Implementation of Safe-by-Design thinking into manufacturing and use of products containing nanomaterials

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Background

- To date, notable effort has been put into research activities related to nanomaterial safety at global, EU and national level.
- Comprehensive risk assessment of various products containing nanomaterials in still missing in many industrial areas.
  - Requirement of case-by-case assessment
- The solution is to pro-actively take into account the potential risks of nanomaterials and ensure their safety over the whole value chain, already at the early stages of product development.

➢ Basis of safe-by-design thinking.

The concept of Safe-by-Design

- OECD definition (still under development):
  - The SbD concept refers to **identifying** the risks and uncertainties concerning the human and environmental safety of an innovation and then **eliminating** or **reducing** the **hazard** or **controlling** the **exposure**, starting at an appropriately **early phase** of the innovation process.
  - The SbD approach addresses the safety of the **whole life cycle** or **value chain** of an innovation
- The SbD concept is based on three pillars:
  1. Safer products
  2. Safer production / processing
  3. Safer use
- SbD targets at an acceptable balance between safety, functionality and costs, while meeting any applicable requirements for safety.

Risk = Hazard x Exposure

Safe Innovation approach (SIA)

- SIA combines SbD approach with regulatory preparedness
- Regulatory preparedness
  - Timely awareness of innovations and whether present regulations cover all aspects of innovations
  - Aims to improve the foresight of regulators and to facilitate development of adaptable safety legislation
- A proactive approach of industry and regulators
  - Dialogue and information sharing between industry and regulators about safety information needs **early** in the innovation process
  - Awareness of regulators on innovations

SbD for cellulose nanomaterials

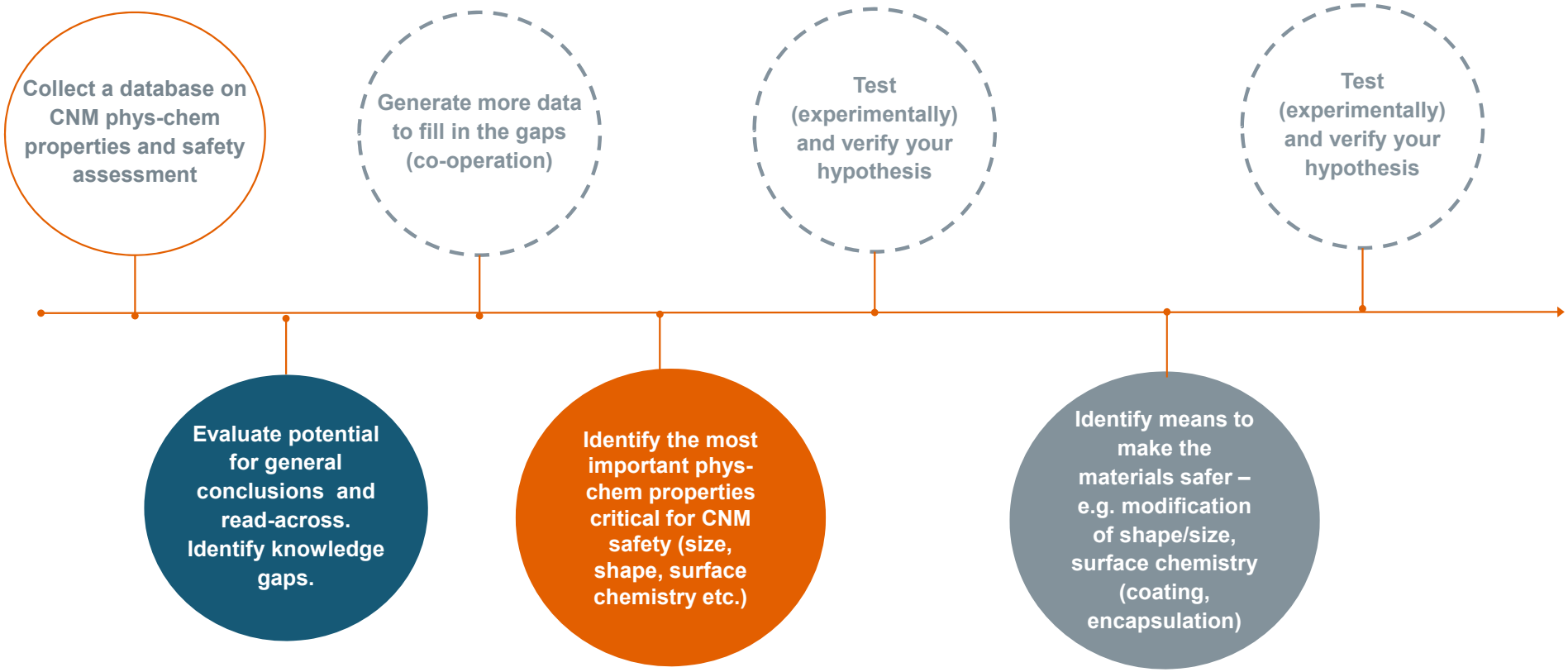
Pillar 1. Safer products - background

- Cellulose nanomaterials (CNM) do not present acute threat to human health or the environment
- However, some minor toxic effects have been reported
  - Dose-dependent toxicity
  - Inflammatory effects in the lungs as well as biodurability
  - Toxicity induced by chemical modification – surface chemistry
  - Raw material and dimension – dependent toxicity
  - Size and shape – Especially high aspect ratio nanomaterials (HARN)

➢ Therefore, we cannot state that they are generally non-toxic

➢ Still a lot of knowledge gaps and systematic view is missing e.g. on long-term effects

