BASF EH&S Experience Using Nanomaterials

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20 nm

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Questions of interest

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- What are the EH&S challenges/solutions?
- How does material and product safety figure into the business model?
- How do we deal with the unknown?
- How do we view regulatory possibilities regarding nanotech and EH&S aspects?

Self-commitment in the absence of regulation: Code of Conduct

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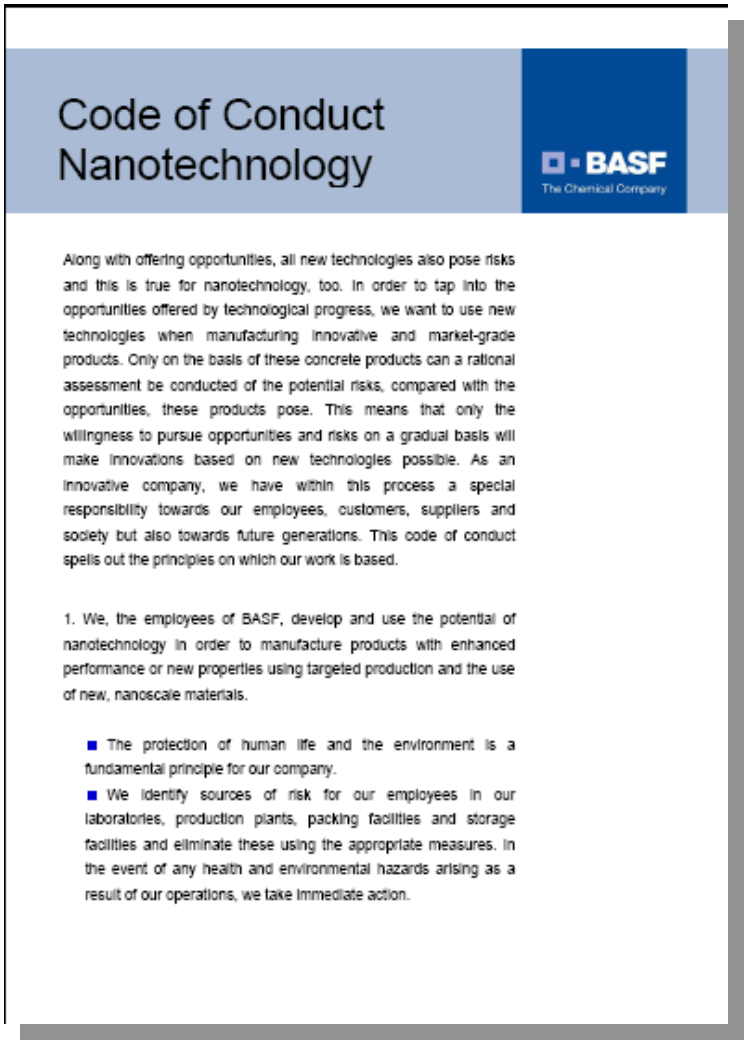
- The Code of Conduct is a voluntary commitment to responsible action based on our Values & Principles:
  - protection of employees, customers and business partners
  - protection of the environment
  - participation in safety research
  - commitment to open communication and dialogue

The Code of Conduct gives guidance to all employees worldwide. It is published on the internet at: www.basf.de/dialogue-nanotechnology



Code of Conduct Nanotechnology

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Along with offering opportunities, all new technologies also pose risks and this is true for nanotechnology, too. In order to tap into the opportunities offered by technological progress, we want to use new technologies when manufacturing innovative and market-grade products. Only on the basis of these concrete products can a rational assessment be conducted of the potential risks, compared with the opportunities, these products pose. This means that only the willingness to pursue opportunities and risks on a gradual basis will make innovations based on new technologies possible. As an innovative company, we have within this process a special responsibility towards our employees, customers, suppliers and society but also towards future generations. This code of conduct spells out the principles on which our work is based.

1. We, the employees of BASF, develop and use the potential of nanotechnology in order to manufacture products with enhanced performance or new properties using targeted production and the use of new, nanoscale materials.

- The protection of human life and the environment is a fundamental principle for our company.
- We identify sources of risk for our employees in our laboratories, production plants, packing facilities and storage facilities and eliminate these using the appropriate measures. In the event of any health and environmental hazards arising as a result of our operations, we take immediate action.

