The concept of Safe and Sustainable by Design (SSbD) of Nanotechnology and its implementation in South Africa

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Definitions

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"The SbD concept refers to identifying the risks and uncertainties concerning humans and the environment at an early phase of the innovation process so as to minimize uncertainties, potential hazard(s), and/or exposure".

"The SbD approach addresses the safety of the material/product and associated processes throughout the whole life cycle: from the research and development phase to production, use, recycling, and disposal".

Safety by Design (SbD) Approach

- The concept of SbD is not new. it has been implemented in:
  - drug design
  - crop breeding innovation
  - biotechnology
  - engineering disciplines
- Safe-by-Design (SbD) concept was introduced in the emerging field of nanotechnology (Kraegeloh et al., 2018).

Kraegeloh, et al., (2018). Implementation of Safe-By-Design for Nanomaterial Development and Safe Innovation: Why We Need a Comprehensive Approach. Nanomaterials. 8 (4), 239.

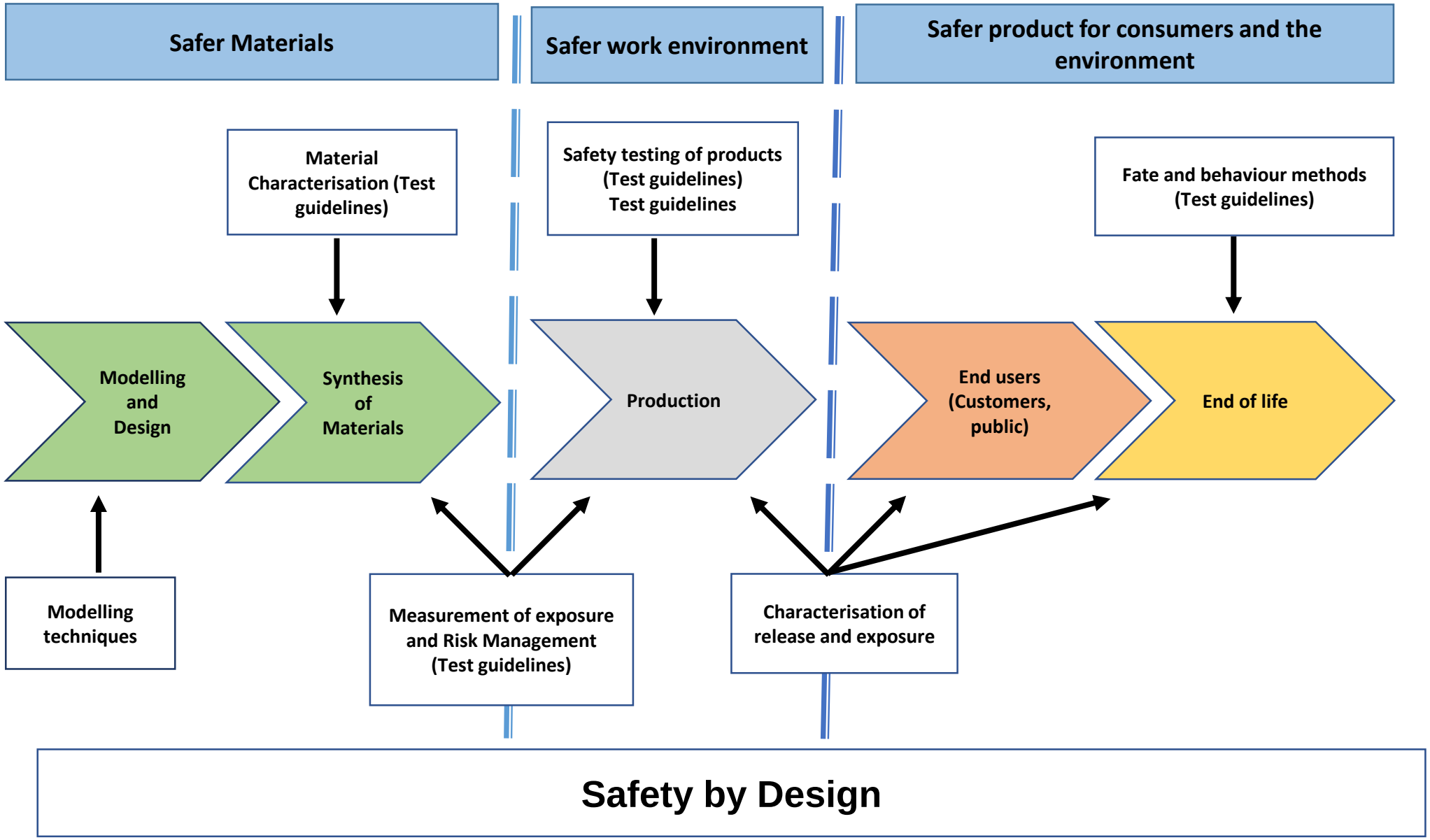
SbD in Nanotechnology

SbD was developed by OECD and the European Commission as a response to observations that nanomaterial safety would be more effective and less costly for companies if it was incorporated earlier into the innovation process.

