

The International Comparative Legal Guide to:

# Environment Law 2007

A practical insight to cross-border Environment Law



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# EU Environmental Challenges for the Electronics Sector

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## 1 Introduction

The electronics sector faces an array of European Union (“EU”) environmental laws and regulatory initiatives that can make compliance planning a daunting task. In the 2006 edition of this article we examined the principal laws and proposals confronting the sector: WEEE and RoHS; Eco-design for EuP; and REACH. As expected, each of these measures has evolved substantially in the past 12 months. We offer this update in order to assist compliance and related strategic planning for 2007 and beyond.

## 2 WEEE & ROHS Directives

At the time of drafting this article almost all of the 27 EU Member States (Bulgaria and Romania having joined on 1 January 2007) have implemented Directive 2002/96/EC on waste electrical and electronic waste (“the WEEE Directive”) in their domestic legislation. Those few who have not yet done so have set a clear timetable for implementation. Directive 2002/95/EC on the restrictions of the use of certain hazardous substances (“the RoHS Directive”) has applied since 1 July 2006, though enforcement during its first six months of application has been limited and is expected to begin in earnest in early 2007.

Many companies - at all stages of the manufacturing chain - are still struggling with the technical, administrative and financial ramifications of these Directives. Some of the difficulties faced by the industry result from legislative ambiguity in the texts themselves (and also, consequently, in the transposing national laws). Substantial delays on key interpretative texts, the finalisation of supplementary standards and agreement on limited exemptions has also made compliance efforts an unduly complex challenge. An additional complication - which is not unique to the WEEE Directive but is true of all European Community (“EC”) environmental law - arises from the fact that environmental measures (adopted under Article 175 EC Treaty) only establish common baseline standards, to which individual Member States may add stricter provisions (so-called “gold plating”) provided that they are consistent with EC law. The effect of this is that there may be important differences in the applicable WEEE regimes in each national market. There is no substitute for the exercise of verifying how each of these operates.

### 2.1 WEEE Scope

The WEEE Directive imposes certain requirements on ‘electrical and electronic equipment’ (“EEE”) before it is put on the market (to do with marking, provision of certain information and financial

guarantees) but is mostly focused upon the end of its life-cycle when it has become waste EEE (“WEEE”) (concerning collection, recycling and/or disposal). The definition of ‘waste’ (established by Article 1(a) of Directive 2006/12 on waste (which replaces the predecessor “Waste Framework Directive”) has been the subject of a considerable body of case law (which continues to evolve) in the European Courts of Justice. For present purposes it is sufficient to note that the term “waste” is not simply to do with the inherent properties of an item but also whether it has, will or must be “discarded”.

EEE is defined by way of a reference to a three stage cumulative test:

1. Equipment which is ‘dependent on electric currents or electromagnetic fields in order to work properly’ [Article 3(a)] and ‘equipment for the generation, transfer and measurement of such currents and fields’. The (non-legally binding) “Frequently Asked Questions” Guidance Paper (last updated in August 2006) issued by the European Commission (“Commission”) provides that “dependent” means the equipment ‘...needs electricity (e.g. not petrol or gas) as its primary energy to fulfil its basic function. It also means that when the electric current is off, the appliance cannot fulfil its basic (primary) function. If electrical energy is used only for support or control functions (e.g.), this type of equipment is not covered...’.
2. The equipment must fall under at least one of the 10 categories set out in Annex IA of the WEEE Directive: (1) large household appliances; (2) small household appliances; (3) IT and telecommunications equipment; (4) consumer equipment; (5) lighting equipment; (6) electrical and electronic tools (with the exception of large-scale stationary industrial tools); (7) toys, leisure and sports equipment; (8) medical devices (with the exception of all implanted and infected products); (9) monitoring and control instruments; and (10) automatic dispensers. Annex IA includes at least, but is not limited to, the products within those categories listed in Annex IB.
3. Finally, the equipment must be equipment designed for use with a voltage rating not exceeding 1,000 Volts for alternating current and 1,500 Volts for direct current.

