Conceptual Considerations to establish a Framework on Release for Nanomaterials

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In recent years much work has been conducted to assess the exposure to engineered nanomaterials (ENM) due to concerns on possible risks stemming from their production and use. Whereas exposure measurements are nowadays established in occupational settings they are less so during other stages of the ENM life cycle. Also, the actual release of ENM as a prerequisite of exposure and the processes involved is much less investigated. The available studies on release pinpoint in many cases only the release of a given material during a special test with fixed conditions (e.g. Froggett et al., 2014). The link between release and exposure as well as the establishment of representative test methods are still needed.

Understanding of the main factors affecting release, i.e. material or process characteristics, is the key for the development of safer designs and in the end safer products. We will therefore present a conceptual framework to understand the mechanisms that lead to the release of airborne ENMs during handling of the pure (bulk) ENMs or products containing ENMs and the main material characteristic that influence release.

Along the life cycle a release of ENM may occur during the production and further processing, the use (or misuse) of products, due to environmental factors (UV radiation and weathering) leading to ageing and in the recycling and disposal phase.

The release characteristics depend on the one hand on the physical form of the ENM which can be either in powder form, incorporated within a solid matrix material or within a liquid. In case of powders release is solely governed by the ENM properties in conjunction with the process taking place. In case of composites or liquids the release is grossly dominated by the properties of the matrix material.

On the other hand different processes acting on the ENM leading to different release characteristics can be identified: chemical processes differ from mechanical and thermal processes. Nanoparticles dispersed in a solid composite matrix will be released in a different form into the environment e. g. during sanding (particle will be mostly embedded in the matrix) compared to incineration (only nanoparticle fillers because carbon may be completely combusted). The physical form and the process lead to the identification of the release scenario and release mechanisms, respectively, which together define the release assessment method.

The release taking place due to different processes can be linked to exposure and to the material life cycle. The envisaged linkage between the different release processes and the regulatory and safety needs within nanotechnology will be presented.

A given activity type, e.g. a process step in the production, can include several release processes and release mechanisms. For example sanding involves heat and mechanical stress. For an exposure scenario we can have several processing steps in one location leading to a combination of release processes emitting particles (including transport and transformation).

Based on experimentally determined release rates for all involved processes, with or without modelling, a predictive exposure assessment indicating the likeliness and level of exposure can be expected. It is thus possible to better inform workers and industrial hygienists about the most relevant processes and to give direction when to use additional safety measures or equipment. Having general knowledge on different release processes and being able to link this to various life cycle scenarios also facilitates the evaluation of different production pathways and product possibilities.

A concise and congruent approach to develop harmonized release tests already linked to their possible future use is an important step towards safe nanotechnology and safer-by-design approaches.

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Froggett et al. (2014) *Particle and Fibre Toxicology*, **11**:17.