Regulatory approaches to worker protection in nanotechnology industry in the USA and European Union.

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Abstract

A number of reports have been published regarding applicability of existing regulatory frameworks to protect consumers and the environment from potential adverse effects related to introduction of nanomaterials into the commerce in the USA and the European Union. However, a detail comparison of the regulatory approaches to nanotechnology occupational safety and health in the two communities is lacking. This report aims to fill this gap by reviewing general occupational safety and health regulatory frameworks and their applications to nanotechnology and nanomaterials.

1. US

In the United States, the Occupational Safety and Health Act of 1970 (OSHAct) serves as the primary national framework for protecting workers from injury and illness at work (Howard and Murashov, 2009). In addition, occupational requirements enter the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Current applications of these acts to nanotechnology and nanomaterials are described in the following sections.

1.1 OSHAct

The OSHAct was enacted by the Congress that declared "it to be its purpose and policy, through the exercise of its powers to regulate commerce among the several States and with foreign nations and to provide for the general welfare, to assure so far as possible every working man and woman in the Nation safe and healthful working conditions" (29 USC sections 651-678). The OSHAct created Occupational Safety and Health Administration (OSHA) in the Department of Labor responsible for promulgation and enforcement of occupational regulatory standard. The OSHAct also established the National Institute for Occupational Safety and Health (NIOSH), as part of the Department of Health and Human Services. NIOSH carries out scientific research and makes recommendations for
the prevention of work-related injury and illness (http://www.cdc.gov/niosh/topics/nanotech/default.html).

Congress gave the Secretary of Labor the power to adopt occupational safety and health standards and to require covered employers to adhere to those standards. Congress provided a broad delegation of authority to the Secretary when it defined an occupational safety and health standard as “reasonably necessary and appropriate to provide safe or healthful employment and places of employment” (29 USC section 652(8)). In adopting a standard that protects workers against toxic materials or harmful physical agents, Congress requires OSHA to set a standard "that most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such an employee has regular exposure to the hazard … for the period of his working life” (29 USC section 667, Howard and Murashov, 2009).

Using these broad authorities, OSHA adopted the majority of its current occupational safety and health standards for toxic chemical and physical agents, including carcinogens, in the 1970s. Beginning in 1980, though, the pace of standards adoption slowed considerably due largely to regulatory requirements added by Congress, the courts and the executive branch. By the mid-1990s, the OSHA standards adoption process was described as "ossified" (McGarity 1992). Now, most of the permissible exposure limits or PELs for toxic agents adopted by OSHA in the 1970s are considered obsolete. The slow pace of OSHA standards adoption, dependent in large part on quantitative risk management approaches (Mendeloff, 1988), has left workers in both traditional and emerging industries unprotected (McGarity and Shapiro 1993, Howard and Murashov, 2009).

Congress envisioned that OSHA would develop occupational health standards by first determining if the hazard posed a risk of “material impairment,” then following the straightforward rulemaking requirements found in the U.S. Administrative Procedures Act (5 USC section 553), making sure to determine if the proposed standard is feasible technically and economically. Beginning in the early 1980s, requirements were added to federal rulemaking by Congress, the courts and the president. These additional requirements greatly slowed standards adoption to the point where from 2000 through 2008, only one occupational health standard for hexavalent chromium was adopted (OSHA 2006). Presently, the only Permissible Exposure Limit (PEL) set by OSHA for a specific manufactured nanomaterials is PEL for carbon black of 3.5 mg/m³ (29 CFR 1910.1000 TABLE Z-1).

Congress. In 1980, Congress enacted the Regulatory Flexibility Act (RFA) (5 USC section 603(a)) which requires federal agencies to conduct a regulatory flexibility analysis when proposing a standard that could have significant economic impact on a substantial number of small businesses, organizations, or state or local governments. In 1996, the RFA was significantly amended by the
Small Business Regulatory Enforcement and Fairness Act (SBREFA) (5 USC section 611). SBREFA (1) requires that OSHA appoint a special panel of Small Business Administration Office of Advocacy personnel, OSHA personnel and Office of Management and Budget (OMB) staff to review any proposed rule and to obtain comments on any proposed rule from small business representatives; (2) mandates that a regulatory flexibility analysis be a part of the rulemaking record if and when the standard is challenged in court; and (3) permits courts to order OSHA to comply with any rulemaking procedure with which it failed to heed and to either remand the rule to OSHA or exempt small businesses from OSHA enforcement until OSHA complies. Since SBREFA gives the courts the right to engage in a substantive review to determine if the standard is supported by substantial evidence, it adds more complexity to the standards adoption process (Rabinowitz 2002).

Another law that impacts the rulemaking process is the Paperwork Reduction Act of 1995 (PRA) (44 USC section 3501 et seq.) and its regulations (5 CFR part 1320). The PRA requires that federal agencies receive OMB clearance before requesting most types of information from the public. Collections of information (paperwork) that are in proposed standards are subject to review by OMB under the PRA.

The Congressional Review Act (5 USC sections 801-808) permits Congress to review every new federal regulation issued by a federal agency, and, by a joint resolution, to nullify the standard. In 2001, OSHA’s ergonomics standard was the first standard to be overruled by Congress. Once nullified, OSHA may not issue another ergonomics standard that is “substantially similar” to the version the Congress overturned without its express permission (5 USC section 801(b)(2)).

In 2001, Congress turned its attention to informational documents that often serve as the scientific foundation for a future health standard. Congress authorized OMB to develop guidelines “for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by Federal agencies” and gave affected individuals the right to file a complaint requesting correction of non-compliant information (Information Quality Act 2001). OMB quickly issued mandatory guidelines for federal agencies to follow (OMB 2001). OMB then proposed a government-wide, peer review policy bulletin to ensure that the science contained in a proposed standard was of the highest quality, but the bulletin was criticized as yet another roadblock to standards adoption (OMB Watch 2005). OMB slightly modified the Peer Review Bulletin and issued a final version in 2005 (OMB 2005).

