The EU model for controlling chemicals in products and articles

Technical Report 1

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The EU model for controlling chemicals in products and articles

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ABBREVIATIONS USED

ATP	Adaptations to Technical Progress
BPR	Regulation (EU) No 528/2012 on biocidal products
CEN	Comité Européenne Standardisation
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
CMR	Carcinogenic, mutagenic and reprotoxic substances
DPD	Directive 1999/45/EC relating to the classification, packaging and labelling of dangerous preparations.
DSD	Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances.
ECHA	European Chemicals Agency
EINECS	European Index of Existing Chemical Substances
ELINCS	European List of New Chemical Substances
EU	European Union
GHS	Globally Harmonised System of classification and labelling of chemicals
GPP	Green public procurement
KEMI	Swedish Chemicals Inspectorate
OECD	Organisation for Economic Cooperation and Developmetn
PBT	Persistent Bioaccumulative and Toxic
PIC	Prior informed consent
POP	Persistent Organic Pollutant
PPPR	Regulation (EC) No 1107/2009 on plant protection products
RAPEX	Community Rapid Information System
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk management measures
RoHS	Restrictions of hazardous substances
SVHC	Substances of very high concern
vPvB	very Persistent and very Bioaccumulative substances
WEEE	Waste electrical and electronic equipment

1 INTRODUCTION

This Report has been prepared by Milieu Ltd for the Brazilian Ministry of Environment with the aim of describing the European Union (EU) model for controlling chemicals in products and articles. The report provides detailed descriptions of EU legislation relevant to this topic. It also reviews the institutional arrangements and jurisdiction for enforcement, as well as public policies, programs and instruments for supporting the reduction of hazardous chemicals in articles. Finally, it looks at national measures in place in two Member States (the United Kingdom and Spain) for ensuring that hazardous chemicals in products meet regulatory requirements.

The main legislative framework in the EU for managing risks from chemicals, including in products and articles, is Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[1] REACH was amended in 2008 by Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP)[2], which introduced the Globally Harmonised System (GHS) for classification and labelling into EU law.

The basic principle under REACH is that producers (manufacturers and/or importers) are responsible for ensuring that the substances that they place on the market are safe for particular uses. This responsibility also extends to the use of a substance in a product, such as a mixture or article.

As part of their responsibility under REACH, manufacturers and importers of substances are required to submit a registration to the European Chemicals Agency (ECHA) for each substance which they manufacture or import into the EU in quantities of 1 tonne or above per year. The registration dossiers present information on any intrinsic hazard posed by the substance and, where relevant, an assessment of the risks associated with all foreseen uses of the substance 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 provided to regulators. In addition, industry is responsible for channelling data to downstream users, including information on risk management measures.

Implementation of REACH is a process that is still ongoing. The first deadline for submitting registrations was in 2010, for substances manufactured or imported in quantities equal to or more than 1000 tonnes per annum. Substances manufactured or imported in quantities between 100 and 1000

[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 L 353, 31.12.2008, p. 1.

tonnes had to be registered by 2013, and quantities between 1 and 100 tonnes must be registered by 2018. Other processes under REACH such as determining which substances of very high concern (SVHC) should be subject to further control such as authorization require considerable time for carrying out the evaluations including socio-economic assessment necessary for regulatory decisions, and will be underway for years to come.

In addition to the framework provided by REACH and CLP, the EU has enacted a number of individual acts regulating specific products that are tailored to deal with particular risks to human or animal health and the environment, including at the end of the product's life. Examples include the Cosmetic Products Regulation, the Detergents Regulation, and the Batteries Directive. These often have gaps in coverage where REACH is the default mechanism for regulatory control.

Another key regulatory mechanism used by the EU is the so-called 'New Legislative Approach'. Under this regime, the EU legislator sets a number of essential safety and performance requirements for a particular product type, and then mandates a European standard-setting body such as the Comité Européenne Standardisation (CEN) to develop technical standards. Products that are in conformity with the technical standards can bear the CE marking and be marketed throughout the EU Member States. The Toy Safety Directive and the Construction Products Regulation are examples of this type of regulatory approach.

The flow chart on the next page is a visual guide to the key EU acts relevant to the issue of hazardous substances in products. They are grouped according to whether the product concerned is a mixture or an article. Note that any product not covered by specific EU legislation is covered by the General Product Safety Directive.

The EU legislative framework relevant for hazardous substances in products

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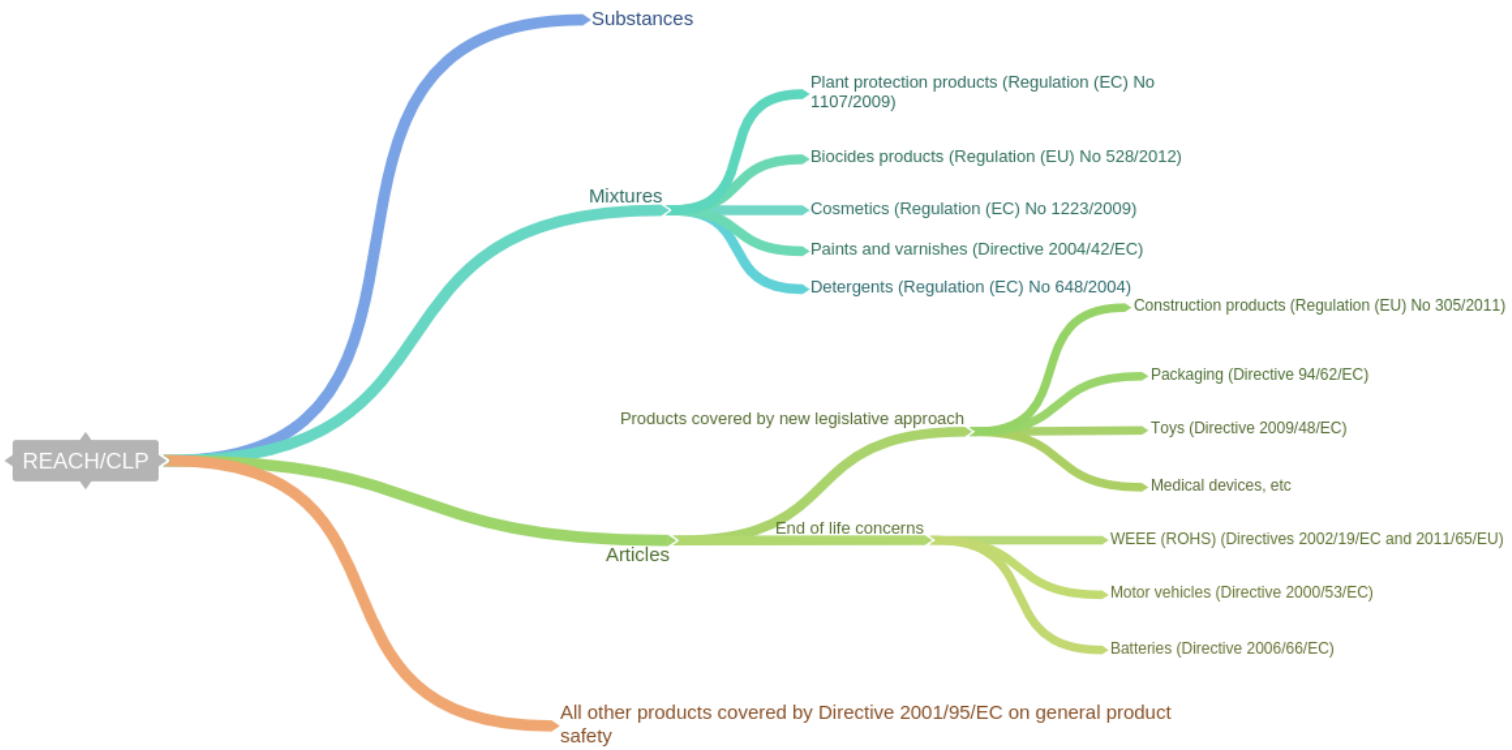

Most of the rules set on EU level are aimed at harmonisation across the 28 EU Member States, so as to facilitate the free movement of goods as well as to protect health and the environment. Member States wishing to go beyond the EU framework must notify any additional technical measures taken and justify why they are considered necessary in that particular territory.

Thus the EU rules have become the norm in most Member States, and additional rules at national level are generally not found, with the exception of the Nordic countries. However, Member States hold primary responsibility for implementation and enforcement of the EU rules within their territories, according to their national administrative systems and judicial traditions.

2 LEGISLATION & STANDARDS ON HAZARDOUS CHEMICALS IN PRODUCTS

2.1 REACH AND CLP AS THE FOUNDATION

Article 1 of REACH sets forth the underpinning objectives of the EU model for controlling chemicals in products:

REACH Article 1 - Aim and scope

1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.
…
3. This 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. Its provisions are underpinned by the precautionary principle.

The EU model for controlling chemicals in products thus balances the need to protect human health and the environment against the also important goal of the free movement of goods on the internal market. The free movement of goods is one of the four freedoms underpinning the internal market, as enshrined in Article 34 (ex Article 28 TEC) of the Treaty on the Functioning of the European Union (TFEU), which prohibits quantitative restrictions on imports and all measures having equivalent effect between Member States. Many of the EU legislative acts related to products are therefore harmonisation measures aimed at eliminating national standards that could create obstacles for products made in other Member States.

2.1.1 Chemicals management in the EU before REACH

The first EU chemicals regulatory act -- Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances (the Dangerous Substances Directive, or DSD) [3] — was a harmonisation measure. It introduced a uniform system for classifying substances on the basis of intrinsic hazard and then communicating those hazards via labelling, including via pictograms and specific warning statements. It also set forth basic requirements for the packaging of substances considered dangerous.

[3] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ 196, 16.8.1967, p. 1.

As Member States reached agreement on harmonised hazard classification for specific substances, the annexes to the Dangerous Substances Directive were updated to include the additional classifications by the so-called 'adaptations to technical progress' (ATPs). The Directive was also amended several times, most notably by Council Directive 79/831/EEC, also known as the 6th Amendment.

The 6th Amendment introduced a procedure for notification of 'new' substances, defined as a substance which was not listed in the EINECS inventory (European Inventory of Existing Commercial Chemical Substances) of chemical substances on the Community market as of 18 September 1981, the date of entry into force of Directive 79/831/EEC in Member States. New substances notified after 18 September 1981 had to undergo specific testing for intrinsic hazards and were then listed in ELINCS (European List of Notified Chemical Substances).

Given that most of the substances on the market prior to 1981 had never been tested for intrinsic hazard, the EU sought to rectify the situation by adopting Council Regulation (EEC) No. 793/93 on existing substances (Existing Substances Regulation) 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. The Existing Substances Regulation focused on substances on the European market in high volumes which were suspected of also being high risk, and therefore considered priorities for an in-depth risk assessment by the Member States following a set methodology.

In 1999, the EU adopted an important act complementary to the Dangerous Substances Directive -- Directive 1999/45/EC on the classification, packaging and labelling of dangerous preparations (the Dangerous Preparations Directive) [4]. The Dangerous Preparations Directive (DPD) set rules for determining when preparations (now defined as 'mixtures' under the CLP Regulation) containing one or more substances classified as dangerous would themselves be considered dangerous, because of the concentration level of the dangerous substance in the preparation.

The process of evaluating risks and setting risk reduction measures for groups of chemical substances under the Existing Substances Regulation proved to be exceedingly slow and resource intensive. In 2001 a situation existed where testing and risk assessment was required for 'new' substances could be marketed in volumes above 10 kg, whereas '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.

[4] Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations, OJ L 200, 30.7.1999, p. 1.

The legislative framework created a disincentive for the chemicals industry to conduct testing on their products[5], and information regarding the hazards and uses of existing substances on the market was severely lacking. In addition, the risk assessment process for new substances was conducted by authorities, not by industry, so impeding innovation and competitiveness in the chemicals sector.[6] It became clear to EU policy makers that another approach covering both 'existing' and 'new' substances was needed.

In recognition that the existing system did not provide sufficient protection, in 2001 the European Commission adopted a White Paper[7] setting out the Strategy for a future Community Policy for Chemicals. Key elements of the Strategy included, *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;
- establishing authorisation for substances of very high concern; and
- substituting hazardous chemicals.

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

2.1.2 The REACH regime

In follow-up to the 2001 White Paper, the EU adopted Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), which entered into force on 1 June 2007. It replaced and repealed the Dangerous Substances and the Dangerous Preparations Directives. REACH is organised under a number of titles that focus on the different REACH mechanisms, such as registration, authorisations and restrictions, as well as on procedural elements, such as fees and charges, and the allocation of responsibilities, such as those of ECHA and the Member State Competent Authorities. In addition, the annexes provide further details on specific

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

provisions, such as the information requirements under different tonnage bands and the list of substances subject to restrictions.

Registration

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. Registration dossiers are to contain 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, the company is no longer allowed to market the substance within the EU.

Registration applies to substances on their own, substances in mixtures and certain cases of substances in articles. Certain substances are exempted from the REACH obligation to register, such as 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). 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.

A pre-requisite to most of the REACH processes, including registration, is to have unambiguous information about the identity of the substance. In order to unambiguously identify the substance, the registration dossier must include the following information on the manufactured or imported 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.

The European Chemical Agency has published "Guidance on the identification and naming of substances under REACH and CLP"[8]. The guidance document aims to assist manufacturers and importers in recording and reporting the identity of a substance within the context of REACH and

[8] http://echa.europa.eu/documents/10162/13643/substance_id_en.pdf .

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 inquiries, for data sharing, for Joint Submission of data, for notification to the Classification and Labelling Inventory and for Harmonisation of Classification and Labelling.

To assist registrants, ECHA has developed "Guidance on registration"[9]. The registration dossier consists of two main components:

- A technical dossier that respects the information requirements according to tonnage manufactured or imported per year; and
- A chemical safety report (CSR), if the registrant manufactures or imports a substance in quantities of ten tonnes or more per year.

REACH Registration 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

[9] http://echa.europa.eu/documents/10162/13632/registration_en.pdf .

* 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

Registration dossiers for substances manufactured or imported in quantities starting at 10 tonnes a year must include a chemical safety report (CSR). The CSR documents the results of the chemical safety assessment (CSA), the main tool for delivering chemical risk assessment under REACH.

The chemical safety assessment (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 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.

The **chemical safety assessment (CSA)** includes the following steps:

- Collection and generation of information on intrinsic properties of the substance;
- Human health hazard assessment;[10]
- Physicochemical hazard assessment;
- Environmental hazard assessment; and
- Persistent, Bioaccumulative and Toxic (PBT) and very Persistent and very Bioaccumulative (vPvB) assessment.

If the substance is assessed as PBT or vPvB, or as meeting the criteria for classification as hazardous according to CLP, the following steps are also needed:

[10] 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.

- Exposure assessment
- Risk characterisation

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 uses which are made known to the manufacturer or importer by his downstream users (including manufacturers of products and articles) 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.

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 degree of purity essential for classification and labelling, total tonnage band, (robust) study summaries, information in the safety data sheet and the trade name. 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.

Evaluation

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

Dossier evaluation. ECHA has responsibility for examination of testing proposals and for checking if the registration dossiers are in compliance with REACH requirements. Information in the registration dossiers is assessed firstly with regards to completeness and secondly with regards to compliance with the legal requirements for submitting information for the relevant tonnage band. 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. Once the evaluation is complete, registrants may be required to submit further information on the substance.

REACH obliges ECHA to check at least 5% of the registration dossiers per tonnage band. ECHA has reported that so far a significant proportion of dossiers have shortcomings and still need to be improved with further information.

***Substance evaluation*.** Member State competent authorities are responsible for evaluating specific substances, in order to determine whether risk management measures are required in order to protect human health or the environment. Substances that trigger initial concerns for human health or the environment are 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)[11]. ECHA is responsible for coordinating the substance evaluation process and ensuring that substances on the CoRAP are evaluated.

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.

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. In many cases, 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. 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.

The outcome of a 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.

If the evaluating Member State considers that the use of the substance poses a risk, it may then proceed with **follow-up actions.** 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

[11] http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

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.

Authorisation

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).

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.

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. 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 below.

REACH Article 57 Criteria for Identifying Substances of Very High Concern (SVHC)

(a) Substances meeting the criteria for classification as carcinogenic, mutabenic ortoxic for reproduction category 1A or 1B ion accordance with 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)

In 2013, the Commission presented a Roadmap on SVHC[12] including a commitment to have all currently known SVHC on the Candidate List[13] 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 process includes a screening of registration dossiers and a Risk Management Options (RMO) assessment. 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.

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 the box below.

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:

[12] European Commission (2013) Roadmap for SVHCs identification and implementation of REACH Risk Management measures from now to 2020, European Commission, Brussels.
[13] The Candidate List is published on ECHA's website, and updated following decisions on SVHCs. http://echa.europa.eu/web/guest/candidate-list-table

Legal obligations regarding Candidate List substances

- 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.

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).

Currently 31 Substances of Very High Concern (SVHCs) are on the REACH Annex XIV Authorisation List[14]. 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 submitted to ECHA.

Authorisations are successful only 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, two principle routes through which authorisations can be granted are:

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)).

At the end of the authorisation process, which includes a public consultation and the development of

[14] http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list.

opinions by ECHA's Committees on Risk Assessment (RAC) and Socio-economic Analysis, the European Commission decides on the granting or refusing of authorisations.

A decision to authorise a substance on the basis of **adequate control** requires consideration of the following elements:

- whether the substance 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.

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:

- the risk posed by the uses of the substance, including the appropriateness and effectiveness of the risk management measures proposed;
- 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;
- the analysis of the alternatives or any substitution plan, and any third party contributions submitted during the public consultation;
- available information on the risks to human health or the environment of any alternative substances or technologies; and
- 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.

Upon receipt of the application for authorisation, 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.

ECHA's Committees for Risk Assessment and Socio-economic Analysis are then required to provide draft opinions on the authorisation application within ten months of the date of receipt of the application. These opinions are intended to add value by assuring that assessments presented in applications for authorisation are in accordance with appropriate technical and scientific standards. 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.

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 and is valid until the Commission decides to withdraw or amend the authorisation in the context of a review. 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.

See Section 2.1.4 for information on how substances of very high concern (SVHC) are regulated in products such as mixtures or articles.

Restriction

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:

1. 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
2. Restrict all uses (ie, total prohibition on use as for example on asbestos, ichloro[(dichlorophenyl)methyl]methylbenzene, Monomethyldibromodiphenyl -methane).

Currently, the Annex XVII List of Restrictions[15] lists 64 categories of restricted substances involving

[15] http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02006R1907-20150925&rid=1 .

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.

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 ECHA registry of intentions[16] before the proposal file itself is prepared so as to give advance warning.

The dossier proposing the restriction must be submitted to ECHA within twelve months after the intention to prepare the proposal was notified. It 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.

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.

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

- 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.

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.

[16] http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/registry-of-intentions .

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.

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.

Many of the restrictions set in REACH are relevant for products, whether mixtures or articles. For example, Annex XVII sets restrictions for lead (entries 16, 17), cadmium (entry 23), mercury (entry 18) and chromium VI (entry 47), with the entry for cadmium setting restrictions specific to certain packaging ('Shall not be used to stabilise the following mixtures or articles manufactured from polymers or copolymers of vinyl chloride: — packaging materials (bags, containers, bottles, lids…'). A broad range of other products is covered by the Annex XVII restriction on cadmium, from office or school supplies, articles of apparel and clothing accessories, and imitation leather, to insulation for electrical wiring and vehicles for road transport.

Other entries are relevant for construction products, including the possibility of specific derogations, including entry 19 on arsenic compounds (derogation for use as wood preservative if applied via certain industrial processes and if the wood is marketed for professional and industrial use and skin contact by the general public unlikely during its service life), entry 31 on creosote (derogation for use as wood treatment under certain conditions), and entry 47 on chromium VI (derogation for higher content in cement and cement mixtures if placed on the market for, and use in, controlled closed and totally automated processes).

2.1.3 Classification, labelling & packaging

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures[17] (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 repeals and replaces, with transitional periods, the Dangerous Substances Directive and the Dangerous Preparations Directive. For substances, 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 CLP Regulation requires manufacturers and importers of substances, downstream users, including formulators of mixtures and re-importers of substances or mixtures, to establish the potential risks to human health and the environment of such substances and mixtures, and to classify them in line with the identified hazards, before placing chemicals on the market. . 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

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.

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.

[17] 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

Labelling must be in accordance with a standardised system so that workers and consumers know about their effects before they handle them. 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 an 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 has two parallel systems for classification, harmonised classifications of substances that are agreed at EU level and, in their absence, self classification.

Under CLP, substances that do not yet have a harmonised classification must be classified by the manufacturer, importer or downstream user on the basis of hazard before being placed on the market, through a process called **self-classification**. Self-classification of a substance or mixture requires four basic steps:

1. Collection of available information;
2. Evaluation of the adequacy and reliability of the information;
3. Review of the information against the classification criteria; and
4. Decision on classification.

Hazard classification generally does not generate 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. Where adequate data is not available, data generation under CLP is restricted to data on physico-chemical properties.

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. To aid in this process, ECHA has published 'Guidance on the application of the CLP criteria'[18].

