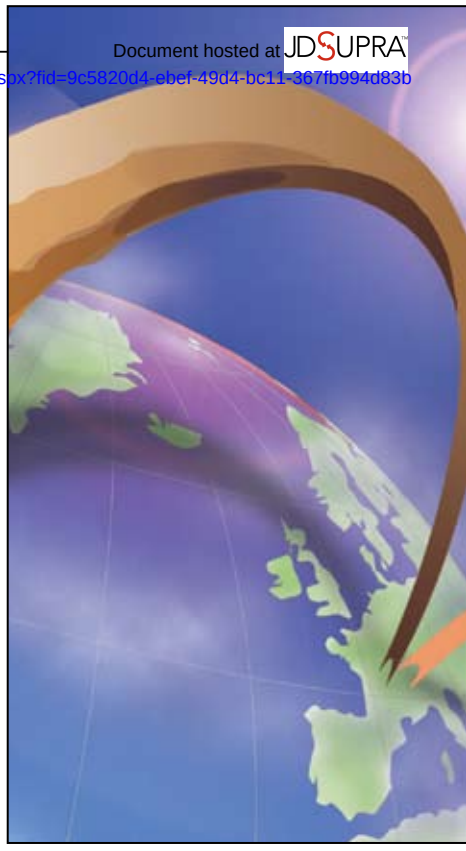
Part 2

REACH: A Timely Overview



A major focus of REACH is to provide much more data on the hazards and risks of chemicals. Each company will need to develop a business strategy for REACH compliance

N. Kathleen Strickland
Ropers Majeski Kohn & Bentley

On Dec. 18, 2006, the European Union (EU) passed a new law creating a single integrated system for the registration, evaluation and authorization of chemicals, which is known as REACH. Described as the most important EU regulation in the last 20 years, REACH places the burden of proof for demonstrating the safe use of chemicals on industry, to ensure that the risks to human health and environment are avoided or adequately controlled. An understanding of this law, effective as of June 2007, is prudent for all who work in the chemical process industries (CPI) as the effects of REACH are not bound to within the EU. This article, together with Part 1 (p. 38) of this cover story, gives the reader an introduction to REACH and its implications for business.

REACH requires companies that manufacture or import products into the EU, over a certain tonnage, and which are either chemical substances themselves or chemicals contained in articles or preparations, to register both those chemicals and the uses of those chemicals contained in those products, both up and down the supply chain. The European Commission's two most important aims are to improve the protection of human health and the environment from the hazards of chemicals and to enhance the competitiveness of the EU chemicals industry.

HOW WILL REACH WORK

Each of the parts of REACH (registration, evaluation and authorization) is discussed here:

Registration

Registration requires producers and importers to obtain relevant information on chemical substances produced in or imported to the EU market in quantities greater than 1 metric ton per year (m.t./yr). It will be compulsory to register in a central database and this registration will take place by the filing of a dossier with the European Chemicals Agency (ECA; Helsinki, Finland). Registration will be accomplished by electronically submitting a technical dossier containing information on the substance and information on how to effectively manage the risk entailed by use of the substance.

Data concerning the properties and uses of chemicals and on the relevant precautionary measures for their use will be included. The data required will be proportionate to the production volume of, and the risks presented by, the substance concerned. The volume thresholds are 1, 10, 100 and 1,000 m.t. with increasing data submission requirements. For quantities above 10 m.t./yr a Chemical Safety Report (CSR) must be submitted to document the safety assessment of the substance. Failure to register a substance means that it cannot be manufactured in or imported into the EU.

REACH impacts all companies in the supply chain that sell chemicals or chemicals in products. The entire supply chain will need to disclose the properties of the substances they use, and ensure that the safety in their downstream use is adequately supported.

There are different registration requirements for products depending on whether they are substances (chemical elements and their compounds in the natural state or obtained by any manufacturing process; preparations (a mixture or solution composed of two or more substances); or articles (objects that during production are given a special shape, surface or design that determines their function to a greater degree than does their chemical composition, such as paper, textiles, and packaging). Whether ink cartridges or cigarettes constitute articles is unclear. For example, bearing in mind that millions of articles are placed on the market in the EU,

registration is compulsory when the substance in question has hazardous properties and is intended to be released from the article. For substances that are released incidentally, simple notification is required, on the basis of which the ECA may request a registration.

