EUROPEAN REGULATION OF HAZARDOUS MATERIALS

THE REACH OF REACH – WHAT COMPANIES NEED TO KNOW ABOUT THE EUROPEAN UNION'S NEW CHEMICAL REGULATION

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INTRODUCTION

The European Chemical Industry Council is expecting a decrease in the growth of the European Union's chemical industry in 2008 from 2007 due in large part to high oil prices and the record high rate of the euro against the dollar.[1] The chemical industry is also bracing for another challenge that will impact manufacturers, importers and users of chemicals in the European Union and around the world. June 1, 2008 begins the mandatory registration and pre-registration process for chemicals under one of the most ambitious, progressive and rigorous systems for the regulation of chemicals in the world - the European Union's[2] Registration, Evaluation, Authorization and Restriction of Chemicals Regula-

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1. *See* Sean Milmo, *Chemical firms brace for 2008*, 5 CHEMISTRY WORLD, Jan. 2008, http://www.rsc.org/chemistryworld/Issues/2008/January/ChemistryFirmsBraceFor2008.asp.

2. Twenty-seven member states currently comprise the European Union. Iceland, Liechtenstein and Norway will be considered part of the European Union for the purposes of REACH once REACH is incorporated into the European Economic Area Agreement between the European Union and those countries. The target date to have REACH incorporated in that Agreement is June 1, 2008. Guidance on Registration, Guidance for the Implementation of REACH April 2008 § 1.5.1, ECHA (2007), http://reach.jrc.it/docs/guidance_document/registration_en.pdf [hereinafter Guidance on Registration].

tion (REACH).[3] The European Commission estimates that approximately thirty thousand existing chemicals will be impacted by the requirements of REACH[4] and that the total direct and indirect costs of REACH will be approximately 2.3-5.2 billion euros over eleven to fifteen years.[5]

The proclaimed aim of REACH is to "ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation."[6] REACH makes it unlawful to manufacture, import or market chemicals in quantities over one metric ton per year in the European Union prior to the registration of such chemicals with the newly established European Chemicals Agency (ECHA).[7] However, REACH does not just apply to chemical manufacturers located in the European Union. REACH has implications for companies outside of the European Union, including United States companies, which manufacture chemicals for import into the European Union and which rely on chemicals from the European Union market for their businesses. REACH also has implications for and imposes obligations on users and distributors of chemicals. Manufacturers, importers, users and distributors of chemicals, respectively, have different and potentially multiple roles and obligations under REACH. Failure to comply with REACH could result in significant business interruptions, delays, lost profits and penalties affecting the chemical manufacturer and traveling all the way down the supply chain to the end user.

This article discusses the principal obligations and implications of REACH on manufacturers, importers and users of chemicals and offers suggestions for ensuring compliance with REACH. To obtain an under-

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3. Commission Regulation 1907/2006, Concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), Establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directive 91/155/EEC, 93/67/EEC, 93/105/EC and 2001/21/EC, 2006 O.J. (L 396) 1 (EC), *amended by* Council Regulation 1354/2007, 2007 O.J. (L 304) 1 [hereinafter REACH]; David A. Wirth, *Issue and Policy: The EU's New Impact on U.S. Environmental Regulation*, 31 FLETCHER F. WORLD AFF. 91, 100 (Summer 2007) (stating that REACH "contains the most rigorous testing requirements of any regulatory regime in the world"); Press Release, European Commission, New European Chemicals Agency Starts Operations as REACH Enters Into Force (June 1, 2007), http://europa.eu/rapid/pressReleasesAction.do?reference=ip/07/745& format=HTML&aged=0&language=EN&guiLanguage=en (stating that REACH "is the most ambitious chemicals legislation anywhere in the world" and quoting Environment Commissioner Stavros Dimas stating that REACH is "the most progressive chemicals legislation in the world").

4. European Commission, Environment Directorate General, *REACH in Brief*, at 9 (Oct. 2007), http://ecb.jrc.it/documents/REACH/REACH_in_brief_0207.pdf [hereinafter EC Guide].

5. *Id.* at 17.

6. REACH, *supra* note 3, art. 1(1).

7. *See id.* arts. 5, 6(1).

standing of how REACH works, it is helpful first to understand the reasons and history behind its enactment.

Chemical Regulation in the European Union[8] prior to REACH

Prior to REACH, the European Union's chemical regulatory scheme largely was made up of an assortment of forty different directives and regulations, based on the risk-assessment approach used in the United States' Toxic Substances Control Act.[9] Under the risk assessment approach, authorities had to determine that a chemical posed an unreasonable risk to health or the environment before they could regulate that chemical.[10] Following that approach, chemicals placed on the European Union market prior to September 18, 1981 (existing chemicals) were not required to be tested to assess potential health and environmental impacts.[11] In 1979, the European Union created a dichotomy between how existing chemicals and chemicals placed on the market after September 18, 1981 (new chemicals) were to be treated, by promulgating a directive that approached the "precautionary principle"[12] of regulation for new chemicals. That new directive required European Union Member States to be notified and provided with production, use and intrinsic property information regarding new chemicals prior to the placement of such chemicals on the market.[13] Thirteen years later in 1992, the European Union moved even closer to the precautionary principle by adopting a directive requiring that risk assessments be conducted by producers and importers of new chemicals in excess of ten kilograms per year prior to the placement of such chemicals on the market.[14] However, insofar as the 1979 and 1992 directives were not accompanied by officially promulgated

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8. For ease of reference, the term "European Union" is used throughout this article to refer to the current European Union established in 1993 as well as its predecessor, the European Community.

9. ECHA About Reach, http://reach.jrc.it/about_reach_en.htm. The principal prior chemical legislation consisted of: Council Regulation 793/93, 1993 O.J. (L 84) 1 (EEC), *as amended*, Directive 1999/45/EC, 1989 O.J. (L 200) 1, *as amended*, Council Directive 67/548/EEC 1967 O.J. (L 196) 1, *as amended*, and Council Directive 76/769/EEC, 1976 O.J. (L 262) 201, *as amended*. REACH, *supra* note 3, recital 9.

10. *See* U.S. Government Accountability Office, GAO-07-825, Chemical Regulation, Comparison of U.S. and Recently Enacted European Union Approaches to Protect Against the Risks of Toxic Chemicals 1, 4 (August 2007) [hereinafter GAO Report].

11. *See* EC Guide, *supra* note 4, at 3.

12. *See* GAO Report, *supra* note 10, at 7, n. 4 (stating that the precautionary principle generally means "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to reduce risks to human health and the environment").

13. Council Directive 79/831, amending for the sixth time Council Directive 67/548/EEC, 1979 O.J. (L 259) 10 (EEC).

14. Council Directive 92/32, amending for the seventh time Council Directive 67/548/EEC, 1992 O.J. (L 154) 1 (EEC).

regulations,[15] European Union Member States were free to determine their own, varied methods to comply with the requirements of those directives.

