



“REACH”
Registration, Evaluation, Authorization
and Restriction of Chemicals:
An Overview of the EU’s New Directive

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The European Union (“EU”) has a new directive – REACH (Registration, Evaluation, Authorization and Restriction of Chemicals). REACH requires EU companies to register their chemical substances before placing them on the EU market. Although REACH does not technically apply to U.S. businesses *per se*, it will still have an impact – possibly a profound impact – on U.S. businesses, particularly those involved with the chemical industry and those whose products may be headed for the EU.

REACH is designed to place greater responsibility on industry for the safe handling of chemicals. REACH creates a new regulatory structure in the EU for chemicals. However, this EU directive is expected to affect all manufacturers and all users of chemical substances.

This memorandum, which highlights some of REACH’s main requirements, is intended to provide an overview of this broad and very detailed new directive. This memorandum focuses on basic REACH questions: Who must register, what is “registration,” when must registration occur, and how U.S. businesses may be affected. This memorandum also notes the potential implications of REACH for U.S. operations. Though intended as primer on REACH, this memorandum also provides a number of references to assist the reader in obtaining more detailed information on various REACH topics.

EXECUTIVE SUMMARY

The registration facet of REACH requires EU manufacturers and importers to obtain relevant information about chemical substances¹ manufactured within or imported into the EU in quantities greater than one metric ton per year. A technical dossier is required for such registration. This document will provide information on the substance and on how to manage risks when using this substance. For quantities above ten metric tons per year, there will be an additional requirement of submitting a Chemical Safety Report (“CSR”), which will provide a further assessment of the chemical substance.

In the evaluation phase of REACH, the EU regulatory authority is to assess whether information provided by industry satisfies the directive’s requirements. Depending upon the results of the evaluation and the potential dangers of the chemical in question, restrictions or authorization procedures may be required for that substance. Authorization will likely be required for substances of very high concern, namely those more likely to pose a threat to human

¹ For convenience, the terms “chemical,” “chemical substances,” and “substances” are used interchangeably throughout this memorandum.

health or to create an environmental risk. Restrictions are intended to be the safety net of the system. Any chemical substance that poses unacceptable risks to health or the environment will be restricted. Such restrictions may take the form of a ban on using that substance in certain products or a complete ban on that substance.

Some chemical substances will require only registration. In contrast, the substances most likely to pose a threat to health or the environment will have other requirements under REACH. The legislation is also designed to encourage safer substitutes, if feasible, for chemicals of very high concern. Overall, and significantly, compliance with REACH will require greater communication between manufacturers and those companies up and down the supply chain. Importantly, as of the deadlines in 2008, only registered and pre-registered chemicals are able to be manufactured in or placed on the EU market. These deadlines apply irrespective of whether the chemical is sold on its own or is contained within preparations or articles.

Companies need to start the process of determining whether and how their products are affected by REACH. To ensure REACH will not cause products destined for the EU to be prohibited in the EU, non-EU companies will need to supply substantial chemical information to their EU counterparts. Though the onus of registration generally falls on EU manufacturers and EU importers, many others outside the EU may be significantly affected.

The full text of the directive can be found at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_136/l_13620070529en00030280.pdf.

REGISTRATION

What Must Be Registered?

The short answer is chemicals. Registration is required for all chemical substances manufactured in or imported into the EU with a volume of one or more metric tons per year. This includes chemicals that are on their own, used in preparations, or contained in articles that release the chemical substance. “Preparations” and “articles” are explained in more detail below.

REACH exempts certain substances. Examples of excluded substances include the following: water, oxygen, noble gases and cellulose pulp. Also, some naturally occurring substances, such as minerals and ores, are not required to be registered so long as they are not chemically modified. In addition, many of REACH’s requirements are exempted for substances in food and pharmaceutical products (mostly because these items are regulated in other specific legislation). More specifically, registration is not required for chemicals found under Article 2, pages 16-17, or Annexes IV and V, pages 92-96, at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_136/l_13620070529en00030280.pdf.

Who Must Register?

EU manufacturers and EU importers of chemical substances must register under REACH. In addition, and significantly, EU-based representatives of non-EU chemical manufacturers must register under REACH; this EU-based representative is called an “only representative” and is

discussed in more detail below. U.S. companies exporting to the EU have two basic options for registration: 1) their EU importer can register their chemical substance or 2) they can register themselves by appointing an EU representative known as an “only representative.” Either way, U.S. exporters will need to prepare their chemical information to assist their importer or only representative with registration.

