DELIVERABLE No.	D1.2
DELIVERABLE TITLE	Overview on guidelines for nanotechnology: material – exposure – hazard – risk
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Executive Summary

The objective of D1.2 was the recommendation of test methods suitable for risk assessment in the various stages of product development and life-cycle. For this, a step-wise approach was applied. In a first step, methods were listed for the six subjects and materials: exposure, hazard – human toxicity, hazard – aquatic ecotoxicity, hazard - terrestrial ecotoxicity, and risk. In a second step, a recommendation with justification was provided, considering the various product phases as well as potential stakeholders with their individual interests.

The data collection includes relevant internationally agreed methods used by government, industry, and independent laboratories on data procurement and assessment related to the safety of nanomaterials (NMs) and implications of nanotechnology. Internationally agreed methods are standardized and available as test guidelines. In addition, new developments not yet internationally agreed upon are summarized if they provide improvements regarding the assessment of the nanomaterial's impact compared to the existing approaches. Improvements shall lead to more reliable results for nanomaterials and can be subjects, such as further endpoints or further organisms. According to the DoA, SOPs have be also been compiled in this deliverable besides guidelines. Therefore, in extension of the title, D1.2 contains a compilation of both guidelines and, where suitable, SOPs.

The following subjects are considered:

- Section "Material"
- Section "Exposure"
    - Focus "experimental approaches"
    - Focus "modelling"
- Section "Hazard - focus human toxicity"
- Section "Hazard – environment"
    - Focus "aquatic ecotoxicity"
    - Focus "terrestrial ecotoxicity"
- Section "Risk"

Every section contains a compilation of available guidelines, further SOPs (if relevant) and a summary with recommendations and conclusions.

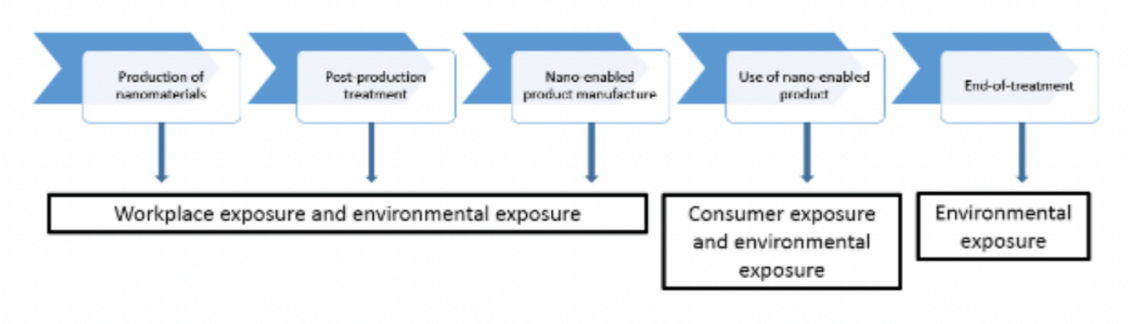

Figure 1. A general overview of exposure to nanomaterials.

Among the recommendations, assessments should be performed at the various stages of the life-cycle, starting from the first idea and first developments of a material via material optimization, development of a product containing the material, and use phase up to the end of the lifecycle with recycling, deposition, or combustion. The risk regarding workers, occupational health, and the environment has to be considered. Depending on the various phases of the life-cycle, the complexity of testing and used methods can differ. Material properties and exposure are connected. Therefore, in the following, both subjects are considered together. For hazard, a tiered approach with a screening level at the beginning and a higher level with comprehensive information at the end of the development with the aim of registration / notification is considered to be suitable. No specific guidelines and standardized approaches have been developed to address the risk during the life-cycle. During the use-phase and at the end of the life, the kind and extent of exposure is highly important. This information triggers the hazard assessment which depends on the affected group of people and environmental compartments. For hazard assessment, the same methods as for the assessment of the final materials are considered appropriate.

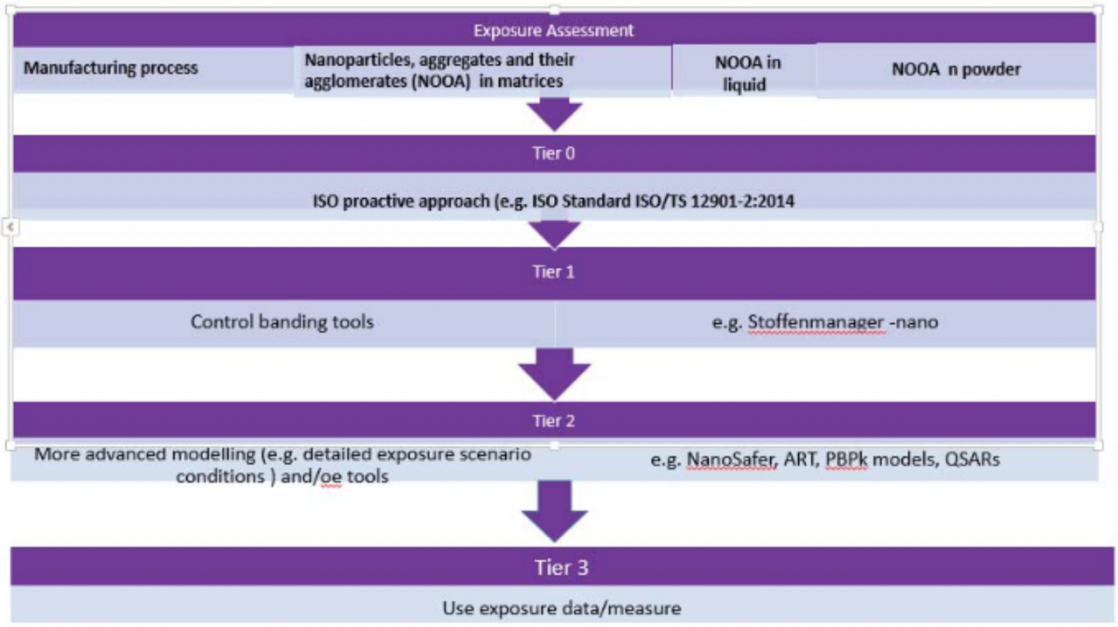

Figure 2. Schematic of a tiered exposure assessment approach.

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