



REACH – European Product Regulation For Chemical Risk

HUNTON &
WILLIAMS

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“REACH” is the European Union’s sweeping new chemical regulation that applies to all products containing chemicals manufactured in or imported into the EU. REACH stands for Registration, Evaluation, and Authorization of Chemical substances. The REACH Regulation imposes a series of complex and onerous obligations on manufacturers, importers, and users of chemical substances, of products comprised of a mixture of substances (“preparations”), and of all other products (“articles”) containing chemical substances. Failure to comply may result in market access problems, sanctions, and liability exposure for product manufacturers, not to mention disruption of supply chains for chemical substances, preparations, and components essential to the manufacture of key products. Further, the EU is bent on persuading other markets from China to California to adopt REACH-like requirements. The REACH Regulation was adopted in December 2006 and entered into force on 1 June 2007.

As members of one of the leading environmental, health and safety regulatory law firms in Europe, the United States and Asia, Hunton & Williams’ attorneys have been involved with the REACH Regulation since its inception, starting with the Commission’s review of the current EC chemical regulatory regime. We have monitored the development of the REACH Regulation for trade associations and other clients, and analyzed the business impact of the proposed REACH Regulation and various proposed amendments. We have commented on the Commission’s proposals, and have participated actively in the public debate on REACH.

Hunton & Williams has had an active chemical law practice for over 15 years. We are intimately familiar with issues arising under the EU’s current chemical legislation, such as the Dangerous Substances Directive, the Dangerous Preparations Directive, and the Marketing and Use Directive. In the chemical regulatory area, knowledge of administrative practice and interpretation is critical, and as important as understanding the law. This will be

particularly true under REACH. In assisting our clients with REACH, we bring to bear our extensive experience with the practice and interpretation of the EU’s current chemical regulatory regimes, as well as our understanding of REACH and of EU administrative law, EU administrative and judicial remedies, and EU liability law.

Now that the REACH Regulation has been adopted, businesses have shifted to preparing for compliance and, in some cases, adjusting their portfolio, products and production processes, and purchasing. For some companies, REACH will necessitate such fundamental decisions as whether to remove a key product from the EU market, or instead to move forward to comply with the applicable requirements, make the necessary filings, and seek any approvals that may be required.

Hunton & Williams has the experience to assist companies with managing the REACH Regulation. The following is a list of the wide range of capabilities and services we offer in respect of REACH:

Management Systems and Strategies:

- Assist companies with establishing a **management system** to manage the implications of REACH for their specific businesses, including identifying (i) **relevant chemical substances**, (ii) the **roles** (chemical manufacturer/importer, article manufacturer/importer, downstream user) that subject companies to REACH's requirements, and (iii) **obligations** companies have in respect of specific substances and specific roles;
- Assess and manage risks involved in taking positions on specific provisions of the REACH Regulation, and related **risk reduction strategies and measures**;
- Help companies integrate REACH compliance strategies into more comprehensive chemical regulatory strategies relating to operations in other countries, including the United States and China; and
- Assist companies with developing cost minimizing strategies, such as single electronic submission of registration dossier for groups of companies, grouping of data, read-across, and use of QSARs.

Compliance:

- Advise companies on the scope of the REACH Regulation and determine whether they can qualify for **complete or partial exemptions**, particularly with respect to registration, evaluation, and authorization;
- Review the legal validity and regulatory implications of technical judgments in connection with registration, chemical safety assessment, and authorization, involving issues such as **substance identity, identified uses, use description, exposure scenarios, risk char-**

acterization, safe use, adequate control, and recommended risk management measures; and

- Advise on the scope of registration and notification requirements relating to "**articles**" (products), including concepts of **intentional release** and **incidental release** of chemical substances, and related risk management strategies.

Pre-Registration, Consortia (Substance Information Exchange Fora or SIEFs), and Use of an "EU Representative":

- Advise on **pre-registration** and the formation by companies of chemical substance **consortia** to deal with REACH, managing consortia, and **consortia agreements** to prevent disputes, ensure compliance with competition law, and protect our clients' positions and intellectual property; and
- Help non-EU manufacturers with setting up of EU "**only representative**" arrangements.

Data Sharing, Antitrust and Intellectual Property Rights:

- Advise on management of confidential data within a SIEF or with public authorities, use of only representative, third party representative and trustee;
- Advise on antitrust compliance during SIEF or consortium formation and data sharing; and
- Advise on rights and obligations in connection with **intellectual property rights, confidentiality, data protection, and data sharing**, and related agreements.

Interacting with Regulators:

- Represent companies in their dealings with, or responding to requests from, the **European Chemicals**

Agency, or other regulatory authorities;

- Represent companies in seeking **opinions** from regulatory authorities on specific issues arising under the REACH Regulation; and
- Represent companies in **regulatory procedures** under the REACH Regulation to ensure compliance with essential procedural requirements and to protect their rights.

Enforcement and Remedies:

- Advise on **remedies** available to companies against adverse findings and decisions of the European Chemicals Agency and other regulatory authorities;
- Advise and represent companies involved in **enforcement actions** pursuant to the REACH Regulation;
- Assist companies in managing the consequences of enforcement actions under the REACH Regulation, including **product recalls**; and
- Advise companies on strategies to **reduce liability risks** associated with the REACH Regulation inside and outside the EU, including the use of information disclosed under REACH in product liability cases outside the EU.

We work closely with our clients' in-house counsel, and with other regulatory and technical experts, as required, to ensure that we achieve the optimum technical/legal results. Hunton & Williams is a global law firm with qualified and experienced lawyers on both sides of the Atlantic, in its offices in Brussels and Washington DC, and also in its Asian offices, including Beijing.

For additional information, please contact any of us.

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