Excluded from the definition of EEE is military-specific equipment [Article 2(3)], equipment covered by a specific EC law waste stream [Article 2(2)] and ‘equipment that is part of another type of equipment that does not fall within the scope of the WEEE Directive’ [Article 2(1)]. In explaining the notion of equipment that is part of another type of equipment the Commission Guidance Paper states that ‘the decision criteria are “Finished Product” or

“Fixed Installation”: *Equipment which is part of another type of equipment is not to be considered a finished product. A finished product is any device or unit of equipment that has a direct function, its own enclosure and - if applicable - ports and connections intended for end users. “Direct function” is defined as any function of a component or a finished product which fulfils the intended use specified by the manufacturer in the instructions for use for an end-user. This function can be available without further adjustment or connections other than simple ones which can be performed by any person... .. “Fixed installation” in the broadest sense is defined as “a combination of several equipment, systems, finished products and/or components (hereinafter called “parts”) assembled and/or erected by an assembler/installer at a given place operate together in an expected environment to perform a specific task, but not intended to be placed in the market as a single functional or commercial unit”.* Examples of fixed installations given by the Commission include ‘heating plants’. Equipment that is part of another type of equipment includes ‘lifts’ and ‘control and monitoring equipment used in oil and gas electronics...’ It should be noted that the Commission’s definition of “fixed installations” is a source of controversy with some Member States (who consider that it only applies to the Category 6 derogation for ‘large-scale stationary industrial tools’). The UK’s Department of Trade and Industry (which supports the Commission’s guidance on this point) provides the following commentary on this term in its own non-binding guidance: *‘My product is bolted down in use. Is it a fixed installation? No, just being fixed is not sufficient. The intention of the fixed installation exclusion follows the same principles as the exclusion for vehicle mounted equipment. ‘Products that become part of a product that is outside the scope of the directive are outside the scope of the directive’. In the case of fixed installations the intention is that the product becomes part of the fabric of the building. Once fitted is the equipment discernable from the rest of the building or has it become part of the building? If a business were to move would they be likely to move or leave the product? Lifts, electric doors and gates etc. are fixed installations, fitted kitchen appliances, large fixed equipment, cctv camera systems are not.’*

“Components”, “subassemblies” and “consumables” of WEEE are covered by the Directive *only* when they are ‘part of the product at the time of discarding’ [Article 3(b)]. When separated from the product prior to disposal they are not covered. None of the three terms are defined in the Directive, but the original Commission proposal [COM (2000) 347 final] included the following explanatory observations which may still be of assistance in interpreting the finally adopted text:

- ‘Components are parts of electrical and electronic equipment, such as housings, screens, keyboards, electric motors, circuit boards, capacitors, rectifiers, transistors, tubes, etc.’
- ‘Sub-assemblies are parts of the equipment - not necessarily parts of the electricity flow - without which the original piece of equipment could not operate as intended by the manufacturer. Examples of sub-assemblies are shelves in a refrigerator.’
- ‘Consumables are short-term replaceable/disposable parts of the equipment, such as toner cartridges or batteries.’

At the risk of further complicating matters, it should be noted that there are some components which may have the characteristics of (and qualify as) EEE in their own right. The question of classification as EEE or as a component of EEE is not only a matter of the inherent properties of a product. The notion of a product being ‘put on the market’ (discussed further below) is also key. Where a product is integrated into a larger product *before* being put

on the market it will “escape” classification as EEE but the same product will be deemed EEE when put on the market as a separate item (e.g. a computer hard drive).

The central obligations under the Directive fall upon the ‘producer’, defined [Article 3(i)] as ‘...any person who, irrespective of the selling technique used, including by means of distance communication in accordance with Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts:

- (i) manufactures and sells electrical and electronic equipment under his own brand;
- (ii) resells under his own brand equipment produced by other suppliers, a reseller not being regarded as the ‘producer’ if the brand of the producer appears on the equipment, as provided for in subpoint (i); or
- (iii) imports or exports electrical and electronic equipment on a professional basis into a Member State.’

It is clear that options (i), (ii) and (iii) are conceived of as alternatives.

## 2.2 Principal WEEE Requirements

The WEEE Directive does not, in strict terms, distinguish between “B2B” and “B2C” sales transactions but classifies and regulates products according to whether they are “WEEE from private households” or “WEEE from users other than private households”. Only the term “WEEE from private households” is defined in the Directive as ‘...WEEE which comes from private households and from commercial, industrial, institutional and other sources which, because of its nature and quantity, is similar to that from private households...’ [Article 3(k)]. Products which can be used in both contexts will tend to be classified as coming from private households (even when as a matter of fact they do not) because the focus of the definition is on the functionality of a product rather than just the nature of the location in which it was last used.

