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Directorate-General for Health & Consumers

Developments in the risk assessment of nanotechnologies

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European Responsible Care Conference,
Prague, 21 October 2009

STRUCTURE

- Historical perspective
- Current understanding
- Remaining issues
- Way forward
- Conclusion

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Original EU Framework

- European strategy for Nanotechnology (2004)
  - Safe, integrated and responsible
- Action Plan for nanosciences and nanotechnologies (2005)
  - Address safety concerns
  - Promote measures to minimize exposure
  - Develop terminology, guidelines, models and standards for RA

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EU scientific developments in RA

- 2006 SCENIHR, appropriateness of existing methodologies
- 2007 SCENIHR, appropriateness of existing methodologies in accordance with the technical guidance documents
- 2007 SCENIHR, scientific aspects of definitions

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EU scientific developments in RA

- 2007 SCCP, nanomaterials in cosmetics
- 2008 EFSA, nanomaterials in food
- 2009 SCENIHR, risk assessment of products of nanotechnologies

- Today, ongoing assessment of 2 cosmetic ingredients by the SCCS

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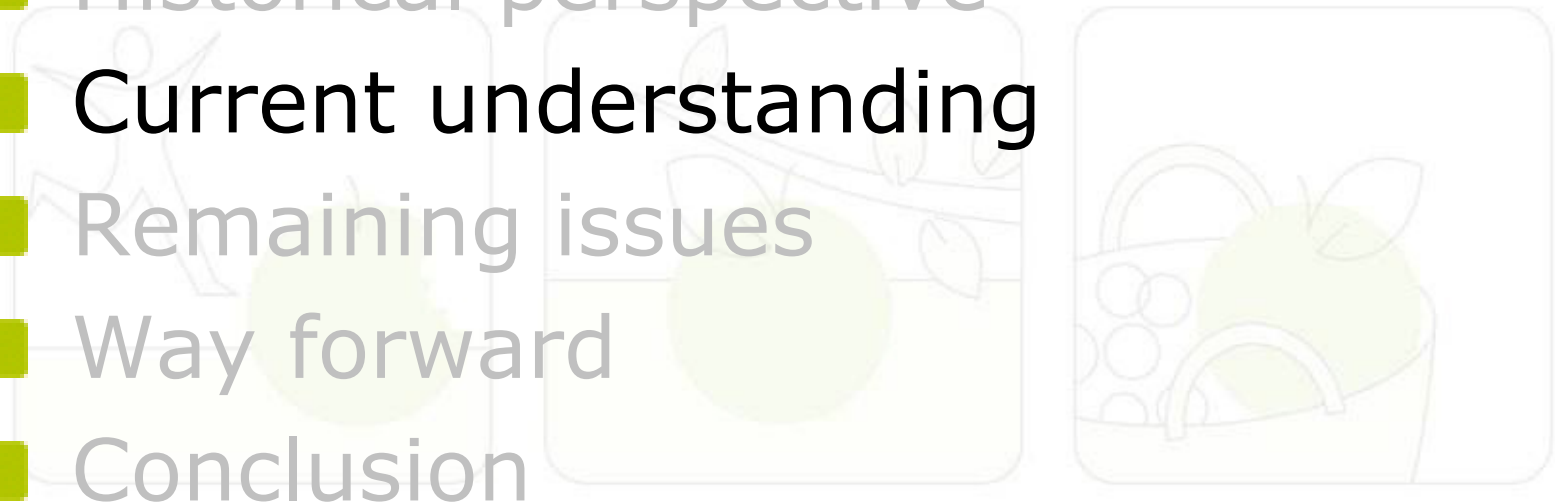

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Current understanding - 1

- Free nanoparticles are considered to present the highest risk
- Identification/characterization
- Importance of dispersion
- Lack of reference materials for characterization
- Adequacy of (eco)tox test methods?

Current understanding - 2

- Exposure assessment methodology
  - Which dose metric ?
  - How to deal with background levels?
- Pragmatic approaches needed for local occupational measurements

