RISK ANALYSIS OF NANOTECHNOLOGY

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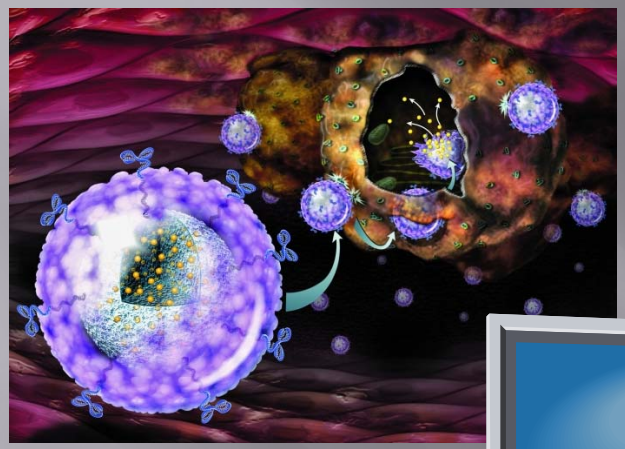
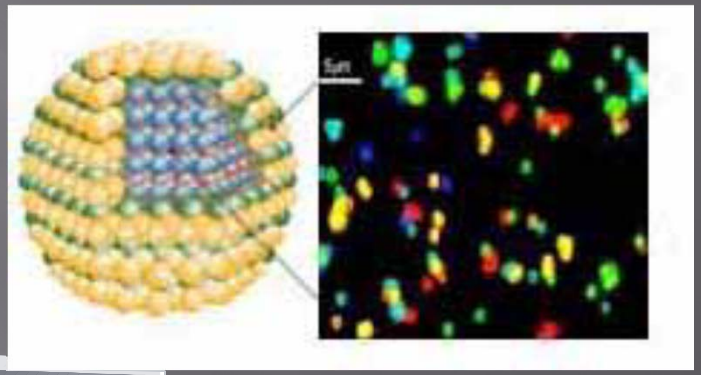
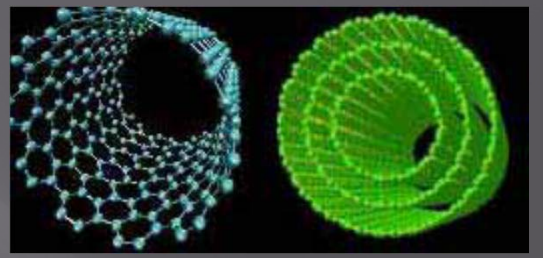
Outline

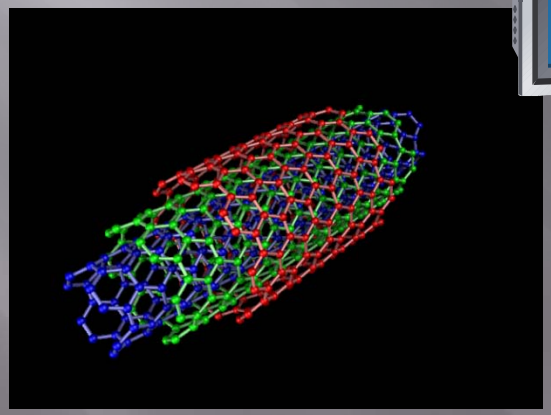
- Nanotechnology; Definition
- Why Nanoparticles?
- Applications
- Nanoparticle Risks
  - Occupational health risks
    - Inhalation
    - Skin absorption
    - Digestive tract absoprtion
    - Environmental
- Risk Assessment and characterization
- Existing and future Regulations
- Conclusion

The Nano World









What is Nanotechnology

- Materials, structures or processes that utilizes engineered nanomaterials
  - Nanomaterials – materials intentionally designed to have one or more dimensions between 1 and 100 nm
- The word "nanotechnology" derives from nanometer ("nm"), which is one-billionth of a meter

Source: ***Risk analysis Vol 30, No. 11, 2010***

Why Nano?

- Nanomaterials exploit some novel feature or property that is enabled or enhanced within the 1-100 nm range.
  - Extraordinary capabilities and unique properties.
  - Size; nanoparticles have different and better properties than their larger counterparts.
  - high surface area-to-volume ratio makes them more chemically reactive.