Executive Branch. Beginning in the 1980s, each presidential administration has added procedural requirements to the standards adoption process. In 1981, Executive Order 12291 required agencies to prepare a regulatory impact analysis for standards that will result in an annual effect on the economy of $100 million or more. In 1985, Executive Order 12498 required federal agencies to publish an
annual regulatory program. In 1993, Executive Order 12866 replaced Executive
Orders 12291 and 12498 and requires agencies to assess the costs and benefits
of various regulatory approaches and select the one that maximizes the net
benefits to society. In 1996, OMB expanded Executive Order 12866, instructing
agencies to consider alternative strategies for standards, advising them to
determine whether standards should require different results for different
segments of regulated industries, requiring publication of agency regulatory
agendas, and requiring that agencies submit proposed standards to OMB for
review prior to adoption.

Courts. During the judicial review of OSHA standards, federal courts have added
more requirements to the standards adoption process. In the 1970s, judicial
review of OSHA's standards was deferential, but that era was short-lived. In its
1980 Benzene decision, the U.S. Supreme Court imposed a new threshold
requirement for adopting an OSHA health standard. Before adopting a health
standard, OSHA must determine if a workplace is unsafe “in the sense that
significant risks are present” (Industrial Union Department vs. American
Petroleum Institute 1980).

As a result of Benzene, OSHA has had to perform a specific risk assessment for
every new toxic agent for which it intends to set a PEL which is a time and
resource-intensive process. In 1989, OSHA tried a streamlined approach to
revising 212 obsolete PELs and establishing 162 new PELs by relying on
occupational exposure limits proposed by NIOSH and others, but it did not
conduct its own risk assessments (OSHA 1989). OSHA's generic approach was
overruled by the court because OSHA had failed to demonstrate separately that
each PEL reduced a significant risk to worker health (AFL-CIO v. OSHA 1992).
These and other court decisions have led to greater time investments by OSHA
in analyzing every detail of a proposed occupational health standard during its
development phase.

Additional requirements may be added in the future. Judges are now required by
the Supreme Court to serve as “gatekeepers” of the scientific testimony that
juries can hear during a trial by screening scientific expert testimony to ensure
that it is not only relevant, but also scientifically "reliable" (Daubert 1993). In the
past, courts have turned thumbs down to requests from industry to conduct a
scientific review of OSHA standards when they are challenged (Public Citizen
1986), but that could change in the future. If a science review principle is
imported into judicial review of OSHA's risk assessments, further "ossification" of
the standard-setting process may occur (McGarity 2005).

General Duty Clause. In addition to requiring employers to comply with specific
occupational health standards, the OSHAct also requires employers to comply
with a "general duty" to provide employees with a workplace "free from
recognized hazards that are causing or are likely to cause death or serious
physical harm" (29 USC 654(a)(1)). The general duty clause serves as a catch-all provision that provides OSHA with an employer-by-employer enforcement option even in the absence of a specific standard that applies to all employers. Use of the general duty clause is limited to cases in which the hazard is shown to be a "recognized hazard," that the injuries suffered were linked to the recognized hazard, and that it was feasible for the employer to eliminate the hazard.

To show that the hazard was "recognized," there must be evidence of risk to workers’ health from authoritative sources such as NIOSH publications, peer-reviewed papers in the scientific literature, industry guidelines, consensus standards, and voluntary national or international codes. The evidence can come from one of three sources: 1) employer recognition; 2) industry recognition; and 3) common sense recognition (OSHA 2009a). As scientific information about the occupational health risks associated with specific nanomaterials accumulates and becomes more widely recognized as sound science, and as that scientific information serves as the basis of industry guidelines and voluntary standards, the hazard becomes more "recognized" from a legal perspective. In the case of nanotechnology, the point at which the emerging information about worker health risks rises to the level to be legally "recognized" remains uncertain at this writing, although the weight of information is certainly moving in that direction. Even now, employers should take into consideration that a standard of care, even absent a specific occupational health standard, may be emerging that creates a general duty to protect workers from nanomaterials.

Use of the general duty clause should be considered as nanotechnology risks to workers become recognized from a legal perspective and as feasible risk management methods are identified. Until then, several existing OSHA occupational safety and health standards are applicable to workplaces in which nanotechnology manufacturing and use occurs and these standards should be used to protect workers (Davies 2008). Specifically, on its nanotechnology topic-page OSHA stated that “most of [nanotechnology research and development] activities fall under OSHA General Industry standards” (http://www.osha.gov/dsg/nanotechnology/nanotech_standards.html). Among these standards are the following: (1) Occupational Exposure to Hazardous Chemicals in Laboratories (29 CFR section 1910.1450); (2) Hazard Communication Standard (29 CFR section 1910.1200); (3) Respiratory Protection Standard (29 CFR section 1910.134); (4) Personal Protective Equipment Standards (29 CFR sections 1910.133; 1910.135; 1910.136; and 1910.138); (5) Recording and Reporting of Occupational Injuries and Illnesses (29 CFR sections 1904); and (6) certain substance-specific standards.

**Voluntary Protection Programs.** Given the obstacles to timely standards adoption, it is not entirely surprising that OSHA has placed greater emphasis on the advantages of Voluntary Protection Programs (VPP). The VPP began in 1982 to promote a more cooperative approach 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. There is no explicit mention of cooperative programs in the OSHAct, but one of the Act’s purposes is “to stimulate employers and employees to institute new and to perfect existing programs for providing safe and healthful working conditions” (29 USC section 651(b)(1)). OSHA has vigorously marketed VPP over the years, but not everyone is convinced of its value (GAO 2004).

