Safe Innovation

Nanotechnologies are characterized by a growing legacy of already marketed and novel engineered nanomaterials (ENMs) and nano-products with a lack of a coherent risk governance system to address their safety effectively. In response to this situation, a proactive system is needed to minimize the gap between the pace of innovation and the pace of developing nano-specific risk governance.

With the Safe Innovation Approach (SIA), under development within the EU project NanoReg2, we seek to enhance the ability of all stakeholders to address the safety assessment of innovations in a robust yet flexible manner. SIA is an approach that combines a) the Safe-by- Design (SbD) concept, which recommends industry to integrate safety considerations as early as possible into the innovation process, and b) the Regulatory Preparedness (RP) concept, which encompasses the development and application of a set of tools and procedures for regulators to prepare for innovations.

SIA promotes a safe and responsible approach for industry when developing innovative products and materials, and stimulates a proactive attitude amongst policymakers and regulators to minimize the time gap between appearance and approval of innovation and appropriate legislation. NanoReg2 introduces SIA framework consisting of creating awareness, developing SIA methodology (SbD scenarios, safety information needs, SbD methodology including functionality, grouping, SIA Toolbox and NanoReg2 database), and building Trusted Environments (TEs). The SIA framework is a future-proof risk governance system for ENMs and nano- enabled products that is adaptive and flexible, agile and accelerated.

Why do we need a Safe Innovation Approach for engineered nanomaterials?

The development, manufacture and use of engineered nanomaterials (ENMs) with novel properties and potentially novel risks growing at a rapid pace. Although nanotechnology offers society economic and technological opportunities, technological innovations pose a challenge to governance of human and environmental safety due to the large difference in the pace between innovation and the development of suited governance.

With the SIA, NanoReg2 seeks to enhance the ability of all stakeholders to address the safety assessment of innovations in a robust yet flexible manner. SIA is an approach that combines the Safe-by- Design (SbD) and Regulatory Preparedness (RP) concepts. SbD stimulates the early consideration and integration of safety into the innovation process. The RP concept encompasses the development and application of a set of tools and procedures for regulators to prepare for innovations. SIA promotes a safe and responsible approach for industry when developing innovative products and materials, and stimulates a proactive attitude amongst policymakers and regulators to minimize the time gap between appearance and approval of innovation and appropriate legislation.

The Safe-by-Design Concept

The SbD concept aims at reducing uncertainties and risks of human and environmental safety of nanotechnology, starting as early as possible during the innovation process, on the basis of mandatory and voluntary safety and efficacy compliance requirements. Within NanoReg2 project, SbD concept implementation was developed to include products, processes, consumers and workers health and environment protection.

This concept, applied to nanotechnology, aims at balancing safety and functionality in an integrated way, in order to improve innovation efficiency for the development of better nanotechnology products, considering all life cycle steps, and not only the product development phase. The properties of the ENMs needed to make the materials useful for a specific application are identified in order to identify the possible SbD options. Such a concept maximises the use of resources and expedites the development of products containing ENMs and new ENMs that are SbD. The SbD approach should be based on the state-of-the-art of reliable and routine methods and tools, as well as best available knowledge and practices. Methods and tools are included in an Inventory which is regularly updated to include latest developments in standards and techniques. In this respect, the identification and implementation of modes of action for nano-induced toxicity and adverse outcome pathways are essential for the successful implementation of SIA.

This project has received €10M in funding from the European Union's Horizon 2020 research and innovation programme under grant agreement 646221

The Regulatory Preparedness (RP) concept

The RP concept aims to improve anticipation of regulators in order that they can facilitate the development of adaptable (safety) regulation that can keep up with the pace of knowledge generation and innovation of ENMs and ENM- enabledproducts. In order to achieve this,regulators need to be prepared by being aware of new materials, technologies and innovations in the early stage of the innovation process. Information about the scientific state-of-the-art and about the innovations is needed in order to timely check on whether current regulations cover all aspects of innovation to ensure human and environmental safety. By engaging in dialogue with innovators, regulators can become aware of the latest advances in innovation and provide innovators with (informal) input on human and environmental safety of emerging technologies such as (novel) ENMs and nano-enabled products.

Safe Innovation Approach framework

A SIA framework was developed in order to have safer ENM and nano-enabled products on the market as well as safer manufacturing processes or as a minimum a safety risk assessment to identify the potential risks in order to take appropriate reduction of exposure and/or hazard measures to protect human health and ensure environmental safety. The SIA stimulates companies to integrate safety in the design and throughout the innovation process and regulators to keep up with the pace of innovation. For this SIA framework to come into implementation, a change of mind-set is needed for regulators and innovators to be more proactive and interactive. By creating awareness, developing and providing motivators for industry, and building TEs, a practical SIA can be achieved (Figure 1).

Conclusion

Safe Innovation Approach framework

NanoReg2 presents a proactive system, the SIA approach, which not only addresses the safety of nanotechnologies in a timely and efficient manner but also aims at reducing the gap between the pace of innovation and the pace of developing nano-specific risk governance. SIA promotes a safe and responsible approach for industry when developing innovative products and materials, and stimulates a proactive attitude amongst policymakers and regulators to minimize the time gap between appearance of innovation and appropriate legislation. The SIA framework involves creating awareness, developing SIA methodology (SbD scenarios, safety information needs, SbD methodology including functionality, grouping, SIA Toolbox and NanoReg2 database), and building Trusted Environments. The SIA framework is a future- proof risk governance system for ENMs and nano-enabled products that is adaptive and flexible, agile and accelerated.

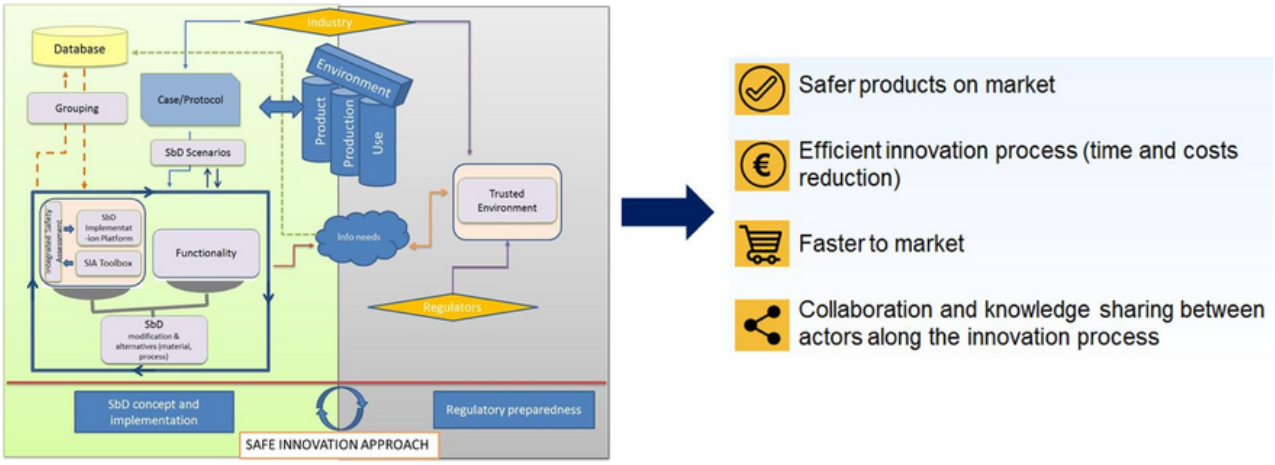

Figure 1 Illustration of SIA methodology (SbD scenarios, safety information needs, SbD methodology including functionality, and grouping, SIA Toolbox and NanoReg2 database)

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