BASF Governance – self governance

Global Directive provides guidance on

- product information management
- hazard assessment and risk characterization
- risk management and communication throughout the value chain
- public communication

These apply to all chemicals, but nanotechnology is highlighted.

Structure and Decision Process for Nanotechnology use in BASF

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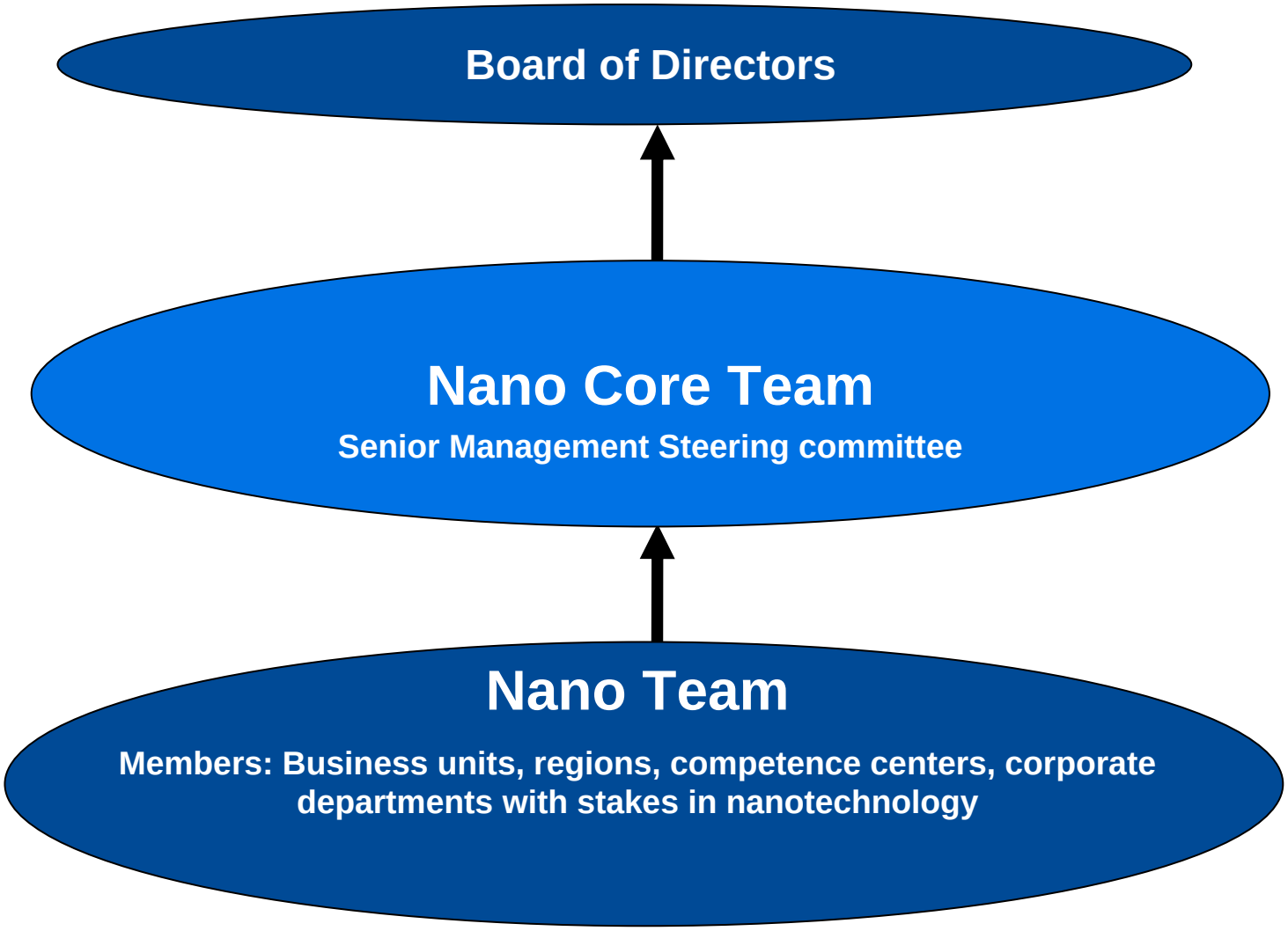
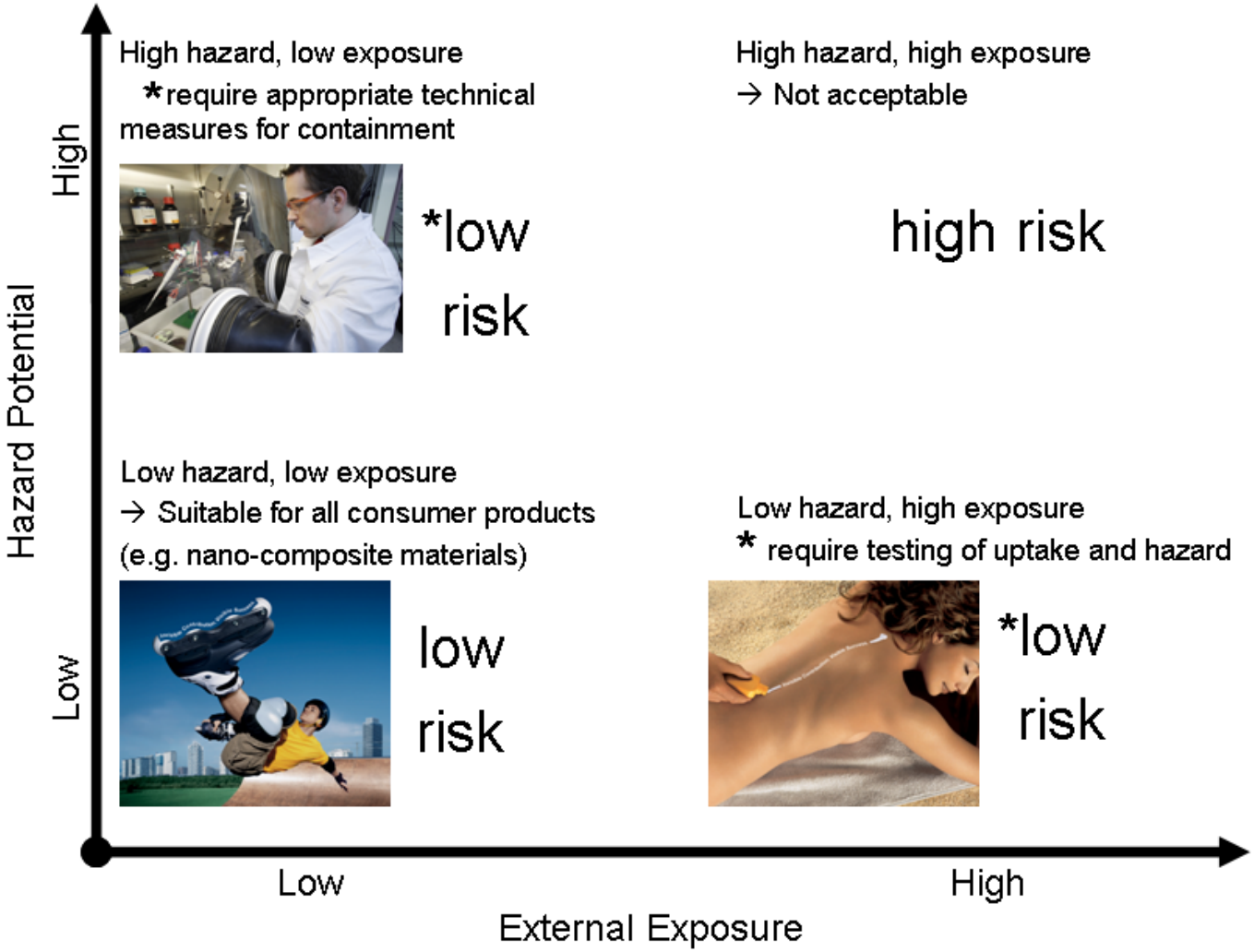
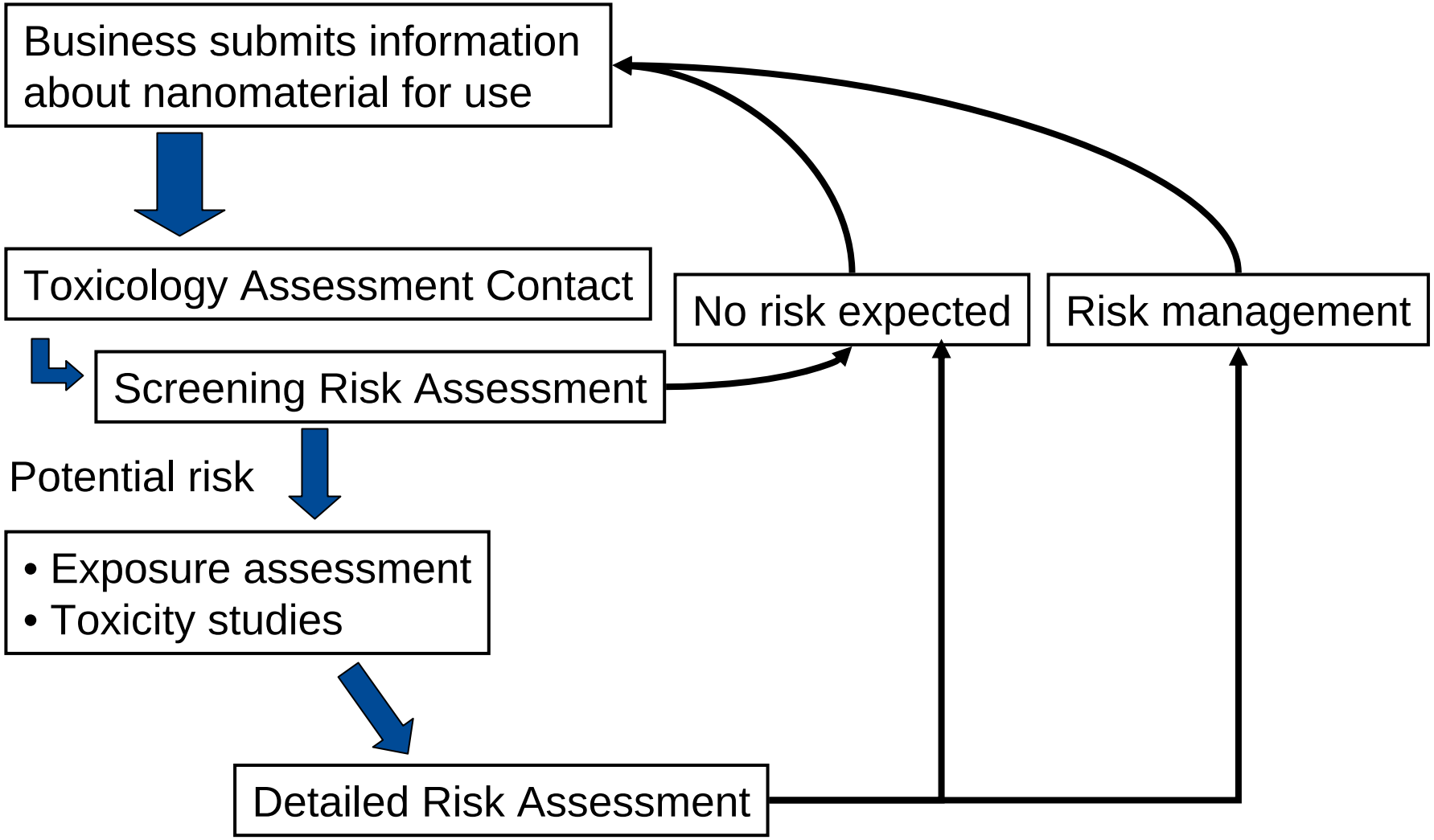