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 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 some 4,500 substances on the 'list of harmonised classification and labelling'[19].

CLP puts in place a Classification and Labelling Inventory (C&L Inventory)[20], 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 information in the inventory is publicly accessible and searchable. While ECHA maintains the

[18] http://echa.europa.eu/documents/10162/13562/clp_en.pdf .
[19] http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/harmonised-classification-and-labelling/annex-vi-to-clp.
[20] http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database .

Inventory, it does not review or verify the accuracy of the information.

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.

The CLP Regulation requires **child-resistant fastening and tactile warnings** of danger to be attached to their packaging, if substances or mixtures supplied to the general public display certain hazards or if the packaging contains methanol or dichloromethane. The table below presents an overview of the different hazards that trigger this obligation:

Overview of hazards that trigger child-resistant fastening or tactile warnings

Hazard Criteria	Child-resistant Fastenings	Tactile Warnings[1]
Acute toxicity (category 1 to 3)	✓	✓
Acute toxicity (category 4)		✓
STOT single exposure (category 1)	✓	✓
STOT single exposure (category 2)		✓
STOT repeated exposure (category 1)	✓	✓
STOT repeated exposure (category 2)		✓
Skin corrosion (category 1A, 1B and 1C)	✓	✓
Respiratory sensitisation (category 1)		✓
Aspiration hazard (category 1)* *Not aerosols or if in container with sealed spray attachment*	✓	
Aspiration hazard (category 1)	✓	✓
Germ cell mutagenicity (category 2)		✓
Carcinogenicity (category 2)		✓
Reproductive toxicity (category 2)		✓
Flammable gases (category 1 and 2)		✓
Flammable liquids (category 1 and 2)		✓

Overview of hazards that trigger child-resistant fastening or tactile warnings		
Hazard Criteria	Child-resistant Fastenings	Tactile Warnings[1]
Flammable solids (category 1 and 2)		✓
Note 1. This provision does not apply to aerosols which are only classified and labelled as "extremely flammable aerosols" or "flammable aerosols".		

More information is available in the 'Guidance on Packaging and Labelling[21] published on the ECHA website.

2.1.4 Products that are mixtures versus products that are articles

Concerning substances in products, REACH distinguishes between **substances** that are themselves chemical elements or compounds, **mixtures** of substances, and **articles** which have a special shape, surface or design.

Key definitions under Article 3 of REACH:

For the purposes of this Regulation:

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

2. **mixture:** means a mixture or solution composed of two or more substances;

3. **article**: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

Products that are mixtures

Products that are substances or mixtures of substances must in general comply with the provisions of the CLP Regulation. Substances with intrinsic hazards must be classified and labelled accordingly. Mixtures containing substances classified as hazardous are subject to the rules on concentrations set forth in the CLP Regulation. If the hazardous substance is present in the mixture in a concentration such that the mixture itself is considered hazardous, then the mixture must be classified and labelled as such.

[21] http://echa.europa.eu/documents/10162/13562/clp_labelling_en.pdf

The CLP Regulation's provisions on labelling include hazard warnings, pictograms, hazard warnings and safety advice. The provisions in REACH requiring safety data sheets for classified substances (in order to communicate hazard information to downstream users, including workers, and the CLP Regulation's rules on packaging also apply.

In addition to these general rules, the EU model also includes a number of individual acts covering specific types of mixtures, from cosmetics to cleaning supplies and detergents, and paints. These are discussed later in this report.

Products that are articles

One of the basic principles of REACH is that, as with substances and mixtures, producers and importers of articles should be responsible for their articles. REACH sets specific rules for chemicals in products in its Article 7: Registration and notification of substances in articles. Article 7 sets forth rules for two situations:

1. Where the substance is intended to be released from the article, or
2. Where the article contains a substance of very high concern (SVHC) as determined under Article 59 of REACH above a concentration of 0,1% weight by weight (w/w), and the substance is in those articles in quantities totalling over one tonne per producer or importer per year.

Substances which are intended to be released from articles must therefore be registered for that specific use.

Substances of very high concern (SVHC) present in articles above a concentration of 0,1% weight by weight (w/w) trigger the requirement of notification set forth in Article 7(2) of REACH, if the substance is present in the article above one tonne per year. 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'[22], as well as a 'Data Submission Manual Part 20 for substances in articles'[23]. ECHA collates the data from the notifications and publishes data on Candidate List substances in articles on their website[24], based on notification received. 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.

If substances of very high concern (SVHC) are present in articles above the thresholds set for tonnage and concentration, if exposure to the substance is possible, and if the substance has not been registered for this use, ECHA must be notified. If ECHA has reason to believe that the release of the substance from the article could pose a risk to human health or the environment, and if the substance is present in those articles in quantities totaling over one tonne per producer or importer per year, ECHA can require the producer or importer to submit a registration. It can also consider whether a restriction is necessary if a risk to human health or the environment from the use of the substance in articles is not adequately controlled.

In supporting suppliers of articles in fulfilling these obligations, ECHA has published 'Guidance on requirements for substances in articles' document[25]. Note that the guidance document has recently been updated to reflect the September 2015 judgment of the Court of Justice of the European Union in case C-106/14[26]. Whereas the guidance document has been interpreting the concentration limit (0.1 % w/w) as applying to the article as a whole, the Court has ruled that the obligations to notify substances in articles (Article 7(2)) and to communicate the presence of those substances (Article 33) also apply to components of complex products (i.e., products composed of several articles) as long as these components of the product keep a special shape, surface or design or as long as they do not become waste.

One of the gaps in this regime is the fact that the provision requiring authorization before an SVHC may be used in an article only covers those articles produced in Europe, and not imported articles. A recent study[27] carried out for the German Environment Agency suggested that an authorization scheme for SVHCs in imported goods such as clothing, sports gear and toys would better protect humans and the environment and would not breach international trade law. The study also proposed introducing a standardized communication format to oblige manufacturers to indicate not only the name of the

[22] http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/NotificationsofSubstancesinarticles
[23] http://echa.europa.eu/documents/10162/13653/dsm_20_notif_sia_en.pdf
[24] http://echa.europa.eu/web/guest/information-on-chemicals/candidate-list-substances-in-articles-table
[25] http://echa.europa.eu/documents/10162/13632/articles_en.pdf .
[26] http://curia.europa.eu/juris/liste.jsf?language=en&td=ALL&num=C-106/14.
[27] http://www.umweltbundesamt.de/publikationen/enhancement-of-the-reach-requirements-for-imported

SVHC, but also the concentrations, total volumes and information about hazardous properties and safe use and disposal through the production chain.

2.2 OTHER BASIC POLICIES AND RULES

2.2.1 General product safety

Directive 2001/95/EC ('the General Product Safety Directive') 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. It also complements the sector specific legislation by covering certain matters such as producers' obligations and the authorities' powers and tasks.

The General Product Safety Directive provides a generic definition of a safe product, with which products must comply. Where specific national rules do not exist, the safety of a product should be assessed in accordance with European standards, Community technical specifications, codes of good practice, the state of the art and the expectations of consumers. In addition to the basic requirement to place only safe products on the market, producers must inform consumers of the risks associated with the products they supply, must take appropriate measures to prevent such risks and be able to trace dangerous products.

Definition under the General Product Safety Directive (Article 2):

Article 2: (…)

(a) '**product**' shall mean any product – including in the context of providing a service – which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned.

This definition shall not apply to second-hand products supplied as antiques or as products to be repaired or reconditioned prior to being used, provided that the supplier clearly informs the person to whom he supplies the product to that effect;

(b) '**safe product**' shall mean any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular:

(i) the characteristics of the product, including its composition, packaging, instructions for

Definition under the General Product Safety Directive (Article 2):
assembly and, where applicable, for installation and maintenance; (ii) the effect on other products, where it is reasonably foreseeable that it will be used with other products; (iii) the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product; (iv) the categories of consumers at risk when using the product, in particular children and the elderly.

Where other EU legislation imposes specific safety requirements on consumer products, the General Products Safety Directive only applies to the aspects and risks not covered by the specific safety requirements. For example, the General Product Safety Directive does not apply where REACH has specific provisions, such as the REACH restrictions of CMR substances for consumer use and the risk assessment of substances, on their own, in mixtures and in articles related to their consumer use.

The General Product Safety Directive has been used by the European Commission for temporarily restricting the use of certain substances in products. For example, phthalates in toys and childcare articles were first subject to a temporary restriction (Commission Decision 1999/18/EC) which was subsequently renewed multiple times, until it was decided in 2005 that the restriction should be permanent, at which time Directive 76/769/EEC (now REACH Annex XVII) took it over.

Also important as a general rule is Directive 87/357/EEC on products which, appearing to be other than they are, endanger the health or safety of consumers ('the Dangerous Imitations Directive'). It prohibits the marketing, import and manufacture of products that are not edible, but which could be confused with foodstuffs by their appearance, smell or packaging, such as soaps, candles and other decorative articles. Member States must carry out checks to ensure that such products are not marketed. Where a Member State imposes a ban on a product under the terms of the Dangerous Imitations Directive, it must inform the Commission and provide the relevant details in order for the other Member States to be informed. In most cases, in order to prevent the risk to consumers, the food-imitating product will be withdrawn from the market.

2.2.2 Integrated product policy

The concept of an **Integrated Product Policy (IPP)** was put forward by the European Commission at the beginning of the millennium, first as a Green Paper and then as a Communication.[28] The Communication describes IPP as seeking to minimise the environmentally negative impacts of products – whether during manufacture, use or disposal -- by looking at all phases of a product's life-cycle and then focusing on where those impacts can be reduced best and most cost effectively. The Communication sets out five key principles for IPP, as follows:

1. **"Life-Cycle Thinking** which considers a product's life-cycle and aims to reduce its cumulative environmental impacts, from the "cradle to the grave". The objective is to prevent individual parts of the life-cycle from being addressed in a way that just results in the environmental burden being shifted to another part. By looking at the whole of a product's life-cycle in an integrated way, IPP also promotes policy coherence. It encourages measures to reduce environmental impacts at the point in the life-cycle where they are likely to be most effective in reducing environmental impact and saving costs for business and society."[29]

2. **Working with the market.** The IPP approach aims to encourage the supply and demand for greener products, and thereby provide incentives for the market to move in a more sustainable direction. The thinking is to reward those companies that are innovative, forward-thinking and committed to sustainable development."[30] Financial incentives for "greener" products as well as fiscal policy and public procurement are relevant here, particularly with respect to the energy efficiency of products.

3. **Stakeholder Involvement.** The IPP approach seeks to motivate all who are involved with a product – e.g., industry, consumers and government – to act where they can. For example, industry can consider how to integrate environmental aspects in the design of products while consumers can determine how to purchase greener products and then use and dispose of them in more environmentally friendly ways. Governments can set economic and legal framework conditions and also act directly, for instance by purchasing greener products.

4. **Continuous Improvement.** The Communication points out that improvements to decrease a product's environmental impacts across its life-cycle are often possible, whether through design, manufacture, use or disposal. Instead of setting a precise goal, the aim under IPP is for

[28] Green Paper (COM(2001) 68 final; then Communication on Integrated Product Policy: Buildiung on Environmental Life-Cycle Thinking, COM(2003) 302 final; available at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52003DC0302&from=EN.
[29] ibid.
[30] ibid.

a continuous improvement. This enables companies to set their own pace and focus on the most cost efficient improvements.[31]

5. **A Variety of Policy Instruments.** Because of the variety of products available and the different stakeholders involved, the Communication suggests using a number of different instruments to achieve an Integrated Product Policy. The tendency within IPP is to work with voluntary approaches (such as Eco-label and EMAS Regulations), although mandatory measures (such as RoHS and ELV Directives). might also be required. Among Member States, green public procurement appears to be the most frequently used instrument, followed by labelling and other informative instruments.[32]

The Communication cites a number of legal instruments which already integrate life-cycle thinking to a varying extent, including the Eco-label Regulation, the Directive on Packaging and Packaging Waste, the Waste Electrical and Electronic Equipment (WEEE) Directive, the End-of-Life Vehicles Directive (ELV), the Batteries Directive and the RoHS Directive. Each of these instruments is relevant to the issue of chemicals in products and is described later in this report. It calls for exchange of information on the actions taken by the Member States and other stakeholders in this direction, including with European industry associations and key trade partners. It also suggests conducting stakeholder consultations at national level[33].

In follow up to the Communication, the Commission's Joint Research Centre carried out a 2006 study on the environmental impact of products. It found that products from only three areas – food and drink, private transportation, and housing – accounted for 70-80 percent of environmental impacts of private consumption. It attempted to identify possible ways in which the life-cycle environmental impacts can be reduced for some of the products. For example, a report on the reduction of environmental impacts from passenger cars concerned *inter alia* the use of chemicals in these cars.[34]

2.3 THE NEW LEGISLATIVE APPROACH METHOD

A very important legal framework for ensuring the free movement of goods is the 'New Approach to Technical Harmonisation and Standards' set in place by the then European Community in 1985. The

[31] COM (2003) 302, p.5.
[3232] ibid.
[33] Commission Staff Working Document accompanying the Report from the Commission to the Council, the European Parliament, the European and Social Committee and the Committee of the regions On the State of Implementation of Integrated Product Policy COM(2009)693 final, SEC(2009)1707 final, p. 8.
[34] The report is available here: http://ec.europa.eu/environment/ipp/identifying.htm.

so-called 'New Approach' was aimed at easing the legislative burden of harmonising standards, in view of the technical specificity of many products.

The 'New Approach' Directives establish essential requirements (on product safety or performance, for example) for particular categories of products. The products covered must meet those essential requirements before being placed on the market. The Directives then delegate the task of setting harmonised technical standards for the essential requirements to the European standard-setting bodies (CEN, CENELEC, and ETSI). If a manufacturer can demonstrate that the product complies with the technical standards, conformity with the essential requirements is presumed, and the product can be labelled with the CE marking and sold anywhere within the EU.

The CE marking is compulsory only for most of the products covered by the New Approach Directives. It is forbidden to affix CE marking to other products. A CE marking does not mean that a product has been approved as safe by the EU or by another authority. Rather, by affixing the CE marking to a product, the manufacturer declares that the product has been assessed and found to meet all legal requirements set by the EU for that particular product type.

The manufacturer is thus responsible for assessing whether the product is in conformity with the legal requirements. In some cases, conformity assessment may be carried out by the manufacturer himself. But in other cases, the relevant legislation may require the assessment to be carried out by an external conformity assessment body which is impartial and fully independent from the organisation or the product it assesses. The Member States are responsible for determining which third party conformity assessment bodies within their jurisdiction they consider technically competent to assess the compliance of products with the EU requirements that apply to them, and for notifying those bodies to the Commission.

The box below summaries the key stakeholders in a conformity assessment procedure, and their respective roles:

The key players in the conformity assessment process	
The legislator	• sets out the essential requirements that products have to fulfill
The manufacturer	• designs, manufactures and tests the product or has it designed, manufactured or tested; • draws up the technical documentation of the product; • takes all measures necessary to ensure compliance of the products; • after positive assessment of the products, draws up the EU Declaration of Conformity and affixes the CE marking on the products if required
The conformity assessment body	• performs checks and assessments, if the legislation so provides; • upon positive assessment issues the approval certificate or attestation as required by the applicable legislation.

See *The 'Blue Guide' on the implementation of EU product rules*[35] for more information on the CE marking system.

The EU recently undertook a process of overhauling the standardization processes. Regulation (EU) No 1025/2012 on European standardisation aims to improve the procedure involved in setting European standards to make it faster and more inclusive. It contains a series of measures aiming to draw up standards more rapidly, to ensure more involvement from environmental and consumer groups, and to enhance cooperation with the leading standardisation organisations[36].

In 2008, the New Approach for marketing of products was also modernised through the adoption of a package of measures aimed at removing the remaining obstacles to free circulation of products in order to boost trade in goods between EU Member States. The package, known as the 'New Legislative Approach', builds upon existing systems to introduce clear Community policies which will strengthen the application and enforcement of internal market legislation. Three legal acts were adopted:

- Regulation (EC) No 764/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State [37]
- Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products[38]
- Decision No 768/2008/EC on a common framework for the marketing of products[39]

[35] http://ec.europa.eu/DocsRoom/documents/12661.
[36] http://ec.europa.eu/growth/single-market/european-standards/policy/index_en.htm .
[37] Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC, OJ L 218, 13.8.2008, p. 21.
[38] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ L 218, 13.8.2008, p. 30.
[39] Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, OJ L 218, 13.8.2008, p. 82.

While the provisions are split for legal reasons, they are to be considered in parallel. The measures include better rules on market surveillance to protect both consumers and professionals from unsafe products, and in particular from products which can pose risks for health or the environment. For example, they set in place procedures for withdrawing an unsafe product from the market.

In addition to strengthening the New Approach procedures, the New Legislative Approach package establishes a new mutual recognition regime. Regulation (EC) No 764/2008 (the Mutual Recognition Regulation) requires competent authorities to recognise certificates or test reports issued by an accredited conformity-assessment body. It also sets rules and procedures for Member State authorities to follow when taking a decision that could hinder the free movement of a product lawfully marketed in another Member State. It covers a range of products not subject to EU harmonisation, such as various types of foodstuffs (for example bread and pasta), furniture, bicycles, ladders and precious metals, etc.

Regulation (EC) No. 765/2008 (the Market Surveillance Regulation) establishes clearer rules on the requirements for notification of conformity assessment bodies (testing, certification and inspection laboratories) including the increased use of accreditation to ensure that these bodies provide the high quality services that manufacturers, consumers and public authorities need. Correct operation of the accreditation infrastructure is needed in order to guarantee control of product conformity assessment bodies and surveillance of the products and economic operators on the European market. In the Market Surveillance Regulation, placing on the market covers only the first placing on the market.

Finally, Decision No. 768/2008/EC sets general principles and reference provisions for drawing up harmonisation legislation, as well as a common set of definitions of product-related legislation. It also provides a range of conformity assessment procedures, along with rules for CE marking.

Also highly relevant to the functioning of the internal market is Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards[40]. It requires that the Commission and the European standardisation bodies are informed of new subjects which are to be included in national standards programmes. Member States must communicate to the Commission any draft technical regulation, and to provide a statement of the grounds which make the enactment of the technical regulation necessary, except where the technical regulation merely transposes the full text of an international or European standard.

[40] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations, O.J.L 204, 21.7.98, p.37.

According to Article 8(1) of Directive 98/34/EC, if a draft technical regulation 'seeks to limit the marketing or use of a chemical substance, preparation or product[41] on grounds of public health or of the protection of consumers or the environment, Member States shall also forward either a summary or the references of all relevant data', where available, together with an analysis of the risk of the chemical substance. The anticipated effects of the measure on public health and the protection of the consumer and the environment should then be communicated to the Commission and the Member States, so that they can make comments on the draft technical regulation. The Member State should take these comments into account as far as possible in the subsequent finalisation of the technical regulation.

In seeking to ensure that Member State technical regulations are communicated to the Commission and the other Member States, and their comments taken into account, Directive 98/34/EC links in with the New Legislative Approach package, and in particular with Regulation (EC) No 764/2008 on mutual recognition. The principle of mutual recognition is thus to be applied to all products lawfully marketed in other Member States, even when not subject to harmonisation at the EU level.

The main risk management method used by these legislative acts is to place the obligation on the manufacturer to show that their products are safe for their intended use. Under the New Approach (and the now updated New Legislative Approach framework), the EU legislator sets essential requirements that are given more detail through the standardisation process. If it can be verified that the product complies with the harmonised standard, the product is presumed to be in compliance with the essential requirements and can bear the CE marking.

The manufacturer holds the main responsibility for:

- ensuring that the respective products are designed and manufactured in accordance with the specific requirements,
- compiling the technical documentation and carrying out the relevant conformity assessment procedure, and
- drawing up an EC declaration of conformity (such as under the Toy Safety Directive) or providing a declaration of performance (as under the Construction Products Regulation) (both discussed below).

[41] The Directive defines 'product' as 'any industrially manufactured product and any agricultural product, including fish products'. Note that Directive 98/34/EC still uses the term 'preparation' rather than 'mixture', the term now used in REACH, CLP and other more recent EU chemicals legislation.

In some cases, the obligations of the manufacturer apply to importers and distributors, i.e. when they are responsible for placing toys or construction products on the market. The Member States are then responsible for setting in place systems of market surveillance to ensure that the toys, construction products, etc. meet the essential safety requirements.

2.3.1 Toy Safety

Directive 2009/48/EC on the safety of toys [42] lays down rules on the safety of toys and on their free movement within the internal market. The main aim is to ensure a high level of safety of toys with a view to ensuring the health and safety of children whilst guaranteeing the functioning of the internal market.

The basic principle of the Toy Safety Directive is that only toys complying with the essential safety requirements of the Directive can be placed on the market, and that the Member States are required to take all the necessary measures to ensure that toys not complying with these requirements are not placed on the market. The Directive contains both a general safety requirement, as well as particular safety requirements applying to specific risks set forth in Annex II.