Before examining the important differences in the way in which each of these waste streams (from private households and from non-private households) is addressed under the Directive there are certain requirements which are common to both for all new EEE:

- Products must be clearly marked with the *identity of the producer* [Article 11(2)].
- Products must be marked with the *crossed-out wheeled bin symbol* [Article 10(3)].
- Products must also bear an *indication that they are new*. To this end a CENELEC standard (EN 50419:2006 - an amended version from that issued in 2005) has been developed. The standard allows marking of the fact that a product is new to be indicated either by marking the date on the product in an un-coded text; and/or (ii) using a solid bar under the crossed-out wheeled bin [Article 11(2)].
- Products must have *reuse and treatment information* provided for them (within one year from the date of its placement on the market) to assist treatment facilities [Article 11(1)].
- Producers must *register with competent national authorities* and provide information on the quantities of EEE put on their market annually [Article 12]. The reason for this is, in part, to allow the Commission to monitor whether targets for collection of WEEE for private households (in Article 5) are achieved (for this reason, some Member States have been refusing registration for producers of EEE which has purely business applications). Registration by manufacturers who do not have a permanent legal presence in the Member State where their products are marketed will often find that they cannot register in their own right but must do so via a third

party who is permanently established in that Member State (who, in effect, takes on the role and obligations of the “producer”). This third party might be the independent importer or distributor of the products in the national territory concerned or one of the collective industry schemes set up for this purpose (which are different in each state). Where these producer obligations are taken on by third parties they will inherit the applicable financial costs. Of course, the importer and the manufacturer (for example) are free to arrange, by contractual terms, how they will bear these costs between them. A further problem area concerns how distance sellers (those selling directly to end users based in another Member State) participate in registration.

■ Finally, *design and production of EEE* should take into account and facilitate dismantling and recovery and in particular reuse and recycling [Article 4]. This is more of an aspirational provision than a strictly binding requirement (and has generally been treated this way in Member State’s implementing legislation). Such design requirements are more likely to be pursued in the context of other EU initiatives impacting upon the electronics sector: including Directive 2005/32/EC on the eco-design of Energy-using Products (“EuP”), the Thematic Strategy on the Prevention and Recycling of Waste [COM (2005) 666 final], the Thematic Strategy on the Sustainable Use of Natural Resources [COM (2005) 670 final] and Integrated Product Policy [COM (2003) 302 final].

For WEEE from private households [Article 8]:

■ New EEE - Producers must provide for the financing of the collection, treatment, recovery and environmentally sound disposal (“WEEE management”) of their own products deposited at collection facilities. There is no requirement to collect directly from final holders. These obligations can be fulfilled either individually or by joining a collective scheme. Producers will need to guarantee that these operations will be carried out before placing products on the market - either by way of participation in a scheme, taking out a recycling insurance or setting aside funds in a blocked account.

■ Historic EEE - Producers will have to finance WEEE management but the allocation of these costs will be proportionate to their market share of that type of equipment at the time that the costs are incurred.

For WEEE from non-private households [Article 9]:

■ New EEE - Producers must provide for the financing of WEEE management of products collected from users.

■ Historic EEE - When an item of WEEE is being replaced by new equivalent products or by new products fulfilling the same function, the financing of WEEE management must be provided for by producers of the replacement product when supplying it (a one for one / “old for new” arrangement). (Member States may, as an alternative, provide that users other than private households also be made, partly or totally, responsible for this financing.) For other WEEE (where there is no replacement product) financing must be provided for by the users.

However, producers and users may conclude agreements stipulating other financing methods for all types of WEEE from non-private households.

As already noted, many of the key obligations under the WEEE Directive (and also under the RoHS Directive) are also triggered by the notion of an item of EEE being ‘put on the market’. The term is not defined in either Directive. Consequently there has been considerable discussion on this issue. The Commission view is, in summary, that it refers to the initial action of making a product available for the first time in the EC market. This occurs when the product is transferred (physically or by transfer of ownership) from the producer to a distributor or final consumer or user on the EC

market. Therefore, a product is put on the EC market when it is made available for the first time on the EC market, *with a view to distribution or use in the EC*. This can be affected by physical transfer or by transfer of legal title (for free as a gift or by sale, loan hire or leasing).

### 2.3 Future Revision of WEEE

No later than 13 February 2008, the Commission must submit a report to the European Parliament and the Council based on the experience of the application of the Directive. The report may include - if deemed necessary - proposals for revision of the Directive. Work on this report, including consultation with stakeholders and commissioning of independent studies, has already begun. Key elements which will be examined include:

- revision of targets for recovery, reuse and recycling of EEE (covering all categories of EEE);
- the scope of the Directive (including exemptions);
- the operation of the producer responsibility provisions (including the effect of the different approaches taken by Member States and whether, for example, national producer registers should be harmonised); and
- WEEE treatment requirements.

