Regulatory Approaches to Nanotechnology
Occupational Safety & Health

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Content

• Regulatory approaches in USA
  - OSH Act
  - Federal government OSH regulations
  - Chemical safety regulations

• Regulatory approaches in European Union
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• Conclusions

Occupational Safety and Health Act of 1970

• Congress 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) and National Institute for Occupational Safety and Health (NIOSH)

OSHA Statutory Authority

• 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 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)
OSHA Statutory Authority

- Using 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, the pace of standards adoption slowed considerably due largely to regulatory requirements added by Congress, the courts and the executive branch.

- The only Permissible Exposure Limit (PEL) set by OSHA for a specific manufactured nanomaterial is PEL for carbon black of 3.5 mg/m³ (29 CFR 1910.1000 TABLE Z-1).

NIOSH Statutory Authority

"The Secretary of Health and Human Services shall 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 safety and health, which may require ameliorative action beyond that which is otherwise provided for in the operating provisions of this chapter."

Occupational Safety and Health Act, 29 U.S.C. § 669(a)(4)

NIOSH Mission

To generate new knowledge in the field of occupational safety and health and to transfer knowledge into practice globally.

Congress

- 1980: Regulatory Flexibility Act 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.

- 1995: Congressional Review Act permits Congress to review every new federal regulation issued by a federal agency, and, by a joint resolution, to nullify the standard.

Executive Branch

- 1981: Executive Order 12291 requires agencies to prepare a regulatory impact analysis for standards that will result in an annual effect on the economy of $100 million or more.

- 1985: Executive Order 12498 requires federal agencies to publish an annual regulatory program.

- 1993: Executive Order 12866 requires agencies to assess the costs and benefits of various regulatory approaches and select the one that maximizes the net benefits to society.

- 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, and requiring that agencies submit proposed standards to OMB for review prior to adoption.
### Courts
- 1980: Before adopting a health standard, OSHA must determine if a workplace is unsafe “in the sense that significant risks are present” (Benzene decision).
- 1992: OSHA’s generic approach to revising 212 obsolete PELs and establishing 162 new PELs was overruled by the court because OSHA had failed to demonstrate separately that each PEL reduced a significant risk to worker health.
- 1993: the Supreme Court requires judges 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.”

### Nanotechnology: General Duty Clause
- Requires employers to provide employees with a workplace “free from recognized hazards that are causing or are likely to cause death or serious physical harm”.
- 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.
- For the hazard to be “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.
- 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.

### Nanotechnology: OSH Standards
- Examples:
  - 1904, Recording and reporting occupational injuries and illness
  - 1910.132, Personal protective equipment, general requirements
  - 1910.133, Eye and face protection
  - 1910.134, Respiratory protection
  - 1910.138, Hand protection
  - 1910.141, Sanitation
  - 1910.1200, Hazard communication
  - 1910.1450, Occupational exposure to hazardous chemicals in laboratories
  - Certain substance-specific standards (e.g., 1910.1027, Cadmium)

### Nanotechnology: Voluntary Protection Programs
- Based on OSHAct’s purpose “to stimulate employers and employees to institute new and to perfect existing programs for providing safe and healthful working conditions.”
- Began in 1982 to promote a more cooperative approach to protect workers and influence employers through recognition of places of employment that have achieved, and are committed to maintaining, superior safety and health performance.
- Employers seeking VPP membership have to comply with existing OSHA standards and a management system approach is recommended to participants by OSHA similar to a draft standard OSHA prepared, but not adopted.

### States
- The OSHAct encourages States to develop and operate their own occupational safety and health programs.
- There are 22 states with approved State Plans and five state plans which cover public sector employment only.
- 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.
- Some states are looking at nano as emerging risk, e.g., CA, MA, but so far there have been no state-developed OSH standards for manufactured nanomaterials.

### National Nanotechnology Partnership
- In 2004 NIOSH initiated a program to study nanotechnology implications in the workplace, which developed collaborations with stakeholders: industry, workers, academia, other government agencies and organizations.
- To meet the challenge of protecting workers so that “no employee will suffer material impairment of health,” A National Nanotechnology Partnership (NNP) was proposed as an expansion of the NIOSH program (Howard & Murashov, 2009).
National Nanotechnology Partnership

- The NNP aims are:
  - protecting workers by encouraging implementation of prudent exposure mitigation measures;
  - promoting nanotechnology risk assessment and risk management research;
  - collecting and sharing exposure information among nanotechnology workplaces;
  - identifying and studying the use of various candidate occupational risk management practices; and
  - developing the evidence base to provide protection for workers now and for NIOSH recommendations for a nanotechnology program standard at a future date.