As a cooperative program, VPP exhibits an interesting feature relative to OSHA standards. Not only do employers seeking VPP membership have to comply with existing OSHA standards, but a management system approach is recommended to participants by OSHA (OSHA 2008), similar to a draft standard OSHA prepared, but did not adopt in the late 1990s (OSHA 1998).

VPP is based on collaboration between government, labor and management. To date, however, VPP participants have not been asked by OSHA to participate in research since including such a request could be viewed by employers as creating regulatory liability.

**States.** The OSHAct’s Section 18 encourages States to develop and operate their own occupational safety and health programs (29 USC 667). Under this authority, OSHA approves and monitors state plans. As of December 9, 2009, there were 22 states with approved State Plans and five state plans which cover public sector employment only (http://www.osha.gov/dcsp/osp/). Under such plans, states must set job safety and health standards that are “at least as effective as” comparable federal standards. They also must conduct inspections to enforce its standards, cover public employees and operate occupational safety and health training and education programs. Even though participating states have the option to promulgate standards covering hazards not addressed by federal standards, most states adopted standards identical to federal ones. It was proposed that “states or localities may choose to adopt standards that are expert driven, such as the nanotechnology workplace standards being developed by ASTM International, the International Organization for Standardization, or other standards bodies” (Keiner 2008). Nevertheless, so far states have not exercised their authorities and there have been no state-developed OSH standards for manufactured nanomaterials.

**Proposed Multi-stakeholder Partnership.** In 2004 NIOSH initiated a programme to study nanotechnology implications in the workplace and published pioneering studies on toxicology of nanomaterials, workplace exposures and effectiveness of respirators to protect against exposure to nanoparticles (http://www.cdc.gov/niosh/topics/nanotech/). The programme was proposed to be expanded into a nation-wide partnership (Howard and Murashov 2009).

The difficulties inherent in the current process for adopting standards to protect workers from toxic agents with well-known risk profiles suggests that an innovative way is needed to protect workers from the possible risks of
nanotechnology before workers suffer permanent harm like those arising from asbestos whose risks were ignored early in its industrial lifespan (Mazurek and Wood 2008). To meet the challenge of protecting workers so that “no employee will suffer material impairment of health,” a National Nanotechnology Partnership (NNP) was proposed to generate knowledge about the nature and extent of worker risk, to utilize that knowledge to develop risk control strategies to protect nanotechnology workers now, and to provide an evidence base for NIOSH recommendations to OSHA for a nanotechnology program standard at a future date (Howard and Murashov 2009). The NNP could utilize a number of different resources to develop risk management strategies to protect workers and help achieve nanotechnology’s promise. These resources include existing occupational safety and health standards, NIOSH laboratory and field research resources, together with partnership contributions from nanotech industry manufacturers and downstream users, workers, academic researchers and safety and health practitioners.

The aims of the National Nanotechnology Partnership (NNP) would include: (1) protecting workers by encouraging implementation of prudent exposure mitigation measures; (2) promoting nanotechnology risk assessment and risk management research; (3) collecting and sharing exposure information among nanotechnology workplaces; (4) identifying and studying the use of various candidate occupational risk management practices; and (5) developing the evidence base to provide protection for workers now and for NIOSH recommendations for a nanotechnology program standard at a future date.

The NNP would develop a proactive risk management program that would provide for controls based on emerging risk assessment information (Murashov and Howard 2009) and be based on models similar to the VPP and NIOSH’s existing industry-labor-government partnerships. In many of NIOSH’s existing partnerships, some involving a regulatory agency like the Mine Safety and Health Administration or MSHA, the regulatory agency participates only by invitation as an observer and not as a partner. This encourages employer participation at the earliest stage of risk knowledge generation when a regulatory focus may be counterproductive. Leading role of NIOSH in NNP and its acting as the data repository would also address possible nanomaterials industry employers concerns that participation in collaborative research activities with OSHA might create regulatory liability.

Without nanomaterial industry employer commitment, there cannot be effective partnership. Similarly, there can be no effective partnership without direct worker participation. Importantly, strong efforts need to be made to identify and include in the partnership small to medium-size companies who are developing start-up operations. These types of companies are least likely to participate in a voluntary partnership but may contain the greatest risks to workers. Incentives to join the NNP could be placed in legislation, as well as specific appropriations, to ensure
its success. Mandatory data-reporting could be included in such legislation with protections for trade secret information (Marchant et al. 2007).

1.2 Federal Government OSH

The Presidential Executive Order 12196 “Occupational safety and health programs for Federal employees” of February 26, 1980 instructs heads of federal government agencies to maintain an effective safety and health program that meets the same standard as private employers. But federal agencies cannot be fined for violating health and safety standards, except for the U.S. Postal Service, which now falls directly under OSHA’s jurisdiction and is treated as a private employer (http://www.osha.gov/as/opa/worker/index.html). The U.S. Department of Energy (DOE) is one of Federal government agencies that established its own OSH regulations and has been one of the more pro-active agencies in regards to occupational safety and health of nanotechnology.

DOE. Under the Atomic Energy Act of 1954 and subsequent reorganization acts the U.S. Department of Energy has authority to develop regulations governing occupational safety and health of its employees and contractors. In 2006 DOE published 10 CFR 851 Worker Safety and Health Program in the Federal Register (DOE 2006). The 10 CFR 851 establishes the framework for DOE’s non-radiological worker safety and health programs just as the Occupational Safety and Health Administration does for the private industry. It provides DOE contractor workers with safe and healthful workplaces in which hazards are abated, controlled, or otherwise mitigated in a manner that provides reasonable assurance that workers are protected from the hazards associated with their jobs. To accomplish this objective, the 10 CFR 851 establishes management responsibilities, workers rights, required safety and health standards, and training on the hazards of their jobs as well as how to control the hazards.

