Chapter 9
Health and Safety Standards*

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9.1 Introduction

Health and safety standards aim at minimizing risk to people and the environment. Often, though, there is a significant time lag between the emergence of any new technology and the generation of sufficient risk information to allow a thorough risk assessment and to write a traditional regulatory quantitative risk management standard [1]. In the early twenty-first century, this time lag is leading society to aim to proactively manage the risks of emerging technologies like nanotechnology [2]. Proactive risk management can serve as an initial response to a new technology and later can lead to traditional regulatory standards that are based on lengthy risk assessment data collection. Proactive risk management should include, at a minimum, the following essential features (1) qualitative – as opposed to quantitative – risk assessment; (2) strategies to quickly adapt to accumulating risk information as it develops and to refine any risk management recommendations; (3) recommendations based on a level of precaution that is appropriate to ensure no material impairment of human or environmental health occurs from exposure to the new technology; (4) steps that are equivalent across the spectrum of global emerging technology firms; and (5) robust stakeholder involvement that can lead to widespread voluntary cooperation between firms [2]. These features of proactive risk management are particularly applicable for the development of health and safety standards for the rapidly emerging field of nanotechnology.

Since workers bear the greatest health risk from exposure to any emerging technology, most organizations which develop safety and health standards for nanotechnology have focused their efforts initially on the workplace. The workplace safety

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and health standards described in this chapter include voluntary, consensus-type standards adopted by the private sector as well as mandatory, or government regulatory, health-related standards. Occupational safety and health standards usually contain the following elements: (1) occupational exposure limits; (2) hazard communication instructions; (3) standard practices, e.g. safety procedures or reference to codes of conduct; and (4) standard guidance, e.g. industrial hygiene guidance for safe handling of nanomaterials. Additional safety and health related standards are covered in other chapters in this book, for example, in Chaps. 3, 7, and 8 on *Reference Materials, Implication Measurements and Biological Activity Testing*. The following subsections of this chapter describe state-of-the-science for each element of the safety and health standards, highlight standards for nanotechnology currently under development nationally and internationally, and map future directions in standards setting.

9.2 Exposure Limits

Exposure limits have been used for over a century to control exposure to a host of chemical and physical agents. They are most often established to control exposures in working environments and to control ambient contamination in air, food and water. Exposure limits are also used to trigger exposure mitigation measures [3]. In the workplace, occupational exposure limits or OELs serve as benchmarks for assessing and controlling exposures in a worker's breathing zone, for triggering the use of personal protective equipment (PPE) when higher order controls do not reduce airborne concentration levels to sufficiently low levels, and for implementing medical surveillance measures. Historically, most OELs were established to minimize the likelihood of adverse effects occurring from exposure to a potentially hazardous chemical or physical agent over the working life of a worker (Section 6(b)(5) in Ref. [4]). The scientific bases for OELs were determined from the observation of workers exposed to the substance (epidemiology) or from the results of laboratory animal studies (toxicology).

For engineered nanomaterials, it is likely that in the foreseeable future most quantitative risk assessments, including dose-response relationships, will involve the extrapolation of animal data to humans. While human epidemiologic studies are considered the most useful for quantitative risk assessment as a basis for regulatory standards, it is not likely that they will be available for some time [5]. In the meantime, there is an increasing amount of data from acute and sub-chronic toxicology animal studies indicating potential health risks from some engineered nanomaterials [6–9] and a wealth of data on adverse health effects resulting from exposures to incidental nanomaterials [10].

Worldwide, only few OELs for engineered nanomaterials have been established. Examples include amorphous silicon dioxide (SiO_2) [11, 12], carbon black [13] and nanoscale titanium dioxide (TiO_2) [14]. In December, 2010, the US National

Institute for Occupational Safety and Health (NIOSH) published a notice requesting comments on the draft Current Intelligence Bulletin "Occupational Exposure to Carbon Nanotubes and Nanofibers" [15]. The bulletin summarized the adverse respiratory health effects that have been observed in laboratory animal studies with single-walled carbon nanotubes, multi-walled carbon nanotubes and carbon nanofibers and provided recommendations for the safe handling of these materials including an OEL set at 0.007 mg/m^3.

In addition to the United States (US) activities, other national efforts to develop OELs for engineered nanomaterials are underway in Germany and United Kingdom (UK). The German Federal Institute for Occupational Safety and Health (BAuA) conducted a risk assessment study on photocopier toner emissions, which are composed of incidental nanoparticles [16]. Using Announcement 910, which was issued by The German Ministry's Committee for Hazardous Substances and which established risk factors for carcinogenic substances [17], BAuA reported the following concentration values for respirable biopersistent toner particles: as of 2008, (1) a tolerable risk of 4 in 1,000 is reached at 0.6 mg/m^3; (2) an interim acceptable risk of 4 in 10,000 is reached at 0.06 mg/m^3, and, as of 2018; (3) an acceptable risk of 4 in 100,000 is reached at 0.006 mg/m^3. The photocopier toner emission study was also used by the Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA) to conclude that in accordance with the German Ministry of Labor and Social Affairs' Technical Rule for Hazardous Substances in the Workplace (TRGS 900) [11] the general dust limit of 3 mg/m^3 for the respirable fraction does not apply to the nanoscale particle fraction, but should not be exceeded [18].

In light of the paucity of data on nanomaterial hazard and exposure, IFA recommended benchmark limits to be used for an 8-h work shift. The following limits (expressed as an increase in exposure concentrations over background) have been recommended for monitoring the effectiveness of protective measures in the workplace [18]:

1. For metals, metal oxides and other biopersistent granular nanomaterials with a density of >6,000 kg/m^3, a particle number concentration of 20,000 particles/cm^3 in the range of measurement between 1 and 100 nm should not be exceeded;
2. For biopersistent granular nanomaterials, with a density below 6,000 kg/m^3, a particle number concentration of 40,000 particles/cm^3 in the measured range between 1 and 100 nm should not be exceeded (Note: for comparison, it is reported that the air in a normal room can contain 10,000 to 20,000 nanoscale particles/cm^3, while these figures can reach 50,000 nanoscale particles/cm^3 in wooded area and 100,000 nanoscale particles/cm^3 in urban streets [19]);
3. For carbon nanotubes, a provisional fiber concentration of 0.01 fibres/cm^3 should not be exceeded, based upon the exposure risk ratio for asbestos [20]; and
4. For nanoscale liquid particles (such as fats, hydrocarbons, siloxanes), the applicable maximum workplace limit or workplace limit values should be employed owing to the absence of effects of solid particles.

These recommended benchmark limits are geared to minimizing exposure in accordance with the state of the art in measurements, and have not been substantiated toxicologically. Even where these recommended benchmark limits are observed, a health risk may still exist for workers. Therefore, they should not be confused with health-based OELs [18].