Nanoparticles

- Better reactivity than larger particles; atoms close to surface
- For example, particles of aluminum large enough for humans to see are chemically inert, but nanoparticles of the element are highly reactive
- Quantum mechanical effects operate better on nanoparticles and can alter their properties; optical, electrical and magnetic

Nanoparticles

- Radically transform the properties of different finished products
- Increased strength, better electrical conductor, unique optical properties, better resistance, etc.
- These unique properties are not found in larger-scale substances with the same chemical composition.

Research

- Immense field of fundamental and applied research called Nanosciences opened up due to nanoparticles engineering
- Change in physiochemical properties of particles when engineered at a nanoscale.
- Research has led to Nanotechnology applications in various areas of consumer products, human life direct impact processes and industrial applications.
- Research specifically targets improvement of material properties.

Applications

- Medicine
- information technologies,
- energy production and storage,
- materials, manufacturing
- environmental applications
- Food
- Consumer products

Nanomedicine

- MEDICINE – Nanorobots make repairs at cellular level
- Drug delivery; the use of nanoparticles to deliver drugs, heat, light to cancer cells
- With the use of nanoparticles, there is reduction in damages to healthy cells in the body
- Early detection of illnesses e.g Cancer
- Therapy techniques: Use of Nanoshells in destroying cancer cells
- Diagnostic and Imaging : Quantum dots used in location of cancer tumors

Nanoelectronics

- Targets improving capabilities of electronic components
- Reduction in size/weight, power consumption
- Memory chips ; Increasing size up to 1 terabyte per square inch
- Transistors: reduction in size for use in Integrated circuits

Energy

- Improving energy generation efficiency: Solar cells cost reduction and efficiency improvement
- Increase in windmill generated electricity: Use of epoxy containing carbon nanotubes for blades
- Pizoelectric nanofibers to generate heat in clothing
- Nanotube sheets: Generation of electricity from waste heat, wrap around hot pipes

Consumer Products

- Clothes, tennis rackets, basketballs
- Aerogel: Best house insulation material, cost effective because it uses less than conventional insulation
- Silica nanoparticles fishing rods: strong and lighter
- Titanium oxide nanoparticles: used as photocatalysts to kill bacteria

Risks

- A measure of the probability that damage to life, health, property, and/or the environment will occur as a result of a given hazard
- Identified risks: When the relation between a cause and an effect is established.
- Hypothetical or potential risks:When the relation between a cause and a damage is not well established.

Nanoparticle Risks

- Engineered nanomaterials like the nanoparticles are so small that they can pass through the skin, lungs and intestinal tract with unknown effects to human health.
- Novel properties might as well be the ones with side effects
- Potential to cause more toxic effect in lungs than bigger particles
- Translocation within environment and body

Nanoparticle risk cont'd

- Different sizes of nanoparticles, so not possible to address risks and hazards in a general way
- Ultrafine nanoparticles – produced unintentionally as a byproduct of a combustion process
- Traditional nanoparticles are produced in larger bulk quantities for already existing applications in the market

Novel nanoparticles

- Deliberately engineered to have properties only existing in the nano-range and specific characteristics in terms of size, shape
- Properties and characteristics are utilized to fill a specific function
- Most potent risk in the occupational health environment due to inhalation

Nanoparticle Health Risks

- **Inhalation** :small particle size, increase in toxicity
  - ultrafine particles made of low-soluble, low-toxicity materials
  - Three types of particles studied : titanium dioxide, carbon black and diesel particles
  - Nickel: indicators of lung injury were greater with ultrafine nickel (20 nm) than standard nickel (5 µm) (Zhang et al., 2003)

Particle lung toxicity

- Increased surface area and/or combination with the increasing number of particles (Warheit, 2004) .
  - Association with lung cancer, fibrosis and lung inflammation
- asthma exacerbations, increased respiratory symptoms, decreased lung function and increased medication use (Utell & Frampton, 2000)
- Free particles become airborne - inhaled fibres that are less than 20 µm are not cleared out of the lungs

Skin Absorption

- Nanoparticle based skin care products
  - Currently, L'Oreal, Lancôme, Estee Lauder, Zelens, and Dr. Brandt
  - fullerenes are thought to prevent premature aging of the skin
- No warning is given to consumers about harmful nanoparticles in products by companies
- Dermal exposure to nanoparticles may lead to direct penetration into top layer of the skin and possibly beyond into the blood stream (Aitken et al., 2004).