Safety of nanomaterials: Differentiate the hazards from the risks.

Need to differentiate exposure by nanocomposites from nanoparticles



Assessment process



BASF approach to Safety Testing – identifying the hazards

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- **Testing scheme based on a combination of appropriate tests and realistic approaches.**
- **Assessment of potential toxicity / hazard**
  - Inhalation (i.e. short-term inhalation test)
  - Dermal penetration
  - Genotoxicity
  - Aquatic toxicity
  - Interpolation using “family approach”
- All include characterization of the neat particle and in the medium.

Hazard assessment – validating the methods in absence of guidance

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Skin	Penetration of nanomaterials through skin
Lung	Uptake and effects of nanomaterials in the lung
Biokinetics	Distribution and excretion
Genotoxicity	Interaction of nanomaterials with DNA
Environment	Distribution and effects of nanomaterials in (aquatic) environment
Test methods	Which test systems are suitable for (regulatory) testing of nanomaterials?

Exposure assessment: for consumers

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- **Dermal exposure:** dermal penetration studies of TiO_2 and ZnO conducted using in vitro test systems such as fresh pig skin and sunburned skin pig skin. Penetration beyond the stratum corneum was not observed.
  - Nearly all the ZnO was recovered in the top 5 tape-stripped layers associated with stratum corneum of pig skin. A small amount was associated with hair follicles. Most TiO2 was washed off the surface.
  - Skin of weanling pigs exposed in vivo to UVB that resulted in moderate erythema. Dermatomed skin samples placed in flow-through cells. Treatment of skin samples with 2 formulations (o/w, w/o) containing 10% TiO_2 (agglomerates 90 - 460 nm), skin samples perfused for 24 hrs.
- **Inhalation exposure:** release of CNTs from polymeric composites not observed following abrasion.

Exposure assessment: for workers

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- **Matrix 1 – inventory** (source/owner: product stewards)**:**
  - product name, chemical identity, particle size distribution
  - affected division, production site and plant, number of affected employees
  - dependant on definition
- **Matrix 2 – registry** (source: plant managers; owner: medical dept)**:**
  - medical history and findings from previous medical examinations. Subject to strict medical confidentiality. No surveillance initiated until clear criteria and endpoints identified.
- **Matrix 3 – exposure data** (source/owner: industrial hygiene/occupational safety)**:**
  - qualitative data: affected production plant, work area and operation
  - exposure data
    - particle concentration and size distribution in the nanoscale and in the microscopic range during operation compared to background
    - chemical identity of captured material

Timeline for developing a Registry

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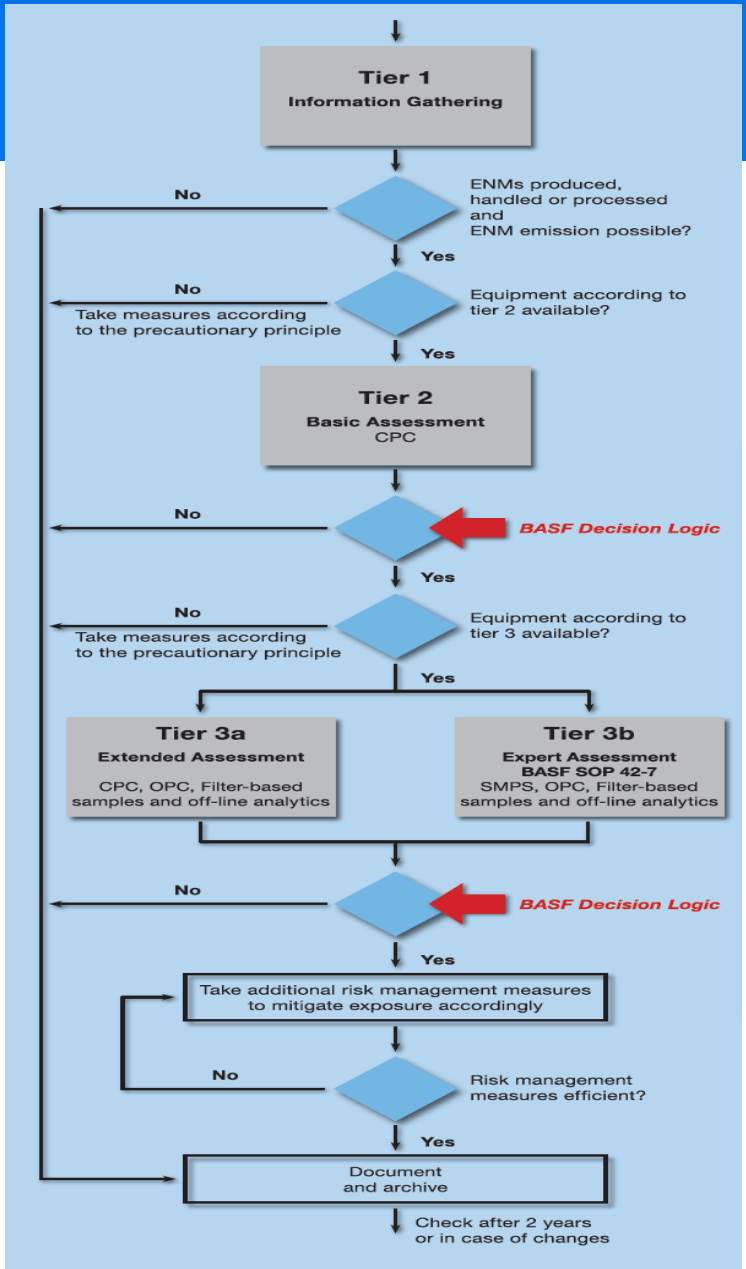
- 10/2008 — kick-off of the global project team
- 02/2009 — matrix 1: start the survey according to BASF definition
- 01/2009 — agree on
  - the structure of the registry
  - the data to be collected
- 08/2009 — matrix 3: draft exposure assessment strategy available
- 01/2010 — matrix 1: candidate list available
- 02/2010 — matrix 2: registry request distributed
- 03/2010 — matrix 1: review of the survey using German Chemical Industry definition
- 06/2010
- 12/2010