In the UK, the British Standards Institution (BSI) published a public document, PD 6699-2 "Guide to safe handling and disposal of manufactured nanomaterials" [21], which provides risk guidance for the development, manufacture, and use of engineered nanomaterials. In this document, all nanomaterials are grouped into four hazard categories with assigned benchmark exposure levels (BELs). Similar to the BGIA recommendations, BELs are described as "pragmatic guidance levels only" and are derived from OELs for larger particle forms "on the assumption that the hazard potential of the nanoparticle form is greater than the large particle form." First, there is the "fibrous" category, defined as an insoluble nanomaterial with a high aspect ratio (ratio >3:1 and length >5,000 nm), which is assigned a BEL of 0.01 fibres/cm³ (one-tenth of the asbestos OEL prescribed in the United States of America (USA) and elsewhere). Second, there is the "CMAR" category, defined as any nanomaterial which is already classified in its larger particle form as a Carcinogenic, Mutagenic, Asthmagenic, or Reproductive toxicant. Nanomaterials in the CMAR category are assigned BELs at one tenth of the mass-based OEL for its larger particle form. Third, there is the "insoluble" category, defined as insoluble or poorly soluble nanomaterials not in the fibrous or CMAR category. Nanoparticles in this category are assigned BELs at one-fifteenth (1/15th) of the mass-based OEL for its larger particle form or 20,000 particles/cm^3. Fourth, there is a "soluble" category, defined as a soluble nanomaterial not in fibrous or CMAR category, which is assigned a BEL at one half of the mass-based OEL for its larger particle form.

In the USA, a programmatic approach based on a national public–private partnership has been proposed for protecting workers from nanomaterials in lieu of mandatory standards. The proposal includes generic provisions for exposure assessment, risk controls, medical surveillance, and worker training [1]. As the quantitative assessment of the nanotechnology risks emerge, the information generated, collected and utilized by the proposed National Nanotechnology Partnership Program [1] could serve as "tentative" OELs [22]. Subsequently, if sufficient evidence of "significant risk" becomes available for a specific nanomaterial, a mandatory occupational health standard could be developed by government. Such a national partnership could help overcome the significant time lag between the generation of sufficient risk assessment information to conduct a thorough quantitative risk assessment and the time needed to write a mandatory governmental regulatory occupational risk management standard. The regulatory requirements in the USA for setting occupational safety and health standards have generally precluded regulators from taking incremental and precautionary steps toward protective standards on the basis of less-than-complete quantitative risk assessment and control information [1].

Worldwide efforts aimed at developing OELs for engineered nanomaterials are intensifying [23]. Those efforts were reviewed at OECD workshops on Exposure Assessment in 2008 [24] and Risk Assessment for Nanomaterials in 2009 [25].

The discussion revealed on-going concerns about the acceptable level of risk, acceptable uncertainty factors and acceptable health end-points. At the June, 2009 meeting of the International Organization Standardization's (ISO) Technical Committee 229 (TC 229) Working Group 3 (WG3), an international group of experts working on the draft Technical Specification "Guide to safe handling and disposal of manufactured nanomaterials" agreed that "[it] will contain guidance for how companies/organizations can make their own decisions regarding Benchmark Exposure Limits, including specific examples for how to develop internal benchmarks as well as citing specific guidelines that can be followed" [26]. Industry-wide and in-house exposure limits have been widely used in the absence of, or in addition to, existing regulatory exposure limits [27]. It requires joint efforts by industry experts in the area of risk assessment and experts on site-specific hazards and exposures familiar with their product and site-specific work environment. Recently, Bayer MaterialScience conducted sub-chronic inhalation studies on MWCNTs and derived in-house an OEL of 0.05 mg/m^3 for its MWCNT product [28]. Nanocyl utilizes a no effect concentration in air of 0.0025 mg/m^3 for an 8-h-per-day exposure [29]. This limit was estimated from the lowest observed adverse effect level of 0.1 mg/m^3 obtained using data from the 90 days inhalation study following OECD 413 test guidelines [8] and by applying an assessment factor of 40 [29].

A number of global efforts are underway to conduct studies aimed at obtaining hazard and exposure data which could be used in quantitative risk assessment analysis to develop OELs. Perhaps the largest effort to generate dose-response and other hazard-related data is OECD Sponsorship Programme for the Testing of Manufactured Nanomaterials [6]. Under this program, OECD member countries, as well as some non-member countries and other stakeholders, are working together to examine the hazard potential of 13 manufactured nanomaterials, which are in, or close to, commercial application [6]. Another Steering Group within the same OECD working party is exploring the feasibility of launching a sponsorship program for exposure assessment for 13 manufactured nanomaterials by conducting a limited number of case studies [30]. The sponsorship program would assemble data that would generate exposure data complementing hazard data for risk assessment analysis [30]. OECD is also looking at a possibility of grouping nanomaterials by hazard potential. Specifically, the Chemicals Committee's Task Force on Hazard Assessment is considering the revision of OECD's guidance on grouping of chemicals [31]. One of the areas under consideration is the possibility to apply the concept of grouping to manufactured nanomaterials, with the aim to fill data gaps by extrapolation or trend analysis [32].

Finally, the World Health Organization (WHO) is the international health organization charged to assist countries to attain "Health for All," and this gives it a unique opportunity to develop solutions for improving safety and health in all countries, especially in developing countries. WHO has the expertise to develop credible and widely accepted approaches in establishing exposure limits [3, 33]. Given the paucity of hazard and exposure data, the WHO could lead the development of guidance on how to establish exposure values in close coordination with OECD efforts.

9.3 Hazard Communication

Hazard communication includes three major categories of information. First, hazard communication includes information passed along the product chain from manufacturers to downstream users and intended to protect workers. Second, hazard communication includes information that accompanies products in transport to warn first-responders and first receivers about specific dangers associated with spills and other accidents. And, third, hazard communication includes information that is designed to inform consumers about specific dangers presented by certain components in consumer products. As a risk management tool, hazard communication is often incorporated into national and international mandatory occupational and environmental standards and plays a large role in product liability laws under a duty to warn of the hazards of a particular product.

9.3.1 Material Safety Data Sheets

Material Safety Data Sheets (MSDSs) provide industrial hygienists, workers, employers and emergency personnel with safety information including guidance about how to safely handle chemical substances. In most countries, manufacturers and importers of chemical substances are required to perform a hazard determination and to report hazard information on MSDS for chemical substances they produce or import (see e.g. [34]). In the USA, the Hazard Communication Standard (29 CFR section 1910.1200) describes the informational elements that are required to be included in a MSDS. Internationally, the Globally Harmonized System for the Labeling and Classification of Chemicals (GHS) was developed to provide a single, harmonized system to classify chemicals, and for producing labels and safety data sheets, with the primary benefit of increasing the quality and consistency of information provided to workers, employers and chemical users. Under the GHS, information on safety data sheets is presented in a designated order.

