Impact of the EU REACH Regulation on the Packaging Supply

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Our huge modern range of goods can only be managed logistically if suitably packed during distribution and warehousing. Packaging [Fig. 1] protects goods against damage and loss. The manufacturing of packaging material and packages cannot be imagined without chemicals like polymers, adhesives [Fig. 2], printing inks, and many others. To ensure a high level of protection of human health and environment from the risks of chemicals when using these chemicals [Fig. 3], the European Commission issued at the end of 2006 a new European chemicals legislation (Regulation (EC) No 1907/2006) called REACH (Registration, Evaluation, Authorization and restriction of CHemicals). REACH is based on the idea that industry itself is best placed to ensure that the chemicals manufactured, put on the market and used in the EU do not adversely affect human health or the environment. This requires that industry has certain knowledge of the properties of its substances and manages potential risks. Authorities should focus their resources on ensuring that industry is meeting its obligation and that it is taking action on substances of very high concern where there is a need for Community action.

The legislation will have far reaching effects both for manufacturers and importers of chemicals, as well as for downstream users of industrial chemical products in quantities exceeding one metric ton per year per legal entity. The amount of information and data needed for registration will depend on the quantities or tonnage of the chemicals, with more data needed at higher tonnage levels. Since for registration both the properties and the end use of the chemicals play a role, it is important that the suppliers of chemicals know their customers' applications. The downstream users themselves must be sure that their specific uses are registered. REACH will impose significant administrative and cost burdens on industry and generate a large bureaucracy.

REACH will create a single system for both what are currently described as "existing" and "new" substances. Substances are now described as phase-in substances (those substances listed in the European Inventory of Existing Commercial Chemical Substances EINECS), or those that have been manufactured in the Community, but not placed on the Community market, in the last 15 years, or the so-called "no longer polymers" of Directive 67/548) and as non-phase-in substances (i.e., those not produced or marketed prior to the entry into force of REACH).

REGULATION (EC) NO 1907/2006

The Regulation (EC) No 1907/2006 [Fig. 4] is the most ambitious regulation on EU level. The regulation consists of 140 paragraphs and 17 annexes on more than 800

pages and replaces 40 old regulations in the EU. It is estimated that more than 27,000 companies in the EU have to register their chemicals, which has to be done for any legal entity of a company. The number of chemicals that have to be registered is about 30,000. To manage all the technical, scientific and administrative aspects of the REACH system at Community level, aiming to ensure that REACH functions well and has credibility with all stakeholders, a European Chemicals Agency (ECHA) will be established in Helsinki, Finland, that will administer the regulations with the assistance of competent authorities within the various European member states. The ECHA will establish a classification and labelling inventory of all industrial chemicals, provide new enforcement authority to the member states, and establish various administrative and legal procedures. The budget for the ECHA with more than 400 employees will be more than 1.2 billion €. In the future the member states will check compliance in their countries and all legal entities have to be able to demonstrate compliance. The total costs of REACH are estimated to be 2.8 billion € to 5.2 billion € in the EU. These costs are mainly for testing. Because of the costs it is expected that 2-8 % of the substances currently on the market will be withdrawn.

ROLES UNDER REACH

Under REACH there are different roles possible [Fig. 5]: manufacturer, importer and user. Manufacturer means any natural or legal person established within the Community who manufactures a substance within the Community. Importer means any natural or legal person within the Community who is responsible for import of substances from non-European countries. A downstream user is any natural or legal person in the Community other than the manufacturer or importer who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. It is also possible that one natural or legal person can play different roles at the same time. A chemical supplier can be a manufacturer or importer, but at the same time also be a downstream user when he buys chemicals and produces preparations like polymers, adhesives, inks, and so on for professional use within the EU.

THE REACH PROCESS - A FOUR-PART REGULATORY SYSTEM

1. Registration

The core element of REACH is the registration of chemical substances that will be used in the EU after 1st December 2008 [Fig. 6]. Almost all chemical substances, both new and old, have to be registered by their respective manufacturer or importer in quantities exceeding 1 metric ton in order to maintain the right to market them. Failure to register means that the substance will be banned from manufacture or importation. In order to register a substance, information about its properties and uses has to be generated, assessed, put together in a registration dossier and submitted to the Chemicals Agency (ECHA) which will be created to oversee the REACH regulation. The registration obligation falls on manufacturers and importers, but downstream users will also need to ensure that their specific uses are registered. The amount of information and data needed for registration will depend on the quantities or tonnage of the chemicals with more data needed at higher tonnage levels. Built into the REACH system are provisions for avoiding unnecessary animal testing and for data sharing among registrants. Where new animal testing is needed to support registration, the registrant must first submit a testing proposal to the

