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Review article

Regulatory relevant and reliable methods and data for determining the environmental fate of manufactured nanomaterials

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ABSTRACT

The widespread use of manufactured nanomaterials (MN) increases the need for describing and predicting their environmental fate and behaviour. A number of recent reviews have addressed the scientific challenges in disclosing the governing processes for the environmental fate and behaviour of MNs, however there has been less focus on the regulatory adequacy of the data available for MN. The aim of this paper is therefore to review data, testing protocols and guidance papers which describe the environmental fate and behaviour of MN with a focus on their regulatory reliability and relevance. Given the often identified need for modification of OECD testing guidelines, the use of these cannot per se be assigned high regulatory adequacy. Though the specific test considerations will differ between conventional chemicals and MN, the ultimate endpoints of interest are similar. The water compartment must be considered as one of the main points of entry, facilitating dispersion of MN in the environment and establishing a link to the other environmental compartments such as soil, sediment, air, and biota. Once released to water various processes like dissolution, agglomeration, heteroagglomeration, sedimentation, interaction with natural organic matter, transformation and uptake by biota are processes of high relevance for the fate of MN in water. In the review it is found that the OECD draft test guidelines for dissolution and agglomeration will greatly assist in the generation of regulatory relevant and reliable data. Gaps do however exist in test methods for environmental fate, such as methods to estimate heteroagglomeration and the tendency for MNs to transform in the environment.

1. Introduction

The production, manufacturing and use of manufactured nanomaterials (MN) in a wide range of products and applications has increased in recent years and environmental release of MN is possible throughout the product life-cycle (Nowack et al., 2012; Hartmann et al., 2014). Releases may occur during the use of nano-enabled consumer and industrial products either by intentional (e.g., MN used for environmental remediation) or non-intentional releases (e.g., due to weathering of products containing MN). Environmental emissions of MN may also occur by accidental spills during production or transportation, and when products are disposed of. Therefore, wastewater treatment effluents and sludges, stormwater, landfill leachates and waste incineration residuals are all likely serve as entry points of MN to the environment. Upon emission the fate and behaviour of MN will be determined by their intrinsic properties as well as the specific environmental conditions (see Fig. 1). It is known today that in the environment MN tend to be transformed from their released form (Nowack et al., 2012) and while some analogies can be made to the behaviour of colloids in the environment, the novel physico-chemical characteristics of MN present a challenge in determining their environmental fate and behaviour. A number of recent reviews have addressed the scientific challenges in disclosing the governing processes for the environmental fate and behaviour of MN (e.g., Peijnenburg et al., 2015; Lowry et al., 2012a) and it is a topic where new experimental insights are published at a rapid pace. While a deeper scientific understanding of underlying processes is crucial to explain MN transformations and distributions in the environment, the urgent need for regulatory decision making regarding the environmental risks of MN calls for reliable and relevant data generated with validated methods (Hartmann et al., 2017). Therefore, the aim of this paper is to review data, testing protocols and guidance papers which describe the environmental fate of MN with a focus on their regulatory reliability and relevance.