At this time, however, some authors concluded that MSDSs do not address many characteristics unique to nanomaterials and need to be modified to effectively communicate nanospecific information related to safety and product stewardship [35]. Uncertainty in terminology and nomenclature for nanomaterials also led in some instances to inadequate information being provided on MSDSs [36, 37]. Preparing MSDSs to serve as a source of hazard communication information about a nanomaterial should include at least four important elements (1) a notation about which of the chemical constituents are nano-sized; (2) a notation that the characteristics of nanoparticles may be different from those of the larger particles of the same chemical composition and any data on different properties; (3) a notation that some nanoparticles may initiate catalytic reactions due to their nano size that would not otherwise be anticipated based on their chemical composition alone; and (4) a mechanism to provide updated toxicity information as such information becomes available [38].

Efforts to adjust information contained on MSDSs have been under way in a number of countries led by a range of stakeholders. In Germany, the German Chemical Industry Association (Verband der Chemischen Industrie/VCI) has been developing the "Guidance for the Passing on of Information along the Supply Chain in the Handling of Nanomaterials via Safety Data Sheets" together with stakeholders in dialogue activities [32, 39]. Safe Work Australia is currently in the process of revising the Code of Practice for Safety Data Sheets (SDS) through public consultations [40]. In the section which lists physico-chemical parameters for which information on chemicals should be provided, Safe Work Australia is proposing the addition of a number of non-mandatory parameters, specifically relevant to engineered nanomaterials (but also relevant for some other chemicals):

1. Shape and aspect ratio;
2. Crystallinity;
3. Dustiness;
4. Surface area;
5. Degree of aggregation or agglomeration;
6. Ionisation (redox potential); and
7. Biodurability or biopersistence.

Safe Work Australia is also considering the addition of a small number of advisory notes relating nanotechnologies to other relevant occupational safety and health regulatory documents. For example, the following was added to the draft Policy Proposal for Workplace Chemicals Model Regulations: "*Note: Manufactured nanomaterials may require a different classification and hazard communication elements (labeling and SDS) compared to the macro-form of the same material*" [41].

Internationally, the ISO's TC 229 Work Group 3 is developing a Technical Report on "Preparation of Safety Data Sheets (SDS) for Manufactured Nanomaterials." This effort aims to complement existing MSDS elements described in GHS with nano-specific characteristics predictive of potential health and safety hazards and exposures for engineered nanomaterials.

9.3.2 Labeling

Labeling of regulated substances in consumer products is a risk management tool, which serves to inform consumers about presence of hazardous substances and to allow them make an informed decision on acquiring and using consumer products. In the last 5 years, there have been numerous calls from non-governmental organizations to national governments to institute mandatory labeling of nanomaterials in consumer products especially for nanomaterials in foods and cosmetics [42–48]. It was suggested that such labeling could have ethical and societal benefits by building public trust through transparency and by providing consumers freedom to express their views on broader societal implications of novel technologies [49].

Similar to traditional chemical substances, some nanomaterials can present hazards at certain concentrations and under certain conditions. As with traditional chemical substances, food and cosmetics regulations in most countries provide tools to require producers to disclose the presence of hazardous substances including hazardous nanomaterials. The US Food and Drug Administration (FDA) Task Force on nanotechnology recommended that "the current science does not support a finding that classes of products with nanoscale materials necessarily present greater safety concerns than classes of products without nanoscale materials" [50]. Similarly, according to the opinions of the EU Scientific Committees [Scientific Committee on Emerging and Newly Identified Risks (SCENIHR), on Consumer Products (SCCP) and on food and feed in the European Food Safety Authority (EFSA)] not all nanomaterials induce toxic effects [51]. The Scientific Committees stress that the hypothesis that smaller necessarily means more toxic cannot be substantiated by the published data. However, certain health and environmental hazards have been identified for a variety of manufactured nanomaterials, indicating potential toxic effects. Long, non-degradable, rigid nanotubes (longer than 20 μm) have in several experiments been found to have effects similar to hazardous asbestos, causing inflammatory reactions for instance. Experiments also indicate that carbon nanotubes with these characteristics could induce a specific form of lung cancer, mesothelioma, which is also observed in relation to asbestos exposure. Whether such nanotubes would pose a risk for humans is not known but cannot be ruled out. This means that nanomaterials are similar to other substances, in that some may be toxic and some may not, and some may be toxic only under certain exposure conditions. As there is not yet a generally applicable paradigm for the identification of potential hazards of nanomaterials, the Scientific Committees continue to recommend a case-by-case approach for the risk assessment of nanomaterials [51].

In another example, Food Standards Australia New Zealand (FSANZ) has undertaken a review of its regulatory preparedness in relation to nanotechnology in food including food additives, processing aids, novel foods, contaminants and nutritive substances. As an outcome of this assessment FSANZ has amended its *Application Handbook*, an Australian regulatory instrument, which sets out the essential information required to make an application to vary the *Australia New Zealand Food Standards Code*. The Amendments include the requirement to report particle size, size distribution and morphology where substances are particulate in nature and will remain so in the final food, and where particle size is important to achieving the technological function or may relate to a difference in toxicity. The Amendments do not specifically mention nanomaterials or nanotechnology, but they were introduced to ensure that hazardous nanomaterials and other substances are adequately assessed during the application process [52].

Labeling based on technology or process rather than on a recognized hazard represent a number of challenges related to its usefulness and legitimacy [49]. For instance, such labeling might be inconsistent with national legal frameworks which focus on managing risks associated with specific hazards and would violate the rules of the World Trade Organization (WTO) Technical Barriers to Trade Agreement. Also, labeling poses a danger of information overload. Labeling can

confuse rather than inform consumers. In fact, the outcome of such an exercise could be increased risk to consumers because effective hazard communication would be diluted and, in effect, masked [49].

Nevertheless, some countries have adopted nanotechnology specific labeling requirements for consumer products. In 2007, French government launched the Grenelle Project aimed at developing legislation to regulate the manufacture, import or marketing of nanomaterials. The project is organized into two proposed laws: Grenelle 1 and 2. Grenelle 1 is intended to establish general principles, while Grenelle 2 is intended to provide details. Grenelle 1, which was adopted by the French Parliament on July 23, 2009, includes the following requirement relevant to labeling: "The State sets itself the goal that, within 2 years after the law is adopted, the manufacture, importation, or marketing of nanoparticle substances or organisms containing nanoparticles or the product of nanotechnology will become the object of obligatory declaration, notably on quantities and uses, to the administrative authority as well as information to the public and to consumers." Grenelle 2, which was adopted by the French Parliament on August 3, 2009, under Article 73 includes the requirement that "Information related to the identity and uses of these nanoparticle substances shall be publicly available under conditions to be established under the law" [53].

In Russia, the Federal Consumer Rights and Human Well-being Department (*Rospotrebnadzor*) adopted a series of basic regulations covering use of nanomaterials in consumer products including "Regulation 79 regarding the conception of the toxicological studies, risk assessment methodology, methods of identification and quantitative description of nanomaterials." Regulation 79 came into force on October 31, 2007 [54] and states the need for commercial enterprises to inform consumers about the use of nanotechnology products and nanomaterials in consumer products.