The ECA will be responsible for managing the database, receiving registration dossiers and developing guidance to assist producers, importers and the "competent" authorities in implementing these provisions. It is anticipated that 80% of all registered substances will not need further action. The regulation sets out a number of rules regarding data sharing in order to reduce animal testing and costs to industry. It encourages the sharing of data on the same chemical substance among registrants by notifying the registrant of other companies that have also pre-registered a substance, so that a SIEF (Substance Information Exchange Forum) can be formed prior to registration.

Exemptions. Some groups of substances are exempt from the obligation to register under REACH, such as certain intermediates, polymers and substances for research and development. (Note that this remains in flux. New guidance registration documents were issued June 5, 2007 on intermediates and polymers per RIP 3.1.) Additionally, REACH exempts radioactive substances, waste materials, medicines, foods and feed, biocides and pesticides, cosmetics, medical devices and food contract materials, military equipment, substances in EU transit under customs control, dangerous substances and preparations subject to existing transport regulations, registered/exported/imported substances, substances less than 1 m.t., and substances identified in Annex II and Annex III of the REACH regulation.

Evaluation

Evaluation allows the regulatory authorities to decide on proposals for further testing and to assess whether information provided by industry (the technical dossier) complies with the requirements. Two types of evaluation are provided for: dossier evaluation and substance evaluation.

Dossier evaluation. This is compulsory for any proposals involving experiments on animals and it is designed to minimize the need for animal testing. REACH encourages the sharing of animal testing data on a substance. Dossier evaluation may be undertaken in order to verify the completeness of a registration.

Substance evaluation. This may be undertaken if there is a reasonable ground for suspecting risk to human health or the environment: this is the ECA's mechanism for requiring industry to obtain more information about a substance. Evaluation may also lead to the conclusion that no further action should be taken, that more data is needed, or that substances have hazardous properties and further action should be taken under the authorization or restriction section.

Authorization

Authorization may be required for substances of very high concern (carcinogens, mutagens, substances toxic to the reproductive system, and substances that are persistent, bio-accumulative and toxic, very persistent and very bio-accumulative or of equivalent concern). Authorization, required for these substances at concentrations greater than 0.1%, will be granted if the registrant demonstrates that the risks are adequately controlled or the substance provides a great socio-economic advantage and no viable substitute is available.

Authorization can be granted and limited as to time on the market in order for the applicant to use that time to develop a substitute product without the attendant risks attached. The burden of proof is on the applicant. Downstream users may use a substance for an authorized use provided that they obtain the substance from a company to which an authorization has been granted and stay within the conditions of use for that authorization.

Restrictions

Restrictions of chemicals are the safety net of the system, making it possible to manage the risks that are not adequately covered by the other provisions of the REACH system. Restrictions are conditions placed on the manufacture or use of certain dangerous substances, preparations or articles. They are to be prepared by Member States or the Commission in the form of a structured dossier. Any substance on its own, in a preparation or in an article may be subject to the Community-wide restrictions if its use poses unacceptable risks to human health or the environment. The Commission can decide on risk management options, to ban certain uses of a substance or to ban the substance entirely, such as asbestos. Currently there are 52 substances listed in REACH Annex XVII.

TIMING

Pre-registration

Pre-registration begins 12–18 months after REACH takes effect, June 1, 2008 through Nov. 30, 2008. It is a must, don't miss the deadline; if you pre-register, you then have up to 10 years to complete the registration process. One substance will have one registration. Companies will pre-register online, with the ECA, the basic information on the identity of the company and the substance. All companies who are liable to register, must pre-register during this time period. If you think your company will ever import or produce more than a metric ton of chemicals per year into the EU — again, this is in a substance, article or preparation — then do not miss this deadline. Pre-registration enables the ECA to "find out" what chemicals are in the European market and to begin assembling this information on companies and substances into an electronic database. The process is as easy as filling out a card and sending it in.

Pre-registration applies primarily to the chemicals already on the market in the ECA, which are those listed in the existing chemicals inventory (EINECS). The advantage of pre-registration is that it enables you to continue to sell pre-registered substances before full registration is complete,

thereby avoiding market disruptions. There is also a benefit from sharing registration costs and data by joining a SIEF, which will automatically include all companies that pre-register the same substance. Once you pre-register, you can expect to receive notification from the ECA informing you what other companies have also submitted information on that same chemical or substance and inviting you to join a SIEF to share data and information on that chemical or substance. The idea of information and data sharing is to make it easier for companies to register under REACH and to minimize animal testing.