Tiered-Type Approach to Exposure Assessment



- Tier 1: Information Gathering
- Tier 2: Basic Assessment using Condensation Particle Counter
- Tier 3: Extended and Expert Assessment using Scanning Mobility Particle Sizer, Optical Particle Counter

Decision points:

- Substance Specific TLV
- BASF Intervention Value
  - Significant increase over background
  - Chemical Identity

Information to workers

- **Internal EH&S website**
  - Definition
  - “GoodNanoGuide” link
  - Guidance to identify nanomaterials
  - Safe handling procedures
  - Presentation on what workers need to know
- **MSDS – under construction**
  - Nano-objects, agglomerates, and composites identified along with likelihood of exposure.
  - Safety procedures and PPE stated.
  - Consistent with current ISO draft documents.

BASF Safe Handling Procedures

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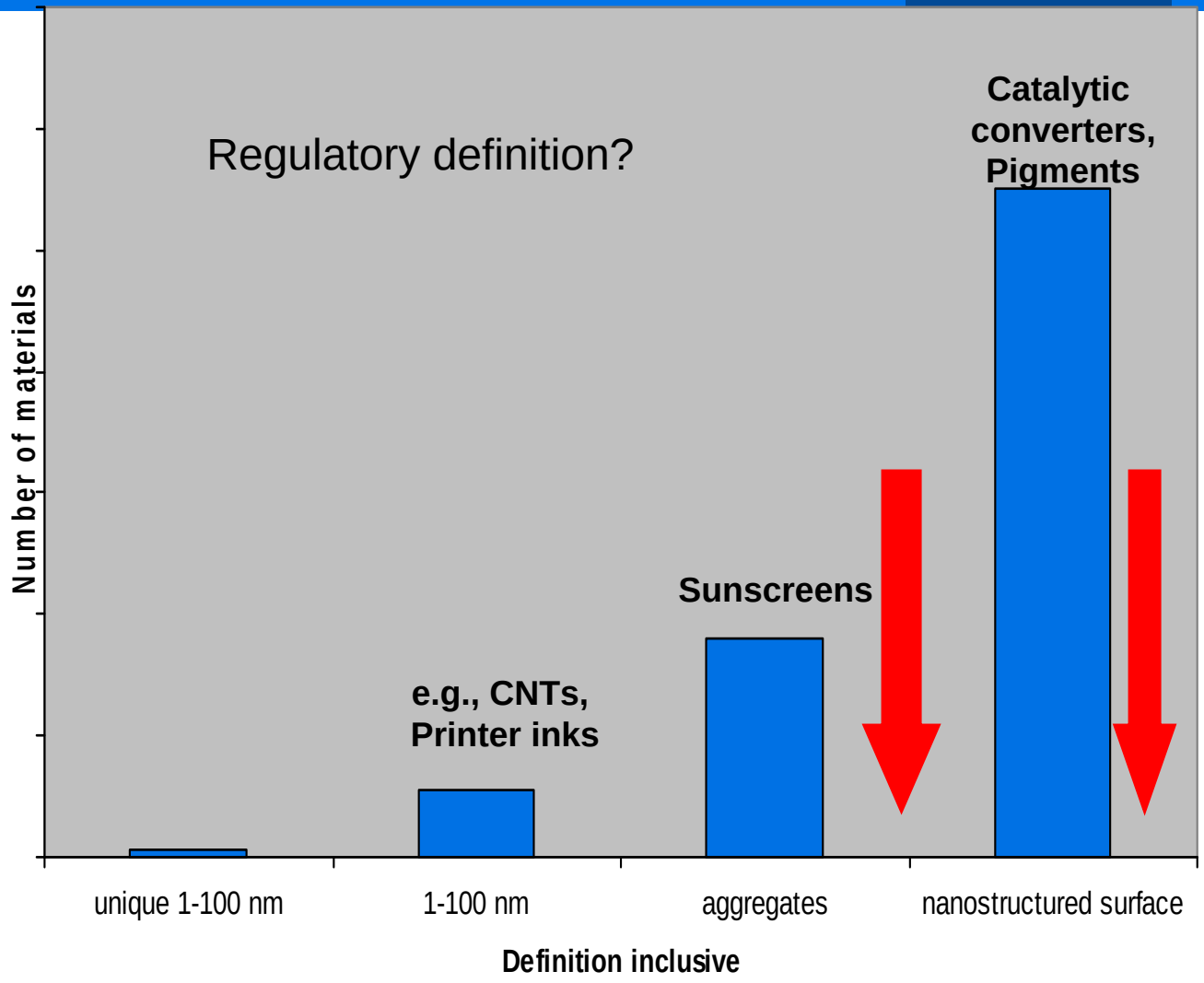
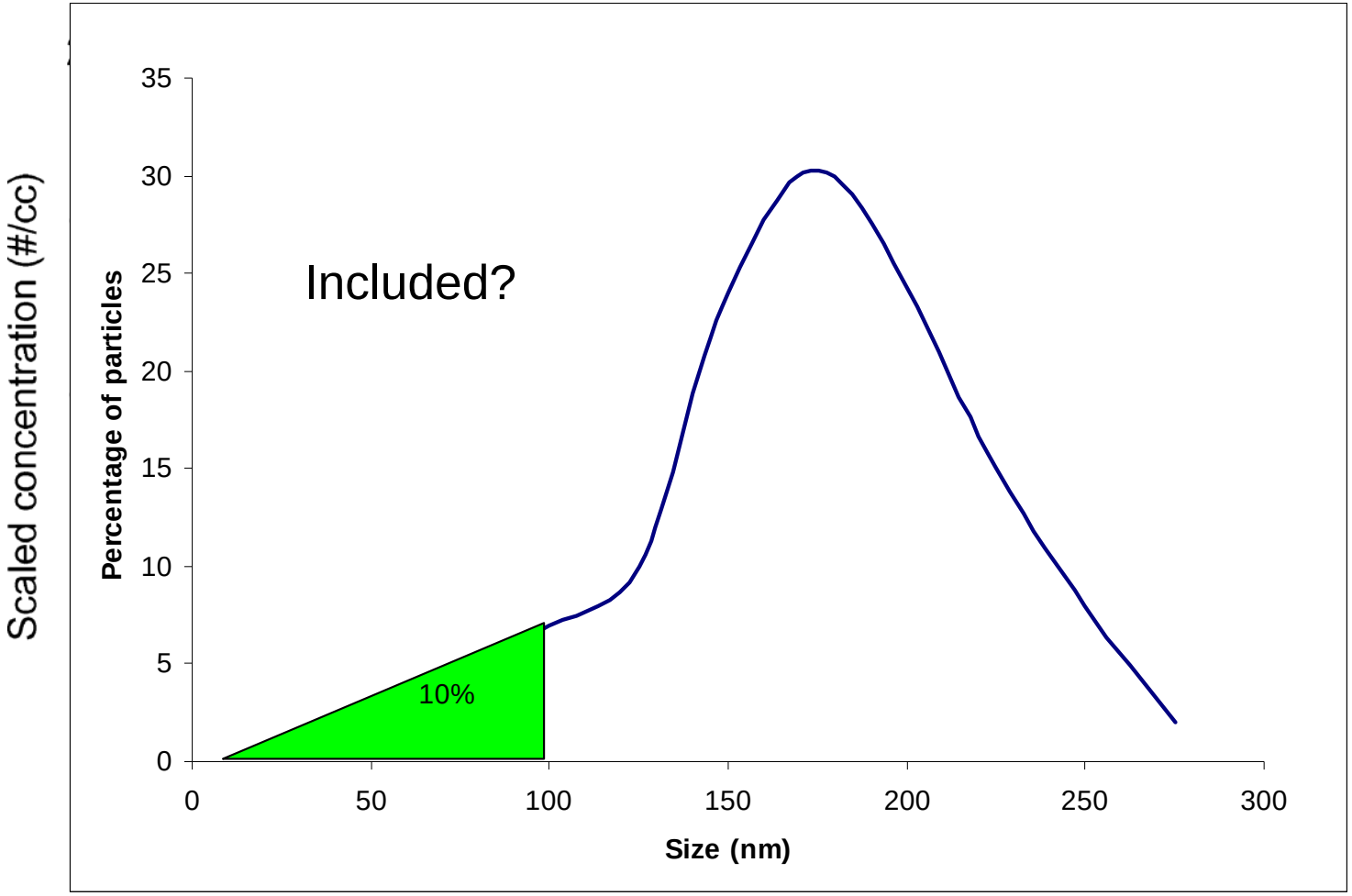
- The inhalation of nanoparticle dust can represent a health hazard. Inhalation exposure should therefore be ruled out by taking suitable protective measures.
- The health risk associated with dermal exposure to nanoparticle dust is currently estimated as low. In activities involving working materials, dermal exposure should be prevented by taking suitable protective measures in accordance with the applicable safety standards.
- Exposure to nanoparticles is prevented mainly through engineering controls and, if required, by procedural and personal protective measures.
- As much as possible, nanoparticles are manufactured and used in closed systems.
- If working steps involving potential emission of nanoparticles are necessary that cannot be performed within closed systems, technical and procedural measures to reduce dust formation are additionally taken.
- Working areas potentially subject to nanoparticle emissions are monitored by workplace or exposure measurement.