regulatory authorities. At the 10-ton level, REACH also requires the preparation of a Chemical Safety Report (CSR), essentially a risk assessment report that describes the chemical, its uses, the hazard and exposure potential, and recommends practices for reducing risk and exposure. Registration means that a manufacturer or importer has provided a registration dossier to the Agency and not received any indication that it is incomplete. This does not by itself mean that the dossier is in compliance with the legislation nor does it mean all the properties of the registered substance have been identified. Registration costs depend on the data requirements, which in turn are dependent on the quantity to be registered. The average costs are estimated to be 30 T€, 250 T€, 400 T€ and 1200 T€ for 1-10, 10-100, 100-1000, >1000 tons/year, respectively. Most of the costs are due to animal testing. Data sharing is mandatory between the registrants of identical chemicals resulting in cost sharing and reduction of animal experiments. If the obligation to register a chemical is not met, this chemical cannot be manufactured, imported or used in the EU. If no data is available, the chemical substance has to be withdrawn from the market [Fig. 7].

Currently there is no obligation for registering polymers. However those monomers have to be registered, which are chemically-bounded in more than 2 mass percent in the polymer, in quantities of 1 ton or more per year. For copolymers this refers to every single monomer. Article 6 paragraph 3 says:

“Any manufacturer or importer of a polymer shall submit a registration to the Agency for the monomer substance(s) or any other substance(s), that have not already been registered by an actor up the supply chain, if both the following conditions are met:

a) The polymer consists of 2 % weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);
b) The total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year”.

Concerning registration of articles the regulation says in article 7: Registration and notification of substances in articles:

“Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both the following conditions are met:

a) The substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;
b) The substance is intended to be released under normal or reasonably foreseeable conditions of use”.

2. Evaluation

Evaluation of registration dossiers and animal testing proposals is done by the regulatory authorities, who may also call for additional data on chemicals of highest concern to the EU regulators [Fig. 8]. ECHA will evaluate testing proposals made by industry and check compliance with the registration requirements, and will co-ordinate substance evaluation by the authorities to investigate chemicals with perceived risks. This assessment may be used later to prepare proposals for restrictions or authorisation.

3. Authorisation

Substances with properties of very high concern will be made subject to authorisation for their use in the EU [Fig. 9]. Around 1,500 such substances may be impacted, including:

- CMRs (substances that are carcinogenic, mutagenic or toxic to reproduction), category 1 and 2,
- PBTs (substances with persistent, bio-accumulative and toxic properties),
- vPvBs (substances that are very persistent, very bio-accumulative).

The authorisation is user and product specific and depends in part on the availability of lower risk substitutes. In these cases the Agency will publish a list of such candidate substances. Applicants will have to demonstrate that risks associated with uses of the more-hazardous substances are adequately controlled or that the socio-economic benefits of their use outweigh the risks. Applicants must also analyse whether there are safer suitable alternative substances or technologies. If there are, they must prepare substitution plans, if not, they should provide information on research and development activities, if appropriate. The Commission may amend or withdraw any authorisation on review if suitable substitutes become available.

4. Restriction

The restrictions provide a procedure to regulate that the manufacture, marketing, or use of high-risk chemicals shall be either subject to conditions or prohibited [Fig. 10]. Thus, restrictions act as a safety net to manage Community-wide risks that are otherwise not adequately controlled.

PRE-REGISTRATION

The Agency is responsible for managing all registrations. Since it is expected that more than 30,000 phase-in substances (plus a number of “non-phase-in” substances) have to be registered, the regulation sets a period of 11 years [Fig.11] for the entire registration process. Depending on quantity the following deadlines are valid:

- More than 1,000 tons until November 2010
- More than 100 tons until June 2013
- More than 1 ton until June 2018

To be able to take advantage of this period, substances must be pre-registered by 30 November 2008. To make sure that manufacturers of packaging material and packages can continue to use their present chemicals, they should start an intensive and open discussion with their suppliers regarding pre-registration. If the obligation to pre-register a chemical substance is not met, this chemical cannot be manufactured, imported or used in the EU after 30 November 2008. With a view to the REACH deadline for pre-registration, one of the first tasks for all manufacturers, importers and users of chemicals is to establish an inventory of the volume of all imported, manufactured and used substances at any legal entity.

