

Regulatory Approaches to Worker Protection in Nanotechnology Industry in the USA and European Union

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*Received July 15, 2010 and accepted September 29, 2010
Published online in J-STAGE March 1, 2011*

Abstract: A number of reports have been published regarding the applicability of existing regulatory frameworks to protect consumers and the environment from potentially adverse effects related to introduction of nanomaterials into commerce in the United States and the European Union. However, a detailed comparison of the regulatory approaches to worker safety and health in the USA and in the EU is lacking. This report aims to fill this gap by reviewing regulatory frameworks designed to protect workers and their possible application to nanotechnology.

Key words: Nanotechnology, Nanomaterials, Occupational safety, Regulation, Risk management, Standards

United States

In the United States (US), the Occupational Safety and Health Act of 1970 (OSHAct) serves as the primary national framework for protecting workers from injury and illness at work¹⁾. Occupational requirements are also included in other national chemical safety legislation in the US, such as in the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Current applications of these US national laws to nanotechnology and nanomaterials are described in the following sections.

OSHAct and Federal OSHA

On December 29, 1970, President Nixon signed into

law the OSHAct. Congress enacted the OSHAct in order “to assure so far as possible every working man and woman in the Nation safe and healthful working conditions”²⁾ and imposed on the Secretary of Labor the responsibility of implementing the OSHAct (see Table). To carry out his responsibilities, the Secretary administratively established on April 28, 1971 the Occupational Safety and Health Administration (OSHA). OSHA is responsible for promulgation and enforcement of national occupational safety and health standards and regulations. The OSHAct established the National Institute for Occupational Safety and Health (NIOSH) and placed it in the US Department of Health and Human Services. NIOSH carries out scientific research in the area of occupational safety and health and makes recommendations for the prevention of work-related injury and illness³⁾. For the purposes of an emerging technology like nanotechnology, Congress envisioned that NIOSH would “... also conduct special research, experiments, and demonstrations relating to occupational safety and health as are necessary to *explore new problems*, including *those created by new technology* in occupational

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Disclaimer: The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

safety and health ...”²). Thus, Congress tasked NIOSH to generate data to support health standards for emerging technologies for OSHA’s standards development effort or to serve as an authoritative recommendation by NIOSH itself.

Congress granted the Secretary of Labor the power to adopt occupational safety and health standards through rulemaking procedures applicable to all US regulatory agencies (US Administrative Procedures Act)⁴, and to require employers covered by those standards to comply with those standards or face civil and criminal sanctions. 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”²). 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”²).

OSHA promulgated the majority of its existing occupational safety and health standards for toxic chemical and physical agents, including carcinogens, during the 1970s. Beginning in the early 1980s, the pace of standards development by OSHA slowed due largely to various new requirements added by the Congress, Federal courts and the executive branch to the Federal rulemaking process. By the mid-1990s, the OSHA standards adoption process was described as “ossified”⁵. Even though OSHA made an attempt in the late 1980s to update scores of out-of-date permissible exposure limits (PELs) first adopted by OSHA in 1972, OSHA’s Air Contaminants Standard was rejected by the Eleventh Circuit Court of Appeals⁶. The vast majority of OSHA PELs are now considered obsolete and not appropriate for protecting workers in the 21st century. OSHA’s “under-regulation” problem has been attributed to the agency’s inclination to “over-regulate” when it does promulgate a health standard⁷. Regardless of cause or causes, the slow pace of OSHA standards adoption has left workers in both traditional and emerging industries unprotected^{1, 8}.

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 “notice and comment” rulemaking requirements laid out in the U.S. Administrative Procedures Act⁴, making sure to determine if the proposed standard is feasible technically, i.e. capable of being done. An OSHA standard does not have to be

feasible economically for every member of a particular industry, but can be “infeasible” if it bankrupts an entire industry. Even though OSHA has had periods in which several health standards were successfully adopted (e.g., in the early and late 1990s), overall production of new PELs and health standards since 1980 has been slow and coincides with new requirements being added to Federal rulemaking by all three branches of the US government: the Congress, the courts and the president.

