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Impact and Effectiveness of Risk Mitigation Strategies on the Insurability of Nanomaterial Production: Evidences from Industrial Case Studies

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Workers involved in producing nanomaterials or using nanomaterials in manufacturing plants are likely to have earlier and higher exposure to manufactured/engineered nanomaterials (ENM) than the general population. This is because both the volume handled and the probability of the effluence of 'free' nanoparticles from the handled volume are much higher during a production process than at any other stage in the lifecycle of nanomaterials and nanotechnology-enabled products. Risk assessment techniques using control banding as a framework for risk transfer represents a robust theory but further progress on implementing the model is required so that risk can be transferred to insurance companies. Following a review of risk assessment in general and hazard measurement in particular, we subject a Structural Alert Scheme methodology to three industrial case studies using ZrO₂, TiO₂ and multi-walled carbon nanotubes. The materials are tested in a pristine state and in a remediated (coated) state and the respective emission and hazard rates tested alongside the material performance as originally designed. To our knowledge, this is the first such implementation of a control banding risk assessment in conjunction with an ENM performance test and offers both manufacturers and underwriters an insight into future applications.

Introduction and Background

Ensuring safe exposure scenarios should be considered an ethical obligation towards all workers involved in the production of nanomaterials. In many jurisdictions there is also a legal obligation for employers to protect these workers from any work-related harm, as exemplified by the UK's Control of Substances Hazardous to Health act. An insurance provider is an important stakeholder and, to a great extent, functions as a proxy regulator by influencing work practices and standard operating protocols (SOP). If insufficient efforts are made by the employer to protect its workforce it may be difficult or prohibitively expensive to obtain insurance. Given the multiplicity of stakeholders and the associated cost/benefits, a strong case can be made that the development of effective risk mitigation strategies offers an economic opportunity as well as assisting in the responsible development of nanotechnology (Schulte, P., et al., 2014). The International Risk Governance Council recommends a corrective and adaptive approach that takes into account the level and extent of available knowledge of nanomaterials so that a societal balance of the predicted risks and benefits can be achieved (Renn, O. and M. Roco., 2006). More recently, ISO standards provide a pragmatic approach for the control of occupational exposures to Engineered

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Nano Materials (ISO, 2011).

Issues and Questions Considered

While workers involved in the manufacture of nanomaterials or nano-enabled products are at the frontline in terms of exposure potential, there is a paucity of research on the assessment of the risks of exposure to ENMs within the nano-manufacturing setting. Risk assessment techniques such as the use of control banding have been suggested by many as a potential framework that can be used for this purpose as a proxy for specific testing, such as on-site measurements of emission levels (Mullins, M., et al., 2013). However further progress on developing and implementing such models is required to improve their predictive power and reliability so that risk associated with nanomaterial production can be effectively quantified and transferred to insurance companies. This is important as it provides a pragmatic and cost effective approach to risk assessment and risk management to ensure the long term sustainability of nanomaterials production. Whilst control banding tools are not being primarily designed for underwriters they can, in many instances, help to categorize both exposure and hazard. The resultant risk location can then be used to rank the acceptability of certain risks or can be associated with certain production processes in the nanotechnology sector so that an insurance premium can be applied to specific scenarios. The economic burden of insurance could encourage companies to adopt a proactive behavior towards their risk management procedures, demonstrating that safety practices have been put in place and proven to be effective at reducing the emission potential and/or the toxicity (if any) of a given ENM. However, the success of a control banding implementation critically depends on identifying hazards, and here, despite the effort of the scientific community (Hubbs, A.F., et al., 2013; Winkler, D.A., et al., 2013) there remains a high degree of ambiguity.

Methodology

In this article, we increase the general applicability and relevance of hazard information data related to a specific nanoparticle by developing a Structural Alert Scheme (SAS) which may also be used by non-specialists. The scheme has been developed within the framework of a European Commission -funded research Project "Sanowork" on the basis of a collation of known, biologically effective doses apparent in particle toxicology (Donaldson, K., et al., 2012). The SAS is based on recognized commonalities in the mechanisms of toxicity, which has been

identified over decades of research by the toxicology community and linked with particle physicochemical properties. Known as "structural indicators", such physicochemical properties of particles are known to infer a hazard. Therefore, the hazard identification scheme uses "structural alerts" such as the classification of an ENM's parent material as a carcinogenic, mutagenic or reproductive toxin, or on the basis of its size, surface area, chemical reactivity, surface charge, solubility and morphology - to evaluate the ENM's toxicological profile. Such key properties enable a rapid classification of particles based upon common physicochemical characterization data.

Outcomes and Findings

Using physico-chemical data provided either by the suppliers (e.g. in the form of safety data sheets) or gathered from EU FP7 Project Sanowork (grant agreement no. 280716), each material and its remediated forms were screened using a structural alerts scheme. In doing so, the results of the hazard identification were compiled into a hazard matrix table to more clearly see the role of remediation strategies on the intrinsic hazard potential of the different nanomaterials. Following a safety by design approach the surface or structure of the nanoparticle was changed and the effect on hazard and/or exposure potential evaluated, together with the expected functional properties. However, whilst in part successful, this approach highlighted knowledge gaps in terms of physicochemical characterization which hampered making strong conclusions in terms of efficiency of some remediations. This lack of information is challenging but if deemed sufficiently useful, could form a base set of recommended physicochemical characterizations required for the identification of hazards in the absence of toxicological testing. By basing the hazard identification on the presence or absence of key physicochemical characteristics influencing toxicity, rather than considering the nanoparticle as a whole, single entity, the SAS provided a flexible approach to identifying hazards in a multitude of samples with numerous physicochemical modifications. For instance it became evident that coating of particles such as TiO₂ and ZrO₂ with citrate resulted in a shift from a highly acidic suspension (representing a hazard) to a more neutral suspension. The demonstrated possibility to tune hazardous properties and exposure determinants allows ENM production risk to reside within acceptability. As an alternative to the more restrictive precautionary principle, a shift towards lower exposure and hazard categories should be implemented and pursued as best practice.

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