Generic Standards: Prospects and Pitfalls

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My definition of a generic standard is one that regulates similar situations or several chemical compounds through a single rule-making procedure. I will limit my presentation to a discussion of two types of generic standards.

First, I will discuss the pros and cons of a generic communications standard that serves as a guide for information sharing. The second part of this short presentation will be on the positive and negative aspects of a generic or chemical class standard.

We have a good example of a generic communications standard in the Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard. Some of the advantages of a generic communications standard are: (1) flexibility; (2) opportunity for professional judgment; (3) a basis for consistency in evaluation; and (4) provisions for timely updating.

The OSHA Hazard Communication Standard permits flexibility in that it allows us to select a method for compliance that applies to a given situation. It allows for professional judgment, for example, in target organ labeling. There is consistency in the general guidelines for producing labels and Material Safety Data Sheets (MSDS). There are provisions for timely updating; complete rule-making is not required to revise a label or to make a change in an MSDS.

It is quite easy to list a number of advantages. Let us look at some of the disadvantages of a generic standard as they apply to the communications area.

One disadvantage is the potential for public confusion. This could happen through different interpretations of a data set that results in the selection of different labels for the same chemical by two or more companies.

Another disadvantage is the difficulty in enforcement. This is particularly true for those who choose to do the bare minimum to comply with a standard. Because of the flexibility that must be inherent in a generic standard, it is more difficult to document a violation.

I believe the advantages outweigh the disadvantages for a generic standard in the communications area.

In my second topic the pros and cons are not as easily defined. This is the area of a generic or chemical class standard in which multiple chemicals with similar structures, toxic endpoints, or physical properties can be regulated through a single rule. For discussion purposes, I found it easier to review the pros and cons together.

It can be argued that a generic standard allows for timely and cost-effective regulation of a large number of chemical compounds. On the surface this appears to be an advantage, but in practice it is difficult to get agreement on which chemicals are to be regulated or how they should be regulated. Such uncertainties can delay, rather than expedite, regulation.

The rule-making process for a risk manager is greatly simplified when a generic standard can be enacted. Establishing a standard is a process that consumes many agency resources, requires much legal input, and usually involves extensive public comment. It takes time. A generic standard in many cases is beneficial to the risk manager because it establishes one set of guidelines for multiple chemicals. In practice, however, it is possible for a generic standard to lead to overregulation. Generic standards tend to identify the chemicals to be regulated in general terms. For example, chemicals that may not show the toxicity characteristic of the class sometimes get included by virtue of the definition.

Another point I would like to make about generic chemical standards deals with basic toxicology. Sometimes the toxic properties of a molecule can change greatly with relatively small changes in structure. An example is provided by ethylene glycol ethers. 2-Methoxyethanol is widely recognized as a potent developmental toxicant in test animals. Adding one carbon to the methoxy chain to form 2-ethoxyethanol reduces the developmental toxicity about fivefold. Adding one more carbon to form 2-propoxyethanol apparently abolishes the prenatal toxicity. Thus, because general standards are based on toxicity, and the toxicity of chemicals can vary greatly with a small change in structure, it is important to define the class in terms of structure and toxicity, not structure alone.

A controversial subject is regulation of chemicals as carcinogens through the generic standard process. There are several classification criteria, guidelines, and models for estimating carcinogenic risk that appear to be leading us to a generic standard for carcinogens.

Our knowledge of the causation and mechanism of cancer induction has increased dramatically over the last few years. The more we know about the mechanism of and factors affecting the carcinogenicity of a specific chemical, the better we can assess the carcinogenic hazard of that agent to humans. Therefore, if there is to be a generic standard, it must be flexible so that it can be adapted as our understanding of cancer and risk assessment increases. For example, the role of oncogenes and the development of the two-stage theory of carcinogenesis, involving initiation and promotion, need to be considered in future risk assessments. In addition, we know from metabolic and pharmacokinetic studies that sometimes different species of animals, including humans, metabolize chemicals in unique pathways and at different rates.

Before leaving this subject, I would like to make several comments on the use of mathematical models for quantitative cancer risk assessment. Mathematical models have been used extensively in recent years in quantitative cancer risk assessment by regulatory agencies. Some of these models, however, do not take into account all of the underlying biology, nor can they make poor data good or compensate for a lack of data. In addition, some mathematical models oversimplify the scientific evaluation process and place undue weight on statistical procedures that use only part of the data. There is no alternative to the use of expert scientific judgment and consideration of all data in a weight-of-the-evidence evaluation of the carcinogenic potential of a chemical.

If there is to be a generic carcinogen standard, then I would like it to be: (1) flexible, to permit later inclusion of new scientific findings; (2) based on the weight-of-the-evidence approach; and (3) technology-driven, that is, with an incentive toward understanding the mechanism of action when a chemical is determined to be an animal carcinogen.

In summary, I have presented some thoughts on generic communication standards and generic chemical standards. I hope my comments will spur discussion and act as a general introduction to one point of view on generic standards.

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