Most 'toys' would be considered as 'articles' under REACH. Some toys, however, may also contain or consist of chemical substances or mixtures regulated under REACH, e.g., paints used in arts and crafts. Though some toys, including those defined in the Directive as 'chemical toy', 'olfactory board game', 'cosmetic kit', and 'gustative game' are likely to contain or consist of 'mixtures' including substances subject to REACH, the Directive does not identify any particular substances for regulation.

The Toy Safety Directive requires toys to comply with general chemicals legislation and specifying in particular REACH. Toys must be designed and manufactured in accordance with the safety requirements set out in Annex II of the Toy Safety Directive, which include the requirements that where toys themselves are substances or mixtures, they must comply with the requirements relating to the classification, labelling and packaging of certain substances and mixtures, as set forth in Directive 67/548/EEC, the Dangerous Preparations Directive and the CLP Regulation.[43]

Article 18 of the Toy Safety Directive requires manufacturers, before placing a toy on the market, to carry out an analysis of the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards that the toy may present, as well as an assessment of the potential exposure to

[42] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys, OJ L 170, 30.6.2009, p.1.
[43] See Point 2, Section III (Chemical Properties) of Annex II on Particular Safety Requirements.

such hazards. Article 21 states that the technical documentation required to show that the toy complies with the essential requirements set out in Article 10 and Annex II shall contain all relevant data or details of the means used by the manufacturer to ensure compliance. In particular, it shall contain the documents listed in Annex IV. These are to include a detailed description of the design and manufacture, including a list of components and materials used in the toy and the safety data sheets on chemicals used (to be obtained from the chemicals suppliers), as well as the safety assessment, a description of the conformity assessment procedure followed and a copy of the EC declaration of conformity, amongst other information.

The Toy Safety Directive prohibits the use of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under the CLP Regulation in toys, but allows for certain derogations, on condition that the substance or mixture is not prohibited for use in consumer articles under REACH. Appendix B of Annex II sets out the criteria to be applied in order to classify substances and mixtures, which takes account of the transitional arrangements in moving to the CLP Regulation. Note that certain substances are covered by restrictions set out in Annex XVII of REACH as well as by restrictions (migration limits stipulated in the Toy Safety Directive.

Annex II on particular safety requirements establishes an extensive list of substance-related requirements for toys or components of toys. Part II (flammability) sets the general requirement that toys must not constitute a dangerous flammable element in the child's environment. Part III (chemical properties) sets the general requirement that toys shall be designed and manufactured in such a way that there are no risks of adverse effects on human health due to exposure to the chemical substances or mixtures of which the toys are composed. Part III, point 3, prohibits substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 for use in toys, in components of toys or in micro-structurally distinct parts of toys.

However, Part III, points 4 and 5 provide for derogation from this restriction for substances or mixtures classified as CMR category 2 under the CLP Regulation or as category 3 under the Dangerous Substances Directive, provided one or more of certain conditions are met. The conditions include if individual concentrations of the substances and mixtures are equal to or smaller than the relevant concentrations established in the CLP Regulation, or if these substances and mixtures are inaccessible to children in any form, including inhalation, or if, after evaluation of the substance or mixture by the relevant Scientific Committee, a decision has been taken via comitology to permit such use and the substance or mixture and its permitted uses have been listed in Appendix A to the Directive's Annex II.

There is also the ban set in point 8 on nitrosamines and nitrosable substances in toys intended for use by children under 36 months, the ban set in point 11 in on a number of allergenic fragrances and the migration limits set in point 13 for heavy metals in various types of materials used in toys. Cosmetic toys must comply with the EU requirements for cosmetic products and fragrances used in olfactory board games etc. must be clearly labelled on the packaging with any applicable warnings and not used by children under 36 months.

The Toy Safety Directive's Article 46(2) also provides a mechanism for setting limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth, which are to be adopted in accordance with comitology. However, the Commission has not yet adopted specific limit values under this provision.

The establishment of harmonised standards for meeting the safety requirements of the Toys Safety Directive involves the European standardisation bodies, the European Commission and the relevant Committee. Article 19 of the Directive sets out the applicable conformity assessment procedures which must be used to demonstrate that a toy complies with the essential safety requirements set out in Article 10 and Annex II. Toys are to be submitted to EC-type examination, which is carried out by conformity assessment bodies meeting the requirements of Article 26. The conformity assessment procedure must also conform to the procedure set out in Decision No 768/2008/EC on a common framework for the marketing of products.

In addition to the obligation on the manufacturer to show that the toy is safe for its intended use, Article 40 requires market surveillance by Member States to ensure that only those toys are placed on the market that meet the requirements of the Directive.

2.3.2 Construction products

The main aim of Regulation (EU) No 305/2011 laying down harmonized conditions for the marketing of construction products [44] (the Construction Products Regulation) is to achieve the proper functioning of the internal market for construction products. It also aims at protecting the safety of persons, domestic animals or property and to prevent damage to the environment.

The Regulation defines construction products as 'any product or kit which is produced and placed on the market for incorporation in a permanent manner in construction works or parts thereof'. The

[44] Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonized conditions for the marketing of construction products and repealing Council Directive 89/106/EEC, OJ L 88, 4.4.2011, p. 5.

concepts of safety or general interest thus apply to construction products only to the extent to which they contribute to the fulfilment of the requirements of the works in which they are to be incorporated.

The overall objective of the Regulation is not to define the safety of products, but to ensure that reliable information is presented in relation to their performances. However, Annex I, paragraph 3, requires that the construction works must be designed and built in such a way that they will, throughout their life cycle, not be a threat to the hygiene or health and safety of their workers, occupants or neighbours. They must also not have an exceedingly high impact over their entire life cycle, on the environmental quality or on the climate, during their construction, use and demolition.

The Regulation achieves its aims by providing a common technical language to be used by manufacturers when placing products on the market and by public authorities when defining the technical requirements of works which influence, either directly or indirectly, the products to be used in those works. This common technical language is set out in the harmonised technical specifications and European Assessment Documents developed under the Regulation's regime. The specifications are established by the European Standardisation bodies on the request of the Commission, a process which involves the Standing Committee on Construction. The Regulation therefore follows the New Legislative Framework in areas such as the criteria for notification of bodies carrying out third party tasks in the process of attestation of declared performance, or market surveillance provisions.

Article 4 of the Regulation requires the manufacturer to draw up a declaration of performance when placing a product on the market. This is to contain the information set out in Article 6, including information on the product type, the system used to assess and verify the performance of the product, and details of the harmonised standard. It also includes the list of essential characteristics, i.e., the basic requirements set out in Annex I, which could include details on particular substances (Annex I, paragraph 3).

Annex I of the Regulation sets out basic requirements for construction works that are to constitute the basis for the preparation of standardisation mandates and harmonised technical specifications. These harmonised technical specifications shall lay down the essential characteristics of various construction products. Where exemptions from restrictions under REACH are relevant to the use of a particular substance in the manufacture of a construction product, this would be considered by the relevant European Standardisation body.

The construction products covered under this Regulation include substances and mixtures as well as 'articles' under REACH. The Regulation's Annex IV lists 35 product areas to be covered by technical standards, including various types of mixtures such as adhesives, coatings, and sealants.

The Construction Products Regulation includes specific reference to REACH. Recital 25 states that the Regulation is without prejudice to Member States' rights and obligations pursuant to other instruments of Union law that may apply to hazardous substances, making particular reference to REACH. Article 6 (and Recital 25) requires the information provided under Articles 31 and 33 of REACH, namely the Safety Data Sheet (SDS) and information on substances in articles, to be provided together with the declaration of performance. This requirement supports the implementation of REACH by confirming that the information on any risks related to a substance gathered through the REACH registration requirements, e.g., via the chemical safety assessment, should be communicated to downstream users and taken into account in the manufacture of construction products.

Article 6(5) specifically requires that REACH Title IV information, namely the SDS required under Article 31 for certain substances or mixtures[45] and the information required under Article 33 on substances in articles (in case of a SVHC present in a concentration above 0,1% by weight), is provided together with the declaration of performance. The Annex I basic requirements require taking into account the health and safety of persons involved throughout the life cycle of the construction works, and the impact on the environmental quality or the climate.

A number of REACH Annex XVII restrictions are specific to construction products: entry 19 on arsenic compounds and entry 31 on creosote restrict their use as a wood preservative (but allow for certain derogations); entry 23 on cadmium restricts its use as a stabiliser for articles manufactured from polymers or copolymers of vinyl chloride, including floor and wall coverings, tubes and pipes and their fittings, swing doors, and insulation of electrical wiring; and entry 47 on chromium VI restricts its use in cement and cement-containing mixtures (but allows derogation for use in controlled closed and totally automated processes).

For any construction product not covered or not fully covered by a harmonised standard, the manufacturer can request a European Technical Assessment from a designated Technical Assessment Body. In addition to the manufacturer's obligation to show that the construction product is safe for its intended use, Article 28 requires assessment and verification of constancy of performance. Articles 56, 57, 58 and 59 set out a number of procedures for dealing with construction products presenting risks,

[45] Product areas listed in Annex IV of the Construction Products Regulation for coverage by technical standards includes mixtures, such as adhesives, coatings, and sealants, in addition to various types of articles.

including procedures at national level, Union safeguard procedures, procedures for dealing with compliant construction products which nevertheless present a risk to health and safety, and formal non-compliance.

Article 18 also provides for a process of evaluation where a Member State or the Commission may consider that a harmonised standard does not entirely satisfy the requirements. Through market surveillance activities, Member States are to ensure that only those construction products which meet the requirements of the Regulation are placed on the market.

2.3.3 Packaging & packaging waste

Directive 94/62/EC on packaging and packaging waste [46] ('the Packaging Directive') covers all packaging placed on the market in the EU and all packaging waste, whether it is used or released industrially, commercially, or in offices, shops, services, households or any situations, regardless of the material used. The Directive harmonises national measures in order to prevent or reduce the impact of packaging and packaging waste on the environment, as well as 'to ensure the functioning of the internal market, avoid obstacles to trade and distortion and restriction of competition within the Community'.

It contains provisions on the prevention of packaging waste, on the re-use of packaging and on the recovery and recycling of packaging waste. Member States should take measures to prevent the formation of packaging waste, and to develop packaging reuse systems reducing their impact on the environment. Member States must also introduce systems for the return and/or collection of used packaging to attain specific targets set out in the Directive.

In addition to covering the waste from packaging, the Packaging Directive also covers packaging in its design and manufacturing stage by setting essential requirements which cover inter alia substances. Packaging may be placed on the market only if it complies with the essential requirements laid down in Annex II, i.e., to limit the weight and volume of packaging to a minimum in order to meet the required level of safety, hygiene and acceptability for consumers, to reduce the content of hazardous substances and materials in the packaging material and its components, and to design reusable or recoverable packaging. Noxious and other hazardous substances and materials as constituents of the packaging material or of any of the packaging components are to be minimised.

[46] European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste, OJ L 365, 31.12.1994, p.10.

In particular, Article 11 sets concentration limits for heavy metals in packaging, i.e., lead, cadmium, mercury and hexavalent chromium. Article 11(3) provides for the possibility of exemptions from the heavy metal concentration levels, e.g., the implementing measures granting derogations for plastic crates and plastic pallets and glass packaging.[47]

Note that lead, cadmium, mercury and chromium VI are also subject to a number of restrictions within Annex XVII of REACH, but these restrictions are not specific to packaging, with the exception of cadmium. As per REACH Annex XVII, entry 23, cadmium is restricted for use as a stabiliser for articles manufactured from polymers or copolymers of vinyl chloride, including packaging materials (bags, containers, bottles, lids).

The information requirements in the Packaging Directive provide for gathering information about the toxicity or danger of packaging materials and components used for their manufacture in order to monitor implementation of the Directive. Finally, Member States should develop information systems (databases) on packaging and packaging waste so that achievement of the targets set out in the Directive can be monitored.

2.3.4 Other products covered by the New Legislative Approach

A number of other product related legislative acts using the New Approach are less relevant for the topic of controls over chemicals in products or articles, since their major focus is to ensure the functionality and safety of the particular product for the intended use. They are:

- Directive 2010/35/EU on transportable pressure equipment[48]
- Directive 2009/105/EC relating to simple pressure vessels (codified version)[49]
- Directive 97/23/EC concerning pressure equipment[50]

[47] Commission Decision 2009/292/EC of 24 March 2009 establishing the conditions for a derogation for plastic crates and plastic pallets in relation to the heavy metal concentration levels established in Directive 94/62/EC of the European Parliament and of the Council on packaging and packaging waste (notified under document number C(2009) 1959), OJ L 79, 25.3.2009, p. 44.. See also Commission Decision 2006/340/EC of 8 May 2006 amending Decision 2001/171/EC of the European Parliament and of the Council for the purpose of prolonging the validity of the conditions for a derogation for glass packaging in relation to the heavy metal concentration levels established in Directive 94/62/EC (notified under document number C(2006) 1823), OJ L 125, 12.5.2006, p. 43.

[48] Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC, OJ L 165, 30.6.2010, p. 1.

[49] Directive 2009/105/EC of the European Parliament and of the Council of 16 September 2009 relating to simple pressure vessels , OJ L 264, 8.10.2009, p. 12.

[50] Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment, OJ L 181, 9.7.1997, p. 1.

- Directive 2009/142/EC relating to appliances burning gaseous fuels[51]
- Directive 2006/42/EC on machinery, and amending Directive 96/42/EC[52]
- Directive 2000/9/EC relating to cableway installations designed to carry persons[53]
- Directive 2004/22/EC on measuring instruments[54]
- Directive 2003/44/EC relating to recreational craft[55]

The products covered under these acts would be considered as 'articles' under REACH. The substances used in the products would need to be registered under the REACH regime.

2.4 CONSUMER PRODUCTS COVERED BY SPECIFIC RULES

2.4.1 Cosmetics

Regulation (EC) No 1223/2009 on cosmetic products (Cosmetics Regulation) harmonises rules, simplifies procedures and strengthens the regulatory framework regarding cosmetic products, in order to ensure a high level of protection of human health.[56] It reinforces the general product safety legislation in relation to cosmetic products, taking into consideration the possible use of nanomaterials.[57] Most of the provisions of this new Regulation have applied as from 11 July 2013.

The Regulation provides for safety rules and imposes obligations on the manufacturers and on persons designated as 'responsible' for a cosmetic product. A safety assessment should be carried out under the responsibility of the 'responsible person' before the cosmetic product is placed on the market and a product information file kept for each product. The Regulation sets in place a notification procedure, which requires that information on the cosmetic product is communicated to the European Commission before the placing on the market, and after it (labelling). The Regulation also establishes restrictions for certain substances in cosmetic products, including substances classified as CMR or as nanomaterials. Finally, it includes provisions regarding consumer protection (labelling, product claims, access to information for the public) and market surveillance.

[51] Directive 2009/142/EC of the European Parliament and of the Council of 30 November 2009 relating to appliances burning gaseous fuels, OJ L 330, 16.12.2009, p. 10.
[52] Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC , OJ L 157, 9.6.2006, p. 24.
[53] Directive 2000/9/EC of the European Parliament and of the Council of 20 March 2000 relating to cableway installations designed to carry persons, OJ L 106, 3.5.2000, p. 21.
[54] Directive 2004/22/EC of the European Parliament and of the Council of 31 March 2004 on measuring instruments, OJ L 135, 30.4.2004, p. 1.
[55] Directive 2003/44/EC of the European Parliament and of the Council of 16 June 2003 amending Directive 94/25/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft, OJ L 214, 26.8.2003, p. 18.
[56] Recital 3 of the Regulation.
[57] See http://ec.europa.eu/consumers/sectors/cosmetics/documents/revision/index_en.htm.

The Cosmetics Regulation is aimed at protecting human health and the functioning of the internal market. Protection of the environment is not included among its aims. It covers all substances used in a cosmetic product placed on the market, and defines 'cosmetic product' as including both substances and mixtures. It focuses on the intended use or function – i.e., any substance or mixture intended to be put into contact with the human body for the purpose of cleaning, changing appearance, etc.

Definition of cosmetic products under the Cosmetics Regulation

'cosmetic product' means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.

The Cosmetics Regulation's definition of 'cosmetic product' includes both substances and mixtures, and focuses on the intended use or function of the product and on the fact that it will be in direct contact with the human body.

The Cosmetics Regulation provides for positive listings in Annexes IV to VI of certain substances, i.e., those substances are authorised for use in the specified type of cosmetic products. The Regulation also has its own set of restrictions, bans and negative listings.

Note that REACH exempts cosmetic products from a number of its provisions. For example, cosmetic products are included in the REACH Article 2(6) exemption for mixtures, in the finished state, intended for the final user, from the Title IV requirements for information through the supply chain. Moreover, under REACH Article 14(5)(b), the CSR need not include consideration of the risks to human health from end uses in cosmetic products.

According to REACH Article 56(5), substances of very high concern (SVHC) which are CMR 1A or 1B or are identified in accordance with Article 57(f) due only to their hazards to human health are exempted from the authorisation requirements for such substances for uses in cosmetic products. Finally, Article 67(2) and Annex XVII of REACH specifically exempt cosmetic products from restrictions addressing risks to human health.

The Cosmetics Regulation requires all cosmetic products –whether substances or mixtures – must undergo a safety assessment before being placed on the market. Annex I sets the parameters for a Cosmetic Product Safety Report: Part A sets requirements roughly equivalent to those for the technical

dossier under REACH and Part B has similarities with the Chemical Safety Assessment. Note that the Cosmetics Regulation requires safety assessment for all cosmetic products (in contrast to REACH which does not require CSA for substances with lower tonnage thresholds) and that Part A covers areas that the technical dossier under REACH does not, such as microbiological quality and information on the packaging. The Cosmetics Regulation also requires margins of safety (MoS) based on a NOAEL rather than using DNELs based on a NOAEL, as required in REACH. In addition, information on nanomaterials used in the cosmetic product is required, whereas this is not specifically required in REACH. Lastly no information on the ecotoxicity of the substance is required under the Cosmetics Regulation, unlike under REACH.

The main risk management tool under the Cosmetics Regulation is the production by the 'responsible person' of a Cosmetic Product Safety Report. This report must document the assessment of the product and justify that it is safe to use before it may be placed on the market. It is an implementation of the Article 3 obligation that a cosmetic product put on the market must be safe for human health when used under normal or reasonably foreseeable conditions of use.

2.4.2 Detergents

The substances covered by Regulation (EC) No 648/2004 on detergents[58] are those substances or mixtures intended for washing and cleaning processes, and marketed for or used in households, or institutional or industrial processes. The Detergents Regulation aims to ensure a high level protection of the environment and human health as well as to achieve the free movement of surfactants and detergents in the internal market. In particular, it aims to improve protection of the aquatic environment through setting biodegradability requirements for the surfactants in detergents and other cleaning products, including fabric softeners.

The Regulation expands the scope of the previous legislation it replaced and imposes stricter testing methods for detergents to determine the ultimate rather than the initial biodegradability. It also introduces specific labelling requirements to inform consumers about the presence in detergents of all allergens, such as certain fragrance substances and preservation agents. Manufacturers must list on the labelling all components in decreasing order of concentration as well as the address of a website where consumers can obtain the complete list of ingredients.

[58] Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents, OJ L 104, 8.4.2004, p. 1.

The Detergents Regulation was amended in 2012 to also cover the use of phosphates and other phosphorous compounds in consumer laundry detergents and consumer automatic dishwasher detergents[59].

All substances used in detergents are subject to REACH. The Detergents Regulation contains no cross-references to REACH but does refer to the predecessors of the CLP Regulation, i.e., the Dangerous Substances and the Dangerous Preparations Directives. Note that REACH Annex XVII, entry 46, restricts nonylphenol and nonylphenolethoxylates for industrial and institutional cleaning and for domestic cleaning.[60]

Whereas REACH covers all substances, including substances in mixtures, the Detergents Regulation covers only those substances and mixtures used in detergents, with a special focus on surfactants used in detergents. Surfactants are included in such products in order to reduce the surface tension of liquids so that they can wet surfaces and clean them more effectively.

Definition of detergent and surfactant under Article 2 of Regulation (EC) No 648/2004:

1. 'Detergent' means any substance or mixture containing soaps and/or other surfactants intended for washing and cleaning processes. Detergents may be in any form (liquid, powder, paste, bar, cake, moulded piece, shape, etc.) and marketed for or used in household, or institutional or industrial purposes.
Other products to be considered as detergents are:
— 'Auxiliary washing mixture', intended for soaking (pre-washing), rinsing or bleaching clothes, household linen,etc.;
— 'Laundry fabric-softener', intended to modify the feel of fabrics in processes which are to complement the washing of fabrics;
— 'Cleaning mixture', intended for domestic all purposes cleaners and/or other cleaning of surfaces (e.g.: materials, products, machinery, mechanical appliances, means of transport and associated equipment, instruments, apparatus, etc.);
— 'Other cleaning and washing mixtures', intended for any other washing and cleaning processes.
…
6. 'Surfactant' means any organic substance and/or mixture used in detergents, which has surface-active properties and which consists of one or more hydrophilic and one or more hydrophobic groups of such a nature and size that it is capable of reducing the surface tension of water, and of forming spreading or adsorption monolayers at the water-air interface, and of forming emulsions and/or microemulsions and/or micelles, and of adsorption at water-solid interfaces.