Congress

Congress has enacted several rulemaking requirements that greatly add more complexity to the standards adoption process⁹. In addition to the 1980 Regulatory Flexibility Act (RFA)¹⁰, 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)¹¹. These two laws add significantly to the time it takes any Federal agency to adopt a new standard or regulation. In 1995, Congress went still further and enacted the Congressional Review Act¹². The CRA 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 (and, thus far, the only) standard to be overruled by Congress using the CRA. Once nullified, OSHA may not issue another ergonomics standard that is “substantially similar” to the version the Congress overturned without its express permission¹².

Courts

Since the OSHAct gives aggrieved parties the right to challenge OSHA rulemaking in court, nearly every OSHA health standard has undergone judicial review. During the judicial review of OSHA standards, federal courts have added more requirements to the standards adoption process. For instance, in its 1980 *Benzene* decision, the US Supreme Court imposed a new quantitative threshold requirement for adopting an OSHA health standard¹³. Before adopting a health standard, OSHA must determine if a workplace is unsafe “in the sense that significant risks are present”¹³. The Court specified a risk of 1 in 1,000 as significant. 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. OSHA’s 1989 PEL update of some 400 out-of-date PELs was overruled by the court because OSHA had failed to demonstrate *separately* that each

PEL reduced a significant risk to worker health⁶⁾.

President

Each presidential administration since Reagan added procedural requirements to the Federal agencies' standards adoption process by Executive Order. Beginning 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 more¹⁴⁾. In 1985, Executive Order 12498 required federal agencies to publish an annual regulatory agenda¹⁵⁾. In 1993, President Clinton's Executive Order 12866 replaced Executive Orders 12291 and 12498 and now requires agencies to assess the costs and benefits of various regulatory approaches and select the one that maximizes the net benefits to society¹⁶⁾. Other Orders have added still more to the rulemaking timeline.

These, and other, additional rulemaking requirements have greatly slowed standards adoption since there were many more steps to satisfy before an occupational safety and health standard became law. In this decade, for instance, the pace of new health standards adoption has nearly grounded to a halt. Only one occupational health standard (for hexavalent chromium) was adopted by OSHA in the first decade of the 21st century¹⁷⁾. Currently, the only PELs that OSHA has for specific manufactured nanomaterials are the PELs for carbon black, which is 3.5 mg/m³, and synthetic graphite, which is 15 mg/m³¹⁸⁾. However, these PELs were adopted long before awareness that these substances were indeed nanomaterials. OSHA has not indicated any regulatory interest in nanotechnology to date.

The National Institute for Occupational Safety and Health (NIOSH) is mandated by the Occupational Safety and Health Act (1970) to develop recommended health and safety standards which "...describe exposure levels that are safe for various periods of employment, including but not limited to the exposure levels at which no employee will suffer impaired health or functional capacity or diminished life expectancy as a result of his work experience"²⁾. To date, NIOSH has issued approximately 700 recommended exposure limits (RELs) none of which explicitly target nanomaterials. However, NIOSH is currently working on nanomaterial specific RELs for titanium dioxide and carbon nanotubes³⁾. Another aspect of NIOSH authority related to nanomaterials involves respiratory certification and recommendations. NIOSH has promulgated a set of regulations for testing and certifying nonpowered, air purifying particulate respirators in 42 CFR 84¹⁹⁾. NIOSH also conducted research on the effectiveness of respirators to filter nanoparticles and has recommended N95 respirators for such purposes²⁰⁾.

State Plans

The OSHAct's Section 18 encourages States to develop and operate their own occupational safety and health programs²⁾. Under this authority, OSHA approves and monitors state plans. Twenty-seven states have their own occupational safety and health plan with four states, and the Virgin Islands, covering public sector employment only²¹⁾.