In regards to nanotechnology, the U.S Department of Energy first published “Approach to Nanomaterials ES&H” guidance document in 2007 (DOE 2007). This guidance document formed a basis for a Notice of January 5, 2009, which offers “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 (DOE 2009). The Notice provides for safe handling of unbound engineered nanoparticles (UNP) 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 DOE-approved Worker Safety and Health Program document. Specifically, the Notice requires to

1) maintain inventories of nanotechnology activities involving UNP at DOE 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;
8) have a documented procedure for managing UNP waste.

1.3 Chemical safety regulations

TSCA. Toxic Substances Control Act (TSCA) provides broad statutory basis for safe manufacturing, processing and use of chemical substances and mixtures defined as “any organic or inorganic substance of a particular molecular identity” (TSCA section 3(2)(A)). Its main criteria for regulation are determination that the substance[s] “may present an unreasonable risk” and “may cause serious health effects”. There are three major obstacles that make it difficult for EPA to take actions under TSCA (Davies 2006). First, the technical standard of judicial review in the act is “supported by substantial evidence in the rulemaking record” (TSCA 19(c)(B)(i)). Second, TSCA implicitly suggests that no knowledge about a chemical assumes that there is no risk (Davies 2006). For example, section 5(e) states that if EPA does not have enough information “to permit a reasoned evaluation of the health and environmental effects of a chemical,” it can delay or prohibit its manufacture only if it can show that the chemical “may present an unreasonable risk”. Third, TSCA is premised on the balancing the risks and benefits (see e.g. TSCA section 6(c)(1)) and requires that a proposed regulation be the “least burdensome” regulation (Davies 2006).

Under the section 5(a)(2) of TSCA, EPA has the authority to require implementation of exposure mitigation measures in the workplace. EPA has been utilizing its authorities and expanding regulation of new chemical substances in the workplace. In regards to nanomaterials, in November, 2008 EPA announced application of Significant New Use Rule (SNUR) to siloxane modified silica and alumina nanoparticles (EPA 2008a). "EPA has determined, however, that use without impervious gloves or a NIOSH-approved respirator with an [Assigned Protection Factor] of at least 10; 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."

Also in 2008, EPA clarified what it considers a new chemical under TSCA: “A nanoscale substance might not have a non-nanoscale counterpart with the same molecular identity (e.g., nanotubes and carbon fullerenes), or a substance might be found in both nanoscale and non-nanoscale forms, but if the substance has not been reported previously to EPA and placed on the Inventory in either form, it is considered a new chemical” (EPA 2008b). It emphasized again through a Federal Register notice in 2008 that it “generally considers CNTs to be chemical
substances distinct from graphite or other allotropes of carbon listed on the TSCA Inventory (EPA 2008c). In 2009, EPA announced initiating rulemaking under section 5(a)(2) of TSCA to require protective measures to limit exposure or otherwise mitigate the potential unreasonable risk presented by two carbon nanotube chemical structures (P-08-177 and P-08-328) (EPA 2009a). On November 6, 2009, the U.S. Environmental Protection Agency (EPA) proposed Significant New Use Rules under Section 5(a)(2) of the Toxic Substances Control Act for two chemical substances that were the subject of pre-manufacture notices (EPA 2009b). EPA identified the substances generically as multi-walled carbon nanotubes and single-walled carbon nanotubes. According to the notice, these substances are subject to TSCA Section 5(e) consent orders issued by EPA. The consent orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The proposed SNURs are based on and consistent with the provisions in the underlying consent orders, and designate as a significant new use the absence of the protective measures required in the corresponding consent orders. Persons who intend to manufacture, import, or process either of these two substances for an activity that is designated as a significant new use would be required by the proposed rule to notify EPA at least 90 days before commencing that activity. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

**FIFRA.** The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) mandates that EPA regulates the use and sale of pesticides to protect human health and preserve the environment. In making a registration decision, EPA must take into account the legal standard set by FIFRA that new pesticide will present “no unreasonable adverse effects on human health or the environment.” Pesticide data submission requires, among other data, information about worker exposure and a copy of the proposed labeling, which contains directions for use, storage and disposal, as well as warnings, restrictions, and other information.

In addition, EPA exercised its FIFRA authorities to develop a regulatory standard aimed specifically at worker protection. The EPA’s Worker Protection Standard for Agricultural Pesticides (WPS) is a regulation aimed at reducing the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. It regulates employment conditions of approximately 2.5 million agricultural workers (people involved in the production of agricultural plants) and pesticide handlers (people who mix, load, or apply pesticides) that work at over 600,000 agricultural establishments. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted-entry intervals after pesticide application, decontamination supplies, and emergency medical assistance (http://www.epa.gov/oecaagct/twor.html).

EPA has been 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 (EPA 2007). On March 7, 2008, an EPA regional office fined $208K ATEN Technology/IOGEAR for "selling unregistered pesticides and making unproven claims about their effectiveness" in the form of a "nanoshield" coating on mouse and keyboard. Most recently, on November 3-5, 2009, the FIFRA Scientific Advisory Panel (SAP) met “to consider and review a set of scientific issues related to the assessment of hazard and exposure associated with nanosilver and other nanometal pesticide products" (EPA 2009c). The discussions covered occupational exposures to nanomaterial pesticides.
2. European Community

The main driver behind the creation of the European Union was to establish a common market, a customs union and common policies. Thus, signatories of the Treaty establishing a European Economic Community in 1957 “decided to ensure the economic and social progress of their countries by common action in eliminating the barriers which divide Europe” (Spaak et al 1957). Similar to the United States, workplace safety and health in the European Union is ensured through targeted occupational regulations as well as through workplace-related articles within chemical safety regulations such as REACH, which are implemented at both community and member-state levels.

