1 Introduction: Importance of Science in the Implementation of TSCA and REACH—Chemical Identity and Risk Assessment

Environmental Regulations and Directives in Europe and laws in the US that regulate the global chemical industry began to emerge in the 1970s in response to increased concern over the potential hazard of chemicals to humans and the environment. These laws included the Toxic Substances Control Act (TSCA) in the US and the Sixth Amendment to the Dangerous Substances Directive in 1979 in Europe. The essence of the review of chemical substances by federal or international agencies is to do a risk assessment.

Under TSCA, the federal US law has been implemented through publication of thousands of pages of regulations written in large part by chemists using chemical terms and chemical substance identifications. In Europe under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), nomenclature and chemical identity issues are beginning to emerge, and to a much greater extent than they did under previous European laws. The cornerstone of the implementation of these laws is a close relationship between lawyers who understand the laws and scientists who understand the chemistry and the principles of risk assessment.

Confusion about nomenclature has been a serious issue that has affected implementation of TSCA over the past 32 years. Regulations are written that specify which chemicals are subject to them. Unambiguous naming conventions are therefore critical to the determination as to who is responsible for compliance to the regulations and for which chemicals. Lack of sufficient attention to detail in this regard has resulted in the US Environmental Protection Agency (EPA) publishing regulations covering one or more

chemicals that are not in commerce as described in the regulations. Nonylphenol and its derivatives are notable examples of this and are discussed in Chapter 4.

REACH will require companies and the European Chemicals Agency (ECHA) to pay much more attention to chemical naming conventions, particularly in terms of the 'One Substance One Registration' (OSOR) principle. The danger is that different companies may use different naming conventions to identify their chemicals, which could lead to multiple registrations for the same substance and the consequent waste of time, money, and resources. Different naming conventions will result in difficulties in organizing Substance Information Exchange Forums (SIEF) and consortia formed to address common interests in issues such as data sharing and testing costs for the same chemical substance.

The essence of the review of chemical substances by federal or international bodies is to carry out a risk assessment. This requires knowledge of two basic factors: hazard and exposure. The fundamentals of risk assessment and how risk assessment is used in the regulation of industrial chemicals and consumer products are addressed in Chapter 2. In Chapter 3, the International Union of Pure and Applied Chemistry (IUPAC) and Chemical Abstracts Services (CAS) nomenclature systems will be discussed. Chapters 4 and 5, address complex nomenclature issues encountered under TSCA, and nomenclature issues described in the Technical Guidance Document (TGD) written to assist companies to comply with REACH respectively. The TGD is titled '*Substance Identification and Naming*' in REACH, and was formerly known as the '*REACH Implementation Project*' (RIP) 3.10 before REACH came into force on 1 June 1 2007. Chapters 4 and 5 discuss non-polymer naming conventions. Chapter 6 discusses polymer nomenclature and implications in the determination of inventory status under TSCA, and confidentiality issues under REACH. Polymers *per se* do not need to be registered under REACH, but present significant problems because monomers and other reactants present in them in reacted form do have to be registered. This requirement leads to significant confidentiality issues

and is being addressed in European courts after a challenge by an industry group.

Chapter 7 discusses regulation of nanoparticles under REACH and TSCA. Chemical identity/nomenclature issues and risk assessment for nanoparticles are included in this discussion. The book therefore concludes with this new chemical technology that has enormous potential in commercial uses and benefits such as in medical applications, and the potential for harm to humans and the environment due to its unique physical state. EPA and ECHA have commented on how they plan to regulate nanoparticles, and the former has begun to do so, but this is one area where traditional and existing regulatory schemes (and even the science used to determine risk) may be insufficient.