When Does Registration Begin?

Deadlines under REACH are imperative but complex. The pre-registration period begins on June 1, 2008 for certain pre-existing chemicals, which the EU defines as “phase-in” substances. Pre-registration for these chemicals ends on December 1, 2008. Companies that pre-register “phase-in” chemicals by this deadline can delay the actual registration for a number of years, depending on their substance’s tonnage and properties. Registration for chemicals that are “new” to the EU begins June 1, 2008.

A more complete delineation of the registration timetable can be found on slide 8, at, http://ec.europa.eu/enterprise/reach/docs/reach/070315_REACH_presentation_industry.pdf.

What Information Must be Submitted for Registration and Pre-Registration?

Pre-Registration

Pre-registrants must submit their contact information along with their chemical substance’s name, identity, volume and expected registration deadline. The pre-registration process is relatively simple (compared to the actual registration process) but very important; pre-registration allows sales of the chemical in question to continue during the more cumbersome registration process. After the 2008 deadlines, no chemicals within the scope of REACH can be manufactured or sold in the EU without being either pre-registered or registered.

Registration

Every substance within the ambit of REACH must be registered. REACH strongly promotes information sharing. Even competitors who manufacture or import a substance are expected to submit certain registration information jointly. In addition, the directive encourages all potential registrants to share information and cooperate in registration.

Technical Dossier: This document requires the registrant to identify itself, name its substance, and provide information on the substance’s manufacturing process, uses, safe uses, classification and labeling, testing, expert assessments, and properties. This includes any physiochemical, toxicological, and ecotoxicological information. Additional information is also required as a substance’s tonnage (quantity) increases over certain thresholds.

Chemical Safety Assessment (“CSA”): The general rule is that if the substance is manufactured or imported in quantities of 10 tons or more per year per registrant, the registrant must complete a CSA to set forth the chemical’s risks. The CSAs, at least for some chemicals, may require a fair amount of research effort.

Chemical Safety Report (“CSR”): A CSR informs the downstream user on how to control the chemical’s risks.

Safety Data Sheet (“SDS”)

Although not part of Registration, suppliers of chemicals classified as dangerous or persistent, bioaccumulative and toxic (“PBT”), or very persistent and very bioaccumulative (“vPvB”), must provide recipients with an SDS. Recipients can request an SDS for concentrated non-dangerous chemicals, if the chemicals pose health or environmental risks, have toxic properties, or exceed exposure limits. The criteria for an SDS is in Article 31, page 33, at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_136/l_13620070529en00030280.pdf.

What Information Should U.S. Exporters Provide?

EU importers and only representatives can only comply with REACH if they have the necessary chemical information from their U.S. exporters. Thus, exporters should obtain the following information about their substances, whether the substances are on their own, in preparations or articles:

- What volumes are exported to Europe?
- Does the substance benefit from any exemptions under REACH?
- Will the substance be subject to Authorization, as set out below?
- What data is available for the substance?
- Has the safety data sheet been updated?
- What is the composition of the substance(s) found in preparations and/or articles?
- What are the substance’s known uses?
- Is the substance’s safety data sheet compliant with REACH?

Why is Communication Important for Registration and REACH?

Delineating the known uses of a given chemical is a critical element of REACH (at least for certain chemicals). Registrants must communicate up and down their supply chains to obtain use information. For instance, a downstream user of a chemical can supply the chemical’s manufacturer with an understanding of the chemical’s uses. For certain chemicals, only their delineated and authorized uses will be permitted within the EU. Additional uses of such chemical are not allowed absent revising the registration. Therefore, it will be important to communicate effectively so that downstream customers’ uses are learned of and identified.

In addition to supply chain communication, REACH requires communication between potential registrants. More specifically, manufacturers and importers of the same substances are anticipated to share their chemical studies and information in a Substance Information Exchange Forum (SIEF). These forums allow pre-registrants to obtain registration information, identify future chemical studies, and set deadlines for those studies. Thus, SIEFs are intended to cause uniformity and avoid the duplication of costly tests. In addition, a specific goal of REACH is to

avoid duplicative animal testing during the registration process. The intent of the directive is for companies, though otherwise competitors, to work together to accomplish pertinent testing in an efficient manner. The research to satisfy REACH requirements is contemplated to necessitate cost-sharing among manufacturers and importers of a given substance. Companies performing authorized laboratory tests on animals will be able to receive “fair compensation” for their data. Testing of vertebrate animals requires compulsory sharing of information. How well such information and cost-sharing methods work among competitors will be interesting to see.