Furthermore, neither directive applied to existing chemicals. Beginning in 1993, the European Commission[16] and Member States were authorized to prepare priority lists of existing chemicals requiring "immediate attention."[17] However, the risk assessment process for existing chemicals conducted by Member States was very slow and resulted in risk assessments being conducted for only a little more than half of the priority listed chemicals.[18]

In 1998, the European Commission evaluated the European Union's primary four pieces of chemical legislation then in existence.[19] That evaluation determined that the existing system did not provide adequate information regarding the risks of chemicals on human health and the environment.[20] There was too little information regarding existing chemicals and no system in place to ensure that testing of new chemicals took into account all intended uses of, and potential exposures, to new chemicals.[21] In the face of testing requirements and associated costs and delays, companies were shying away from developing new and potentially less hazardous chemicals in favor of continued production of existing chemicals.[22] In addition, the evaluation concluded, inconsistencies between Member States' regulatory systems had resulted in disparities in the level of protection of human health and the environment and led to unequal competitive conditions within the European Union's internal market.[23]

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15. A regulation is binding in its entirety and directly applicable to member states as soon as it comes into force without any action by the member states. A directive, on the other hand, establishes the required result, but allows members states to determine the method and form for achieving that result. *See* European Commission, Directorate-General for Communication, *How the European Union Works,* at 7 (July 2007), http://www.eurunion.org/infores/HowEUWorks072007.doc.

16. For ease of reference, the term "European Commission" is used throughout this article to refer to the current European Commission and its predecessor, the Commission of the European Communities.

17. Council Regulation 793/93, art. 8(1), 1993 O.J. (L 84) 1 (EEC); Commission Regulation 1488/94, 1994 O.J. (L 161) 3 (laying down the principles for risk assessments).

18. Of the 141 substances listed, only eighty-three have completed the risk assessment process and only thirty-nine of those have been evaluated for the imposition of restrictions. *Opinion of the European Economic and Social Committee on the Proposal for a Decision of the European Parliament and of the Council amending Council Directive 76/769/EEC*, at 2-3, COM (2007) 599 final (March 12, 2008).

19. *Commission Working Document, Report on the Operation of Directive 67/548/EEC, Directive 88/379/EEC, Regulation (EEC) 793/93 and Directive 76/769/EEC*, SEC (1998) 1986 final (November 11, 1998).

20. *See* EC Guide, *supra* note, 4 at 3.

21. *See id*.

22. *See* Cross-Border Handbook, Environment 2007-2008, *REACH – Basic Principles and Practical Issues*, at 30 [hereinafter Cross-Border Article].

23. *See* REACH, *supra* note 3, recital 9.

WHAT IS REACH?

REACH was adopted on December 18, 2006 to address the deficiencies of the European Union's chemical regulatory system then in existence by broadly adopting the precautionary principle of regulation for chemicals.[24] REACH shifts the burden of ensuring that chemicals do not adversely impact human health or the environment from the government to the manufacturers and importers placing those chemicals on the market.[25] REACH requires manufacturers and importers to assess the potential health and environmental impacts of chemicals that are manufactured,[26] imported,[27] or placed on the market[28] in quantities of over one metric ton per year,[29] or that fall into certain categories of dangerous chemicals, and to register such chemicals by providing risk assessment information to ECHA prior to the manufacture, import or marketing of such chemicals in the European Union. REACH also requires certain data sharing among registrants to reduce costs and duplicative tests and to further another goal of the European Commission to reduce animal testing.[30] In addition, because REACH is a regulation, it is directly applicable to Member States thereby providing an equal playing field for companies doing business on the European Union market.[31] Since REACH came into force on June 1, 2007, ECHA has been preparing for the commencement of the chemical registration and pre-registration process on June 1, 2008, including the development and management of REACH-IT, ECHA's central on-line database to which pre-registrants and registrants will submit their registration information.

What Does REACH Cover?

REACH applies to substances, defined under REACH as chemicals and their compounds in the natural state or obtained as a result of any manufacturing process.[32] REACH also applies to substances in mixtures

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24. *See id.* art. 1(3).

25. *See id.*

26. "Manufactured" means substances produced or extracted in their natural state. *Id.* art. 3(8).

27. "Imported" means physically introduced into the customs territory of the European Union. *Id.* art. 3(10).

28. "Placed on the market" means supplied or made available, whether in return for payment or free of charge, to third parties. *Id.* art. 3(12). Items that are imported are considered to be placed on the market.

29. The one metric ton per year threshold was designed to allow for experimental and testing use. *See* Cross-Border Article, *supra* note 22, at 31.

30. *See* REACH, *supra* note 3, art. 25(1); *see also supra* recitals 33, 47, 49.

31. *See id.* recital 2 (stating that "the efficient functioning of the internal market for substances can be achieved only if requirements for substances do not differ significantly from Member State to Member State").

32. "Substance" includes any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which many be separated without affecting the stability of the substance or changing its composition. REACH, *supra* note 3, art. 3(1); See Guidance for Identification and Naming of Substances

or solutions that are composed of two or more substances (e.g., paints and varnishes),[33] known as "preparations"[34] under REACH, and "articles"[35] (e.g., manufactured goods). REACH requires that each substance present within a preparation in quantities of over one metric ton per year be registered.[36] Substances that have been registered and that are put into a preparation by a down-the-supply-chain user do not need to be registered again.[37] REACH requires that all substances present in an article in quantities over one metric ton per year that are intended to be released from the article during normal and reasonably foreseeable conditions of use (e.g., toner from a printer cartridge) be registered.[38] In addition, manufacturers and importers must notify ECHA of any substances meeting certain hazard criteria[39] that are present in articles above a concentration limit of 0.1% weight by weight and present above one metric ton per year unless exposure can be prevented during normal conditions of use, including disposal.[40]

Exemptions

Certain substances are specifically exempt from regulation under REACH. Radioactive substances and dangerous substances and preparations transported by rail, road, water or air are exempted because they are specifically covered by other legislation.[41] Substances that are in the European Union only because they are being transported somewhere else through the European Union are exempt provided that they are kept under customs supervision.[42] In addition, waste is specifically excluded from the definition of substance under REACH.[43] REACH also exempts non-isolated intermediates, which are substances that are manufactured for and consumed in, or used for, chemical processing in order to be transformed into another substance and that are not intentionally removed from the equipment in which the synthesis takes place.[44] Any

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under REACH June 2007, ECHA (2007), http://reach.jrc.it/docs/guidance_document/substance_id_en.pdf, for guidance on how to name and identify substances under REACH.

33. Guidance on Registration, *supra* note 2, § 1.4.

34. REACH, *supra* note 3, art. 3(2).

35. An "article" is an object which during production is given a special shape, surface or design which determines its function to a higher degree than does its chemical composition. *Id.* art. 3(3).

36. *Id.* art. 6(1).

37. Guidance on Registration, *supra* note 2, § 1.4.

38. REACH, *supra* note 3, art. 7(1).

39. See REACH, *supra* note 3, art. 57 for the referenced criteria.

40. *Id.* art. 7(2). Suppliers of such articles are required to provide to the recipient, and upon request, the consumers of the article with sufficient available information to allow safe use of the article. *Id.* art. 33.

41. *Id.* arts. 2(1)(a) and (d).

42. *Id.* art. 2(1)(b).

43. *Id.* art. 2(2).

