Essential features for proactive risk management

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We propose a proactive approach to the management of occupational health risks in emerging technologies based on six features: qualitative risk assessment; the ability to adapt strategies and refine requirements; an appropriate level of precaution; global applicability; the ability to elicit voluntary cooperation by companies; and stakeholder involvement.

Detailed information about the risks associated with new technologies is often missing during the early stages of research, development and commercial marketing, so people working with these new technologies in industrial settings can be potentially exposed to serious harm before sufficient risk assessment information has been generated. Legislation on occupational health is normally based on research into these risks, but in the absence of detailed research into the risks associated with many nanomaterials, we believe that voluntary approaches need to be developed and implemented to complement existing regulations and to provide guidance on prudent measures to control risk.

Most countries have laws that are intended to reduce the occupational health risks associated with a variety of hazardous agents, and most of these laws reflect a mid-twentieth century approach to risk management that is based on quantitative risk assessment[1–3]. These various laws emerged through harmonization processes that transformed occupational risk management from a heterogeneous mix of locality-specific voluntary and regulatory approaches into nationwide mandatory duties for employers and rights for employees (for example, see refs 4–6).

During the twentieth century, the use of quantitative risk assessment in setting these laws ensured that occupational health standards were based on a well-accepted scientific foundation. However, it also delayed the onset of protective rules until sufficient quantitative information about new risks had accumulated[2,3]. Adopting new occupational health standards has grown more complex, which has greatly slowed efforts to adopt protective standards for toxic agents that are well-known to pose significant risks[1]. Such a regulatory risk management approach is more reactive than proactive and leaves many workers in industries with emerging technologies potentially unprotected[2,3].

Many new technologies have been developed since these laws were enacted, and these new technologies, together with the increased globalization of trade and finance, have put pressure on national governments to provide just-in-time risk management approaches to emerging hazards. Failure to recognize the importance of showing that a new technology is safe has contributed to new technologies, such as genetically modified foods, not fulfilling their initial promise, or products like asbestos mineral fibres causing untold suffering to tens of thousands of workers[7,8].

The rate of development of emerging technologies, and their introduction in the global market, has been rapidly accelerating in the early twenty-first century, as exemplified by the rise of nanotechnology. The increasingly rapid pace of technology development has come into conflict with the slow pace of the governmental standard-setting process, thus increasing the chances that any new technology, like nanotechnology, may cause damage to workers' health before strategies based on quantitative risk assessment can be implemented[3]. The lessons of asbestos, nuclear power, chlorofluorocarbons, polychlorinated biphenyls and other costly episodes of modern technology have not been lost on the public, and the mismatch between new risks and the management of these risks can fuel public concerns about the inability of government to protect the public. Indeed, nanotechnology could share the fate of other technologies — such as nuclear power and genetically modified foods — that did not achieve their full potential in part because of a lack of proactive risk management[8].

There is a significant time lag between the emergence of any new technology and the generation of sufficient risk assessment information to be able to conduct a thorough quantitative risk assessment and to write a traditional regulatory occupational risk management standard. Yet, occupational risk management can include both mandatory (regulation) and voluntary (guidance) approaches including exposure-mitigation techniques to reduce the risk of occupational injury or disease.

In the case of nanotechnology, the remarkable variability of nanomaterial compositions, the new properties of these nanomaterials and the introduction of new manufacturing processes bring extra challenges to the process of adopting either mandatory or voluntary risk management approaches. While risk assessment information accumulates, we need to protect workers from the potential hazards of nanomaterials. We believe that, in addition to any existing regulations that are relevant, a proactive approach to the management of the occupational health risks associated with any emerging technology should include, at a minimum, the following six essential features: (1) qualitative risk assessment; (2) strategies to quickly adapt to accumulating risk assessment information and to refine risk management requirements; (3) embody an appropriate level of precaution; (4) be equivalent across the spectrum of global emerging technology firms; (5) have the ability to elicit strong voluntary cooperation by firms; and (6) stakeholder involvement. These features represent a starting approach to address the potential risks arising from the rapidly emerging field of nanotechnology and are presented in more detail in the following sections.