During 2007 stakeholders will need to ensure that their views and experiences are taken into account by EU legislators.

### 2.4 RoHS Scope and Main Requirements

RoHS and WEEE are linked. The RoHS Directive introduces substance bans for:

- Lead.
- Mercury.
- Cadmium.
- Hexavalent chromium.
- Polybrominated biphenyls (PBB).
- Polybrominated diphenyl ethers (PBDE).

Maximum concentration values are set out for each in Commission Decision 2005/618/EC. The RoHS Directive applies to EEE falling in categories 1, 2, 3, 4, 5, 6, 7 and 10 of Annex IA to the WEEE Directive and to electric light bulbs, and luminaires in households. It covers EEE put on the market (from 1 July 2006) and sub-assemblies and components of EEE (from 1 July 2006). The Directive excludes sub-assemblies and components which are ‘spare parts for the repair or to the reuse’ of EEE put on the market before 1 July 2006 [Article 2(3)] and consumables. The Commission consider that Article 2(1) of the WEEE Directive (excluding ‘equipment that is part of another equipment’) applies equally to the RoHS Directive. Therefore, for example, equipment that is specifically designed to be installed in airplanes, boats and other means of transport is considered to fall outside its scope. This conclusion is by no means evident on the terms of the Directive itself (though the intention was most probably as expressed by the Commission). This may be an area where only litigation will settle which interpretation is correct.

Narrow exemptions to these restrictions for specific applications have been adopted. This is an ongoing process. Exemptions are being added and withdrawn (as alternatives, not containing the banned substances, become available) so these need to be monitored closely by producers. To date, the exemptions are contained in Commission Decisions 2005/717/EC, 2005/747/EC, 2006/310/EC, 2006/690/EC, 2006/691/EC, and 2006/692/EC.

Exemptions have become a politically sensitive issue, so further legal challenges to these (as has already happened on several occasions) cannot be ruled out.

### 2.5 RoHS Enforcement Policy

The first six months of the application of the RoHS Directive has seen relatively little enforcement. There are a number of reasons for this, including the fact that many Member States have not yet designated their national enforcement authority (at the time of drafting this article only 8 Member States have responded to the Commission's request that these bodies be notified to it). The "honeymoon period" is expected to end early in 2007. Producers need to ensure that their products are RoHS compliant and (no less important) that they can be shown to be so. Sanctions imposed for breach of RoHS requirements vary in each Member State but include fines (in some cases calculated as a multiple of each individual non-compliant item of EEE), criminal sanctions and / or removal of products from the market. The "EU RoHS Enforcement Authorities Informal Network" (comprised of Member State representatives) issued a non-legally binding "RoHS enforcement guidance" document in May 2006 which sets out the approaches that Member States might take to enforcement and means by which producers might demonstrate compliance. Since there is currently no common standard for demonstrating compliance (producers simply make a self-declaration) this guidance is particularly helpful. Producers should have in place *at least* the following:

- a designated point of contact within the organisation that will deal with the RoHS enforcement (and customer) requests;
- information on production activities including the product range and approximate levels of sales;
- a statement of the compliance approach taken, by way of a general overview of systems implemented; and
- an overview of the data quality systems in place, (in those cases where the producer relies significantly upon supplier information to demonstrate compliance), including for example, risk assessments, acceptance criteria, purchasing procedures and any other relevant documentation (both process-based and product/part-based documentation).

Over and above the points noted above, the nature of the additional documentation and measures required will depend upon the type of RoH compliance approach taken: (a) a process-based scheme (focusing on information relating to the producer's internal compliance system); or (b) a product/part-based approach (focusing on information relating to a product's/part's physical attributes).

### 2.6 Future Revision of RoHS

The RoHS Directive currently excludes EEE in categories 8 (medical devices) and 9 (monitoring and control instruments). This exclusion is the subject of an ongoing review. A report produced for the Commission in July 2006 has recommended that RoHS be applied to most products in these categories from 2012, with three sub product category exceptions:

- active implanted medical devices (which would be continued to be excluded or to which RoHS would apply from 2020);
- *in-vitro* medical devices (to which RoHS would apply from 2016); and
- industrial test and measurement equipment (to which RoHS would apply from 2016 or 2018).

A series of context specific (Annex I) exemptions would also be adopted.