44. *Id.* arts. 2(1)(c) and 3(15)(a). See Guidance for Intermediates February 2008, ECHA (2007), http://reach.jrc.it/docs/guidance_document/intermediates_en.pdf

quantities of the intermediate that are used in other operations or under different conditions will not qualify for exemption as a non-isolated intermediate.[45] However, the intermediate may qualify for reduced registration requirements provided certain conditions are met.[46]

Certain other substances, including those used in food and pharmaceuticals, substances deemed as causing minimum risk to health or the environment (e.g., substance of natural origin, such as soybean oil and cellulose pulp),[47] substances for which registration is deemed inappropriate or unnecessary (e.g., by-products, provided that they are not imported or placed on the market themselves),[48] recycled or recovered substances already registered, substances that have been registered, exported and then re-imported, polymers[49] and substances manufactured or imported for the purpose of product and process oriented research and development (PPORD), are exempt from the registration requirements of REACH, but are subject to other requirements under REACH.[50] For example, although substances used for PPORD are exempt from registration requirements, manufacturers and importers of substances used for PPORD must provide notification to ECHA and abide by any conditions imposed by ECHA to qualify for an exemption from registration.[51] In addition, any quantities of a substance that is exempt based on its use, such as substances used in food and pharmaceuticals and for PPORD, that are used for purposes other than that exempted use are not exempt from registration.[52]

[hereinafter Guidance for Intermediates] for guidance on the treatment of intermediates under REACH.

45. Guidance for Intermediates, *supra* note 44, § 2.

46. The isolated intermediate must be manufactured or imported only for use as an intermediate and the manufacture or use of the intermediate must be under strictly controlled conditions to qualify for reduced registration requirements. *Id.* § 2.

47. REACH, *supra* note 3, Annex IV Exemptions from the Obligation to Register in Accordance with Article 2(7)(a).

48. REACH, *supra* note 3, Annex V Exemptions from the Obligation to Register in Accordance with Article 2(7)(b).

49. Monomers or other substances used for the manufacture of polymers may be required to be registered. *See* Guidance for Monomers and Polymers March 2008, ECHA (2007), http://reach.jrc.it/docs/guidance_document/polymers_en.pdf for more information on monomers and polymers.

50. REACH, *supra* note 3, art. 2.

51. *See* Guidance on Registration, *supra* note 2, § 1.6.4.8.

52. *See id.* §§ 1.6.4.1-1.6.4.2.

Who Is Responsible for Registration?

Manufacturers[53] and importers of substances, and, in some cases, producers[54] and importers[55] of articles, that are based or established in the European Union are responsible for registration. Non-European Union manufacturers cannot directly register substances or articles. Registration must be made by the importer of the substance or article or an "only representative" based or established in the European Union who is appointed by the outside manufacturer.[56] The "only representative" becomes the registrant and is responsible for fulfilling all of the REACH obligations.[57] Outside manufacturers should consider appointing an "only representative" if they want to avoid reliance on the importer and to maintain control of their confidential information. If an "only representative" is appointed, the importer is relieved of its registration obligations and becomes a downstream user[58] who is not responsible for registration.[59] This is true even if the importer imports a substance directly from the non-European Union manufacturer.[60] However, if the importer imports the same substance from other outside manufacturers, the importer is required to register the tonnage of the substance that is imported from such other manufacturers.

When a substance is manufactured or imported by several European Union legal entities belonging to the same company group (e.g., a parent company and its subsidiaries), each entity must register its respective quantities of the substance separately.[61] However, if one legal entity has one or more manufacturing plants which are not separate legal entities, only one registration is required.[62] ECHA's central on-line database, REACH-IT, will enable parent companies to submit pre-registration information for several legal entities belonging to the same company group.[63]

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53. Manufacturers of substances are any natural or legal persons established in the European Union who manufacture a substance in one or more Member States. REACH, *supra* note 3, art. 3(9).

54. Producers of articles are any natural or legal persons established in the European Union who make or assemble articles in the European Union. *Id.* art. 3(4).

55. Importers of substances and articles are any natural or legal persons established in the European Union who are responsible for the physical introduction of a substance or article into the customs territory of the European Union. *Id.* arts. (3)10, (3)11.

56. The only representative must be established in the European Union and have sufficient background in the practical handling of the substance. *Id.* art. 8(1)-(2).

57. *See id.* art. 8(1).

58. A downstream user is a person who uses a substance, either on its own or in preparations, in his industrial or professional activities. *Id.* art. 3(13).

59. Guidance on Registration, *supra* note 2, § 1.5.3.4.

60. Guidance for Downstream Users January 2008, ECHA (2008) § 2.5.3, table 3, http://reach.jrc.it/docs/guidance_document/du_en.pdf [hereinafter Downstream User Guidance].

61. Guidance on Data Sharing September 2007, ECHA 2007 § 3.4, http://reach.jrc.it/docs/guidance_document/data_sharing_en.pdf [hereinafter Data Sharing Guidance].

62. *See id.*

63. *Id.* § 3.8.

Existing vs. New Substances

Unlike the previous regulatory system, REACH treats new and existing chemicals largely the same. One difference, however, is that existing substances qualify for pre-registration, a process that delays the registration deadline, while new substances do not. New substances that have not been produced or marketed in the European Union prior to the entry into force of REACH on June 1, 2007 are considered "non-phase-in substances" under REACH.[64] Non-phase-in substances cannot be manufactured, imported or placed on the market in the European Union until they are registered by the submission of a registration dossier to ECHA. The registration dossier may be required to include extensive information and be time and labor intensive and costly to prepare.[65] ECHA will begin accepting registration dossiers on June 1, 2008.

Existing substances that have been listed in the European Inventory of Existing Commercial Chemical Substances (EINECS), those that have been manufactured in the European Union but not placed on the market since 1992[66] and those that are "no-longer polymers,"[67] are called "phase-in substances"[68] under REACH. Between June 1, 2008 and December 1, 2008, companies may pre-register phase-in substances. Pre-registration is free of charge and requires submission of basic and far less extensive information than is required for the formal registration dossier, including the name of the substance, contact information for the pre-registrant and anticipated registration deadline and volume of the substance.[69] Once pre-registered, a phase-in substance can continue to be manufactured, imported and marketed without the submission of a registration dossier until the applicable registration deadline (discussed below). REACH also allows a phase-in substance that is manufactured or imported for the first

64. *See* Guidance on Registration, *supra* note 2, § 1.7.1.2.

65. *See infra* discussion of the registration dossier pp. 8-10.

66. This category would primarily include substances produced solely for export purposes. The manufacturer must have documentation that such substances were manufactured since 1992, such as order sheets or stock lists. *See* Guidance on Registration, *supra* note 2, § 1.7.1.1.

67. A "no longer polymer" is a substance placed on the market between September 18, 1981 and October 31, 1993 and considered as notified under Article 8(1) of the sixth amendment to Directive 67/548 EEC, but which does not meet the REACH technical definition of a polymer. *Id.* § 1.7.1.1.

68. REACH, *supra* note 3, art. 3(20). There are approximately 100,200 existing substances currently listed on EINECS. *See* ECB Existing Chemicals http://ecb.jrc.it/existing-chemicals/ (last visited May 10, 2008).

69. *See* REACH, *supra* note 3, art. 28(1). For information on pre-registration, see Preparation for Pre-Registration Guide, CEFIC (April 2008), http://www.cefic.org/Files/Publications/Cefic%20REACH%20Pre-registration%20guidance.pdf [hereinafter CEFIC Guide], Data Sharing Guidance, *supra* note 61, § 3, and Guidance on Registration, *supra* note 2, § 2.2. ECHA is in the process of preparing a specific guidance on pre-registration that is expected to be available at http://reach.jrc.it/03_rdds_web_content/pre-registration_en/pre-registration_en.pdf. At the time this article was written, the guidance was not yet available.

time after December 1, 2008 to be pre-registered after the December 1, 2008 deadline, but within six months of the first manufacture or import of the substance and no later than twelve months before the applicable registration deadline.[70]

Although the pre-registration process is voluntary, failure to pre-register a phase-in substance by December 1, 2008 or, if applicable, the relevant late pre-registration cut-off date, means the manufacturer or importer must stop manufacturing, importing or marketing the substance until at least three weeks after the submission a registration dossier for the substance.[71] In addition, downstream users will not be able to place on the market a phase-in substance after December 1, 2008 until it is registered, unless it has been pre-registered. Thus, the failure to use the pre-registration process could have critical business consequences for manufacturers, importers and users who rely on phase-in substances.

