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Advances in Water Security

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Emerging Pollutants

Protecting Water Quality for the Health of People and the Environment

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Advances in Water Security

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Editors

Emerging Pollutants

Protecting Water Quality for the Health of People and the Environment

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Chapter 18

Curbing the Environmental Implications of Emerging Nano-Pollutants: Current Developments in Preventing Environmental Exposure Potential and Adverse Effects

Mbuyiselwa Shadrack Moloi, Thabiso Mzinyati, Raisibe Florence Lehutso, Paul J. Oberholster, and Melusi Thwala

Abstract Commercialization of nano-enabled products (NEPs) being products that contain engineered nanomaterials (ENMs) is rapidly increasing. Most NEPs in markets exhibit high likelihood of ENMs release into the aquatic environment where they may induce undesirable effects; current data suggests rising nanopollution driven by rising commercialization of NEPs. Thus, measures to reduce the environmental exposure and impact of ENMs are required across all lifecycle phases. Herein, two strategies are proposed: safer- and sustainable-by-design (SSbD) strategy and policy development at the international level for ENMs/NEPs' environmental safety. The SSbD strategy seeks to balance the full exploitation of ENMs in NEPs while reducing their environmental exposure and impact at the design and manufacturing phase. This is achieved by integrating the knowledge of ENMs' physicochemical properties, exposure, and risk and designing out (reducing) the unfavourable properties. For both strategies, the current knowledge, shortcomings, and recommendations for successful implementation are discussed. Overall, SSbD and policy development can play a significant role in curbing the aquatic environmental risks associated with ENMs/PR-ENMs. However, both strategies are still in infancy and require comprehensive research for further development and implementation at country and international levels.

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18.1 Introduction

Nanotechnology has revolutionized material design and product formulation due to the ability of engineered nanomaterials (ENMs) (1–100 nm) to improve the properties and functionalities of materials and products (Batchelor-McAuley et al. 2014). The application of ENMs is property-functionality-specific; meaning that ENMs are applied to improve specific properties and functionalities of products (Surette et al. 2019). Therefore, different ENMs are incorporated into products in a wide array of applications, for instance, nAg in textiles is used for antimicrobial properties and thus prevent odour (Gagnon et al. 2019), dietary supplements used in nanoscale to improve their bioavailability and maximize their bioactivity and safety (Jampilek et al. 2019), in the personal care industry various cosmetic products (e.g., UV filtration) have adopted nanotechnology (Kaur and Agrawal 2008; Mu and Sprando 2010). As a result, nano-enabled products (NEPs) commercialization has risen rapidly (Hansen et al. 2020). Various databases have been established to document NEPs' commercialization.

The earliest database published was the Consumer Product Inventory (CPI) by the Woodrow Wilson International Center for Scholars and the Project on Emerging Nanotechnologies with 54 products listed in 2005 (Vance et al. 2015). In 2016, the number of NEPs recorded was just over 1800 (Vance et al. 2015). However, this database has not been updated since. In 2012, the EU established The Nanodatabase with 1012 products reported in Europe by 2016 (Hansen et al. 2016). The total number of NEPs recorded is currently over 5,300 (Nanodatabase 2022); The Nanodatabase is an online inventory and is frequently updated. Others (Moeta et al. 2019; Zhang et al. 2015) have focused on country-level inventories and reported respectively for Singapore and South Africa; overall trends being somewhat similar to Consumer Product Inventory and The Nanodatabase (Moeta et al. 2019). Over an estimated 10,000 NEPs globally are currently in markets (StatNano 2023). Notably, the most used ENMs in NEPs globally include titanium dioxide ($nTiO_2$), silver (nAg), silicon dioxide (SiO_2), graphene, tungsten disulfide, and others (Fig. 18.1). These ENMs contain the beneficial properties for high consumption NEPs, such as high refractive index and broad UV spectrum ($nTiO_2$), chemical and photostability (nZnO), broad-spectrum antimicrobial and antifungal activity (nAg), and increased absorption, self-cleaning, transparency, and abrasion resistance (Moloi et al. 2021).