Qualitative risk assessment

In the absence of sufficient quantitative data on the risks associated with new nanomaterials, we can instead use various combinations of expert judgments and extrapolations from existing data for similar materials. In this qualitative approach to risk assessment, occupational safety and health professionals use their professional judgment in evaluating site-specific risks and in recommending implementation of exposure-mitigation options. For example, in a guidance document[9] published by the US National Institute for Occupational Safety and Health (NIOSH) (hereafter called *NIOSH Approaches*), it is recommended that "the decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and the frequency and likelihood of the worker's exposure".

More formalized techniques, such as 'expert elicitation', which uses a systematic process of formalizing and quantifying several different experts' judgments about uncertain quantities[10–12], can be used in grouping nanomaterials according to their hazard properties and exposure potential[13]. Such hazard and exposure groupings could facilitate the further development of techniques using banding to assess and stratify risks to select appropriate risk control techniques for work with nanomaterials[14]. Hazard grouping of new chemicals based on the toxicity of other materials, which is associated with an exposure-mitigation technique, was initially developed in the pharmaceutical industry[15]. This approach is broadly referred to as 'control banding' and is often implemented in the form of a user-friendly toolkit. Control banding was used by the UK Health and Safety Executive[16], the German Federal Institute for Occupational Safety and Health[17] and the Dutch Ministry of Social Affairs and Employment[18] as a national quasi-regulatory scheme aimed to help small- and medium-sized enterprises establish site-specific occupational safety programmes. The 'International Chemical Control Toolkit' developed by the International Labour Organization to assist small- and medium-sized enterprises in developing countries is an example of a voluntary global approach to occupational risk management based on control banding[19].

Adaptive strategies

Emerging technologies rapidly evolve and continuously generate new safety and health information. In a qualitative approach to risk management, it is critically important to periodically reassess the occupational risk profile to adapt it to newly available hazard and exposure information. For example, *NIOSH Approaches* is designed as a living document, which is revised by an interdisciplinary team of NIOSH experts as new data — in the form of scientific papers, unpublished research from NIOSH laboratories and the results of NIOSH field-team activities[20] — becomes available. NIOSH field teams collaborate with research laboratories, producers and manufacturers working with engineered nanomaterials to gather data on the health and safety implications of exposure to engineered nanomaterials. Similar collaborative programmes between national and international government agencies, nanotechnology industry manufacturers and downstream users, workers, researchers and safety and health practitioners could most effectively generate scientific data about the nature and extent of worker risk[1].

Adaptive approaches to risk management ensure that mechanisms exist to maintain ongoing risk assessments using the most recent data on hazards and exposures. Furthermore, information about the effectiveness of current approaches is monitored and augments the adaptive approach. To be effective, adaptive approaches must exist in 'real time'. One mechanism is to use web-based platforms established for the development of consensus-based dynamic global standards. For example, a consortium of stakeholders launched the wiki-based *GoodNanoGuide* project[21], and the International Organization for Standardization (ISO) is establishing the ISO Concept Database to provide an environment for ISO committees to develop and maintain items for which they are responsible[22].

Precaution

In the absence of quantitative risk assessment information that leads to the adoption of regulatory occupational exposure limits that specify levels of exposure and control measures, a prudent approach can be taken to minimize exposures through the use of precaution. The use of precaution as a guiding principle for risk management when scientific uncertainty exists arises from the environmental protection arena and has become known as the 'precautionary principle' by environmental policy experts. A widely publicized expression of the principle is the 'Wingspread Declaration', from a meeting of environmentalists in 1998, which states: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not established scientifically"[23]. Another version can be found in Principle 15 of the United Nations Rio Declaration on Environment and Development[24]: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." The European Commission describes measures based on the precautionary principle as "proportional to the chosen level of protection, non-discriminatory in their application, consistent with similar measures already taken, based on an examination of the potential benefits and costs of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis), subject to review in the light of new scientific data, and capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment"[25].

In practice, tools to implement the precautionary principle, which would also include considering its unintended consequences[26], have yet to be developed and are much needed[27]. Nevertheless, we believe that risk precautions should be an important feature of any voluntary occupational risk management program in the absence of 'proof' about nanotechnology risk.