[59] Regulation (EU) No 259/2012 of the European Parliament and of the Council of 14 March 2012 amending Regulation (EC) No 648/2004, OJ L 94, 30.3.2012, p. 16.
[60] Note that Commission Regulation (EU) No 207/2011 has deleted entry 53 of Annex XVII restricting perfluoro-octane sulfonates, because PFOS are now banned under the Stockholm Convention.

The Detergents Regulation sets criteria for biodegradability of substances used as surfactants in detergents. If the product does not meet the criteria, it is prohibited from being placed on the market unless derogation is obtained from the Commission. Note that derogation can only be granted for industrial and institutional detergents.

The Detergents Regulation sets a number of requirements with respect to the labelling of detergents sold to the general public. In addition to requiring labelling if a substance or mixture is classified under the CLP Regulation, it requires instructions for use and any special precautions to be taken, if required. Specific labelling is required to inform consumers about any fragrance substances and preservation agents that are present in detergents that may be allergens, and therefore human health and consumer protection are part of the overall regulatory package.

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. Finally, if a derogation is granted to an institutional or industrial detergent not meeting the ultimate biodegradability criteria, the derogation may include limits and severe restrictions on the use of the surfactants as ingredients in detergents, including the possibility of a phase-out. Annex V lists the surfactants that have obtained derogation.

In addition to specific labelling requirements to inform consumers about perfumes, disinfectants, enzymes, preservation agents, etc. present in detergents, the Detergents Regulation provides that medical personnel are entitled to request from the manufacturer a full listing of all ingredients of a detergent. Member States may require that such information is also made available to a public body designated to provide this information to medical personnel.

Article 3 of the Detergents Regulation exempts surfactants that are also biocidal active substances within the meaning of the Biocidal Products Regulation and used as disinfectants (hence authorised for that biocidal use) from the requirements in the Regulation's Annexes II, III, IV and VIII (although such substances remain subject to the labelling provisions of Annex VII).

Like REACH, the Detergents Regulation focuses on risks from substances – in this case the risk to the environment if substances used in detergents do not ultimately biodegrade. While the focus is on the risk to the aquatic environment,, sewage sludge and the soil compartment are also covered by the risk assessment provisions. The substances to be assessed are those that the manufacturer wishes to place on the market in a detergent product. The information that manufacturers must have on file and at the disposal of the competent authorities (which are to contain the result of the tests stipulated in Annexes

II, III and IV) are similar to the environmental endpoints in registration dossiers required under REACH. Note that the Detergents Regulation provides for 'complementary risk assessment' in the case where a manufacturer of industrial or institutional detergents applies for derogation for a detergent containing surfactants for which the level of ultimate aerobic biodegradation is lower than that stipulated in Annex III.

The Detergents Regulation obliges Member State competent authorities to control whether detergents placed on the market are in compliance with the provisions of the Regulation; this may involve analysis and testing. A list of approved laboratories that Member States have found competent and authorised to carry out the tests required by the Regulation is published and regularly updated by the Commission.

Finally, a safeguard clause provides that Member States may take temporary measures to prohibit or restrict the placing on the market of a specific detergent that complies with the requirements of the Regulation if there are justifiable grounds to believe that it poses a risk to human health, animal health or the environment. In such cases, Member States must inform the Commission, which will take a decision on the measures.

2.4.3 Paints and varnishes

Directive 2004/42/EC on the limitation of VOC emissions in certain paints and varnishes[61] sets maximum limits for the volatile organic compound (VOC) content of decorative paints and vehicle refinishing products. It regulates volatile organic compounds because of the contribution of VOCs to the formation of tropospheric ozone, which can lead to negative health and environmental effects. The requirements are without prejudice to legislation on protection of consumer health and/or workers setting more specific requirements.

Paints are considered mixtures under REACH/CLP, and are subject to CLP requirements for classification and labelling. Under REACH registration requirements, the solvents and other substances making up these mixtures will be subject to chemical safety assessment. The CSAs should consider i.a. the environmental effects of the use of VOC-containing compounds in paints (provided the manufacturer/importer placing it on the market knows one of its intended uses is for paints). The risk assessment carried out during the CSA will help to inform the regulator concerning whether

[61] Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC, OJ L 143, 30.4.2004, p. 87.

additional controls over solvents used in paints may be necessary to control risks to human health and the environment from such uses.

Annex I defines the scope of the Directive by providing lists of categories of paints and varnishes (defined as coatings applied to buildings, their trim and fittings; and associated structures for decorative, functional and protective purpose) as well as of categories of 'vehicle refinishing products' (defined as used for the coating of road vehicles or part of them, carried out as part of vehicle repair, conservation or decoration outside of manufacturing installations). However, aerosols are not within its scope. The Directive exempts products sold for the exclusive use in installations covered by Directive 1999/13 (the Solvents Directive) because such an installation should provide alternative means of achieving equivalent VOC emission reductions.

The Paints Directive requires the products listed in its Annex I to be labelled to indicate the subcategory of the product and the relevant VOC limit values, and the maximum content of VOC in the product when ready to use. Products falling within these categories can be marketed in the EU only if they comply with the specifications in Annex II, which sets limit values for VOCs in paints, varnishes and vehicle refinishing products. The paints must be labelled in accordance with the Directive. Member States may authorise the sale and purchase of paints that do not meet the VOC limit values but in strictly limited quantities and only for the purposes of restoring/maintaining historical buildings and vehicles.

Member States must develop market surveillance systems to verify the VOC content of the products covered by this Directive. They must ensure that such products are placed on the market only if they comply with the limit values laid down in Annex II and carry a label showing VOC content.

2.5 END-OF-LIFE PRODUCTS

Related to the Integrated Product Policy discussed earlier in this report are a number of legislative acts aimed at minimizing the impacts of waste on the environment by placing responsibility on producers for their products, including at end-of-life product life.

2.5.1 Restriction of hazardous substances in electrical & electronic goods

The issue of chemicals in electrical and electronic goods is covered by two closely linked acts:

1. Directive 2012/19/EC on waste electrical and electronic equipment (recast) (the WEEE Directive) [62]; and
2. Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast) (the RoHS Directive)[63].

Under the WEEE Directive, Member States must require producers to provide for, or financially support, the separate collection and treatment of WEEE. The Directive sets targets for the amount of WEEE recovered and recycled, in the absolute and as a proportion of the average weight per appliance. It also requires that EEE users be provided with information regarding hazards and available means of disposal, and that treatment facilities receive detailed instructions to facilitate the safe treatment of each type of EEE. Subject to certain conditions, WEEE may be exported from the EU for treatment.

The 2012 recast of the WEEE Directive aims to increase the amount of WEEE that is appropriately treated and to reduce the volume that goes to disposal. It also aims to reduce administrative burdens and ensure coherency with newer policies and legislation, which includes REACH. It sets mandatory collection targets of 65% of the average weight of EEE placed on the market. Recycling and recovery targets would cover the re-use of whole appliances and weight-based targets would increase by 5%. Targets are also proposed for the recovery of medical devices.

The RoHS Directive limits the use of certain hazardous chemicals in the types of EEE listed in its Annex I, so as to minimise environmental impact at the end of product life. Categories of EEE now covered include medical devices and monitoring and control instruments.

Like REACH, the recast Directive aims at contributing to the protection of human health and the environment. It does so by requiring Member States to prevent the placing on the market of new electrical and electronic equipment (EEE) containing lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE). In contrast to REACH,

[62] Directive 2012/19/EC of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment, OJ L 197, 24.7.2012, p. 38.
[63]Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, OJ L 174, 1.7.2011, p.88.

the main regulatory focus of the recast Directive is on the design and manufacturing stage and the waste stage of the life-cycle.

The substances included in Annex II are very hazardous to human health and the environment even at very low doses and moreover will persist in the environment. The limit values do not represent safe levels but are aimed at minimising the content to what is technically achievable for those types of products and with a view to a possible future cessation of the use.

The recast Directive applies to all EEE falling under the categories set out in Annex I. It does not provide general exemptions for the substances it regulates. Rather, it exempts certain specific uses of those substances from its general prohibitions on their use in electrical and electronic equipment. None of the exemptions from the restrictions set out in Annex XVII of REACH duplicate those found in the recast Directive, as they do not cover the same uses.[64]

For example, lead carbonates and sulphates, which are covered by entries 16 and 17 in Annex XVII of REACH respectively, are restricted when used in paints, while the recast Directive restricts its use generally in EEE, unless exempted in accordance with Annex III. None of the applications exempted from the restriction in Article 4(1) of the recast Directive covers the use of lead in paint, which use is covered by the restriction under REACH. Similarly, in relation to mercury, entry 18 of Annex XVII REACH restricts the use of mercury compounds in treatment/preservation applications and entry 18a restricts the use of mercury in fever thermometers and other measuring devices. However, according to Annex III of the recast Directive, the use of mercury in fluorescent tube lighting and other lighting applications is exempted from the general prohibition in the Directive's Article 4(1) of using certain substances in EEE placed on the market.

In particular, Article 5(1)(a) of the recast Directive requires that when adding materials and components of EEE for specific applications to the lists in Annexes III and IV, as exempt from the prohibition of certain substances in EEE, these must 'not weaken the environmental and health protection of' REACH. Annex III of the recast Directive lists applications exempted from the restriction set by Article 4(1) of the recast Directive for all EEE. These exemptions include the use of cadmium except as banned under amended Directive 76/769/EEC, which was replaced by REACH with effect from 1 June 2009.

More specifically, Annex II of the RoHS Directive lists polybrominated diphenyl ethers (PBDE) as restricted. Though entry 45 of Annex XVII REACH also restricts the use of diphenylether, octabromo

[64] The issue of potential overlaps between RoHS and REACH was raised by stakeholders – see further Section 5.1.2.6.

derivative, in mixtures and articles, by way of derogation, the entry 45(2) restriction on concentrations of the substance in articles does not apply to EEE within the scope of the RoHs Directive.

The recast Directive requires manufacturers to carry out a conformity assessment and affix CE marking to their products, and also places further obligations on importers and distributors in relation to market surveillance. The recast Directive also introduces new product conformity assessment requirements and market surveillance mechanisms.

2.5.2 End-of-life motor vehicles

Directive 2000/53/EC on end-of-life vehicles[65] EC (the ELV Directive) aims to protect the environment by reducing waste and by reducing the presence of hazardous substances in materials and components used in vehicles. It requires Member States to establish collection systems for waste arising from vehicles and to ensure that end-of-life vehicles are transferred to authorised treatment facilities, which shall issue the owner or holder of an end-of-life vehicle with a certificate of destruction. The storage and treatment of end-of-life vehicles at authorised treatment facilities are to be carried out in accordance with the Waste Framework Directive (2008/98/EC).

The ELV Directive also places obligations on vehicle manufacturers and importers of vehicles into the Community to limit the use of hazardous substances in new vehicles, to design and produce vehicles in a way which facilitates re-use and recycling, and to increase the use of recycled materials. In particular, it covers hazardous substances in vehicles (specifically lead, mercury, cadmium and hexavalent chromium) due to their presence in these products and as a result of the particular problems they present in terms of waste treatment.

The use of mercury, hexavalent chromium, cadmium and lead in the components of vehicles placed on the market is prohibited, except in trace amounts (0.1% by weight, except 0.01% in the case of cadmium), or in certain limited, listed usages, which are regularly reviewed under the comitology procedure. However, these substances may be used for certain applications set out in Annex II of the Directive, which lists the materials and components subject to the exemption and the scope and expiry date of the exemption in each case. For example, in the case of batteries for electrical vehicles, the placing on the market of NiCd batteries is only allowed as replacement parts for vehicles put on the market before 31 December 2008. Secondly, while the ELV Directive prohibits the use of hexavalent

[65] Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of-life vehicles, OJ L 170, 21.10.2000, p. 34.

chromium in vehicles, it does permit their use for refrigeration in recreational vehicles, or as a corrosion preventive coating on components.

In addition to restricting the use of hazardous substances in vehicles, the ELV Directive further seeks to limit the amount of waste disposed of, which could potentially contain further hazardous substances, through recovery and reuse. The Directive requires that vehicle manufacturers produce information on dismantling for each type of new vehicle placed on the market, and use material and component coding standards, including indications of which components are suitable for reuse, and which contain hazardous substances, in order to facilitate dismantling.

Article 7 of the ELV Directive sets targets for the reuse and recovery in order to reduce the use and extend the recovery of components. It also sets targets for recycling, as a proportion of the average weight per vehicle per year.

It aims to improve the environmental performance of operators directly involved in the treatment of ELV's by setting out minimum technical requirements in Article 6 and Annex 1 of the Directive. In particular, Annex I requires treatment facilities to take measures to guard against leakage of fluids during dismantling.

Although monitoring is not specifically required, the ELV Directive requires Member States to 'take the necessary measures' to ensure compliance with its minimum requirements for treatment of end-of life vehicles as waste. In particular it mandates removal and separate handling of components that may contain hazardous substances.

Member States are permitted to exempt producers or importers of small-series vehicles from the informational requirements (Articles 8 and 9), to exempt certain special-purpose vehicles from the reuse and recovery requirements (Article 7), and to require three-wheeled motor vehicles to comply only with the collection and treatment requirements (Articles 5(1), 5(2), 6).

2.5.3 Batteries

Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC[66] (the Batteries Directive) covers all batteries (with exceptions for e.g. military use) rather than only those containing mercury, cadmium or lead. The Batteries Directive

[66] 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, *OJ L 266, 26.9.2006, p. 1.*

aims to protect the environment and human health through reducing the amount of heavy metals in batteries, in particular mercury, cadmium, and lead, disposed of in mixed municipal waste. It also seeks to ensure the functioning of the internal market by levelling disposal costs across the Member States. REACH Article 2(2) applies to waste batteries and accumulators.

The Batteries Directive specifically prohibits the placing on the market of most batteries or accumulators that contain more than trace amounts of cadmium or mercury (>0.0005% mercury or 0.002% cadmium by weight), but permits button cells containing less than 2% mercury. The Batteries Directive also provides exemptions from the equivalent provision concerning cadmium for portable batteries and accumulators for use in emergency and alarm systems, medical equipment, or cordless power tools (Article 4(3)).

The Directive establishes minimum collection targets and requires special labelling of all batteries or accumulators. Batteries or accumulators containing more than 0.0005% mercury or 0.002% cadmium by way of exemption under Article 4(2) or (3) from the general prohibition, or 0.004% lead, must be labelled to indicate the presence of those substances. End-users must be informed of the hazards posed by these substances contained in batteries, the desirability of their separation from municipal waste, and the availability of collection schemes.

Untreated batteries and accumulators may not be disposed of via landfill or incineration. Member States must ensure that producers provide for or finance the separate collection and treatment of waste batteries or accumulators.

Under the Batteries Directive, Member States may exempt small producers from the obligation to finance net costs of collection, treatment and recycling of waste batteries and accumulators under certain conditions. Subject to certain conditions, waste batteries and accumulators may be exported from the EU for treatment, i.e., recycling or recovery.

2.6 BIOCIDE-TREATED ARTICLES

Articles or materials are treated with biocides for two main reasons:

1. To protect the article or material from degradation, e.g., deterioration due to fungus or other microorganism;
2. To serve as a means of delivering a biocidal product, e.g., a flea collar for a pet.

The Biocidal Products Regulation (BPR) establishes a harmonised regulatory framework for the authorisation and the placing on the market of biocidal products and the mutual recognition of these authorisations within the EU. It also provides for the establishment at EU level of a positive list of active substances that may be used in biocidal products.

REACH exempts from registration those substances for which data has already been submitted for evaluation and approval under the BPR. However, if the substance will be marketed for a use other than as a biocide, it will also be subject to REACH registration for those other uses, according to tonnage thresholds.

Biocide-treated articles are covered by both REACH and Regulation (EU) No 528/2012 on biocidal products [67]. While REACH refers to substances, mixtures and articles, the BPR refers to products, and the substances or mixtures comprising those products. The BPR also covers articles in form of devices generating active substances *in situ* as well as articles treated with or incorporating biocidal products, which are also addressed by REACH.

According to the BPR, active substances have to be assessed and the decision on their inclusion into Annex I, IA or IB of the Directive (eligible for use in biocidal products) shall be taken at EU level. For inclusion in the Annexes, an applicant submits a dossier to the competent authority of one of the Member States ('Rapporteur Member State'). Once this authority has checked that the dossier complies with a set of data requirements on the properties of the substance and product provided by the Directive, the application is sent to the other Member States and the Commission. The Rapporteur Member State submits a report on the assessment of the active substance with a recommendation to the Commission. The final decision on the inclusion or non-inclusion is taken through a comitology procedure.

The producers and formulators responsible for the placing on the market of the biocidal products (usually mixtures under REACH) must apply to Member States for authorisation and submit all necessary studies and other information needed for the evaluation and the decision-making. Member States authorise the biocidal products in accordance with the rules and procedures set out in the Common Principles for the Evaluation of Dossiers for Biocidal Products. They can however only authorise products which contain active substances approved for a particular use.

[67] Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the placing on the market and use of biocidal products, OJ L 167, 27.06.12, pp. 1-128.

The BPR introduced the possibility for certain biocidal products to be authorised at Union level. It also revised the concept of low-risk biocidal products, simplified data protection rules, and established rules for parallel trade of biocidal products. Finally, it introduced coverage of articles or materials treated with biocidal products.[68]

The BPR has both positive and negative listings. On the positive list are those active substances which are eligible for use in biocidal products, and listed in Annex I of the Regulation. Decisions made not to include substances in Annex I have *de facto* the same effect as a negative list. In such cases the Commission can bring forward proposals for restricting the marketing and use of these substances under REACH Annex XVII.

Moreover, Article 16 of the BPR provides for the possibility to make the authorisation subject to conditions that are more or less equivalent to restrictions under REACH. Other Community provisions setting conditions for use of a biocidal product must be taken into account by Member State authorities when they deliver an authorisation under the BPR. The active substance can be made subject to a number of limit values.

2.7 NANOMATERIALS

The EU considers nanomaterials as covered by the definition of a "substance" in REACH, even though there is no explicit reference to nanomaterials. In a 2012 Communication on the Second Regulatory Review on Nanomaterials[69], the European Commission stated that REACH together with CLP provided the best regulatory framework for managing risks from nanomaterials occurring either as substances or in mixtures. Accordingly, nanomaterials and mixtures containing nanomaterials that fulfill the criteria for classification as hazardous under the CLP Regulation must be classified and labelled.

Many related requirements, including for safety data sheets, already apply if the nanomaterial is classified as hazardous, regardless of the annual tonnage of manufacture or import, since all substances meeting the classification criteria as hazardous should have been notified to ECHA by 3 January 2011. Any new classifications must also be notified without undue delay.

[68] Explanatory Memorandum, p. 2, of the Proposal for a Regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products COM(2009)267 Final, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0267:FIN:EN:PDF.
[69] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52012DC0572 .

Nonetheless, there is recognition that specific requirements for nanomaterials are necessary. In 2011, the European Commission adopted a Recommendation on the definition of a nanomaterial[70]:

EU recommended definition of 'nanomaterial'

'A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and 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.

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 %.

By derogation from the above, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials. '

The Recommendation provides for a review of the definition "*in the light of experience and of scientific and technological developments. The review should particularly focus on whether the number size distribution threshold of 50 % should be increased or decreased*". The Commission is in the process of carrying out a consultation with stakeholders and expects to conclude the review in 2016.

The definition was intended for use in identifying materials for which special provisions might apply, e.g. for risk assessment or ingredient labelling in specific legislation where the definition would be used, in order to avoid inconsistencies. For example, the 2009 Cosmetic Products Regulation -- the first EU act to specifically regulate nanomaterials as used in cosmetic products – defines 'nanomaterial' as 'an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm'[71].

The Biocidal Products Regulation (EU) No 528/2012 is the first regulation to implement in the legal text the definition of nanomaterials from the Commission recommendation. Further it provides for a separate assessment for chemicals in nanoform**.**

In 2012, ECHA updated its Guidance on Information Requirements and Chemical Safety Assessment in REACH with three new appendices containing recommendations for registering nanomaterials[72], and in 2013 the Commission launched a public consultation concerning possibilities for modifying certain technical provisions in the REACH Annexes. The REACH Annexes that may be amended to

[70] Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU), http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011H0696&from=EN .
[71] Article 2(k) of the Cosmetic Products Regulation.
[72] http://echa.europa.eu/web/guest/view-article/-/journal_content/3df5b7b9-a36d-4e74-811b-3aeee23366f8 .

cover nanomaterials adequately include Annex III on eco-toxicological information, Annex VI on substance identification and physical chemical properties, and Annexes VII- XI on human and Eco-toxicology.

The Competent Authorities for REACH and CLP ('CARACAL') – a group of technical experts representing Member States – has a Subgroup on Nanomaterials ('CASG Nano') which is working closely with the Commission to develop advice on how to manage nanomaterials under REACH and CLP.

