

A Framework for Risk-Informed Assessments of Nanomaterials

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International Congress of Nanotechnology
November 2, 2005
San Francisco, California

Overview

- Why be concerned about nanoscale material impacts?
- The importance of addressing risks now
- Risk assessment: Its not just hazards
- Assessing risks of nanoscale materials
- Adaptive decision making framework

Why be concerned about nanomaterial impacts?

- Novel properties
- History dictates action
- Technology advancing quickly
- Paucity of information
- Potential for wide dispersion in the environment amidst uncertainty
- No standards - yet!



Source: K. Thompson, 2004.

Commercial Development of Nanotechnology

Benefits from Risk Assessment

Risk assessment:

- Will be the basis for regulatory decision making
- Allows decision making under uncertainty
- Keeps pace with technology
- Prioritizes research directions
- Identifies areas for product innovation
- Reduces potential for unforeseen impacts

Assessing risks of nanoscale materials

- Identify and characterize hazards
- Assess exposure potential
- Evaluate toxicity
- Characterize risk
- Communicate about risks

Differentiating hazards from risks

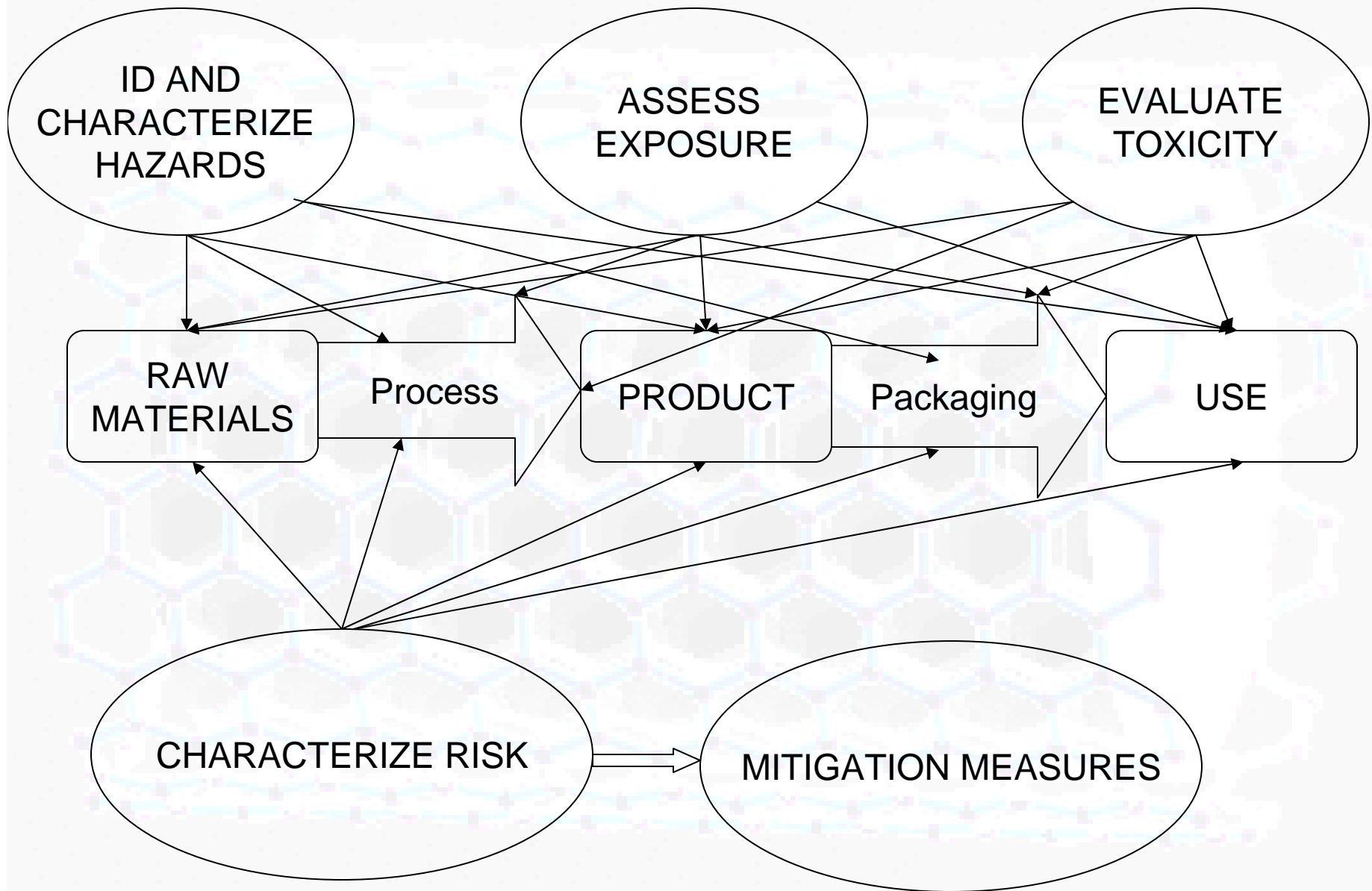
- All materials are toxic at some concentration
- There is no risk if there is no exposure
- Risk = hazard * exposure probability

