Nanosafety Workshop for the Central and Eastern European Region

Lodz, Poland – 22 and 23 February 2018

Workshop summary

1. Overview

On 22 and 23 February 2018, UNITAR and OECD, hosted by the Government of Poland and with financial support from the Government of Switzerland, organized a workshop in Lodz, Poland, on nanosafety, for the Central and Eastern European (CEE) region. This workshop took place as part of a series of workshops on manufactured nanomaterials and nanotechnologies, the emerging policy issue under the Strategic Approach to International Chemicals Management (SAICM). Fifty participants attended the workshop, from governments, industry, civil society and academia.

The below workshop summary provides some key points and outcomes from the workshop: the presentations and associated documents can be found on the UNITAR website (alongside the agenda, the list of participants and this workshop summary).

2. Inter-governmental work on Chemicals Management

The representative of UNITAR presented updates in international policy, noting resolution IV/2 from the fourth session of the International Conference on Chemicals Management (ICCM4), in September 2015. This reaffirmed previous resolutions and encourages SAICM stakeholders to address the sound management of manufactured nanomaterials in relevant national and international instruments, including regulatory frameworks, among other activities.

The relevance of the Global Chemicals Outlook was also presented, with a chapter on "SAICM emerging policy issues: state of the knowledge", currently under development. Participants were encouraged to support the review process, if desired, with a launch scheduled for February 2019.

Decision 13/17 of the Basel Convention was outlined in a presentation by a representative of the Basel Convention secretariat, indicating new work to be undertaken on waste containing nanomaterials. A report on issues related to waste containing nanomaterials and options for possible work under the Basel Convention is to be considered by the Open-ended Working Group at its 11th meeting (Geneva, Switzerland, 3-6 September 2018). This will help to stimulate further the discussion of nanomaterials and their potential effects on human health and the environment, and lifecycle issues.

Work under the United Nations Economic Commission for Europe's sub-committee of experts on the Globally Harmonized System of Classification and Labelling (GHS) continues to consider the applicability of the GHS to nanomaterials.

The World Health Organization (WHO) released guidelines in 2017 on protecting workers from potential risks of manufactured nanomaterials (with more information provided later in the workshop).

3. Overview of UNITAR's work on manufactured nanomaterials and nanotechnologies

The representative of UNITAR outlined UNITAR's latest work. Recent national policy development projects have been completed in Armenia and Vietnam, with ongoing activities in Jordan. A summary was also provided of the outcomes of the 2015 nanosafety workshops in the African, Asia-Pacific, and Latin American and Caribbean

regions. Each region created a nanosafety network from among the participants, identified and prioritized needs in the respective regions, and committed to sharing information among experts and national focal points.

The UNITAR representative also noted the e-Learning course on nanosafety that is available, but has not recently had enough interest from participants to take place. With integration of information from the 2017 WHO guidelines, this may be revised and offered again to the public.

4. Overview of OECD's work on manufactured nanomaterials

The representative from OECD introduced the various aspects of OECD's work, notably on testing and assessment, exposure and risk assessment.

The main areas of work for 2018-2020 will be test guidelines for hazard characterisation of manufactured nanomaterials, and exposure assessment and exposure mitigation.

5. WHO guidelines on protecting workers from potential risks of manufactured nanomaterials

Through Skype, a representative from WHO introduced the agency and its work on the recent guidelines, available from the WHO website. She presented background to WHO, and noted that WHO's mandate covers all aspects of public health, including occupational health, which has been on the organization's agenda since its inception. This is the first global guideline for occupational health.

A WHO guideline:

- assists providers and recipients of health care and other stakeholders to make informed decisions
- contains recommendations about health interventions (clinical, public health or policy)
    - A recommendation implies a choice between different interventions that have an impact on health and that have implications for the use of resources.
    - The recommendations may be: 1) Strong – for everyone, or 2) Conditional – will probably be adapted according to local context

WHO has adopted the GRADE approach for recommendations (*Grading* of Recommendations, Assessment, Development and Evaluations), for the transparency of processes and the evidence used. The guidelines had two guiding principles, the precautionary approach and a hierarchy of controls[1].