In addition to the Cosmetics Products Regulation, several food safety acts have provisions related to nanoforms in products, as per the table below:

Food safety act	Provision re: nanomaterials
Regulation (EU) No 1169/2011 on the provision of food information to consumers	All ingredients present in the form of engineered nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets.
Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	Substances in nanoform shall only be used if explicitly authorised No specific authorisation exemption for substances in nanoforms in case of multi-layers Certain nanoparticles have been authorised (e.g. titanium nitride, nanoparticles)
Regulation (EC) No 450/2009 on active and Intelligent materials intended to be in contact with food	Nanoparticles should be assessed on a case by case basis
Regulation No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control	Nanoform of bulk substances should be reevaluated Food safety of engineered nanomaterials must be demonstrated on the basis of adequate test methods.

In April 2013, the Commission launched 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*", with a focus on those nanomaterials currently falling outside existing notification, registration or authorisation schemes.

Note that since 1 January 2013, France has required manufacturers to identify the use of "substances with nanoparticle status" that they produce, import, distribute, or formulate[73]. Both Denmark and Belgium have since also adopted special registers for nanomaterials[74].

[73] http://www.cnbss.eu/index.php/editorial/item/84-compulsory-registry-of-%E2%80%9Cnanomaterial%E2%80%9D-in-france-part-1 .

3 INSTITUTIONAL ARRANGEMENTS & JURISDICTION FOR ENFORCEMENT

3.1 EUROPEAN COMMISSION

The European Commission has a key role to play in proposing legislation, as well as supporting implementation. It has the right of initiative to propose new legislation for adoption by the European Parliament and by the Council of the EU, i.e., the 28 Member States as represented by their national ministers for the area under consideration. Once EU legislation is adopted, the Commission is responsible for overseeing that it is correctly implemented by the Member States.

In the area of controls over dangerous chemicals in products, competence is shared among a number of Commission services and agencies. For example, competence in the areas regulated by REACH is shared between the Directorate-General on Environment (DG ENV) and the Directorate-General on Internal Market, Industry, Entrepreneurship and SMEs (DG GROW). DG ENV holds competence for waste, and hence for the legislation aimed at preventing impacts at end of product life.

DG GROW has primary responsibility for the CLP Regulation and much of the product-related legislation discussed above, including cosmetics and construction products. The Directorate General on Health and Food Safety (DG SANTE) is responsible for the Biocidal Products Regulation.

3.2 EUROPEAN CHEMICALS AGENCY (ECHA)

The European Chemicals Agency (ECHA)[75] was established in June 2007 according to the mandate set forth in REACH. It is an executive agency within the European Commission, and the key institution 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:

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74 http://www.lexgo.be/fr/articles/2014/07/The%20future%20Belgian%20register%20for%20nanomaterials%3A%20what%20companies%20should%20know%20about%20it,88277.html

75 http://www.echa.europa.eu/

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

ECHA is comprised of a number of structures, including the core staff of the Agency and a number of committees that includes representatives from the Member States, the European Commission and the European Parliament, as well as stakeholders from industry and NGOs. 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.

For example, the Biocidal Products Committee (BPC)[76] prepares the opinions of ECHA related to several processes under the Biocidal Products Regulation, 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.

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.

[76] http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/meetings-of-the-biocidal-products-committee

3.3 ROLE OF MEMBER STATES IN IMPLEMENTATION & ENFORCEMENT

While one of the main tasks of the European Commission is to ensure the proper implementation of EU legislation, including the REACH and CLP Regulations, actual implementation and enforcement is the responsibility of the Member States. Both REACH and CLP require 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.

For example, the European Chemical Agency's FORUM for Exchange of Information on Enforcement[77] coordinates the network of Member State authorities responsible for enforcement of REACH and CLP. 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 below.

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 Forum has published non-binding guidance materials on enforcement, including *Strategies for Enforcement of REACH and CLP*[78], *Minimum Criteria for REACH and CLP Inspections*[79] and *Guidance for handling complaints under article 33.2*[80].

[77] http://echa.europa.eu/about-us/who-we-are/enforcement-forum
[78] http://echa.europa.eu/documents/10162/13577/strategies_enforcement_reach_2011_en.pdf
[79] http://echa.europa.eu/documents/10162/13577/mcri_minimum_criteria_reach_inspections_2011_en.pdf
[80] http://echa.europa.eu/documents/10162/13577/guidance_for_handling_complaints_under_article33-2_en.pdf

3.4 INTRA-EU COMMUNICATION ON CHEMICALS IN PRODUCTS (RAPEX)

Directive 2001/95/EC ('the General Product Safety Directive') establishes rules to ensure the safety of consumer products. In addition to its provisions concerning market surveillance and enforcement, it provides for an alert system, known as the. The Directive's Article 12 requires that where a Member State adopts or decides to adopt, recommend or agree with producers and distributors, whether on a compulsory or voluntary basis, measures or actions to prevent, restrict or impose specific conditions on the possible marketing or use, within its own territory, of products by reason of a serious risk, it shall immediately notify the Commission thereof through RAPEX. If the notifying Member State considers that the effects of the risk do not or cannot go beyond its territory, it shall follow the procedure laid down in Article 11.

RAPEX thus ensures that the relevant authorities throughout the Member States are rapidly informed whenever a dangerous product has been identified. 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. Note that Commission Decision 2010/15/EU[81] establishes guidelines for the management of RAPEX, including the notification procedure set up under Article 11 of the General Product Safety Directive.

The market surveillance mechanisms provided for in the General Product Safety Directive have been reinforced as regards products presenting a serious risk by Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (the Market Surveillance Regulation). Article 20 of the Market Surveillance Regulation provides for products presenting a serious risk, by stating that Member States shall ensure that products which present a serious risk requiring rapid intervention, including a serious risk the effects of which are not immediate, are recalled, withdrawn or that their being made available on their market is prohibited, and that the Commission is informed without delay thereof, in accordance with Article 22.

The Regulation's Article 22 provides for the exchange of information under RAPEX. Where a Member State takes or intends to take action in accordance with Article 20 and considers that the reasons which prompted the measure or the effects of the measure go beyond its territory, it must immediately notify the Commission of that measure, as well as the modification or withdrawal of any

[81] Commission Decision 2010/15/EU of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive) OJ L 22/1, 26.1.2010, p. 1.

such measure. Article 22(2) also requires that if a product presenting a serious risk has been made available on the market, Member States shall notify the Commission of any voluntary measures taken and communicated by an economic operator. The information must include all available details, in particular the data necessary for the identification of the product, the origin and the supply chain of the product, the related risk, the nature and the duration of the national measure taken and any voluntary measures taken by economic operators. Finally, Article 22(4) specifically refers to the use of the market surveillance and information exchange system provided for in Article 12 of the General Product Safety Directive

The entry into force of the Market Surveillance Regulation in January 2010 extended the scope of the RAPEX system to risks beyond those affecting the health and safety of consumers, to include risks to health and safety in the workplace, the environment and to security, and also to some products for professional use. The RAPEX system therefore covers all dangerous consumer products, with the exception of food, pharmaceutical and medical devices.

Where such products are found to be dangerous, the competent national authority is required to take appropriate action to eliminate the risk, either through withdrawal of the product from the market, recall of the product from consumers or by issuing warnings. Following this, the RAPEX system allows for the rapid exchange of information between Member States, as central National Contact Points notify the European Commission about the product, the risks it poses to consumers and the measures taken to prevent or restrict the marketing or use of the product. Both measures ordered by national authorities and measures taken voluntarily by producers and distributors are covered by the RAPEX system.

The European Commission then circulates the information notified to it, to all other National Contact Points, who have their own authorities check whether the notified product is present on the market or not. In certain cases therefore, following notification by one National Contact Point, similar measures (withdrawal, recall or the issue of warnings) will be taken in another Member State.

The European Commission publishes weekly overviews of the RAPEX notifications on its website every Friday[82]. The weekly overview gives information on the products posing a serious risk, as reported by the national authorities, the risk that was identified, and the measures taken by the notifying country. It also lists other countries where the notified product was found, and details of

[82] Available at: http://ec.europa.eu/consumers/safety/rapex/alerts/main/index.cfm?event=main.listNotifications

measures taken in those other countries. It should be noted that currently all 28 Member States as well as the EFTA/EEA countries of Iceland, Liechtenstein and Norway participate in the RAPEX system.

A 2012 study[83] carried out by Milieu for DG GROW based on information received from Member States as well as details of RAPEX notifications showed that the majority of non-compliant products are imported products. The measures carried out by Member States in order to control imports range from 1) no specific measures being taken, as market surveillance or specific enforcement campaigns covered imported products along with other products, 2) informal cooperation with customs authorities in order to receive information on imports or specific products, 3) testing of imported products by customs, to 4) specific cooperation agreement in place between customs and the authorities responsible for the enforcement of REACH.

The Milieu study reviewed all RAPEX notifications from 2005 until the beginning of December 2011[84] that were publicly available on the website of the European Commission, focusing in particular on ten restrictions of substances as set forth in Annex XVII of REACH. The RAPEX notifications for these substances over the last six years are summarised below, in terms of the total number of notifications, and including general product categories, where a significant number of notifications were involved.

Entry 46 (Nonylphenol and nonylphenol ethoxylates). In relation to this restriction, two notifications were made, both by Germany. One product, a bathroom cleaner, which originated from China, contained approximately 0.9% of nonylphenol ethoxylate. The other product was a lime scale remover spray, which originated from Turkey. In both cases a ban on sales was imposed.

Entry 47 (Chromium VI compounds). Three notifications were made relating to cement originating from Latvia and the Ukraine, where the content of chromium VI found within the cement was found to exceed 0.0002%. The notifications were made by Estonia, Lithuania and Hungary. In each case the product was withdrawn from the market.

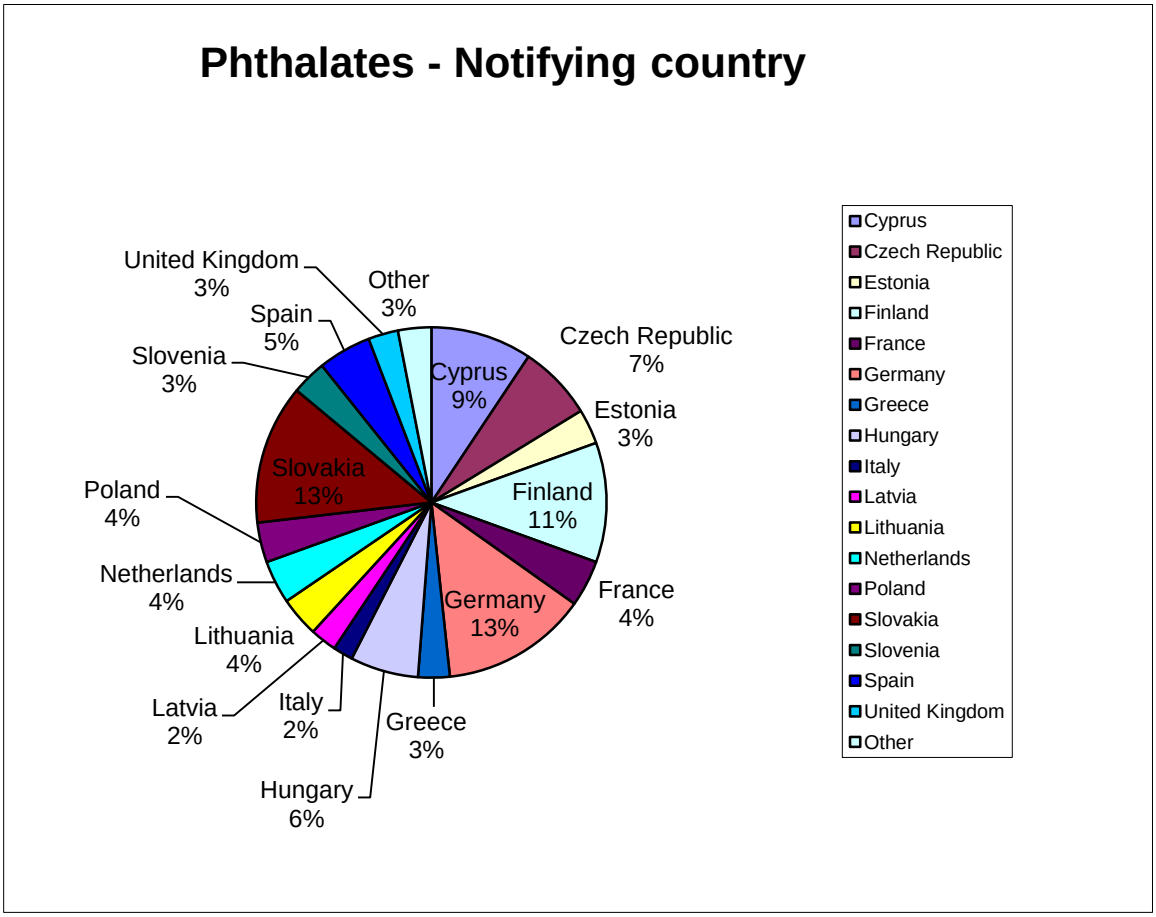
Entry 6 (Asbestos fibres). In total, 34 notifications were made in relation to asbestos fibres, which are restricted with respect to the manufacture, placing on the market and use of asbestos fibres and of articles containing asbestos fibres added intentionally. Of these cases, 25 of the products originated from China, two from the Czech Republic, one each from Germany, Malaysia, Turkey and the United States, and six were of unknown origin.

[83] *Implementation and Enforcement of Restrictions under Title VIII and Annex XVII to REACH in the Member States (*Milieu 2012). Available at: http://ec.europa.eu/environment/chemicals/reach/pdf/studies_review2012/report_study4.pdf.
[84] All reports up until Report 48 (02-12-2011) have been reviewed for the purposes of this analysis.

Entry 27 (Nickel). The restriction on nickel prohibits the use of nickel or nickel compounds in articles intended to come into contact with the skin, such as jewellery and buttons and other items on clothing. In total, 49 notifications have been made covering nickel, of which 31 of the products originated from China, four from India, two each from Thailand, Italy, and Turkey, one each from Taiwan, the Czech Republic, Poland and the United States, and four of unknown origin.

Entry 48 (Toluene). The use of toluene is restricted in adhesives or spray paints intended for supply to the general public. In total, 39 notifications have been made covering toluene, of which 15 of the products originated from China, six from Taiwan, six from the United States, five from Germany, three from Poland, and one each from France, Italy, Monaco and Sweden.

Phthalates (Entries 51 and 52). The use of phthalates as substances or mixtures is restricted in toys and childcare articles. In total 652 notifications have been made concerning the phthalates subject to this restriction. In terms of country of origin, 551 cases (85%) were notified by non-EU countries, 62 cases (9%) were notified by EU countries, and 39 cases (6%) were of unknown origin. The notifying countries, according to the number of cases notified, are represented in the following figure:



The degree to which customs authorities are involved in the implementation and enforcement of restrictions in each Member State varies from country to country. In some Member States, customs are specifically designated as an enforcement authority under REACH, while in other countries there is no legislative basis or guidelines available regarding the role of customs in the implementation and enforcement of restrictions.

3.5 METHODS FOR INSPECTION & MONITORING TO ENSURE COMPLIANCE

The **General Product Safety Directive** discussed above requires Member States to carry out market surveillance to ensure that producers comply with their obligations to make sure the products they place on the market are safe. Member States have powers to take special measures to address risks posed by products, including recall as a last resort. Article 8(3) requires Member States, in cases where a product may pose a serious risk, to assess each case on its individual merits, in deciding which risk management measures may be appropriate. Such measures need to be notified via RAPEX, so that other Member States and the Commission are informed. If the measure involves limiting the marketing or use of an individual consumer product, a risk assessment according to the ECHA Guidance on Information Reporting and Chemical Safety Assessment would need to be carried out.

The Commission also has powers under Article 13 to take special risk management measures if appropriate in view of a product's risk. The Commission may adopt a decision, using the comitology procedure, requiring all Member States to take the same measures (from those listed in Article 8(1)(b) to (f)), if the serious risk of a product requires urgent action at EU level. This could include restriction of of a substance on its own or in a mixture or as used in an article. This would have implications for the scope of REACH. Exports from the EU of dangerous products subject to an EU-wide measure adopted under Article 13 would be prohibited, unless the Commission Decision specified otherwise.

Finally, the Directive provides for giving mandates to CEN/CENELEC/ETSI to generate a safety standard for a specific product where a risk has been identified. This would serve as a type of restriction in that only products verified as being in compliance with the standard would be presumed as in compliance with the Directive.

The **Cosmetics Regulation** provides for a system of 'in-market control' according to which Member States must monitor compliance via controls of the cosmetic products made available on the market. They must perform appropriate checks on cosmetic products, as well as checks on the economic

operators through the product information file, and, where appropriate, carry out physical and laboratory checks on the basis of adequate samples. Member States must also monitor compliance with the principles of good manufacturing practices.

To ensure the effectiveness of the system, Member States must entrust to market surveillance authorities the necessary powers, resources and knowledge in order for those authorities to properly perform their tasks. Member States must periodically review and assess the functioning of their surveillance activities. Such reviews and assessments must be carried out at least every four years and the results thereof must be communicated to the other Member States and the Commission and be made available to the public, by way of electronic communication and, where appropriate, by other means.

The requirement that Member States must have market surveillance systems in place is also found in the Toys Safety Directive, the Paints Directive, the Detergents Directive, and the RoHS Directive.

4 PUBLIC POLICIES, PROGRAMS & INSTRUMENTS FOR SUPPORTING REDUCTION OF HAZARDOUS CHEMICALS IN ARTICLES

4.1 GREEN PUBLIC PROCUREMENT

Green public procurement (GPP) is a term that refers to efforts by public authorities to buy goods such as office equipment and to purchase services such as building maintenance and transportation that supply the same quality and functionality as the conventional choice but have lower environmental impacts. In addition to providing direct environmental benefits, such as reductions in CO_2 emissions by buying power from renewable energies, GPP can also help drive the markets towards more ecological products in general.

4.1.1 Green public procurement at EU level

Since public procurement accounts for some 16% of the European Union's overall GDP, the green public procurement approach can have a significant impact. In recognition of this potential, a 2008 Communication from the European Commission on 'Public procurement for a better environment'[85] set an indicative target of having 50% of all public tendering procedures in the EU be considered 'green' by 2010. It defined "green" as meaning that the procedures would comply with common EU GPP criteria for ten priority product/service groups such as construction, transport, cleaning products and services.

Two types of criteria were proposed for each sector covered:

- 'Core criteria' for use by any contracting authority across the Member States. These focused on the key environmental impacts and required minimum additional verification effort or cost increases.
- 'Comprehensive criteria' for those who wished to purchase the best environmental products available on the market, while acknowledging that additional verification effort or slight cost increases might be needed in comparison to other products with the same functionality.

Since 2008, the Commission has developed more than 20 common GPP criteria for priority sectors. The sectors were selected on the basis of a multi-criteria analysis including: scope for environmental improvement; public expenditure; potential impact on suppliers; potential for setting an example to private or corporate consumers; political sensitivity; market availability; economic efficiency; and the

[85] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0400:FIN:EN:PDF .

existence of relevant and easy-to-use criteria, such as the ecolabelling criteria described in the following subsection.

The table below lists the products and services for which common EU-level GPP criteria have been developed or are in the process of being developed.[86] The products and services having relevance for reducing hazardous substances in articles and products are highlighted in bold.

Products & services for which EU GPP criteria have been developed:	
Cleaning products	Indoor lighting
Cleaning services (in progress)	**Indoor/ outdoor paints, varnishes and road markings** (in progress)
Combined heat and power	**Office IT equipment**
Computers and laptops (in progress)	Road construction and traffic signs (under revision)
Construction (in revision as 'office buildings')	Sanitary tapware
Copying and graphic paper	Street lighting and traffic signals
Electrical and electronic equipment used in the Health Care Sector	**Textiles** (under revision)
Electricity (under revision as 'renewable electricity')	Toilets and urinals
Food and catering services (under revision)	Transport
Furniture (under revision)	**Wall panels**
Gardening products and services	Waste water infrastructure
Imaging equipment (in progress)	Water-based heaters

The Commission also developed a "GPP Training Toolkit"[87] consisting of three independent modules:

1. A strategic module aimed at raising political support for GPP;
2. A legal module on how to integrate environmental criteria into the public procurement process; and
3. An operational module aimed at purchasing officers.

However, according to a 2011 study for the Commission aimed to measure if the 50% target set in 2008 had been met, the uptake of GPP across the EU has been uneven[88]. In the absence of systematic statistics on GPP in the Member States, over 850 public authorities from 26 Member States were

[86] http://ec.europa.eu/environment/gpp/gpp_criteria_wp.htm.
[87] http://ec.europa.eu/environment/gpp/toolkit_en.htm
[88] http://ec.europa.eu/environment/gpp/pdf/CEPS-CoE-GPP%20MAIN%20REPORT.pdf .

surveyed concerning the "greenness" of their overall procurement in the period 2009/2010, including the use of core GPP criteria for one of the ten priority product/services. The survey found that only 26% of the contracts for the ten priority product/services had included all of the EU core GPP criteria. However, 55% of those contracts included at least one EU core GPP criterion, which indicated an overall positive trend. The uptake of the core GPP criteria varied significantly across the Member States, with as many as twelve countries using the core GPP criteria in less than 20% of the contracts surveyed. On the other hand, four countries (Belgium, Denmark, Netherlands and Sweden) stood out as having applied all EU core GPP criteria in 40% - 60% of the contracts surveyed.