The rising commercialisation of NEPs has since triggered research into the environmental exposure and effects assessment of product-released ENMs (PR-ENMs) due to suspected and known effects of ENMs. Since around 2007, interest has grown focusing on categorising ENMs risk, concerning PR-ENMs this has been linked to the location of ENMs in the NEPs which influences ENMs' ease of release during the product lifecycle (Hansen et al. 2007, 2008). Accordingly, the products in the health

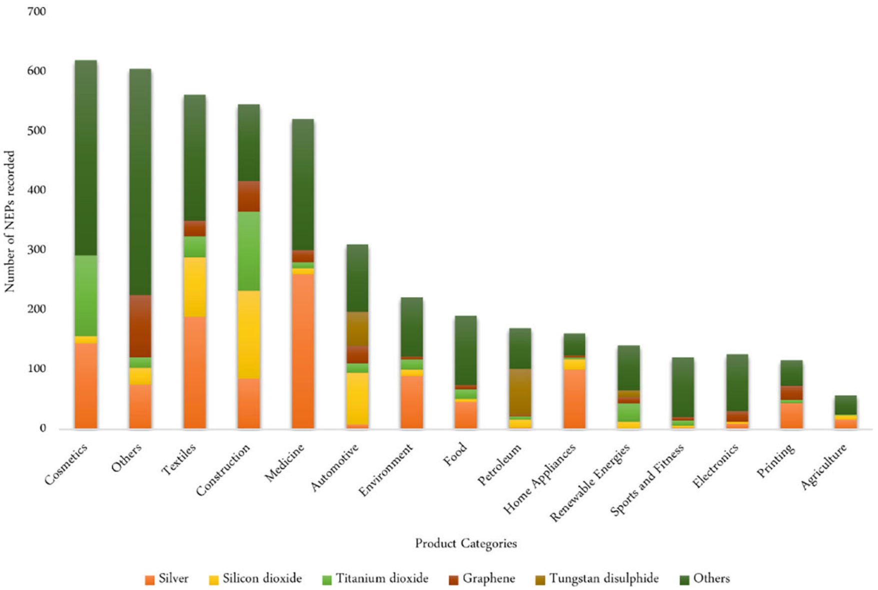

Fig. 18.1 Number of NEPs recorded on StatNano database by product category and ENMs types. *Source* Reproduced by the authors by using open-access data from StatNano 2023. *Note* StatNano is an open-access Nanotechnology Products Database. https://product.statnano.com/

and fitness category have the highest environmental exposure potential due to the ENMs' suspension within the liquid matrix (Hansen et al. 2016; Moeta et al. 2019). Thus, the PR-ENMs associated with this category have been reported in several environmental reports.

PR-ENMs which are either suspended in liquids or surface coated are most likely to be released in massive quantities to the aquatic environment during the product lifecycle which contributes towards escalating water nanopollution. Thus far, evidence shows considerable release of PR-ENMs from sunscreens, personal care products, paints, and textiles (Lehutso and Thwala 2021; Moloi et al. 2021). The release and evidence of nano pollution in aquatic environments have been reported (Lehutso and Thwala 2021; Moloi et al. 2021). A handful of studies have recovered PR-ENMs in surface water with concentrations of 10–15 µg/L (PR-nZnO), 0.0003–0.619 µg/L (PR-nAg), and 10–15 µg/L (PR-nTiO_2) (Gondikas et al. 2014; Labille et al. 2020; Markus et al. 2018; Reed et al. 2017). With these findings, it is evident that PR-ENMs occur in the aquatic environments which may lead to detrimental effects to the aquatic ecosystem as concentrations rise.

Once released, PR-ENMs enter the aquatic environment and interact with biotic and abiotic constituents in the water system (e.g., natural organic matter, electrolytes, and other pollutants) (Abbas et al. 2020). The interaction of PR-ENMs with surface water parameters/natural organic matter influences their transformation and subsequent bioavailability (Gagné et al. 2019). Ecotoxicity investigations have so far shown detrimental effects of PR-ENMs in aquatic bacteria (*Vibrio fischeri*), *Daphnia magna*, copepods (*Tigriopus japonicus*) microalgae (*Raphidocelis subcapitata*), zebrafish (*Danio rerio*), and plants (*Spirodela polyrhiza*) (Gao et al. 2022; Jahan et al. 2017; Künniger et al. 2014; Lehutso et al. 2021; Reed et al. 2016; Wong et al. 2020; Wu et al. 2019). The knowledge and understanding of the fate, behaviour, exposure, and risk of PR-ENMs provides a platform to devise mitigation strategies to reduce environmental exposure and risks. So far, mitigation strategies have been investigated using the knowledge from pristine ENMs.

Herein, this chapter reviews strategies used in mitigating the environmental exposure and toxicity of PR-ENMs. The chapter focuses exclusively on (1) a safer-by-design strategy for ENMs synthesis and product formulation, and (2) policy approaches adopted in different countries to regulate the industry to minimize potential adverse environmental effects. The data reported herein was obtained from Google Scholar, Science Direct, and various governments/institutional websites, and is restricted to the 2008 (NEPs categorization)—July 2023 period.

