Nanomaterials: Applications, Implications and Safety Management in the SAICM Context

Rob Visser

The Regulatory Challenge of Nanotechnology
20 January 2012
Bern, Switzerland

SAICM context:

- ICCM-2 considered manufactured nanomaterials an emerging policy issue
- Resolution of ICCM-2 includes requests to:
  + increase global understanding about nano, using SAICM framework
  + prepare a report on nano-issues , in particular those of relevance for developing countries and economies in transition
- OEWG-1 discussed nano and started work on a new Resolution

Contents of SAICM nano report

- Introduction
- Applications
- Beneficial uses
- Risk assessment and management
- Economic and social impacts
- Ethical issues
- Public dialogue
- Capacity building
- Intergovernmental organizations
- Recommendations

Main assessment issues

- Material characterisation
- Physical- chemical (PC) characterisation
- Measurement methodology
- Sample preparation for testing
- Property-response relationships
- Dose-response relationships

Health and environmental safety

- Fibers
- Worker exposure
- Inhalation exposure
- Development of exposure limits
- Biodegradation
- Bioaccumalation
- Transformation in environment

Nano-waste

- Disposal of products is diverse
- Not yet in waste classification systems
- Not yet under Basel Convention for transboundary movement of waste
- In developing countries problems with:

  + waste management practices

  + waste management skills

  + regulatory frameworks

Harmonized Testing and Assessment: OECD

OECD works on:

- Database on research
- Safety testing : representative set
- Test Guidelines adaptation
- Voluntary and regulatory management schemes
- Risk Assessment
- Alternative test methods
- Exposure measurement
- Sustainable use

Mutual Acceptance of Data

System for OECD members and adhering non-members:

Legally binding Council Decision:

One test done using OECD Test Guidelines and Good Laboratory Practices will be accepted by all countries for purposes of safety assessment

Results:

- No duplicative testing
- Minimizing non-tariff trade barriers
- Saving of test animals
- Countries have similar basis for assessments

Testing of a Representative Set

- Testing of 13 representative nanomaterials (e.g. fullerenes, SWNCTs, DWNCTs, metal particles and oxides, dendrimers, nanoclays)
- 60 test endpoints:
  + Identification: 9
  + PC properties and characterisation : 17
  + Environmental fate: 15
  + Environmental toxicology : 7
  + Mammalian toxicology : 9
  + Material safety : 3

Sponsors

- OECD countries: Australia, Austria, Belgium. Canada, Denmark, France, Germany, Japan, Korea, Netherlands, Spain, Switzerland, UK, US
- Non-members : China, South Africa
- European Commission
- Nordic Council
- Industry

Co-operation with ISO

Provisional outcomes

- Identification and Characterisation: 4 methods can be used as they are, 16 need adaptations, 2 not possible
- Environment : most applicable with adaptations, some not
- Mammalian toxicity : many can be used, some modified – for all actual exposure conditions need to be considered

Overall provisional conclusion: Existing Test Guidelines still provide a good basis for safety testing in most cases, but for a number of tests adaptations are needed and special considerations apply (sample preparation, characterisation, actual exposure)

Risk Assessment and Management

- Assessment basis probably similar to traditional chemicals
- Large knowledge base on effects and exposure of traditional chemicals
- Scientific bodies (EC, EFSA, FAO) conclude existing assessment framework applicable, but specific aspects need further development
- Technology assessment has been applied in the past to many new technologies

Many governments still use current risk management concepts, with the application of uncertainty factors

Nano-labeling

- Information on nano-content of products is unclear and limited
- Discussions on establishing a government register of nano products to get better knowledge on this
- Proposal from NGOs to introduce a nano-label for products
- A general nano-label is not informing about hazards, only about nano-content
- A Globally Harmonised System (GHS) for Classification and Labelling exists, which gives hazard warnings
- Not clear if current classification criteria apply to nano

Precaution

- Lack of specific data
- Limitations in establishing dose-response relationships
- Mass based metrics might not be toxicologically relevant
- No full, unequivocal hazard characterisation possible

Many civil society groups advocate taking a precautionary approach

Regulatory considerations

- Most countries do not develop a nano-specific regulatory framework
- Integrate in existing chemical safety regime
- EU will apply REACH, US will apply TSCA
- Additional suggestions include:
  + nano-product register
  + nano-entry in Safety Data Sheets
  + specific nano-label for products

Economic considerations

- Useful applications, direct economic benefit
- Benefits for society – health, environment, energy
- Developing countries more dependent on commodity production, less advanced in application of new technologies - concern about changes in commodity markets, trade and employment
- Better understanding of nano-induced changes in economy needed

Responsible development of nano

OECD Science and Technology work:

- Statistics on production, use etc
- Benchmarking nano-developments
- Business challenges
- Global challenges
- International scientific co-ooperation
- Policy round tables

Social considerations

- Re-allocation of jobs over sectors?
- Skills development
- Distribution of benefits over population
- Distribution of risks over population

Public dialogue and communication is essential in addressing social context – lessons from biotechnology introduction