Why SbD in nanotechnology?

- To identify risks and minimize or even eliminate these during the early stages of the technological development.
  - The concept of SbD envisages including safety into innovation from the design phases and early development of a new nanomaterial or nano-enabled products, instead of conducting toxicity assessments only after nanomaterials reach the market

- Safety issues at the product development stage


Safer Materials
Safer work environment
Safer product for consumers and the environment
Material Characterisation (Test guidelines)
Safety testing of products (Test guidelines) Test guidelines
Fate and behaviour methods (Test guidelines)
Modelling and Design
Synthesis of Materials
Production
End users (Customers, public)
End of life
Modelling techniques
Measurement of exposure and Risk Management (Test guidelines)
Characterisation of release and exposure
Safety by Design

Therefore:

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- The importance of addressing the potential health and safety risks at different stages of the development of nanomaterials.
  - Synthesis (safe material/product)
  - Processing, handling, and incorporation into products (safe production) stages,
  - Disposal at end-of-life cycle (safe use and end of life).

Safety by Design (SbD) Approach

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- Safer Nanomaterials.
- Safer work environment.
- Safer product for consumers and the environment

DSI initiated Health, Safety and Environment (HSE) Project

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- To establish the required tests in South Africa to assess the safety of synthesized nanomaterials (Safer nanomaterials).
- To establish tests to ensure safety of those working with these nanomaterials during synthesis (Safer work environment).
- To assess safety to consumer and end of life (Safer product for consumers and the environment)

Definition: SSbD

- "*Safe-and-sustainable-by-design (SSbD) is a concept that takes a systems approach by integrating* ***safety****,* ***sustainability****, and* ***functionality*** *throughout a product's life cycle*"

- Any new material or product by **industry** should not only be functional and cost-efficient but also **safe** and **sustainable (SSbD)**, so as to ensure compliance with regulations, acceptance by consumers and users and, consequently, a fast and successful access to the market

- Overall sustainability should be ensured by minimising the environmental footprint of **chemicals used** and **nanomaterials produced** in particular in relation to:
  - **Climate change**
  - **Resource use**
  - **Protecting ecosystems and biodiversity**
  - **Adopting a lifecycle perspective**

- **SSbD is** a pre-market approach to nanomaterial design that focuses on providing a function (or service), while **avoiding volumes and chemical and material properties that may be harmful to human health or the environment, in particular groups of chemicals likely to be (eco)toxic, persistent, bio-accumulative or mobile.**
- SSbD is to ensure the ability of a nanomaterial to deliver its function without exceeding environmental and ecological boundaries along its entire life cycle, while providing welfare, and socio-economic benefits

- Implement the Safe Innovation Approach (SIA) for nanomaterials, combining Sustainable Safe-by-Design (SSbD) in industrial settings and Regulatory Preparedness (RP) by authorities.

Regulatory Preparedness

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- Regulatory Preparedness "refers to the capacity of regulators, including policymakers, to anticipate the regulatory challenges posed by emerging technologies such as nanotechnology, particularly human and environmental safety challenges.
- This requires that regulators become aware of and understand innovations sufficiently early to take appropriate action, and that appropriate regulatory tools are modified or developed as needed.
- Regulatory Preparedness helps to ensure that innovative materials and products undergo suitable safety assessment before entering the market.

Trusted Environment

- A Trusted Environment is a physical or virtual space in which industry, innovators and governmental institutions and, as appropriate, other stakeholders can share and exchange knowledge, information and views on new technologies, such as innovative nanomaterials and nano-enabled products.

- A Trusted Environment invites trust by ensuring confidentiality and protecting intellectual property.

Collaboration between these groups is needed to develop well-adapted and consensual approach to achieve SSbD

- Expanding SbD to SSbD can be beneficial for industry as it might lead to price incentives (less energy, less resource use, etc.), consumer acceptance and shorter time to market;
- In addition, SbD and SSbD present collaborative opportunities for industry and regulators.

SbD and SSbD in South Africa

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- Implementation of SbD and SSbD:
  - A collaborative approach between innovators (research), industry, and regulators.
    - Create a trusted environment between industry and regulators.
    - Create opportunities to transfer knowledge between the stakeholders.
    - Increase collaborations between South Africa and international agencies
      - Great number of industries internationally have already implemented the process in compliance with the requirements of the OECD and the European Commission.

SbD and SSbD in South Africa

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- Provision of guidelines through the DSI HSE project are designed to identify risks at an early state and information to be considered to identify those risks.

- Each industry may adapt the approach to its specific needs and circumstances as industry decisions influence the way forward.