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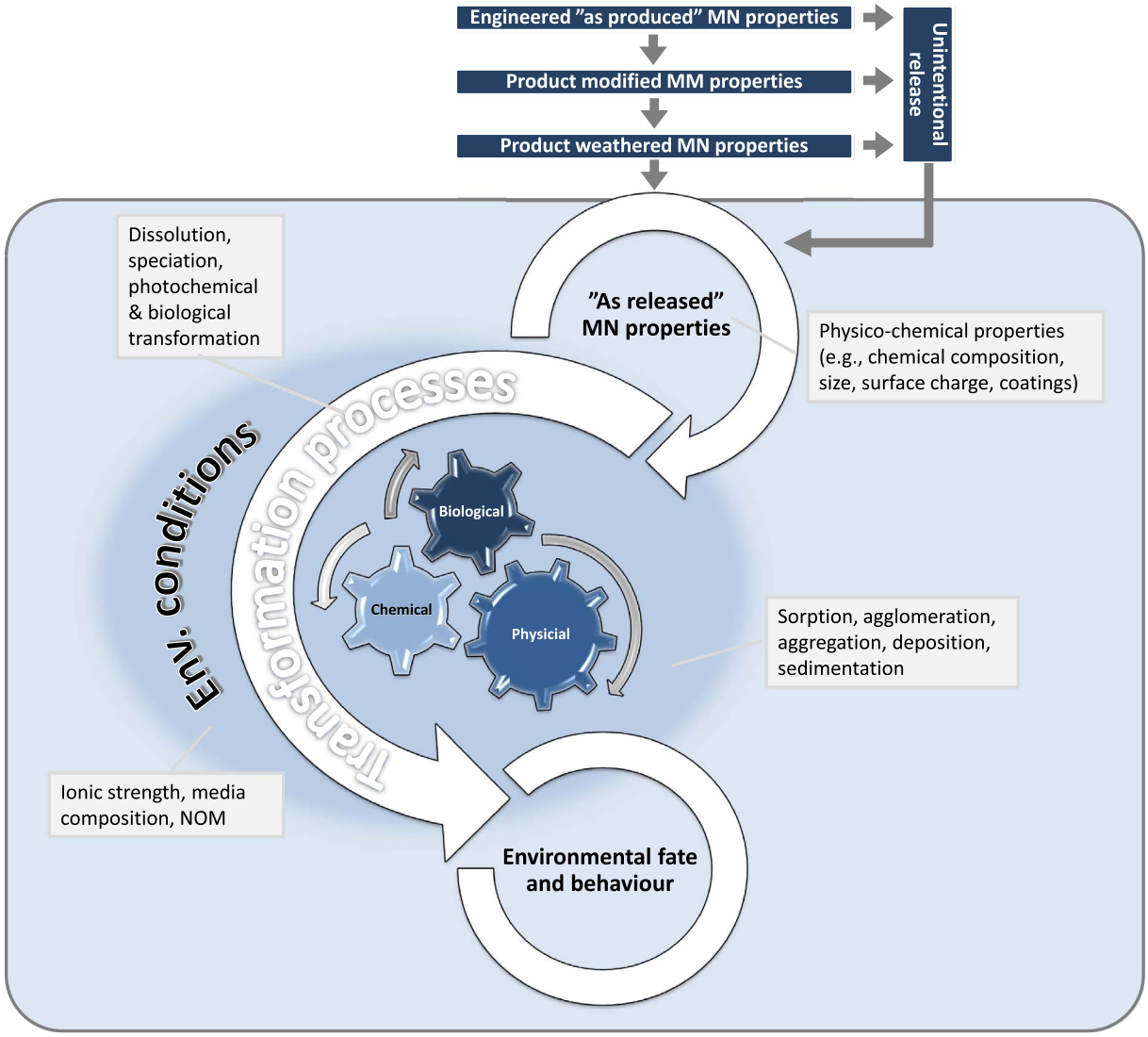

Fig. 1. Potential transformations of MN in the environment. The figure illustrates how "as released" MN are transformed by a combination of interlinked processes. The resulting environmental fate and behaviour of the MN is further influenced by the properties of the transformed MN in combination with the environmental conditions in question (modified from Hartmann et al., 2014).

Fate processes for MN are predominantly kinetically controlled (Praetorius et al., 2014a), in contrast to the equilibrium based partitioning processes of dissolved chemicals. This means that the regulatory relevance and reliability of environmental fate data for MNs is not easily defined as it is not by default linked to the use of standard or guideline testing, which in most cases are intended to derive equilibrium based partitioning constants.

The regulatory relevance of environmental fate data for conventional chemicals is strongly linked to the use of fate descriptors for the estimation of Predicted Environmental Concentrations (PEC). In chemical safety assessment of industrial chemicals, the software program EUSES (The European Union System for the Evaluation of Substances, https://ec.europa.eu/jrc/en/scientific-tool/european-union-system-evaluation-substances) is applied. This tool contains models for exposure assessment using established chemical fate models. With regard to MN the final report from the NanoImpactNet FP7 project concluded that the fate models included in EUSES are: "…insufficient for nanoparticles for a number of reasons: (a) the extent/rate of dissolution is unknown or not included in current models and the same goes for (b) the extent/rate of aggregation/settling and (c) the extent of association with sediment." (Hansen et al., 2011). As stated by Peijnenburg et al. (2015) it is known that the traditionally used fate descriptors for chemicals do not apply to nanomaterials and as demonstrated by Praetorius et al. (2012) extensive adjustments of environmental fate models must be implemented before they can be applied to MNs.

The starting point for this review is the fate endpoints addressed in the OECD test guidelines and guidances for conventional chemicals. Though the specific test considerations will differ between conventional chemicals and MNs the ultimate endpoints of interest are similar. The fate endpoints of relevance for MN in the current OECD test guidelines (e.g. OECD TG 105–106, 301–309, 312, 314–317) will automatically be considered of regulatory relevance in the context of this review. With regards to regulatory reliability, papers describing methods with a potential for high reproducibility of methods will be given priority, but it should be recognised that standardized protocols and test guidelines for environmental fate descriptors of MN are currently under development. The use of the test guidelines mentioned above will not per se contribute to assigning a high regulatory reliability to the studies reviewed. This review will mainly focus on the fate descriptors for MN in water, and to a less extent on sediments and soils. While the processes described are equally important to the behaviour of MN during ecotoxicological and bioacummulation testing (Hjorth et al., 2017), the focus here is directed towards the fate of MN in the environment.