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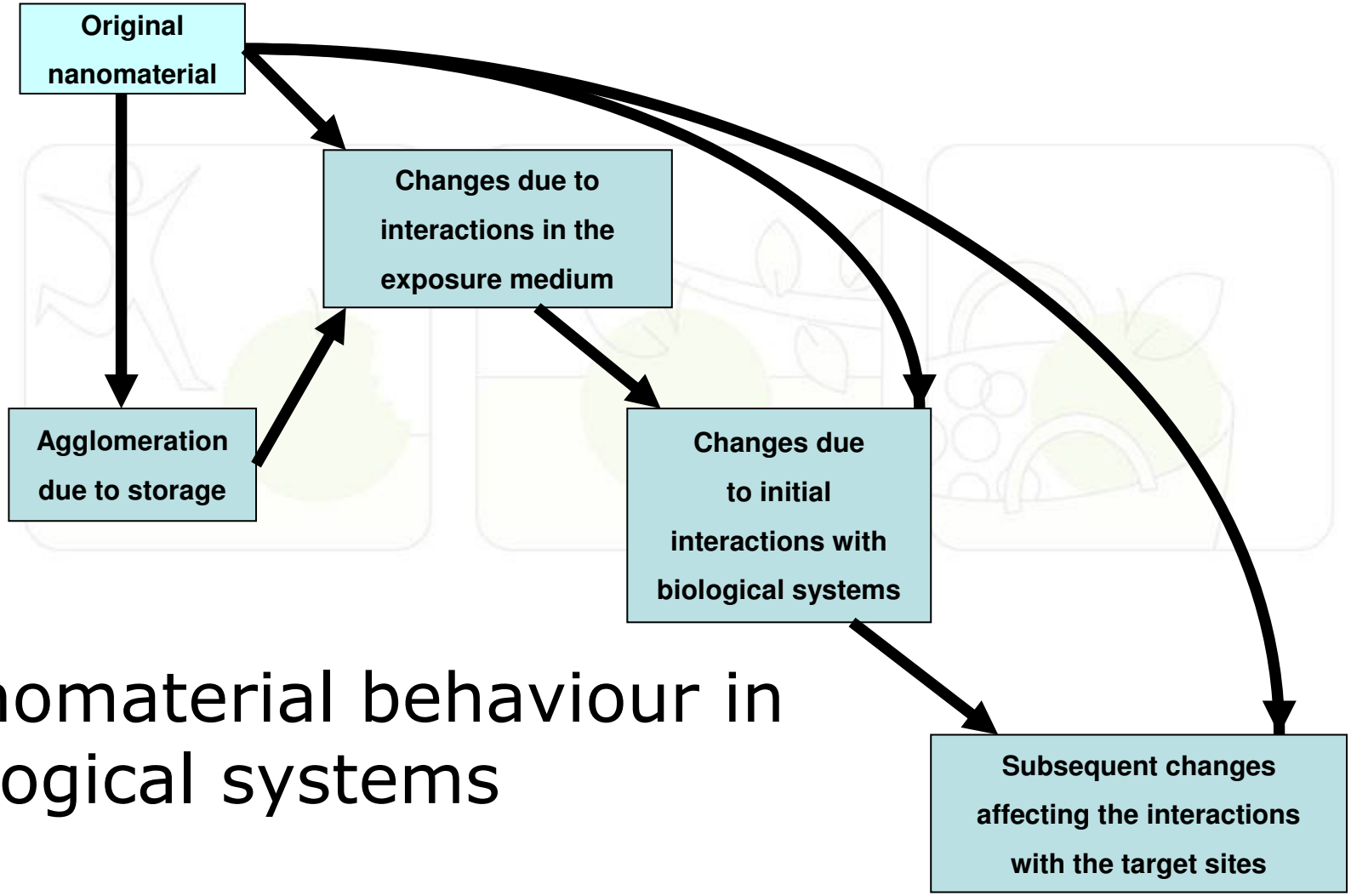
Current understanding - 3



Nanomaterial behaviour in biological systems

Current understanding - 4

- NM behaviour affects biological response
  - Protein adherence, specific receptors,
    - Mechanisms aimed at removal of particles from the body
    - Important for transport across biological barriers
  - Protein fibrillation
    - NM translocation nose-brain: amyloid plaque formation? Alzheimer's?

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Current understanding - 5

- Toxicokinetics
  - Found in brain, kidney, heart, lung, testes
  - Minimal translocation from lung / gut (<1wt%) but could still mean high particle numbers!
  - Main target organs liver and spleen but smaller NM can have wider distribution
  - Coating plays an important role (e.g. can prolong time spent in blood circulation)
  - Trojan horse function?
  - Inadvertent overdosing due increased bioavailability (food supplements)
  - Specific MW-CNT (L>20 µm, rigid, persistent) induce asbestos-like inflammation

Current understanding - 6

- Genotoxicity
  - Contradictory results obtained (pos vs negative for ENM and between asssays)
- Cardiovascular effects
  - Epidemiological association ultrafine particles and cardiovascular disease
  - Various NM for drug delivery showed no or minimal effects on platelet function