Registration Deadlines

REACH sets forth a phased approach to registration for phase-in substances over an eleven-year period. The registration deadline for a phase-in substance depends on the volume of the substance that is manufactured or imported in one year[72] and whether the substance meets certain hazard criteria, such as having carcinogenic, mutagenic or reprotoxic characteristics, set forth in Annex III of REACH.[73] Substances meeting the Annex III criteria and higher volume phase-in substances are required to be registered sooner because they are deemed to present the most significant exposure issues. The first registration deadline is November 30, 2010 and applies to phase-in substances in quantities greater than one thousand metric tons per year, substances meeting the Annex III hazard criteria, and phase-in substances classified as being toxic to aquatic organisms in quantities greater than one hundred metric tons per year.[74] The second registration deadline is May 31, 2013 and applies to phase-in substances in quantities greater than one hundred metric tons per year.[75] The final registration deadline is May 31, 2018 and applies to phase-in substances in quantities greater than one metric ton per year.[76] Any substance meeting the Annex III hazard criteria or other phase-in substance over one metric ton per year that is not registered by the applicable registration deadline cannot be manufactured, imported or marketed in the European Union.

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70. REACH, *supra* note 3, art 28(6).

71. *See id.* art. 21(1).

72. The tonnage for phase-in substances is calculated as a three year average as long as they have been manufactured for three consecutive years. EC Guide, *supra* note 4, at 7.

73. REACH, *supra* note 3, Annex III Criteria for Substances Registered in Quantities Between 1 and 10 Tonnes [hereinafter Annex III].

74. REACH, *supra* note 3, art. 23(1).

75. *Id.* art. 23(2).

76. *Id.* art. 23(3).

Registration Dossier

To complete the registration process, the registrant must submit a registration dossier to ECHA.[77] Submission of the registration dossier is required to promote transparency and to ensure that manufacturers and importers meet their burden of assessing the risks posed by the substances that they manufacture and import.[78] The amount and type of information required to be submitted depends on whether the substance meets the Annex III hazard criteria of REACH and the volume of the substance that is manufactured or imported in the European Union per year.[79] REACH sets forth the following four volume tiers: (i) one to ten metric tons, (ii) ten to one hundred metric tons, (iii) one hundred to one thousand metric tons, and (iv) over one thousand metric tons.[80] Information that is required to be submitted for all substances manufactured or imported in quantities over one metric ton per year includes the identity of the registrant and substance, information on manufacture, use and exposure, classification and labeling information,[81] and guidance on safe use.[82] More extensive information, set forth in Annexes VII to X of REACH, is required for phase-in substances in the three highest volume tiers, phase-in substances meeting the Annex III hazard criteria[83] and non-phase-in substances.[84] The higher the volume tier, the more extensive is the information that is required. Registrants must submit the information required for their applicable tier as well as the information re-

77. REACH requires that the format of the dossier be International Uniform Chemical Information Database (IUCLID). The software for IUCLID can be downloaded from http://ecbwbiu5.jrc.it/. See IUCLID 5 Guidance and Support, End User Manual Vol. 1 June 2007, European Communities (2007), http://reach.jrc.it/docs/guidance_document/iuclid_en.pdf. for guidance on using the IUCLID software.

78. *See* REACH, *supra* note 3, recital 19.

79. *Id.* art. 12; Annex III, *supra* note 73.

80. REACH, *supra* note 3, art. 12(1).

81. To determine the required classification and labeling information, registrants must apply Articles 4, 6, 23, 24, and 25 of Directive 67/548/EEC and Articles 4 to 7 of Directive 99/45/EC. REACH, *supra* note 3, Annex VI Information Requirements Referred to in Article 10 [hereinafter Annex VI]. It is expected that sometime in 2008, the United Nation's Globally Harmonized System of Classification and Labeling of Chemicals will amend the classification and labeling provisions of Directive 67/548/EEC and Directive 1999/45/EC and will be incorporated into a new Annex XV of REACH. *See* Downstream User Guidance, *supra* 60, § 2.4.

82. *See* REACH, *supra* note 3, art. 10; Annex VI, *supra* note 81.

83. Annex III, *supra* note 73.

84. The referenced information requirements are set forth in REACH, *supra* note 3, Annex VII Standard Information Requirements for Substances Manufactured or Imported in Quantities of One Tonne or More [hereinafter Annex VII]; REACH, *supra* note 3, Annex VIII Standard Information Requirements for Substances Manufactured or Imported in Quantities of 10 Tonnes or More; REACH, *supra* note 3, Annex IX Standard Information Requirements for Substances Manufactured or Imported in Quantities of 100 Tonnes or More [hereinafter Annex IX]; REACH, *supra* note 3, Annex X Standard Information Requirements for Substances Manufactured or Imported in Quantities of 1000 Tonnes or More [hereinafter Annex X].

quired for each lower tier.[85] Registrants of substances in the one hundred to one thousand metric tons and over one thousand metric tons volume tiers are required to submit testing proposals for the studies required by, respectively, Annexes IX and X of REACH.[86] The testing proposals must provide justification that the testing is necessary to comply with REACH requirements and to increase the knowledge of dangerous properties of the substance and that the testing proposal is reliable and relevant.[87] Registrants may adapt the standard testing regimes set forth in Annexes VII-X on the basis that the testing does not appear scientifically necessary, is not technically possible or is not necessary based on the exposure scenario developed in the chemical safety report (discussed below).[88]

The registration dossier for substances in the three highest volume tiers also must contain a chemical safety report.[89] The chemical safety report documents the results of specific health and environmental hazard assessments that take into account all of the intended uses of the substance for all stages of the substance's life cycle.[90] If the assessments reveal that the substance is "dangerous,"[91] the chemical safety report must also contain document exposure scenario assessments for all intended uses of the substance during its life cycle and recommendations for controlling health and environmental exposures to the substance.[92]

Once the registration dossier is submitted, ECHA will conduct an automated completeness check of the dossier to ensure that all of the required information is included.[93] ECHA will also examine all testing proposals to ensure that they are appropriate and that unnecessary animal testing is not proposed.[94] ECHA may perform a random compliance check of the dossier to ensure the information is adequate and cor-

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85. *See* Annex VII, Annex IX and Annex X, *supra* note 84.

86. *See* Annex IX and Annex X, *supra* note 84.

87. Guidance on Registration, *supra* note 2, § 8.1.3.4.

88. REACH, *supra* note 3, Annex XI General Rules for Adaptation of the Standard Testing Regime Set Forth in Annexes VII to X.

89. The requirements for the chemical safety report are set forth in REACH, *supra* note 3, Annex I General Provisions for Assessing Substances and Preparing Chemical Safety Reports [hereinafter Annex I]. ECHA is developing Guidance on Information Requirements and Chemical Safety Assessment that is expected to be available at http://reach.jrc.it/03_rdds_web_content/csr_en/csr_en.pdf. At the time this article was written, the guidance was not yet available.

