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"Training and Capacity Building for the Development of a Nano Safety Pilot Project in Armenia"

PROJECT

ELEMENTS OF A NANO SAFETY POLICY

Introduction

Nanotechnology is a fast-advancing area of research and development, which is increasingly gaining importance for business, research and society. Therefore, it is crucial to carefully consider potential risks, as well as risk-associated possibilities and if necessary to take measures for protection of humans and the environment.

During the last years the production, trade, and use of chemicals has significantly increased. The use of chemicals has significant advantages in many spheres, but the wrong use (production, storage, calculation, import/export, packaging, labeling, and use) of chemicals in any phase may cause adverse impact on human health and the environment.

The continuous growth of chemical production and their adverse impact on human health and the environment brought to risk assessment necessity.
The risk assessment implementation, connected with chemicals adverse impact, must be regarded as essential part of sustainable social, economic development both on national and international levels.

It is necessary to carry out activities aimed at limitation of adverse impacts on the environment and human health. The above mentioned objective can be reached by reducing the danger and the adverse impact caused by chemicals. The risk may be reduced by taking chemicals out of the turnover, or by limiting its use, changing

them with substances having less toxic, bio-accumulating properties, or by keeping the safety rules of chemical use and reducing the accumulation of hazardous waste. The activities, directed to risk reduction, may be promoted by making stricter legislation, by economic benefit or by other impulse.
The chemical impacts risks prevention, reduction and elimination is a necessary condition for chemical (including production containing chemicals) management.

Nanotechnologies present a relatively "new" area for sound chemicals management. They are also a rapidly developing field, with new applications and uses of nanotechnology being identified on a regular basis in many countries around the world. Many new products are coming into the marketplace as a result of the manufacturing of novel, nano-containing products. With the introduction of such new products and manufacturing processes, and taking into account the sometimes unique physical properties of chemicals as they interact in their "nano" form, a new area of sound chemicals management is emerging.
Regulators and others who are responsible for nano issues are attempting to ensure that the environment and human health are protected from the potential negative effects of nano products and production processes.

Area of Application

Nanotechnologies are the set of technologies that enable manipulation, study or exploitation of very small structures and systems, that deals with the research, production and the application of these structures and systems, at the same time emphasizing novel properties of chemicals.
These include various kinds of analyses and processing of materials, which have one common feature: usually their size – at least one dimension –is in the nanometer range, from one to one hundred nanometers (one nanometer is one-millionth of a millimeter). Nanotechnologies use the special characteristics of many nanostructures. Mechanical, optical, magnetic, electrical and chemical properties of these small structures depend not only on the original material, but also on their size and shape. They are used in the field of energy technology (fuel cells and solar panels), ecology-related technologies (material use and utilization

cycle), and an information technology (new memory devices and processors), as well as in the field of optics, health care and for production of consumer goods.
A precondition for the emergence of nanotechnologies is the proposed opportunity to work with the individual particles of matter, as well as the associated improved understanding of self-organization of these particles.

Identification of products manufactured using nanotechnologies and containing nanomaterials is very important for both understanding of the "nano revolution" scale, and for revealing problems encountered in the risk management and regulation.
The produce will be successfully marketed in the long-term only if it is safe. Safety of nanomaterials can be achieved only through the joint efforts made by researchers, manufacturers, and legislative authorities.

Nanotechnologies are a relatively new branch in the sphere of chemicals sound management. The main areas for nanotechnology application involve: household appliances, electronic devices and computers, food and drinks (for example, antibacterial packaging, cooking utensils, food supplements, etc.), machinery, cosmetics (e.g., sunscreen, anti-wrinkle creams, etc.), clothing (e.g., waterproof fabrics, etc.), sportswear and items, cleaning products, building materials, as well as health and environmental preservation area (water cleaning /purification, soil restoration) and the use in public health for diagnosis setting through “chipset laboratories”, in medicine – for drug delivery, etc.

Identification of products manufactured with the use of nanotechnologies and articles containing nanomaterials is very important to understand both the scope of “nano-revolution” and for revealing the problems that arise upon related risks management and regulation.

Although there is no unanimous opinion on risks associated with certain types of nanomaterials released to the environment, especially in the aspect of their impact to the ecosystem, a number of benefits of nanomaterials were declared. These benefits involve not only sustainable and sound use of resources, but also the support to so-called “environmentally-friendly production”, “green chemistry” and “green energy”, which are associated with the rational use of natural resources.

Overview: Nanoparticles and Nanomaterials

Currently, all around the world a great attention is devoted to the prospects for development of nanotechnology aimed at development and use of substances and materials in a size-range of up to 100 nm (10^{-9} m).

Intrinsic behavior features of such size particles open wide prospects for the targeted obtainment of materials with new properties: a unique mechanical strength, specific spectral, electrical, magnetic, chemical, and biological characteristics.