Intestinal tract absorption

- Nanoparticle based food: if swallowed, food ends up in intestinal tract
- under 300 nm reach the bloodstream, while particles that are smaller than 100 nm are also absorbed in various tissues and organs (Hett, 2004).
  - smaller the particles are, the more of them are absorbed and go deeper into the body

Translocation of particles through the body

- nanoparticles enter the body ;
  - involuntary through the lungs
  - the digestive system
  - deliberately for medical purposes
- Smaller size- means can no longer be absorbed by phagocytes but other cells
  - Increased mobility , diffuse more easily and behave more like gas molecules in air
- bind, absorb and carry compounds such as drugs, probes and proteins so are other toxic metals

Novel Properties

- **Single-walled carbon nanotubes**: very light and can become airborne
  - If reach lungs, they are more toxic than carbon black
  - serious occupational health hazard in chronic inhalation exposures
  - Different paradigm of toxic dusts from the known quartz and silica suggesting a potentially new mechanism of pulmonary toxicity
  - exposure limits for graphite-based material may not be adequate for setting a safe exposure level

Chemical composition and coating

- nickel, cobalt and titanium dioxide give dramatically different inflammatory responses in the lung
- Nickel was more toxic than cobalt with titanium dioxide giving the least toxic effect (Zhang et al., 1998)
- Surface coating: coatings on titanium dioxide particles
  - Quantum dots demonstrated toxicity when exposed to air or ultraviolet radiation

Environmental

- nanoparticles become colloids due to natural enzymes
  - colloidal particles carry toxic material, such as water-repelling pollutants and heavy metal and potentially pollute aquifiers.
  - If plants roots absorb nanoparticles, they could enter the food-chains
  - exposure of the entire ecosystem to engineered nanomaterials through the water and soil.
- Lipophilic fullerenes – redox active, affect aquatic organisms

Risk Assessment

Risk assessment, the process by which risk is estimated or calculated, assumes a good knowledge of the identity of the danger (safety and toxicity of products, dose response relationships) and the exposure levels and characterization of the dangers at the various workstations.

Risk assessment is therefore a way of determining whether the condition prevailing in the work environment can:

- Allow the emission of toxic NPs into the ambient air at concentrations high enough to impair workers' health;
- Allow the accumulation of solid aerosols of flammable or explosive

NPs at concentrations and under conditions that favour the occurrence of an accident.

Risk Assessment

- Quantitative risk assessment
  - provide the basic data for the selection of measures
  - level of control to be put in place to limit these risks.
- The control measures thus must be proportional to the different risks estimated during this approach.

Risk Characterization

- The final phase of the risk assessment process
- Intergrates
  - Hazard identification
  - Dose respondent assessment
  - Exposure assessment
- A synthesis and summary of information about a hazard
- Risk characterization must contain,
  - key information from the hazard identification, exposure assessment, and the
  - Potency (dose-response) stages of the risk assessment

Risk Characterization

- exposure assessment
- description of the concentration of the hazardous substance (nanomaterials) in the product
- human intake on a body–weight basis,
- the route(s) of exposure (i.e., oral, inhalation, absorption),
- Frequency and duration of exposure.
- Epidemiological data is superior than any data

Risk Management

- Risk management approches;
  - The "precautionary approach" forbids the activity or technology to go forward until its safety has been demonstrated with some specified degree of certainty,
  - "risk-based approach" monitors its impact after introduction into commerce, regulating it if it is found to be unsafe
- The U.S. regulatory structure treats new drugs and new food and color additives with a precautionary approach
  - precautionary approach does not guarantee that society will be safer overall for some types of risks