2.1 OSH directives

Article III-210 of the European Constitution (Verhofstadt et al 2004) states that the Community's objective is to support and complement the activities of the Member States in the fields of social security and justice, improvement in the working environment to protect workers’ health and safety, the information and consultation of workers, representation and collective defense of worker interests. Based on this article, a wide variety of Community measures in the field of safety and health at work have been adopted and include directives and standards. European directives are legally binding and have been transposed into national laws by the Member States. As these Directives introduce minimum requirements, national authorities have the possibility to introduce more stringent rules. The European Agency for Safety and Health at Work (EU-OSHA) located in Bilbao, Spain was formed in 1996 to inform, coordinate, and monitor current national and European regulatory efforts in their respective areas of work, while Member States have enforcing authorities to implement the relevant EU regulatory frameworks.

The OSH framework directive (Council Directive [CD] 89/391) with its wide scope of application is the cornerstone of European safety and health legislation. Additional directives on specific safety and health issues set out minimum requirements and fundamental principles, such as the principle of prevention and risk assessment, as well as the responsibilities of employers and employees. Those include:


4) Exposure to biological agents (EP&CD 2000/54/EC);

5) Provisions on workload, ergonomical and psychosocial risks (CD 90/270/EEC, CD 90/269/EEC);


These directives follow a similar structure requiring the employer to assess the workplace risks and put in place preventive measures based on a hierarchy of control. This hierarchy starts with elimination of the hazard and ends with personal protective equipment.

Standardization needs to meet occupational safety and health requirements of individual European Community directives are addressed by the European Committee for Standardization (CEN), which is a non-profit organization developing voluntary standards and the only recognized European organization according to Directive 98/34/EC for the planning, drafting and adoption of European Standards in all areas of economic activity with the exection of electrotechnology (CENELEC) and telecommunication (ETSI). Standardization of individual protective products is handled by the Personal Protective Equipment (PPE) sector, whereas standardization of collective protection of workers is handled in CEN by the Occupational Health and Safety sector. The CEN Strategic Advisory Body for Occupational Health and Safety coordinates all relevant activities within CEN and gives advice to all technical committees on OH&S-related aspects.

A number reports (for example, by the European Commission, EU-OSHA European Risk Observatory and UK Royal Institute of International Affairs) has been published on the applicability of present regulation within EU to nanotechnology and nanomaterials (European Commission 2008, Breggin et al. 2009, Kaluza et al 2009). It is recognized that at present in Europe regulations regarding occupational safety and health of nanotechnology and nanomaterials are based on existing laws and regulations. According to the information given in the Communication “Regulatory Aspects of Nanomaterials” (European Commission, 2008) the Framework Directive 89/391/EEC applies to all substances including nanomaterials and work activities including manufacturing and use of nanomaterials at all levels of the production process, regardless of the number of workers involved and quantities of materials produced or technologies used. Employers, therefore, must carry out a risk assessment and, where a risk is identified, take measures to eliminate this risk. The planning and introduction of new technologies must be subject to consultation with the workers or their representatives, as regards the working conditions and the working environment in accordance with Articles 11 and 12 of the Framework Directive 89/391/EEC.
Individual directives including more specific provisions in relation to particular aspects of safety and health and workplace exposures also apply to nanotechnology and nanomaterials.

For example, the Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (Chemical Agents Directive) presents minimum requirements for the protection of workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents (98/24/EC). The text of the document includes employers’ obligations related to identification and assessment of risk due to use of hazardous chemical agents, implementation of prevention measures, provision of information and training of workers. There are also definitions of chemical agents and hazardous chemical agents, but nanomaterials are not mentioned specifically (Kaluza et al 2009). The Chemical Agents Directive also provides legal basis for EU Commission Indicative Occupational Exposure Limits (IOELs) and Binding Occupational Exposure Limits (BOELs) for airborne chemicals that are “set to protect the health of workers in the European Union from the ill-health effects of hazardous substances in the workplace.” As of December 22, 2009, there are 103 IOELs and 10 BOELs and none of them is specifically for a nanomaterial (available from http://ec.europa.eu/social/).

**Member States.** While European regulations establish minimum occupational safety and health standards, Member States translate them into country-specific national regulations and enforce them.

In the UK, The Health and Safety at Work etc Act (HSWA) 1974 established the framework for health and safety regulation. It places an obligation upon all employers to ensure, “so far as is reasonably practicable, the health, safety and welfare of their employees” while at work and any other persons affected by their business activities. The European Framework Directive covering general workplace safety and health provisions (Articles 5(1) and 5(4) 89/391/EEC) requires all employers “to ensure the safety and health of workers in every aspect related to the work” without costs considerations. The European Court of Justice agreed with UK that the HSWA wording including “so far as is reasonably practicable,” as interpreted by the UK courts, achieves the aims of the 89/391/EEC articles (http://www.hse.gov.uk/press/2007/c07007.htm).