90. REACH, *supra* note 3, art. 14; Annex I, *supra* note 89.

91. A "dangerous" substance is a substance that meets the criteria for classification of dangerous under Directive 67/548 and 99/45, including a substance that is toxic, flammable, corrosive or explosive, or that meets the criteria for persistent, bioaccumulative and toxic or very persistent and very bioaccumulative substances set forth in Annex XIII of REACH. *See* REACH, *supra* note 3, art. 31(1).

92. Annex I, *supra* note 89, ¶ 3.

93. *See* Guidance on Dossier and Substance Evaluation June 2007, ECHA (2007), § 2.2.1, http://reach.jrc.it/docs/guidance_document/evaluation_en.pdf [hereinafter Guidance on Evaluation].

94. *See id.* § 2.1.

responds to the requirements of REACH.[95] Based on the results of the compliance check, ECHA may request additional information from the registrant and set deadlines for receipt of that additional information.[96] A registrant may begin or continue manufacturing or importing a substance or article three weeks after the dossier submission date unless the registrant hears otherwise from ECHA.[97]

In order to promote the goal of transparency, ECHA will make certain information included in the registration dossier publicly available on its website, including the name of the substance, classification and labeling information for the substance, physicochemical information, results of toxicological and ecotoxicological studies and guidance on safe use.[98] ECHA also will make certain other information (including the registered volume tier, trade name of the substance and the degree of purity of the substance and the identity of impurities and/or additives that are known to be dangerous) publicly available unless the registrant submits a justification acceptable to ECHA as to why that information is commercially sensitive and therefore should not be available.[99]

Registrants are required to update their registration dossier upon certain changes, including upon changes in the composition of the substance and tonnage, upon new identified uses and new knowledge of environmental and health risks posed by the substance, or the identification of the need to perform a higher level test.[100] The update requirement also applies to any change in the details of a legal entity, such as a merger, spin-off, acquisition or bankruptcy.[101] For example, if a company spins off a division resulting in the formation of a legal entity separate from the original company, the new entity will need to submit a new registration dossier.[102] If two companies merge resulting in one legal entity, the company resulting from the merger must submit a new registration dossier.[103] In addition, in the event that a registrant ceases to manufacture a substance, the registrant must inform ECHA.[104]

Information Sharing Requirements for Pre-Registration and Registration

Although each registrant is required to submit an individual dossier, registrants of the same substance are required to jointly submit certain information, including information on classification and labeling, required studies and testing proposals.[105] The information sharing require-

95. *See id.* § 2.2.
96. *See id.*
97. REACH, *supra* note 3, art. 21(1).
98. *See id.* recital 117; *id.* art. 119(1).
99. *See id.* art. 119(2).
100. *See id.* art. 22(1)
101. Guidance on Registration, *supra* note 2, § 1.5.3.2.
102. *See id.*
103. *See id.*
104. *Id.*
105. *See* REACH, *supra* note 3, art. 11(1).

ment is aimed at increasing the efficiency of the registration system, reducing costs and duplicative tests and to further the European Union's goal to reduce testing on vertebrate animals.[106] In addition to the required joint information, registrants of the same substance also may jointly submit the chemical safety report and guidance on the safe use of the substance.[107] During the pre-registration process, all pre-registrants will be placed into a Substance Information Exchange Forum (SIEF) of pre-registrants of the same phase-in substance.[108] By January 1, 2009, a list of all pre-registered phase-in substances is expected to be published on ECHA's website.[109] Other stakeholders, such as downstream users or manufacturers of a phase-in substance in quantities of less than one metric ton, who have information regarding phase-in substances on the list may participate in the SIEF and provide information that they have regarding phase-in substances in exchange for compensation.[110]

Before conducting any test to comply with the information requirements of REACH, SIEF members are required to determine whether a relevant study for the phase-in substance is available from other members within the SIEF.[111] If a relevant study is not available within that SIEF, the members may request the study from members of other SIEFs.[112] If the relevant study that is required pursuant to Annexes VII or VIII of REACH is not available, one member of the SIEF will be required to conduct the study on behalf of the other members.[113] If the relevant study is a more extensive study required pursuant to Annexes IX or X and it is not available, a testing proposal will need to be submitted to ECHA for one member of the SIEF to conduct the study.

If a study involving vertebrate animal testing is available within the SIEF, the members are required to request that study from the owner of the study in exchange for compensation.[114] If the owner of the vertebrate animal study will not provide the study to the other members, the owner will be prohibited from registering the substance in question until the information is provided to the other members of the SIEF.[115] The other members will be able to proceed with registration without the study for a period of twelve months.[116] If the owner has not provided the informa-

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106. *See id.* art. 25(1); *see also id.* recitals 33, 47, 49.

107. *See id.* art. 11(1).

108. *See id.* art. 29(1). See Data Sharing Guidance, *supra* note 61, §§ 4, 5 and CEFIC Guide, *supra* note 69, at 12-14 for more information on SIEFs.

109. Data Sharing Guidance, *supra* note 61, § 4.4.2.

110. *See* REACH, *supra* note 3, art. 28(7).

111. *Id.* art. 30(1).

112. *See* Data Sharing Guidance, *supra* note 61, § 5.3.6.

113. *See* REACH, *supra* note 3, art. 30(2). If the SIEF members cannot agree on which member will conduct the test, ECHA will determine which member will conduct the test in exchange for compensation from the other members.

114. *See id.* art. 30(1).

115. *See id.* art. 30(3)

116. *See id.*

tion within twelve months of the registration, the vertebrate animal study will be conducted only if so determined by ECHA.[117] If a study not involving vertebrate animal testing is available, the members have the option to request that study from the owner in exchange for compensation or to submit a proposal to ECHA to conduct their own study.[118] If the owner of a non-vertebrate animal study will not provide the study to other participants, the SIEF members will need to proceed with registration as if the study did not exist.[119] Owners of non-vertebrate and vertebrate animal studies who refuse to provide the studies to other SIEF members in exchange for compensation will be subject to penalties.[120]

There is no prescribed legal form for the organization of a SIEF. SIEF members can cooperate indirectly through on-line data sharing tools provided by ECHA or create structured groups, such as consortia, through contracts.[121] Regardless of whatever form of cooperation is chosen, a written agreement regulating, at a minimum, rules for data sharing, ownership of jointly developed studies and cost allocation should be created.[122] SIEF members may consider asking a law firm or trade association to assist them in creating a form of cooperation.[123]

ECHA will provide SIEF members with the names and contact information for all other SIEF members. In some cases, members of a SIEF may be competitors. In order to protect confidentiality within the SIEF, pre-registrants may appoint a third party representative to fulfill their data sharing obligations.[124] In this case, the pre-registrant would remain anonymous to members of the SIEF. Companies with a number of subsidiaries in the European Union may name one of their companies as a third party representative to keep confidential which substance is produced by which subsidiary.[125]

Prior to registering, registrants of non-phase-substances or registrants who have not pre-registered are required to submit a request to ECHA to determine whether a registration has already been submitted for the same substance.[126] If so, and if the substance was registered more than twelve years earlier, the studies provided in support of the registration will be freely available for downloading from ECHA's website.[127] If

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117. *Id.*

118. *See id.* art. 30(1).

119. *See id.* art. 30(4).

120. *See id.* art. 30(6).

121. *See* Data Sharing Guidance, *supra* note 61, § 10.1.

