Risk Management
&
Control Measures

EU-US COR6

Report: Larry Gibbs and Keld Alstrup Jensen

CoR6: Nanosafety Risk Management and Controls

The focus of the Community of Research for Risk Management and Controls is to engage scientists and nanosafety professionals in **identifying and sharing methodologies, control strategies and demonstrated effective solutions for the common purpose of reducing and preventing adverse health, safety and environmental exposures to nanomaterials**. Through participation in active exchange of interested and knowledgeable scientists and professionals, development of best practices can emerge that can be widely shared. Also, the CoR will identify specific research needs to improve risk management decision-making where gaps are found in the fundamental risk management variables.

CoR6 Co-Chairs:

- Larry Gibbs, Stanford University
- Tom Van Teunenbroek, Ministry of Infrastructure and Environment, The Netherlands

Larry Gibbs, Co-chair
Keld Jensen, Co-chair/Rapporteur
Status and Agenda

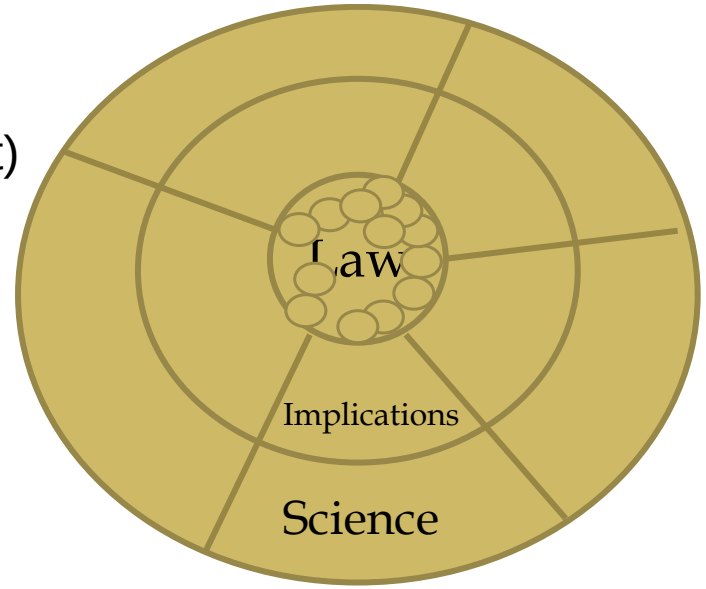
- Webinar discussion Nov, 2013
  - 56 people attended
- Today
  - 9 people in the room
- Talks: Nanotechnology Risk Management
  - Ilise L Feitshans (Law and Regulation) need for international harmonization
  - Don Ewert (Good Practices OEHS certification as an interval approach to harmonization)
  - Chuck Geraci (Safety by Design)
- Horse-shoe table discussion

Key Issue for Risk Management and Controls for nano

Given the need/probability for globally harmonized risk management procedures and policies which are protective of human health and the environment, there is a need for an approach to guide and manage the process using good HSE risk management principles and practices.

Elise L Feithans (IST, University of Lausanne)
The Need for International Harmonization of Nanotechnology Laws

- Action and participation is required to establish good ideas and good laws.
- Example: Definition of MNM in EC as a working definition that might change if we observe that it is technically not feasible.
- Now we are in a very early stage of nanotechnology and law
- Why a laws?
  - Avoid liability
  - Avoid administrative fines
  - Prevent injury (societal and finansial cost)
- Advantages of law harmonization?
  - Best practise (if it is a good law)
  - Shows due diligence
  - Predictability
  - Consistency that avoids legal conflicts
- How are laws made?
  - Europe (EU and EC) as an example



Donald Ewert (nanoTOX)
Nanotechnology & OHS Good Practices
Global Approach to Harmonization
nanoTox (Company)

- Introduction with discussion on market size and operational needs of regulation
  - Definition by US-EPA versus the EC-definition
  - Doing nothing creates a loop-hole
- nanoTOX OHS management system and certification programs
  - ISO standards 45001 has activities in OSH, but it is uncertain whether it will result in a protective approach
  - Instead nanoOHS certification programs (currently in place for pharmaceutical companies)
- nanoOEHS (abilities and needs to make it work)
  - Voluntary stakeholder involvement
  - Ability to be proactive and catch early uncertainties
- Certification (nOMS) program for nanoOEHS in companies (model)
  - International program established by an voluntary advisory panel
  - Conduct OHS Harmonization Training, audition, certification
  - Establish a knowledge bank on good practise and RM