The background work concluded that there is sufficient information available to provide interim recommendations and guidance about approaches to handling of nanomaterials in the workplace (applying the precautionary approach). The target group for the guidelines has two phases: 1) policy-makers in low and medium income countries, and (potentially) 2) as an implementation guide for employers and workers.

A senior expert, who supported the development of the guidelines, provided further information and facilitated the agenda item. He outlined five recommendations. These are:

1. Assess health hazards of manufactured nanomaterials
    a. Assign hazard classes to all manufactured nanomaterials according to the Globally Harmonized System of Classification and Labelling of Chemicals for use in safety data sheets. For a limited number of manufactured nanomaterials, this information is made available in the guidelines.

[1] Hierarchy of controls- The implementation of controls to reduce workers' exposure should be considered the goal of a successful industrial hygiene programme: eliminate the hazard; substitute the hazardous material by a less harmful agent; apply engineering controls such as isolation, local exhaust ventilation or dust suppression techniques; consider administrative controls such as worker education, and training or scheduling; use as a last resort, personal protective equipment (PPE).

b. Update safety data sheets with manufactured nanomaterial-specific hazard information or indicate which toxicological endpoints did not have adequate testing available.

c. For the respirable fibres and granular biopersistent particles' groups, use the available classification of manufactured nanomaterials for provisional classification of nanomaterials of the same group.

2. Assess exposure to manufactured nanomaterials

    a. Assess workers' exposure in workplaces with methods similar to those used for the proposed specific occupational exposure limit (OEL) value of the manufactured nanomaterial.

    b. Assess whether workplace exposure exceeds a proposed OEL value for the manufactured nanomaterial. A list of proposed OEL values is provided in Annex 1 of the guidelines.

    c. If specific OELs for manufactured nanomaterials are not available in workplaces, use a stepwise approach for inhalation exposure. For dermal exposure assessment, there was insufficient evidence to recommend one method of dermal exposure assessment over another.

3. Control exposure to manufactured nanomaterials

    a. Focus control of exposure on preventing inhalation exposure with the aim of reducing it as much as possible

        i. especially during cleaning and maintenance, collecting material from reaction vessels and feeding manufactured nanomaterials into the production process.

        ii. In the absence of toxicological information, implement the highest level of controls to prevent workers from any exposure. When more information is available, take a more tailored approach.

    b. Use the principle of hierarchy of controls

    c. Prevent dermal exposure by occupational hygiene measures such as surface cleaning and the use of appropriate gloves.

    d. When assessment and measurement by a workplace safety expert is not available, use control banding for nanomaterials to select exposure control measures in the workplace.

4. Health surveillance should be in place

5. Training and involvement of workers is needed

In terms of best practice, the guidelines suggest:

1. Classifying manufactured nanomaterials into three groups: specific toxicity, respirable fibres, and granular biopersistent particles.
2. Worker involvement: workers should be involved in health and safety issues, leading to more optimal control of health and safety risks.
3. Training and education of workers: workers potentially exposed to manufactured nanomaterials should be educated on the risks of and trained in how they can best protect themselves.

6. Working groups on the WHO guidelines

The participants split into two working groups (one in English, one in Russian), using the following questions to prompt their discussions:

1. How could these guidelines be utilized in your organization?
2. Which recommendations do you consider most important to be implemented?

3. What is needed most for implementation? (e.g information, expert training, financial support, local OEL)
4. Is the current occupational health infrastructure sufficient to deal with manufactured nanomaterial problems?
5. Should there be additional regulation?

Working group 1- summary

1. Nanomaterials are used in CEE countries in the production of cosmetic products, medical products, pesticides, fertilizers, electronics, building materials, and textile products, among others. Nanomaterials are also synthesized in scientific laboratories, and imported from other countries.

   The restriction of manufactured nanomaterials is neither realistic nor necessarily desirable, since they have unique properties and they can have beneficial properties. However, the available scientific data is not enough to act with complete confidence about the safety of nanomaterials. It is difficult to develop modelling to evaluate the safety of materials, and develop principles and approaches for regulating and establishing standards for nanomaterials. Mandatory labelling of products containing nanomaterials is still not implemented. In some countries, nanomaterial safety studies are conducted in vivo and in vitro, but only for scientific purposes. There is no national legal framework for the evaluation of nanomaterials, to control the manufacturing, import and export of nanomaterials.