122. *See id.*

123. *See id.* § 10.3.

124. *See id.* § 4.2.1. The third party representative merely acts as an agent for data sharing purposes. The pre-registrant retains full responsibility for complying with REACH.

125. *Id.* § 11.3.

126. REACH, *supra* note 3, art. 26(1). If several potential registrants have inquired about the same substance, ECHA will provide each potential registrant with the contact information for the others.

127. *See id.* art. 25(3).

the substance was registered less than twelve years earlier, the potential registrant is required to request from the previous registrant information involving studies on vertebrate animals and may request information on studies not involving vertebrate animals.[128] The potential and previous registrants are required to attempt to reach an agreement as to the sharing of the information and the associated costs.[129] Once an agreement is reached, the potential registrant may use the previous registrant's studies for purposes of registration. In the event that an agreement cannot be reached, ECHA will grant the potential registrant the right to use the requested studies for purposes of registration provided that the potential registrant provides proof of payment to the previous registrant for use of the studies.[130]

REACH does not prescribe any mechanism for cost allocation or compensation within SIEFs or among registrants.[131] SIEF members and registrants may allocate costs in any way that is "fair, transparent and non-discriminatory."[132] SIEF members and registrants may allocate costs based on the number of parties involved or proportionally based on production or sales volume.[133] Factors to consider in the allocation process include the reliability, relevance and adequacy of the data, economic value of the data and any data usage restrictions.[134]

In the event that little information or very few co-registrants exist for a substance that must be registered, potential registrants should compare the costs involved in registering the substance to the loss of profits in ceasing to manufacture or import the substance. If there is no existing information and no co-registrants with whom to share the testing costs, the cost of complying with the testing requirements for a substance may outweigh the potential loss in profits for ceasing to manufacture that substance.

To prevent anti-competitive behavior, REACH requires that individual registrants must separately submit certain information such as company details, production volume information, intended uses and exposure information.[135] Registrants must avoid violating European Union competition law in connection with data sharing, such as exchanging information that would allow competitors to identify company details and influence market behavior.[136] In order to reduce suspicions of anti-com-

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128. *See id.* art. 27(1).

129. *Id.* art. 27(3).

130. *See id.* arts. 27(5), (6); Data Sharing Guidance, *supra* note 61, § 6.3.

131. Under REACH, ECHA is tasked with developing cost sharing guidance. *See id.* arts. 27(3), 77(2)(g).

132. *Id.* arts. 27(3), 30(1) .

133. *See* Data Sharing Guidance, *supra* note 61, § 7. If cost sharing will be based on production or sales volume, registrants should appoint a third party to assess that information to avoid anti-competition issues.

134. *See id.*

135. *See* REACH, *supra* note 3, arts. 11(1), 25(2).

136. *See id.* art. 25(2); *see also* Data Sharing Guidance, *supra* note 61, § 9.2.

petitive behavior, registrants may want to reduce the frequency of data exchanges, refer to tonnage bands rather than individual volume figures and consider using an independent third party when company-specific sensitive information needs to be exchanged, such as production or sale volume information.[137]

A registrant may opt out of joint submission if its dossier contains an explanation as to why joint submission would be disproportionately costly, leads to disclosure of commercially sensitive information and is likely to cause substantial commercial detriment, or the registrant disagrees with the selection of joint information to be submitted.[138] There is no definition of "disproportionate" costs or what constitutes a "substantial" detriment provided in REACH. Registrants who want to opt out should provide a sufficient explanation as why costs are disproportionate and an estimate of the value of the confidential business information at stake.[139] Alternatively, if the registrant is concerned about sharing confidential information, they may consider entering into confidentiality agreements with SIEF members that limit access to information or agree to allow a third party expert to review and assess the information.[140]

Authorizations

By then end of 2008, ECHA expects to publish a list of approximately two thousand substances of very high concern (SVHCs).[141] The SVHCs on the list will gradually be included in Annex XIV of REACH.[142] None of the listed SVHCs will be permitted to be manufactured, imported, used or placed on the European Union market beyond a certain date without an authorization, unless the SVHC is otherwise exempt.[143] In addition, once substances are registered, Member States will identify substances to be evaluated for potential risks to health or the environment.[144] The purpose of that evaluation process is to identify SVHCs that should be subject to authorization and other substances that should be subject to restrictions (discussed below).[145] The authorization requirement is aimed at promoting the development of less harmful substances to replace SVHCs.[146] Applicants for an authorization will be required to show that

137. *See* Data Sharing Guidance, *supra* note 61, § 9.2.3.

138. *See* REACH, *supra* note 3, art. 11(3).

139. *See* Data Sharing Guidance, *supra* note 61, § 8.4.2.

140. *See id.* §§ 11.4, 11.5.

141. *See* REACH, *supra* note 3, arts. 57, 59. SVHCs are substances that are carcinogenic, mutagenic or reprotoxic, substances that meet the criteria set forth in Annex XIII of REACH, or other substances that give rise to concern due to evidence of their serious effects to health and the environment as determined on a case-by-case basis by ECHA and Member States.

142. *See id.* art. 59.

143. *See* REACH, *supra* note 3, arts. 56(1), 58(2).

144. *See* Guidance on Evaluation, *supra* note 93, § 3.

145. *See* REACH, *supra* note 3, recital 21.

146. *See id.* art. 55.

the risks of the SVHC are adequately controlled or the socio-economic benefits of the use of the SVHC outweigh the risks and that there is no suitable alternative substance.[147] If a suitable alternative substance is available, the authorization application must include a substitution plan.[148] Even if an authorization is obtained, the European Commission has the right to amend or withdraw any authorization if suitable alternative substances become available.[149]

Restrictions

Annex XVII of REACH contains a list of substances that cannot, on their own or in preparations or articles, be manufactured, imported, placed on the market or used except for in compliance with certain restrictions.[150] Benzene, asbestos and mercury compounds are examples of substances that are subject to such restrictions.[151] Member States and ECHA can propose additional restrictions for existing restricted substances or new restrictions for existing or new substances.[152] In order for a restriction to be established, there must be a showing that such restriction is required in order to reduce the risk that the substance, preparation or article poses to human health or the environment.[153]

Obligations of Suppliers in the Supply Chain

Unlike the previous chemical regulatory system, the supply chain communication requirements of REACH are designed to provide all actors in the supply chain with the information that they need to use potentially harmful substances safely.[154] REACH requires that suppliers[155] of dangerous substances and preparations, SVHCs and preparations containing SVHCs must provide recipients[156] with safety data sheets that con-

147. EC Guide, *supra* note 4, at 5; REACH, *supra* note 3, art. 60(4). See REACH, *supra* note 3, Annex XVI Socio-Economic Analysis for the information to be addressed in a socio-economic analysis. ECHA is developing Guidance on the Preparation of an Application for Authorization which is expected to be available at http://reach.jrc.it/03_rdds_web_content/authorisation_application_en/authorisation_application_en.pdf. At the time this article was written, the guidance was not yet available.

148. REACH, *supra* note 3, art. 62(4)(f).

149. EC Guide, *supra* note 4, at 5.

150. REACH, *supra* note 3, art. 67(1); REACH, *supra* note 3, Annex XVII Restrictions on the Manufacture, Placing on the Market and Use of Certain Dangerous Substances, Preparations and Articles [hereinafter Annex XVII].

151. *See* Annex XVII, *supra* note 150.

152. *See* REACH, *supra* note 3, art. 69.

