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SUN: Paving sustainable nanoinnovation

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Abstract: Our understanding of the environmental, health and safety (EHS) risks from nanotechnologies is still limited, which may result in over-balancing regulations and demolished consumer confidence. SUN is based on the hypothesis that the current knowledge on environmental and health risks of nanomaterials, whilst limited, can nevertheless guide nanomanufacturing to avoid future liabilities, provided that an integrated approach that addresses the complete product lifecycle of production, use and disposal is applied. This approach aims to give clear answers to questions from regulatory authorities, and open new possibilities for innovators to design greener nanotechnologies through development and application of new methods and tools for prediction of long-term exposure,

effects and risks for humans and ecosystems (services), practices for risk prevention and management and tools to streamline effective decision making about safer products and processes.

Keywords: manufactured nanomaterials, long-term risk assessment, lifecycle assessment, decision support, risk prevention and management

1. Introduction

Nanotechnology is one of the key emerging technologies identified in the European Union (EU) 2020 Strategy. It has enormous potential to contribute to innovation and economic growth, which fosters large investments in developing new industrial applications. However, the increasing number of nanoproducts that reach the market (nanodb.dk) may reveal health and environmental risks.

Several EU research projects (e.g. ENPRA, MARINA) have studied the short-term risks from production and use of MNs. However, most of them have used pristine MNs produced specifically for testing, which are not representative for real lifecycle scenarios. Pristine MNs undergo weathering and transformation reactions when incorporated into products and when released from them[1]. Few emerging results for textiles, paints and nanocomposites suggest that the released particles undergo significant transformation and aging[2], and may pose different occupational, consumer and environmental risks compared to the pristine MNs[3]. However, the identity of MNs released from actual products used by occupational users and consumers is largely unknown. The NANORELEASE (Consumer Products) project identified the end-of-life (e.g. shredding, incineration, landfilling, recycling) as the lifecycle stage where significant release could occur, especially for product where the MNs are bound in a matrix[4], but only few projects (e.g. SUN, GUIDEnano) are investigating MNs end-of-life exposure scenarios.

Some new modelling studies have investigated consumer exposures to MNs[5] released from products, but no empirical data on consumer release and exposure measurements are available. In contrast, data are slowly emerging on workplace emission, exposure characteristics and source strengths from different release scenarios in the production stage, such as synthesis, powder handling[5b], simulated sanding[6], drilling and cutting of Nanocomposites[6].

MNs released from industrial processes and consumer products will ultimately end up in the environment[7]. Several studies have shown that MNs accumulate to a significant extent in the sludge of Sewage Treatment Plants[8]. Sewage sludge is used as fertilizer in many countries[9]. Therefore it is a relevant source of MNs entering soil affecting terrestrial organisms and potentially humans[10]. In addition, the waste water can be a dominant source of MNs in the aquatic compartment[11]. Since many MNs react when they come into contact with natural media such as freshwater or seawater, typically by agglomeration, it is expected that they will preferentially partition to sediments[8b]. Many NMs are (designed to be) persistent, which may lead to the long-term exposure of humans, terrestrial and aquatic organisms, thus posing long-term health and ecological risks and disrupting vital ecosystem services.

Toxicity data for MNs have been produced in various EU projects: e.g. NEURONANO, NANOSH, PARTICLE_RISK, NANOMMUNE, NANOSUSTAIN, NANOTEST, ENPRA, MARINA, NANOMICEX, INLIVETOX and SANOWORK. As a result, a coherent profile of NMs health hazards begin to emerge, demonstrating that reactive oxygen species[12], oxidative stress[13] and modified inflammatory responses[14] play important roles in their animal and cellular toxicity. The results of the above projects also show relationships among key physico-chemical characteristics, modes of action and biological responses, indicating that factors such as surface area and reactivity[15], surface charge[16], solubility, shape[17] and chemical composition are all key. However, our understanding of the long term effects of MNs is at an early stage, especially for MNs released from real products and for environmental species. Moreover, risk analyses still face considerable remaining knowledge-gaps concerning biological uptake and toxicity action modes as well as environmental behaviour, fate and exposure to MNs[18]**.**

Until now, the risks and the environmental impacts of only few nanoproducts have been studied from lifecycle perspective[19] and a handful of generic LCA studies exist, mainly focusing on material synthesis and product formulation[20]. This is mainly due to the lack of reliable Lifecycle Inventory data for the use and the end-of-life stages.

Risk management measures currently applied to MNs (e.g. engineering controls, administrative controls, personal protective equipment) do not significantly depart from conventional safety practices for handling chemicals. These procedures are based upon the properties of the bulk form or the solvent carrier and not on nano-specific characteristics. The same is valid for the current waste management practices (e.g. composting, landfilling, incineration and recycling). Only recently, $S_{by}D$ has become a national initiative in the US. This concept is material-specific and aims to retain the functionality of materials and products, while reducing their health and environmental risks[21].