REACH requires full registration within one year for substances not pre-registered; for those companies not pre-registered, they will have to bear all the data and costs of the registration and not be able to piggyback and share information on that substance with others, which they could have done had they been in a SIEF. They may be able to join an existing SIEF later, but there will be added costs.

Registration process

Pre-registration will be followed by registration in 3, 6 or 11 years depending on the volume or level of concern of a particular substance. Registration is proposed to take place for substances that are manufactured or imported or in preparations based on production and usage tonnage:

- 1–100 m.t./yr = register within 11 years
- 100–1,000 m.t./yr = register within 6 years
- 1,000 m.t./yr = register within 3 years

Both new and old substances, including those that were listed in the EU's EINECS list, will be subject to the registration requirement. So-called "phase-in" substances (mostly EINECS listed substances) will benefit from a phase-in period of eleven years only if they are pre-registered.

Technical dossier

Registration will require submitting a technical dossier with extensive data on the toxic characteristics of the substance. The data entered will include listing the toxicological properties, the physical-chemical properties, the human health effects, and the environmental health effects of the registered substance, as well as guidance on safe use. This data will be entered into a database, now called Euclid 5, but which is currently being revised.

The amount of information required in a technical dossier depends on the production volume. If you import more than 10 m.t. of a chemical substance per manufacturer or importer per year, then you will need to submit an additional CSR, which will assess the hazards, exposure and risks for use over the entire lifecycle of the substance(s) manufactured or imported. Registration will be specific to each substance and to each chemical manufacturer or importer. Only those chemical manufacturers and importers that have registered within the deadlines will be allowed to market their substances. The ECA expects that 30,000 substances and 14,000 technical dossiers will be submitted during the first 11 years.

SPECIAL ITEMS

Structure of REACH

The REACH regulation includes 14 titles, and title V is downstream users. There are 17 annexes: sections with lists, detailed requirements and methods, including some appendices. Registration data requirements are discussed in Annex V for 1 m.t., Annex VI for 10 m.t., Annex VII for 100 m.t. and Annex VIII for 1,000 m.t.. The Annexes discuss test methods, toxicology standards, reference substance lists and chemical safety reporting.

Regulatory guidance tools, which provides technical guidance and tools for industry, have been developed by the Reach Implementation Project (RIP) and are called RIPs. RIP 3.1 is Preparing a Registration Dossier; 3.2 is Preparing a Chemical Safety Report; 3.3 is Information Requirements; 3.4 is Guidance on Data Sharing; 3.5 is Guidance for Downstream Users; 3.6 is Guidance for Classification and Labeling; 3.7 is Guidance for Applying for Authorization; 3.8 is Guidance on Articles; 3.9 is Guidance on Socio-Economic Analysis; 3.10 is Guidance on Substance Identification.

Safety data sheets

According to REACH, suppliers must provide a safety data sheet (SDS) that complies with REACH Annex 1a. The SDS is organized according to the format of the Globally Harmonized System (GHS) of classification and labeling of chemicals.

Annex 1a provides guidance to compiling each section of the SDS. REACH includes standards for hazard communication, classification and labeling. When a CSR is required, the regulation requires the SDS to have an annex, which includes use and exposure data. REACH requires that the use data in the SDS be consistent with the use data in the associated CSR. An SDS is required for any substance above a REACH-specified threshold level that is classified as a persistent, bioaccumulative, toxic (PBT) or very persistent, bioaccumulative, toxic (vPvB) and for any substance posing a health or environmental impact.

Classification and labeling requirements. Classification and labeling (C&L) data for registered substances and any substance classified as dangerous must be submitted and added to a new database established by REACH. The C&L inventory data content to be provided to the ECA must: identify the manufacturer or importer, identify the substance, state the hazard classification of the substance, provide a hazard label for the substance and list the concentration limits. Classification and labeling involve an evaluation of the hazard of a substance or preparation. Hazards are classified in accordance with Directive 67/548/EEC for substances and Directive 1999/45/EEC for preparations. The hazards are to be communicated via the label.