Precautionary approaches involve taking steps to control risk, when the nature and extent of risk are not well established[7]. For example, *NIOSH Approaches* suggests using prudent measures in establishing appropriate levels of controls through engineering techniques and personal protective equipment. Precautionary approaches can also include 'green' approaches, which more broadly aim at reducing or eliminating hazards to human health and the environment through product design and process optimization[28]. An example of how such an approach can be applied to the workplace is NIOSH's Prevention-through-Design (PtD) initiative. As precaution emphasizes elimination of hazards at the earliest stage, PtD also emphasizes the critical role of eliminating hazards at the design stage of any process. The PtD initiative is defined as: "The practice of anticipating and 'designing out' potential occupational safety and health hazards and risks associated with new processes, structures, equipment or tools, and organizing work, such that it takes into consideration the construction, maintenance, decommissioning and disposal/recycling of waste material, and recognizing the business and social benefits of doing so."[29] The PtD initiative is a practical tool for ensuring that in the design phase of new processes protection of occupational safety and health is included.

Global

Economic globalization increases the pressure on governments and firms alike to establish Globally Harmonized Systems (GHS) of risk management for all technologies, but especially for emerging technologies whose risks are not fully understood. Other than the United Nation's initiative of GHS for the classification and labelling of chemicals[30], existing international agreements dealing with the health hazards of materials tend to establish moratoria on well-recognized and highly toxic pollutants only[31], and therefore cannot serve as models for establishing international proactive risk management programs for nanotechnology where hazard information is only just emerging. However, several international standards organizations are in the process of developing guidelines for the safe handling of nanomaterials and for collection of risk information.

The Organization for Economic Co-operation and Development (OECD) established a 'Working Party on Manufactured Nanomaterials' and approved its programme of work in November 2006 (ref. 32). One of eight projects focuses on information exchange on national regulatory programs and voluntary schemes, with a goal of identifying recommended approaches and elements to establish a successful information gathering programme. Another project looks at 'Co-operation on Exposure Measurement and Exposure Mitigation' for manufactured nanomaterials starting with occupational exposures[33,34]. And last year the ISO published a report[35] with the aim of assembling the most recent information on hazards, exposure assessment and exposure-mitigation techniques pertinent to nanotechnologies to facilitate development of site-specific programmes by health and safety professionals[36].

Voluntary

A broad spectrum of approaches to risk management has been proposed for nanotechnology[37]. These range from recommendations of a total moratorium[38] on any development and use of nanomaterials if and until they are proven to be safe to humans and the environment, to recommendations for relying on existing occupational safety and health laws and regulations such as the Hazard Communication Standard[39–41].

The use of voluntary consensus-driven safety and health standards arises from economic forces that drive organizations to minimize risk. An example of such an economic driver is the risk of future liabilities stemming from adverse health and environmental effects that can increase insurance premiums, provoke legal action and hinder venture capital investments. Furthermore, as public acceptance of any nanomaterial-containing consumer product is crucial for commercial success, conformance to voluntary standards, which provide safety assurance to consumers, may prove economically advantageous.

Industry-generated voluntary standards in combination with existing government regulations have been recommended as a viable risk management approach for the nanotechnology workplace[42]. One prominent approach is the 'Nano Risk Framework' developed jointly by the Environmental Defense Fund and DuPont[43]. This framework describes a detailed risk assessment and risk management process for ensuring the safe development of nanoscale materials that can be adapted by different companies and organizations. The framework was praised as "well designed to produce and disseminate accurate information, develop unconventional forms of 'regulation' in the form of safe handling protocols, and build trust among stakeholders and the general public"[44], and is being used as an outline for a technical report under development by ISO (ISO/AWI TR 13124, unpublished). The framework was also criticized as imposing high costs on small- and medium-size enterprises and, therefore, as putting them at a competitive disadvantage to large companies[45]. Another example of the voluntary approach, the CENARIOS® certification program, relies on semi-qualitative risk assessment techniques within a voluntary risk management framework[46].