The new FP7 Sustainable Nanotechnologies (SUN) project is based on the idea that the above knowledge on EHS risks of MNs, while limited, can nevertheless guide nanomanufacturing to avoid future liabilities if an integrated approach addressing the complete product lifecycle is applied to generate sufficient information on long-term effects and exposures of not only prisitne, but also released/aged MNs.

SUN was launched on 1 October 2013 and will continue for 42 months, bringing together 35 partners from 12 EU countries. With a total budget of about 13 539 313 euro, SUN is among the highest funded projects of the EU FP7 research programme.

Unlike other nano-EHS projects advancing the understanding of the properties, interactions, fate, impacts and risks of nanomaterials, SUN was envisioned to walk down the road from scientific implications to industrial applications while at the same time inform regulatory oversight.

The SUN research process integrates the bottom-up generation of nano-EHS data and methods with the top-down design of a Decision Support System (DSS) for practical use by industries and regulators.

The SUN industrial partners will test the DSS against supply chains of real products. This validation will culminate in guidelines for safe nanoscale product and process design. In addition, SUN will identify needs for future research and assign priorities for current regulation. We will work with major international stakeholders to implement the SUN results into practice and regulation.

2. Results and Discussion

2.1. SUN strives to address technological and EHS challenges

As with any new technology, large-scale production and commercialization of nanotechnologies require an understanding of their ESH impacts, and must develop strategies for their safe production, use and disposal. Today we face a challenge to achieve reproducibility in industrial/product performance; and to understand and mitigate the potential risks emerging from innovation in nanotechnology. The fundamental issue is that nanomaterials undergo complex transformations during their lifecycles, which affect not only their environmental and health effects, but also their industrial applications.

In order to address these challenges the SUN consortium identified a set of objectives within the following 3 central themes of sustainable nanoinnovation.

Theme 1 : Materials, products and processes

- Perform a data gap analysis with regard to the SUN case studies in order to prioritise data production in the project
- Map hot spots release of nanomaterials during different stages of the value chains in order to guide cost-effective strategies for release and exposure estimation
- Assess the environmental impacts arising from each lifecycle stage of MNs and compare the results to conventional products with similar uses and functionality
- Develop and validate criteria and guiding principles for green nanomanufacturing (low energy consumption, eco-friendly materials) and for setting environmental quality targets

Theme 2 : Risk assessment

- Collect and characterize MNs released from real products in different lifecycle stages for use in (eco) toxicological and behaviour/fate studies
- Model the behaviour/fate of MNs and assess their exposure concentrations in the environment (i.e. air, water, sediment and soil compartments)
- Develop and validate methods (incl. high-throughput and content tools) for prediction of long-term effects of MNs in humans and on ecosystem services in environments subjected to multiple stressors
- Develop and validate a three-step tiered approach for qualitative to quantitative assessment of inhalation and dermal to gastro-intestinal occupational and consumer exposure to MNs, based on high-quality collated and project-generated emission rates, exposure measurements and contextual information
- Use the exposure and effects data acquired from other projects and the data newly produced in SUN for quantitative lifecycle-oriented ecological and human health Risk Assessment

Theme 3 : Safe product and process design

- Describe best available technologies/practices for reduction of exposure and effects of MNs in different lifecycle stages

- Develop the following innovative risk reduction methods and practices and include them in guidelines for safe nanoscale product and process design:

  - Safety by design elimination/substitution and waste isolation practices to reduce the release of nanomaterials from products/composites or to induce their accelerated alteration/degradation in order to reduce their environmental persistence and bioaccumulation.

  - Methods to analyse the evolution of the product quality parameters, process conditions and interactions, in real-time, to subsequently exercise control over them, increasing both product safety and quality.

  - Best practices to minimise release and exposure of MNs during handling of waste flows containing MNs.

- Develop/validate the user-friendly software-based Decision Support System for estimating MNs risks for different targets (e.g. workers, consumers, ecosystems) in each lifecycle stage and evaluating to which extent the available technologies/practices could reduce this risk (incl. cost-effectiveness analysis)

2.2. SUN is organised as an iterative process

SUN consists of 8 scientific Work Packages (WP) distributed among three main themes.

