REACH Brings a Major Challenge for the Chemical and Leather Imports into the European Community*

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Abstract

The European Union (EU) regulation REACH is due to come enter into force into force on 1 June 2007 and shall apply from 1 June 2008. It's important that all manufacturers, importers and downstream users of chemicals and articles are prepared and fully aware of the impact this new legislation will have on their business.

This poses a new challenge not only for the chemical industry in the EU but also very importantly for the EU trading partners. They will be required to gather more information on the properties of their substances and articles. The chemical industry and to some part also the article producer must prepare itself for a considerable additional workload to fulfill the new requirements. To enable a smooth transition from the existing EU chemicals legislation to REACH, the EU and trading partners must be adequately prepared for the practical application of the new system by the time REACH comes into force. This paper provides background information and practical advice to the relevant business.

Resumen

La regla de la Unión Europea REACH debe entrar en vigencia en junio de 2007 y se aplicará desde el 1 de de junio de de 2008. Es importante que todos los fabricantes, importadores y usuarios de productos químicos y de artículos estén preparados y completamente enterados del impacto que esta nueva legislación tendrá en su negocio.

Esto presenta un nuevo desafío no solamente para la industria química en la Unión Europea (UE) sino también muy importante para los socios comerciales de la UE. Serán requeridos para recopilar más información sobre las características de sus sustancias y artículos. La industria química y en cierta manera también los productores de artículos deben prepararse para una carga considerable de trabajo adicional para satisfacer los nuevos requisitos. Para permitir una suave transición de la actual legislación sobre productos químicos en la UE hacia REACH, la UE y los socios comerciales deben prepararse adecuadamente para el uso práctico del nuevo sistema para el momento en que el REACH entre en vigencia. Este papel proporciona información de fondo y el consejo práctico relevante del negocio.

Introduction

REACH stands for Registration, Evaluation, Authorization and Restriction of CHemicals. The regulation lays new obligations on the industry and defines a new approach to chemicals control. Enterprises which manufacture or import more than one ton of a substance per year will be required to register these chemicals. When this is the case, registration obligations apply to producers and importers of chemicals who need to gather comprehensive information on the properties of the substance. This information and evidence demonstrating the safe use of the substance need to be submitted in a registration dossier to new European Chemicals Agency which will be located in Helsinki, Finland. A natural or legal person established outside the EU who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the EU must appoint a natural or legal person in the EU as his only representative for registration or mandate the importer.

The registrant is obliged to register substances as such, not preparations, but all the substances in a preparation. This includes substances in articles if the chemical(s) is (are) intended to be released under normal or reasonably foreseeable conditions of use e.g. inkjet printers.

REACH definition (short form):

Substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process.

* A Technical Note based on a presentation at the XXIX IULTCS Congress and103nd annual meeting of the American Leather Chemists Association at the JW Marriott Hotel, Washington, DC, on June 21, 2007

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Manuscript received June 23, 2007, accepted for publication July 30, 2007

Preparation: means a mixture or solution composed of two or more substances.

Article: means an object which during production is given a special shape, surface or design which determines its function.

REACH regulation (EC) No 1907/2006 and directive 2006/121/EC amending directive 67/548/EEC were published in the official journal on 30 December 2006 exceeding more than eight hundred pages. In addition, guidance documents are prepared. The aim of the appropriate REACH guidance documents called Implementation Projects (IP's) is to ensure an efficient implementation of the legislation through the development of guidance and IT-tools for the Agency, industry and the authorities. Some of the guidance documents are still not finished and others are quite bulky.

The new regulation aims to improve the protection of human health and the environment while maintaining competitiveness and enhancing the innovative capability of the EU chemicals industry.

These EU directive and regulation do not only affect the 27 EU member nations, EU standard could become a trade barrier and impact thousands of businesses around the world that are directly or indirectly linked to the EU substantial share in the world market through international trade. Twenty minutes are too short to explain REACH and its global waves in deep. Therefore, I remind you “Einstein's theorem”: *Explain it as easy as possible but not easier.*

THE EU CHEMICAL LEGISLATION

The current EU chemicals legislation distinguishes between so-called "existing" and "new" chemicals based on the cut-off date of 1981. All chemicals that were reported as being on the European Community market between 1 January 1971 and 18 September 1981, listed in the **E**uropean **IN**ventory of **E**xisting **C**ommercial **C**hemical **S**ubstances (EINECS), are called "existing" chemicals. In 1981, they numbered more than 100'000 different substances. Chemicals introduced to the market after 1981, are termed "new" chemicals and published in the **E**uropean **L**ist of **N**otified **C**hemical **S**ubstances (ELINCS). The current ELINCS contains 4'381 chemicals.