A notice issued by the Japanese Ministry of Health, Labor and Welfare to directors of labour departments in every prefecture in February 2008 is, so far, the only example of a specific mandatory governmental occupational risk management standard for nanomaterials[47]. The notice instructs those involved in the manufacture, repair and inspection of nanomaterials to carry out processes under sealed, unattended or automated conditions, or to install a local exhaust system. However, there are mandatory and voluntary government programmes that aim to assess the environmental risk of nanomaterials through data collection in a number of countries and that include some occupational nanotechnology risk management considerations.

For example, in January 2008 the US Environmental Protection Agency (EPA) launched a voluntary 'Nanoscale Materials Stewardship Program' to develop model risk assessment and management schemes, using its authority under the Toxic Substance Control Act (TSCA)[48]. This initiative is intended to serve four functions: (1) to help the agency assemble existing data and information from manufacturers and processors of existing chemical nanoscale materials; (2) to identify and encourage use of emerging risk management practices in developing and commercializing nanoscale materials; (3) to encourage the development of test data needed to provide a firmer scientific foundation for future work and regulatory/policy decisions; and (4) to encourage responsible development, which is defined as "a commitment to develop and use technology to help meet the most pressing human and societal needs, while making every reasonable effort to anticipate and mitigate adverse implications or unintended consequences." Participants in the EPA programme agree to implement a risk management programme that includes consideration of the risks of nanoscale materials, and to consider risk management information provided by the EPA and developed through consultations with NIOSH and the public[49]. Within 11 months, the EPA received submissions from 29 companies or associations covering 123 nanoscale materials under the 'basic' level of participation, and commitment from 4 companies to participate under the 'in-depth' level[50].

In May 2006 the German Federal Institute for Occupational Safety and Health (BAuA) conducted a survey on 'Aspects of Worker Protection during the Production and Handling of Engineered Nanomaterials' through the German Chemical Industry Association (VCI) to ensure anonymity. The questionnaire attempted to collect information about amount, characteristics (for example, size distribution) and chemical nature of nanomaterials produced, used or released during work processes; handling of nanomaterials; exposure assessment; protection measures; medical surveillance and any observed health effects. The information collected was used to develop voluntary guidance for handling and use of nanomaterials in the workplace[51].

Some local governments have recently made it mandatory to provide health and safety data on nanomaterials. In January 2009, for example, the California Department of Toxic Substances Control announced that carbon nanotube manufacturers had to report "information regarding analytical test methods, fate and transport in the environment"[52]. The information requested includes measurement methods, safety data and details of exposure-mitigation techniques in the workplace.

Stakeholder involvement

All stakeholders should be included in the development of risk management requirements for emerging technologies. The involvement of the entire spectrum of stakeholders — workers, employers, industry associations, insurance companies, researchers, venture capitalists, consumers, occupational health and safety practitioners, and other members of the interested public — is critical to broadening the discussion about potential benefits and risks of nanotechnology. The dialogue with stakeholders should be as expansive as possible to provide a forum to thoroughly air concerns and fears about the new technology and to solicit and incorporate stakeholder contributions to the development of risk management requirements[53].

Conclusion

In the absence of exhaustive risk assessment information that could guide the development of mandatory occupational risk management approaches to an emerging technology like nanotechnology, other approaches need to be developed and implemented. We believe that the approach proposed in this article would allow an easy-to-implement international voluntary risk management toolkit to be developed by building on existing efforts in a number of national and international organizations. An ideal occupational risk management toolkit would be based on a qualitative grouping of nanomaterials by the degree of hazard, grouping of processes and tasks by exposure potential, and classification of exposure-mitigation techniques by their protection factors, and would allow prudent site-specific risk management measures to be established. This approach would need to be developed and updated through the consensus of global experts and the relevant stakeholders, and would have to be the product of an established international organization to ensure transparency and scientific credibility.

Developing proactive approaches to occupational risk management of emerging technologies is crucial not only to protect workers, but also to ensure that the promise of this new technology is fulfilled. Voluntary risk management approaches as a complement to existing regulations may not be as protective for workers as government risk management regulations are, but may be a critical interim measure to fill the current risk management gap before our knowledge of the emerging technology and the associated risks matures. Until mandatory risk reduction approaches become more proactive themselves, serious consideration should be given by the occupational safety and health community to crafting voluntary approaches to occupational risk management of emerging technology risks. ❒

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