Chemical safety data reports

If your company imports into the EU or manufactures in the EU chemical substances in a quantity over 10 m.t., or a substance of very high concern (SVHC) over 1 m.t./yr, you will need to complete both a CSR and a Chemical Safety Assessment (CSA) that comply with Annex I of REACH. The CSA shall include (REACH Title II, Registration of Substances, Article 13) the following: a human health-hazard

assessment, a physiochemical hazard assessment, an environmental hazard assessment and PBT and vPvB assessments. If the CSA determines that the substance should be classified as dangerous (per Directive 67/548/EEC) or as a PBT or vPvB, the assessment must include the following:

- Exposure assessments for all identified uses
- Generation of exposure scenarios for all identified uses, with input from downstream users
- Quantification of exposure levels for all human populations and the environment
- Characterization of degradation, transformation, estimation of environmental distribution and fate
- Risk characterization, specific to European populations using the substance
- Human exposures and environmental concentration
- Risk management measures (RMMs) based on quantitative exposure assessment

The CSR will discuss how a substance is used, its conditions of use and the quantity of use. RMMs will be provided to ensure that risks of use of the substance are controlled through measures such as process controls, emissions controls, ventilation, product use and labeling instructions, and concentration limits.

Control measures for risks identified by the CSA shall be listed in the CSR, which must be available and updated. Annex I of REACH defines the format and content of the CSR, which is intended to communicate both hazard and risk information and must address all identified uses of a substance. The Annex I guidance requires a quantitative, health risk assessment of every substance that falls under this annex for all identified use conditions — a time consuming task. It requires the same health risk assessment for preparations (mixtures). The safety assessment must consider all identified uses and consider the substance on its own, in a preparation and in an article. Therefore, a chemical manufacturer has to consider all uses. This poses great challenges considering all stages of a substance's life cycle.

DOWNSTREAM USERS

Obligations and options

A company needs to determine whether REACH applies to it and then to determine what that company's role is in the supply chain. REACH distinguishes four roles in the supply chain: manufacturer, importer, distributor and downstream user (DU).

Obligations. Under REACH, a downstream user's obligations can be classified into four general categories: DU's must communicate their usage to their supplier, must ensure that the CSA covers their use, must implement RMMs suggested by their supplier and must ensure good communication up and down the supply chain.

REACH imposes obligations on EU manufacturers using substances in their manufacturing processes, and on importers of the substances, to register all uses of a substance. It is therefore incumbent on the DU to communicate to its manufacturer all uses of that substance, both up and down the supply chain or to register the uses itself if, for some reason, it does not want the manufacturer to know the uses it makes of that chemical substance.

Should the DU choose to let the manufacturer of the substance register the substance with the ECA, then the DU needs to ensure that the CSAs include all uses. The DU needs to verify that its uses are covered by the exposure scenarios communicated in its suppliers' SDSs, which should reflect the supplier's registration and CSR. If not, the DU needs to prepare a CSR for its particular use of a substance or preparation and to submit that information either directly to the ECA or to its supplier with the understanding, secured by contract, that the supplier will register that information with the ECA.

The DU is under an obligation, if the supplier has registered all uses of the substance with the ECA, to implement the RMMs suggested by the supplier in that registration. Finally, the DU needs to play its role in ensuring a flow of communication both up and down the supply chain.

The CSRs of EU manufacturers of goods must assess the environmental and health risks that result from the use of the substance during manufacturing of the product as well as part of the final product. In contrast, importers of goods must assess the health and environmental risks resulting from the use of that substance as contained in the product.

In practice, the manufacturer will develop the reported exposure scenarios to cover all identified uses, and the DU role will vary from case to case. Exposure scenarios will be communicated to the DUs via SDSs. Information reported in these sheets will trigger whether the DU needs to take further action. The DU does need to ensure that the ECS has been notified either of its specific use or to register the substance. The DU may have more information on the ultimate use of the product. Thus, the DU may have an increased role in understanding and assessing the "end" of the product cycle. The difficulty of gathering information will be exacerbated for users and producers of articles with many different parts and components made with chemical substances, because one must know the exact content of each of the product's component parts.

Options. As mentioned, DUs have a right to identify a use, or they may choose to keep its use of a substance confidential. In the latter case, the DU assumes the responsibility of notifying its use of that chemical substance to the ECA. Registration by manufacturers and importers must cover all "identified uses": those uses that are either identified by the DU's or uses for which the manufacturers and importers intend to market or use the substance. DU's should take no further action in the following cases:

- It is operating inside an exposure scenario communicated in an SDS
- SDS is not required for the substance (it is not hazardous)
- A CSR is not required to be completed by this supplier (for example, the substance is produced or imported below 10 m.t.)

