2nd meeting

Innovative approaches for risk management in nanotechnologies

Safe-by-Design and Safe and Sustainable-by-Design approaches

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Abstract

Safe-by-Design (SbD) and Safe and Sustainable-by-Design approaches foresee occupational and environmental risk assessment and management of nanotechnologies development throughout their lifecycle. Following these innovative approaches, any new NM or nano-product (and associated production process) should be functional, cost-efficient, safe and sustainable, so as to ensure compliance with regulations, acceptance by consumers and users and, consequently, has a fast and successful access to the market. The experience that has been gained by ISQ from participating in critical H2020 projects is crucial in disseminating these approaches between the key players of nanotechnologies to create the future background conditions for general adoption by industry players.

Keywords: **Risk assessment, Risk management, Nanotechnologies, Safe-by-Design, Safe and Sustainable-by-Design**

1. Introduction

Nanotechnologies are used in countless products and applications of our daily lives, due to the unique and attractive properties of materials at the nano-scale. However, the exposure to nanomaterials (NMs) need to be controlled, as NMs have the capability of crossing biological barriers without losing their integrity and reaching some parts of human body inaccessible to larger materials.

The interest in using conceptual and holistic approaches such as **Safe-by-Design (SbD)**[1,2] and **Safe and Sustainable-by-Design (SSbD)**[3] for nanotechnologies development and safe innovation have been rising, as a result of recent European Union initiatives (e.g., the Green Deal and its actions related to the Circular Economy) and due to the uncertainties and big knowledge gap associated to the hazards and risks of NMs on human health and environment, particularly when using the classical risk assessment framework (i.e., European REACH regulations for chemicals).

2. Methodology

Innovative approaches foresee risk assessment and management since the early stages of a NM/nanoproduct innovation process. Functionality and safety are assessed in an integrated manner in the course of product development (Fig.1).

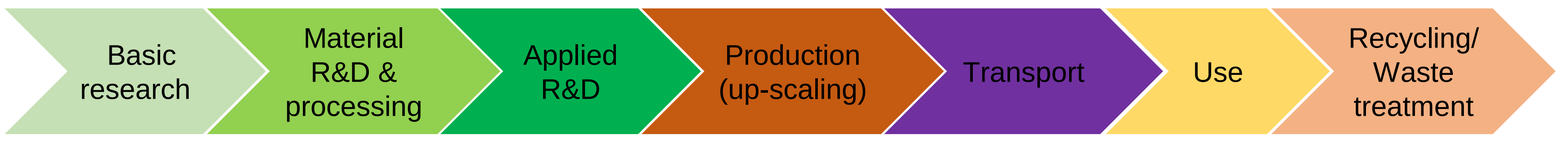

Fig.1 Typical innovation process workflow[1]

2.1. Safe-by-Design (SbD) approach: Aims at identifying, estimating and reducing uncertainties and risks related to materials/product and associated process for humans' health and the environment at the earliest possible/feasible time in the innovation process. At each stage of the innovation process (Fig.1), an assessment of the functionality, risk to human health and environment, and cost is carried out, and a compromise agreed with the aim of achieving a safer NM and process[2] (Fig.2).

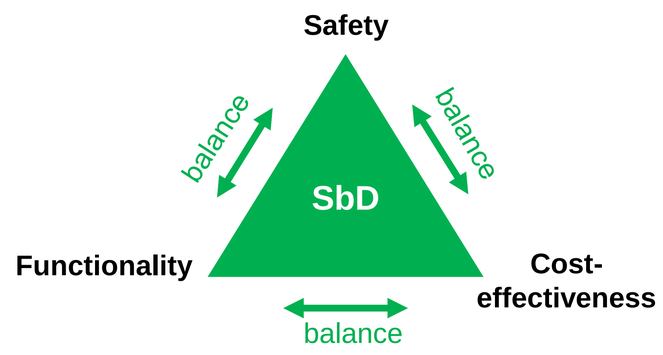

Fig.2 Safe-by-Design (SbD) concept

2.2. Safe and Sustainable-by-Design (SSbD) approach: Aims to ensure that upcoming new NMs/products are safe and sustainable, and thus facilitate the realisation of their full socioeconomic potential in line with the European Green Deal in a circular economy[3] (Fig.'s 3 and 4). This approach target the minimization of the environmental footprint of materials/products and processes, in particular on climate change, resources use, ecosystems and biodiversity, from a lifecycle perspective.

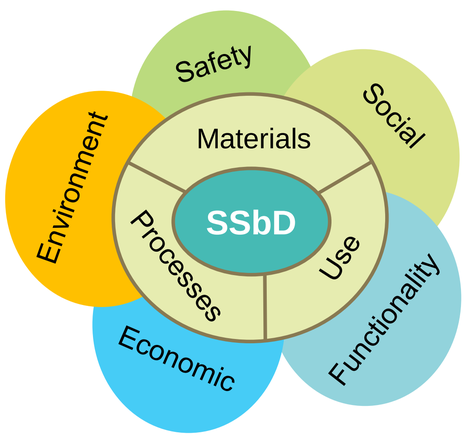

Fig.3
Safe and Sustainable-by-Design (SSbD) concept

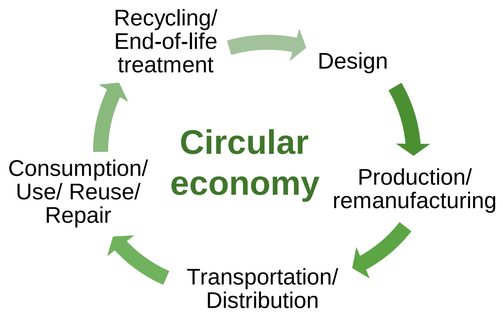

Fig.4
Circular economy flow chart

Example of a **SbD strategy** application

The company ABC wanted to increase the performance of a specific type of batteries using pure X NMs at production (up-scaling) stage (Fig.1), based on a SbD approach (Fig.5), i.e.,