Adaptive decision framework

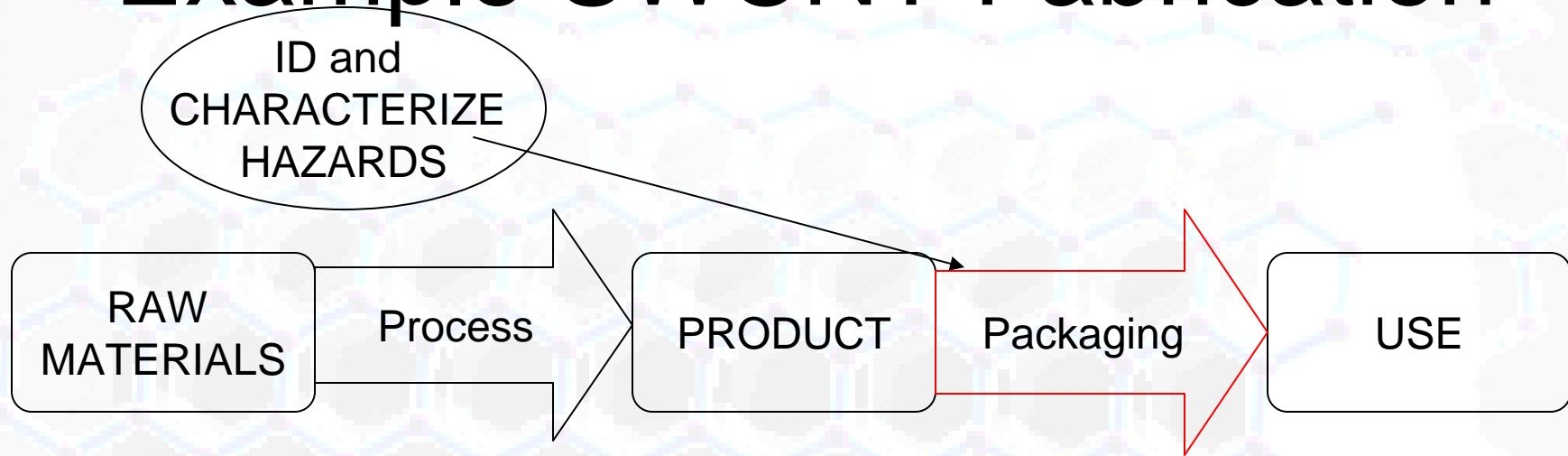
- A screening tool to identify and prioritize key health and process issues
- Dynamic approach applies broadly to array of hazards
- Identifies key uncertainties
- Revisits early decisions with new information
- Applies to health and safety concerns

