Toxicology is the science of poisons and toxic effects. Regulatory toxicology is a subdiscipline concerned with the question of how man and the environment can be protected from toxic effects. Much regulatory toxicology is aimed toward making appropriate regulations and setting suitable standards. This difficult task requires a high degree of scientific understanding across a number of disciplines associated with the chemical, biological, and medical aspects of toxicology as well as an interest in practical implementation. Usually there is a logical division of labor between industry, government, and research institutions. Unfortunately, sometimes there is still a lack of institutional contacts between the different use sectors (e.g., drugs, personal care products, food, and industrial chemicals). Undoubtedly, a good basic education in toxicology coupled with effective cross-sector continuing professional development is the best guarantee for consistency in working practices.

**Aims and Institutions**

The aim of regulatory toxicology is the protection of human health and the environment from the hazards of chemicals, including drugs. Although the collection and evaluation of data must proceed according to scientific criteria, setting up the legislative background also requires political and legal input and depends on the psychological background and sociological attitudes to risk of the relevant population. Historically, different ministries and departments have made regulations independently of one another. Cross-departmental collaboration between the toxicologists in different institutions is improving this situation. Supranational harmonization means that, in recent years, much of the critical legislation is based on international agreements.

**Procedures and Standards**

A regulatory process defines the target populations that must be protected and the way(s) in which protection can be undertaken, identifies possible exposure scenarios, assesses toxicological hazards, and describes data gaps that need filling. Based on all available information, a first risk estimation can be made. The next step is risk evaluation. It incorporates nonscientific arguments, such as sociological or psychological or economic criteria. The aim is to define either what exposure level constitutes the maximum “acceptable” or “tolerable” risk (i.e., a standard) or
to decide that a particular exposure level (and hence risk) is acceptable. Process quality and outcome quality should be assured and examined at several levels. The professional independence of the toxicologists involved is an important quality factor.