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 (ISO), or other standards bodies"²²⁾, but thus far, state plan states have not exercised their authorities to develop occupational safety and health standards for engineered nanomaterials.

Proposed Multi-Stakeholder Partnership

In 2004, NIOSH initiated a program 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 nanoparticles²³⁾. The program was proposed to be expanded into a nation-wide partnership¹⁾.

The difficulties inherent in the current process for adopting standards to protect workers from toxic agents with well-known risk profiles suggest 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 lifespan²⁴⁾. To meet the challenge of protecting workers so that "no employee will suffer material impairment of health", a National Nanotechnology Partnership (NNP) was proposed. NNP would generate knowledge about the nature and extent of worker risk, utilize that knowledge to develop risk control strategies to protect nanotechnology workers now, and provide an evidence base for NIOSH recommendations to OSHA for a nanotechnology program standard at a future date¹⁾. 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 information²⁵⁾ and be based on models similar to OSHA Voluntary Protection Program 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 information²⁶⁾.

Federal Government OSH Exclusive of OSHA

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 employers²⁷⁾. 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. 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.

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 (see Table 1)²⁸⁾. In 2006 DOE published 10 CFR 851 *Worker Safety and Health Program* in the Federal Register²⁹⁾. 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 2007³⁰⁾. 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

Table 1. Major US and EU legislations with occupational components

Legislation focus	US	EU
Occupational safety	29 U. S. C. §§ 651-678 ²⁾ 42 U. S. C. § 2011 ²⁸⁾	Directive 89/391/EEC ⁴⁷⁾
Chemical safety	15 U. S. C. § 2601 et seq ³²⁾	Council Regulation 1907/2006 ¹⁰⁰⁾
Pesticide safety	7 U. S. C. § 136 et seq ⁴⁰⁾	Directive 98/8/EC ¹⁰⁴⁾

acceptable level the risk of worker injury, worker ill-health and negative environmental impacts” in DOE laboratories³¹). 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.

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))³²). 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 TSCA³³). First, the technical standard of judicial review in the act is “supported by substantial evidence in the rule-making record” (TSCA 19(c)(B)(i))³²). Second, TSCA implicitly suggests that no knowledge about a chemical assumes that there is no risk³³). 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” regula-

tion^{33, 34}).

Under the section 5(a)(2) of TSCA describing Significant New Use Rule and 5(e) describing Orders, 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 nanoparticles³⁵). Specifically it stated that “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”³⁵).

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”³⁶). 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”³⁷). 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)³⁸). 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 notices³⁹). 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 d 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 (see Table 1)⁴⁰. 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”⁴⁰. 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 assistance⁴¹.

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 risk⁴². 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”⁴³. The discussions covered occupational exposures to nanomaterial pesticides.

States

Similar to occupational safety legislation, Congress gave authorities to individual states to implement federal chemical safety laws as long as states agree to meet minimum federal regulatory standards for oversight and enforcement. Presently, there are no states with laws similar to TSCA and, therefore, no state has implemented legislative authority to take TSCA enforcement actions. Specific areas of shared responsibility include clean air, clean water and waste disposal and cleanup. Some states started to explore application of their authorities in these areas of responsibility to provide oversight for nanomaterial safety²².

On 22 January, 2009 the Director of California Environmental Protection Agency’s Department of Toxic Substances (DTSC) Control sent a letter to over two dozen universities and companies that manufacture or import carbon nanotubes into California⁴⁴. The letter announced that DTSC was exercising its authority under California Health and Safety Code, Chapter 699, sections 57018-57020 and was “requiring information regarding analytical test methods, fate and transport in the environment, and other relevant information from manufacturers of carbon nanotubes”. Specific questions included those of relevance to the workplace safety:

- What is the value chain for your company? For example, in what products are your carbon nanotubes used by others? In what quantities? Who are your major customers?
- What sampling, detection and measurement methods are you using to monitor (detect and measure) the presence of your chemical in the workplace and the environment? Provide a full description of all required sampling, detection, measurement and verification methodologies. Provide full QA/QC protocol.
- What is your knowledge about the current and projected presence of your chemical in the environment that results from manufacturing, distribution, use, and end-of-life disposal?
- What is your knowledge about the safety of your chemical in terms of occupational safety, public health and the environment?
- What methods are you using to protect workers in the research, development and manufacturing environment?
- When released, does your material constitute a hazardous waste under California Health & Safety Code provisions? Are discarded off-spec materials a hazardous waste? Once discarded are the carbon nanotubes you produce a hazardous waste? What are your waste handling practices for carbon nanotubes?

Recipients were given 365 d to respond. By the deadline, DTSC received 16 responses and seven of those from companies and the rest from government-affiliated research labs and universities. Eight organizations missed the deadline.

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”⁴⁵⁾. 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.

OSH directives

European Community

Article III-210 of the European Constitution⁴⁶⁾ 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 to be 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 89/391/EEC⁴⁷⁾ 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:

- 1) Workplaces, equipment, signs, personal protective equipment (Directives 89/655/EEC, 92/58/EEC, 89/656/EEC, 1999/92/EC, 89/654/EEC)^{48–52)};
- 2) Exposure to chemical agents and chemical safety (Directives 98/24/EC, 83/477/EEC, 2006/15/EC, 2004/37/EC, 91/322/EEC, 2000/39/EC)^{53–58)};
- 3) Exposure to physical hazards (Directives 2006/25/EC, 2003/10/EC, 2002/44/EC, 96/29/Euratom, 2004/40/EC)^{59–63)};
- 4) Exposure to biological agents (Directive 2000/54/EC)⁶⁴⁾;
- 5) Provisions on workload, ergonomical and psychosocial risks (Directives 90/270/EEC, 90/269/EEC)^{65, 66)};
- 6) Sector specific and worker related provisions (Directives 92/104/EEC, 91/383/EEC, 94/33/EC, 92/85/EEC, 93/103/EC, 92/91/EEC, 92/29/EEC, 92/57/EEC)^{67–73)}.

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 Standards⁷⁴⁾ in all areas of economic activity with the exception 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 of 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^{75–77)}. It is recognized that at present regulations regarding occupational safety and health of nanotechnology and nanomaterials in Europe are based on existing laws and regulations. According to the information given in the Communication “Regulatory Aspects of Nanomaterials”⁷⁵⁾ 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 pro-

cess, 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/EEC⁴⁷⁾.

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, 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)⁵³⁾ 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. 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 specifically⁷⁷⁾. The Chemical Agents Directive also provides legal basis for EU Commission Indicative Occupational Exposure Limit Values (IOELVs) and Binding Occupational Exposure Limit Values (BOELVs) 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 IOELVs and 10 BOELVs and none of them is specifically for a nanomaterial (available from <http://ec.europa.eu/social/>).

United Kingdom

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 activities⁷⁸⁾. The European Framework Directive covering general workplace safety and health

provisions (Articles 5(1) and 5(4) 89/391/EEC)⁴⁷⁾ requires all employers "to ensure the safety and health of workers in every aspect related to the work" without economic feasibility 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 articles⁷⁹⁾.

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)⁸⁰⁾;
- 2) The Provision and Use of Work Equipment Regulations 1998 (SI 1998/2306)⁸¹⁾;
- 3) The Manual Handling Operations Regulations 1992 (SI 1992/2793)⁸²⁾;
- 4) The Workplace (Health, Safety and Welfare) Regulations 1992 (SI 1992/3004)⁸³⁾;
- 5) The Personal Protective Equipment at Work Regulations 1992 (SI 1992/2966)⁸⁴⁾;
- 6) The Health and Safety (Display Screen Equipment) Regulations 1992 (SI 1992/2792)⁸⁵⁾.