Adaptive decision framework

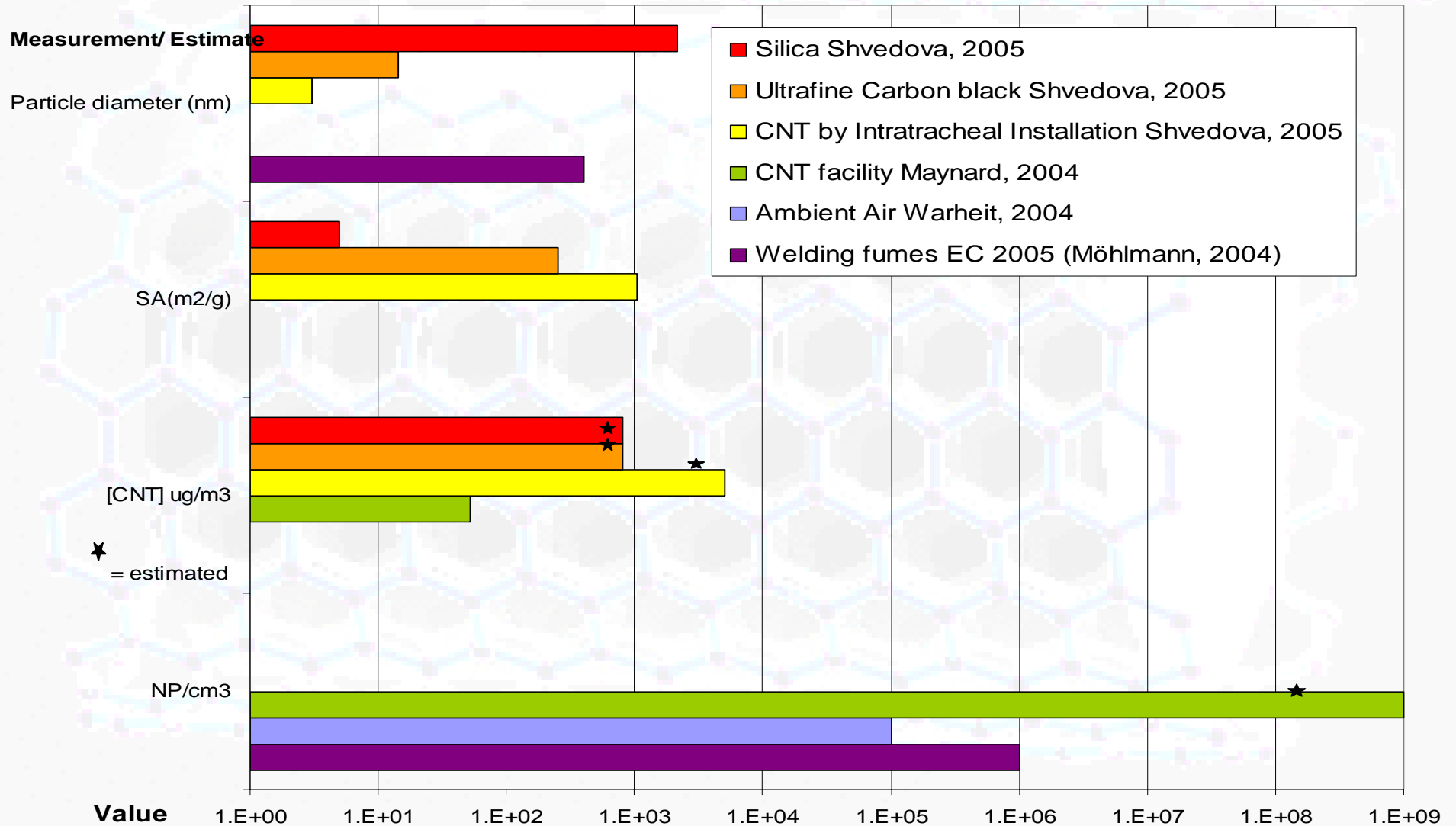
- Steps sequentially across processes through product or lifecycle
- Evaluates risk at each step
- Focuses on exposure potential
- Transparent decision framework allows comparison of different products and processes amidst uncertainty
- Proactive approach for evaluating safety of novel materials