Current understanding - 7

- Environmental exposure
  - No info yet on concentrations of ENM in environmental compartments
  - Lack of methods to discriminate between natural and engineered NM
  - Metrics still under discussion
- Ecotox
  - Toxicity of some NM detected in a variety of environmental species

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Remaining issues - 1

- No generally applicable paradigm for NM hazard identification,

Therefore

- Case-by-case approach recommended

Remaining issues - 2

- Large need for new data
- Calls for definitions
  - Not based on a single parameter (size, SSA…)
  - Broad vs narrow
  - Decision trees?
- Data sharing
  - Based on the REACH requirements?
  - Additional specific nano requirements?

Remaining issues - 3

- 14 nanomaterials seem to be of main industrial interest today
- Should RA be tailored to these cases?
- As many nanomaterials as production batches?
- Lots of info needed from Industry
- Detailed characterisation is crucial!

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Way forward - 1

- Nanohearing (September 10, 2009)
- How to move forward on RA?
- We know how to formulate the questions
- Strong needs for methodology
- Need to share databases/data quality
- Vital to share information!
- Strong fundamental research programme for RA needed

Way forward - 2

- 3rd Nano Safety for Success Dialogue
  - 3-4 November, 2009
- Focus on case studies
- Lessons?
- Desire to move on in a pragmatic way
- Can risk reduction measures be taken before the full knowledge is available?
- How to apply the Precautionary Principle?

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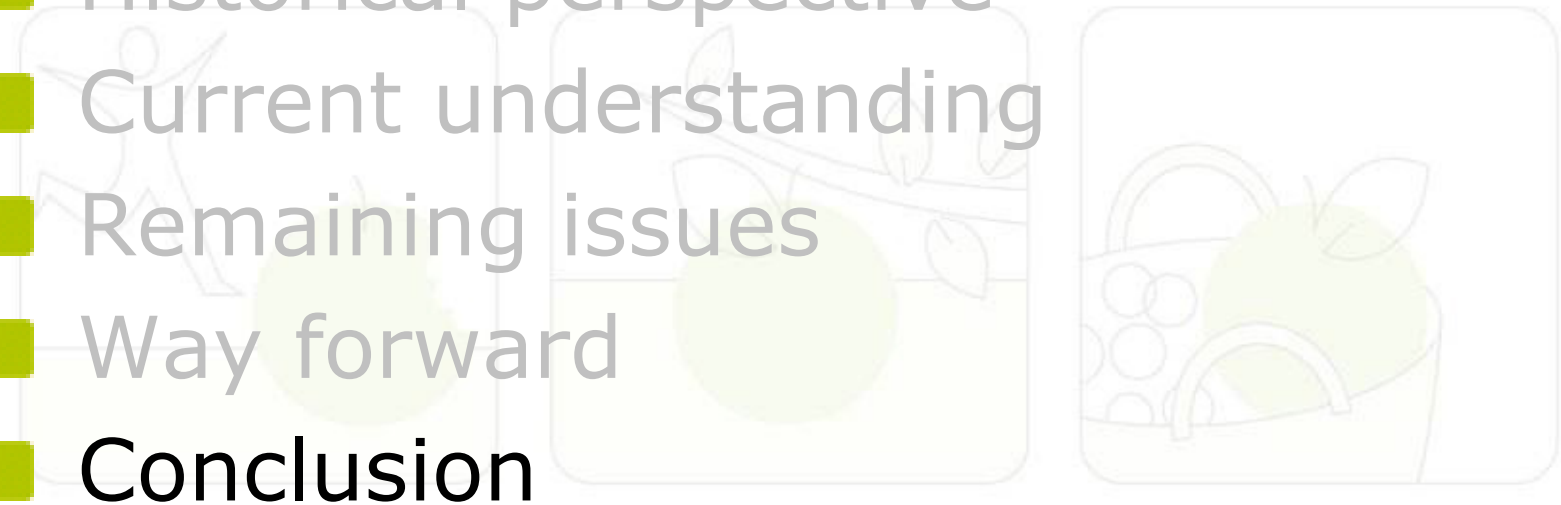

Conclusion

- Risk assessment of nanomaterials has made significant progress over the last 5 years
- Framework in place
- Many remaining knowledge gaps, so case-by-case approach recommended using substance specific data
- More data & information needed!
- Problems to solve, issues to address
  - Size thresholds
  - Production levels
  - Dose metrics and dose responses
  - Functionalization of surfaces

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Thank you!

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