18.2 Safer- and Sustainable-By-Design Strategy for Engineered Nanomaterials' Safety

The increasing usage of NEPs and the rising ENMs' environmental exposure linked to NEP commercialisation have since triggered the investigation and implementation of a safety-by-design approach to ENMs synthesis and NEPs manufacturing. Safety and sustainable-by-design, also referred to as safe and sustainable-by-design, or safer and sustainable-by-design (herein SSbD for all versions) is a concept that integrates the knowledge of ENMs' potential adverse effects on the environment, and human health, in designing safer ENMs and NEPs to minimize the unfavourable aspects of the ENMs (Schwarz-Plaschg et al. 2017). This ensures that the environmental health and safety concerns of ENMs are minimized during the early stage of ENMs/NEPs development to control exposure, hazard, and risk (Rose et al. 2021). The simple schematic in Fig. 18.2 depicts measures that must be considered for successful SSbD implementation.

Although the SSbD research is still in the infancy stages, a few studies have investigated the implementation of SSbD in the various stages of the ENMs/NEPs' life cycle. The purpose of the reported studies was to establish the effectiveness of SSbD in limiting the potential nanopollution and toxicological impact on the aquatic ecosystem. In this section, investigations that assessed implementation of SSbD to decrease ENMs release from NEPs, reduction of ENMs' adverse effects, and reduction of ENMs persistence in the environment are discussed.

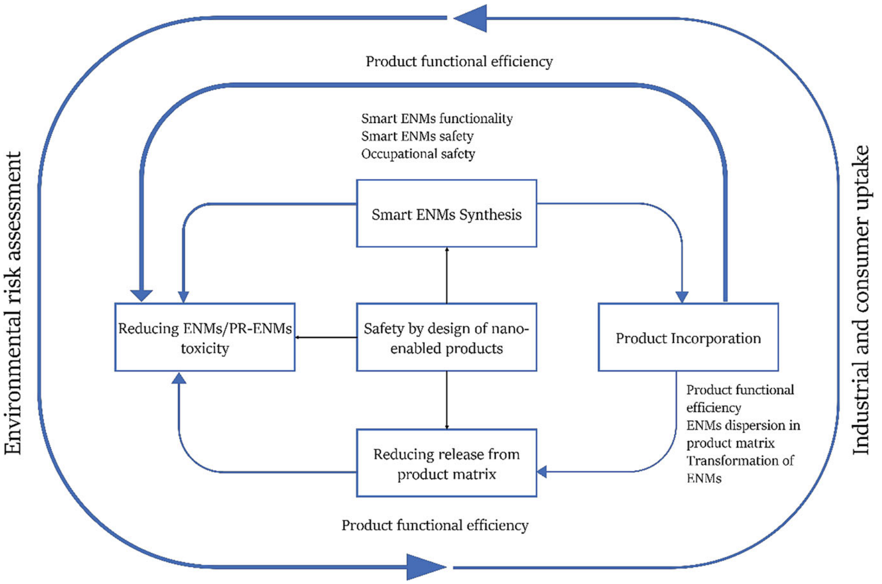

Fig. 18.2 Simple schematic indicating the considerations that must be made in successful SSbD implementation in product manufacturing. *Source* Authors

18.2.1 Synthesis of Smart Engineered Nanomaterials

The synthesis of smart ENMs is aimed at altering the specific physicochemical properties of the ENM to reduce their environmental exposure and toxicity (Kraegeloh et al. 2018). This is achieved by using methods such as doping (Aydın et al. 2019; Bayan et al. 2020; Pathak et al. 2018, 2020), surface coating or encapsulation (Marchioni et al. 2020; Moraes Silva et al. 2016), or reduction of ENM concentrations used (Shandilya and Capron 2017). Smart ENMs are therefore intended to be as efficient, but without the high release, bioavailability, and impact consequences. Currently, different 'smart' ENMs have been synthesized and investigated (Laisney et al. 2021; Marchioni et al. 2020; Shandilya and Capron 2017).

For $nTiO_2$, an ENM type that is frequently used in cosmetics (Hansen et al. 2016; Moeta et al. 2019; Vance et al. 2015; Zhang et al. 2015), a hybrid nanostructure was designed as an alternative to the currently used $nTiO_2$ (e.g. T-AVO, T-S) (Shandilya and Capron 2017; Slomberg et al. 2021). In this study, the smart $nTiO_2$, referred to as a hybrid, was synthesized by grafting $nTiO_2$ to cellulose nanocrystals (CNC). Compared to conventional $nTiO_2$ currently used in NEPs, the properties of the hybrid were intended to enhance the UV absorbance and stabilize the emulsion pickering with a lesser amount of $nTiO_2$ (Shandilya and Capron 2017). The smart $nTiO_2$ was synthesised using the sol–gel, a method that meets the requirements of safety by design (Shandilya and Capron 2017). Smart $nTiO_2$ (CNC-$nTiO_2$) exhibited a higher UV absorbance when compared to conventional $nTiO_2$ (Shandilya and Capron 2017).