While “new” chemicals have to be tested before they are placed on the market, there are no such provisions for "existing" chemicals. Thus, although some information exists on the properties and uses of existing substances, there is generally a lack of sufficient information publicly available in order to assess and control these substances effectively.

Many countries have similar national legislation and chemical registers. However, the EU authorities main concern is that the current systems for “existing” chemicals has not produced sufficient information about the effects of the majority of the traded chemicals on human health and the environment.

As regards “new” substances, the current EU system has also hampered research and innovation. New chemicals manufactured in quantities as low as 10 kg were subject to heavy testing requirements, causing the EU chemical industry to lag behind its counterparts in the US and Japan in this regard. In the past 18 years, only 2'700 new substances above 1 ton per year have been placed on the EU market, compared to the around 2'000 chemicals notified in the US every year. Consequently, the Environment Council decided in 1998 that the set of existing legislation should be reviewed. REACH should replace 40 existing legal acts and create a single system for all chemical substances.

INTERNATIONAL CHEMICAL AGREEMENTS

It has always been recognized that the best way of improving safety is by developing international regulations that are followed by all nations. The chemical industry is one of the most highly regulated industrial sectors. This is important in ensuring that the products can be used safely. Good regulation is vital to instill public confidence and maintain good business performance.

Regarding international trade we have to bear in mind that shipping is perhaps the most international of all the world's great industries and one of the most dangerous.

Today, uniform regulations to manage the risk associated with transportation of dangerous (respectively hazardous) materials - basically chemicals as such and articles which release chemicals - are essentially in place worldwide. At the United Nations level, all work related to the transport of dangerous goods is coordinated by the **ECO**nomic and **SO**cial **C**ouncil (ECOSOC) Committee of Experts on the **T**ransport of **D**angerous **G**oods (TDG) and on the **G**lobally **H**armonized **S**ystem of Classification and Labeling (GHS).

The UN recommendations on the transport of dangerous goods provides procedures on an international basis for shippers and operators that dangerous goods can be safely transported using the appropriately packing, label, and transport vehicle by air, water and inland. They continue to strive to identify and manage potential hazards, the probability of occurrence of incidents in transportation, and the consequences of such incidents.

Harmonization had not been achieved in the workplace or consumer sector. The **U**nited **N**ations **C**onference on **E**nvironment and **D**evelopment (UNCED), Rio de Janeiro, 1992, provided the international mandate to complete this task. The GHS has been enveloped at UN level and the plan of implementation of the **W**orld **S**ummit on **S**ustainable **D**evelopment (WSSD), adopted in Johannesburg in 2002, encourages countries to implement the GHS as soon as possible with a view to having the system fully operational by 2008. The EU has decided to implement GHS at the same time as REACH.

THE *REACH* APPROACH

For the “existing” substances, approximately 30'000 on the EU market and maybe more than 100'000 world-wide, the majority of whose possible dangerous characteristics are only incompletely investigated, the manufacturers and importers are

required to generate data and to provide a registration dossier. They are called **Registrant**. The registration takes place over 11 years depending production and usage tonnage. Pre-registration for currently manufactured or imported „existing" substances permits longer deadlines for full registration depending on the properties of the substance and the production volume.

- o Above 1000 tons/year - must be registered within 3.5 years, **before 1 December 2010**
- o 100 - 1000 tons/year - must be registered within 6 years, **before 1 June 2013**
- o 1 - 100 tons/year - must be registered within 11 years, **before 1 June 2018**

The pre-registration timetable for substances currently manufactured or imported is 1 June 2008 to 1 December 2008. Certain substances which are identified as being of (very) high concern to human health or the environment have to be registered early i.e. within 3.5 years. New made substances or not pre-registered imported substances must be registered before they attain 1 ton per year. A list of all pre-registered substances will be published on the website of the Agency by 1 January 2009.

The costs to European industry have been estimated at 2 to 6 billion Euro.

After 11 years all chemicals used in the EU market can be properly labeled, packed, transported und used according GHS requirement - thanks the REACH regulation.

The heart of the future European Chemical Agency's operations will be the Internet REACH-IT system. It is still in development. The goal is to have a paperless coordination whereby 30 000 companies can register 100 000 substances, and to provide a work flow system for valuation and authorization processes. However IUCLID 5, the basis software tool for it can be downloaded from the homepage of the European Chemical Bureau. Once installed, IUCLID 5 is the essential tool to capture, store, submit, and exchange data on chemical substances according to the REACH requirements.