With the aim of inspiring public purchasers to select greener products and services, the Commission has recently published a brochure of good practice examples of green public procurement[89]. One example is that of the city of Barcelona, which carried out a tender procedure for awarding new contracts for street cleaning and rubbish collection. The tender introduced a number of requirements to enhance the quality and sustainability of the services, including more frequent rubbish collection, environmentally-friendly vehicles, separate collection of organic waste, and recycling containers accessible to all users. Under the new contracts, noise and emissions from vehicles have been dramatically reduced, the increase in recycling and organic waste collection has allowed for a reduction in the number of ordinary waste bins, and Barcelona's streets are noticeably cleaner

Only a few of the GPP good practice examples collected by the Commission to date[90] are related to chemicals in articles and products, and these are mostly with respect to cleaning products. For example, in 2011 the French city of Ville de Venelles carried out a public tender for cleaning products for its preschools and elementary schools. It required bidders to provide a technical dossier outlining the environmental characteristics of all products to be supplied, and asked for samples. Products bearing the EU Ecolabel or equivalent were awarded additional marks. As well as presenting the most competitive offer financially, the successful tenderer is supplying products that contain no substances known as hazardous. Most are solvent free or with very low solvent content and biodegradability is high. Moreover, 96% of the products are available with refill packs or in reusable canisters, thus reducing waste. The city was very satisfied with the results of the tender process and stated it will follow this approach for future tenders.

[89] http://ec.europa.eu/environment/gpp/pdf/GPP_Good_Practices_Brochure.pdf.
[90] For other examples of GPP in practice, see http://ec.europa.eu/environment/gpp/case_group_en.htm.

4.1.2 The Swedish PRIO system

A useful tool for green public procurement with respect to chemicals in articles and products is the PRIO system developed by the Swedish Chemicals Agency (KEMI)[91]. PRIO is a web-based guide for decision making that aims to help purchasers, product developers and environmental managers to assess the health and environmental risks from chemical substances.

In particular, PRIO is helpful for identifying chemical substances of high concern because of their health or environmental effects. It divides these substances into two levels, based on their hazardous properties: (1) phase-out substances and (2) priority risk-reduction substances. Phase-out substances have properties of such high concern that they should not be used; these properties largely correspond to the criteria for substances that might be subject to authorisation under REACH. Priority risk-reduction substances have properties that are of concern and therefore should be assessed on the basis of the risk that could occur with respect to a particular use.

Every substance in the PRIO database has been given a prioritisation level that indicates how highly the substance should be prioritised in any risk-reduction effort. In addition to providing a priority setting-guide[92] based on individual substances, it also has tools for identifying what chemical products may be in a particular product or article. If the product is itself a substance or mixture of substances, a list of the chemicals used should be available, e.g., via the product's label.

It is more difficult to determine what chemicals may be contained in a particular article. PRIO suggests finding out the different materials that make up the article and then considering which substances are associated with various materials or additives. It provides the following simplified list of chemicals that might be found in articles.

Examples of chemicals in articles	
Textiles	formaldehyde, anti-mildew agents, flame retardants, dyes and impregnation agents, such as PFOS (perfluoroctane sulphonate)
Plastics & rubber	lead contaminants, chromates, tin contaminants, chloroparaffins, phthalates and possibly aromatics
Leather	tanning substances such as chrome
Metals	basic elements such as lead, iron, copper, mercury, aluminium, nickel, silver, tin and zinc, and also including alloys
Glass	lead, arsenic or antimony
Wood	wood preservatives which in turn contain chrome, arsenic, copper, creosote, etc.
Paper	colouring

[91] http://www.kemi.se/en/prio-start.
[92] http://www.kemi.se/en/prio-start/priority-setting-guide/start-the-priority-setting-guide/substances-in-chemical-products-or-in-articles.

PRIO then advises to consider what additional functions are intended to be achieved chemically, such as providing the product or material with colour, smell, sustainability, fire protection, impregnation, mildew protection, softness, etc., as a first step in identifying which chemical substances were added to achieve those functionalities. One suggestion is to find out which substances cannot be used in a product if it is be environmentally-labelled.

While the PRIO web-based tool provides a wealth of information about individual substances, it nonetheless requires a considerable commitment on the part of the user to be able to apply the information in a concrete public procurement situation.

4.2 EU ECOLABEL

The EU Ecolabel is a voluntary scheme, based on Regulation (EC) No 66/2010 on the EU Ecolabel[93], intended to promote those products which have a high level of environmental performance. It may be applied to any goods or services which are supplied for distribution, consumption or use on the Community market, with the exception of medicinal products and medical devices. Producers, importers and retailers can choose to apply for the right to use the label on their product.

4.2.1 EU Ecolabel criteria

In order to bear the EU Ecolabel, companies must comply with the EU Ecolabel criteria which set out the environmental requirements that a product must fulfil in order to participate in the scheme. The criteria are determined on a scientific basis considering the whole life cycle of products and taking into account factors such as the substitution of hazardous substances by safer substances, as such or via the use of alternative materials or designs, wherever it is technically feasible. The potential to reduce environmental impacts due to durability and reusability is also relevant, as is the net environmental balance between the environmental benefits and burdens, including health and safety aspects, at various life stages of the products.

Significant environmental impacts to be considered in the development of the EU Ecolabel criteria include pollution through physical effects and use and release of hazardous substances. The EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for

[93] Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel, O.J.L27, 30.1.2010, p.1.

reproduction (CMR), in accordance with the CLP Regulation, nor to goods containing substances referred to in Article 57 of REACH.

Development or revision of EU Ecolabel criteria may be initiated and led by the Commission, Member States, Competent Bodies or other stakeholders. The process can be started following consultation of the European Union Ecolabelling Board (EUEB), a body consisting of the representatives of the Competent Bodies of all the Member States and other interested parties. After this step the process is carried out in close collaboration with the European Commission and the EUEB.

The European Commission manages the scheme at the EU level to ensure that the Ecolabel Regulation is implemented correctly. The Commission also plays a key role in the development or revision of the EU Ecolabel criteria, even when the process is led by other parties, by preparing the final draft of the criteria documents and officially adopting the criteria as Commission decisions.

The EUEB is an advisory body that contributes to the development and revision of EU Ecolabel criteria and to any review of the implementation of the EU Ecolabel scheme. It also provides the Commission with advice and assistance in these areas and, in particular, issues recommendations on minimum environmental performance requirements. According to the Ecolabel Regulation, the EUEB must observe a balanced participation of all relevant interested parties in respect of each product group, such as competent bodies, producers, manufacturers, importers, service providers, wholesalers, retailers, notably SMEs, and environmental protection groups and consumer organisations.

At the national level, the scheme is managed by the Competent Bodies – independent and impartial organisations designated by states of the European Economic Area within government ministries or outside ministries. They act as the first point of contact for questions from applicants, assess applications and award the EU Ecolabel to products that meet the criteria set for them. They are responsible for ensuring the consistent, neutral and reliable implementation of the verification process. In order to exchange experiences and ensure consistent implementation of the scheme in different countries, the Competent Bodies meet three times a year at the Competent Body Forum in Brussels.

The EU Ecolabel may also be used in connection with other EU incentives for high environmental performance, such as the Green Public Procurement scheme.

4.2.2 EU Ecolabel Product Groups

To date, EU Ecolabel criteria have been developed for a wide range of product groups, from cosmetic and hygiene products to do-it-yourself and household items and tourist accommodation services. The

product groups currently under development include food and feed products, office buildings and cleaning services.

Example product groups containing chemicals	
Product Group	**Criteria**
Textiles	The EU Ecolabel criteria for textiles aim, in particular, at identifying products that have a lower environmental impact along their life cycle, with specific improvements so that they are: o sourced from more sustainable forms of agriculture and forestry o manufactured using resources and energy more efficiently manufactured using cleaner, less polluting processes o manufactured using less hazardous substances o designed and specified to be of high quality and durable The section in the criteria that addresses chemicals includes a Restricted Substance List (RSL) which provides concentration limit values for the substances included on the List, with specific requirements applicable for various production stages in the textile supply chain. The criteria also prohibit the use of certain hazardous substances in dyeing, printing and finishing. This list is additional to the general prohibition on the inclusion of Substances of Very High Concern, or those on the candidate list, in the final product. The complete ecological criteria for the award of the EU Ecolabel for textile products can be found here: http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1403869165475&uri=OJ:JOL_2014_174_R_0015.
Industrial and Institutional Laundry Detergents	The criteria for industrial and institutional laundry detergents have the particular aim of promoting products that have a reduced impact on aquatic ecosystems, contain a limited amount of hazardous substances and whose performance has been tested. The criteria furthermore aim at reducing the energy consumption from laundering by promoting products that are efficient at lower temperatures. Part of the criteria are dedicated to addressing toxicity to aquatic organisms and specify limit values for the Critical Dilution Volume, calculated by using the weight, degradation factor and the chronic toxicity factor of the substance, which the product must not exceed. The criteria also limit the use of certain substances and mixtures, and provide that substances meeting criteria for classification with certain hazard statements or risk phrases may not be used at all in the product. The complete ecological criteria can be found here: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32012D0721
All-Purpose Cleaners and Sanitary Cleaners	The EU Ecolabel criteria for all-purpose cleaners and sanitary cleaners aim, in particular, at promoting products that have a reduced environmental impact by limiting the quantity of harmful substances, by reducing the quantity of detergent used and by reducing packaging waste. The criteria furthermore aim at reducing or preventing of risks for the environment and for human health related to the use of hazardous substances, minimising packaging waste, providing information that will enable the consumer to use the product in the way that is efficient and minimising environmental impact.

	Similarly to the criteria for Industrial and Institutional Laundry Detergents, these criteria also provide limitations on and exclude various substances. They also address toxicity to aquatic organisms by prescribing the Critical Dilution Volume for each product type in the group. The complete ecological criteria can be found here: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011D0383

The complete list of product groups for which Ecolabel criteria have been developed

Cosmetics and Hygiene
- Rinse-off Cosmetic Products
- Absorbent Hygiene Products

Cleaning Up
- All-Purpose Cleaners and Sanitary Cleaners
- Detergents for Dishwashers
- Industrial and Institutional Automatic Dishwasher Detergents
- Hand Dishwashing Detergents
- Laundry Detergents
- Industrial and Institutional Laundry Detergents

Clothing and Textiles
- Textiles
- Footwear

Do-It-Yourself
- Paints and Varnishes

Electronic Equipment
- Imaging Equipment
- Personal Computers
- Notebook Computers
- Televisions

Coverings
- Wooden Floor Coverings
- Hard Coverings
- Textile Floor Coverings

Furniture
- Wooden Furniture

Gardening
- Growing Media* and Soil Improvers (*materials in which plants can grow, excluding soil)

Household Appliances
- Light Sources
- Heat Pumps
- Water-Based Heaters

Lubricants
- Lubricants

Other Household Items
- Bed Mattresses
- Sanitary Tapware
- Flushing Toilets and Urinals

Paper Products
- Converted Paper
- Newsprint Paper
- Printed Paper
- Copying and Graphic Paper
- Tissue Paper

Holiday Accommodation
- Campsite Services
- Tourist Accommodation Services

4.3 INITIATIVES TO PROMOTE SUBSTITION OF HAZARDOUS CHEMICALS

The table below lists private and public initiatives in the EU that have been identified as aiming to promote substitution of hazardous chemicals in products or that have objectives that overlap with substitution.

Initiatives to promote substitution			
Name of the initiative	**Who's behind it**	**Scope**	**Link/source**
SUBSPORT (Substitution Support Portal)	NGOs working together with academics, trade unions and government institutions under the LIFE+ Programme of the EU	The portal aims to provide companies, looking to substitute a hazardous substance, with legal information on substitution, a database on restricted and priority substances and analysis of existing substitution tools and case studies, among others	http://www.subsport.eu/
Norden – Nordic Innovation	Nordic Council of Ministers	Builds partnerships between Nordic public and private sector institutions to promote sustainability and innovation	http://www.nordicinnovation.org/no/
Substitution-cmr A tool to support the substitution of CMR substances	Anses - French Agency for Environmental and Occupational Health Safety	Aims to publicise CMR substitution activities and. By offering multiple levels of information, it aids those looking for alternative solutions to the use of CMR 1A and 1B substances.	www.substitution-cmr.fr
York Green Chemistry Centre of Excellence	University of York	Development and implementation of green and sustainable solutions	http://www.york.ac.uk/business/facilities-and-services/green-chemistry/
ChemSec	Swedish Society for Nature Conservation, WWF Sweden, Nature and Youth and Friends of the Earth Sweden	Mission is to substantially reduce the use of hazardous chemicals and their impact on health and the environment. Offers guidance and tools for effective chemicals management	http://www.chemsec.org/
The Great Recovery	Royal Society for the encouragement of Arts, Manufacture and Commerce	Builds new networks to explore the issues, investigate innovation gaps and incubate new partnerships.	http://www.greatrecovery.org.uk/
C2C Bizz	11 partners representing public bodies, research institutes and private companies from six EU countries.	The development of tools, instruments and guidelines to facilitate the application of C2C on business sites.	http://www.c2cbizz.com/
Circular Economy Task Force	Eight companies including BASF and Unilever convened by the Green Alliance	Compiles reports on barriers to the circular economy for business and has convened a workshop to identify new novel materials	http://www.green-alliance.org.uk/CETF
Circle Economy Netherlands	A network of around 50 companies	A cooperative aiming to create industrial systems that are restorative by design by decoupling growth and resource needs	http://www.circle-economy.com/
Sustainable Textile Production (STeP)	OEKO-TEX® association	Certification system for brands, retail companies and manufacturers from the textile chain who want to communicate their	https://step.oeko-tex.com/en/step/step_infopage/step_infopage.html

Initiatives to promote substitution			
Name of the initiative	**Who's behind it**	**Scope**	**Link/source**
		achievements regarding sustainable production to the public	

4.4 THE DATABASES MANAGED BY ECHA

The EU system for controlling chemicals in products depends on a number of tools at national as well as EU-level for managing and sharing information on substances and related hazards, and how they are used in products. The European Chemicals Agency in particular is an invaluable source of information on the chemicals manufactured and imported in Europe.

ECHA manages over two dozen databases containing information on chemicals and products collected by the EU over the past several decades, in the course of implementing the legal requirements that started in 1967 with the enactment of Directive 67/548/EEC on the classification, labelling and packaging of dangerous substances, and which took a major step forward with the adoption of REACH in 2006. Annex I provides a table that lists the databases held by REACH. It also describes the information held in each database and gives the URLs.

At the core of the ECHA information management system is REACH-IT, the central IT system that supports ECHA, Member State competent authorities and industry to submit, process and manage data and registration dossiers securely. The system provides the three parties with access to specific functions of REACH-IT as needed to fulfil their obligations under the REACH and CLP regulations. Other databases linked to REACH and to CLP and its predecessors are:

1. IUCLID 5 – International Uniform Chemical Information Database
2. Registered substances
3. Pre-registered substances
4. EC Inventory :
5. EINECS (European Inventory of Existing Commercial Chemical Substances),
6. ELINCS (European List of Notified Chemical Substances)
7. NLP (No-Longer Polymers)
8. Dossier Evaluation decisions
9. Current Testing Proposals
10. Substance evaluation - CoRAP
11. Information on Candidate List substances in articles
12. Candidate List of substances of very high concern for Authorisation
13. Authorisation List
14. List of Restrictions
15. PACT – RMOA and hazard assessment activities

16. C&L Inventory

ECHA also manages the databases necessary for implementing the Biocidal Products Regulation (Biocidal Active Substances, Biocidal Products, List of active substances and suppliers) and the PIC Regulation (Chemicals subject to prior informed consent (PIC), Export Notifications, Import Notifications, Explicit Consents and Waivers, Designated National Authority).

4.5 THE NORDIC COUNTRIES' PRODUCT REGISTERS

Four of the Nordic countries (Denmark, Finland, Norway and Sweden) maintain registers of chemical substances and of products comprised of those substances. Manufacturers and importers are required by national legislation to declare information on the uses and functions of the chemical mixtures and substances, as well as their classification, composition, quantities (volumes) and the industries where they can be found. None of the countries with product registers require notification of solid processed articles, such as textiles.

List of product registers in Nordic Countries		
Denmark	Arbejdstilsynet	http://engelsk.arbejdstilsynet.dk/en/Produktregistret.aspx
Sweden	Kemi - Produktregistret	https://www.kemi.se/en/Start/The-Products-Register/
Finland	Tukes - Kemikaalituoterekisteri	http://www.tukes.fi/en/Branches/Chemicals-biocides-plant-protection-products/Submitting-information-on-chemicals-/
Norway	Miljødirektoratet - Produktregisteret	http://miljodirektoratet.no/no/Tema/Kjemikalier/Produktregisteret/
The SPIN Database		http://195.215.202.233/DotNetNuke/default.aspx

Brief descriptions of each national database are provided below. Note that the four countries have collaborated to link their databases via the SPIN (Substances in Preparations in Nordic Countries) database.

4.5.1 Denmark

The Danish Product Registry is a joint registry under the Danish Working Environment Authority (WEA) and the Environmental Protection Agency. Companies that manufacture, import or change the trade name of any hazardous chemical substance and material used for commercial purposes in quantities equal to or exceeding 100kg per year must notify the Product Registry. Registration is free of charge.

The scope of the chemicals which must be notified includes (1) substances and materials that must be classified as hazardous in accordance with Danish regulations concerning classification and the CLP Regulation; (2) substances and materials included with a limit value in the WEA Executive Order on Limit Values for Substances and Materials; and (3) substances and materials that contain 1% or more of a substance included in the first two categories.

Categories of products exempt from the registration requirement include substances and materials used only in private households, those imported/manufactured in quantities of less than 100kg per year, and those that are manufactured or imported solely for research purposes in quantities less than 1000kg, for use by only a few individuals.

Biocidal products must be registered regardless of quantity or whether the use is commercial or private, and must also be approved by the Environmental Protection Agency. Special rules apply to the registration of substances or materials that are used in the offshore industry, covered by the OSPAR guidelines.

The data from the Product Registry is used by health authorities in connection with treating allergic reactions or dealing with accidents. The Environmental Protection Agency and the Working Environment Authority use extracts of the data to support and guide their regulatory functions.

4.5.2 Finland

In Finland, declarations for chemical products are made to the Product Register administered by the Finnish Safety and Chemicals Agency (Tukes). The duty to submit information to the registry is on the company responsible for placing the chemical on the market or into use in Finland. This may be the manufacturer, importer or another actor.

Registrations are processed for chemicals which have been classified in relation to health, environmental or physical hazard. Unclassified chemicals must also be declared if they contain a substance which is hazardous to health or environment, or a substance which has been assigned a limit value with regard to work-related exposure. The relevant limit values for work-related exposure can be found in Directives 91/322/ETY, 98/24/EY, 2000/39/EY, 2006/15/EY and 2009/161/EY.

Chemicals intended for professional use or general consumption must also be registered, with the exception of chemicals that are used in scientific research and development or product development

and supplied in quantities that are sufficiently small so as not to cause hazards. Non-hazardous chemicals, articles or cosmetics do not need to be notified.

4.5.3 Norway

Norway's Product Register is administered by the Norwegian Environment Agency. Chemicals classified as hazardous must be declared to the Register by manufacturers of consumers who manufacture, import and/or place substances on the market for occupational or personal use. The duty to declare applies when the annual volume of chemicals involved is 100kg or more, and the products which are covered include all chemical products (substances and mixtures) that are classified with respect to health, environmental or fire and explosion hazards under section 6 of the Chemical Labelling Regulations or article 3 of the EU's CLP Regulation.

Physical data that is relevant for determining the potential hazardous properties of the chemical must be declared, and this includes information about the content of substances in nano form in the chemical products. Microbiological products must be declared regardless of their quantity, as must biocidal products. Chemicals that do not normally be declared can also be made subject to declaration due to the Product Control Act / Working Environment Act.

All Norwegian authorities can be granted access to the Product Register for professional purposes such as supervision of labelling and documentation, risk analyses and different areas of use, compiling statistics, planning and exercising inspections etc.

4.5.4 Sweden

Manufacturers and importers wishing to place products subject to chemicals control on the Swedish market are obliged to register products to the Products Register which operates under the Swedish Chemicals Agency (KemI). Regardless of the annual volume of the chemical products, any company planning to start an operation in Sweden involving manufacture or import of chemicals is obliged to file an Activity report to the Products Register.

If the product volume manufactured or imported reaches the minimum amount of 100kg per product, the company which manufactures, imports or changes the name of the chemical product must submit a Product Report. This applies to products which are determined to be reported under the statistical Customs Tariff Number in the annex to the Chemical Products and Biotechnical Organisms Ordinance (2008:245). It may be possible for a commercial agent to obtain a permit to fulfil the reporting obligation instead of the company responsible for importing.

In order to place pesticides on the market, the company must also apply for product authorization, in addition to the other steps.

The information in the Register is used to support supervisory activities and to gain an overview of chemical products used in Sweden. It is also used to calculate the amount of the annual chemical charge applicable to the company reporting products. Other authorities, researchers, various organisations and the general public may request the information, subject to a confidentiality evaluation.