   Based on the above, the group welcomed the work of WHO in the field of assessment of nanomaterials. The guidelines on protecting workers from potential risks of manufactured nanomaterials is a very important step. The group hoped that there will be future guidelines for evaluating nanomaterials at all stages of their life cycle (the consumption of products containing nanomaterials, waste containing nanomaterials, recommendations for their disposal).

2. The guidelines describe important principles for controlling the impacts of manufactured nanomaterials. However, the main problem of both the guidelines and safety assessment of nanomaterials as a whole is the lack of scientific data for each of manufactured nanomaterials. The main principle of the guidelines is to minimize the effect of manufactured nanomaterials on workers. But in order to manage the production process soundly, it is necessary to prove the need for such a measure and bring in legislation. However, this is extremely difficult without scientifically-based standardized data on the hazards of nanomaterials. The use of personal protective equipment in the production process may prove ineffective; the development of special means of protection against nanomaterials is needed.
3. The guidelines were considered useful for developing national documents on risk assessment and control of nanomaterials. The implementation of the guidelines at the regional level would be facilitated by a full translation of the manual into the main UN languages.
4. In some countries, the regulation of nanomaterials is planned based on the national technical regulation of the Eurasian Economic Union “On the safety of chemical products”. Nanomaterials would be standardized and regulated on the basis of the same principles and approaches that are now applied to all other chemical products, but taking into account their specific properties.

   One of the main difficulties is the lack of clear, standardized methodological approaches to their dosing and research. Nanomaterials should have a safety data sheet, be labelled, their production and trade should be controlled. The long-term effects of nanomaterials must be investigated.

   There is no scientific database, and no generalized report on nanomaterials for controlling production, use and disposal. The group felt the international community should take responsibility for the preparation of such a document.

   All these problems require a global approach and standardized, generally accepted scientific data. SAICM can become a platform for solving problems related to the assessment of the safety of nanomaterials, but only on condition of scientific support in solving these problems.

Working group 2- summary

Participants first discussed a number of difficulties with respect to implementing safety guidelines at the workplace. One problem is that it was considered that the definition of a nanomaterial might be clear for scientists and regulators, but it is not always so for industry. Another issue is that government agencies often do not know which companies deal with nanomaterials: there is no list of such companies available. A further challenge is how inspectors at the workplace can detect the presence of a nanomaterial. In addition, it should be kept in mind that there is a wide array of nanomaterials, which cannot always be treated in the same manner. This can make it difficult for agencies to take specific action related to nanosafety.

There is, however, progress to help address these points. Workable definitions are now available through WHO and OECD, many test methods are in the process of being developed and efforts are ongoing to find a common language among scientists, industry and regulators on nanosafety. Also, the sharing of information in this field advances, as is demonstrated by work under SAICM and the UNITAR-OECD regional workshops.

Participants in the group felt that the region, considering that some countries are included in the European Union, typically would await further guidance from the European Commission before acting on nanomaterials. A suggestion involved updating the European Union's REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals). As it is, each country is now responsible to develop its own nanosafety policy, but the level of regulatory action is still low, mainly due to the issues identified earlier.

With respect to occupational safety, the WHO Guidelines offer a good route for implementation, and they could be used voluntarily by industry when clear national regulations and standards are not yet in force. Governments could promote this. Based on the WHO Guidelines, authorities should develop new Occupational Exposure Limits with involvement of all the relevant stakeholders

Finally, group members noted the need to keep the precautionary approach in mind, though this should not block progress as nanomaterials can have a number of technological and social benefits. It is important not to communicate too negatively while there are still uncertainties.

7. OECD Good Laboratory Practices and Test Guidelines

The representative from the OECD introduced more specific work on mutual acceptance of data, good laboratory practices and test guidelines.

By combining a single quality standard for testing of all chemical substances (test guidelines) and a single quality standard for test facilities throughout the OECD (good laboratory practices), data generated shall be accepted in OECD Member countries for the purposes of assessment and other uses relating to the protection of humans and the environment.

This helps to avoid duplicate testing, has been shown to save EUR150 million per year, reduces animal testing, and facilitates more and quicker evaluations.