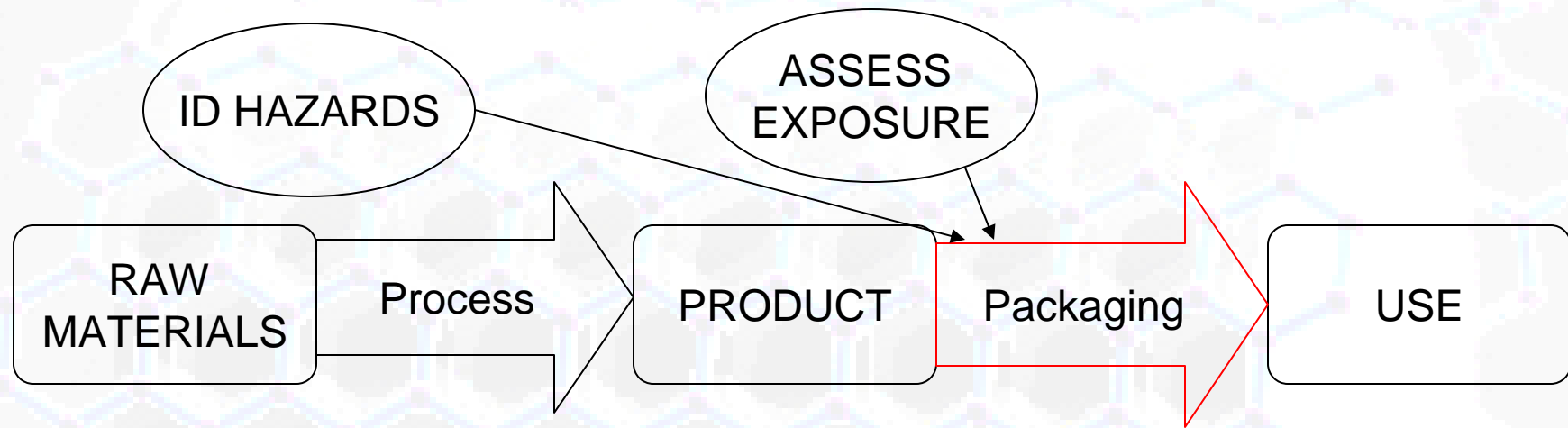
Example SWCNT Fabrication



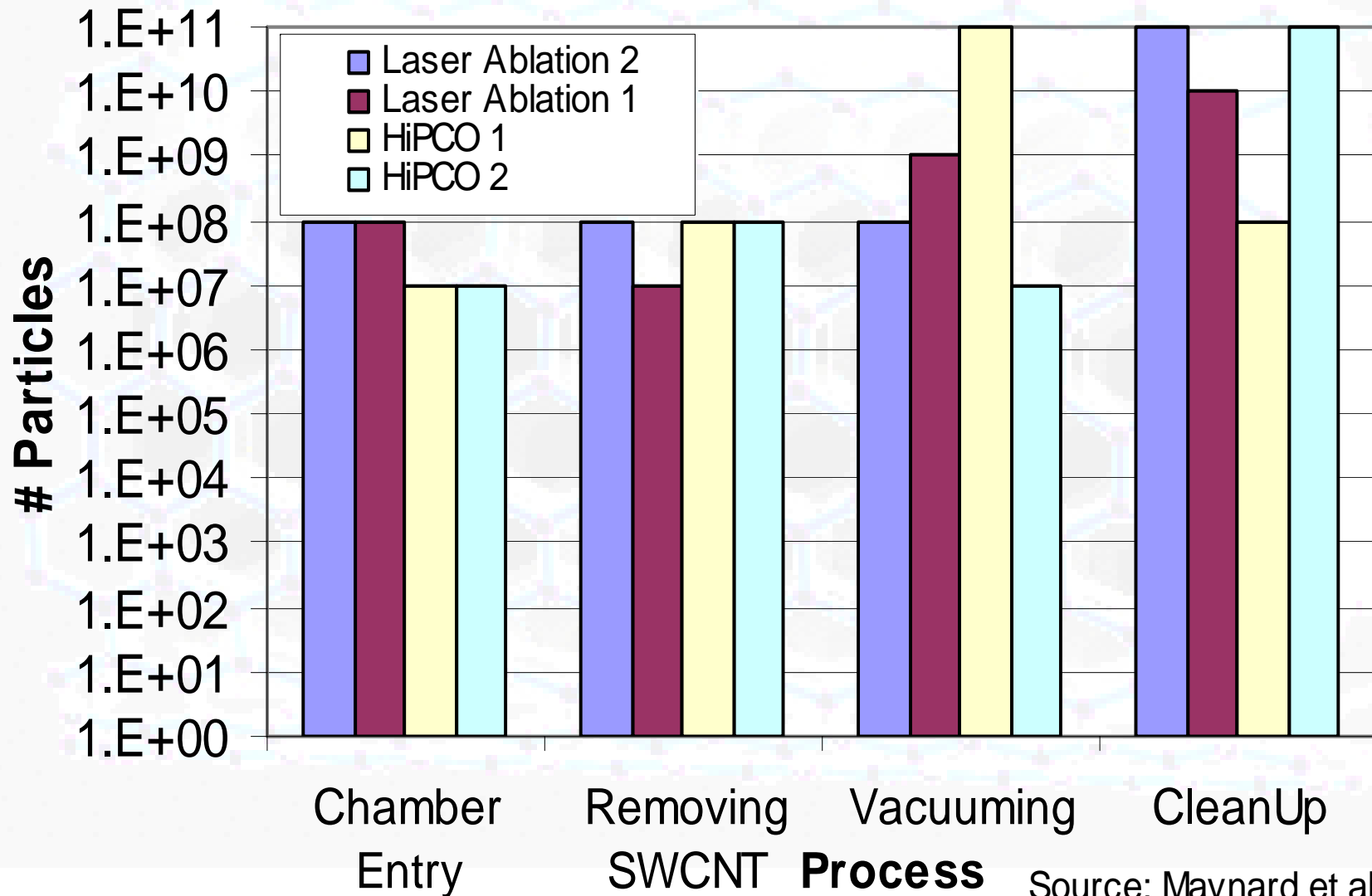
Nanoparticle Characterization Across Studies