The European Parliament adopted regulation in November of 2009 on cosmetic products which requires all producers of cosmetics containing nanomaterials to record their presence on the list of ingredients by using "[nano]" after the names of such ingredients. The scope of reporting on cosmetics products related to nanomaterial is defined as "insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nanometers (nm)" [55].

In 2007, BSI released a Publically Available Specification on labeling of nanoparticles and products containing them [56]. The BSI document provides "guidance on the format and content of voluntary labels for manufactured nanoparticles and products or substances containing manufactured nanoparticles…for use by businesses and other organizations involved in the manufacture, distribution, supply, handling, use and disposal of manufactured nanoparticles or products containing manufactured nanoparticles and/or products exhibiting nano-enabled effects." However, until labeling is required by the UK government, the BSI document remains a voluntary guidance. The BSI document also served as an outline for Technical Specification "*Guidance on the labeling of manufactured nanomaterials and products containing manufactured nanomaterials*" under

development in the European standardization body, the European Committee for Standardization (CEN), Technical Committee 352 Nanotechnologies. Since the Technical Specification is developed under the Vienna Agreement between ISO and CEN, a limited number of ISO TC 229 experts serve as observers in this CEN activity. The main challenges that this project is facing include: (1) lack of agreed-upon terminology to describe nanomaterials; (2) need to ensure consistency with existing voluntary standards and national and international regulations; (3) need to explain that labeling does not represent judgement about safety or benefits of nanomaterials in the product to avoid consumer confusion at the time of product purchase; and (4) the need to ensure its global rather than regional applicability.

Within the United Nations system, there are food standards developed by the Codex Alimentarius Commission which was created in 1963 by the UN's Food and Agriculture Organization (FAO). The main purposes of food standards are protecting health of the consumers, ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations. While the Codex has made progress in a number of areas, an international agreement on standards for the labeling of food products based on emerging technologies, such as biotechnology-aided food products, has so far proved elusive [57]. No activities on nanomaterial labeling for foods have been initiated so far.

9.3.3 Globally Harmonized System

The Globally Harmonized System of Classification and Labeling of Chemicals provides an internationally agreed upon system of hazard classification and labeling and is a common and consistent approach to defining and classifying hazards, and for communicating hazard information on labels and material safety data sheets [58]. The GHS, which is administered within the United Nations system, covers all hazardous chemicals, such as substances, products, and mixtures.

The major target audiences for GHS-based health and safety information include manufacturing workers, consumers, transport workers, and emergency responders and first receivers. Under this system, chemical substances and mixtures are classified according to their physicochemical, health, and environmental hazard characteristics. GHS has been adopted by the European Union and a number of nations. On September 30, 2009 the US Occupational Safety and Health Administration (OSHA) published a proposed rule to align OSHA's Hazard Communication Standard with provisions of the United Nations GHS [59]. Changes to the GHS are made through the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labeling of Chemicals (UNSCEGHS).

Initial discussions on potential modifications to GHS specific to nanomaterials have centered on how the format of Safety Data Sheets can adequately address the novel hazard and exposure potential of nanomaterials. A paper on this matter,

prepared by the Australian delegation for the UNSCEGHS meeting in December 2009 [60], proposes that consideration be given to adding the following non-mandatory parameters to *Annex 4 – Guidance on the Preparation of Safety Data Sheets (SDS)*:

1. Particle size and size distribution;
2. Shape and aspect ratio;
3. Crystallinity;
4. Dustiness;
5. Surface area;
6. Degree of aggregation or agglomeration; and
7. Biodurability or biopersistence.

At the December 2009 meeting, it was decided that given the work underway in European Union, OECD, and ISO, the UNSCEGHS will "postpone the consideration of this issue until more information about [nanomaterials] intrinsic properties and characteristics [is] available" [61].

9.4 Risk Mitigation

Standards on nanomaterial risk mitigation have been evolving as more information becomes available on the hazards, exposures and the effectiveness of risk mitigation techniques. Initially, most standards developing organizations focused their efforts on the workplace. For example, the OECD Working Party on Manufactured Nanomaterials (WPMN) Steering Group 8 "Co-operation on Exposure Measurement and Exposure Mitigation" organized its work into three phases (1) exposure in the workplace; (2) exposure to the general population; and (3) exposure to the environment [62, 63].

9.4.1 Occupational Guidance

Within the initial phase covering exposures in the workplace, standardization efforts began with surveys of current practices and general guidance recommending prudent measures to control emissions of nanomaterials in the workplace.

In 2005, one of the first general guidance documents on workplace safety was released by NIOSH as an online internet draft publication called "Approaches to Safe Nanotechnology." After three updates, it was published as a NIOSH numbered publication in 2009 [64]. In regards to exposure mitigation, the document states that according to the current state of the science:

1. For most processes and job tasks, the control of airborne exposure to nanomaterials can be accomplished using a variety of engineering control techniques similar to those used in reducing exposure to general aerosols;

2. The use of good work practices can help to minimize worker exposures to nanomaterials; and
3. Certified respirators provide stated levels of protection [64].

In 2006, the International Council on Nanotechnology's (ICON) "Survey of Current Practices in the Nanotechnology Workplace" [65] was published. The ICON report summarizes results of an international survey of current environmental health and safety and product stewardship practices in the global nanotechnology industry [65]. According to the report:

> Surveyed organizations reported that they believe there are special risks related to the nanomaterials they work with, that they are implementing nano-specific EHS programs and that they are actively seeking additional information on how to best handle nanomaterials. Actual reported EHS practices, however, including selection of engineering controls, PPE, cleanup methods, and waste management, do not significantly depart from conventional safety practices for handling chemicals.…In fact, practices were occasionally described as based upon the properties of the bulk form or the solvent carrier and not specifically on the properties of the nanomaterial.

A number of companies and trade associations have developed safety guidelines for nanomaterials. For example, Degussa (now Evonik) developed voluntary safety and health standards for production facilities working with nanoscale materials [66]. These standards include (1) regular monitoring of microscopic particle concentration in the workplace; (2) health protection of employees through the use of closed systems; and (3) additional technical precautions such as engineering controls and personal protective equipment to maintain concentration of microscopic particles in the air at below 0.5 mg/m^3. In 2007, the German Chemical Industry Association (VCI) and German Federal Institute for Occupational Safety and Health (BAuA) released "Guidance for handling and use of nanomaterials in the workplace" [67]. The VCI/BAuA document provides guidance regarding OSH measures in the production and use of intentionally produced nanomaterials primarily for chemical industry.