REACH Article 5: No data, no market (in the EU)

The most hazardous substances - an estimated 1'500 - could be banned or restricted. Included on that list are some compounds used in electronics, furniture, clothing, toys and other everyday items. Whenever safer substitutes exist for the most dangerous chemicals, they must be used. Companies must submit plans to replace them. Where no alternative exists, the companies should work to find one. This applies to substances that cause cancer, infertility, genetic mutations or birth defects, and to those which are persistent and accumulate in the environment.

Chemical supply chain

REACH also covers downstream users, extending the regulatory scope considerably. It places greater responsibility on industry to manage the risks of chemicals and provide appropriate safety information to professional users and, as far as the most hazardous substances are concerned, also to consumers.

Downstream users may be any industrial user of chemicals, whether formulators of preparations (e.g. paint producers) or users of chemicals such as lubricants (e.g. fat liquors) in industrial processes like tanning or producers of manufactured articles such as computers, automotives, textiles or leather goods. Formulators have to pass the information from the Registrant down to the end users. All 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, to get the information they need in the **S**afety **D**ata **S**heet (SDS) supplied to them. In particular they will have to check that their use(s) are covered by the SDS.

Downstream users have a right to make their use of a substance known to the manufacturer in order to make it an identified use and have it covered in their supplier's chemical safety assessment. In this case they have to provide sufficient information to allow the supplier to prepare an exposure scenario for the use. Alternatively they can conduct their own chemical safety assessment and report this use to the Chemicals Agency, especially in the case of confidential non standard applications.

Restrictions of certain dangerous substances, preparations and articles

The use of certain dangerous chemicals is acceptable as long as appropriate risk management measures are implemented. If measures at company level are not sufficient to keep the risks for human health and environment acceptable, REACH foresees limitations or even bans of substances for certain uses, for instance in consumer products.

The most dangerous substances, those of very high concern, will be subject to authorization or restriction. A substance on its own, in a preparation or in an article, for which REACH Annex XVII (replacing Council Directive 76/769/EEC) contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. The annex XIV, list of substances subject to authorization, will be granted for these uses if the manufacturer or importer is able to demonstrate that risks can be adequately controlled.

Both the restriction and the authorization processes can also be applied to substances produced or imported in volumes below 1 ton per year. This would for instance allow risks from particles on a nano-scale to be addressed.

The effects of substitution could be broader than one might expect as few things are easily substituted. It will demand that many firms reformulate products, which may produce inferior products and may trigger need for new registrations.

OUTLOOK

As the EU will probably ban more products under REACH, one can be sure that they will propose they are also banned under international agreements. Some are afraid that this may potentially remove more valuable products from the world market.

Many international conglomerates like automotive companies, furniture, textile and shoe producers as well as retailers and brand houses have their own specific lists of unwanted chemicals, so called **R**estricted **S**ubstance **L**ist (RSL) mainly taken from the existing EU regulation and doubtless in the future will be based on REACH.

As chemicals and chemicals related articles are traded internationally, chemical safety is a global concern and has inspired a number of international initiatives. The EU is playing a leadership role in all of them. In particular, REACH is likely to become a focus of the UN's **S**trategic **A**pproach to **I**nternational **C**hemicals **M**anagement (SAICM), a relatively new effort designed to create institutions that will coordinate global chemical and waste policies.

However, EU trading partners have suggested REACH would benefit more from harmonization with existing international regulatory efforts such as accepting test data developed under **O**rganization for **E**conomic **C**o-operation and **D**evelopment (OECD) guidelines and other international or national bodies and using informed substitution. The high costs of compliance, could particularly burden some smaller companies, EU and particularly non-EU firms may not have the resources to comply with REACH, forcing them out of European markets.

At all events REACH is a radical step forward in EU chemicals management with international implications. Therefore REACH has to be observed closely by all EU trading partners and their representatives including national and international organizations. The link to the **E**uropean **Ch**emicals **A**gency (ECHA) http://ec.europa.eu/echa/home_en.html is highly recommended as it is constantly updated. The ECHA website is a single point of entry for all information on REACH. It provides access to technical guidance, frequently asked questions (FAQs), software tools and helpdesks.

In the meantime, a corrigendum to Directive 2006/121/EC of the European Parliament and of the Council of 18 December 2006 amending Council Directive 67/548/EEC has been published in official Journal of the European Union L 136/281 of 29 Mai 2007. No changes to the legal text are believed to be included. The republished format has removed some blank pages and corrected typographical errors.