Example SWCNT Fabrication

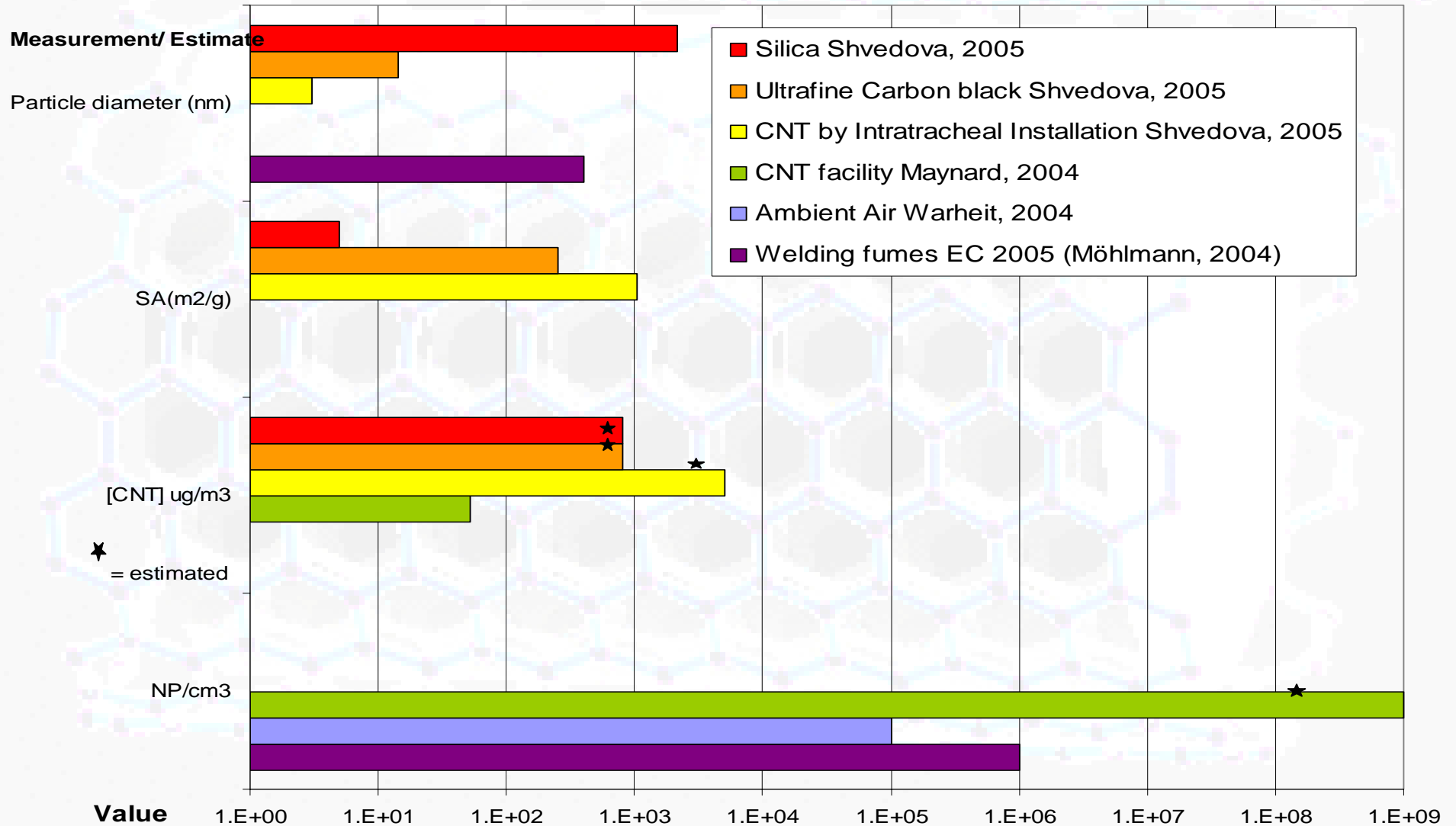


Exposure Measures of SWCNT (Particles/m3)