National Nanotechnology Partnership

- The NNP resources include:
  - existing occupational safety and health standards,
  - NIOSH laboratory and field research resources,
  - partnership contributions from nanotech industry manufacturers and downstream users, workers, academic researchers and safety and health practitioners.
- The NNP would develop a proactive risk management program that would provide for controls based on emerging risk assessment information.
- 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.

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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.
- Federal agencies cannot be fined for violating health and safety standards.
- 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.

U.S. Department of Energy

- 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. It provides DOE 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.
- 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.

Nanotechnology: U.S. Department of Energy

- 2009: Notice by Order of the Secretary of Energy 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.
Nanotechnology: U.S. Department of Energy

- The Notice requires to
  - maintain inventories of nanotechnology activities involving unbounded nanoparticles (UNP) at DOE sites;
  - maintain registries of all personnel designated as nanomaterial workers;
  - provide all nanomaterial workers and their supervisors with training specific to nanotechnology activities;
  - conduct exposure assessment and establish air monitoring program for UNP based on preliminary exposure assessments;
  - offer baseline medical evaluations to all nanomaterial workers including general physical exam, pulmonary function test, and general blood work;
  - control exposures to UNP using a risk-based graded approach;
  - post signs indicating hazards and exposure mitigation requirements;
  - have a documented procedure for managing UNP waste.

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Toxic Substances Control Act

- 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".
- Its main criteria for regulation are determination that the substance/s "may present an unreasonable risk" and "may cause serious health effects".
  - the technical standard of judicial review in the act is "supported by substantial evidence in the rulemaking record"
  - no knowledge about a chemical assumes that there is no risk (section 5(e))
  - premised on the balancing the risks and benefits and requires that a proposed regulation be the "least burdensome" regulation

Toxic Substances Control Act: OSH

- Under the section 5(a)(2) of TSCA, EPA has the authority to require implementation of exposure mitigation measures in the workplace.

Toxic Substances Control Act: Nanotechnology

- 2008: Application of Significant New Use Rule (SNUR) to siloxane modified silica and alumina nanoparticles. "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."
- 2008: "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."

Toxic Substances Control Act: Nanotechnology

- 2009: Significant New Use Rules under Section 5(a)(2) of the Toxic Substances Control Act for multi-walled carbon nanotubes and single-walled carbon nanotubes that were the subject of pre-manufacture notices. 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.
Federal Insecticide, Fungicide, and Rodenticide Act

- The Federal Insecticide, Fungicide, and Rodenticide Act provides statutory basis for the use and sale of pesticides to protect human health and preserve the environment.
- Registration requires proof 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.
- Worker Protection Standard for Agricultural Pesticides is a regulation aimed at reducing the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers.

Federal Insecticide, Fungicide, and Rodenticide Act: Nano

- 2007: Federal Register notice stating that any company marketing a product using silver nanoparticles to kill bacteria must provide scientific evidence that particles do not pose unreasonable environmental risk.
- 2008: Regional office fined a CA company for "selling unregistered pesticides and making unproven claims about their effectiveness" in the form of a "nanoshield" coating on mouse and keyboard.
- 2009: FIFRA Scientific Advisory Panel 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."

California Department of Toxic Substances Control

- In a 22 Jan, 2009 letter to over two dozen universities and companies that manufacture or import carbon nanotubes into California, DTSC is "requiring information regarding analytical test methods, fate and transport in the environment, and other relevant information from manufacturers of carbon nanotubes." CA H&S Code Chapter 699, §§ 57018-57020
  - 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 sampling, detection, measurement and verification methodologies.
  - What is your knowledge about the current and projected presence of your chemical in the environment? Does the state have any regulations related to nanotubes? Does the state have any regulations related to the use of nanotubes?
  - What are the health and environmental impacts associated with your chemical? Does the state have any regulations related to nanotubes? Does the state have any regulations related to the use of nanotubes?
  - 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 have 365 days to respond

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OSH Directives

- Article III-210 of the European Constitution 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.
- A wide variety of Community directives and standards in the field of safety and health at work have been adopted.
- 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.