Risk Management

- Risk must be envisioned in principle, and safety demonstrated on a case-by-case basis
- Traceability and management;
  - Identification, labeling, consumer information of all nanoparticle causing substances
- Control and surveillance of occupational exposure
  - The recommended provisions concern:
  - the obligation to contain the particles within closed systems whenever possible
  - limitation and assessment of exposure
  - exclusion of pregnant or nursing women from the jobs concerned
  - availability of collective and individual protective methods
  - safe collection, removal and treatment of waste
  - information for workers, their representatives, and all monitoring bodies
  - special medical monitoring

Risk Characterization factors

- Risks will be characterized depends on;
  - framework for analysis, for example, risk/benefit, aprecautionary threshold, or some other standard; a
  - related question of whether the decision is ex ante approval or ex post regulation;
  - the degree of concern about consumer market acceptance and the unit of analysis.
- Description the unit of analysis for which the risk is being assessed

Regulatory and institutional Aspects

- Current law includes no texts applicable to manufactured nanoparticle
  - complete series of existing regulations certainly appears potentially applicable
  - European Community regulations are very likely , to be interpreted as applicable to nanoparticles
    - The first category concerns physical agents or chemical substances: the law endeavors to oversee their production, use and disposal.
    - The second category covers laws that aim to limit exposure of humans or the ecosystem to diverse hazards.

Regulations for assessment of the hazards and risks

- As chemical substances, nanoparticles may first come under the regulations for chemical agents.
  - This regulation — of "existing" substances and of "new" substances — will soon be replaced by the proposed "REACH" (Registration, Evaluation, and Authorisation of Chemicals) regulation.
- Nanoparticle-related solid waste;
  - Air filtration before release to atmosphere
  - Packaging in sealed labelled containers before disposal

Regulations on Nanoparticle Cosmetics

- Nanoparticle based cosmetics;
  - Both federal and state laws regulate cosmetics marketed in the United States.
  - The "two most important [federal] laws pertaining to cosmetics" are the Federal Food, Drug and Cosmetic Act ("FDCA") and the Fair Packaging and Label Act ("FPLA").
  - The FDCA "prohibits the marketing of adulterated or misbranded cosmetics in interstate commerce,"107 and the FPLA requires cosmetic companies to list the ingredients contained in their products on product labels

FDA on nanoparticles and food

- U.S. Food and Drug Administration (FDA) currently does not specifically require nanoparticles to be proved
- Manufacturers are required to provide tests showing that the food goods employing them—be it beer or baby products—are not harmful.
- few published industry, government or scientific studies on the health and environmental impacts of nanoparticles.
  - Further complicating the matter is the fact that nanoparticles have been in the food supply for years

Occupational Health Risk Regulation

- Occupational safety on nanoparticle rquire the following
  - Classification,
  - Labelling
  - Occupational exposure limits
- Official occupational exposure limits for nanomaterials have been set only for amorphous silicon dioxide (e.g. in Germany: Greim et al. 1989, TRGS 900 2007) [240, 241].
- A draft occupational exposure limit for nanoscale titanium dioxide is also available from the US-American National Institute for Occupational Safety and Health

Nanoparticle Material Safety

- Permissible exposure limits are already stated in exixting occupational healthy safety regulations
  - Does not account for particle granulaometry which is one of the characterization aspect of nanoparticles
  - Does not cover toxicity based on size
- The current MSDS does not account for size and deal with large particles

Societal Aspects

- Involving consumers into the entire risk analytic process will be particularly important in assessing and managing novel risks, like those from nanotechnology
- Risk communication research has uncovered a much richer way that consumers think about risks.
- Cosmetic companies do not conduct adequate animal testing, so society may be at danger
- Democratize scientific and technical choices, to foster the conditions for debate to nourish decision-making processes

Conclusion

- Nanotechnology has been highly researched as a way of utilizing the novel material property to improve existing products
- Less research has been done on the risks involved
- The available regulating laws cover existing products based on large particles and little is known about the nanoparticles.
- Until full operational laws governing nanoparticle risks are available, intensive research needs to be untaken and continue to practice precautions