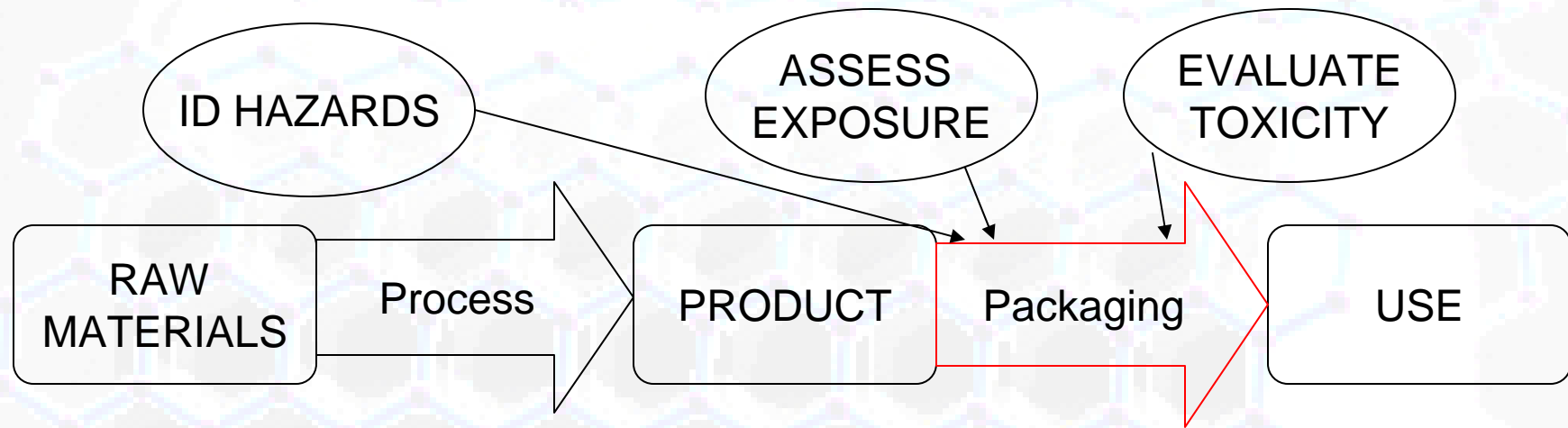


Source: Maynard et al. 2004

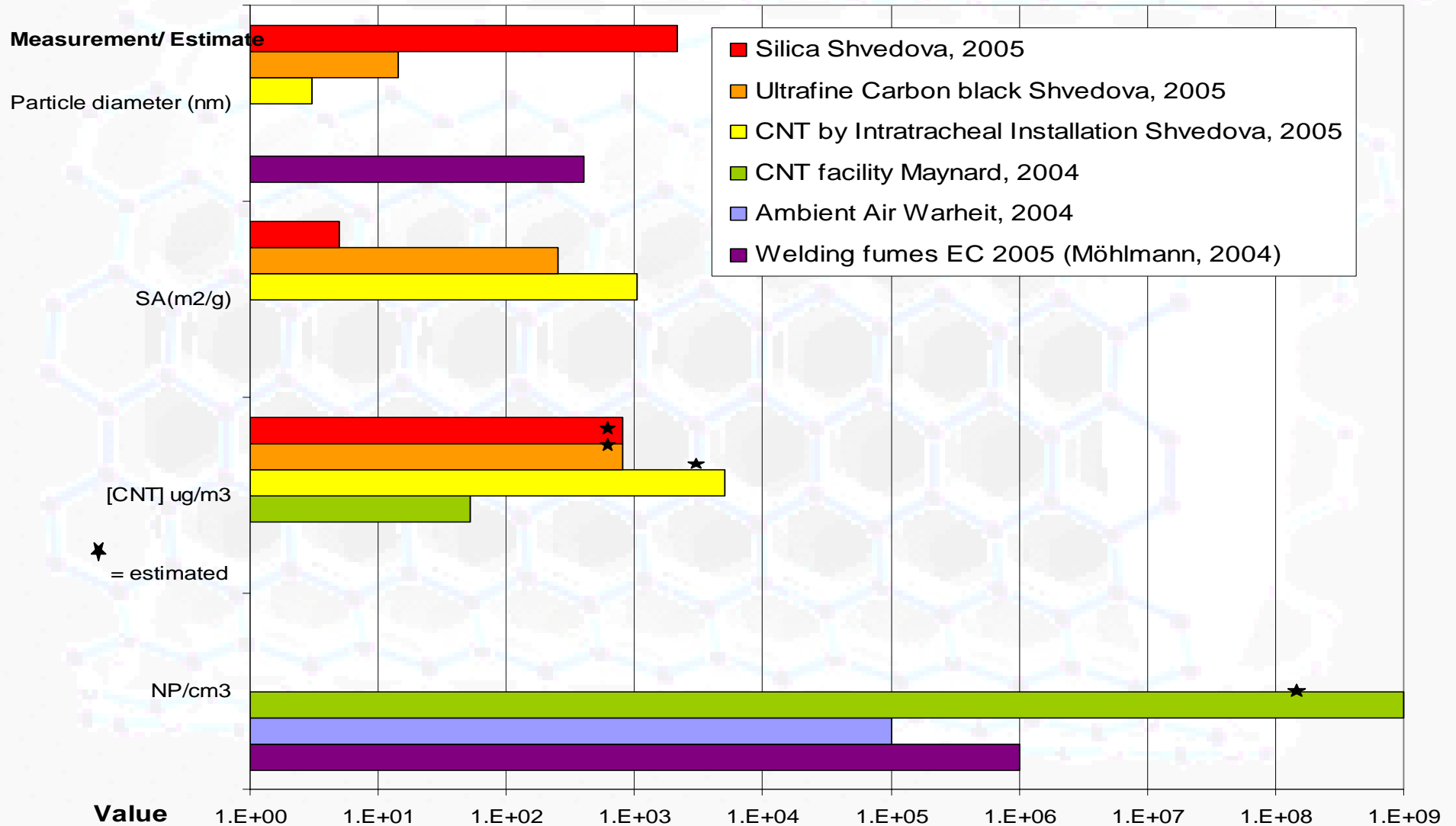