Under HSWA, health and safety legislation in the form of Statutory Instruments (SI) is drawn up and enforced by the Health and Safety Executive and local authorities (the local council). The statutory instruments implementing key European directives on workplace health and safety came into force in Britain in 1992 and became known as the "six pack". These safety regulations are:

1) The Management of Health and Safety at Work Regulations 1999 (SI 1999/3242);
2) Safe Use of Work Equipment, Provision and Use of Work Equipment Regulations 1998 (SI 1998/2306);
4) Workplace (Health, Safety and Welfare) Regulations 1992 (SI 1992/3004);
5) Personal Protective Equipment at Work Regulations 1992 (SI 1992/2966);

The Health and Safety Executive also produces Approved Codes of Practice to accompany the regulations. Increasingly in the UK the regulatory trend is away from prescriptive rules, and towards risk-based approaches to protect workers (UK House of Commons, 2007). Recent major changes to the laws governing asbestos and fire safety management embrace the concept of risk assessment.

On April 1st, 2009 the Health and Safety Executive announced the creation of the Chemicals Regulation Directorate, which brings together HSE’s responsibilities for regulatory science, operational policy and enforcement for pesticides, biocides, detergents, and industrial chemicals (REACH, Classification, Labelling and other legislation, http://www.pesticides.gov.uk/corporate.asp?id=2663).

Since 2004 HSE has published a number of guidance documents for nanomaterials. Even though guidance is not compulsory, following such would be considered as enough to comply with the law. An HSE Information Note on nanotechnology published in 2004 (HSE, 2004) gives information on the health and safety issues surrounding some aspects of nanotechnology including considerations for monitoring, control measures, personal protective equipment. In general as with other chemicals the legislation dealing with the control of exposure to harmful chemicals is the Control of Substances Hazardous to Health Regulations 2002 (COSHH; www.coshhessentials.org.uk).

In regards to risk management of carbon nanotubes, another HSE guidance (HSE 2009) states that people who create risk through work activities have a legal duty to understand those risks, and make sure they are kept as low as reasonably practicable. The principles of risk assessment are well established and apply even though all the necessary information on nanoparticles is not yet available. Although there is uncertainty about the risks of exposure to CNTs, the regulatory response is to take a precautionary approach. An assessment under COSHH should be carried out for all work involving CNTs and suitable and sufficient risk management measures put in place.

Specific measures described in the guidance include:
- Avoid using carbon nanotubes.
- Use appropriate work processes, systems and engineering controls, and provide suitable work equipment and materials to minimise the likelihood of release. This means processes that minimise the amount of CNTs produced, or
production of CNTs in a form that reduces the chance of them becoming airborne. Where possible, use equipment that fully encloses the process.

- Control exposure at source by carrying out all tasks, including packaging for disposal, in a ducted fume cupboard with a HEPA filter, or by using other suitable effective local exhaust ventilation (LEV) with a HEPA filter. When using other types of LEV, try to enclose the process as much as possible. HSE considers ductless fume cupboards and recirculating biological or safety cabinets unsuitable for use with CNTs, because these methods do not control exposure so that risks are reduced as low as reasonably practicable.

- Make sure the LEV achieves and maintains adequate control of exposure at all times. The system requires regular maintenance, periodic monitoring to ensure controls are working and thorough examination and testing once a year (legally you are allowed 14 months between tests). Make sure employees are trained in how to check and use the LEV. Keep records of all the daily, weekly and monthly LEV checks.

- Reduce the number of employees exposed, and minimise:
  - the level and duration of exposure;
  - the quantities used;
  - CNT handling.

- If possible, keep the material wet or damp to reduce the risk of it becoming airborne.

- Provide respiratory protective equipment (RPE). This is for emergencies, and only for use in addition to other control measures. All employees who use RPE must be trained and have had face fit testing. HSE recommends RPE with an assigned protection factor (APF) of 40 or higher.

- Provide personal protective equipment (e.g., gloves, coveralls). Use single use disposable gloves where possible. If you must use latex, provide low protein powder-free gloves. Provide protective clothing that does not retain dust – do not use wool, cotton or knitted material.

- Consider cleaning, maintenance, filter replacement, storage and disposal in risk assessments for the control of exposure to CNTs. Emergency procedures should be in place to deal with spills, accidents and emergencies (HSE 2009).

Germany. Germany adjusted its Occupational Health and Safety Act ("Arbeitsschutzgesetz") to align with the EC directives in 1996 (Germany’s Federal Ministry of Justice, 1996). Similar to the UK legislation, cost considerations are included in the German Federal Occupational Health and Safety Act. Specifically, under Section 4(1) employers shall “duly consider …[that] the work shall be so designed as to ensure that hazards for the life an health of the worker are avoided to the largest possible extent, and that remaining hazards are minimized wherever possible” (Germany’s Federal Ministry of Justice, 1996).

In addition to the Federal Occupational Health and Safety Act, German accident insurance institutions enact occupational safety and health accident-prevention regulations (referred to as "Unfallverhütungsvorschrift" in German and
abbreviated to "UVV") in the form of "autonomous bylaws". Section 15 of the Seventh Volume of Germany's "Sozialgesetzbuch" (Code of Social Law, SGB VII, http://bundesrecht.juris.de/sgb_7/index.html) grants them the powers to do so.

UVVs must be approved by the Federal Ministry of Economics and Labor or the highest federal-state authority with responsibility for such matters. The regulations prescribe binding technical, organizational and personal measures, aimed at securing the safety and health of employees at work, in the form of general protection objectives. The "Durchführungsanweisungen" (implementing instructions) which have supplemented the UVVs in the past contain specific examples of how the protection objectives can be fulfilled. They also explain the regulations and indicate the technical rules to be applied. The accident insurance institutions are currently preparing and, in some cases, conducting a reform of the rules and regulations to bring the UVVs in line with national legislative developments and to make them easier to use and more effective.