OSH Directives

- 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 89/391) is the cornerstone of European safety and health legislation.
OSH Directives

- 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.
  - Workplaces, equipment, signs, personal protective equipment
  - Exposure to chemical agents and chemical safety
  - Exposure to physical hazards
  - Exposure to biological agents
  - Provisions on workload, ergonomical and psychosocial risks
- Sector specific and worker related provisions
- The European Committee for Standardization (CEN) addresses standardization needs to meet occupational safety and health requirements of individual European Community directives.

OSH Directives: Nanotechnology

- At present regulations regarding occupational safety and health of nanotechnology and nanomaterials in Europe are based on existing laws and regulations.
- 2008: the Communication “Regulatory Aspects of Nanomaterials” stated that 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.

OSH Directives: Nanotechnology

- Individual directives including more specific provisions in relation to particular aspects of safety and health and workplace exposures also apply to nanotechnology and nanomaterials.

OSH Directives: Nanotechnology

- 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.
  - includes definitions of chemical agents and hazardous chemical agents, but nanomaterials are not mentioned specifically.
  - 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.” There are 103 IOELs and 10 BOELs and none of them is specifically for a nanomaterial.

Member States: UK

- The Health and Safety at Work etc Act (HSWA) 1974 established the framework for health and safety regulation, which 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.
- Under HSWA, health and safety legislation in the form of Statutory Instruments is drawn up and enforced by the Health and Safety Executive and local authorities. The statutory instruments implementing key European directives on workplace health and safety came into force in Britain in 1992.

Member States: UK

- 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. Recent major changes to the laws governing asbestos and fire safety management embrace the concept of risk assessment.
- In 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.
UK: Nanotechnology

- 2004: HSE Information Note on nanotechnology published 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.
- 2009: Guidance on Risk Management of Carbon Nanotubes 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. 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.

Member States: Germany

- Germany adjusted its Occupational Health and Safety Act ("Arbeitsschutzgesetz") to align with the EC directives in 1996.
- 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."

Member States: Germany

- 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 (BAuA) is a public-law institution without legal capacity based in Dortmund and directly reporting to the Federal Ministry of Labour and Social Affairs.
- 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 of the German Accident Insurers. 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.

UK: Nanotechnology

- The CNT guidance describes specific measures including:
  - Avoid using carbon nanotubes
  - Where possible, use equipment that fully encloses the process
  - Control exposure at source by carrying out all tasks in a ducted fume cupboard with a HEPA filter
  - Make sure the local exhaust ventilation achieves and maintains adequate control of exposure at all times
  - Reduce the number of employees exposed, and minimize the level and duration of exposure, the quantities used, CNT handling
  - If possible, keep the material wet or damp
  - Provide respiratory and personal protective equipment
  - Consider cleaning, maintenance, filter replacement, storage and disposal in risk assessments for the control of exposure to CNTs.

Member States: Germany

- Section 15 of the Seventh Volume of Germany’s "Sozialgesetzbuch" (Code of Social Law, SGB VII) grants German accident insurance institutions the powers to enact occupational safety and health accident-prevention regulations (referred to as "Unfallverhütungsvorschrift" in German and abbreviated to "UVV") in the form of "autonomous bylaws".
- 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.
- The accident insurance institutions are conducting a reform of the rules and regulations to bring the UVVs in line with national legislative developments.

Germany: Nanotechnology

- 2006: The Federal Institute for Occupational Safety and Health (BAuA) and the German Chemical Industry Association (VCI) conducted a joint survey on occupational health and safety in the handling and use of nanomaterials among VCI member companies and developed "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.
Germany: Nanotechnology

- 2009: BGIA published a report on “Protective measures against ultrafine aerosols and nanoparticles at the workplace.”
- Conclusion: “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.”

France: Nanotechnology

- 2008: The General Directorate for Labor (DGT) reminded its units throughout the country that the legislation governing the prevention of occupational risks arising from exposure to chemical substances applies to nanomaterials.
- 2009: The High Public Health Council (HCSP) issued an Opinion on the safety of workers exposed to carbon nanotubes, in which it recommends to adopt regulatory measures including 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.