By origin the natural and artificial nanostructures are distinguished. Natural nanostructures include small-size viruses are, DNA molecules, suspension of sand in the desert areas of the world, products of volcanoes emissions, smoke particles from forest fires, sea salt crystals.

Artificial nanostructures are created on the basis of modern technological processes: condensation from the gas phase, deposition from a colloidal solution and disintegration of a solid substance.

Nanomaterials may be three-dimensional (fullerenes, nanocrystals), two-dimensional (nanotubes), one-dimensional (nanofilms). They may differ dramatically, both in manufacturing technology, and by functional features.

Nanomaterials have the entire complex of physical and chemical properties and produce biological effects, which are often radically different from the properties of the same substance in the form of continuous phase or macroscopic dispersions.

The following physical-and-chemical features of nanomaterials can be emphasized:

- The increase in chemical potential resulting in a significantly changed solubility, reactivity and catalytic ability.

- Large specific surface area (per mass unit) that increases their adsorption capacity, chemical reactivity and catalytic properties, which can serve as the trigger of still unknown chemical reactions, or if combined with toxins – allow them to enter cells, to which they otherwise would have no access.

- Ability to communicate with nucleic acids, proteins, become embedded in membranes, to penetrate the cellular organelles and thus change functions of biostructures.

- High adsorption activity, the ability to absorb manifold greater amount of absorbable substances per own mass unit than macroscopic dispersions. For example, adsorption of various contaminants onto nanoparticles (hereinafter: NPs) facilitates their transport into the cell which can increase their toxicity.

- High capacity for accumulation. Perhaps, because of the small size the NPs can remain unrecognized by the body's defense system, undergo no biotransformation and accumulate in the body. This can lead to the accumulation of NPs in plant, animal organisms, with subsequent transfer through the food chain to humans.

The most common nanomaterials used in nanoindustry of consumer products are: silver (55%); carbon, including fullerenes (16%); titanium (10%); silicon (8%); zinc (6%), and gold (5%).

Properties of Nanomaterials

As shown by analytical studies, currently nanoscale silver particles are in the lead for the application in consumer goods. Colloidal silver (CS) is widely used as a disinfectant, antimicrobial, antiseptic agent in cosmetics and food products, in the manufacture of packaging for food and in water purification systems. Its use in systems for purification of water from centralized and non-centralized water supply sources against microbial decontamination (i.a., against viruses and bacteria), humic acids, colloidal particles, a wide variety of organic and inorganic dissolved impurities, including chlorine and organochlorine contaminants, pesticides, – all these eliminate the unpleasant smell of the water and improves its organoleptic properties.

As disinfectant, antimicrobial and antiseptic means nano-sized silver particles are also used in medical dressings, products for the care of sick persons, in ndividual garments, different kinds of household utensils and tools, in detergents, etc. In addition, colloidal (nano-sized), silver is used in the composition of dietary supplement products (food additives).

Carbon nanotubes, due to their unique properties such as high strength (63 GPa) superconductivity, capillary, optical, magnetic properties, etc. became widely used in science and economy. They can be used in a huge number of areas:

- additives in polymers;
- materials for water treatment;
- catalysts (auto-electron emission for cathode rays of lighting elements, flat panel displays, gas discharge tubes in telecom networks);
- absorption and shielding of electromagnetic waves;
- transformation of energy;
- anodes in lithium batteries;
- hydrogen storage;
- composites (fillers or coatings);
- nanoprobes;
- sensors;
- composites strengthening;
- supercapacitors.

Due to unique physical and chemical characteristics and the prolonged antibacterial effect the nanoforms of titan of dioxide are also among the most demanded nanomaterials. Nanodimensional particles of titan (TiO_2) are widely applied for production of cosmetics and toothpaste, pharmaceuticals, packings for food, paints, fillings, plastics, papers and in medicine as a component for formation of prosthetic implants and joints.

It should be noted that nanodimensional particles of zinc are also among nanomaterials, which are rather often used in consumer production are also Nanodimensional particles of zinc are used in food, pharmaceutical industry, production of perfumery and cosmetics, in paint and varnish industry, products of medical indication (as a part of disinfectants). Nanoparticles of zinc have broad application in the construction industry at galvanization of surfaces of constructional materials and coverings in order to render anticorrosive properties.

Nanodimensional particles of the titan, zinc are actively used in autocosmetics. When drawing hydrophobic nanostructural moisture- and dirt-resistant protective films to varnish-applied, textile, metal surfaces of cars specified particles render protective effect to those surfaces.

One of the leading areas to use the unique properties of NM is production of packing materials for foodstuff. Introduction of nanodimensional particles of titan, silver, and zinc to the structure of packing allows to render new useful characteristics, including gas-barrier properties, impermeability for ultraviolet rays, antibacterial activity.

The analysis on the use of nanomaterials in products is of great interest, since it allows to outline priority prospects for toxicological and hygienic studies and risk assessment of their impact towards the human organism, the purpose of which is hygienic regulation of nanomaterials in products and environmental samples.