The Commission was currently reviewing the study and is expected to submit proposals to the Council and the European Parliament at the beginning of 2008. The Commission has indicated that its proposals may go beyond the issue of categories 8 and 9 and address other RoHS issues. During 2007 stakeholders will need to ensure that their views and experiences are taken into account by EU legislators.

## 3 EuP

By 11 August 2007 Member States will have to have implemented in their domestic legislation Directive 2005/32/EC concerning eco-design requirements for energy-using products ("EuP"). The Directive establishes a framework for the setting of eco-design standards (so-called "implementing measures"). Work on the development of these measures is already well underway and will need to be monitored closely. It is important to note that these standards will be mandatory and products which do not comply with them will be subject to a marketing and sales prohibition (enforced by appropriate sanctions). Therefore, all occasions to shape the scope and content of implementing measures should be taken. Adoption of first implementing measures expected in the first half of 2008.

The Commission will finalise a working plan for these implementing measures by July 2007, however (as already indicated) there will also be some immediate action, before the working plan is finalised, concerning:

- measures implementing the European Climate Change Programme ("ECCP"), starting with those products which have been identified as offering a high potential for cost-effective reduction of greenhouse gas emissions, 'such as heating and water heating equipment, electric motor systems... consumer electronics and HVAC (heating ventilating air conditioning) systems' will be taken; and
- a separate implementing measure reducing stand-by losses for a group of products will be developed.

### 3.1 What will EuP Target?

The Commission will adopt implementing measures (generic or specific eco-design requirements) when the EuP:

- represents a significant volume of sales and trade, indicatively more than 200,000 units a year within the Community according to most recently available figures;
- considering the quantities put on the market and/or put into service, has a significant environmental impact within the Community, as specified in Community strategic priorities as set out in the 6th Environmental Action Plan (Decision No 1600/2002/EC); and
- presents significant potential for improvement in terms of its environmental impact without entailing excessive costs, taking into account in particular (i) the absence of other relevant Community legislation or failure of market forces to address the issue properly; and (ii) a wide disparity in the environmental performance of EuPs available on the market with equivalent functionality.

Implementing measures will have to meet the following criteria:

- there shall be no significant negative impact on the functionality of the product, from the perspective of the user;
- health, safety and the environment shall not be adversely affected;

- there shall be no significant negative impact on consumers in particular as regards the affordability and the life cycle cost of the product;
- there shall be no significant negative impact on industry's competitiveness;
- in principle, the setting of an eco-design requirement shall not have the consequence of imposing proprietary technology on manufacturers; and
- no excessive administrative burden shall be imposed on manufacturers.

### 3.2 How will standards be set?

Consultation of interested parties is promised to be a key part of the production of implementing measures, in a "Consultation Forum" (which should be established during 1st half of 2007). In preparing a draft implementing measure the Commission will:

- consider the life cycle of the EuP and all its significant environmental aspects, inter alia energy efficiency. The depth of analysis of the environmental aspects and of the feasibility of their improvement shall be proportionate to their significance. The adoption of eco-design requirements on the significant environmental aspects of an EuP shall not be unduly delayed by uncertainties regarding the other aspects;
- carry out an assessment, which will consider the impact on the environment, consumers and manufacturers, including SMEs, in terms of competitiveness including on markets outside the Community, innovation, market access and costs and benefits;
- take into account existing national environmental legislation that Member States consider relevant;
- carry out appropriate consultation with stakeholders;
- prepare an explanatory memorandum of the draft implementing measure based on the assessment referred to above; and
- set implementing date(s), any staged or transitional measure or periods, taking into account in particular possible impacts on SMEs or on specific product groups manufactured primarily by SMEs.

Alternatively, the Commission may accept a "self-regulation measure" which achieves 'more quickly or at lesser expense than mandatory requirement' the same objectives. A set of criteria for assessing self-regulation measures is set out in Annex VIIA to the Directive, and includes in its criteria: 'well-designed monitoring, with clearly identified responsibilities for industry', 'openness of participation', and 'involvement of civil society'. To date, studies are being carried out in 14 areas:

- boilers and combi-boilers (gas/oil/electric);
- water heaters (gas/oil/electric);
- personal computers (desktops & laptops) and computer monitors;
- imaging equipment: copiers, faxes, printers, scanners, multifunctional devices;
- consumer electronics: televisions;
- standby and off-mode losses of EuPs;
- battery chargers and external power supplies;
- office lighting;
- (public) street lighting;

- residential room conditioning appliances (aircon and ventilation);
- electric motors 1-150 kW, water pumps (commercial buildings, drinking water, food, agriculture), circulators in buildings, ventilation fans (nonresidential);
- commercial refrigerators and freezers, including chillers, display cabinets and vending machines;
- domestic refrigerators and freezers; and
- domestic dishwashers and washing machines.