The DU must complete a CSR and report to ECA in the following cases:

- It is operating outside an exposure scenario communicated in an SDS, or the DU does not regard its supplier's exposure scenario as appropriate

PREPARING FOR REACH

REACH will create a massive new regulatory structure and electronic database for chemical products placed on the market in the EU. REACH compliance will involve many departments within a company, plus communication by and between all users up and down the supply chain of a product. Now is the time for companies to start gathering information that will be needed for pre-registration.

A company will need to establish administrative and product management systems to facilitate compliance with REACH. This means that companies need to start inventorying the chemicals and the uses of those chemicals that they are importing into the EU, including annual production volumes, toxicity testing and import volumes for customers both up and down the supply chain. A company should be developing portfolios of substances affected by REACH, so as to identify gaps in the information currently available, and begin filling those gaps by gathering the needed information. A company will need to review available data contained in the SDSs for those substances and their uses that will be registered with the ECA. Start communicating with your downstream and upstream users about REACH. Identify the EU importer of each substance. Analyze your supply contracts with users in your supply chain, as these will have to be modified due to REACH. ❑

- It has chosen to keep the use confidential

Costs of REACH. The costs associated with REACH to DUs are the costs related to formulating, using replacements and the diversity of available products. A substantial cost impact will be seen if adaptation is needed in a chemical's supply chain to comply with REACH due to lower availability and poorer performance of chemical substances or preparations. The key factor is elasticity of substitution, and the cost of substituting one product for another. It is anticipated that most manufacturers will pass along their REACH testing and registration costs to the DU. Banned or withdrawn substances, because they cannot comply with REACH registration requirements, will be replaced by increased production of other chemicals remaining on the market. There is concern that companies will withdraw substances and products when testing or registration costs make production unprofitable. Cost increases are expected if a company needs to fund substitutes for withdrawn and/or banned substances and preparations. Higher prices of chemicals are expected as testing and registration costs are passed through to users.

Communication down the supply chain. REACH Title IV, Information in the Supply Chain, Article 30, requires suppliers who do not need to provide a SDS to provide recipients with information including available, relevant risk management information, information on any substance subject to authorization, and information on any substance subject to restriction.

Communication up the supply chain. REACH Title IV, Information in the Supply Chain, Article 31, requires a DU to communicate to the first person up the supply chain the following information: new information on hazardous properties, regardless of uses, and any other information that could raise questions about the appropriateness of risk management measures identified in the SDS. Distributors who receive such information must pass the data to the next person up the chain.

Specific DU issues

Commercially confidential information. When submitted by downstream producers to the manufacturers or importers of the substances, this information will end up in ECA's database and may be disclosed to the public. This does have product liability implications. This might also make enforcing patents or other intellectual property rights practically difficult. Chemical suppliers face similar problems with their own products, with any loss of exclusivity on their part affecting their customers. Some chemical users will choose to seek registration to avoid disclosing to their suppliers commercially confidential information on the use to which they put the chemicals they purchase.

Withdrawal or substitution of chemical constituents. Chemicals may be taken off the market or replaced by less effective or more costly substitutes due to: a) a refusal to authorize, b) the imposition of a restriction on a chemical or certain of its uses; or c) a chemical producers' unwillingness to incur substantial registration costs for low-volume chemicals. These chemicals may be key to a DU's business, and their withdrawal may mean poorer product performance or loss of competitiveness. Producers who rely on a particular, discontinued chemical for a product manufacturer or who produce goods that contain a banned substance may be forced to stop selling certain product lines in Europe.

Direct registration. Some chemical users will choose to directly register with the ECA to avoid disclosing to their suppliers commercially confidential or sensitive information on the use to which they put the chemicals they purchase.