Challenges

- **Definition:** A common understanding of what will qualify a material as being a nano-material has not yet been established.



Challenges



From Lee et al, 2005

Challenges

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- **Raw Materials:**
  - Raw materials are not yet explicitly identified in practice.
- **Analytical Methods:**
  - The relevant metric to be assessed at the workplace is still under discussion.
  - Various exposure assessment methodologies are available. Regrettably, most of them have not yet been standardized and their validation requires profound expertise and substantial effort.
- **Guidance Documents:**
  - Commonly accepted Technical Guidance Documents for exposure assessment have not yet been established.

Challenges

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- **Global Interdisciplinary Team:**
  - A global interdisciplinary team established:
    - industrial hygiene
    - product stewardship
    - occupational medicine
    - metrology
    - production
  - A harmonized approach and training applicable for all regional organizations.
- **IT Infrastructure:**
  - A suitable, globally applicable IT infrastructure for archiving has to be established.
  - A process for updating the inventory on a regular basis has to be defined.
  - A process to “tag” raw materials as “nano” in SAP.

Unknowns

- **Waste treatment** – regulatory agencies have indicated that the environmental fate of nanomaterials, especially in consumer products, is a question.
  - Most large companies (including BASF) have private treatment facilities.
- **MSDS** – what information to add in the absence of regulatory guidance or standardization.
  - BASF continues to add nano-specific phrases to MSDS
- **OEL** – what exposure levels are acceptable in the absence of regulatory guidance
  - BASF developing a strategy and participating in governmental activity

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Answers

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- BASF recognized the need for safety information, workplace practices, and business practices for success. The company instituted governance to address these needs. Challenge is global harmonization both internal and external.
- Product development focused on use of nanomaterials in a way that presents the least risk to the worker and consumer.
- Large companies have experience dealing with unknown hazards. In the unknown regulatory environment, BASF establishing its own internal policies.
- BASF looks for reasonable, consistent regulation of nanomaterials and nano-enabled products that take into account the real risks. We look to work with regulators in developing these regulations.