Switzerland: Nanotechnology

- 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. 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. Risk potential is classified and matched with appropriate measures to protect health and the environment. This voluntary risk management tool is a part of the first phase in a national plan to create regulatory framework for the responsible handling of synthetic nanomaterials.

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Registration, Evaluation, Authorization and restriction of Chemicals

- 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.
- Under the REACH system, enterprises must register a chemical substance to be produced or imported 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.

Registration, Evaluation, Authorization and restriction of Chemicals

- 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”.
- Only EU Commission Indicative Occupational Exposure Limits can be used as DNELs and only for the same exposure route and duration.
- DNELs, exposure scenarios and Risk Management Measures must appear on REACH Safety Data Sheet for a substance or product.
REACH: Nanotechnology

- 2008: The Communication “Regulatory Aspects of Nanomaterials” of the European Commission stated that all manufactured nanomaterials must meet the requirements of REACH. Although there are no provisions in REACH referring explicitly to nanomaterials, they are included by the definition of a “substance”.
- Until REACH is fully implemented, the notification scheme under the Dangerous Substances Directive applies for new substances and notified substances with significant new uses.

Biocidal Products Directive: Nanotechnology

- The European Directive on Biocidal Products provides a framework of rules that apply to the marketing of biocidal substances and products, which are defined as any substance 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.
- 2008: The Communication “Regulatory Aspects of Nanomaterials” of the European Commission stated that the European Directive on Biocidal Products fully applies to biocidal products based on nanomaterial.

Control of major-accident hazards: Nanotechnology

- The control of major-accident hazards involving dangerous substances Directive (Seveso II) applies to establishments where named dangerous substances are present above specific quantities. It imposes a general obligation on operators to take all measures necessary to prevent major accidents and to limit their consequences for humans including workers and the environment.
- 2008: The Communication “Regulatory Aspects of Nanomaterials” of the European Commission stated that 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.

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  - Principles guiding US OSHA activities:
    - a permanent system where employers and workers come together, on a basis of mutual respect, to assess and abate hazards is needed;
    - more efforts should be placed in assessing chemical safety of industrial chemicals;
    - occupational risk management should transition from reactive to preventive occupational safety and health by adopting Prevention through Design paradigm for the workplace;
    - OSHA must move ahead on rulemaking for urgently needed standards;
    - workers must have a stronger voice in workplace safety.
  - US OSHA Administrator, David Michaels, December 2009

Conclusions: Similarities

- Regulatory frameworks in the USA and EU have similar features relying on occupationally specific and general chemical safety legislations.
- Both communities have been moving towards proactive/preventive paradigm to risk assessment and management in general and in the workplace specifically.
- Both stated that existing regulatory approaches to occupational safety and health apply to nanotechnology and nanomaterials.
Conclusions: Outlook

- “Open method of co-ordination” – EU governance model to overcome legislative deadlocks resulting from uncertainty in solutions to policy problems within proactive risk management paradigm:
  - fixing guidelines for the Union combined with specific timetables for achieving the goals in the short, medium and long terms;
  - 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;
  - translating these European guidelines into national and regional policies by setting specific targets and adopting measures, taking into account national and regional differences; and
  - periodic monitoring, evaluation and peer review organized as mutual learning processes.

Lisbon European Council 2000

Conclusions: Outlook

- Principles for a new US chemical risk management law:
  - Chemicals should be reviewed against risk-based safety standards based on sound science and protective of human health and the environment.
  - 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.
  - 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.
  - Manufacturers and EPA should assess and act on priority chemicals, both existing and new, in a timely manner.
  - Green Chemistry should be encouraged and provisions assuring Transparency and Public Access to Information should be strengthened.
  - EPA should be given a sustained source of funding for implementation.

US EPA Administrator, Lisa Jackson, November 2009

Conclusions: Outlook

- European Union is addressing significant technical challenges associated with REACH implementation. So far European Chemicals Agency published 22 guidance documents on the different processes, and methods and sixteen technical manuals for REACH.

Conclusions: Outlook

- 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.

Further reading

- NIOSH Nanotechnology topic page: www.cdc.gov/niosh/topics/nanotech/default.html