nanOEHS Certification Program

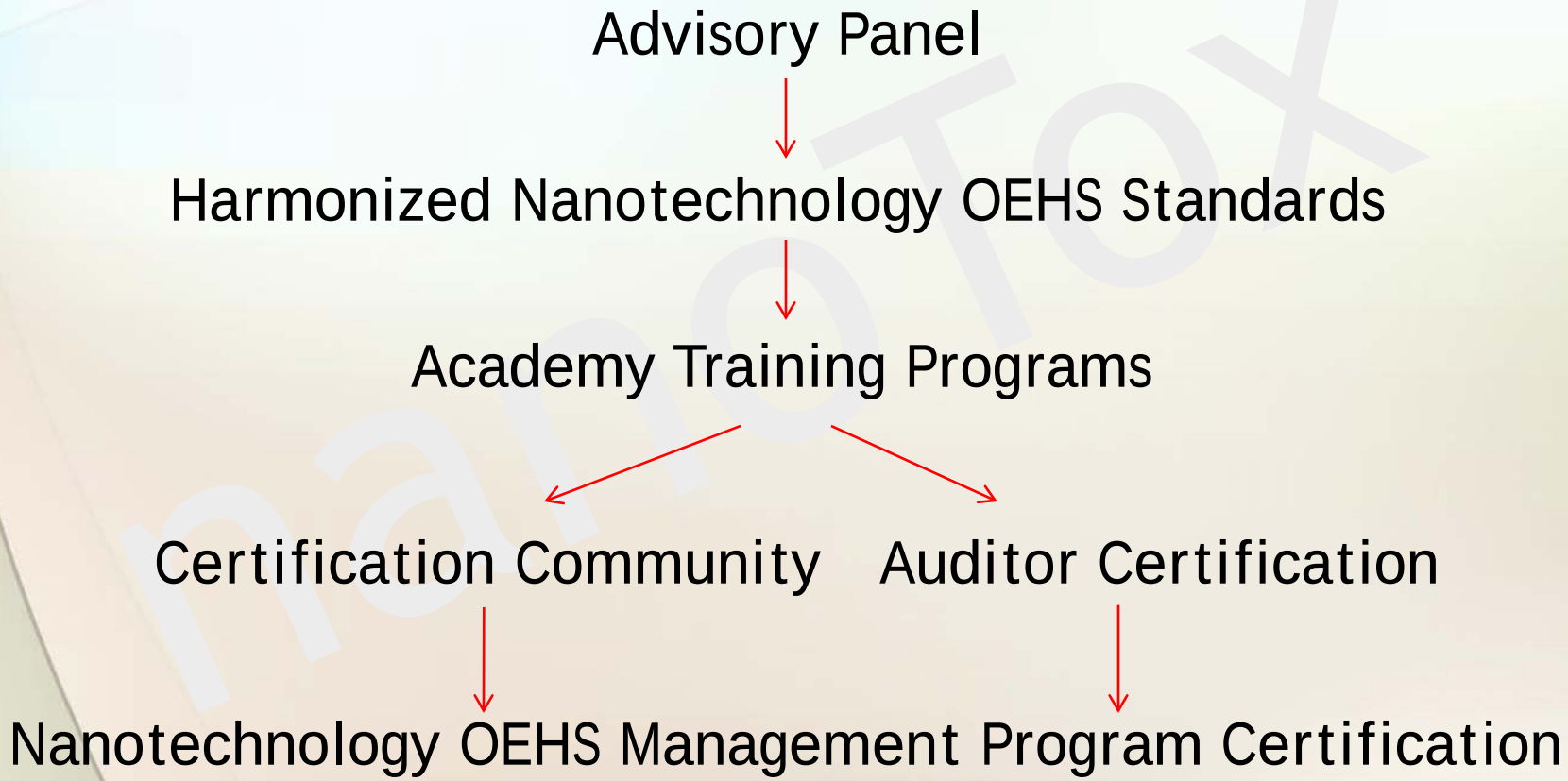
What is needed?

Certification Process Which is:

- Voluntary in Nature and Non-Regulatory in Character
- Specifically Based on Current Industry Standards in OEHS
- Capable of Rapidly Changing With Advances in Technology
- Able to Focus on Nanotechnology OEHS Program Tenets
- Based on Input From All Nanotechnology Stakeholders
- Not Based on the Performance of Executive Management
- Not Based on the Quality of the Products or Recall Criteria
- Inclusive of a Host of Yet to be Stated Considerations

nOMS Certification Program

Executive Overview



Principles for Safe by Design of Nanomaterials(-processes) AND discussions - Charles Geraci

- SbyD is actually a Good RM Process
  - Good Example1 - protective shell on Ag
  - Good Example2 - Functionalization of CNT
  - Good Example 2- Exposure reduction by change of formulation
    - All still needs to be tested ….
- CoR 6 could possibly catalyze the dialogue for SbyD
- How do we learn from other risk management programs (e.g., investment forecasts) about the market size and importance, market volume and products (e.g,. Future Markets)
- Concerns about labelling and hazard communication (especially for workers; label requirement on MSDS that this is a MNM).

Discussion on potential CoR 6 Activities

- Model for identification of a nanomaterial in the workplace
- Ressource of good practise in synthesis and downstream manufacturing
- Efficiencies of good practise and PPE for containment (PPE last choice)
  - Develop a standard procedure for verification of containment control efficiency (maybe not the full rigerous validation)
- How significant is the change in a risk when adding a nanocomponent to existing production process
  - Paint, plastics, …..
- Safety by design – what designs are actually good ideas
- Focus a webinar on occupational exposure assessment – challenges of good quantitative monitoring and workplace hazard assessment
- What can we learn from other areas involved with risk management (e.g., insurance, investment)
- To make the COR6 more functional we agreed to map out the EU-US activities to develop specific coordination actions

Post-meeting Announcement

- Germany: (German Federal Ministry of Labour and Social Affairs (BMAS) published the Announcement 527 on Hazardous Substances – Manufactured Nanomaterials; May 2013)
  - Hazard assessment and risk management guide

- Denmark: (Working Environment Authorities announced that specific workplace evaluations should be made when producing or working with MNM; Dec. 2012)
  - No tool associated with announcement

- …..