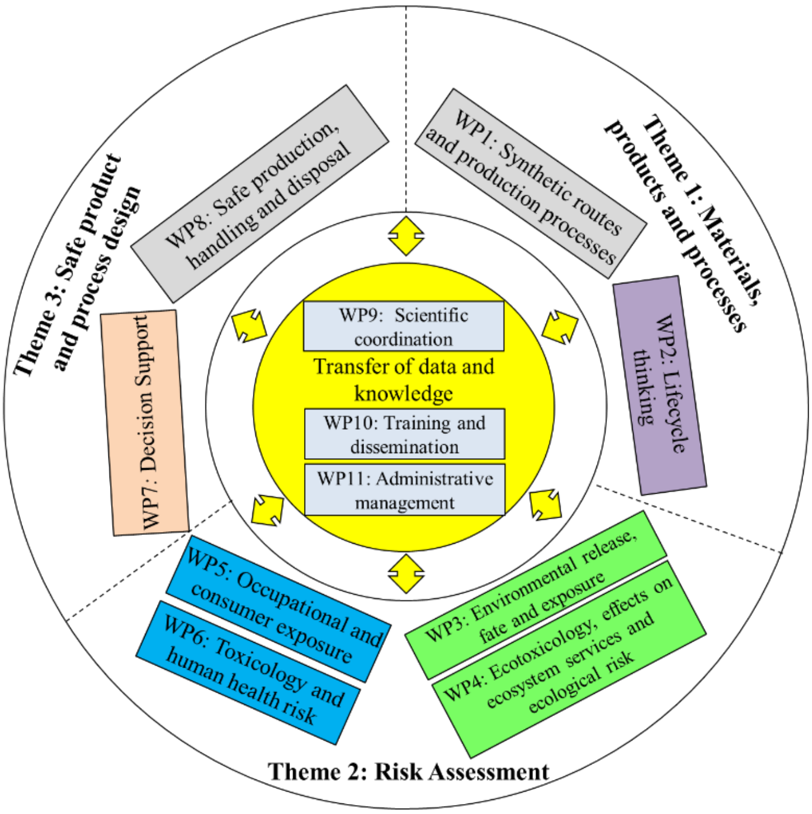

Figure 1. SUN's iterative structure.

WP1 is both the start point and end point of SUN: real products and processes throughout all stages of the lifecycle set the stage for all activities in WP 3-6. The outcomes, both direct feedback from WP3-6 as well as the results of WP7 and WP8, namely the Decision Support System and guidelines, feed into the current practice of the industry partners.

WP3-6 will produce data on physico-chemical characteristics, hazard, exposure, risk and environmental impact in a number of 'real-life' case studies (cf. page 6) where such data does not already exist in sufficient quality. WP3-6 benefit from the excellent network of the partners; most major European national projects will provide data, which SUN does not have to duplicate. WP7 will develop practices, methods and tools to facilitate safe production, handling and disposal of MNs and incorporate them into case-specific guidelines for safe product and process design. Finally, the tools (and data, where needed) produced in WP1-7 will be integrated into the SUNDS in WP8.

In addition we foresee three horizontal Work Packages. Sharing results and taking decisions in a consortium of thirty-five partners is a challenge, but the partners have a long history of collaboration; so, we are confident that the size of SUN will not affect its efficiency. WP9 will deal with the scientific coordination, which comprises scientific steering to keep the work plan up to date and to avoid 'mission creep'. The non-scientific, administrative management of the project is done in WP11, shared between the Coordinator and a dedicated project management company (ERS). WP10 is dedicated to dissemination activities. This does include conventional publications, conference-contributions and website, and a significant commitment to collaborate with other initiatives (e.g. in the Nanosafety Cluster), but as well workshops and trainings for the 'end users' of SUN's results, namely industry and regulators.

2.3. SUN's impact

The overall impact of SUN is to provide nanomanufacturers and regulators with data and tools to address the above scientific and technological challenges. The project aims to give clear answers to questions from regulatory authorities, and open new possibilities for innovators to design greener nanotechnologies. This will be achieved through development and application of new methods and tools for prediction of exposure and effects on humans and ecosystems and implementable practices for risk prevention and management covering the complete lifecycles of nanomaterials. This approach aims to protect innovation by providing industries with data and prospective tools to streamline effective decision making about safer products and processes.

To test and validate the proposed tools and to maximize the impact of the project, we carefully scoped the data generation and analysis to address the most important concerns that regulators and manufacturers currently face. The markets covered by the SUN case studies Titanium Dioxide, Silica and Irgazin are large: plastics: 235,000,000 tons worldwide, thereof EU sales worth € 295 billion and 1,450,000 jobs in EU; pigments: 317,000 tons, worth €4 billion, and nano-fillers: 242,000 tons. Because the highest profit margins for material producers are in the formulation and synthesis of compounds we focus the SUN activities on these steps of the value chains. A sintering ceramic Tungsten Carbide (WC) material was selected to ensure the applicability of the methods developed in the project also to the impressive portfolios of the cement/concrete and fillers industries. The rest of the materials were selected less for their commercial impact, but because of their very considerable consumer and environmental safety impact: Copper Oxide and Silver: fewer than 1,000 tons, but of ecotoxicity concern; Multi-walled Carbon Nanotubes: less than 300 tons, but of human toxicity concerns.

4. Conclusions

SUN combines the bottom-up generation of environmental, health and safety (EHS) data and methods with the top-down design of a DSS for both manufacturers and regulators. From the level of expertise in the SUN consortium, we are confident that the project will deliver strategies and methods that advance beyond the state-of-the-art understanding of the properties, interactions, fate, impacts and long-term risks of MNs. The top-down integration of these results in the SUN DSS will enable more sustainable nanomanufacturing processes, it will result in more solid risk prevention and mitigation strategies, and it will be easily applicable to different materials and industrial settings.

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Conflict of Interest

The authors declare no conflict of interest

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