The two regulatory responsibilities for occupational safety and health give rise to two federal institutes conducting research into occupational safety and health. The Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin/BAuA) is a public-law institution without legal capacity based in Dortmund with branches in Berlin and Dresden. As a federal authority it is directly responsible to the Federal Ministry of Labour and Social Affairs. In addition, the Institute for Occupational Safety and Health in Sankt Augustin of the German Social Accident insurance in Germany (BGIA) conducts occupational safety and health research in support the German Accident Insurers (institutions for statutory accident insurance and prevention and social accident insurance) and their organizations particularly in solving scientific and technical problems relating to safety and health protection at work. As of January 1st, 2010 the former BGIA is known as the "Institute for Occupational Safety and Health of the German Social Accident Insurance" and is abbreviated as "IFA". Both agencies have been active in the field of occupational safety and health of nanotechnology.

In the spring of 2006 the Federal Institute for Occupational Safety and Health (BAuA) and the German Chemical Industry Association (Verband der Chemischen Industrie/VCI) conducted a joint survey on occupational health and safety in the handling and use of nanomaterials among VCI member companies. The purpose of the survey was to obtain an overview of occupational health and safety methods currently applied in the chemical industry in activities involving nanomaterials. Survey results were used to develop "Guidance for Handling and Use of Nanomaterials at the Workplace", which contains recommendations and operating instructions for the handling and use of nanomaterials in the chemical industry (BAuA and VCI 2007).

BGIA conducted a risk assessment of nanoparticles in the workplace and published a report on "Protective measures against ultrafine aerosols and nanoparticles at the workplace"
Main conclusions are “The studies conducted to date show that the protective measures commonly taken against dusts are also effective against ultrafine particles and nanoparticles. In the context of risk assessment and the specification of protective measures, the priority of measures as set out in Section 9 of the German regulation on hazardous substances (Gefahrstoffverordnung) must be observed. … All other obligations under the Gefahrstoffverordnung, such as those concerning the instruction of employees or occupational medical check-ups, are not affected by the fact that a substance is present in nanoparticulate form, but should be observed as normal.”

Other. In addition to the United Kingdom and Germany, France and Switzerland have announced regulatory actions related to occupational safety and health of nanotechnology.

In France the High Public Health Council (Haut Conseil de Santé Publique, HCSP) issued an Opinion of January 9th, 2009 on the safety of workers exposed to carbon nanotubes, in which it recommends to adopt regulatory measures. The measures include requirement that the production of carbon nanotubes and their use in manufacturing intermediate products and consumer and health products is carried out under conditions of strict containment in order to protect workers from being exposed when these activities involve a risk of aerosolisation and/or dispersion (Haut Conseil de la santé publique, 2009). In addition, through an instruction dated February 18th, 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. Regarding the national legislation applicable to nanomaterials, 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 if the substance falls within their scope of application (OECD, 2009).

In December 2008, the Swiss Federal Office for Public Health and the 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 (Höck et al., 2008). The matrix is a screening tool based on a control-banding approach to estimate the “nanospecific 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.
2.2 Chemical Safety

The European Union Registration, Evaluation, Authorization and restriction of Chemicals (REACH) regulation is the corner-stone of the new EU-wide chemicals legislation, which came into force on June 1, 2007 (EC 1907/2006). Under the REACH system, enterprises must register a chemical substance in a central database should they wish to produce this substance or import it into the EU in quantities of 1 metric ton per annum or over. Registration process requires submission of risk assessment and risk management data including information on exposure, classification and labeling, guidance on safe use such as handling and storage, exposure control/personal protection as described in Annex VI of the regulation. The requirement to demonstrate that the chemical does not adversely affect human health includes derivation of the so-called Derived No Effect Levels (DNELs) which are defined as “the level of exposure above which humans should not be exposed”. Thus, DNEL is a benchmark rather than health-based exposure limit in that it is used in the risk characterization part of the Chemical Safety Assessment as a benchmark to determine adequate control (Risk Management Measures) for specified exposure scenarios. Risk to humans can be considered to be adequately controlled if the exposure levels estimated do not exceed the appropriate DNEL. REACH specifies that industry must derive DNELs using recommended guidance, based upon the likely population exposed (e.g. workers, consumers), route(s) of exposure (e.g. inhalation, dermal, ingestion), and duration of exposure (e.g. long-term or acute). The calculation of DNELs follows a rule-based approach in which a series of standardized assessment factors are applied to the toxicological endpoints to allow for uncertainties and inter-/intra-species differences. Where data gaps exist, default assessment factors are used instead of expert judgments as with health-based OELs. Based on REACH guidance (ECHA 2008), only EU Commission Indicative Occupational Exposure Limits can be used as DNELs and only for the same exposure route and duration, unless new scientific information does not support the use of the IOEL for this purpose. REACH also requires that DNELs, exposure scenarios and Risk Management Measures appear on REACH Safety Data Sheet for a substance or product.

In regards to nanomaterials, European regulations are based at present on existing laws and regulations applicable to chemicals (Kaluza et al 2009). According to the information given in the Communication “Regulatory Aspects of Nanomaterials” (European Commission, 2008) all manufactured nanomaterials must meet the requirements of REACH (EC No 1907/2006). Although there are no provisions in REACH referring explicitly to nanomaterials, they are included by the definition of a “substance”. The principal objective of the directive is to ensure a high level of relevant protection of human health and the environment. Until REACH is fully implemented, the notification scheme under the Directive 67/548/EEC applies for new substances and notified substances with significant new uses.
The European Directive 98/8/EC on Biocidal Products provides a framework of rules that apply to the marketing of biocidal (including nanomaterials) substances and products (ED 98/8/EC), which are defined as any substance which is used to control or kill harmful organisms, such as bacteria, fungi, moulds and yeasts. The directive is intended to provide a high level of protection for humans including workers, animals and the environment against results of use of biocidal substances. Specifically, Article 5.1(b) requires that Member states shall authorize a biocidal product only if it is established that the biocidal product has no unacceptable effects on humans directly or indirectly through consequences in the place of work. This directive fully applies to biocidal products based on nanomaterial.