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 workers⁸⁶⁾. 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)⁸⁷⁾.

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 nanotechnology⁸⁸⁾ published in 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^{89, 90}).

In regards to risk management of carbon nanotubes, another HSE guidance⁹¹) 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 minimize the likelihood of release. This means processes that minimize 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 emergencies⁹¹).

Germany

Germany adjusted its Occupational Health and Safety Act (“Arbeitsschutzgesetz”) to align with the EC directives in 1996⁹²). Similar to the UK legislation, economic feasibility 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 and health of the worker are avoided to the largest possible extent, and that remaining hazards are minimized wherever possible”⁹²).

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 “BG-Vorschriften” in German and abbreviated to “BGV”) in the form of “autonomous bylaws”. Section 15 of the Seventh Volume of Germany’s “Sozialgesetzbuch” grants them the powers to do so⁹³). BGVs 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 BGVs 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 BGVs 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 of the German Social Accident Insurance (IFA) in Sankt Augustin conducts occupational safety and health research to support the German Accident Insurers (institutions for statutory accident insurance and prevention and social accident insurances) and their organizations particularly in solving scientific and technical problems relating to safety and health protection at work. 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 industry⁹⁴.

IFA conducted a risk assessment of nanoparticles in the workplace and published a report on "Protective measures against ultrafine aerosols and nanoparticles at the workplace"⁹⁵. 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)⁹⁶ 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 European countries

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 measures⁹⁷. 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 dispersion⁹⁷. 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 application⁹⁸.

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 knowledge⁹⁹. 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 nanomaterials.

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 (see Table 1)¹⁰⁰. 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. Therefore, primary responsibility for specifying appropriate exposure mitigation measures at the point of use is placed on manufacturers or importers, while users of chemicals are required to implement such control measures.

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 guidance¹⁰¹, 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.

Unlike OSH-specific regulations in EU described in the previous section, which are based on establishing minimum standards and which are implemented by member states, REACH is a direct-acting regulation, not requiring national implementation¹⁰². This feature of REACH brings European regulation landscape closer to that in the United States.

In regards to nanomaterials, European regulations are based at present on existing laws and regulations applicable to chemicals⁷⁷. According to the information given in the Communication “Regulatory Aspects of Nanomaterials” all manufactured nanomaterials must meet the requirements of REACH⁷⁵. 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 direc-

tive 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 Dangerous Substances Directive (67/548/EEC)¹⁰³ applies for new substances and notified substances with significant new uses.

The European Directive 98/8/EC on Biocidal Products¹⁰⁴ provides a framework of rules that apply to the marketing of biocidal (including nanomaterials) substances and products, 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)¹⁰⁵. 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 nanomaterials⁷⁷. Thus, it is recommended that these rules are further developed to support the primarily responsible industry with the appropriate characterization and assessment of the nanomaterials⁷⁷. The data collection as well as the characterization and assessment of risks must be shaped in cooperation with competent bodies and companies and communicated transparently⁷⁷.

Conclusions

Regulatory frameworks in the US and EU have similar features relying on occupationally specific and general chemical safety legislations (see Table 1). 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 and to protect wellbeing of their citizens. Thus it comes as no surprise that although two communities were formed at different stages of the development of their welfare-state functions¹⁰⁶, more convergence has been observed recently. Both communities stated that existing regulatory approaches to occupational safety and health apply to nanotechnology and nanomaterials. And 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 administration¹⁰⁷:

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 risk²⁵. 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 involvement²⁵.

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 as a means to overcome legislative deadlocks resulting, for example, from uncertainty in solutions to policy problems within proactive risk management paradigm¹⁰⁸. 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 organized as mutual learning processes"¹⁰⁸. 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, and methods and sixteen technical manuals for REACH available at http://echa.europa.eu/publications_en.asp.

In the US, discussions of revisions to chemicals safety legislation are underway¹⁰⁹. In September 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 commerce¹¹⁰:

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.

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