4.5.5 The SPIN Database

Product Registries in Norway, Sweden, Denmark and Finland have collaborated to create the SPIN database (www.spin2000.net), which contains data on the use of substances in products in the Nordic Countries. It is financed by the Chemical Group of the Nordic Council of Ministers. The SPIN database is available as a program and a database for download on the internet. It is also available as a stand-alone version, which gives some further possibilities when reporting and exporting the data.

The SPIN database has a toolbox called SPIN Exposure Toolbox, which includes a 'Use Index' tool that makes it possible to search for indicative exposures of humans and the environment from different chemical uses.

5 NATIONAL MEASURES IN THE UNITED KINGDOM

5.1 THE LEGAL FRAMEWORK

The United Kingdom's regulatory framework relevant for controlling hazardous substances in products, including articles, virtually mirrors the framework in place on EU level. For example, the UK's General Product Safety Regulations 2005 transposed the requirements of Directive 2001/95/EC, including that no producer should place a consumer product on the market unless it is safe. Moreover, the UK regulations on the safety of toys are based on Directive 2009/48/EC on the safety of toys, including the limits set therein concerning the permissible limits of certain chemicals for certain types of toys.

Note that both REACH and CLP have the legal form of an EU Regulation and therefore are directly applicable in the UK and other Member States. The table below shows some of the national acts that have been set in place to implement the various EU acts.

The EU act	The equivalent UK act
Regulation (EU) No 1272/2008 on classification, labelling and packaging of hazardous substances	The Classification, Labelling and Packaging of Chemicals (Amendments to Secondary Legislation) Regulations 2015
Regulation (EU) No 1907/2006 (REACH)	The REACH Enforcement Regulations 2008
Regulation (EU) No 528/2012 on biocidal products	The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 (SI 2013/1506)
Regulation (EC) No 1223/2009 on cosmetic products	The Cosmetic Products Enforcement Regulations 2013 (SI 2013/1478)
Directive 2009/48/EC on the safety of toys	The Toys (Safety) Regulations 2011 (SI 2011/1881)
Directive 2001/95/EC on general product safety	The General Product Safety Regulations 2005

5.2 INSTITUTIONAL ARRANGEMENTS FOR IMPLEMENTATION & ENFORCEMENT

The UK authorities given enforcement responsibilities by the REACH Enforcement Regulations 2008 (the 'Enforcement Regulations') are those which already have mandates to protect human health, consumer safety, and the environment:

- the Health and Safety Executive (HSE);
- the Health and Safety Executive for Northern Ireland (HSENI);
- the Environment Agency (EA);
- the Scottish Environment Protection Agency (SEPA);

- the Northern Ireland Environment Agency (NIEA);
- the Department of Energy and Climate Change (DECC); and
- - local authorities (LAs), as regards occupational health and safety and consumer protection (trading standards).

The UK Department for Business, Innovation and Skills (BIS) is responsible for providing guidance to manufacturers concerning product safety, and for enforcement of product standards. Other relevant public bodies involved in the implementation and enforcement of controlling hazardous substances in products and articles are described below.

1.2.1 The Department for the Environment, Food and Rural Affairs (DEFRA)

The Department for the Environment, Food and Rural Affairs (DEFRA) is the lead UK Government department for REACH, and acts in this capacity on behalf of the devolved administrations (England, Scotland, Wales and Northern Ireland). It is responsible for the implementation of REACH in the UK, which includes developing and implementing the UK enforcement regime[94].

1.2.2 The Health and Safety Executive (HSE)

The UK Health and Safety Executive (HSE) acts as the lead UK Competent Authority for REACH. It enforces REACH requirements concerning registration, as well as supply related duties up to the point of sale. The HSE is also responsible for administering the Control of Pesticides Regulations (COPR) requirements.

The HSE has a number of inspectors placed around the country who carry out product surveillance along the supply chain until point of sale. The HSE uses a proactive inspection model, i.e., a targeted intelligence driven approach. They gather intelligence on supply chain activity and compare this information to existing records. This enables them to target those companies that seem to be in breach of the core requirements of REACH. The HSE also provides a helpdesk to provide information with all inquiries related to REACH compliance.

1.2.3 The Department for Business, Innovation and Skills (BIS)

The UK Department for Business, Innovation and Skills (BIS) is responsible for providing guidance to manufacturers concerning product safety. It oversees enforcement of the General Product Safety

[94] http://www.hse.gov.uk/reach/resources/enforcementstrategy.pdf

Regulations 2005, as well as the implementation and enforcement of the safety regulations for cosmetic products and for children's products, including toys[95].

The BIS publishes an annual general national market surveillance programme for the UK[96]. It also hosts the UK's RAPEX unit. It is the go-to authority, to ensure consistency in surveillance/enforcement throughout the 230 local trading authorities in the UK. The RAPEX unit ensures that the Trading Standards departments (see below) have correct information and use adequate documentation when issuing notifications to the European Commission.

The RAPEX unit also relays information on possible dangerous products to the Local Trading Standards Departments so that they can investigate those products that are of the highest risk in the UK market. For larger risks, the RAPEX unit will also advise each Trading Standard Department what measures were taken to restrict its marketing and distribution.

The RAPEX unit advises on the information required when there is a divergence in the risk assessment of a UK supplied product notified by other Member States. The unit also deals with enquiries on RAPEX procedures or information on products notified on the RAPEX.

1.2.4 Local Trading Standards Departments

In the UK, the local authorities, i.e., the local councils, are responsible for consumer protection and for market surveillance at point of sale, through their Local Trading Standards Departments. The Local Trading Standards Departments have the necessary powers to take measures to prevent or restrict the selling or use of dangerous products.

The Local Trading Standards Departments employ trained trading standards officers (TSOs) who advise on consumer law, investigate complaints and prosecute traders who break the law. This is on the ground enforcement at the level of point of sale. Each local authority acts independently and sets out its own priorities for investigation.

The trading standards officers will notify the RAPEX unit in the Department for Business, Innovation and Skills (BIS) or other relevant national competent authority to take appropriate action as necessary to eliminate any risks identified risk, e.g. by withdrawing the product from the market. When serious risks are identified, the RAPEX unit will issue an alert to the other 230 Local Trading Standards Departments across the UK.

[95] https://www.gov.uk/guidance/product-safety-for-manufacturers#introduction
[96] https://www.gov.uk/government/publications/general-national-market-surveillance-programme-for-the-uk-december-2012-2013-new-legislative-framework

1.2.4 Other Enforcing Authorities

Other authorities and organisations that have important roles to play include:

• *the UK Border Agency (UKBA)* is responsible for controls at UK points of entry to detect illegal imports of prohibited and restricted goods. UKBA may provide assistance by detaining goods at import for a maximum of two working days, either when requested to do so or in the event that UKBA have reasonable grounds to suspect that goods may be being imported which are in breach of REACH.

• *HM Revenue & Customs (HMRC)* is responsible for delivering customs clearances for imports from non EU countries and for operating the import customs declaration system. HMRC may disclose information obtained or held in the exercise of its functions relating to imports, to facilitate the exercise of a duty of an enforcing authority under the Enforcement Regulations.

Due to the large number of organizations involved in enforcement of REACH, cooperation and coordination is essential. An enforcement liaison group has been set up to coordinate among enforcing agencies. It provides advice to industry on REACH developments, determines priority issues for enforcement activity, and discusses merging enforcement issues.

1.2.5 UK Chemicals Stakeholder Forum

The UK Chemicals Stakeholder Forum (UKCSF) [97] advises government on managing risks to the environment and to human health via the environment that may result from the production, distribution and use of chemicals. The forum works alongside other departments and government bodies including the Health and Safety Executive, the Department for Business Innovation and Skills and the Environment Agency.

The forum is intended to serve as a strategic body that looks at sustainable consumption and production throughout the chemicals supply chain, the life cycle of chemicals, the precautionary principle, and the need to add value and not replicate activities undertaken elsewhere. Among other things, it is charged with

- reviewing the effectiveness of REACH in realising its goals in the light of the experience and needs of UK stakeholders;
- communicating and encouraging best practice and innovation; and

[97] https://www.gov.uk/government/groups/uk-chemicals-stakeholder-forum

- promoting more effective linkages throughout the chemicals supply chain.

The Forum also receives expert advice from the Hazardous Substances Advisory Committee (HSAC)[98] on how to protect the environment, and human health via the environment, from potentially hazardous substances and articles, including nanomaterials. HSAC is the successor body to a previous UK Advisory Committee on Hazardous Substances (ACHS).

5.3 GREEN PUBLIC PROCUREMENT IN THE UK

A 2009 study on green public procurement in the EU[99] that compared seven Member States (Austria, Denmark, Finland, Germany, the Netherlands, Sweden and the UK) found that the UK procures 75% green products by percentage of total procurement value, and 59% by proportion of total contracts awarded. The study looked mostly at the overall reduction in lifetime CO_2 emissions achieved compared to non-green public procurement of the same product categories, primarily arising from construction and electricity procurement, with a concurrent 5.7% reduction in total costs (considering Life Cycle Costing). It did not look at how green public procurement had affected the use of toxic substances in the product categories reviewed. Nonetheless, the study concluded that considerable scope remained to increase GPP, and to increase the proportion of GPP assessed by more stringent criteria[100].

In 2008, the UK government established the Centre of Expertise in Sustainable Procurement within the Office of Government Commerce, with the aim of coordinating the achievement of the "Sustainable Procurement Action Plan (SPAP)" commitments and to support departments of government in achieving these GPP goals by identifying and removing barriers and building capability. As part of this effort, DEFRA has developed a number of sustainable public procurement standards.[101]

[98] https://www.gov.uk/government/groups/hazardous-substances-advisory-committee
[99] http://ec.europa.eu/environment/gpp/pdf/statistical_information.pdf
[100] http://www.gov.scot/Publications/2009/08/18161245/8
[101] http://www.amec-ukenvironment.com/downloads/pp_1772.pdf

6 NATIONAL MEASURES IN SPAIN

6.1 THE LEGAL FRAMEWORK

Spain's regulatory framework for controlling hazardous substances in products also basically follows the framework in place on EU level. The table below shows some of the national acts that have been set in place to implement the various EU acts.

The EU act	The equivalent act in Spain
Regulation (EU) No 1272/2008 on classification, labelling and packaging of hazardous substances	Royal Decree 1436/2010 modifying several Royal Decrees to adapt them to Directive 2008/112/EC
Regulation (EU) No 1907/2006 (REACH)	Royal Decree 1802/2008 modifying the Regulation on notification of new substances and CLP of hazardous substances adopted by Royal Decree 363/1995 to adapt it to Regulation (EC) 1907/2006 (REACH Regulation). Law 8/2010 establishing the sanctions regime foreseen in the Regulations (EC) on REACH and on CLP which modifies it.
Regulation (EU) No 528/2012 on biocidal products	Royal Decree 1054/2002 regulating the evaluation procedure for the register, authorisation and commercialisation of biocidal products.
Regulation (EC) No 1107/2009 on plant protection products	Royal Decree 1311/2012 establishing the action framework to achieve a sustainable use of plant protection products. Royal Decree 971/2014 regulating the evaluation procedure of plant protection products. Law 43/2002 on plant health.
Regulation (EC) No 1223/2009 on cosmetic products	Royal Decree 1599/1997 on cosmetic products. Amended by Royal Decree 209/2005 of 25 October.
Directive 2009/48/EC on the safety of toys	Royal Decree 1205/2011 on the safety of toys.
Directive 2001/95/EC on general product safety	

6.2 INSTITUTIONAL ARRANGEMENTS FOR IMPLEMENTATION & ENFORCEMENT

In Spain, competences on environmental issues are distributed between the federal State, the Autonomous Regions (*Comunidades Autónomas, CCAAs*) and local entities (*Entidades Locales, EELLs*). Although under the Spanish Consistution (CE), the State holds the exclusive competence to issue framework legislation on environmental matters[102], the CCAAs can adjust this legislation to the specific needs at regional level, as can EELLs.

[102] Article 149.1.23 CE.

6.2.1 Ministry of Health Social Services and Equality (MSSI)

The competent authority regarding hazardous substances at national level is the Ministry of Health, Social Services and Equality (*Minsiterio de Salud, Servicios Sociales e Igualdad*, MSSSI). In particular, the General Secretariat of Health and Consumers (*Secretaría General de Sanidad y Consumo*), is in charge of promoting the defence of consumers and carrying out the highest level surveillance functions[103]. The MSSI establishes and develops the requirements regarding the classification, packaging, labelling and safety sheets of hazardous substances.

In carrying out these activities, the MSSSI coordinates with the Ministries of Work, Social Security, Industry, Energy, Public Works, Transport and Environment and the public authorities with tasks related to chemicals. For example, the Ministry of Agriculture, Food and Environment (*Ministerio de Agricultura, Alimentación y Medio Ambiente*, MAGRAMA) holds competences regarding the environmental aspects related to the use of chemicals through its General Directorate of Environmental Quality and Evaluation (*Dirección General de Calidad y Evaluación Ambiental del Ministerio de Medioambiente*) and, regarding plant-protection products, through its General Directorate on Agriculture (*Dirección General de Agricultura*).[104]

Sub-Directorate General on Environmental and Occupational Health

Directly falling within the scope of the General Secretariat, the General Directorate on Public Health, Quality and Innovation (*Dirección General de Salud Pública, Calidad e Innovación*) has a Sub-Directorate General on Environmental and Occupational Health (*Subdirección General de Sanidad Ambiental y Salud Laboral*) is in charge of carrying out the control of chemical products hazardous to health aiming to protect the environment and the human health against the risks resulting from hazardous substances. In particular, the Sub-Directorate is in charge of[105]:

- Registering, authorising and evaluating the risk to human health of biocides and chemical products.
- Implementing the communications system of new chemical substances.
- Examining plant protection products.
- Transposing the EU legislation on control of chemical products in all issues having an impact on human health.

[103] Royal Decree 200/2012, developing the basic organic structure of the Ministry of Health, Social Services and Equality and modifying Royal Decree 1887/2011 establishing the basic organic structure of the Ministerial Departments, available in Spanish at http://www.boe.es/buscar/act.php?id=BOE-A-2012-1034&p=20151030&tn=1#a10, Art. 10.
[104] Art. 17 (1) (b) and (c) Royal Decree 255/2003 of 28 February adopting the Regulation on the classification, packaging and labelling of hazardous compounds, available in Spanish at http://www.boe.es/buscar/act.php?id=BOE-A-2003-4376.
[105] Website of the MSSSI.

6.2.2 Spanish Agency on Consumption, Food Safety and Nutrition (AECOSAN)

AECOSAN is a public entity operating under the MSSSI[106]. It is in charge of supervising and controlling the presence of chemicals in food products and non-food products which could have an impact in the health and safety of consumers. AECOSAN is the contact point for RAPEX, and as such communicates to the European Commission any action taken on the matter of control of chemical substances both in the national Spanish market and in the imports of products that might be considered as hazardous.

In addition, the Inspection Service SOIVRE (*Servicio Oficial de Inspección Vigilancia y Regulación de las Exportaciones*) monitors imports of products which could pose risks to health and safety. This Service informs AECOSAN on the products that have been refused for importation, those which have been imported under the condition that the defects are corrected and those which have been imported and, after examination, have been determined to be unsafe. Based on this information, AECOSAN decides on which data has to be notified to RAPEX.[107]

According to the European Commission[108], Spain was the Member State which submitted the third highest number of alerts (after Germany and Hungary) to RAPEX during 2014 with a total of 272 notifications on dangerous products. In 198 of these cases, Spain took immediate measures to handle the dangerous products, such as not allowing the import of certain products and immediately notifying RAPEX on the existence of such products.

In 2013, Spain submitted 254 alerts to RAPEX. That same year, AECOSAN received information on the withdrawal from the market of 1,112,997 unsafe products. Of the 514,086 products refused for importation by SOIVRE, 86% came from China. The main breaches detected were: irregularities in the composition of products, presence of chrome VI, presence of phthalates, small pieces and presence of forbidden substances under the applicable legislation.[109]

[106] Royal Decree 19/2014 merging the National Consumption Institute and Spanish Agency on Food Safety and Nutrition in a new public independent entity named Spanish Agency on Consumption, Food Safety and Nutrition, available in Spanish at http://www.boe.es/buscar/act.php?id=BOE-A-2014-1092.
[107] Website of the Spanish State Secretariat on Trade, 'The number of RAPEX notifications grows in Spain in 2013' (*Crece el número de notificaciones RAPEX de España durante el año 2013*).
[108] European Commission, 'Keeping European consumers safe. Rapid Alert System for dangerous non-food products 2014. Complete Statistics' (2014).
[109] See The number of RAPEX notifications grows in Spain in 2013'.

6.2.3 Spanish Agency of Medicines and Medical Devices (AEMPS)

MSSSI also oversees the public entity *Agencia Española de Medicamentos y Productos Alimentarios* (AEMPS)[110]. In addition to controlling the presence of chemical hazardous substances in medicines and medical devices, and carrying out inspections and following up on products which could hinder the health of consumers, this Agency monitors the safety of cosmetics and other personal care products. The AEMPS has coordination committees with competent authorities from the Autonomous Communities (*Comunidades Autónomas*, CCAA).

6.2.4 The Autonomous Communities at regional level

The Autonomous Communities hold surveillance, inspection, control and sanctioning competences under the Spanish legislation on hazardous chemical substances and compounds.[111] Although each CCAA may structure the competent entities following their own criteria, most of them use the Health Councils (*Consejería de Salud*) competent in each Autonomous Community for carrying out the monitoring, control and detection of chemicals which could pose a risk to the safety and health of people and the environment, including hazardous substances. These Health Councils gather information on chemicals and provide it to the information system of the MSSSI which keeps centralised records and registers on chemical substances and compounds, including hazardous substances (see below).

6.2.5 National Network on Toxic Surveillance

The Spanish National Network on Toxic Surveillance (*Red Nacional Toxicovigilancia*, RNT)[112] operating under the MSSSI also carries out surveillance. This Network detects and identifies risks posed to health by hazardous chemical substances and compounds, spotting the concerned products and substances and controlling their presence in the market. Data is provided to the RNT on a voluntary basis through an on-line questionnaire in poisoning or accident cases attended in hospitals belonging to the Network.

6.2.6 National Institute of Toxicology and Forensic Sciences

The National Institute of Toxicology and Forensic Sciences (*Instituto Nacional de Toxicología y Ciencias Forenses*, INTCF) also contributes to monitoring the use of chemicals in Spain. Importers and downstream users trading with hazardous chemical compounds have to notify them to the

[110] Website of the AEMPS.
[111] Website of the MSSSI and Art. 24 (2) RD 363/1995.
[112] Website of the Spanish National Network on Toxic Surveillance.

INTCF.[113] Breaching this obligation is considered a serious offence. The Institute is responsible for receiving information relating to emergency health response as required under the CLP Regulation.[114]

6.2.7 Register of chemicals

Under Spanish legislation, the manufacturer placing in the market a hazardous substance or a compound manufactured in the EU has the obligation to notify it to the competent authorities. For substances or compounds from outside the EU, this obligation lies with the natural or legal person established within the EU who places them in the market or has been appointed as only representative of the manufacturer.[115] This information then enters the information system set up by the MSSSI, which is composed of the following tools:[116]

- The General Directorate on Public Health of the MSSSI keeps a register of biocides and new chemical substances.
- The General Directorate of Pharmacy and Healthcare Products maintains a register of pesticides.
- The National Network on Toxic Surveillance maintains a network of hospitals where data on accidents and intoxications due to chemicals is gathered.

The information system also coordinates at regional level, with the Health Councils of the Autonomous Communities.

6.3 GREEN PUBLIC PROCUREMENT IN SPAIN

The Council of Ministers issued the State Plan on Green Public Procurement in 2008.[117] The State GPP Plan aims at implementing environmental friendly practices in the public procurement sector to achieve the goals set therein for eight different sectors: construction and maintenance, transport, energy, office equipment, publications, furnishing, cleaning and events. The objectives for each of these sectors are in line with the objectives established at EU level.[118] For instance, the Plan aims to ensure a 20% in water saving by 31 January 2010 by installing saving systems in all buildings or reducing in 20% the consumption of fossil fuels.[119]

[113] Third Additional Provision (*Disposición Adicional* Tercera) of Law 8/2010.
[114] Art. 45 (1) Regulation 1272/2008.
[115] Art. 2 (1) (d) in relation with Art. 7 of RD 363/1995.
[116] Art. 16 RD 255/2003.
[117] Order PRE/116/2008, of 21 January, publishing the Resolution of the Council of Ministers adopting the State Plan on Green Public Procurement, available in Spanish at http://www.boe.es/boe/dias/2008/01/31/pdfs/A05706-05710.pdf.
[118] Website of MAGRAMA, Plans and Strategies, 'Green Public Procurement Plan' accessible in Spanish at http://www.magrama.gob.es/es/ministerio/planes-estrategias/plan-de-contratacion-publica-verde/default.aspx.
[119] Annex to Order PRE/116/2008.

