



Ministry of Infrastructure and the
Environment

Data needs and research strategy

Tom van Teunenbroek
Ministry of I&M,
the Netherlands



My role in nano-safety

- Ü Policy coordinator
- Ü Research coordinator
- Ü Representative for the Netherlands for WPNM (since 2006)
- Ü Responsible for developing the policy in the Netherlands for nano-technology en nano materials
- Ü Set up a research programme for nano technology innovation in the Netherlands, which is an integral part of R&D on risk and nano safety (15% of 100 € over 5 years)
- Ü Member of high level planning group FP7 nano technologies
- Ü Participant in “safety for success” dialogue for DG SANCO



Background

Ü The Netherlands and Germany were asked by WPMN in 2009 to help develop the process of structuring the 2nd phase of the OECD Sponsorship Programme. Main objective link EU FP7 nanosafety research to the WPMN agenda.

Ü The Netherlands, in agreement with Germany, has organised three Workshops in the Netherlands and Brussels, to review expert opinions on EHS issues related to nano technology:

Ø Workshop with Industry, including multinationals, (held at the University of Utrecht) ~15 participants

Ø Workshop with toxicologists and researchers (held at RIVM), ~15 participants

Ø Workshop with EU, OECD and Industrial experts in Brussels, held with support of OECD, ~ 25 participants



Content of the Brussels Workshop

Session 1: Principles for the 2nd phase of the OECD Sponsorship Programme

Session 2: Further testing strategies

- Ü Theme 1: Data requirements for regulatory purposes
- Ü Theme 2; Heterogeneity of nano materials
- Ü Theme 3; Sample preparation and dosimetry
- Ü Theme 4: ADME considerations



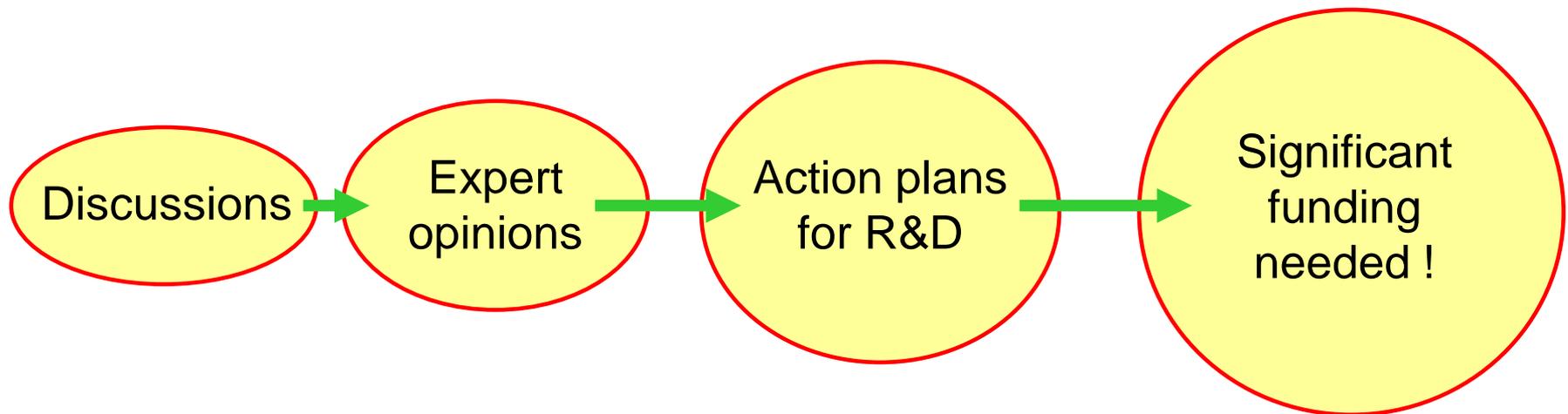
Relevance of Brussels workshop for OECD

Several of the themes to be discussed in this workshop are topics of several SGs, or are the focus of EU research projects. We need to think about which topics should be included in Phase 2 of the Sponsor Programme. In any case we need:

- Ü More focussed research
- Ü Better efforts to harmonise the work
- Ü Sufficient resources to carry out meaningful studies



Turning conclusions into actions!



Words without action are meaningless – there is a real need for significant concerted funding of research in nano-EHS issues!!



Procedural aspects to be considered in Phase II

- It is essential to have in depth discussions on the outcome of SP1 in order to develop clear views for phase 2.
- It is important to organise horizontal meetings in the short term to evaluate the results of Phase 1, so that this information can provide input to the preparations for Phase 2. A first meeting should focus on inhalation, as was previously proposed by the NL delegation.
- It is also essential that there are clear aims and verifiable deliverables for both Phases. The experiences gained during Phase 1 must clearly be a guiding principle when formulating Phase 2.
- Reporting should be done following an agreed and standardised format, in order to facilitate evaluation of results, which also must be a common practise.



Procedural aspects to be considered in Phase II

A core issue for Phase 2 is the applicability of the existing TGs, and in how far these need to be modified or improved. In this area we need to look at:

- Ü Guidelines for sample preparation
- Ü Guidance on dosimetry and standardisation of procedures
- Ü How to develop an Intelligent Testing Strategy
- Ü Evaluation of which standardised exposure scenarios can be developed for NMs



Procedural aspects to be considered to fill the data gap

- Demand driven
- Top down structured
- Tender structure with detailed agenda and deliverables
- Apart from deliverables standardized procedures
- Still innovative but more interdisciplinary
- No research call



Practical suggestions for R&D in Phase II

- Start a major, simultaneous investigation into in vitro / in vivo for a representative range (6?) of nano materials. The investigation should evaluate the relevance and effectiveness of different test instruments and methodologies for EHS issues.
- A main focus should be on evaluating the applicability of a range of new and promising in vitro test methods, which clearly need to be validated. Given the huge diversity of NMs, we need to see if a standard approach to testing will allow the development of criteria for “sameness” in test results with universal applicability.
- The coupling of in vitro and in vivo test results has to be understood in depth, and sufficient data generated by testing to give an unambiguous picture of whether in vivo can, and to what extent, be replaced by in vitro.



Practical suggestions for R&D in Phase II

- More focus should be given to the physico-chemical characterisation of NMs, whereby a database of characteristics could be formed which will provide essential input to toxicity assessment; without this data it will be hard to determine which of the individual characteristics can be linked to specific tox effects. Research needs to focus on searching for common factors in characteristics of NMs in a horizontal review of data.

- Define and evaluate the possibilities for a standardised exposure scenario, in order to differentiate between different situations. We can envisage four typical scenarios:



Practical suggestions for R&D in Phase II

- Scenario 1: A nano-material is added to a matrix, reacts, and is subsequently not a nano any more
- Scenario 2: A nano-material is added to a matrix, remains in a nano state, and is later released
- Scenario 3: A nano-material is added to a product, reacts, and is subsequently not a nano any more
- Scenario 4: A nano-material is added to a product, but remains in a nano state and is later released

These four options cover the main scenarios by which a nano-material interacts with other materials, and should be evaluated for a range of nano materials