A further 5 studies will be launched in 2007 concerning:

- solid fuel small combustion installations;
- laundry driers;
- vacuum cleaners;
- set-top boxes; and
- domestic lighting.

During 2007 stakeholders will need to ensure that their views and experiences are taken into account by EU legislators and that they are prepared to comply with the technical adaptations which may be required for products. Astute operators will try to support adoption of strict eco-design measures which effectively exclude competitors from their market.

## 4 REACH

In December 2006 the European Parliament and Council of the European Union took historical final decisions to adopt the proposed EU Regulation on Registration, Evaluation and Authorisation of Chemicals (REACH). The REACH text was published in the EU's *Official Journal* on 30 December as Regulation (EC) No. 1907/2006, comprising 141 Articles, 17 Annexes and covering a total of 849 *Official Journal* pages. It is mammoth in its concept, in its detailed rules and in the burden for parties in the supply chain to comply. Overall, the legislation is expected to affect the placing on the EU market of some 30,000 chemical substances, imposing major administrative responsibilities and costs on EU producers and importers of these substances. Producers in the electronics industry as "downstream users" of these substances will be significantly affected as well.

This contribution highlights and summarises key elements of REACH but the Regulation requires detailed examination in its entirety to ensure that all necessary steps are taken to comply with the requirements within the applicable deadlines, and of course to remain compliant in the future. Failure to timely register and, if necessary, secure authorisation of a substance means that the respective EU manufacturer or importer cannot place the substance in question onto the EU market ("no data, no market" principle), this clearly also impacting EU downstream users' use of the substance and non-EU producers who want to export products containing the substance to the EU. Everybody in the supply chain must be aware of how REACH can affect their operations and ensure that all requirements are fulfilled.

REACH will enter into force on 1 June 2007, meaning that suppliers and users must actively ready themselves for this new EU chemicals regulatory regime. The key requirements are discussed below.

### 4.1 REACH Policy Objectives

The central policy objective is to transfer responsibility for the safety of chemical substances from governmental authorities to the parties placing them on the EU market. This concerns substances

used on their own, in preparations or incorporated into finished articles. Placing on the market means supplying or making available to a third party, whether for payment or free, including importation into the EU. Another key objective is transparency, to be achieved initially by requiring registration with the newly established European Chemicals Agency (the “Agency”) of all chemical substances placed on the market; registration will entail submission of detailed information about the substance, its uses, related risks and guidance on safe use. Transparency also entails making certain (non-confidential) information available throughout the supply chain as well as to final consumers, e.g., concerning certain dangerous substances (“substances of very high concern”) in the finished products they purchase.

#### 4.2 Registration by Manufacturers/Importers

The registration of substances manufactured or imported in quantities of 1 tonne or more, whether on their own, in preparations or finished articles or as intermediates, is the fundamental requirement of REACH. What specific information has to be submitted for the registration, and when the registration must be made, depends on the classification of the substance in question and the volume manufactured or imported, as summarised below.

The Regulation provides for transitional registration periods for so-called “phase-in” substances (mainly substances listed in the European Inventory of Existing Commercial Chemical Substances - EINECS) according to the volumes manufactured or imported but only if the substances in question are pre-registered between 1 June and 1 December 2008. Downstream users (“DUs”) of a substance that has not been pre-registered may ask the Agency to extend the pre-registration period by 6 months to give them time to find a supplier or to pre-register the substance themselves. DUs are defined as any EU natural or legal entity that uses a substance in the course of its industrial or commercial activities, excluding distributors and consumers. The Agency must publish a list of the pre-registered substances by 1 January 2009 and DUs can see from the list whether the substance of concern has been pre-registered or not.

If properly pre-registered, the transitional deadlines for registration of phase-in substances are:

- 30 November 2010 for phase-in substances i) manufactured or imported (“M/I”) in quantities  $\geq 1,000$  per year per manufacturer or importer, ii) substances classified as very toxic to the aquatic environment and M/I in quantities  $\geq 100$  t/a per manufacturer or importer, and iii) substances classified as carcinogenic, mutagenic or toxic to reproduction (“CMRs”) M/I in quantities  $\geq 1$  t/a per manufacturer or importer.
- 31 May 2013 for phase-in substances M/I in quantities between 100 and 1000 t/a per manufacturer or importer.
- 31 May 2018 for phase-in substances M/I in quantities between 1 and 100 t/a per manufacturer or importer.