The emergence of nanotechnology – marked by increase in the number of new nano products – is accompanied by a significant delay in the development of safety regulations for production and use of nano products.

Likewise the comprehensively studied pollutants, migration of nanoparticles into the environment and the subsequent effects to the living organisms are related to the following processes:

- inhalation, that is, entering with the inhalated air through the lungs;
- intake wirh water and food through the gastrointestinal tract;
- entering through the skin and mucous membranes;
- exposure from contaminated surfaces;
- entering through the gills of aquatic organisms into bloodstream.

Relevant Identified Problems

As a result of discussions with the country stakeholders the nano safety problems relevant to Armenia were identified:

- Import of nanomaterials to Armenia occurs without the appropriate notification of National Regulatory Bodies. Moreover, the officials are not aware about the characteristics of these nanomaterials brought to the country or in some cases the properties of chemicals used to produce nanomaterials are not known.
- National authorities are unaware of the importance and after-effects of nanotechnology and materials possibly resulting from it probably because the nation-wide awareness raising is insufficient
- Law "On Chemicals" that would regulate chemicals management, including nanomaterials, throughout the life-cycle different stages is lacking. The Law would also allow to differentiate the responsibilities of the stakeholders**.**

Presently, the following elements are also lacking:

- the system of nanomaterials identification
- appropriate labels on the packaging
- contra-indications
- safety-data sheets.
- standards on nanomaterials imported to the country,
- regulations/instructions on storage, usage, transportation and disposal of nanomaterials
- confident data on effects of nanomaterials on soil, water and human lives.
- legislative platform relevant to nanotechnology-based materials
- No standards are set for nanomaterials use, as well as for the wastes disposal.
- State officials and population are unaware of the implications towards human health and the environment.
- In Armenia no information is available regarding the nanomaterial-containing products, because such products are not subject for obligatory declaration.

The following actions should be performed at country level:

1) To establish the system for identification of nanomaterials;
2) To introduce the appropriate labeling system on packaging;
3) To introduce the appropriate warning signs, including contra-indications;

4) To fill out safety data sheets;
5) To develop and use standards on nanomaterials imported to the country;
6) To establish legislative platform relevant to nanotechnology-based materials;
7) To create and develop capacity in the academia for exchanging appropriate knowledge and understanding of nano safety issues in general public;
8) To facilitate cooperation between public and private nanotechnology laboratories for further certification of nano products;
9) To identify target groups of stakeholders to be trained;
10) To include risk management concepts in trainings;
11) To develop special programmes on the subject matter at various levels.

The general public, policy-makers and the national economy require free access to information on the currently drawn conclusions, rules, regulations and recommendations. Moreover, present-day scientific findings concerning the risks associated with synthetic nanomaterials should be available and accessible, taking into account such initiatives at both EU and the global level. On the basis of a joint communication plan, the responsible authoritative bodies must collect specific and updated information for these groups.

Effective and broad-based approaches to the safe handling of synthetic nanoparticles should be created in a dialogue with all parties to the discussion. Representatives from industry, government and wide layers of the general public should participate in the discussion about the possibilities and risks of nanotechnology. This debate should be an integral part of nanotechnology development.

Based on currently available principles of science and methodology, no conclusive requirements to the safety of synthetic nanomaterials can be formulated. However, precautionary measures should be taken. These measures should primarily focus on strengthening the personal responsibility of the industry and on more public-accessible information about the possible risks of products with the use of synthetic nanomaterials. Upon availability of methodological grounds and reasonable risk assessment of manufactured nanomaterials, the regulatory framework for the safe handling of synthetic nanomaterials can also be created, if necessary.

Because of lacking scientific data and absence of methods for measurements and tests, the risks of manufactured nanomaterials, in principle, cannot be estimated at present. The safety matrix, which is based on existing knowledge, should help to evaluate for which materials or application modes the potential risks should be considered. The matrix will be developed in cooperation with industry, science, authorities, consumers and environmental organisations, as well as international institutions; this matrix should be also adapted in accordance with the achievements of science.

In performing their supervisory functions, the official institutions also play an important role in advising companies and industries regarding protection strategies. Research institutes at universities and universities of applied sciences are important partners when referring to scientific research and development, which are new, not generally accepted technological and operational approaches.
Till present, there are no specific limits on professional levels of nanoparticles. With the increasing production and application of synthetic nanoparticles, one can expect the increase of occupational exposures as well. For ensuring protection of workers, medium and long-term reliable maximum permissible concentrations (MPC) should be set based on scientific results. The campaigns to measure concentrations at the workplace and to assess effectiveness of applied protective measures should be conducted by official authorities and within research projects at universities.

Information transfer (communications) and social dialogue are key prerequisites for the sound interactions of the society with nanotechnologies, and should therefore be encouraged. The involvement of the public, industry and science to the debate on the opportunities and risks of nanotechnology should become an integral part of nanotechnologies development. Only in this case it will be possible to develop technologies that bring forth sustainable economic and environmental benefits and find public recognition.