Furthermore, the CNC-nTiO_2 was effective in replacing surfactants in product formulation and thus forming a highly stable oil-in-water pickering emulsion (Shandilya and Capron 2017). The higher efficiency of these smart ENMs meant that lower concentrations of nTiO_2 could be incorporated into NEPs. While this study successfully synthesized smart nTiO_2 and provided evidence of its improved efficiency compared to conventional nTiO_2 currently in use, the study failed to prove the full environmental aspects of SSbD (i.e., reduced ENMs release, toxicity, and bioavailability). Notwithstanding, the data presented here indicates that the hybridization was successful in improving the UV absorbance of nTiO_2. This implies that less quantity of the smart synthesized nTiO_2 can be incorporated into the products but still achieve the same efficiency as higher concentrations of conventional nTiO_2. However, further research is required for a better understanding of the interaction of the hybrid materials with the other components within the product emulsion or matrix, skin interaction, and SPF to ascertain their efficiency as alternatives for commercialization. The next step would then be to investigate the rate of release of the smart nTiO_2 when compared to the conventional nTiO_2 and subsequent ecotoxicity impact.

One of the challenges that conventional ENMs such as nAg present is their ability to undergo dissolution. The dissolution of pristine nAg (P-nAg) and the bioavailability of its ionic forms is well documented (Batchelor-McAuley et al. 2014; Beer et al. 2012; Kittler et al. 2010; Ma et al. 2012). Drawing from the P-nAg knowledge, the challenge of nAg dissolution used in biocidal products was addressed; nAg ions often cause the adverse effects induced by nAg (Van Aerle et al. 2013). Marchioni et al. (2020) synthesized 'smart' nAg by connecting nAg with a tri-thiol molecule to form larger and more stable nAg. The diameter of the smart nAg ranged between 40 and 200 nm, with the number of ENMs in each assembly ranging from 5 to 60 (Marchioni et al. 2020). Overall, the 'smart' nAg physicochemical properties were indicated to limit the release of nAg because of tight bondage with an organic coating that ensured minimal nAg dissolution (Marchioni et al. 2020). The 'smart' nAg design controlled the dissolution rate during NEPs use compared to conventional nAg (Marchioni et al. 2020). As evidenced in this study, the tri-thiol molecules protected the nAg from surface modification, thereby rendering the nAg assemblies more robust against bacteria (*Escherichia coli* and *Bacillus subtilis*). This means that this smart nAg efficiently delivered the results with a decreased risk of dissolution and thus the risk to the environment. Future studies should also investigate the period of degradation of these assemblies and the potential impact over time. Furthermore, this method needs to be assessed on another array of NEPs to establish the possible standardization of the NEPs created for biocidal activity.

Elsewhere, Laisney et al. (2021) controlled the reduction in ENM's environmental exposure by reducing the amount of ENMs incorporated in NEPs. In this study, the ENMs were coated with ligands [dopamine and polyacrylic acid (PAA)] during NEPs formulation (Laisney et al. 2021). The synthesized 'smart' TiO_2-PAA (nTiO_2-Dopa and n TiO_2-PAA) were found to adhere strongly to the NEPs matrix and thus prevent or limit the release and reduce environmental exposure and by extension, impacts (Laisney et al. 2021). To assess the SSbD concept, TiO_2-PAA was added to the paint at a concentration of 3.5% (w/w), and the paint aged for a year in the dark and interior light conditions. The photocatalytic activity was the main endpoint of this study and was investigated at 50 μg/mL (Laisney et al. 2021). Smart ENMs photocatalytic activity increased by 20% compared to the conventional $nTiO_2$ (Laisney et al. 2021). An increase in photocatalytic activity of 'smart' ENMs provided means to reduce the amount of ENMs added into NEPs; an exercise that maintains the ENMs' efficiency in NEPs and simultaneously limits environmental exposure (Laisney et al. 2021). While it is evidenced that the photocatalytic activity is significantly enhanced at low ENM concentrations due to the ligand coating, robust environmental investigations need to be conducted to ascertain the risk or non-existence thereof to the environment. This can be achieved through weathering studies using the paint incorporated with smart ENMs and subsequently, ecotoxicity studies of both the smart ENMs before incorporation into the product and the released smart ENMs from the weathering studies; the comparison of the latter and the former will shed the light into the durability of the ligand during the NEP's lifecycle.

It is worth appreciating that nanotechnology, and by extension nanotoxicology, is still developing, and thus, many data gaps still need to be filled. Therefore, the work reviewed herein provides initial evidence of ENMs' alteration to improve their safety. Specifically, evidence shows that if the concentration or volume of specific ENMs required for a specific activity can be established beforehand, it will enable manufacturers to produce NEPs with a more targeted amount of ENMs and thus a lower amount of ENMs per unit product. This will imply environmental exposure and risk reduction.