OTHER IMPLICATIONS

Chemicals of concern

The primary focus of REACH is on what this author calls "the chemicals of concern" — the carcinogens, mutagens, reproductive toxins, persistent bioaccumulative and toxic chemicals, endocrine disruptors and chemicals harmful to aquatic life. The goal of REACH is to know where these chemicals are, in what products, and to restrict their use and encourage research and development toward substitute chemicals. There are approximately 1,700 chemicals of concern on the EU's list of suspected problem chemicals; 20% of those chemicals currently registered fall into this category. Under REACH, what the ECA can do with chemicals of concern is to restrict their use and deny marketing authorization and/or impose use restrictions, either by limiting the time of use or specifying the use of the chemical. Authorities can restrict the use of other chemical substances in some circumstances.

REACH shifts the burden onto the manufacturer and importer to demonstrate that the risks posed by the substance can be adequately controlled, or where this is not possible, to show that the socio-economic benefits and lack of a suitable substitute justify the risk. The manufacturer and importer must show that they have taken steps to limit the risks of exposure, particularly to vulnerable populations.

Timelines. By June 2009, the ECA is likely to have identified the first list of substances of very high concern, which may later be subject to the prior authorization requirement. Such substances may include Category 1 and 2 carcinogens, mutagens, toxic reproductive substances, PBTs and vPvBs. The list will

specify the date by which EU producers of goods must ensure that they or their suppliers have applied for an authorization, after which, persons who do not hold or did not apply for an authorization must no longer market or use the substance. EU manufacturers and importers of goods will not be allowed to use the listed substances after the sunset date unless they or their suppliers have applied for an authorization.

By December 2010, importers of goods in the form of preparations will be required to report to the ECA the chemical classification of substances classified as dangerous or subject to registration (imported in quantities of 1 m.t. or more per importer per year) that are contained in their imported preparations. The same requirement will apply to EU manufacturers importing substances or preparations classified as dangerous or subject to registration. Importers of goods in the form of articles will also have to report to the ECA the chemical classification of substances in their articles that are subject to registration.

Between December 2010 and June 2018, producers of goods in the form of preparations or articles must ensure that pre-registered "phase-in" substances contained in, or used in the manufacture of their goods, are registered. After 2010, all producers marketing goods in the form of preparations that contain a substance that has been authorized will be required to label their preparations with the authorization number. In addition, all users whose suppliers have already received authorization for a substance will be required to notify ECA of their use of that substance.

After June 2011, producers of goods in the form of articles must notify the ECA of the presence in their articles of substances listed as being of "very high concern" unless the use of the substance in the article has already been included in the registration of any third party.

Quality and accuracy

In registration documents submitted to the ECA, companies must be truthful. I cannot emphasize this enough. As we all know, it's not often the act but the cover-up that gets one in trouble. From a product liability and litigation perspective, don't fudge — report it and then go on to qualify/distinguish, but don't fail to report it. Remember, companies will be working in SIEFs. You can expect that if you don't include an unfavorable study, your competitor will and then the ECA will be asking you why you failed to include the study. So, submit as full a set of data as possible, both 1) to meet the detailed information requirements set out in the regulation and 2) to ensure that your registration documents present a convincing case for approval of the substance in question, formulated on the correct technical issues and supported by a full set of data.

There is a tension in the selection process, in deciding what data to include in the registration and what data to exclude because one wants to avoid the public dissemination of commercially sensitive information. Remember, the ECA is not interested in confidential information about your product's precise composition, use or function, nor in your market share. The ECA is interested in the environmental, scientific and health-effects data on the chemical, that is, on physiochemical data, pathways and routes of exposure, the results of toxicological and eco-toxicological testing, effect thresholds and whether or not a substance has been tested on animals. The information used to support your submission must be retained for ten years. ■

Edited by Dorothy Lozowski

Author

Kathleen Strickland, formerly of Greenberg Traurig LLP, is now a partner with Ropers Majeski Kohn & Bentley (201 Spear Street, Suite 1000, San Francisco, CA 94105; Email: kstrickland@rmkb.com; Phone: 415.972.6328). Strickland's practice includes defending large multinational corporations in mass tort litigation and complex class actions in product cases involving the chemical, pharmaceutical and healthcare industries. She has served as national and regional trial counsel in cases alleging personal injury and property damage from various products, such as asbestos, breast implants, air, drinking water and groundwater contamination, benzene, dioxin, lead paint and others. Strickland's career has earned her numerous accolades, such as the highest ranking membership in the American Board of Trial Advocates, recognition as a National Leader in Products Liability in Chambers & Partners USA Guide, recognition in The Best Lawyers in America for the last five years and recognition in Bay Area SuperLawyers.