Why Consider Registration Through An “Only Representative”

Non-EU entities that appoint an “only representative” can exercise more control in the registration process than if they rely on EU importers to handle registration. For example, utilizing an only representative may allow a non-EU exporter to avoid disclosing sensitive information to its EU importers.

EVALUATION

What Is Evaluated?

Dossier Evaluation. On June 1, 2007, the REACH Agency (“Agency”) was established. It is responsible for evaluating the dossier’s information. The Agency is to ensure that the dossier is complete and accurate by checking a fraction of the dossiers received. The Agency also decides whether to allow the dossier’s testing proposals. The scrutiny for such proposals will be more critical for tests involving vertebrate animals.

Chemical Substance Evaluation. The Agency is responsible for coordinating the evaluation of chemical substances, but EU member states are tasked with actually evaluating the substances. Member states can appoint other bodies to act on their behalf for this purpose.

What Does Evaluation Entail?

The Agency and member states develop the criteria for prioritizing evaluation, taking into account a chemical’s volume, exposure risks and hazardous traits. The Agency then decides what chemicals will be evaluated each year. Member states choose certain chemicals and are then identified as that chemical’s competent authority. As a competent authority for the selected chemicals, the member state evaluates its allocated chemicals. It can request any additional information from registrant(s) before deciding whether to approve the chemical.

What Occurs While a Company’s Chemicals are being Evaluated?

Evaluation has no effect on a company until its conclusion, e.g., that further testing is or is not needed. There is no impact on the marketing of a substance during the evaluation process. After an entity’s substance is evaluated, the Agency makes a draft decision. The company or entity can comment on the draft decision. The Agency and competent authority may take these comments into account and may amend the draft decision accordingly.

AUTHORIZATION

What is Authorization?

Authorization requires a manufacturer, importer or downstream user to gain permission before placing a substance of very high concern (SVHC) on the EU market.

What Substances of Very High Concern Require Authorization?

The list of substances requiring authorization is not expected until June 1, 2009. However, likely chemicals include: carcinogens, mutagens, toxins affecting reproduction, chemicals having endocrine disrupting properties, and chemicals causing serious effects to human health or the environment. More specifically, and with using REACH terminology, there is anticipated to be more focus on chemicals that are persistent, bioaccumulative and toxic (“PBT”) and substances that are very persistent and very bioaccumulative (“vPvB”).

Who Grants Authorizations?

The European Commission (“Commission”) grants authorizations. The Commission also determines what chemicals require authorization based on the Agency’s recommendations.

What is the Role of Alternatives?

For applicable chemicals, the registrant includes in its application the intended uses for the chemical along with an analysis of possible alternatives. If there is no suitable alternative, an authorization will most likely be granted as long as the chemical’s risk to human health or the environment can be adequately controlled and documented.

RESTRICTIONS

What is a Restriction?

A restriction prohibits a chemical substance from being manufactured, placed on the market or used unless it complies with the conditions of that restriction. Restrictions are intended for substances believed to be capable of causing serious effects to human health or the environment.

What Chemicals have Restrictions?

A current list of chemicals with restrictions can be found at Annex XVII of the directive, pages 127-144, at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_136/l_13620070529en00030280.pdf.

REACH Appeals

What REACH Decisions can be Appealed?

An appeal may be taken from Agency decisions that require safe handling controls for a substance, disallow exemptions for substances used in research and development, define registration documents as incomplete, proportion data sharing costs between registrants, and involve evaluations.

Who is Entitled to an Appeal?

Any natural or legal person may appeal against a decision directed toward them or having a direct and individual concern to them.

Who Hears Appeals?

The Board of Appeal consists of a Chairman and two other members, each with equal voting rights.

What Does an Appeal Entail?

An appealing party must file a written statement, outlining the appeal and its grounds, to the Agency within three months of the notification of the Agency's decision being appealed. The Chairman then has 30 days to examine whether the appeal is admissible. If the appeal is admissible, it is remitted to the Board of Appeal for an examination of the grounds. Parties involved in the proceeding can make oral presentations. However, if the Agency's Executive Director, after consulting with the Chairman, finds an appeal to be well founded, the Executive Director can circumvent the aforementioned process and rectify the situation.