18.2.2 Reducing the Release of Engineered Nanomaterials from the Product Matrix

Although ENMs improve the efficiency of NEPs, one of the main challenges is that the ENMs are not permanently fixed to the NEPs matrix and are released throughout the NEPs life cycle (Azimzada et al. 2020a, b; Kaegi et al. 2010; Limpiteeprakan et al. 2016; Wong et al. 2020). Controlling the ENM concentrations, size, and rate of release may decrease the environmental exposure and subsequent ecotoxicity (Hwang et al. 2018; Lynch et al. 2014). Methods to limit environmental exposure across the life cycle have been assessed.

Reduction of the release of ENMs from NEP was investigated by depositing nAg onto the glass surface using a liquid flame spray (Brobbey et al. 2018). This was followed by depositing a thin layer of Al_2O_3 coating (2 and 15 nm) to improve the nanoparticle adhesion to the glass surface while immobilizing nAg to the glass surface. To assess the degree of reduction of leaching reduction by the surface coating, the rate of leaching of nAg from the surface was continuously measured over 48 h. The results indicated that the thin layer of Al_2O_3 was able to control the release of the nAg from the glass surface and reduce the initial leaching (Brobbey et al. 2018).

The thin layer (2 nm) of the coating material inhibited the release of nAg for 4 h while the thicker layer (15 nm) inhibited release for 48 h (Brobbey et al. 2018).

Although in this study, nAg was not coated before use but deposited on the NEP (glass surface) before being coated, the results show that nAg surface modification can help in reducing the leaching of ENMs into the environment. Surface coating of ENMs must be conducted with a material that will not be degraded by other materials within the product matrix. Furthermore, the durability of the specific coating material should be investigated over time. The thickness of the coating material has also been evidenced to play a role in the leaching rate and thus must be considered; the coating layer should be thick enough to decrease the release of ENMs but thin enough not to hinder the specific properties of the specific ENMs that enhance the NEP concerned.

18.2.3 Reducing Engineered Nanomaterials' Toxicity

Different types of ENMs are known to induce varying extent of adverse effects on aquatic organisms (Jahan et al. 2017; Künniger et al. 2014; Sendra et al. 2017; Spisni et al. 2016). Since ENMs' environmental release at varying amounts is invertible, efforts to lessen the effects and reduce the risk of the released ENMs have been explored. In the study of Xia et al. (2011), the toxicity effect studies showed that smart nZnO induced lesser effect compared to conventional nZnO. The smart nZnO (Fe-doped nZnO) was synthesized by flame spray pyrolysis doping and had a size range of 8.3–15 nm, while conventional ENMs were sized at 20.2 nm. The high crystallinity of nZnO was not affected by the smart nZnO synthesis procedure (Xia et al. 2011). The ecotoxicological assay was conducted by exposing the zebrafish embryo (*D. rerio*) to conventional and Fe-nZnO at 5–120 h post-fertilization (hpf). Conventional nZnO interfered with embryo hatching but did not directly affect viability (Xia et al. 2011). Contrary, at maximum exposure concentration (5 μg/mL), the Fe-nZnO did not interfere with the hatching rate of the *D. rerio* embryo. Instead, the hatching rate increased with increasing amounts of Fe doping and reached near-normal hatching at 10 wt% doping level when compared to the control (without any particles) (Xia et al. 2011). This study showed that Fe–nZnO could significantly reduce the toxicity of nZnO to zebrafish. The toxicity reduction was owed to the Fe dopant's ability to reduce nZnO dissolution. In this study, the changes in ENMs' physicochemical properties reduced the potential toxicity. Future studies, therefore, need to investigate the extent to which doping can reduce the toxicity of nZnO at different organizational levels, i.e., microbial, invertebrate, and vertebrate levels. Doping has been proven to reduce dissolution which several studies attribute the toxicity to. Other studies therefore need to focus on other mechanisms of toxicity of various ENMs, especially the ENMs that do not undergo dissolution, and how doping can assist in reducing the toxicity of these ENMs.

Elsewhere, smart SiO_2 with lower toxicity potential, intended to be used for *in vitro* biological testing, was synthesised (Jiménez et al. 2020). To reduce the toxicity of conventional quantum dots doped $nSiO_2$ (CdSe-$nSiO_2$) typically used in *in vitro* biological testing as tracers, the toxic CdSe were substituted with organic pigment (dye) (Jiménez et al. 2020). Smart $nSiO_2$ induced reduced toxicity on the fish cell lines when compared to conventional $nSiO_2$; findings that indicates reduced ENMs risk (Jiménez et al. 2020). The life cycle assessment (LCA) analysis also showed that smart $nSiO_2$ posed negligible risk due to the reduced waste production because of the lesser amounts of water required during the $nSiO_2$ synthesis. The toxicity bioassays (*in vitro*, ROS) showed reduced toxicity in different freshwater organisms (Jiménez et al. 2020).