In 2008, the OECD WPMN published a survey of national guidance for nanomaterial handling, which highlighted available general industry guidance [68]. In addition, WPMN regularly releases national summaries of activities on safety and health of nanomaterials as Tour-de-Table for WPMN meetings. More specifically for risk mitigation, OECD made public in 2009 its guidance on the use of personal protective equipment [69].

Private standards developing organizations without national membership such as ORC Worldwide and ASTM International also developed guidance available to its members and the public. The ORC website entitled "Nanotechnology Consensus Workplace Safety Guidelines" contains a selection of Health, Safety & Environment tools and reference materials that may be useful to practitioners involved in deployment of nanotechnology [70]. Specifically, there are a number of detailed and practical documents on exposure mitigation on the ORC website (1) General Considerations for Engineering Controls for Nanomaterials (guidance on physical and chemical containment, ventilation and flow extraction, HEPA filtration), (2) Workplace Operational Guidelines (qualitative description of housekeeping

standards), and (3) Guidelines for Safe Handling of Nanoparticles in Laboratories (recommendations on exposure risk assessment, engineering controls, PPE and respirators, spill cleanup and disposal). In 2007, ASTM International published "Standard Guide for Handling Unbound Engineered Nanoparticles in Occupational Settings" [71]. This ASTM document describes actions that could be taken in occupational settings to minimize human exposures to unbound, intentionally produced nanometer-scale particles, fibers and other such materials in manufacturing, processing, laboratory and other occupational settings where such materials are expected to be present. It is intended to provide guidance for controlling such exposures as a precautionary measure where relevant exposure standards and/or definitive risk and exposure information do not exist [71].

In 2008, the ISO's TC 229 WG3 "Health, Safety and the Environment" published its first safety and health standard titled "Health and safety practices in occupational settings relevant to nanotechnologies" [72]. The report is based on NIOSH's "Approaches to Safe Nanotechnologies" [64] and aims at assembling the most current information on hazards, exposure assessment and exposure mitigation techniques pertinent to nanotechnologies to facilitate development of site-specific programs by health and safety professionals. Using existing knowledge as a starting point for the control of fine and ultrafine particles (including incidental nanoparticles), guidance is presented for the control of engineered nanomaterials. The Technical Report has become a foundation for the development of national safety and health guidance in a number of countries such as Korea [73], Thailand and Canada. As a next step towards an authoritative normative standard, ISO TC 229 WG3 is developing a Technical Specification "Guide to safe handling and disposal of manufactured nanomaterials" based on the UK BSI guidance with the same title [21].

Mandatory standards on safe handling specific to nanomaterials are implemented in a growing number of countries. Since 2008, US Environmental Protection Agency (USEPA) has been applying its authorities under Section 5(a)(2) describing "Significant New Use Rule" and Section 5(e) describing "Consent Orders" of the Toxic Substances Control Act (TSCA) [74] to require implementation of specific risk mitigation measures for nanomaterials in the workplace including use of NIOSH-approved respirators and wearing gloves and protective clothes. For example, on November 5, 2008 USEPA announced application of Significant New Use Rule (SNUR) to siloxane modified silica and alumina nanoparticles previously registered as P-05-673 and P-05-687, respectively [75]. The generic use of both substances stated in Pre-Manufacture Notices (PMNs) was as an additive. In the ruling EPA announced that "use without impervious gloves or a NIOSH-approved respirator with an [Assigned Protection Factor] of at least ten; the manufacture, process, or use of the substance[s] as a powder; or uses of the substance[s] other than as described in the PMN[s] may cause serious health effects."

On November 6, 2009, USEPA proposed Significant New Use Rules for multi-walled carbon nanotubes and single-walled carbon nanotubes that were the subject of pre-manufacture notices, P-08-177 and P-08-328, respectively [76]. The PMNs describe use of substances as "a property modifier in electronic applications

and as a property modifier in polymer composites." According to the notice, these substances are subject to TSCA Section 5(e) consent orders issued by USEPA. The consent orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk including wearing a NIOSH-approved full-face respirator with N-100 cartridges, gloves and protective clothing impervious to the chemical substance. The proposed SNURs designate the absence of the protective measures required in the corresponding consent orders as a significant new use.

On February 3, 2010 USEPA proposed SNUR for multi-walled carbon nanotubes, P-08-199, based on determination that "certain changes from the use scenario described in the PMN [Pre-Manufacture Notice] could result in increased exposures" [77]. The PMN states that the substance will be used as an additive/filler for polymer composites and support media for industrial catalysts. In the ruling EPA announced that "use of the substance without the use of gloves and protective clothing, where there is a potential for dermal exposure; use of the substance without a NIOSH-approved full-face respirator with an N100 cartridge, where there is a potential for inhalation exposure; or use other than as described in the PMN, may cause serious health effects."

A Notice issued by the Japanese Ministry of Health, Labor and Welfare (MHLW) to directors of Labour Departments in every prefecture in February 2008 is an example of a specific mandatory governmental general occupational risk management standard for nanomaterials [78]. MHLW revised their Notice in March of 2009 based on recommendations of a committee which was established to discuss safety of nanomaterials in occupational settings [32, 79]. The Notice instructs those involved in the manufacture, repair and inspection of nanomaterials to carry out processes under either sealed, unattended or automated conditions, if there is possibility of exposure to nanomaterials. A local exhaust ventilation system or push–pull type ventilation system must be installed to prevent dispersion of nanomaterials in a location where manufacturing/handling equipment is to be installed which cannot be enclosed or contained. The Notice also instructs to measure concentration of nanomaterials in working environment and provides specific procedures for waste disposal, cleaning, operating procedures, use of protective equipment, health surveillance, worker education etc.

In France, the High Council of Public Health (*Haut Conseil de Santé Publique, HCSP*) issued an Opinion on January 9, 2009 on the safety of workers exposed to carbon nanotubes, in which it recommends mandatory measures. The measures include a requirement that the production of carbon nanotubes, and their use in manufacturing intermediate products and consumer and health products, must be carried out under conditions of strict containment in order to protect workers from aerosolisation and/or dispersion exposure [80]. In addition, through an instruction dated February 18, 2008, the General Directorate for Labour (*Direction Générale du Travail*) reminded its units throughout the country of the legislation governing the prevention of occupational risks arising from exposure to chemical substances containing nanoscale particles. It was emphasized that risk prevention in this field does not lie outside the scope of the regulations of the Labour Code, the provisions

of which cover at the very least chemical risk prevention and possibly the special provisions applicable to CMR category 1 and 2 agents (i.e. agents that are carcinogenic, mutagenic or toxic to reproduction) if the substance falls within their scope of application [32].

In 2007, the US Department of Energy (USDOE) published "Approach to Nanomaterials ES&H" [81] to minimize risk to workers in USDOE laboratories. This guidance document formed a basis for a Notice of January 5, 2009, which offered "reasonable guidance for managing the uncertainty associated with nanomaterials whose hazards have not been determined and reducing to an acceptable level the risk of worker injury, worker ill-health and negative environmental impacts" in DOE laboratories [82].