Additional environmental regulation relevant to nanotechnology occupational safety and health is the control of major accident hazards involving dangerous substances outlined in the Seveso II Directive (96/82/EC). The Seveso II Directive applies to establishments where named dangerous substances (or substances falling within certain classification categories) are present above specific quantities (or thresholds). It imposes a general obligation on operators to take all measures necessary to prevent major accidents and to limit their consequences for humans and the environment. If certain nanomaterials are found to demonstrate a major accident hazard, they may be categorized, together with appropriate thresholds, in the context of the Directive.

It was also concluded that the sub-statutory body of rules (e.g. Technical Guidance Documents, REACH Implementation Plans) do not currently address the specific problem posed by nanomaterials (Kaluza et al 2009). Thus, it is recommended that these rules are further developed to support the primarily responsible industry/ies with the appropriate characterization and assessment of the nanomaterials (Kaluza et al 2009). The data collection as well as the characterization and assessment of risks must be shaped in cooperation with competent bodies and companies and communicated transparently (Kaluza et al 2009).

3. Conclusions

Regulatory frameworks in the US and EU have similar features relying on occupationaly specific and general chemical safety legislations. At the core of these similarities are legislative powers given to parliamentary structures within democratic governing frameworks in both communities to facilitate trade between member states. Thus it comes as no surprise that more convergence has been observed recently. Both communities have been moving towards proactive/preventive paradigm to risk assessment and management in general and in the workplace specifically. These trends are reflected in the regulatory changes.
In December 2009, in his first speech after taking the office, the newly appointed US OSHA administrator, David Michaels, outlined five principles that would guide OSHA activities in the current administration (OSHA 2009):

1. a permanent system where employers and workers come together, on a basis of mutual respect, to assess and abate hazards is needed;
2. more efforts should be placed in assessing chemical safety of industrial chemicals;
3. occupational risk management should transition from reactive to preventive occupational safety and health by adopting Prevention through Design paradigm for the workplace;
4. OSHA must move ahead on rulemaking for urgently needed standards;
5. workers must have a stronger voice in workplace safety.

Specifically for emerging technologies, it was proposed that voluntary approaches need to be developed and implemented to complement existing regulations and to provide guidance on prudent measures to control risk (Murashov and Howard 2009). These proactive approaches to the management of occupational health risks in emerging technologies, such as nanotechnology, would be based on the following 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 (Murashov and Howard 2009).

Similar approach has been proposed to improve general European Union governance model. A new governance model called “open method of co-ordination” was outlined in 2000 by the Lisbon European Council (2000) as a means to overcome legislative deadlocks resulting, for example, from uncertainty in solutions to policy problems within proactive risk management paradigm. The “open method of co-ordination” involves four elements: “1) fixing guidelines for the Union combined with specific timetables for achieving the goals which they set in the short, medium and long terms; 2) establishing, where appropriate, quantitative and qualitative indicators and benchmarks against the best in the world and tailored to the needs of different Member States and sectors as a means of comparing best practice; 3) translating these European guidelines into national and regional policies by setting specific targets and adopting measures, taking into account national and regional differences; and 4) periodic monitoring, evaluation and peer review organised as mutual learning processes” (Lisbon European Council 2000). At the core of this model is iterative development of best-practice standards by affected stakeholders which would serve as the basis for regulatory standards.

Environmental legislations in both communities are undergoing re-evaluation as well. European Union is addressing significant technical challenges associated with REACH implementation. As of December 22, 2009 European Chemicals Agency (ECHA) published 22 guidance documents on the different processes,

In the US, discussions of revisions to chemicals safety legislation are underway. In November 2009, the U.S. EPA Administrator, Lisa Jackson, announced six principles for a new chemical risk management law that will give EPA the mechanisms and authorities to expeditiously target chemicals of concern and promptly assess and regulate new and existing chemicals in commerce (EPA 2009d):

1. Chemicals should be reviewed against risk-based safety standards based on sound science and protective of human health and the environment
2. Manufacturers should provide EPA with the necessary information to conclude that new and existing chemicals are safe and do not endanger public health or the environment
3. EPA should have clear authority to take risk management actions when chemicals do not meet the safety standard, with flexibility to take into account sensitive subpopulations, costs, social benefits, equity and other relevant considerations.
4. Manufacturers and EPA should assess and act on priority chemicals, both existing and new, in a timely manner
5. Green Chemistry should be encouraged and provisions assuring Transparency and Public Access to Information should be strengthened.
6. EPA should be given a sustained source of funding for implementation

TSCA overhaul conducted along these principles would bring US chemical safety regulatory framework more closely aligned with EU REACH regulation.

Trends towards trans-Atlantic harmonization in workplace safety and health in general and for nanotechnology in particular are expected to continue in the upcoming years. Proactive and preventive approaches to worker safety in nanotechnology workplace would emphasize exposure mitigation within comprehensive workplace safety and health programs in which workers and management work together to continually assess and abate hazards.
4. References

Administrative Procedures Act 5 USC § 553:2000

American Federation of Labor-Congress of Industrial Organizations v. OSHA, 965 F.2d 962 (11th Cir. 1992)


Industrial Union Department vs. American Petroleum Institute, 44 U.S. 607, 642 (1980)


Paperwork Reduction Act, 44 United States Code § 3501

Public Citizen Health Research Group v. Tyson, 796 F2d 1479 (D.C. Cir. 1986)

Regulatory Flexibility Act, 5 United States Code § 603(a)


