Closer to the Market (CTTM) Roadmap

EU-U.S.: Bridging NanoEHS Research Efforts

Prof Kai Savolainen, 13 March 2015

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Introduction

- New technologies make their advance faster than the safety management related to them
- The level of safety achieved from any application varies with space and time and is related to the quality and benefits the new technology offers, and consideration of safety in them
- New technology application > regulation

  > Regulatory Research Roadmap
- Development of new rules/practices should be based on solid scientific knowledge
- The safety of a technology is a market itself

  -opportunity!

Closer to the Market – Scope:

Supporting innovation and the commercialization of new technology

- Provide the technology, skills, processes, necessary for science-based best NanoSafety practices in the industrial & commercial activities (based on coordinated NSC and national platforms activities)
- Setting minimum requirements for jobs and required skills
- Addressing bottle-necks
- Building capacity, building reliable tools, organizational tasks, international cooperation, epidemiology

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Building capacity for formalisation of jobs

- Risk monitoring
- Risk prevention
- Risk mitigation
- Risk communication

- Monitoring of Exposure (benchmark levels)
- Epidemiological studies (using harmonized protocols)
- Data combination of hazard and exposure > Risk assessment > “safe and/or tolerable”
- Safety-by-Design
- Control mechanisms and measurements
- Best practices

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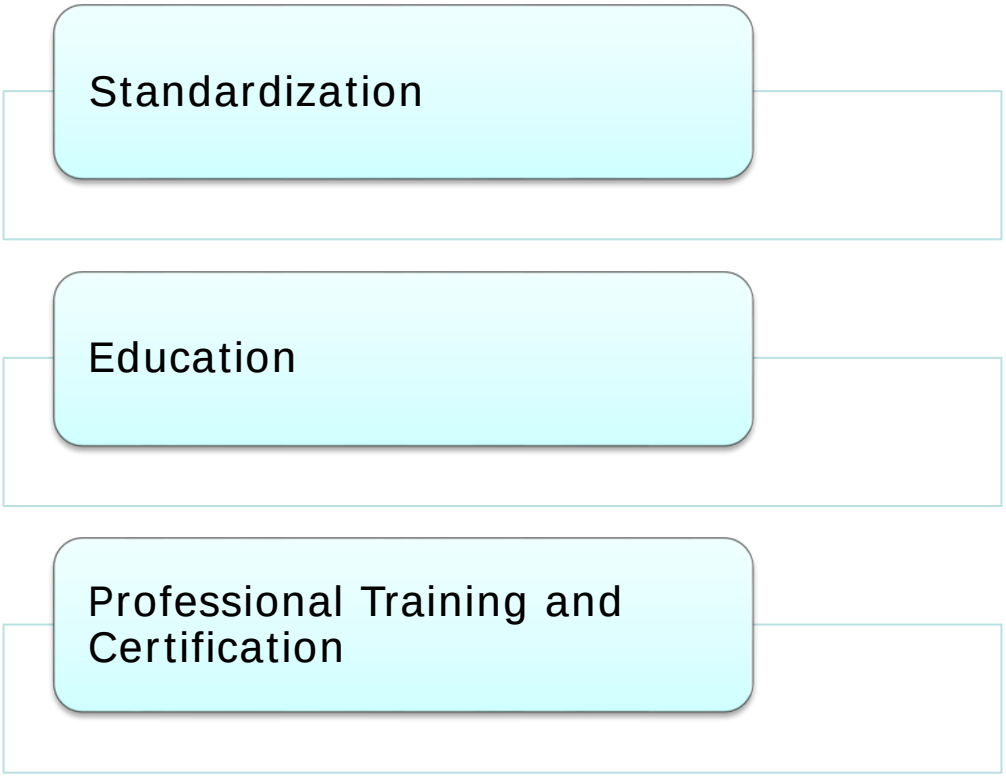
Building capacity for formalisation of skills



- Documents on requirements, specifications and guidelines
- Informed public
- Workplace safety

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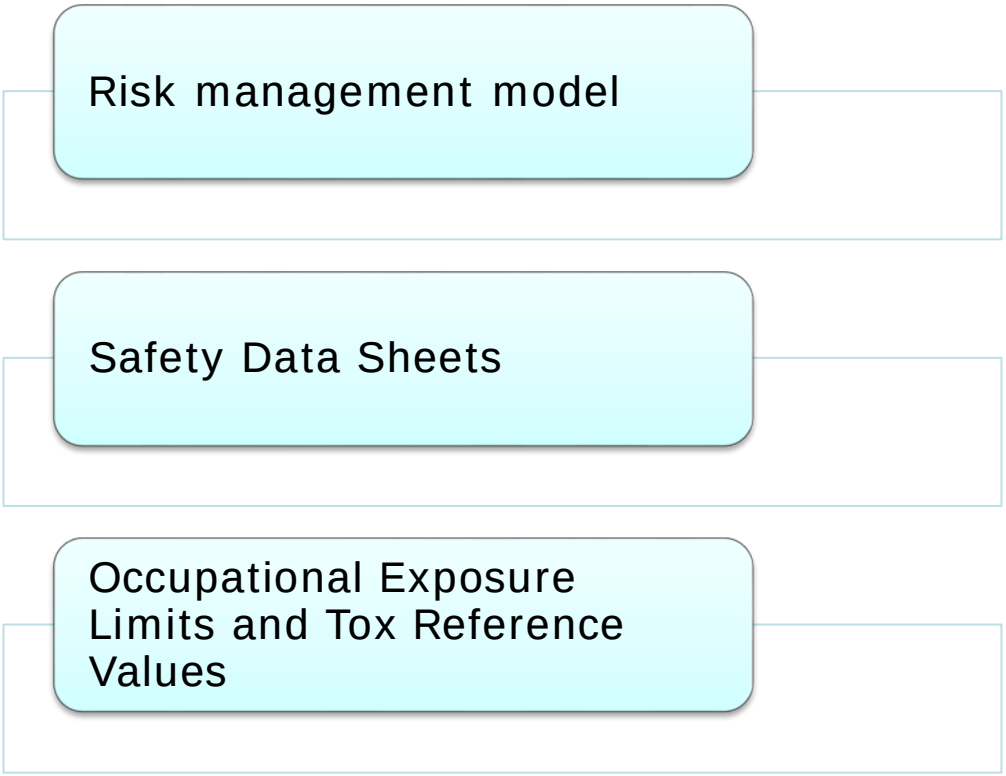
Building reliable tools for nanosafety at work