While the first study introduces the superiority and benefits of doping, the second study highlights the importance of the doping material. The more toxic dopant (CdSe) was substituted with the organic dye. The results show reduced toxicity and environmental risk throughout the lifecycle of the ENMs. Firstly, the doping process with more organic material produces less waste. Secondly, it induces comparably lower toxicity than CdSe doping. Therefore, Future studies need to not only dope materials but also assess the different dopants for benefit/risk analysis purposes. Secondly, there is also a need to use more organic and environmentally friendly materials for the doping process.

18.2.4 Challenges with Safer and Sustainable-by-Design Strategies Implementation at the Manufacturer Level

The use of ENMs and commercial penetration of NEPs is rapidly increasing worldwide, and proportional environmental exposure is expected. To reduce environmental exposure and subsequent effects, SSbD concepts must be explored and implemented in the early stages of production (i.e. manufacturing stage) (Cobaleda-Siles et al. 2017). SSbD in the initial stages enables the design of smart ENMs and incorporation into NEPs. Due to the infancy of the field (SSbD concept), fewer studies have investigated the concept; investigations have focused on the synthesis of smart ENMs as opposed to reducing adverse effects and reducing environmental exposure.

Although the synthesis of smart ENMs has been the main focus of the SSbD concept, one study (Laisney et al. 2021) incorporated the smart ENMs into the product to understand the holistic impact of such ENMs. In all other cases, the concepts of SSbD were assessed without incorporating smart ENMs into products, a limitation that can provide wrong prediction, as the matrix of NEPs is not accounted for; the matrix has previously been shown to contribute to the overall toxicity of the ENMs/NEPs (Reed et al. 2016; Schiavo et al. 2018; Wong et al. 2020). Therefore, smart ENMs must be analysed within the product matrix to understand the full exposure potential and impact of such ENMs.

Other challenges arising within the SSbD concepts are that manufacturers of NEPs depend on the readily available conventional ENMs. This significantly reduces the cost of production. However, it also means that the nanotoxicologists/risk assessors are not involved anywhere in the manufacturing processes of the NEPs. Only a few manufacturers have been reported to own the entire manufacturing chain and therefore can innovate to create smart ENMs that take into consideration human and environmental health (Jiménez et al. 2020). Although the current literature pool is small, it is apparent that there is an increasing interest in the concept of SSbD, specifically in synthesizing smart ENMs. However, most studies have not assessed the environmental exposure and subsequent toxicity of the released smart ENMs. Based on the successful synthesis of the smart ENMs, conclusions about environmental exposure and subsequent toxicity were assumed based on the physicochemical properties of the smart ENMs and not experimental data. While the physicochemical property data of ENMs can predict their behaviour, fate, and effects, in the case where NEP matrix is involved, the prediction is not clearcut as the ENMs interact with the NEPs matrix. The interaction of the ENMs with the NEPs matrix may alter ENMs' physicochemical properties.

The implementation of SSbD strategies depends solely on the information on the ENMs' detrimental physicochemical properties, the environmental release, and their toxicity. Currently, there is data paucity in all three areas, making it challenging to assess the SSbD competence. While information is available and a few studies have successfully implemented SSbD, the release, and ecotoxicity data are still crucial in informing the full implementation of SSbD.

Gaining extensive knowledge about ENMs released from NEPs and the toxicity of product released ENMs remains central to understanding the application of SSbD in any industry. However, this remains a great challenge due to the paucity of data that exists in ENM release and PR-ENMs toxicity. Thus, SSbD is still only a theoretical concept. Nevertheless, it holds great promise for the design of ENMs/NEPs with less potential detriment to the environment. The synthesis of smart ENMs and their incorporation into NEPs will ensure reduced environmental exposure. This will further lead to reduced toxicity. The case studies reviewed above show that, given the limited knowledge available, SSbD of NEPs should be prioritized while ENM release and toxicity data are concurrently being made available.

To ensure the exploration and uptake of SSbD, regulatory bodies may develop technical guidelines and policies for industries. These guidelines may include information on methods for SSbD implementation and the allowable concentration limits allowed for NEP formulations. The policies may further require the data for the environmental safety of the SSbD-based ENMs/NEPs.