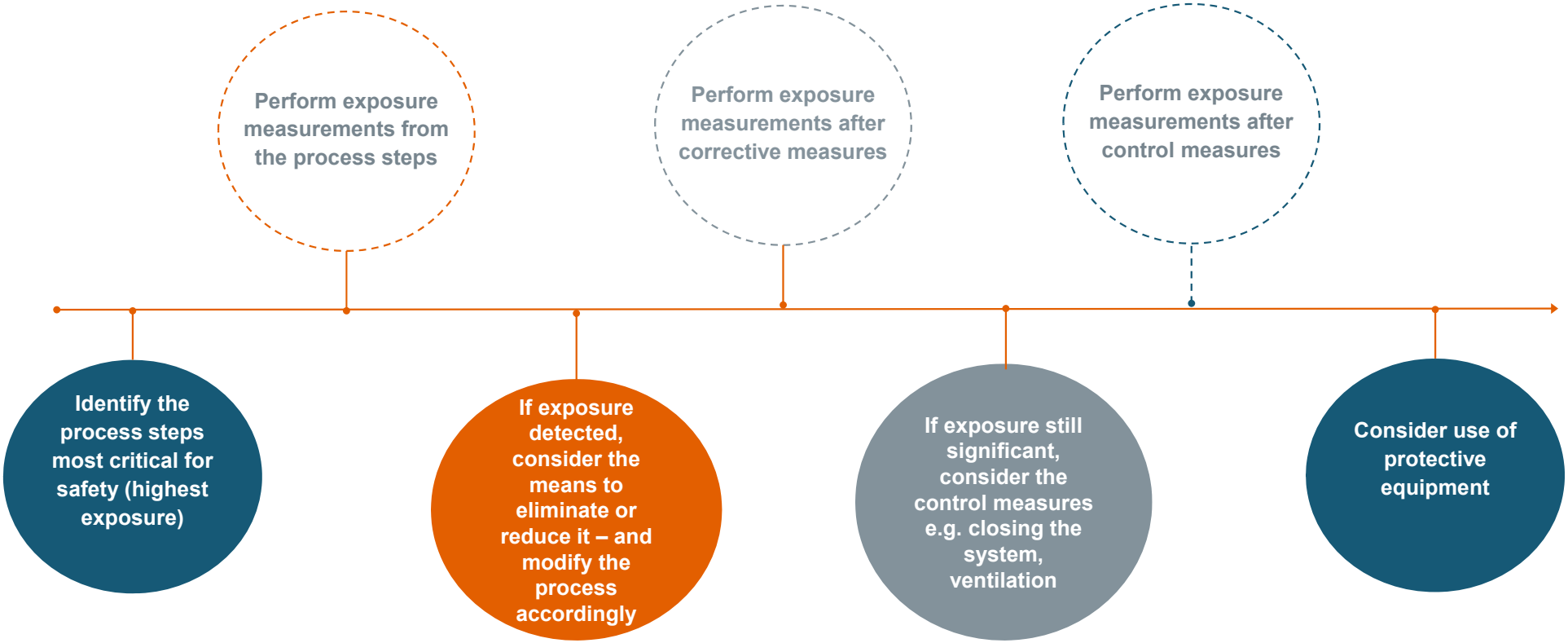
Pillar 1. Safer products – how to succeed?



Pillar 2: safer production & processing - background

- Limited amount of data on occupational exposure to CNMs available
  - Most likely to occur via skin or inhalation
  - Depends on the state of the material – dry or wet
  - Agglomeration likely to take place in the air resulting in micro-sized particles
  - Highest likelihood when unbound materials are handled (e.g. pouring, weighing) and finishing of the product (machining, drilling etc.)
- No information from industrial processes yet

Pillar 2: how to succeed?



Pillar 3: safer use - background

- Due to limited amount of products in the market, consumer / environmental exposure has not been studied in detail (at least no published results)
- Some products are more likely to release the nanomaterials into their surroundings than others
  - Products where CNM are strongly bound to the matrix material are less likely to release them

Pillar 3: safer use

Consider the behaviour of CNMs in the product – what is the potential risk?

Identify all the potential scenarios during the life cycle of the product – from the gate to end-of-life
Consider both human and environmental exposure

Perform exposure measurements (humans / environment) during the whole life cycle

Identify the scenarios with the highest risk for exposure

Consider the means to eliminate or reduce the exposure from the products – any feedback to material / product processing?

Advise consumers on the correct use and disposal of the product

Case example: Food contact material containing CNF

SbD evaluation for FCM containing CNF

- Pillar 1: Safer products
  - Not enough data on CNF phys-chem properties and toxicity to make general conclusions on the hazard of CNF
  - Indications (from the literature) that surface chemistry, shape and dimensions might be the most important properties to determine toxicity
  - Need to generate more data to verify
  - Need to consider means to modify the critical properties
- Pillar 2: Safer production & processing
  - The most critical process steps are related to the handling of loose CNF and when the material is still in the slurry form, for both internal and surface application
  - Exposure not known (no published data)
  - Process modification remains ?

SbD evaluation for FCM containing CNF - continued

- Pillar 3: Safer use
  - The highest potential risk during use is leaching of CNF into food
  - During end-of-life, leaching into soil (if composted) or accumulation into recycling systems and new materials (if recycled).
  - Performance of exposure measurements suffers from the lack of suitable analytical methods.
  - The situation in reality is not known – feedback or advice cannot be given at this stage.

Thank you

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