Environmental risk assessment and management of engineered nanomaterials - The role of ecotoxicity testing - DTU Orbit (16/05/2019)

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In 2004, the first article on ecotoxicity of engineered nanomaterials (ENMs) was published, subsequently giving birth to the field of nanoecotoxicology. Today, approximately a thousand peer-reviewed articles have been published on the topic albeit many challenges remain within the field. Central to these is the continued examination of the applicability of ecotoxicity testing to encompass the testing of particles, as the tests originally are developed for dissolved chemicals. Furthermore, the ability of such testing to inform environmental risk assessment and environmental risk management, including the applicability of these concepts, has been questioned.

The present thesis provides an overview of the challenges facing ecotoxicity testing of ENMs and investigates whether we can rely on such testing to inform risk assessment and eventually management of the potential environmental risk of ENMs.

Although the Organisation for Economic Co-operation and Development (OECD) launched a seven year long testing programme around the use of standardized OECD test guidelines (TGs) for ENMs, which concluded that the TGs are generally applicable to ENMs, this thesis argues that it is not possible to offer any conclusions based on their analysis. Efforts within nanoecotoxicology are focused on modifying existing TGs to improve the stability and dispersion of suspended ENMs, although it is paramount to acknowledge that the underlying assumption of the dissolved nature of the test compound is violated. Furthermore, several dilemmas - so called-double binds - should also be acknowledged as they dictate the limitations of standardization and therefore also its ability to guide risk assessment.

The paradigm of conducting in vivo animal toxicity testing and extrapolating the data to either humans or the environment is gradually being replaced with a focus on in silico and in vitro studies with an even greater need for and reliance on extrapolation. However, in this thesis it is argued that within ecotoxicity, whole organism models remain at the foundation of environmental risk assessment, and as such, they are likely to remain in use for nanoecotoxicology. Indeed, the use of more complex in vivo systems such as microcosms and mesocosms are recommended to enable and validate current risk assessment practices. But just as envisioned in human toxicology, an integrated approach must be pursued to reap the benefits of simplified as well as more complex testing systems, each fit for purpose for different tasks.

It is concluded that it is not possible to conduct environmental risk assessment of ENMs with a satisfactory level of certainty, primarily due to knowledge gaps and the uncertainty imbedded in current ecotoxicity data. Albeit with time better data will be available, it is important that tools encompassing uncertainty are utilized to facilitate decision-support. As the risk constituted by ENMs cannot be quantified, the use, need and ability of risk management options to encompass the potential risk are similarly challenged. This should invoke a precautionary stance on the use of ENMs.

Within the field of nanotoxicology the concept of creating ‘safety by design’ has received much attention, arguably both due to these risk assessment and management issues, but also in spite of them. Instead of focusing on managing complexity and uncertainty, the rise of ‘safety by design’ indicates that the field is going towards a more deterministic approach with a misplaced promise to solve these management issues scientifically.

Finally, identifying risky ENMs and safer alternatives through alternatives assessment should be encouraged. Importantly, in doing so we will also be forced to look at risk in combination with benefits, as addressing risk in isolation rarely leaves room for resolving societal issues.

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