

REACH – Complying with the EU’s Wide-Ranging Product Regulation for Chemical Risk

Product manufacturers in the European Union (EU), and product importers into the EU, will likely be obligated to comply with the EU’s REACH Regulation (REACH). This is true for manufacturers and importers of chemicals in bulk, but also for many manufacturers or importers of products containing chemicals.

REACH—Registration, Evaluation, and Authorization of Chemical substances—is the European Union’s sweeping chemical regulation that, subject to limited exceptions, applies to all products containing chemicals manufactured in or imported into the EU.

The REACH Regulation, enacted in December 2006, imposes a series of complex and onerous obligations on manufacturers, importers, and users of chemical substances, of products comprised of a mixture of substances and of all other products (“articles”) containing chemical substances. Failure to comply with REACH may result in market access problems, sanctions, and liability exposure for product manufacturers. It could also disrupt the supply chains for chemical substances, mixtures, and components essential to the manufacture of key products. Further, other jurisdictions, such as Korea, are beginning to adopt REACH-like requirements.

There often are several options to comply with REACH, and smart compliance is critical to business and competitive success. To help you achieve business success, Hunton Andrews Kurth brings to bear our deep understanding of REACH at the interface of law, science, and policy.

As members of one of the leading environmental, health and safety regulatory law firms in Europe, the United States and Asia, Hunton’s attorneys have been involved with the REACH Regulation since its inception, starting with the Commission’s review of the previous EU 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. Since the REACH Regulation entered into force in June 2007, Hunton had advised many companies and consortia on strategic compliance and risk management under the REACH Regulation.

In assisting our clients with a wide range of challenges associated with REACH, we bring to bear our extensive experience with the practice and interpretation of the REACH Regulation, and of EU administrative law, administrative and judicial remedies, and liability law. Our practice covers compliance issues, strategy development to control cost, investigations and disputes, transactions impacted by REACH, and legal analysis of proposed policies and regulatory actions pursuant to REACH.

Hunton has the experience to assist companies with managing any issue arising under the REACH Regulation. The following is a list of our capabilities and services with respect to REACH. Hunton has the experience to assist companies with managing any issue arising under the REACH Regulation. The following is a list of our capabilities and services with respect to REACH:

Risk and Cost Management Systems and Strategies:

- Assist companies with establishing strategies and systems to manage and, as needed, minimize, the implications of REACH for their specific businesses, including identifying (i) relevant chemical substances, (ii) the various roles (chemical manufacturer/importer, article manufacturer/importer, downstream user) that subject companies to REACH's requirements, and (iii) obligations companies have with regard to specific substances or roles;
- Assess and manage risks involved in structuring business relations and taking positions on specific provisions of the REACH Regulation, and develop 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;
- Assist companies with assessing their product and substance flows, and related REACH implications, and restructuring of business operations to reduce REACH impacts; and
- Assist companies with developing cost minimizing strategies, such as concentrating imports into a single legal entity or spreading imports over several entities, taking advantage of exemptions, and using alternatives to animal testing, such as read-across and use of QSARs.

Compliance, Investigations, and Dealing with Authorities:

- Advise on a wide range of strategic and compliance issues arising under the REACH Regulation and other EU chemical legislation, including substance identity and impurities, registration, labeling, informational requirements and safety data sheets, dossier evaluation, substance evaluation, authorization, restriction, and related administrative processes and procedures, from draft ECHA decisions to appeals before the Board of Appeal;
- 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 characterization, safe use, adequate control, and recommended risk management measures, and advise on queries or investigations by chemical regulatory authorities;
- 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;
- Represent companies in seeking opinions from regulatory authorities on specific issues arising under the REACH Regulation; and
- Represent companies in their dealings with, or responding to requests from, the European Chemicals Agency, or other regulatory authorities, and in regulatory procedures under the REACH Regulation to ensure compliance with essential procedural requirements and to protect their rights.

Consortia and Use of an Only Representative:

- Advise on the formation and operation of, or dealing with, REACH consortia, including structuring and managing consortia, drafting of consortia agreements to smooth operations and prevent disputes, ensure compliance with competition law, and protect clients' positions and intellectual property;
- Advise the LOA REACH Consortium bringing together 50 of the World's leading petrochemical companies (including ExxonMobil, LUKOIL, Petrobras, BP, Shell, LyondellBasell, INEOS, Total and Chevron ConocoPhillips), on structuring, agreements, competition and tax laws, data- and cost-sharing, registration-related issues, dossier and substance evaluations, testing, and other issues associated with consortium and SIEF management and compliance with the REACH Regulation; and
- Help non-EU manufacturers with setting up of EU only representative arrangements, including contractual arrangements.

Data Sharing, Antitrust and Intellectual Property Rights:

- Advise on management of confidential data within a consortium, SIEF or with public authorities, use of only representative, third party representative and trustee;
- Advise on antitrust compliance during SIEF or consortium formation, data sharing, and join activities under the REACH Regulation, including joint application for authorization; and
- Advise on rights and obligations in connection with intellectual property rights, confidentiality, data protection, data sharing, cost sharing, and related agreements.

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 withdrawals and 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.

Hunton 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. 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 and legal results.

Our lawyers are highly knowledgeable and experienced in REACH, having edited and co-authored a leading treatise on the EU REACH Regulation published by Oxford University Press (Lucas Bergkamp, Editor, The European Union REACH Regulation for Chemicals: Law and Practice, Oxford University Press, 2013, <https://global.oup.com/academic/product/the-european-union-reach-regulation-for-chemicals-9780199659791?cc=us&lang=en&>).