Selectively applied legal standards can be used as barriers to bringing a product to market, as pointed out by modern biotechnology.

This impairs freedom of action not only for industries directly concerned: the insurance industry, too, is facing a culture of exploding expectations and a legal framework which makes it increasingly difficult to carry out risk transfer and management, according to business axioms like profitability and the freedom of contract.

Where no risk is allowed, the notion of insurability is challenged, for society can only bear those risks that insurers can indemnify with benefits in monetary form. But a risk that according to general consensus cannot be allowed to happen also cannot have a price tag – and cannot be insurable.

Outlook

Sustainably introducing nanotechnology requires uniform, risk-appropriate assessment criteria that consider nanomaterials' special properties. Such guidelines would not only reduce uncertainty, but also create a favourable climate for investment.

The challenge is to highlight those criteria that identify the changes taking place in the risk profiles of the materials – and of business sectors – as production methods shift to nanotechnology.

If these challenges are met, both public and private researchers will be able to assess the up and down sides of nanotechnology with scientifically proven, comparable criteria; and authorities and insurers, and other stakeholders interested in controlling risk, will be able to prepare themselves to cope with possible future losses.

A new technology always presents opportunities and threats; society needs to decide whether the benefits outweigh the potential disadvantages. This is not always easy in a pluralistic society, and one that calls for risk expertise, respect, tolerance and a sense of proportion.

Nanotechnology

The terminology challenge

by Clive Willis, Convenor, ISO/TC 229/WG 1

The need for early standards

Nanotechnology is a relatively new domain that holds major potential gains for both economic performance and improved social programmes. As a result, many nations have afforded a very high priority for basic research activities in nanotechnology and many major corporations are exploring the potential of nanotechnology to improve the performance and quality of their products and production processes.

Although relatively few products are currently in world markets, there is a very significant public interest in ensuring that the introduction of nanotechnology into consumer products and health care services and other sectors is done in a way that does not have a negative impact on health, the environment and the quality of life.

This widely held public position has led national governments to place a high priority on ensuring that appropriate regulatory systems for nanotechnology are in place early and that the standards upon which such systems will be based are reasonably harmonized on a global basis.

It is for these reasons that ISO has chosen to launch early efforts to define a comprehensive set of science-based standards for nanotechnology. National and international organizations, such as the Organization for Economic Co-operation and Development (OECD), have indicated that they may defer to the ISO process the task of building a coherent terminology and standards base upon which governance systems can be established.

An important key to the development of nanotechnologies is a coherent and comprehensive vocabulary and terminology for nanotechnology. This is necessary to avoid the vast and confusing set of definitions that has been evolving as individuals and corporations choose their own terms to describe their interests in nanotechnology.

Creating a coherent and consistent terminology is also important

for commercial and general communications purposes since agreement on what everyone is talking about (or buying or selling) is critical to rational commercial and public discourse.

The challenge of integration into existing standards

Since nanotechnology represents a group of technologies that will lead to applications across many, if not all, industrial sectors and social programme areas, the development of coherent standards for nanotechnology is a major challenge.

Concerns are sharply focused on how definitions and terminology for nanotechnology will be integrated into the spectrum of existing standards and how they will be interpreted, in particular in commercial security, health and environmental fields.

The challenge then is to respond to the urgent need to develop a comprehensive standard vocabulary and terminology for the nanotechnology field, while at the same time ensuring that the impact upon other standards development fields is as seamless as possible and without losing the coherent basis upon which clear regulations for nanotechnology can be written or transactions conducted.

About the author

Dr. Clive Willis served in a number of senior management positions during his time (1971-1997) at the National Research Council of Canada and was Vice President for research programs from 1986 to 1997. Since leaving NRC, he has been involved in numerous major science and technology projects from across Canada, including launching major nanotechnology efforts in Quebec.

The challenge of a single, basic definition

Nanotechnology is built upon the recognition that the properties of materials exhibit different attributes when dimensions approach the nanoscale.

Using an array of techniques ranging from molecular engineering and thin film technology to the mechanical reduction of bulk materials to ultrafine powders, it is possible to develop materials that have very different physical and chemical properties and combinations of materials that provide unique functionalities of interest.

The Holy Grail would be the definition of a single, "bright-line" description that could distinguish materials and systems that have nanoscale characteristics from those materials and systems that have characteristics that are indistinguishable from existing, well-known, macro-scale applications.

"Creating a coherent and consistent terminology is important for commercial and general communications."

This type of definition could be very simple indeed, with a single, specific dimensional cut-off value identified for "things nano". However, the dimensional dependence for the onset of such nanoscale attributes differs from property to property.

For example, the onset of dominant quantum characteristics occurs at dimensional scales of a few nanometres ; typically, in the range of up to about 20 nm, nanoscale magnetic characteristics occur up to a maximum of 50 nm to 60 nm while electronic properties show size-dependent variation in a range that extends beyond 1 000 nm.

The variation in dimensional dependence poses difficult challenges in creating terminology that is both accurate (i.e. reflecting physical reality) and precise (i.e. not so vague or general as to encompass such a potentially broad range of materials so as to be relatively useless).

The impact of these differing ranges on clear definitions is significant and requires the development of a carefully structured, taxonomic terminology into which precise definitions can be embedded.

For such a terminology to be useful as a basis for both standards development and as a basis for writing regulatory system entries, it must be searchable in a way that it can provide a basic nomenclature system for nanotechnology.

In turn, such a structured terminology must have the potential for being comprehensive and coherent for nanotechnology terms across the entire field of nanotechnology and must be translatable into existing definitions and terminology across the entire field of standards.

Differentiating nanomaterials from their macro-usage[1)]

It would seem useful to distinguish between nanomaterials and the macro or bulk materials that might contain nanomaterials.

Limiting the definition of nanomaterials to materials that are truly in the nanoscale will achieve clarity in definition and will not in any way limit the ability of industry or governments to evaluate, control or regulate the presence, emissions, discharges, etc., of nanomaterials that may be contained in macro or bulk materials.

Most regulatory regimes recognize this distinction (e.g. not every material that contains a detectable concentration of cadmium is called cadmium).

Similarly, excluding bulk or macro materials from the definition, nanomaterials will not prevent industry from controlling or governments from regulating the presence of nanomaterials in bulk or macro materials.

1) I am grateful to Chris Bell for providing insightful clarity to this section and elsewhere in the text.