153. *See id.* art. 68; *see also* EC Guide, *supra* note 4, at 13-14.

154. *See* EC Guide, *supra* note 4, at 10.

155. Suppliers include manufacturers, importers, distributors and downstream users who place substances or preparations on the market, producers and importers of articles and distributors or other actors who place articles on the market. REACH, *supra* note 3, arts. 3(32), 3(33).

156. Recipients of substances and preparations are downstream users or distributors who are supplied with a substance or preparation. *Id.* art. 3(34). Consumers are not

tain appropriate safety information prepared in accordance with the requirements of REACH.[157] In addition, a supplier is required to provide a recipient with a safety data sheet upon the recipient's request in the event that a preparation is not classified as dangerous but meets certain other conditions.[158] The exposure scenario developed as part of the chemical safety report must be attached to the safety data sheet.[159] Suppliers are required to provide updated safety data sheets as soon as new hazard information or new information which may affect risk management measures for a substance is available, once an authorization for a substance has been issued or denied and once a restriction has been imposed on a substance.[160] For substances and preparations that do not require a safety data sheet, suppliers must provide recipients with the registration number of the substance, the details of any authorization issued or denied, the details of any restriction imposed or any other information about the substance that is necessary for appropriate risk management measures to be identified and implemented.[161] Suppliers of articles that contain SVHCs in a concentration above 0.1% weight by weight must provide recipients[162] and, upon request, consumers with sufficient available information to allow for safe use of the article, including, at a minimum, the names of the SVHCs.[163]

Suppliers may want to include provisions in supply contracts, especially in the case of SVHCs, giving them the right to opt out of the contract or to provide a substitute substance or preparation if supplying the substance or preparation becomes impossible due to lack of supply (e.g., the substance does not become pre-registered or registered) or cost-prohibitive (e.g., an authorization is required or a restriction is imposed). Since the implementation of the requirements of the Directive on Waste Electrical and Electronic Equipment[164] and the Directive on the Restriction of Certain Hazardous Substances in Electrical and Electronic Equip-

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considered to be recipients of substances or preparations under REACH. *See id.* arts. 3(13), 3(14) (defining the terms downstream user and distributor so as not to include consumers).

157. See REACH, *supra* note 3, art. 31 and REACH, *supra* note 3, Annex II Guide to the Compilation of Safety Data Sheets for the requirements pertaining to safety data sheets.

158. See REACH, *supra* note 3, art. 31(3) setting forth those conditions.

159. *See* Guidance on Registration, *supra* note 2, § 3.1.1.

160. REACH, *supra* note 3, art. 31(9).

161. *Id.* art. 32(1).

162. Recipients of articles are industrial or professional users, or distributors, who are supplied with articles. Recipients of articles do not include consumers. *Id.* art. 3(33).

163. *Id.* art. 33.

164. The Directive on Waste Electrical and Electronic Equipment requires that manufacturers, importers and retailers of domestic appliances, office equipment and other items ensure and finance the proper disposal, including recycling and recovery, of old products. Directive 2002/96/EC, 2003 O.J. (L 37) 24.

ment[165] by Member States, buyers have terminated relationships with suppliers that cannot meet the applicable requirements or will not covenant to doing so in supply contracts.[166] In light of REACH, suppliers should review existing supply contracts to determine whether they may have liability, or whether buyers may have a termination right, in the event that a substance to be supplied pursuant to that contract is not available because it is not pre-registered or registered.

Implications on and Obligations of Downstream Users and Other Actors in the Supply Chain

To ensure that information on hazards and risks of substances and risk management measures are passed up and down the supply chain, REACH imposes obligations on downstream users of substances and preparations and other actors in the supply chain.[167] A downstream user is a person who uses a substance, either on its own or in preparations, in his industrial or professional activities.[168] For example, a downstream user may be a formulator who mixes substances or preparations to make a preparation to put on the market (e.g., paint or detergent formulators), an industrial user who uses a substance solely as a processing aid in the manufacturing process (e.g., users of oil or lubricants) or a user who incorporates a substance or preparation into an article so that the substance or preparation becomes an integral part of the article (e.g., dyeing textile fibers or lacquering steel).[169] Downstream users also include refillers who transfer substances and preparations from one container to another (e.g., re-packaging) and re-importers who import substances or preparations produced in the European Union, subsequently exported out of the European Union and then re-imported into the European Union.[170]

Downstream users are not required to register the substances that they place on the market or use. However, REACH prohibits a downstream user from placing on the market any substance that is not registered or pre-registered in accordance with REACH.[171] Downstream users should confirm that their suppliers for each substance understand, and are in compliance with, the requirements of REACH applicable to them and that they have, or will, pre-register or register such substances by the applicable deadlines. Once the list of pre-registered substances is pub-

165. The Directive on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment bans the placing on the European Union market of more than certain levels of lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyl and polybrominated diphenyl ether flame retardants. Directive 2002/95/EC, 2003 O.J. (L 37) 19.

166. Cross-Border Article, *supra* note 22, at 34.

167. *See* EC Guide, *supra* note 4, at 5.

168. REACH, *supra* note 3, art. 3(13).

169. *See* Downstream User Guidance, *supra* note 60, § 2.5.3, Table 3.

170. *See id.*

171. REACH, *supra* note 3, art. 5.

lished by ECHA in January 2009, downstream users will be able to determine whether all of the substances that they need have been pre-registered. If not, the downstream user may want to request that its supplier pre-register the substance under REACH's late pre-registration mechanism.[172] The downstream user also may contact ECHA to request that ECHA list the substance so that an importer or manufacturer interested in supplying and pre-registering that substance can contact the downstream user.[173] However, downstream users must be aware that just because a substance has been pre-registered, does not mean that it will ultimately be registered.[174] This is especially the case with respect to SVHCs that will be subject to the authorization process. Some companies already have begun receiving notices from suppliers that SVHCs will no longer be available. Suppliers may determine that they cannot meet the criteria for obtaining an authorization for the SVHC or that meeting those criteria is cost-prohibitive. Users of SVHCs may want to start considering replacing SVHCs to give themselves time to find alternative affordable substances before they face an imminent deadline.

In addition, under REACH a downstream user cannot use a SVHC outside of the conditions set forth in the exposure scenario provided by its upstream supplier unless the downstream user prepares its own chemical safety report and exposure scenario covering its conditions of use.[175] This requirement is aimed at addressing the previous regulatory system's failure to ensure the assessment of the risks of all downstream uses of a potentially harmful substance prior to its placement on the market. REACH provides downstream users the right to communicate their uses upstream for inclusion in the exposure scenario.[176] However, the manufacturer or importer of the substance is not required to include that use in the exposure scenario.[177] In addition, a downstream user cannot use a substance that is subject to an authorization or restriction, unless its conditions of use are consistent with the conditions of use set forth in the authorization or restriction.[178] If the downstream user's conditions of use are not consistent with the conditions of use included in the exposure scenario, authorization or restriction, the downstream user must stop using the substance, change its practices to comply with the conditions of use covered by the exposure scenario, authorization or restriction, find an alternate substance or prepare its own chemical safety report and exposure scenario or application for an authorization for the substance.[179] However, due to the potential costs involved, preparation of a chemical

172. *See* Data Sharing Guidance, *supra* note 61, § 4.4.3.

173. REACH, *supra* note 3, art. 28(5).

174. *See* Data Sharing Guidance, *supra* note 61, § 4.4.3.