The USDOE Notice provides for safe handling of unbound engineered nanoparticles (UNP) including measures to minimize environmental releases of nanomaterials and requires registries of all nanomaterial workers by requiring establishment of safety and health policies and procedures for activities involving UNP as part of the USDOE-approved Worker Safety and Health Program. [Note: In this document *nanoparticles* are dispersible particles having two or three dimensions greater than 1 nm and smaller than about 100 nm and which may or may not exhibit a size-related intensive property. *Engineered* nanoparticles are intentionally created. This definition excludes biomolecules (proteins, nucleic acids, and carbohydrates), materials for which an occupational exposure limit, national consensus, or regulatory standard exists. Nanoscale forms of radiological materials are also excluded from this definition. *Unbound engineered nanoparticles* are defined by the DOE to mean those engineered nanoparticles that, under reasonably foreseeable conditions encountered in the work, are not contained within a matrix that would be expected to prevent the nanoparticles from being separately mobile and a potential source of exposure.] Specifically, the Notice requires laboratories to:

1. Maintain inventories of nanotechnology activities involving UNP at USDOE sites;
2. Maintain registries of all personnel designated as nanomaterial workers;
3. Provide all nanomaterial workers and their supervisors with training specific to nanotechnology activities;
4. Conduct exposure assessment and establish air monitoring program for UNP based on preliminary exposure assessments;
5. Offer baseline medical evaluations to all nanomaterial workers including general physical exam, pulmonary function test, and general blood work;
6. Control exposures to UNP using a risk-based graded approach;
7. Post signs indicating hazards and exposure mitigation requirements; and
8. Have a documented procedure for managing UNP waste.

In December 2010, OECD announced publication of the Compilation and Comparison of Guidelines related to Exposure to Nanomaterials in Laboratories developed under the leadership of the German delegation to OECD WPMN.

This report revealed that a surprisingly large number of research organizations have developed and made publicly available guidance for safe handling of nanomaterials in laboratories [83].

At the same time, activities are underway to provide guidance for Small- and Medium-size Enterprises (SMEs) through the development of control banding tools and easy to understand communication material targeting workers, management and professionals. In 2008, NIOSH published a brochure for employers, managers and safety and health professionals explaining potential hazards, exposures and effective exposure mitigation tools available for nanomaterials in easy to understand terms [84]. In the UK, the Health and Safety Executive published an Information Note on Nanotechnology in 2004 [85], which gives information on the health and safety issues associated with some aspects of nanotechnology including considerations for monitoring, control measures, and personal protective equipment.

In December of 2008, the Swiss Federal Office for Public Health and the Swiss Federal Office for the Environment published the initial version of the precautionary matrix for synthetic nanomaterials, which will be updated on a regular basis to include new scientific knowledge [Note: "In the context of the precautionary matrix, synthetic nanomaterials are those that comprise nanoparticles or nanorods (abbreviated to NPR in the precautionary matrix) that were specially manufactured for a defined purpose. As a general rule, it is recommended that the precautionary matrix be used for all NPR with at least two dimensions smaller than 500 nm"] [86]. The matrix represents a screening tool based on a control-banding approach to estimate the "nano-specific potential risk" of synthetic nanomaterials and of their applications for workers, consumers and the environment, based on parameters such as stability, reactivity and exposure or emission to the environment of nanomaterials. Risk potential is classified and matched with appropriate measures to protect health and the environment. This risk management tool is provided to the industry to be implemented voluntarily as part of the first phase in a national plan to create regulatory framework conditions for the responsible handling of synthetic nanoparticles.

Also in 2008, an international consortium of stakeholders was created to launch and maintain the *GoodNanoGuide* Project [87]. The *GoodNanoGuide* is based on a wiki software platform, and was described as a "collaboration platform designed to enhance the ability of experts to exchange ideas on how best to handle nanomaterials in an occupational setting. It is meant to be an interactive forum that fills the need for up-to-date information about current good workplace practices and highlights new practices as they develop" [87]. Freely available to the public, the *GoodNanoGuide* guidance on handling of nanomaterials in the workplace is organized in a matrix format. The body of the matrix provides links to specific steps to identify hazard, assess exposure potential and choose controls for given common formulations of nanomaterials (e.g., dry powder, liquid dispersion, solid polymer matrix and non-polymer matrix) and common workplace operations (e.g., material unpacking, synthesis, weighing and measuring, dispersing, mixing, spraying, machining, packing, process equipment cleaning, workplace

cleaning, spill cleanup, wastemanagement, reasonably foreseeable emergencies). These common formulations and operations represent the highest potential for exposure. The *GoodNanoGuide* could be particularly valuable to SMEs and to safety and health professionals in low and medium-income countries, who often do not have access to commercial standards.

In March of 2009, the ISO TC 229 WG3 approved a project developing Technical Specification TS 12901-2 "Guidelines for occupational risk management applied to engineered nanomaterials based on a control banding approach." Major challenges facing the project are defining hazards and exposure bands of nanomaterials under the paucity of hazard and exposure data and correlating them with an appropriate and limited number of exposure mitigation bands. Resulting proactive control banding method will be based on the synergy of precautionary and pragmatic approaches and will be significantly different from traditional reactive control banding methods.

Safe Work Australia is an independent statutory agency with primary responsibility to improve occupational health and safety and workers' compensation arrangements across Australia's jurisdictions including six states and two territories. In November of 2009, research commissioned by Safe Work Australia recognized the control banding approach "where similar control measures are used within categories of nanomaterials that have been grouped ('banded') according to their exposure potential and hazardous properties, i.e. grouped according to risk," as "an appropriate method because of the current lack of data available for the risk assessment of individual nanomaterials but there is some understanding of hazards posed by different groups of nanomaterials" [88].

The WHO also has a history of utilizing the control banding approach to providing guidance on how to establish site-specific occupational safety and health program for SMEs in developing countries. Specifically, WHO developed a series of Practical Solutions for the Workplace in the form of toolkits [89]. In collaboration with the UN International Labour Organization (ILO), WHO created the International Chemical Control Toolkit [90]. As a first step in this field, WHO initiated development of WHO Guidelines tentatively titled "Protecting Workers from Potential Risks of Manufactured Nanomaterials." The project aims at providing easy to understand and implement guidance for safe handling of nanomaterials in the workplace targeting SME's and other enterprises with limited access to the most advanced exposure measurement and mitigation technologies and industrial hygiene expertise (http://www.who.int/occupational_health/topics/nanotechnologies/en/).

9.4.2 Environmental and Consumer Guidance

Most of the voluntary and mandatory standards for workplace safety and health described in the previous subsection also include measures to control emissions of nanomaterials into the air or water environments. Thus far there have been few

mandatory standards development activities specific to engineered nanomaterials and related to the environment and consumer exposures beyond those initial steps.

