NANOMATERIALS: RISK ASSESSMENT NEEDS

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TOPICS TO BE ADDRESSED

- General requirements for risk assessments (RA)
- Properties of nanomaterials of interest for RA purposes
- Current understanding and the views of SCENIHR
- Areas where more work is needed

REQUIREMENTS OF THE RISK ASSESSMENT PROCESS

- Access to sufficient, good quality, relevant, data
- High scientific expertise in interpreting this data
- Independence of the assessors
- Transparency of the process
- Clear explanation of the findings for each assessment along with the rationale and the areas of uncertainty

REQUIREMENTS FOR HUMAN AND ENVIRONMENTAL RISK ASSESSMENT (RA)

i) determination of the range of exposure conditions (during manufacture, use and disposal), to each substance of interest, likely to be experienced by man and other species

ii) identification of its hazard properties and characterisation of the relationship between these exposure estimates and the hazardous properties in that species or surrogates for each species

iii) consider particularly susceptible population groups and uncertainties in the RA

BACKGROUND TO THE RA OF NANOMATERIALS

- The development of new nanomaterials and nanostructures is advancing rapidly, however much of the relevant information is not accessible to risk assessors.
- Frequently the nano form described substances in a range of physicochemical properties eg size.
- Experience has been gained in risk assessment of a very limited number of complex substances in the nano form (eg carbon black, combustion products).
- The methodology required to measure the nano form of substances is in many cases not adequate for risk assessment purposes.

KEY ISSUES FOR RISK ASSESSMENT PURPOSES

- Does a substance in the nano form necessarily constitute a higher risk to man and/ to the environment than other forms of the same substance?
- To what extent can hazard data on a substance in other physico-chemical forms be utilised if the substance is proposed for use in a nano form?
- Is our scientific understanding sufficient to enable read across from one nano-material to another (SAR)?

CURRENT UNDERSTANDING ON THESE ISSUES

- Some substances in a particular nanoform may be more hazardous than in other physico-chemical forms. However this is not necessarily the case.
- There is no good evidence that unique hazardous properties can arise from exposure to substances in the nanoform
- Our current knowledge is insufficient to conduct ‘read across’ with any confidence

POSITION OF SCENIHR .

- In the absence of sound rules each substance in a new nanoform needs to be considered individually.
- Priority for an assessment should be for products where there is anticipated to be significant human and/or environmental exposure (during manufacture, use and/or disposal) and potential uptake of the nano form of a substance.

FRAMEWORK RECOMMENDED BY SCENIHR 1.

- **Stage1** A proper characterisation of the physico-chemical properties of the relevant nanoform eg size distribution, solubility, stability. Primary interest is on stable entities with at least two dimensions in the nanoscale.
- **Stage 2A** Identification of realistic exposure scenarios for both man and other species. Further consideration needed in situations where significant exposure is identified.

FRAMEWORK RECOMMENDED BY SCENIHR 2.

- **Stage 2B** Consideration of toxico-kinetic properties, particularly the potential for uptake by man and other species

- **Stage 3*** identification of hazardous properties using a tiered system of in vitro and in vivo methods (including consideration of mechanisms)

FRAMEWORK RECOMMENDED BY SCENIHR 3.

- **Stage 4***. Characterisation of dose response relationships and conclusions on the risks for each relevant exposure scenario.

* An important issue is the expression of exposure/dose. The number of particles is likely to be preferable often to the traditional expression in mass units

REQUIREMENTS FOR THE DEVELOPMENT OF THE RA FRAMEWORK

- An evolving data base of RA's on properly characterised substances in the nanoform
- A strong international research programme on the behaviour of different types of nanoparticle in biological systems coupled with prompt availability of findings for RA purposes.
- Monitoring programmes where exposure to relevant nanoproducts is already occuring eg in the workplace.

OTHER NEEDS

- Wide availability of high quality well characterised reference nanomaterials
- Regular reviews of the framework in the light of new information
- International agreement on terminology
- A transparent and acceptable format for risk comparison
- Effective collaboration between stakeholders

CONCLUSIONS

- The RA of nanoforms of substances cannot be based simply on the known properties of the same substance in another physical form, rather each new nanoform needs to be considered specifically.
- A rationale framework has been identfied for such RA's. this needs to evolve as new information becomes available
- The process must be transparent and independent and needs to involve a range of stakeholders.