- Test, validation and dissemination
- Risk Management Model -occupational exposure
- Detailed information on health and safety
- Exposure to workers and population
- Translation of scientific data

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Examples of current bottle-necks

(hindering large access to the market)

1) Occupational safety:

- sustainable marketing requires that employees and employers are confident in the safety of the process
- IARC CNT classification – signal to actors
- Lack of
  - awareness of employees and employers;
  - reference control banding tools;
  - of reference protocols for NanoSafety assessment;
  - of Occupational Exposure Limits (OELs);
  - of transmission of the nanosafety information through the Safety Data sheets;

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Examples of bottlenecks (continues)

- Lack of nanosafety management systems;
- Lack of regulation specifying requirements to ensure the safety and health of workers exposed to nano-risks; …
- Uncertainties in risk assessment and in efficiency of prevention/ protection measures; …in the agreement system;
- Mistrust towards employers in the field of Nano-OSH

Examples of bottle-necks (continues)

2) Public safety:

...that consumers are confident in the safety of the products

- Mistrust towards regulation (REACH: adapted to nanos?); towards employers in the field of Nano-OSH...
- Lack of Toxicological Reference Values (TRVs)
- Lack of communication

Actions proposed

- Networking
- Benchmarking
- Data collection
- Reporting
- Communication
- Validation and Standardisation
- Assistance to new-comers
- Feedback for fixing next research priorities
- Assistance to regulators
- Professional training and Certification
- Certification of skills
- Pooling of funding/resources and international collaboration

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Organisation / Inventory

- Current situation:
  The challenge of guiding in the managing safety is in many cases in nanosafety platforms in countries.
- **NanoSafety Research Centers**
  - E.g NanoSafety Research Centre at FIOH, the Danish Nano Safety Centre, Namur nanoSafety Centre, EURO-NanoTox, Veneto Nanotech, LEITAT, RIVM, TNO, EMPA, INRS, DGUV
- **NanoSafety (experts) platforms**
  - E.g. KIR nano; BioNanoNet
- **NanoSafety Collaborations**
  - E.g. Nanocentre; NanoHouse

International cooperation

- **Current situation**
  - EU-U.S. CoR collaboration
  - Research Call between AT – Shanghai (China) on Nanoscience and Nanotechnology
  - SIINN ERA-NET for EU MS and US on potential risks of ENM for environment, human health, and safety
  - EU-Brazilian NANoREG collaboration

International cooperation

- **Need for enhanced regional and international cooperation for greater impact**
  - Building long-term, structured collaboration
  - Networking of the centers internationally: active nanosafety hubs, sharing and promoting best practices
  - Joint activities and research to accelerate innovation and closer to the market aspects
  - FUNDING – solutions for joint actions

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CTTM- Core (suggestions)

- To create a European/International hub structure in applied nanotoxicology and safety of nano-enabled products/ consumer health risks, facilitated by a scientific expert committee
- The hub platform would provide services and support for stakeholders (e.g. industry, governments, researchers etc.) to contribute to marketable, societal approved products and goods in a sustainable way.
- International collaboration in significant role

CTTM- Core (suggestions)

- Tasks and research priorities of the hub:
  - European Service Provider Platform (SPP) on nanotoxicology and safety of nano-enabled products
  - Finalize, validate and characterize uncertainties and limits of test protocols - establish Toxicological Reference Values (TRVs) (OELs etc.)
  - Evaluate the relevance of industrial nanosafety techniques
  - Develop/propose New Test-Methods
  - Up-to-date consumer/environmental exposure monitoring
  - Life-Cycle Assessment
  - Professional training and Education, Certification

Expected outcomes

Guidance to market actors (industry, public authorities)

Best practices

Standards, technical approvals

Environment protection

Operational certification systems

- SCCS, ECHA, REACH, EFSA, OECD...
- reducing the uncertainties contributes to acceptance of nano-enabled products
- translating the results of research in a battery of practical methods, strategies and management of nano-risks, usable by end-users
- practical approach: new knowledge, guidance and practices to the end-users, customers and the market

Next steps (2015)

- Elaboration on the CTTM roadmap and send it for comments to the EU NanoSafety Cluster
- Alignment with RRR and SRA, finalization of the CTTM
- EU-funded CSA topic bringing together the nanosafety platforms and institutes under H 2020
  - The timeline is to get the topic published in 2016 and the action operational (2017)
  - The aim is to use this CSA to develop further actions and enhance international collaboration

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and Nanotechnologies
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Thank you!

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