175. *See* REACH, *supra* note 3, art. 37(4).

176. *Id.* art. 37(2).

177. *See id.* art. 37(3); *see also* Downstream User Guidance, *supra* note 60, §8.1.

178. *See* REACH, *supra* note 3, arts. 56, 67.

179. *See* Downstream User Guidance, *supra* note 60, §§ 6.1, 12, 13.

safety report or authorization application may be a downstream user's last resort.[180]

Although it may not be possible to avoid a use being excluded from the exposure scenario or authorization, downstream users should act as early as possible to provide notification of their intended uses of a substance up the supply chain so that they have time to make alternative plans if needed. Downstream users also should communicate their customers' known or anticipated uses up the supply chain to prevent losing business from customers who can no longer use substances that the downstream user supplies. If the downstream user wants to keep its uses confidential from its supplier, the downstream user may want to check with its industry association to determine if the association will be submitting generic use information covering the downstream user's use to the supplier.[181] In the alternative, if the downstream user has sufficient resources and time, it could prepare its own chemical safety report and exposure scenario for its intended uses.[182]

Downstream users should consider adding provisions to supply contracts requiring that suppliers comply with REACH and that suppliers ensure that their upstream suppliers comply with REACH, including the pre-registration or registration of the substance needed by the downstream user. Downstream users also should consider including contractual provisions giving them the right to walk away from the contract if the needed substance is not pre-registered or registered and to collect damages, including loss of profits and incremental costs in locating a different supplier or alternative substance.

Downstream users are required to pass information up the supply chain, including any new information on hazardous properties of a substance or preparation or any other information that affects the effectiveness of the risk management measures identified in the safety data sheet.[183] In addition, downstream users are required to pass information to recipients of substances and preparations and recipients of articles supplied by the downstream user, including safety data sheets and exposure scenarios.[184] Downstream users also are required to follow safety instructions contained in safety data sheets and exposures scenarios that they receive and to implement the risk management techniques set forth therein.[185] Risk management measures that are deemed reasonable upstream may present a large cost burden on downstream users and other

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180. *See* Cross-Border Article, *supra* note 22, at 32.

181. *See* Downstream User Guidance, *supra* note 60, § 3.6.

182. *See* EC Guide, *supra* note 4, at 11.

183. REACH, *supra* note 3, art. 34.

184. *See id.* art. 31 (setting forth the requirements for passing safety data sheets to recipients of substances and preparations.); *id.* art. 32 (setting forth the information required to be passed to recipient of substances and preparations when safety data sheets are not required); *id.* art. 33 (setting forth the information required to be passed to recipients of articles).

185. *See id.* art. 37(5).

actors in the supply chain, and exceed or overlap with other regulatory requirements.[186] It is important for downstream users to contact their suppliers prior to registration to confirm that the risk management measures that will be included in the safety data sheet are reasonable for the downstream user.[187]

Other actors in the supply chain who are not considered downstream users for purposes of REACH include distributors and retailers.[188] Under REACH, distributors are actors who store, place on the market and make available to third parties substances, preparations and articles without further processing.[189] Retailers are considered to be a subgroup of distributors who store and place on the market substances, preparations or articles for final customers or professional users in retail stores.[190] Distributors and retailers are required to pass safety data sheets and exposure scenarios and information from suppliers regarding SVHCs or substances subject to authorizations or restrictions to recipients down the supply chain.[191] However, REACH provides that safety data sheets are not required to be supplied to the general public.[192] Distributors and retailers also are required to pass requests for information from customers up the supply chain and to respond to questions from suppliers regarding uses of substances.[193] In addition, distributors and retailers are required to pass up the supply chain any new information on hazardous properties of a substance or preparation or any other information that affects the effectiveness of the risk management measures identified in a safety data sheet.[194]

Companies need to understand that an actor in the supply chain may have more than one role. An example of an actor with multiple roles is a company using a substance that it buys from two different suppliers, one located in the European Union and one located outside of the European Union.[195] The company is a downstream user of the quantity of the substance that it buys from the European Union supplier and an importer of the quantity of the substance that it buys from the non-European Union supplier.[196] In that case, the company would have the re-

186. *See* Cross-Border Article, *supra* note 22, at 32.

187. *See* Downstream User Guidance, *supra* note 60, § 3.2.1.

188. *See* REACH, *supra* note 3, art. 3(14).

189. *Id.* art. 3(14); Downstream User Guidance, *supra* note 60, § 2.5.4, Table 4.

190. Downstream User Guidance, *supra* note 60, § 2.5.4, Table 4.

191. *See id.* § 15.3.

192. Safety data sheets are not required to be supplied to the general public provided that sufficient information is supplied to allow users to take necessary safety measures in using the substance or preparation. REACH, *supra* note 3, art. 31(4). Also, consumers are not considered to be downstream users, distributors or recipients of substances, preparations or articles under REACH. *See id.* arts. 3(13), 3(14), 3(34), 3(35).

193. *See* Downstream User Guidance, *supra* note 60, § 15.

194. REACH, *supra* note 3, art. 34(a).

195. REACH Navigator – Actors, http://reach.jrc.it/actors_en.htm (last visited May 22, 2008).

196. *Id.*

sponsibility to comply with downstream user obligations under REACH as well as registration obligations as an importer of the substance. To understand all of their potential roles under REACH, companies should take an inventory of all of the substances, preparations and articles that they manufacture, produce, import, supply and use, where they manufacture and produce substances, preparations and articles, to where and to whom they import and supply substances, preparations and articles, from where and from whom they receive substances, preparations and articles, and how they use substances, preparations and articles.

Penalties

Under REACH, Member States are tasked with establishing penalties for violations of the provisions of REACH by December 1, 2008. REACH does not specify the monetary amounts of penalties; rather it states that such penalties must be "effective, proportionate and dissuasive."[197] In the event that a substance is manufactured, imported or placed on the market without being pre-registered or registered, it is possible that fines may be imposed on manufacturers, importers and downstream users dating back to June 1, 2008 or to the first day of the production, importation or placement on the market of the substance.[198]

Conclusion

It is clear that REACH will have an impact on the European Union's and the world's chemical markets. How extensive that impact will be remains to be determined. The implementation of REACH and the substances it regulates are subject to continued assessment and evaluation by Member States, ECHA and the European Commission. What is clear now, however, is that manufacturers, importers, suppliers and users must act promptly to identify the substances, preparations and articles they manufacture, import, supply and use that may be subject to requirements under REACH. United States companies may find their products have been banned from the European Union's market or lose needed products or raw materials from European Union companies if they or their European Union suppliers fail to meet REACH's potentially costly, time consuming and labor intensive requirements. Once that inventory is compiled, each actor in the supply chain must identify their roles and obligations under REACH. Companies also must implement mechanisms to ensure that they and those that they rely on in the supply chain comply with REACH, and that they have taken necessary measures to protect confidential information and to avoid liability to others in the supply chain and to governmental authorities. In addition, international companies should consider conducting a global evaluation of all of the different re-

197. REACH, *supra* note 3, art. 126.

198. *See* CEFIC Guide, *supra* note 69, at 9; *see also* Downstream User Guidance, *supra* note 60 § 2.3 n. 9.

quirements applicable to their substances, preparations and articles.[199] If compliance with REACH seems to be too daunting a task for a company to tackle on its own, the company may want to retain one of the number of consulting firms specializing in REACH compliance.

199. *See* Cross-Border Article, *supra* note 22, at 34.