stresses that a scientific evaluation of the potential adverse effects (risk assessment) should always be undertaken based on the available data (hazard identification, hazard characterisation, estimation of exposure and risk characterisation). This should lead to a conclusion on the possibility of the occurrence and the severity of a hazard's impact on the environment, or health of a given population including the extent of possible damage, persistency, reversibility and delayed effect and to a description of the remaining uncertainties that helps the decision makers in the risk management phase.

14.2. Application of the Precautionary Principle to Chemicals Management

The application of the precautionary principle requires *inter alia* taking decisions on what is considered an "acceptable" level of risk for society, identifying gaps in knowledge that result in uncertainty concerning the nature of a potentially unacceptable risk, and managing that risk in the face of uncertainty. Applying the precautionary principle (PP) in the context of chemicals regulatory decision-making can present numerous challenges. These challenges are partly due to the specific nature of regulating chemicals, and the more general nature of the precautionary principle. The Commission Communication on the precautionary principle provides some general guidance. However, these guidelines are not tailor-made for the application of the precautionary principle to chemicals. Also, in the meantime, significant legal and practical developments in the field of chemicals regulation and application of the precautionary principle have occurred at the EU and national level[124].

In particular, some research[125] examined how the precautionary principle has interacted with the development of the present chemicals regulatory regime, in particular REACH. The study concluded that the precautionary principle is manifest in both the design of the testing strategy and in policy provisions. However, in order to ensure the practical functioning of the principle, the study argues that there is a need for more transparency in the decision-making process.

[124] Milieu (2011) Review of Environmental Legislation for the Regulatory Control of Nanomaterials, Contract № 070307/2010/580540/SER/D, 2011, Milieu, Brussels

[125] Søren Løkke, The Precautionary Principle and Chemicals Regulation: Past Achievements and Future Possibilities, in Chemicals Regulation – Review Articles, 2006. Available at: http://envirohealth.berkeley.edu/271E/2007/S13/Lokke2006.pdf

Application of the precautionary approach under chemicals management is tested in the way the EU currently deals with emerging risks, such as nanomaterials, endocrine disrupting chemicals and cocktail effects. The outcome of the decision-making process in these areas will indicate to what extent the EU is listening to "early warnings" and adopting precautionary measures. Also, the extent of substitution of hazardous substances is an important element of testing the application of the precautionary principle in the context of REACH.

In particular, a Milieu report on nanomaterials[126] concludes that the precautionary principle seems applicable to the management of the potential risks from these substances. In the case of nanomaterials, the scientific knowledge needed to inform the scientific evaluation is currently limited, serving to increase the overall level of uncertainty and ultimately affect the foundation for preventative action. The precautionary principle could be applied to the management of the potential risks of nanomaterials in general, or to the management of potential risks from specific nanomaterials. In the case of some specific nanomaterials, the body of evidence that could feed into a risk assessment is expected to be somewhat larger, possibly creating a foundation for more stringent preventative action, such as product controls. In conclusion, given the particular emphasis on managing limitations in scientific knowledge, recourse to the precautionary principle would seem to be extremely relevant to the regulation of nanomaterials.

On endocrine disrupting chemicals, a recent own initiative report by the European Parliament[127] explicitly refers to the precautionary principle stating that on the basis of an overall assessment of the state of knowledge, the precautionary principle requires legislators to take measures to reduce human exposure to endocrine disruptors to a minimum. It stresses that the criteria determining what constitutes an endocrine disruptor should be scientifically based and that the precautionary principle should be applied in the development of such criteria. An EEA report[128] on the impacts of endocrine disrupters on wildlife, people and their environments also concludes that limiting our exposure to EDCs even before we have full scientific knowledge on the basis of the precautionary principle would seem a rational approach to take.

Finally, a 2013 EEA report[129] entitled "Late Lesson from Early Warnings" specifically examines the application of the precautionary principle to emerging risks. The report reviews a number of historical

[126] Milieu (2011) Review of Environmental Legislation for the Regulatory Control of Nanomaterials, Contract № 070307/2010/580540/SER/D, 2011, Milieu, Brussels
[127] European Parliament Draft Report on the protection of public health from endocrine disruptors (2012/2066(INI)), ENVI Committee, Rapporteur : Åsa Westlund, November 2012.
[128] European Environment Agency (2012) The impacts of endocrine disrupters on wildlife, people and their environments, EEA Technical report No 2/2012.
[129] EEA (2013) Late lessons from early warning: science precaution and innovation, EEA Technical Report No 1/2013, EEA, Copenhagen, Denmark

case studies where potential risks where identified and explores the types of risk management options that were adopted. In particular, the report reviews incidents of 'false positives', where government regulation was undertaken based on precaution but later turned out to be unnecessary. It argues that fear of false positives should not be a rationale for avoiding precautionary actions where they are warranted.

The report highlights links between sources of scientific knowledge about pollutants, changes in the environment and new technologies, and strong vested interests and states that despite its presence in EU legislation and case law, "*the application of the precautionary principle has been strongly opposed by vested interests who perceive short term economic costs from its use."* The report calls for greater public engagement in decision‑making on upstream innovations and their downstream hazards, including interpreting the '*high level of protection'* required by the EU treaty.

Finally, arguing that application of the precautionary principle is particularly relevant where the ratio of knowledge to ignorance is low, as with emerging technologies, the report highlights nanomaterials as a field where application of the precautionary principle is required. Noting that decision‑makers have yet to address shortcomings in legislation, research and development, and limitations in risk assessment for nanotechnologies, the report identifies a developmental environment in the field of nanotechnology that hinders the adoption of precautionary strategies.

15. Conclusion

Despite the wide ranging and significant reforms and in some cases as a result of information generated through on going risk assessment, scientific research continues to advance and provide greater clarity regarding potential risks to human health and the environment from exposure to chemical substances. The EU is able to respond to such challenges with targeted actions, for example growing evidence regarding the potential risks from endocrine disruptors resulted in the development of the Community Strategy for Endocrine Disruptors. In addition, the appearance of novel materials on the market, such as nanomaterials, triggers consideration of whether and if so how such substances should be regulated. At the same time, specific acts have reviews built into them, with the Commission required to generate targeted reports on specific issues for consideration (i.e. the REACH review process). The consequence of these processes is that chemicals regulation at EU level is under continuous scrutiny and subject to regular review by the European institutions.

Finally, the EU recently published a draft decision for an Environmental Action Programme to 2020[130] (7EAP) including a number of specific targets for chemicals up until 2020. In particular, the Programme specifically reiterates the EU commitment to meeting the chemicals goals for 2020 set out in the Johannesburg Plan of Implementation at the World Summit for Sustainable Development. One of the thematic priorities of the 7EAP is to promote better implementation of EU environmental law, an objective that will serve to increase progress on chemicals legislation.

[130] European Commission (2012) General Union Environmental Action Programme to 2020: Living well within the limits of our planet, COM(2012)170 Final, Brussels