INFORMATION IN THE SUPPLY CHAIN

An important element of REACH is the fact that besides the properties of a substance used in a process the exposition of these materials during processing has to be observed. The communication requirements of REACH ensure that not only manufacturers and importers but also their customers, i.e., downstream users and distributors, have the information they need to be able to use the chemicals safely. Information relating to health, safety and environmental properties, risks and risk management measures must be passed both down and up the supply chain.

The primary tool for information transfer is the well-established and familiar safety data sheet (SDS) for all dangerous substances [Fig. 12]. The provisions of the current Safety Data Sheets Directive (91/155/EEC) are carried over into the REACH Regulation, which added the requirement for SDS to be provided for persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) substances and preparations containing them. Since more information will be available as a result of registrations the quality of safety data sheets will improve. Where chemical safety assessments are performed according to the registration requirements, relevant exposure scenarios will be annexed to the safety data sheet and will thus be passed down the supply chain. New information on hazardous properties and information that challenges the quality of risk management measures in the safety data sheets shall be passed up the supply chain.

DOWNSTREAM USERS

Companies that use chemicals for the production of preparations (like paint or adhesives producers) or in industrial or professional processes (like producers of packaging materials or packages) are regarded as downstream users under the REACH regulation. Downstream users must ensure that their use of chemicals, even including process chemicals like oils and lubricants, is in compliance with the use registered by the manufacturer or importer.

To recap: downstream users are any industrial or professional users of chemicals such as manufacturers of packaging material and packages, formulators of paints, inks, and adhesives, or users of chemicals such as oils and lubricants. Downstream users are required to consider the safety of their uses of substances, based primarily on information from their suppliers, and to apply appropriate risk management measures. Downstream users will need to communicate effectively with their suppliers in order to get the information they need incorporated into the SDS supplied to them. In particular they will have to check that their use(s) are “covered” by the SDS -- that they use a substance within the conditions described in the exposure scenarios in the annex to the SDS, and apply these conditions.

To get the relevant information, downstream users are encouraged to make their uses known to their suppliers so that suppliers can include these uses in their chemical safety assessments as “identified” uses, or pass the request on up the supply chain [Fig. 13]. Downstream users can apply a system of brief general descriptions of uses that can be used as a minimum to identify such uses to the supplier. The relevant exposure scenarios developed for these uses will need to be annexed to the SDS.

A downstream user can choose to keep his use confidential or decide to use a substance outside the conditions described in the exposure scenario(s) communicated to him. In these cases he will have to perform a chemical safety assessment (CSA) developing the exposure scenarios for his intended uses and, if necessary, a refinement of the supplier's hazard assessment [Fig. 14]. This obligation does not apply if the downstream user uses less than 1 ton of the substance per year. However, a downstream user relying on the 1 ton exemption still needs to consider the use(s) of the substance and identify, apply and recommend appropriate risk management measures. In rare cases, the downstream user may propose additional testing if he considers this necessary to complete his chemical safety assessment.

The costs of REACH to downstream users of chemicals were estimated in the Commission's Impact Assessment of 2003 at 0.5 to 1.3 billion €, under the assumption that 1 to 2% of the substances would be withdrawn because continued production would no longer be profitable. Costs could rise to 1.7 – 2.9 billion € if industry faces higher substitution costs in downstream supply chains.

SUMMARY

The present EU legislative framework for chemical substances is a patchwork of many different directives and regulations that has developed historically. There are different rules for "existing" and "new" chemicals. However, this system has not produced sufficient information about the effects of the majority of existing chemicals on human health and the environment. The identification and assessment of risks – covering the possible hazards of a substance as well as exposure of humans and the environment to it – have proved to be slow, as have been the subsequent introduction of risk management measures. In the Strategy for a Future Chemicals Policy, published in 2001 (COM (2001) 88), the Commission outlined the result of a review of the current system and its new strategy for ensuring a high level of chemicals safety and a competitive chemicals industry through a system for the Registration, Evaluation, Authorisation and restriction of Chemicals – the REACH system. Because of the costs of REACH it is expected that 2-8 % of the substances currently on the market will be withdrawn.

Without packaging materials and packages modern life would not be possible. All those who currently use chemicals, including the producer of packaging materials and packages, therefore have to confirm whether they will get these chemicals in the future. REACH will require many decisions such as those on pre-registration and registration. Depending on the chemical, these decisions may affect several different uses, several legal entities and several business processes. Efficient decision structures, management attention, and coordinated technical execution are therefore crucial to safeguard the business.

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