18.3 Policies for Nanotechnology Environmental Safety

The current environmental exposure and risks of nanotechnology are uncertain. The development and implementation of policies as risk mitigation for nanotechnology relies heavily on the successful generation of robust data on environmental exposure and risk. Currently, there are huge gaps in the relevant scientific knowledge of the exposure and risks of ENMs and NEPs. Notwithstanding, several countries and/

or corporations have drafted and are implementing different policies to proactively address the imminent risks of nanotechnology.

In 2014, the U.S. Food and Drug Administration (FDA) published the guidance for industry, which was not meant as a regulatory policy document, to guide the industry in addressing the potential risks of nano-based products under FDA regulation (FDA 2014). This guidance would allow the FDA to assess the products' safety, effectiveness, public health impact, and regulatory status based on the materials' size (as per the provision of the U.S. National Nanotechnology Initiative) (NNI 2023), its associated physicochemical properties and behaviour (FDA 2014). Although this was just a guidance on the FDA's thinking process on regulating nano-based products under its jurisdiction, the official regulatory frameworks were subsequently published. The first was the regulation on the safety of nanomaterials in cosmetics which aimed to guide the use of nanomaterials in nano-enabled cosmetic products. According to this framework, manufacturers are expected to provide information on the safety of their products following the traditional safety assessment of other cosmetic products (FDA 2014). However, the FDA regulation does not require the pre-market registration of nano-enabled products. According to the regulation, nano-enabled cosmetic product manufacturers are just expected to not misbrand or adulterate their products (FDA 2014). Although the regulation seems flexible and unenforceable, the FDA does require that the manufacturers conduct full characterization of the products/nanomaterials used (physicochemical properties) and provide a complete toxicological profile (FDA 2014). Other regulatory frameworks include the use of nanomaterials in food for animals (FDA 2015), and most recently the guidance on drug and biological products that contain nanomaterials (FDA 2022). This work in the U.S.A is also supported by the U.S. Environmental Protection Agency (EPA)'s ongoing Research on Nanomaterials (U.S. Environmental Protection Agency (EPA) 2023a, b), which has also informed the Control of Nanoscale Materials under the Toxic Substances Control Act (U.S. Environmental Protection Agency (EPA) 2023a, b).

The European Commission published the regulatory framework (2018/1881, EC No 1907/2006 amendment) for 'nanoforms' materials through its Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) program (Juncker 2018). The purpose of the regulation was to provide guidelines on how manufacturers and importers and nano-based materials/products need to assess and document how the risks of the materials/products are controlled during manufacturing, usage, and throughout the supply chain (Juncker 2018). According to this regulation, the manufacturers/importers need to create a chemical safety document that provides complete information on characterization of the nanoform materials (size, shape, type, surface characteristics), toxicological and ecotoxicological profile, water solubility, and dustiness, among others (Juncker 2018). The regulation requires a full screening of the nano-based materials' health and environmental safety. Through the registration of these nano-based materials/products, the EU would be able to keep track of the market penetration and address safety concerns of nano-based products throughout manufacturing (occupational), usage (absorption/adsorption and environmental release), and disposal (end of life). The European Chemicals Agency

(ECHA) has also published a technical guideline that outlines the technical details of this regulation, to guide compliance (ECHA 2019).

The EU, through the Scientific Committee on Consumer Safety (SCCS), further introduced the Guidance on the Safety Assessment of Nanomaterials in Cosmetics which seeks to guide the safety of ENMs used in cosmetic products. In their framework, SCCS addresses the safety assessment of ENMs, their physicochemical characterization, exposure assessment, hazard identification, and dose–response characterization, and risk assessment (SCCS 2023). Through these pillars, SCCS guides the use of ENMs in cosmetic products; guidance is provided on the ENMs types, physicochemical properties, and safety measures to reduce environmental release and risk (SCCS 2023). Additionally, SCCS also guides the concentrations of ENMs that can be used in NEPs to ascertain their environmental and human health safety (SCCS 2019). The work done by the EU is currently underway, especially in the European region, to influence safer implementation of nanotechnology and nano-based products.

On the African continent, South Africa introduced the National Nanotechnology Strategy in 2007 which aimed to influence the uptake of nanotechnology to support industrial and economic development. Specifically, the strategy established R&D hubs with specific objectives to develop nanomaterials and nano-based devices for application purposes (Musee et al. 2010). Although the strategy does highlight that nanotechnology should be applied according to environmental safety standards (DST 2006), no provision was made on guiding safety and risk assessment, environmental exposure, and toxicity assessment. To this end, the Department of Science and Innovation established the Nanotechnology HSE Research Platform in 2015 to generate comprehensive data on safety and environmental risks of engineered nanomaterials in South Africa (Gulumian et al. 2023). Under this platform, the risk assessment of ENMs is conducted at production (ENMs synthesis), occupational (ENMs/NEPs manufacturing), usage, and end-of-life of ENMs and NEPs stages. This platform will inform and support regulation, decision-making, and successful implementation of the nanotechnology industry (Gulumian et al. 2023). Although this platform has generated some data (Project 0085/2015), experimental investigations are ongoing, and no policies or regulations have been effected; policies and regulations in other African countries are non-existent.