The Ministry of Agriculture, Food and Environment (*Ministerio de Agricultura, Alimentación y Medioambiente*, MAGRAMA) is responsible to promote policies in this matter and ensure the implementation of the Plan through the Sub-Secretariats of the corresponding Ministry in regard of the sector concerned.[120] Two reports have been issued to follow up on the implementation of the Plan, one in 2011[121] and one in June 2015[122]. The latter notes the achievements to date in implementing the Plan and recommends expanding the Plan to new sectors. It also suggests development of more guidelines and promotion of information exchanges with the stakeholders involved. Note that the MAGRAMA has already carried out GPP training for entities at central, regional and local level as well as established a helpdesk.[123]

Some CCAAs have also developed regional GPP programmes, for example, Madrid,[124] Catalonia,[125] Aragon[126] and Basque Country[127]. In general, the implementation of these programmes is overseen by the regional environmental authority. For example, the Basque government does so through the environmental agency IHOBE.[128] At local level, some bigger cities such as Barcelona ("+SCC Programme") and Madrid have GPP Plans. +SCC also covers monitoring the implementation and achievement of the targets set therein. Awareness raising and training is also being carried out by networks of local authorities in Catalonia, the Basque Country, Navarra and Andalucía.129

The main focus of Spain's State Plan on GPP is to save energy and water and to recycle more and better. With respect to chemicals in products, the State Plan specifies that wood shall not be treated with substances or compounds considered as pesticides by the WHO under categories 1A and 1B. It also provides that for new public contracts in the furnishing sector, one criterion will be that the products are hazardous-chemical free. In the cleaning sector, the Plan also specifies that the separate

[120] Part IV (1) Order PRE/116/2008.
[121] MAGRAMA, General Report on the Status of GPP, available in Spanish at http://www.magrama.gob.es/es/ministerio/planes-estrategias/plan-de-contratacion-publica-verde/Contrataci%C3%B3n_P%C3%BAblica_Verde_en_la_AGE_tcm7-181224.pdf.
[122] MAGRAMA, II General Report on the Status of GPP at State level, available in Spanish at http://www.magrama.gob.es/es/ministerio/planes-estrategias/plan-de-contratacion-publica-verde/segundoinformegeneralsobreelestadodelacontratacionpublicaverdeenlaage_tcm7-389194.pdf.
[123] European Commission, 'National GPP Strategies - Spain' available at http://ec.europa.eu/environment/gpp/pdf/national_gpp_strategies_en.pdf.
[124] Website of the Government of Madrid, Entrepreneurship and GPP, accessible in Spanish at http://www.compraenverde.org/quienes-somos.
[125] Website of the Government of Catalonia, Sustainable GPP, accessible in Spanish at http://comprasostenible.net/.
[126] Website of the Government of Aragon, 'GPPs', accessible in Spanish at http://www.aragon.es/DepartamentosOrganismosPublicos/Departamentos/DesarrolloRuralSostenibilidad/AreasTematicas/MA_EducacionSensibilizacion/ComprasVerdes/ci.03_Compras_Verdes.detalleDepartamento?channelSelected=f1f736552883a210VgnVCM100000450a15acRCRD.
[127] Website of the Government of Basque Country (IHOBE Basque Agency for Environmental Management) accessible in Spanish at http://www.ihobe.eus/Paginas/Ficha.aspx?IdMenu=95390acd-6155-45cc-b339-1e2b3e4435ef&Idioma=es-ES.
[128] European Commission, 'National GPP Strategies - Spain' available at http://ec.europa.eu/environment/gpp/pdf/national_gpp_strategies_en.pdf.
[129] Ibid.

collection of waste and its proper treatment will be a target to achieve, which might be interpretable as including hazardous substances.

7 CONCLUSIONS

7.1 THE LEGAL FRAMEWORK

The European Union has one of the most robust regulatory frameworks in place for controlling hazardous substances in products – surpassed only by a few of the more northern EU Member States such as Sweden and Denmark. The EU legislation in this area is intended to address concerns related to the health of humans and the environment, and at the same time set common standards to enable the free circulation of goods. Because of this internal market aspect, most Member States legislation on hazardous substances in products essentially mirrors the EU requirements.

The REACH and CLP Regulations provide a strong legal foundation that clearly puts the burden on chemical manufacturers and importers to provide data on the hazardous properties of the substances they introduce onto the EU market. They must also assess, classify and label those substances and mixtures and to communicate that information downstream, so as to ensure that the substances and mixtures are safe for the intended use.

As a result, the EU is the first jurisdiction to work on filling the gaps in hazard information for those substances already marketed in Europe back in the 1960s and 1970s, when the industrialised economies first set chemicals controls in place. While this is certainly an advantage, it is proving burdensome for certain small and medium-sized enterprises, e.g., importers of substances from third countries. Moreover, it is proving to be a time-consuming process.

In addition to these basic rules, the EU has adopted a number of rules covering specific substances and mixtures in light of certain concerns. In some cases, the various acts in combination provide important coverage, such as in the case of the Detergents Regulation which focuses on the biodegradability of surfactants, and where any ingredients included for their antibacterial effect are governed by the Biocidal Products Regulation.

However, because these rules are aimed at addressing specific risks, gaps may arise vis à vis other risks. For example, the Cosmetics Products Regulation focuses on preventing harm to human health, but does not consider environmental risks related to those products.

In light of the highly technical nature of some product standards, the EU is increasingly relying on the so-called 'New Legislative Approach'. Under this regulatory regime, the legislator sets a number of essential safety and performance requirements for a particular product type, and then delegates responsibility to the European standard-setting bodies such as the Comité Européenne Standardisation

(CEN) to develop technical standards. Products that are assessed as being in conformity with the technical standards are then presumed to meet the essential requirements. They can then bear the CE marking and be marketed throughout the EU Member States. The Toy Safety Directive and the Construction Products Regulation are examples of this type of regulatory approach.

The advantage of the New Legislative Approach is that the manufacturers have the most information about a product and are therefore the best placed to consider technical standards. The disadvantage is that it is industry setting the rules, which some have likened to asking the fox to guard the henhouse. The first draft setting standards for the essential requirements set in the Packaging and Packaging Waste Directive was rejected because the standards covering hazardous substances in packaging were not stringent enough. In the case of electrical and electronic equipment, requirements related to hazardous substances were separated from the essential requirements set in the WEEE Directive and are now covered by the RoHS (Restrictions of Hazardous Substances) Directive.

In the EU regime, the General Product Safety Directive plays a special role. It establishes the general rule that producers shall place only 'safe' products on the market. Producers are also responsible for informing consumers of any risks associated with the products they supply, and for taking appropriate measures to prevent such risks including tracing of dangerous products when required. The Directive provides the legal basis for removing any products or articles from the marketplace which are found to be unsafe because of their hazardous substance content. The Directive thus acts as a type of safety net for catching any product not covered by a specific safety requirement.

7.2 INSTITUTIONAL ARRANGEMENTS FOR IMPLEMENTATION & ENFORCEMENT

The EU Treaties charge the European Commission with responsibility for ensuring the proper implementation of EU legislation. However, on the ground implementation and enforcement is the responsibility of the Member States. Both REACH and CLP require 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. Similarly, most of the EU product-related acts require Member States to set in place market surveillance structures, in order to monitor the goods on sale within their boundaries.

The RAPEX network established under the General Product Safety Directive is an important structure for circulating information among the Member States when an unsafe product is identified. RAPEX is also important for coordinating the responses taken to protect consumers from those risks.

As the brief summaries of the institutional arrangements in place in both the United Kingdom and Spain reveal, the monitoring of the marketplace for compliance of products with the EU requirements is largely the role of regional and local authorities. In both Member States, the RAPEX network is important for linking the various local and regional authorities to the national coordinating body, which in turn links to the market surveillance activities under way in other Member States.

7.3 PUBLIC POLICIES, PROGRAMS & INSTRUMENTS

EU-level efforts to provide incentives for reducing the use of hazardous substances in products have to date mainly focused on green public procurement and eco-labelling. With respect to green public procurement (GPP), the uptake has been uneven across the EU Member States. A 2011 study found that four countries (Belgium, Denmark, Netherlands and Sweden) had applied all EU core GPP criteria in 40% - 60% of the contracts surveyed; however, another twelve countries had used the core GPP criteria developed by the EU in less than 20% of procurement procedures. Moreover, the core GPP criteria related to energy use and CO2 emissions appear more frequently as examples of good practice, with fewer examples to be found relating to chemicals in articles and products, and these mostly with respect to cleaning products.

Another incentive that may be used in connection with green public procurement is the EU Ecolabel, a voluntary scheme intended to promote those products which have a high level of environmental performance. The EU Ecolabel has a direct link to the goal of reducing hazardous substances in products in that it may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR), nor to goods containing substances referred to in Article 57 of REACH, such as PBT or vPvB.

The EU's efforts to support the process of substitution of hazardous substances in products have mainly consisted of funding. In this regard, the SUBSPORT project funded by the LIFE+ programme – which provided a web-based portal with information on substitution -- should be mentioned. However, in the absence of new funding, the future of SUBSPORT is uncertain.

The information systems maintained by the European Chemicals Agency (ECHA) should be mentioned as an essential element of the effort to reduce the use of hazardous substances in products. Also important are the product registers maintained by the Nordic countries. However, these product registers focus mainly on products that are mixtures of substances, and information on what substances might be in a given article is still lacking.

The PRIO database maintained by Sweden's KEMI is an effort to provide guidance to manufacturers, designers and regulators wishing to reduce chemicals-related risks, particularly with respect to products. It focuses mainly on substances that are in the process of undergoing restriction or are already severely restricted, such as SVHCs, so could be more comprehensive. Moreover, it requires a series of judgments on the part of the user in order to identify measures for reducing risks related to hazardous substances in products, which could limit its reach.

In sum, the EU system for controlling hazardous substances in products has many positive features that are useful for other countries to use as a model. However, it is not perfect. REACH in particular is a massive scheme that is still in the process of implementation, and gaps in data and in coverage remain. Thus the effort to control hazardous substances in products remains a challenge that requires continued attention from legislators, regulators and the regulated industry as well as from downstream users and the general public.

ANNEX I: DATABASES MAINTAINED BY THE EUROPEAN CHEMICALS AGENCY

ECHA databases		
Name	**Summary**	**URL**
REACH-IT	REACH-IT is the central IT system that supports Industry, Member State competent authorities and the European Chemicals Agency to securely submit, process and manage data and dossiers. These three parties each have access to specific functions of REACH-IT which they can use to fulfil their requirements under the REACH and CLP regulations. REACH-IT also provides a secure communication channel between these three parties to help them coordinate the processing and evaluation of data and dossiers.	http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it
IUCLID 5 – International Uniform Chemical Information Database	IUCLID 5 plays a central role in the IT environments of all organisations that have to cope with data submission requirements of REACH and other programmes (OECD HPV, EU Biocides and others). Industry stakeholders, EU Member States, the European Chemicals Agency (ECHA) , and any other interested party obtain the IUCLID installation kit from this web site; once installed, the local IUCLIDs are a tool to capture, store, submit, and exchange data on chemical substances stored according the format of the OECD	http://iuclid.eu/
Registered substances	The data on this list comes from registration dossiers submitted to ECHA by the date indicated as last update. The Total Tonnage Band is compiled from all the dossiers with two exceptions; any tonnages claimed confidential and any quantity used as an intermediate to produce a different chemical. The Total Tonnage band published does not necessarily reflect the registered tonnage band(s).	http://echa.europa.eu/information-on-chemicals/registered-substances
Pre-registered substances	These pre-registration intentions were submitted to ECHA between 1 June and 1 December 2008. Organisations can use this list to find other potential registrants of their substance so that they can submit a registration dossier jointly, as required by REACH.	http://echa.europa.eu/information-on-chemicals/pre-registered-substances
EC Inventory : EINECS (European Inventory of Existing Commercial Chemical Substances), ELINCS (European List of Notified Chemical Substances)	The EC inventory is comprised of the following lists: EINECS (European Inventory of Existing Commercial chemical Substances) as published in O.J. C 146A, 15.6.1990. EINECS is an inventory of substances that were deemed to be on the European Community market between 1 January 1971 and 18 September 1981. EINECS was drawn up by the European Commission in the application of Article 13 of Directive 67/548/EEC, as amended by Directive 79/831/EEC, and in accordance with the detailed provisions of Commission Decision 81/437/EEC. Substances listed in EINECS are considered phase-in	http://echa.europa.eu/information-on-chemicals/ec-inventory

ECHA databases		
Name	**Summary**	**URL**
NLP (No-Longer Polymers)	substances under the REACH Regulation. ELINCS (European List of Notified Chemical Substances) in support of Directive 92/32/EEC, the 7th amendment to Directive 67/548/EEC. ELINCS lists those substances which were notified under Directive 67/548/EEC, the Dangerous Substances Directive Notification of New Substances (NONS) that became commercially available after 18 September 1981. NLP (No-Longer Polymers). The definition of polymers was changed in April 1992 by Council Directive 92/32/EEC amending Directive 67/548/EEC, with the result that substances previously considered to be polymers were no longer excluded from regulation. Thus the No-longer Polymers (NLP) list was drawn up, consisting of such substances that were commercially available between 18 September 1981 and 31 October 1993.	
Dossier Evaluation decisions	This section contains the non-confidential versions of the decisions originating from compliance checks and examination of testing proposals (the two dossier evaluation processes). Decisions can be searched by evaluation process, decision number, the date on which the decision was issued. Additionally the search can be based, solely, on the substance name, EC or CAS number when these data are public. Pressing directly on <Search> leads to displaying all decisions published to-date. By publishing the dossier evaluation decisions, ECHA increases the transparency of its process, and offers registrants and third parties an opportunity to follow and increase their insights in the evaluation processes of compliance check and testing proposal examinations. Before publication of the decision, ECHA consults the addressees on the non-confidential version it intends to publish. ECHA notes that any personal data are removed and that the published documents represent decisions with blanked out sections that have been claimed confidential by the registrant and which were deemed to harm their commercial interest if disclosed. The decisions are only available in their original language.	http://echa.europa.eu/information-on-chemicals/dossier-evaluation-decisions
Current Testing Proposals	This list includes the substances and hazard endpoints for which ECHA is currently inviting third parties to submit scientifically valid information and studies.	http://echa.europa.eu/information-on-chemicals/testing-

ECHA databases		
Name	**Summary**	**URL**
		proposals/current
Substance evaluation - CoRAP	If a substance is on this list, it means that a member state **has evaluated or will** evaluate it over the coming years. **The list** is called the Community Rolling Action Plan (CoRAP). For each substance, the table shows the evaluating Member State, the (planned) year of evaluation and a short description of the concern which led to it being placed on the list. Documents to do with substance evaluation are also available here. They include: decisions to request more information; Member States' conclusions and Member States' final evaluation reports for substances added to the list. Since 2013, documents justifying selection of the substances are also included.	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table
Information on Candidate List substances in articles	This database provides examples of articles containing Substances of Very High Concern (SVHCs) that are included in the Candidate List, which are available for consumer use on the EU market. The data is based both on the notifications that companies have submitted to ECHA as well as on the information contained in the registration dossiers.	http://echa.europa.eu/information-on-chemicals/candidate-list-substances-in-articles-table
Candidate List of substances of very high concern for Authorisation	(published in accordance with Article 59(10) of the REACH Regulation)	http://echa.europa.eu/candidate-list-table
Authorisation List	List of substances included in Annex XIV of REACH ("Authorisation List")	http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list
List of Restrictions	The list of restrictions is the 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 consequent restrictions conditions. The latest consolidated version of REACH presents the restrictions adopted until that date. Subsequent changes are included in the amending Commission	http://echa.europa.eu/addressing-chemicals-of-concern/restrictions/list-of-restrictions

ECHA databases		
Name	**Summary**	**URL**
	regulations.	
PACT – RMOA and hazard assessment activities	The Public Activities Coordination Tool (PACT) lists the substances for which a risk management option analysis (RMOA) or an informal hazard assessment for PBT/vPvB (persistent, bioaccumulative and toxic/very persistent and very bioaccumulative) properties or endocrine disruptor properties is either under development or has been completed since the implementation of the SVHC Roadmap commenced in February 2013.	http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact
C&L Inventory	This database contains classification and labelling information on notified and registered substances received from manufacturers and importers. It also includes the list of harmonised classifications. The database is refreshed regularly with new and updated notifications. However, updated notifications cannot be specifically flagged because the notifications that are classified in the same way are aggregated for display purposes. Classifications derived from joint submissions to the REACH registration process are flagged accordingly. More information on these substances can be found in the Registered substances database.	http://echa.europa.eu/information-on-chemicals/cl-inventory-database
Biocidal Active Substances	The active substance / product-type combinations listed are all those for which an application for approval has been submitted under Directive 98/8/EC or Regulation (EU) No 528/2012, including "existing" active substances included in the Review Programme and "new" active substances.	http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances
Biocidal Products	In this database it is possible to search for those products authorisations in accordance with Directive 98/8/EC (The Biocidal Products Directive) and Regulation (EU) No 528/2012 (The Biocidal Products Regulation) which are available in the R4BP3 IT system.	http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-products
List of active substances and suppliers	The list of relevant substances and the respective substance and product suppliers, in accordance with Article 95 of the Biocidal Products Regulation (BPR), as amended by Regulation (EU) No 334/2014 of 11 March 2014. The purpose of this list is to "*ensure the equal treatment of persons placing active substances on the market*" (recital 8 of the Biocidal Products Regulation).	http://echa.europa.eu/web/guest/information-on-chemicals/active-substance-suppliers
Chemicals subject to PIC	The section on chemicals subject to PIC includes all chemicals listed in the relevant annexes of the PIC Regulation.	http://echa.europa.eu/information-on-chemicals/pic/chemicals

ECHA databases		
Name	**Summary**	**URL**
Export Notifications	Exports of all chemicals, mixtures, or articles that contain one or more chemicals subject to PIC must be notified in advance. In this database it is possible to search for export notifications by year, exporting EU member state, importing country, chemical and/or mixture name and type of chemical. A refined search is possible by using multiple search criteria.	http://echa.europa.eu/information-on-chemicals/pic/export-notifications
Import Notifications	In accordance with obligations under the Rotterdam Convention, other Parties to the Convention should notify exports from their country to the EU of chemicals which are banned or severely restricted on their territory. This list includes the import notifications for the EU. The import notification contains information on the date/period of export, the exporting and importing country, the name of the chemical(s) and (optionally) the CAS number. It is possible to search for import notifications by exporting and/or importing country, year, chemical name and CAS number. A refined search is available by using multiple search filters.	http://echa.europa.eu/information-on-chemicals/pic/import-notifications
Explicit Consents and Waivers	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 provided by the designated national authority of the importing country outside the EU. The explicit consent provision can be waived under certain circumstances. On this list is possible to search for Explicit Consents and/or waivers based on the chemical/mixture name, importing and or exporting country, category of use, date of request, validity start and end date, and status. A refined search is possible by using multiple search criteria.	http://echa.europa.eu/information-on-chemicals/pic/explicit-consents
Designated National Authority	Each Member State shall designate the authority or authorities (DNAs) to carry out the administrative functions foreseen by the PIC regulation. Information on DNAs includes contact details and whether they are responsible for industrial chemicals, pesticides or both. To the extent possible, ECHA also makes similar information available for non-EU countries. In this database it is possible to search for DNAs either by country or by selecting EU, non-EU, or all DNAs.	http://echa.europa.eu/information-on-chemicals/pic/designated-national-authority
Information from the Existing Substances Regulation (ESR)	Before REACH entered into force, chemicals were regulated by a number of different regulations and directives. The Council Regulation (EEC) No 793/93 -- also known as the Existing Substances Regulation	http://echa.europa.eu/information-on-

ECHA databases		
Name	**Summary**	**URL**
	(ESR) -- was one of these. It introduced a comprehensive framework for the evaluation and control of "existing substances" (substances on the market before 1982). The ESR stated that the Commission, in consultation with the Member States, would regularly draw up lists of priority substances which require immediate attention because of their potential effects to human health or the environment. Between 1994 and 2007 (the entry into force of REACH), four such priority lists were published, with a total of 141 substances. This table gives a complete overview on the risk assessments performed by the Member States for each of the 141 substances listed in the four priority lists.	chemicals/information-from-existing-substances-regulation
Annex XV transitional reports	This list includes Annex XV transitional reports of existing substance risk assessments and risk reduction strategies developed under Regulation (EEC) No 793/93, where the work was not finalised by 1 June 2008.	http://echa.europa.eu/information-on-chemicals/transitional-measures/annex-xv-transitional-reports
PBT/vPvB assessments under the previous EU chemicals legislation	The TC NES sub-group on identification of PBT and vPvB substances assessed suspected PBTs (persistent, bioaccumulative and toxic) and vPvBs (very persistent and very bioaccumulative) under the previous EU chemicals legislation. The group's assessment outcomes and Summary Fact Sheets are provided in this database. Currently, the assessment of suspected PBT and vPvB substances can be informally discussed with the PBT Expert Group, which is coordinated and hosted by ECHA.	http://echa.europa.eu/information-on-chemicals/pbt-vpvb-assessments-under-the-previous-eu-chemicals-legislation