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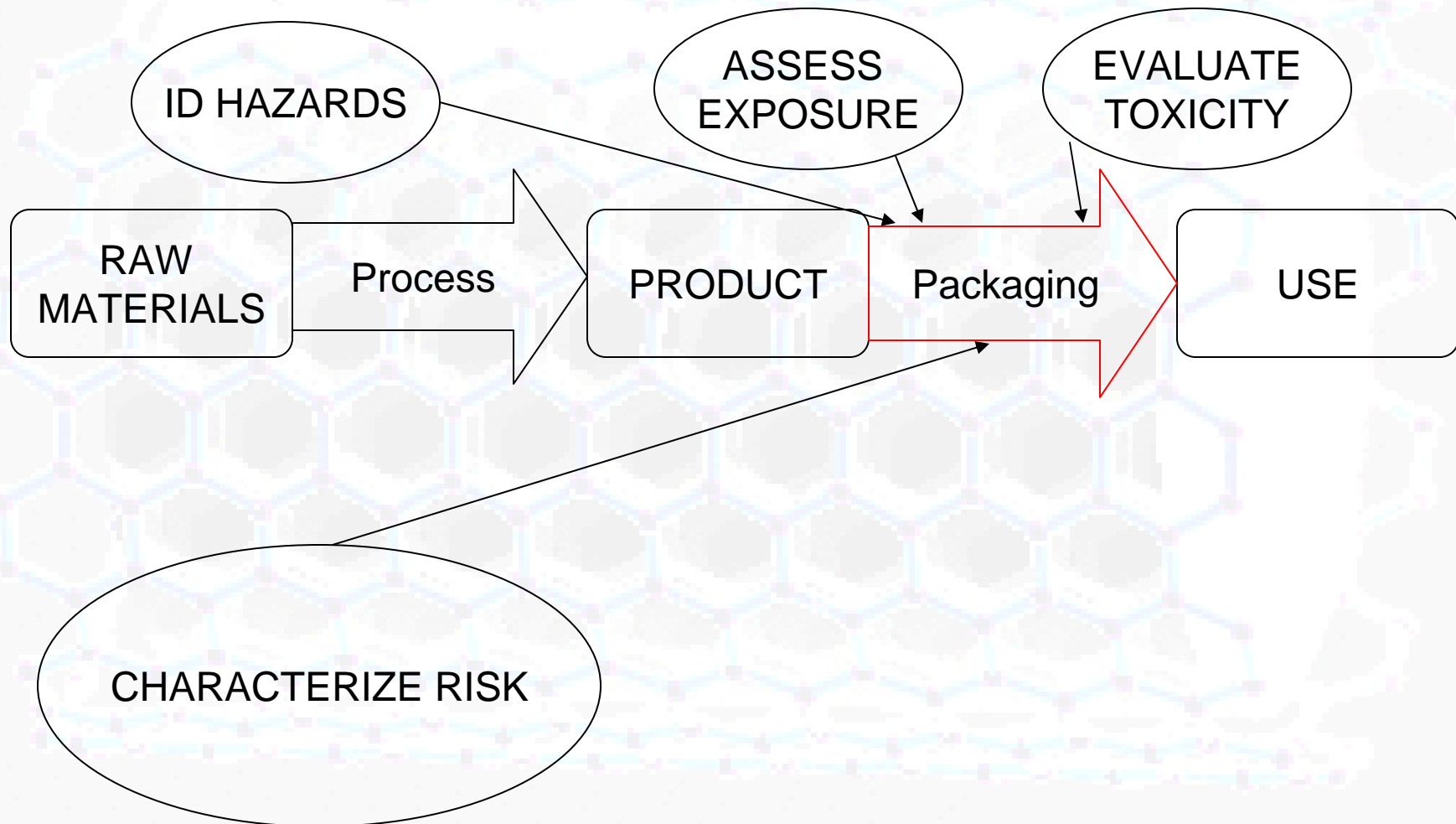
Example SWCNT Fabrication