ENFORCEMENT

How is REACH Enforced?

After certain deadlines in 2008, chemicals – whether on their own or in preparations or articles – cannot be manufactured or placed on the market in the EU unless they have been registered (or at least pre-registered) under REACH. In addition, member states are responsible for maintaining a system of official controls for entities that fail to comply with REACH. Each member state is responsible for notifying the EU Commission of these controls no later than December 1, 2008.

MISCELLANEOUS

Guidance with REACH?

REACH Implementation Projects (“RIPs”) are meant to provide guidance on REACH as it develops. RIPs can be found at <http://ecb.jrc.it/reach/rip/>.

Who is an “Only Representative”?

A natural or legal person who is established in an EU community, who has sufficient background in chemicals, and who fulfills the REACH obligations for a non-EU manufacturer or exporter.

What is a “Preparation”?

A preparation is a mixture or solution of two or more substances, such as paint or the aerosol spray in a can. However, a printer cartridge is seen as an article. Preparations and articles do not need to be registered under REACH; however, under certain circumstances, the chemicals that comprise preparations or articles not only must be registered but also must be counted towards the tonnage of the imported or manufactured chemical.

What is an “Article”?

An article is an object whose special shape, surface or design determines its function to a greater degree than does its chemical composition. Articles do not need to be registered under REACH. Examples of articles include clothes, furniture, vehicles, toys, and computers. *However*, chemicals in articles do have to be registered if the substance gets released from the article as part of the function of that product (for example, a printer cartridge). In addition, chemicals in articles may also trigger REACH requirements if they are chemicals of very high concern; these requirements are irrespective of whether the chemical is released from the article by design.

What about Polymers and Monomers?

At this time, polymers are exempted from registration and evaluation. However, monomers must be registered. It is also anticipated that polymers may become subject to registration subsequently.

IMPACT ON BUSINESSES IN THE UNITED STATES

In today’s world, if information about a chemical’s potentially harmful effects is provided to EU authorities, can such information be limited to just the EU? Research on toxicity and mutagenic effects, among other things, for some substances will be performed in the next few years because of REACH. Is it realistic to expect that such research can or will be ignored domestically?

Private Sector Concerns

As companies obtain and provide more chemical data and perform further tests under REACH, the EU will soon learn more about the risks and properties of certain chemicals in the

marketplace. In response, the EU will likely require companies to comply with higher requirements for chemical warnings and labels on certain substances. The new warnings in the EU for certain chemicals may make U.S. manufacturers more vulnerable to tort suits (unless the same warnings are given domestically). What if the EU chooses to forbid the use of a certain chemical because of its potentially harmful properties (particularly if a safer and reasonable alternative is available)? Could a voluntary decision by a U.S. business to continue selling that same chemical domestically (though banned in the EU) give rise to tort exposure in the U.S.?

Although REACH does not directly implicate U.S. chemical companies, such companies surely will still feel the affects of the potential changes in the labeling and warning of certain chemicals, in addition to alternative products that may be developed to replace chemical substances banned by the EU. A number of questions will arise. For example, how much information can be shared among competitors to comply with the information-sharing provisions of the REACH legislation without triggering antitrust concerns? What steps can companies take to protect their proprietary information?

Governmental Actions

If REACH-driven research reveals that certain chemicals are more hazardous or more of a cause for concern than previously understood or believed, then what might the United States Environmental Protection Agency do? Will the EPA change clean up levels, action levels and/or maximum contaminant levels? Will OSHA adjust permissible exposure limits and what effects could that have?

There are certainly more questions than answers at this juncture. The more in depth research triggered by REACH has not yet begun. So, it is hard to predict all of the ramifications that may arise from REACH. Although REACH only regulates EU countries, its impacts are most certainly international.

Notwithstanding the difficulty associated with predicting REACH's future impacts, U.S. companies need to be conducting important analysis *now*. Companies that sell chemicals (or sell products that are made of chemicals that may be released during normal use of that product) must promptly determine whether their products going to the EU may be affected by REACH and, if so, what they or others in their supply chains need to be doing to ensure they do not miss the critical 2008 pre-registration deadline.

All information in this memorandum is for educational purposes only. It should not be construed as legal advice.