Substances that must be registered but which miss the pre-registration period cannot benefit from the above transitional deadlines and become subject to the “no registration, no market” rule, i.e., the party is barred from placing the substance on the EU market pending proper registration.

The data required for pre-registration is not extensive (name of substance including CAS and EINECS number, contact body, foreseen deadline for registration and tonnage band). However, many companies will have substantial work to identify all of their substances (substances on their own, all substances in preparations, substances in finished products) that are subject to the REACH

registration requirements and to ready the files for the pre-registration. Each substance needs to be individually pre-registered.

#### 4.3 Content of Registrations

All registrations must include, at a minimum, a “technical dossier”. The technical dossier will include the identity of the manufacturer/importer, identity of the substance, information on the manufacture and use(s) of the substance, the classification and labelling of the substance, exposure information, and guidance on safe use. Study summaries (or more detailed “robust study summaries” in specified cases) must also be provided concerning information derived from testing required under Annexes VII to XI - the level of testing required varies according to the tonnages manufactured or imported (e.g., the most extensive testing for substances M/I in quantities  $\geq 1,000$  t/a). If necessary, proposals for further testing must be submitted.

In addition, chemical safety assessments and a chemical safety report (“CSR”) are required for substances M/I in quantities  $\geq 10$  t/a. The CSR sets out the hazards and classification of a substance and an assessment whether it is a persistent, bioaccumulative and toxic (PBT) or very persistent very bioaccumulative (vPvB). The CSR must also provide exposure scenarios, including recommendations for measures to ensure that risks to humans and the environment are adequately controlled, regarding all “identified uses” of the substance. Identified uses means the manufacturer/importer’s own use(s) and uses made known by a downstream user of the substance. If a DU does not notify its use to the supplier/registrant or uses a substance outside the conditions covered in the registrant’s CSR, the DU itself must perform the safety assessment concerning its intended uses.

#### 4.4 Data and Cost Sharing

Given the required testing and information that must be generated for an individual registration, the Regulation provides for sharing of data, tasks and costs. The above-noted pre-registration of phase-in substances, for example, results in establishment of a Substance Information Exchange Forum (“SIEF”) for each substance. Each SIEF will group all intended registrants of the particular substance (manufacturer, importer, potentially also downstream users or other holders of information on the substance) and enable them to share certain information and determine, for example, which studies are available and/or still need to be carried out. Owners of full study reports are required to permit reference to existing vertebrate testing reports and, if requested, also concerning non-vertebrate testing reports. The SIEF parties are to agree on generation of any required new testing. Costs for testing must be shared fairly. Fines might be imposed if a study owner refuses to provide either proof of the cost of its study (for purposes of cost sharing and, upon payment, granting permission for the other party to refer to the full study report in its own registration) or the study itself.

In the case of non-phase-in substances and registrants of phase-in substances who have not pre-registered, each potential registrant must inquire to the Agency if a registration has already been submitted for the substance in question. If so, it will be put in contact with previous registrants in order that information and costs can be shared if necessary in order to make the registration.

Also to help reduce registration costs, the Regulation provides that certain data (e.g., on hazardous properties of the substance and classification) should normally be submitted jointly. Thus, a “lead registrant” would submit the data with the agreement of the other

registrants. Specified other data must be individually submitted. Certain data, including the CSR, can be submitted jointly but nonetheless might be submitted separately if, for example, this would result in disclosure of commercially sensitive information or a joint submission would be disproportionately costly to the company in question.

#### 4.5 Special provisions on substances in articles

A special regime applies concerning substances contained in articles. “Articles” includes finished products from paints and toys to electronic chips, computers and cars. Clearly many articles placed on the EU market contain a large number of substances that are subject to REACH, with some of these substances being potentially dangerous if released from the article during its use.

REACH requires that all substances intended to be released from articles during normal and reasonably foreseeable conditions of use (e.g., ink from cartridges) must be registered by the producer or importer according to the normal REACH rules (including pre-registration, volume deadlines and information rules) if those substances are present in the articles above 1 t/a per producer or importer.