The first test guideline, (TG318) for dispersion behaviours of nanomaterials in different environmental media, is now published. This guideline aims to determine the dispersion stability of nanomaterials in aqueous media independent of environmental conditions.

8. Updates from the region

Participants from the region were invited to provide updates on their work, in relation to nanosafety, including from Ms. Anahit Aleksandryan, Mr. Bogdan Walkowiak and Mr. Ali Khalmurzaev.

For more information, please access the presentations saved online, or contact the presenters directly.

9. Prioritising the Needs in the CEE Region and identifying the common issues, steps for the future

The participants again split into two groups to discuss priority actions and common issues.

Working group 1- summary

There is little doubt that nanomaterials require special control, regulation and arrangement, but the overriding problem is that there is no legislative basis for nanomaterials. However, this is a consequence of other fundamental problems:

- the lack of a clear approach for studying the effects of nanomaterials, taking into account their specific properties
- the lack of standardization of nanomaterials, as criteria for the standardization of nanomaterials with regard to their specific properties have not yet been developed
- the lack of clear scientific conclusions on the issue of nanosafety and the use of nanomaterials means there is no clear, common position from the international community
- the need to increase information to the public and government about the properties of nanomaterials and the effects

In order to establish priority actions, the group looked beyond 2020:

- development of a clear methodology for studying the effects of nanomaterials, taking into account their specific properties
- harmonization of laboratory studies on the safety of nanomaterials at the global level (development of OECD test methods). Studies conducted by OECD test methods would be easier to publish and submit for discussion by the world community
- development of laboratory-validated methods for controlling the content of nanomaterials in the workplace and in products
- the creation of a global scientific database of nanomaterials, including the description of their specific effects, classification, labelling requirements, general conclusions, recommendations for production and use (some nanomaterials may well be used even if their negative effects are proven, but with appropriate restrictions in production and use)
- development of recommendations for relevant waste containing nanomaterials (the Basel Convention could be responsible for such a development)
- creation of a common information platform on nanomaterials in the region, which should be harmonized with a global information platform.
- initiating projects to raise awareness among the public and governments in the region about nanomaterials and the issues associated with them
- translation into Russian of the main relevant documents. This will help inform the population and representatives of the authorities, and implementation in national programmes

Creation of a science-based mechanism for the assessment of safety of nanomaterials is possible on the platform of the Eurasian Economic Union (EEU). This process can be launched under the technical regulations “On the safety of chemical products”. On this platform, the development of general legislation for the countries

of the Union is possible. However, this development will only take place if there is a clear, global view of the problem. Perhaps it is necessary to create a broader platform beyond the EEU; SAICM might be able to connect to this. Strengthening the scientific component within SAICM would help develop a common view of the problem, which must be carried out together with scientists.

Working group 2- summary

Current gaps in the region:

There is a gap in the flow of information; with no common language to translate science to the public, and no dialogue between scientists and regulators. It is important to acknowledge that some information is available and needs to be transposed into legislation.

To share information there is a need to create a network, focusing on tools that can be used and the involvement of experts. More workshops, such as regional workshops and lectures from experts would be useful.

It would be important to identify producers and users of nanomaterials so as to regulate such materials on the market. There could be a need to have different regulations related to the production and use of nanomaterials compared to larger-scale materials.

The group felt that the Global Chemicals Outlook II could be a useful tool for advancing understanding of the topic. Likewise, SAICM could be a good platform for discussions and sharing of information.

Priority actions up to 2020:

Create a programme for nanotechnologies and manufactured nanomaterials that can be followed beyond 2020.

Exchange information and increase technical cooperation at all levels.

Utilize available guidance and tools and continue the work and action in this area, in collaboration with the IOMC. This could include developing guidance in how to communicate about nanosafety.

It is important to acknowledge that the basis for sharing more information is to start at the basic level, given the very specific area of science.

Raising awareness through workshops, cooperation with scientists and involving industry partners.

Priority actions beyond 2020:

A regional platform/network could be useful in the future in order to collect information, from legislative updates to in-depth scientific knowledge, including all relevant actors. National platforms would be encouraged and could be a solid base for a regional platform.