OECD Working Party on Manufactured Nanomaterials Steering Group 8 is planning a series of projects aimed at providing guidance on mitigating nanomaterial exposures to the environment and consumers [30].

An example of implemented mandatory standards in the area of environmental or consumer protection includes regulatory actions by USEPA. In 2008, USEPA designated certain nanomaterials "new chemicals" and started issuing consent orders for nanomaterials under TSCA Section 5(e) [91, 92]. The consent orders triggered by PMN review can require specific risk mitigation actions to protect the environment. For example, in September, 2008, USEPA issued consent orders for multi-walled carbon nanotubes and single-walled carbon nanotubes that were the subject of pre-manufacture notices, P-08-177 and P-08-328, respectively [76]. The consent order prohibited any predictable or purposeful release of the PMN substance into the waters of the USA.

USEPA has been also monitoring pesticidal claims made for nanotechnology based products as it would for any other chemical-based products. In the September 21, 2007 Federal Register notice EPA stated that any company marketing a product using silver nanoparticles to kill bacteria must provide scientific evidence that particles do not pose unreasonable environmental risk [93]. On March 7, 2008, an EPA regional office fined ATEN Technology/IOGEAR $208K for "selling unregistered pesticides and making unproven claims about their effectiveness" in the form of a "nanoshield" coating on mouse and keyboard.

In another example, the Review Committee on Basic Research into the Environmental Impact of Nanomaterials, Japanese Ministry of the Environment published the "Guideline for Preventive Environmental Impact from Industrial Nanomaterials (March 2009)" [94]. The document instructs that each company must take suitable action for each circumstance in order to control the environmental release of nanomaterials and describes generally recommended measures.

9.4.3 Comprehensive Risk Management Frameworks

Examples of standards which attempt to provide comprehensive risk assessment and risk management frameworks have also been developed. These standards incorporate guidelines on risk evaluation and mitigation throughout the life of a nano-enabled product.

In 2007, the Environmental Defense Fund and the DuPont Corporation launched the *Nano Risk Framework*, which 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 [95]. The framework consists of six distinct action elements:

1. Describe the nanomaterial and its application(s);
2. Profile the lifecycle(s) of the nanomaterial;

3. Evaluate risks associated with its use;
4. Determine risk management strategies;
5. Decide, document, and act; and
6. Review and adapt.

Nano Risk Framework was used as an outline for an ISO TC 229 Technical Report under development, which is presently titled "Nanomaterial Risk Evaluation Process."

Another risk management tool for nanotechnology is CENARIOS® [96] which is the first certifiable risk management and monitoring system specifically adapted to nanotechnologies. The system has been developed by TÜV SÜD (Munich, Germany) and the Innovation Society (St. Gallen, Switzerland) and is already being used in practice. The system uses four individually combinable modules "Risk Estimation and Risk Assessment," "Risk Monitoring," "Issues Management" and "Certification" to integrate the latest findings from science and technology as well as societal, legal and market related factors into risk management.

A recent African and Latin American/Caribbean regional meetings on implementation of the Strategic Approach to International Chemicals Management (Abidjan, Côte D'ivoire, 25–29 January 2010 and Kingston, Jamaica, 8–9 March 2010) adopted resolutions instructing the Open Ended Working Group (OEWG) and International Conference on Chemicals Management (ICCM) 3 to include standards in the form of developments and recommendations related to risk management of nanotechnology [97]. The standards would cover occupational, general public and environmental safety and health throughout nanomaterial life-cycle including nanomaterial waste and would be based on the precautionary approach. On March 2, 2010, the Strategic Approach to International Chemicals Management released for public comments a draft outline of a report focusing on nanotechnologies and manufactured nanomaterials including issues of relevance to developing countries and countries with economies in transition [98]. The report will provide overview of the potential risks to (1) human health, (2) to those who work with them in their production, use and disposal, and (3) to the environment and recommendations on how these could be minimized and managed.

9.5 Codes of Conduct

Another type of standard is based on a code of conduct. Codes of conduct (CoC) standards for nanotechnology aim to address ethical and societal dimensions of developing and commercializing nanotechnology. There have been a number of initiatives in this field within individual organizations, stakeholder groups and governments, mostly in Europe [32]. The CoC put in place by BASF [99, 100] is an example of a code limited to one company. It is a voluntary commitment to guide in a responsible manner the actions of BASF's employees. The Code is based on four principles: (1) protection of employees, customers and business

partners; (2) protection of the environment; (3) participation in safety research; and (4) open communication and dialogue.

Another CoC, the Responsible Nano Code, was developed by a non-government multi-stakeholder group in the UK. The Responsible Nano Code provides a framework of best practice for organisations working on the development, manufacture, retail or disposal of products using nanotechnologies. Participating organizations agree to abide by Seven Principles of the Responsible Nano Code:

1. Board Accountability: Each organization shall ensure that accountability for guiding and managing its involvement with nanotechnologies resides with the Board or is delegated to an appropriate senior executive or committee;
2. Stakeholder Involvement: Each organization shall identify its nanotechnology stakeholders, proactively engage with them and be responsive to their views;
3. Worker Health and Safety: Each organization shall ensure high standards of occupational health and safety for its workers handling nano-materials and nano-enabled products. It shall also consider occupational safety and health issues for workers at other stages of the product lifecycle;
4. Public Health, Safety and Environmental Risks: Each organization shall carry out thorough risk assessments and minimize any potential public health, safety or environmental risks relating to its products using nanotechnologies. It shall also consider the public health, safety and environmental risks throughout the product lifecycle;
5. Wider Social, Environmental, Health and Ethical Implications and Impacts: Each organization shall consider and contribute to addressing the wider social, environmental, health and ethical implications and impacts of their involvement with nanotechnologies;
6. Engaging with Business Partners: Each organization shall engage proactively, openly and co-operatively with business partners to encourage and stimulate their adoption of the Code; and
7. Transparency and Disclosure: Each organization shall be open and transparent about its involvement with and management of nanotechnologies and report regularly and clearly on how it implements the Responsible Nano Code [101].

The first example of a CoC specifically aimed at nanotechnology usage in consumer products was published in April 2008 by the Switzerland's Food and Packaging Retailers Association (IG DHS) [102]. The Code contains obligations for IG DHS members regarding personal responsibility, procurement of information and information for consumers. Organizations signing the Code have to consider product safety as a first priority, placing on the market only products that can be judged safe according to the best available evidence. Signatory organizations are also responsible to provide open information to consumers about nanotechnology products, in particular ensuring that "*products described as employing nanotechnologies actually contain components and/or modes of action corresponding to these technologies.*"

In February 2008, the European Commission (EC) adopted the Code of Conduct for Responsible Nanosciences and Nanotechnologies Research. The EC

CoC provides EU Member States, employers, research funders, researchers and more generally all individuals and civil society organisations involved or interested in nanosciences and nanotechnologies research with guidelines favouring a responsible and open approach to nanosciences and nanotechnologies research. The EC CoC is based on a set of general principles:

1. Meaning: Nanosciences and nanotechnologies research should be comprehensible to the public;
2. Sustainability: Nanosciences and nanotechnologies research should be safe, ethical and contribute to sustainable development;
3. Precaution: Nanosciences and nanotechnologies research should be conducted in accordance with the precautionary principle;
4. Inclusiveness: Governance of nanosciences and nanotechnologies research activities should be the principles of openness to all stakeholders;
5. Excellence: Nanosciences and nanotechnologies research should meet the best scientific standards;
6. Innovation: Governance of nanosciences and nanotechnologies research activities should encourage maximum creativity, flexibility and planning ability for innovation and growth; and
7. Accountability: Researchers and research organizations should remain accountable for the social, environmental and human health impacts [103].