On the international network, the Organisation for Economic Cooperation and Development (OECD) has been working on generating data, compiling test guidelines and legislative guidelines for manufacturing (occupational), usage (exposure and hazard), and disposal (end-of-life) of ENMs for over a decade (OECD 2023). In one of their earliest reports, the OECD Working Party on Manufactured Nanomaterials (WPMN) indicated that there was a need for ENMs/NEPs regulation due to the increasing commercialisation and marketing of ENMs (OECD 2011). This was based on the Questionnaire on Regulated Nanomaterials: 2006–2009, the results of which were reported in 2010 (OECD 2011). Accordingly, legislative provisions such as consideration of ENMs safety, explicit labelling of ‘nano’ for products that incorporated ENMs, and pre-market notification (6 months) to the European Commission for nano-based cosmetic products (OECD 2011). In 2012, the OECD also published a framework for the risk assessment of manufactured nanomaterials (OECD 2012). Specifically for environmental risk assessment, this framework recommends the consideration of ENMs' behaviour (dissolution, agglomeration/aggregation, adsorption), persistence and degradation, distribution, transformation products, and bioaccumulation in the environmental matrices (OECD 2012). For water specifically, the water solubility of the ENMs is crucial (OECD 2012). Although this risk assessment framework has been adopted in different ways in various OECD countries, three components remain consistent for ENMs risk assessment: physicochemical properties of the ENMs, their toxicity and ecotoxicological profiles (OECD 2012). More than the ENMs in their pristine forms, this framework also highlights the research needs in the understanding of the concentrations of ENMs used in the NEPs, and their release into the environment (OECD 2012). Over the years, OECD has completed several projects and proposed several methodologies and test guidelines (OECD 2023) to address the objectives of these frameworks. Unsurprisingly, countries such as Japan, the USA, Chile, and Canada have developed their regulatory frameworks based on OECD recommendations (Allan et al. 2021).

The European Commission is deliberate in ensuring the regulation of nanotechnology, specifically for environmental safety. This includes the water resources, which are the major recipients of environmental contaminants. Although organizations such as the FDA (U.S.A.) and other countries are investing in the regulation of this industry, the EU is more deliberate in the implementation and ensuring compliance with the regulatory requirements. The FDA has so far only focused on nano-based products that are within their regulatory jurisdictions. Therefore, much more work is required to ensure that nanotechnology innovations do not compromise water resources. Data shows that even within the EU, the PR-ENMs in water resources are increasing; this could be biased due to a lack of data in other countries. The existing data in the EU can therefore be used as a baseline for influencing further research and policy development in OECD countries and beyond. It is worth noting that the current uptake of nanotechnology, globally, is increasing rapidly. While research data is necessary, policy development, implementation and compliance can be the fastest tool available to curb the potential risks of ENMs to the aquatic environment.

18.4 Conclusions and Recommendations

The environmental exposure and impact of ENMs/PR-ENMs are evident. The SSbD approach is therefore critical to ensuring that the increase in NEPs in the consumer market and their use do not compromise the environment. However, there is a paucity of data in critical areas needed to implement the SSbD strategies. The conducted studies indicate the possibility of a major shift to creating safer nanomaterials. Nonetheless, more data still need to be generated to validate these different methods. Moreover, more resources and access to research are needed at the industry/manufacturing level; manufacturers need to invest in research for the development of safer NEPs through safer ENM development. There is a need for the involvement of nanotoxicologists/risk assessors through the lifecycle of product development. Industries with limited access to such resources may depend on other partners or academic institutions for this research and development aspect. As a proposed concept and minute data pool currently available, only the advantages of SSbD can be presented with certainty. It can only be assumed that there will be reluctance on the uptake by the industry due to the potentially excessive costs of reconstructing their current processes.

At the regulatory level, there is some movement in research-based policy development. The EU has developed clear policies although the implementation still lags. This holds for other institutions such as the FDA. It is worth appreciating the work being done by the OECD in guidelines and test development for comprehensive risk assessment. However, this highlights the current challenge; there are only guidelines and recommendations put forward with the policy development and implementation at different countries' levels. Due to the import/export nature of nano-based products, there necessitate an international framework and/or treaties to guide policy implementation at an international level.

Overall, the aquatic environmental risk assessment of PR-ENMs and mitigation measures should be at the forefront of nanotechnology development. SSbD and policy development, as detailed herein, are the most effective and industrially relevant strategies to balance the uptake of nanotechnology and environmental safety.

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