- Step 1: **Scenario identification** (i.e., SbD pillar, stage/gate, functionality, and relevant regulation);
- Step 2: **Preliminary risk assessment, LCA (life-cycle assessment), LCC (life-cycle cost analysis), and human and ecotoxicity tests** (if not previously performed);
- Step 3: **Establish SbD goa**l (e.g., achieve a NM with a higher performance, lower risk of explosion and low human and ecotoxicity);
- Step 4: **Identify potential SbD measures** to achieve the goal (step 3), and based on preliminary results from step 2 (e.g., increase NM size and coat the NM);
- Step 5: **SbD verification** based on a final risk assessment, LCA, LCC, and human and ecotoxicity tests with SbD measures implemented;
- Step 6: **Decision making**: proceed to the next stage of the innovation process or revise this stage (Fig.1)?

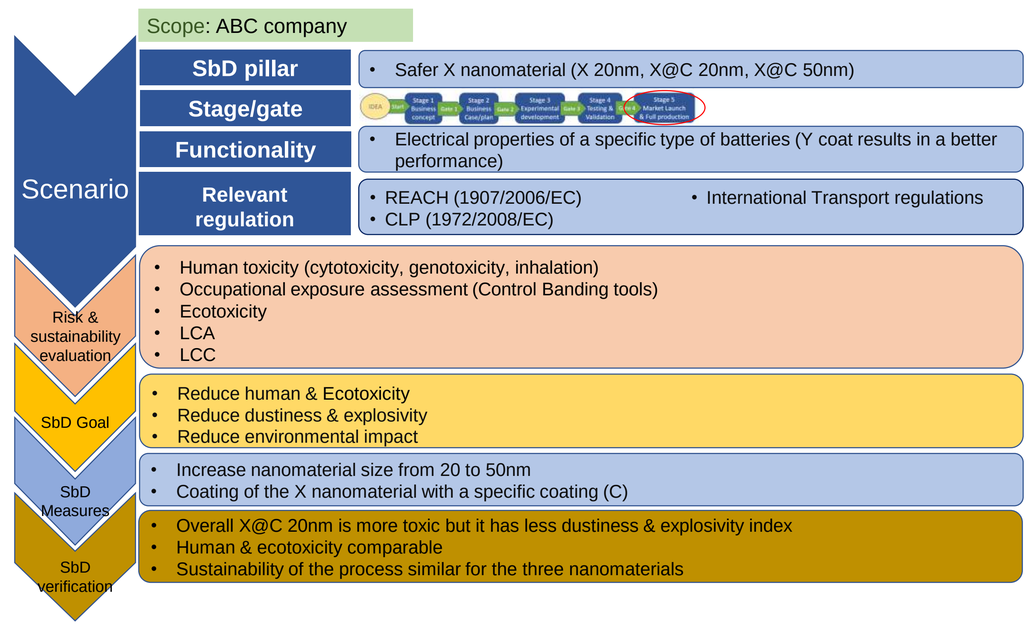

Fig. 5 Flow chart of SbD strategy implementation for production (up-scaling) stage (adapted from 2)

3. ISQ as a key player

ISQ as a research technological organization has been contributing to the research, development and application of the occupational and environmental safety of nanotechnologies, by gathering the knowledge, resources and by participating in European projects (namely under Horizon 2020 programme), clusters (Nanosafetycluster, Technical committee 194 "nanotechnologies") and partnerships (PToNANO).

Following the Safe-by-Design (SbD) and Safe and Sustainable-by-Design (SSbD) approaches, any new NM or nano-product (and associated production process) should be functional, cost-efficient, safe and sustainable, so as to ensure compliance with regulations, acceptance by consumers and users and, consequently, has a fast and successful access to the market[4]. The experience that has been gained by ISQ from participating in critical H2020 projects (i.e., DIAGONAL, NANoREG, PROCETS, and PURENANO) (Fig.6) is crucial in disseminating these innovative approaches between the key players of nanotechnologies to create the future background conditions for general adoption by industry players.

Fig. 6
ISQ participation in H2020 projects applying SbD or SSbD

4. References

[1]Kraegeloh et al., (2018). Implementation of Safe-by-Design for nanomaterial development and safe innovation: why we need a comprehensive approach. Nanomaterials, 8.
[2]Jiménez, et al., (2019). NANoREG^2 - D4.6: Guidance on the practical implementation of SbD in the nanotechnology community (Ref. Ares(2019)2377582). European Commission.
[3]Gottardo et al., (2021). Towards safe and sustainable innovation in nanotechnology: State-of-play for smart nanomaterials. NanoImpact, 21.

Acknowledgements
DIAGONAL: Development and scaled implementation of safe by design tools and guidelines for multicomponent and harn nanomaterials (953152)
NANoREG: Guidance for safer by design implementation in the nanotechnology industry (646221)
PROCETS: Protective composite coatings via electrodeposition and thermal spraying (686135)
PURENANO: A purification/regeneration process of spent plating baths base on functionalized magnetic nanoparticles (821431)