In addition, the producer or importer must notify the Agency and provide certain specified information for each substance in the article that meets the “substances of very high concern” (“SVHC”) criteria and is identified in a published “candidate list” of substances considered by the Agency to meet the SVHC criteria if 3 conditions apply: i) the substance is present in those articles in quantities totalling over 1 t/a per producer or importer; ii) the substance is present in those articles above a concentration of 0.1% weight by weight (w/w); and iii) the producer or importer cannot exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use of the article including disposal. Upon notification, the Agency can require full registration of any substance in the article if the volume criterion is met and the Agency “has grounds for suspecting” that the substance is in fact released and presents a risk to humans or the environment.

Note that these provisions on registration/notification of substances in articles do not apply to substances that have already been registered for that use. Importantly, non-EU manufacturers can appoint a single natural or legal person in the EU to fulfil the REACH obligations that must otherwise be carried out by each importer in the manufacturer’s supply chain; in that case the actual importers are deemed to be downstream users.

#### 4.6 Authorisation of SVHC

Annex XIV of REACH will comprise a list of substances determined to be of very high concern in respect of human and environmental safety. Substances to be listed in Annex XIV are those which meet the criteria set out in Art 57, including CMRs, PBTs, vPvBs as well as certain other substances, such as endocrine disrupters, for which there is scientific evidence of probable serious effects “which give rise to an equivalent level of concern”. A producer, importer or downstream user shall not place a substance on the market if it is included in Annex XIV unless, *inter alia*, the use(s) of that substance on its own or in a preparation or the incorporation of the substance into an article has been properly authorised.

Applications for authorisation can be made by one or several parties, can cover one or several substances if they are part of the same group and can concern one or multiple uses (own uses and/or uses intended downstream). The application must include an

analysis of potential alternative substances (including any relevant R&D undertaken by the applicant) and, if suitable alternatives exist, a substitution plan including a timetable for proposed actions by the applicant.

The provisions on authorisation criteria distinguish between the different hazard classifications and situations where safety thresholds can or cannot be determined. In general, authorisations will be granted if the risk to humans/environment is “adequately controlled”. However, more restrictive conditions apply concerning i) CMRs and certain other SVHC for which safety thresholds are not possible to determine, ii) PBTs and vPvBs, and iii) other SVHC identified as having PBT or vPvB properties. In these cases, authorisation can be granted only if it is shown that socio-economic benefits outweigh the risk to human health or the environment and there are no suitable alternative substances or technologies. In this context, consideration will be given to, *inter alia*, the information submitted by the applicant and/or other parties concerning alternatives.

Decisions on suitability of alternatives will take into account technical and economic feasibility for the applicant and whether substitution would actually result in reduced overall risks. When granted, authorisations will be subject to time-limited reviews determined on a case-by-case basis and normally subject also to conditions, such as monitoring.

#### 4.7 Information in the supply chain

Suppliers of substances and preparations must provide recipients with safety data sheets (SDS) whenever a substance or preparation is classified as dangerous, is a PBT or vPvB or is listed in the candidate list for substances requiring authorisation for other reasons. Instances are also specified for when an SDS is required or not. Importantly, REACH requires any supplier of an article containing a SVHC to provide recipients (for free) with available information to allow safe use including, at a minimum, the name of the substance. Also in these circumstances the supplier must provide the same information to any consumer who requests it.

#### 4.8 Classification and Labelling Inventory

Any manufacturer, producer of articles or importer who places a substance requiring registration on the market must provide information to the Agency to enable it to compile, and keep updated, a classification and labelling inventory that will be publicly accessible. The obligation to supply this information will apply from 1 December 2010.

#### 4.9 Conclusions on REACH

It is evident that REACH imposes significant and complex obligations on all parties placing chemical substances onto the EU market, whether on their own, in preparations or in finished articles. The overview provided by this article is, hopefully, useful but is necessarily brief and incomplete. It is absolutely essential for companies subject to these requirements to:

- actively inventory the substances that they place on the EU market and which are subject to REACH;
- assess the precise nature of the requirements concerning each substance (some substances are exempt from registration requirements but not other REACH requirements) for each party in the supply chain;
- assess for each substance needing registration what

registration data is already held/owned and what data, if any, must be secured from others by way of the SIEF;

- identify and ensure means for protection of own confidential business information concerning each substance;
- for the owner of a study(ies) that may have to be shared (as such or citation rights) within the SIEF, establish a "fair" cost for the cost-sharing on that information; and



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- establish internal company structures and any necessary external consultant expertise to coordinate and ensure effective compliance.

The Commission will publish technical guidance documents in several of these regards in early-mid 2007 but much of the recommended preparation can and should be started already.



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