The US must help set international standards for nanotechnology

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International standards have a crucial role in supporting global trade and protecting human health and the environment. US government agencies and the private sector must become more involved in international efforts to establish such standards, and representatives from all nations must ensure that all standards are based on sound science.

International standards are essential to support global trade and provide a foundation for risk management programmes that protect human health and the environment[1,2]. Such standards are widely used to support the regulatory work of global intergovernmental organizations such as the Organization for Economic Cooperation and Development (OECD), the United Nations International Labor Organization, the World Health Organization and the World Trade Organization. In 1997, the OECD recommended that member countries "develop and use, wherever possible, internationally harmonized standards as a basis for domestic regulations, while collaborating with other countries to review and improve international standards to assure that they continue to achieve intended policy goals efficiently and effectively"[3].

International safety and health standards take many different forms and can include voluntary standards, such as the International Standards Organization's (ISO) 9000 series of standards; codes of conduct, such as the Biological Weapons Convention; framework conventions (or standards), such as the United Nations Framework Convention on Climate Change; substantive treaties, such as the Stockholm Convention on Persistent Organic Pollutants; or intergovernmental regulatory guidelines, such as the OECD's Good Laboratory Practice Guidelines. ISO standards are entirely voluntary, whereas the other four types of standard described above are, in theory, legally binding on the governments that sign up to them[4]. The organizations that establish science-based international standards in occupational and environmental health are the ISO and the OECD.


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Figure 1 Researchers from the National Institute for Occupational Safety and Health measure the concentration of engineered nanomaterials in the air as a reactor for manufacturing metal oxide nanoparticles is unloaded.

The success of voluntary consensus standards in occupational and environmental health depends on robust participation of experts from the relevant industries (management and workers), academia, non-governmental organizations and the government sector. Many countries provide dedicated support for participation by their government sector representatives on international standards committees, but other countries, including the United States, do not. The US National Technology Transfer and Advancement Act of 1995 encourages federal government employees to participate in standards development, as does the Office of Management and Budget[5]. Even so, there is no special Congressional appropriation to ensure participation in either national or international standards development by US science agencies, and the area of nanotechnology is no exception. The US National Nanotechnology Initiative has an annual budget of about $1.5 billion, but none of it is directly appropriated for the development of international standards, so each US science agency must make resources available for participation from its base budget. As a result, government employees and government-funded researchers often lack the resources necessary for robust participation in international standards-setting, and therefore cannot make it a high priority.

Concern about the potential risks of nanotechnology, and the need to manage those risks at an early stage of development[6,7], has captured the interest of non-governmental organizations, and national and international standard developing organizations. As a result, international standards for risk management in nanotechnology are already being developed. For example, in 2005, ISO established a technical committee for nanotechnologies (TC 229), which now has 29 participating members and 10 observers. TC 229 quickly established a sub-group, Working Group 3 on Health, Safety and the Environment, which is convened by the

United States. The first project initiated by this working group — the compilation of a comprehensive compendium of knowledge in the emerging area of nanotechnology risk assessment and management — was led by one of the present authors (V.M.). The report was approved by TC 229 at a meeting in Bordeaux in May 2008 and has now been published by ISO[8].

Soon after the Bordeaux meeting, the British Standards Institute (BSI) submitted a safety guide[9] to TC 229 for approval for development into a nanotechnology risk control standard. The BSI document (known as PD 6699-2) provides prescriptive risk guidance for the development, manufacture and use of nanomaterials. The most controversial element of the BSI proposal is the grouping of nanomaterials into four hazard categories with assigned benchmark exposure levels (BEL). These levels are described as "pragmatic guidance levels only" and are not rigorously derived using generally accepted principles of risk assessment[10], but rather are derived "on the assumption that the hazard potential of the nanoparticle form is greater than the large particle form" and using existing occupational exposure limits (the maximum allowable concentration of a contaminant in the workplace environment) for large particle forms.

The first hazard category in PD 6699-2 is the "fibrous" category, which is defined as an insoluble nanomaterial with an aspect ratio of greater than three and lengths in excess of 5,000 nm, which is assigned a BEL of 0.01 fibre per cubic centimetre of air (one-tenth of the US Occupational Safety and Health Administration's occupational exposure limit for asbestos). Second, the "CMAR" category is defined as any nanomaterial that is already classified as carcinogenic, mutagenic, asthmagenic or reproductive toxicant: nanomaterials in this category are assigned a BEL equal to one-tenth of an existing occupational exposure limit for its large particle form. Third, the "insoluble" category is defined as an insoluble or poorly soluble nanomaterial, not in the fibrous or CMAR category, which is assigned a BEL equal to one-fifteenth of an existing occupational exposure limit for its large-particle form or to 20,000 particles per cubic centimetre. Finally, the "soluble" category is defined as a soluble nanomaterial not in the fibrous or CMAR category, which is assigned a BEL equal to half of an existing occupational exposure limit for its large-particle form.

Although the grouping of nanomaterials into categories is necessary at the present level of knowledge, given the many possible combinations of physico-chemical parameters for nanomaterials, exposure limits should be based on generally accepted principles of risk assessment[10]. If BSI is successful in converting this PD 6699-2 into an ISO standard, such an international standard could lead to controls and restrictions on the manufacturing and use of nanomaterials, similar to the way that asbestos risk control standards of the twentieth century culminated in import and use restrictions. However, unlike the asbestos standards, which were based on exhaustive risk assessment analyses, the control measures for nanomaterials are proposed in the absence of the evidence of "significant risk"[11]. Clearly, the potential for such a risk management paradigm becoming global should attract the attention of all countries engaged in development of nanotechnology applications.

In response to the needs of the user community and the speed with which nanotechnology is emerging, international standards organizations are also adjusting their existing adoption mechanisms to reduce the time required to develop consensus standards. For instance, the ISO established an International Workshop Agreement process, in which standards are developed and approved by consensus in an open workshop organized by a national standards body. It is also working to establish the ISO Concept Database to improve access to (and maintenance of) existing ISO standards[12]. International standards organizations are also exploring wikis (for example ref. 13) and other web-based approaches to the development of consensus-based dynamic global standards.

In the twentieth century, US national standards were accepted as *de facto* international standards and were adopted by many countries as their own national standards. But the obsolescence of many US occupational health exposure limits, combined with the slower pace of the United States in adopting new (or updating many out-of-date) occupational exposure limits[14], has now led countries to turn to international organizations like the ISO and OECD for risk management guidance for emerging technologies such as nanotechnology. The new global political and economic realities of the twenty-first century have reduced the traditional barriers (capital and resources) to the flow of scientific information, and have also reduced global reliance on US risk management standard practices. International standards in nanotechnology risk management are now being developed, and we encourage more US participation by management, labour and government representatives in international standards-setting for nanotechnology to ensure that global safety and health standards are scientifically sound, and technologically and economically feasible.

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