Nanoparticle Characterization Across Studies



Example SWCNT Fabrication



Example: SWCNT

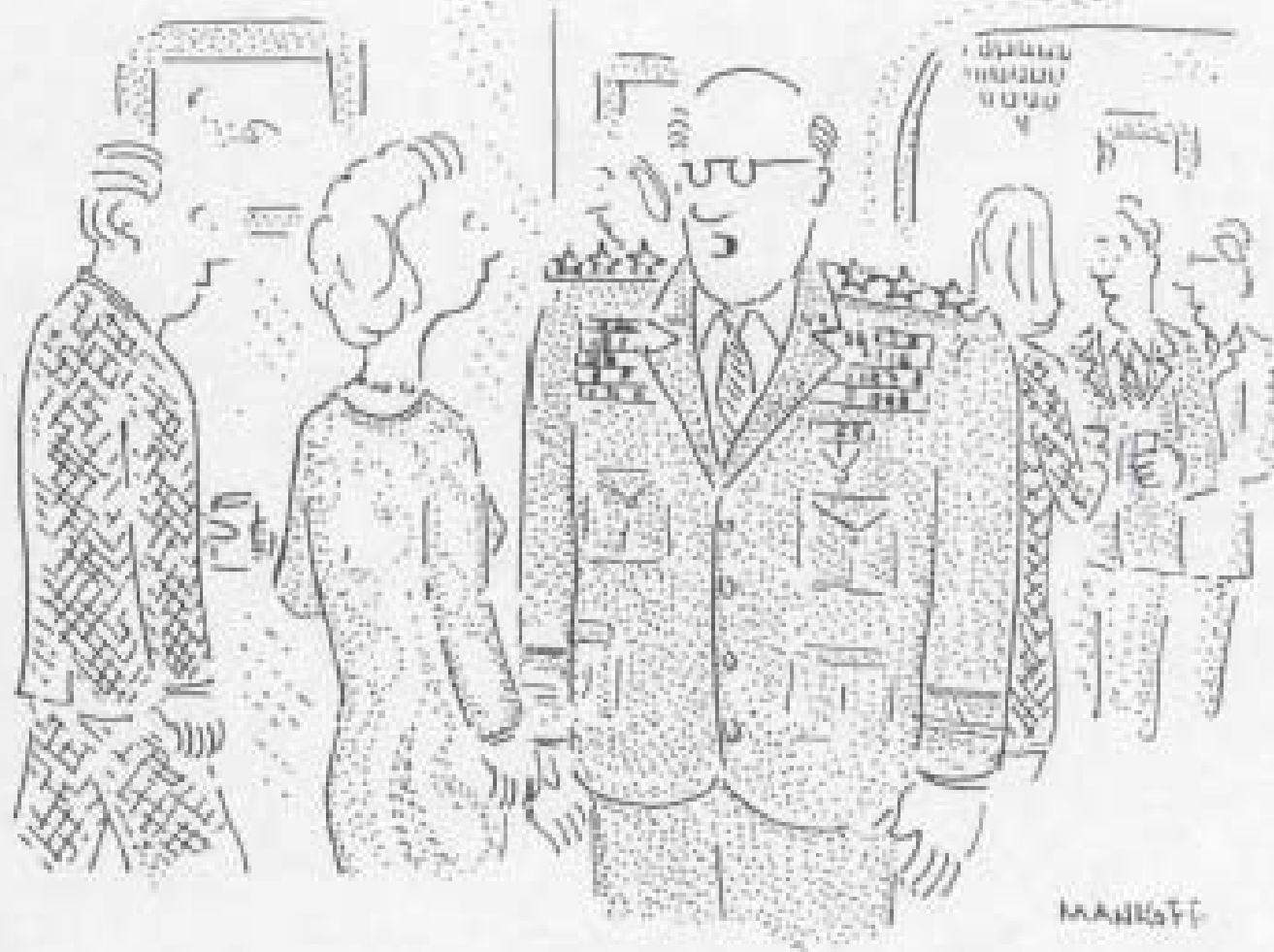
Single Walled Carbon Nanotubes; packaging

Hazard ID: particle diameter, surface area, particle number, concentration.

Exposure Assessment: post production handling personal air sample concentrations ranged from 0.001 -0.052 mg/m³ (Maynard et al., 2004)

Toxicity Evaluation: inflammatory responses in lung following intratracheal administration at doses approaching OSHA standard for graphite (5 mg/m³) (Shvedova et al., 2005), but vastly different particle numbers

Risk Characterization: toxic responses possible, exposures appear to be orders of magnitude lower; much uncertainty over exposure and toxicity in realm of interest.



"Look, I'd like to avoid overkill, but not at the risk of underkill."

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Source: K. Thompson, 2004.