The EC intends to regularly monitor and revise its CoC biennially in order to take into account developments in nanosciences and nanotechnologies worldwide and their integration in European society.

9.6 Future Directions

9.6.1 Trends and Outlook

Efforts aimed at development of safety and health standards for nanotechnology are in transition. Early efforts have produced standards that are descriptive in nature. Recently, standards that have been developed reflect a more prescriptive approach. The change in approach arises from that fact that more hazard and risk data are being generated and more risk management techniques are being validated. In addition, the scope of nanotechnology standards is expanding to include not only nanotechnology workers, but also to include environmental exposures to the general public, to consumers, and to the air and water environments. The organizational scope and applicability of nanotechnology standards is expanding from the single organization to collaborations between private sector entities and to involvement by industrial associations. Standards for nanotechnology are beginning to demonstrate regional, national and global levels of involvement.

In most developed countries, well-known occupational, environmental and consumer hazards are covered by mandatory governmental standards. These

governmental approaches reflect application-dependent acceptable levels of risk and also incorporate application-dependent uncertainty factors into risk assessment calculations. Many governmental organizations across the world believe that unless emerging technologies like nanotechnology bring about novel types of hazards, or revolutionary types of applications, the governments' existing regulatory regime should suffice or undergo minor modifications [32, 104, 105]. The main challenges to mandatory standards development are in addressing how to best incorporate higher levels of uncertainty in assessing risks that have not yet been well quantified and how existing governmental standards development frameworks can be adapted to protect workers, consumers and the public from nanomaterials whose risks have not fully emerged.

9.6.2 Performance-Based Risk Management Program for Nanotechnology

Based on the efforts to date to develop standards to protect workers, consumers, the general public and the environment from potential adverse impacts of nanotechnology, a performance-based risk management approach may be the best format for the near term.

For a general risk management approach to be successful, metrics to measure the progress towards the use and application of nanotechnology in a safe and responsible manner are needed. Three methods to measure such progress should be considered.

In the first method, single indicators are measured to describe a system. Indicators for the occupational safety and health component of a nanotechnology safety program can be categorized into three groups:

1. Physical indicators, such as exposure measurements and control below benchmark levels;
2. Information/education indicators such as adequacy of MSDS, Standard Operating Procedures (SOPs) and training; and
3. Safety and health indicators such as frequency of injuries and fatalities, sick days, worker compensation claims, reduction in use of Personal Protective Equipment if replaced by measures higher up the hierarchy of controls, productivity level, and exposure accidents (e.g., the Seveso II Directive at [106]).

In the second method, quantitative aggregates of several indicators, or indices, are measured. Indices are expressed as a single score by combining various indicators through a scientifically sound normalization, weighing and aggregation.

In the third method, metrics can be classified into frameworks which present large numbers of indicators in qualitative ways [107]. Frameworks do not aggregate data and therefore values of all indicators can be easily observed.

The three methods have advantages and disadvantages. The first method is the simplest, but does not provide the full account of progress towards occupational safety and health within a comprehensive program. The second and the third

method are better suited to comprehensively assess safety and health programs. It is easy to measure progress with the second method and there is a full account of input information with the third method. On the other hand, it can be unclear how to determine weight factors in the second method and there could be difficulties in measuring progress with the third method [107].

Using this approach, a periodic (e.g. annual) assessment of the baseline level for indicators is required in order to identify and recognize effective risk management performance. In the case of the workplace, the existing OSHA Voluntary Protection Programs (VPP) could be adjusted to accommodate novel metrics of success for nanotechnology. The VPP began in 1982 to promote a more cooperative approach between government, labor and management to protect workers and influence employers. VPP is a program to recognize places of employment that have achieved, and are committed to maintaining, superior safety and health performance [108]. The VPP is an example of the third approach utilizing frameworks to measure progress. The progress is measured through two tiers of success: the Star Program and Merit Program. In order to be recognized in the Star Program the participants must achieve certain benchmark values of indicators. For example, a 3-year total case incidence rate and a 3-year days away, restricted, and/or job transfer incidence rate must be below at least 1 of the 3 most recent years of specific industry national averages for nonfatal injuries and illnesses published by the Bureau of Labor Statistics. Specific safety and health management system elements and subelements must be implemented. The Merit program recognizes participants that have a good safety and health management system, but they must take additional steps to reach Star quality. The VPP's Star Demonstration Program was created to demonstrate the effectiveness of methods for achieving excellence in safety and health management systems that are potential alternatives to current Star requirements. This program could be considered as a basis for a performance-based risk management program for nanotechnology.

Once the performance-based risk management program is shown to be successful within a single country, it could be implemented in other countries. This could be facilitated by United Nations agencies such as ILO and WHO.

9.6.3 Global Health and Safety Standards Development Coordination

Many national and international standards developing organizations have activities in safety and health standards for nanotechnology and nanomaterials. A concerted effort by all major players is necessary to ensure the most effective and safe development of nanotechnology, as well as any other technology whose risk emergence outstrips the ability to generate quantitative risk information in a timely fashion. For instance, public standards setting bodies could specify mandatory requirements, while the private sector could develop technical standards to satisfy risk assessments and risk management requirements. Under such an effort, a public body such as WHO could be tasked to set maximum exposure limits for specific

hazards, while private international standards organizations could set operational and methodological standards for achieving these levels. Similarly, the UN GHS program could define adjustments to the format of hazard communication as necessary and private international standards organizations could develop technical standards on measuring new parameters. A consortium of stakeholders could develop quasi-regulatory standards such as control banding approaches to assess and manage risk of nanomaterials to workers, the public and the environment.

9.7 Conclusion

This chapter has described the current efforts to fashion nanotechnology health and safety standards for workers, consumers, the general public and the environment. It is clear, though, that standards development is in its early stages and non-governmental efforts dominate. While several current mandatory safety and health standards are also applicable to nanomaterials, government efforts are underway to facilitate development of mandatory standards specific to nanomaterials. The absence of sufficient quantitative risk assessment information in animals or in humans limits governments in establishing such mandatory standards at this time. Nevertheless, the call for such standards is growing and it may not be too much longer before governments are forced to answer that call.

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