A common European approach to the regulatory testing of nanomaterials

Assessment of value chain case studies
Deliverable 1.06

Case studies of the different investigated materials and the different proposed answers
Deliverable 1.07

Case study summary report including feasibility check of the proposed answers
Deliverable 1.08

Introduction

NANoREG aimed to perform a number of Safety in the Value Chain Case Studies (SVCCSs) on nanomaterials (NMs) and/or nano-enabled products. All studies focussed on fate and behaviour of the NMs to assess release of particles, thus considering possible exposure to NMs in the working environment, for consumers or for the environment in general. The obtained knowledge from these case studies contributes to answering the regulatory questions that are NANoREG's central theme. Three deliverables result from the work done for the SVCCSs.

Deliverable 1.06 'Assessment of value chain case studies' provides procedures for acquisition of SVCCSs, as well as for performing and evaluating the case studies; highlighting definitions, value chain characteristics within the NANoREG project, the NANoREG SVCCS process, SVCCS on NMs and other emerging technologies, risk assessment (RA) of NMs and connections to SVCCS, challenges for NM RA, bringing SVCCS and RA together.

Deliverable 1.07 'Case studies of the different investigated materials and the different proposed answers' covers methodology, results, and conclusions of three established case studies. Information has been included on uncertainties of safety issues, risk-reduction strategies and the impact of these strategies for existing and future risk potentials.

Deliverable 1.08 'Case study summary report including feasibility check of the proposed answers' gives a first stage evaluation of the NANoREG value chain approach, mainly based on the GALANT study. Knowledge generated, fed into NANoREG Task 1.3 answering issues and questions to regulatory needs, Task 1.4 the Framework development and Task 1.7 the Toolbox.

Description of Work

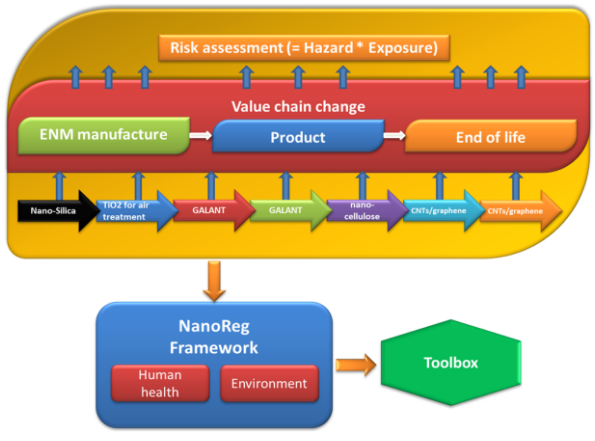

Figure 1: NANoREG SVCCS approach and connection to the NANoREG Framework and the NANoREG Toolbox (D1.06)

Prior to the examination of safety of NMs in SVCCSs themselves, the process and necessary procedures were designed. Case studies should include an assessment of potential human / environmental risks along the value chain and solutions -development and implementation- for their management. Generated results were expected to be useful for the key NANoREG outcomes, such as Framework and Toolbox. The main information was obtained by literature searches, which proved that only a limited number of studies available are truly value chain analyses/case studies.

In D1.06, the process designed for the whole SVCCS has been depicted in figure 1: NANoREG Guideline for Safety in the Value Chain Project Proposals.

This project has received funding from the European Union Seventh Framework Programme (FP7/2007-2013) under grant agreement no 310584

In total, three SVCCSs have been performed in NANoREG:

1. **SVCCS 1: GALANT – Glass surface coating to reduce leaching using nanoTiO_2**
With this study, possible leaching of titanium dioxide (TiO_2) nanoparticles out of nano-coatings on the inner surface of glass containers has been analysed. The glass containers are used for storage of pharmaceutical solutions. Interactions, such as degradation of the active pharmaceutical ingredient (API) or precipitation of biopharmaceuticals, both leading to inefficacy of the drug could occur. Coating with TiO_2 nanoparticles should prevent the known leaching of alkali metals and alkaline earth metals from the glass into the contents.

2. **SVCCS 2: CNTs/graphene: End of life considerations for carbon-based MNM in Li-ion batteries**
This SVCCS for carbon-based manufactured nanomaterials (MNM) in electronic goods was performed with a particular focus on end-of-life handling and processing of nano-enabled batteries, with a view to determining the potential for nano-object release and potential occupational exposure during the several stages of waste handling, e.g. collecting and sorting, recovery of parts/materials and disposal.

3. **SVCCS 3: Development of workplace exposure scenarios of NMs on the production of ceramic honeycombs activated by nanoTiO_2**
For this SVCCS, a number of scenarios have been designed to examine exposure of NMs during the production of ceramic honeycombs used in air purifiers and activated by an applied liquid suspension of nanoTiO_2. The research plan included 5 scenarios of possible exposure to the worker and or the environment: production, application, exercise, maintenance and end-of-life. For each phase, environment (ambient) and personal samples have been gathered and analysed in terms of organic substances, as well as nanoTiO_2.

Main Results

The **GALANT-study** proved there are significant differences in TiO_2 leaching by using different approaches along the value chain. This turned out to be valuable knowledge to the industrial partner. The new knowledge resulted in an adjustment of procedures for coating of glass and, thus, improvement of the surface quality of their product.

All three experiments in the **CNTs/graphene study, for end of life considerations for carbon based MNM in Li-ion Batteries**, showed release of carbonaceous NMs used within MNM+ electrodes during shredding, handling and incineration. The results only allow for a qualitative assessment of risk potentials. This value chain project concluded that end-of-life processes that involve handling of shredded battery material should be controlled to prevent emission of any hazardous substance.

The main outcome of the study on **exposure to nanoTiO_2 in ceramic honeycombs** is that for none of the analysed environment (ambient) and personal samples – production, application, exercise, maintenance and end-of-life – the TiO_2 exposure level was higher than the safety value[1].

Summary

In general, the procedures developed for initiating and performing SVCCS have been tested in too few instances to justify any conclusions regarding their appropriateness. However, with minor adjustments, they have functioned well in the actual cases that have been studied. It was recommended for future case studies of this type to consider activities that enhance industry interest. This may be accomplished by specific “calls for interest” or by allowing “organic” processes to rule, and await proper industrial partners.

The SVCCSs performed show potential to provide support for the questions related to fate, persistence and long-term effects, as well as certain aspects of exposure determinants, exposure and life cycle analysis. The need for risk assessment can be addressed by the SVCCSs, although risk assessment advances themselves will not be a topic for a SVCCS. Finally, in the specific cases, SVCCSs can provide valuable input regarding risk management issues and actions.

For more details about NANoREG please visit the NANoREG Results Repository.

[1] Scientific literature studies have been reviewed in order to determine the safety values that can be compared with the exposure levels measured experimentally. Conservative safety levels from literature range from 0.3 mg/m^3 to 1.2 mg/m^3; as assumption, this study used the value of 0.3 mg/m^3.