Ethical considerations

- Global distribution of positive and negative effects of introduction of nanotechnology
- Avoid a « nano-divide », especially in areas that concern basic needs – water, food, health
- Affordability of this type of applications
- Excessive patenting
- Consider nano in light of Millenium Development Goals
- Capacity building in developing world is essential

First Step: Awareness Raising

- Following up to ICCM-2 Resolution UNITAR and OECD in 2009/2010 organized first round of four Regional Awareness Raising Workshops
- UNITAR organized in 2011 second round, facilitating regional dialogue in preparation for OEWG-1 and ICCM-3
- Co-operation with SAICM Secretariat
- Support from Switzerland

UNITAR Guidance

Integrate nano-safety management in existing national chemical safety frameworks

- Update National Profile
- Identify priorities
- Develop national nano-policy
- Inclusion in existing programme
- Identify training needs

Guidance is being tested, with Swiss support, in projects in three pilot countries

Nano work in IGOs

In addition to OECD, UNEP and UNITAR:

- FAO/WHO : food safety
- ILO : occupational health and safety
- UNESCO : ethics and politics
- WHO : worker protection
- IOMC : co-ordinates

UN Conventions (Basel, Rotterdam, Stockholm) could possibly deal with nano-issues, but currently do not consider them

Conclusions of Report

- Opportunities for societal benefits of nano
- Challenges with respect to safety management
- Current Risk Assessment and Risk Management methods and regulatory frameworks can probably be applied

Essential for global use of its full potential:

- Open communication
- Public dialogue – not one-way process
- Global awareness raising
- Global capacity building – applications and implications
- Avoid nano-divide

Role for SAICM

- Only global forum to bring countries together to discuss overarching chemical safety issues
- Includes all stakeholders – governments, IGOs, industry, trade unions, civil society, academia
- Voluntary approach – focus on facilitating co-operation, information exchange, mutual understanding
- Identified nano as an emerging policy issue
- Co-operation with UNITAR in awareness raising
- Has a financing mechanism which can be used for capacity building

Draft Resolution for SAICM ICCM-3

Considerata:

- Johannesburg World Summit on Sustainable Development 2002 goal on safe use of chemicals by 2020
- Specific needs of developing countries and economies in transition
- Resolutions of African and Latin American-Caribbean regions
- Work of IGOs
- Report on nano and its recommendations

Possible SAICM actions - 1

- SAICM is a suitable framework to address nano
- All stakeholders to facilitate information exchange on nano
- Specifically on risk assessment, risk reduction measures, environment, health, safety research
- Improve global tranparency
- Allow better decision making processes

Possible SAICM actions - 2

- [In particular the International Council of Chemicals Associations is invited to identify nanomaterials and generate information on their safe handling and use, throughout their life cycle and make this information available through its own dissemination mechanisms]

Possible SAICM actions - 3

- All stakeholders to support public dialogues on all aspects of nano, including benefits and risks throughout their life cycle
- [Invites Conferences of Parties of Basel, Rotterdam and Stockholm Conventions to consider if nano and its applications fall under their respective mandates, and if not, if they should]

Possible SAICM actions - 4

- [Invites/Calls on] industry to continue and enhance their stewardship role and responsibilities, to participate in and support [also financially] awareness raising, information exchange and training activities, public dialogue and risk research

Possible SAICM actions - 5

- [Invites relevant UN Committees to monitor progress in science, review applicability of GHS criteria to nano and if needed prepare a work plan for adaptation of the criteria]
- [Intersessional activities to give special attention to full life cycle and occupational exposure]

Possible SAICM actions - 6

- Develop international technical and regulatory guidance and training materials for sound management of nano
- [Develop pilot projects at national level to enhance capacity to address nano]
- Invites IGOs, specifically UNITAR and OECD,to support and facilitate information exchange, develop guidance and training materials and support public dialogues on nano

Nano in Global Plan of Action

- Proposal to add activities on nano to Global Plan of Action (GPA) was made by Switzerland
- Was discussed in 2011 Regional UNITAR nano-workshops and at Regional SAICM meetings
- Revised proposal prepared by Switzerland
- Discussed at OEWG-1
- Recommendation to ICCM-3 to include nano in GPA
- Further discussions needed on details of a number of the 22 proposed activities and on their place in GPA

Some further Recommendations of the Report

- Set up an international nano-portal for information exchange
- Develop Regional SAICM strategies on nano, including co-operation on research, risk assessment and risk management
- Facilitate transfer of technology concerning beneficial applications for health and environment, possibly through partnerships, including public/private ones
- Hold a Global Conference on nano to discuss the state of the art in various fields and address issues of wide public interest

Final remarks

- Nano provides a lot of opportunities for society, but has also safety challenges

- In order to realize globally its potential in a safe way and obtain public acceptance, there is a need for:
  + learning the lessons from the introduction of biotechnology
  + having an open public discussion on risk
  + building capacity in developing world
  + integrating safety management in existing regulatory framework
  + developing guidance on how to do this
  + sharing of knowledge on applications and safety
  + working in an international context

- SAICM is a good forum for international discussions with all stakeholders

Thank you very much for your attention

SAICM/OEWG.1/INF/8

www.http://www.saicm.org/documents/OEWG/OEWG1%20INF8%20Nano%20Report.doc