NANoREG

A common European approach to the regulatory testing of nanomaterials

The innovative and economic potential of Manufactured Nano Materials (MNMs) is threatened by a limited understanding of the related EHS (Environmental Health and Safety) issues. While toxicity data is continuously becoming available, the relevance to regulators is often unclear or unproven. The shrinking time to market of new MNM drives the need for urgent action by regulators. NANoREG is the first FP7 project to deliver the answers needed by regulators and legislators on EHS by linking them to a scientific evaluation of data and test methods.

Achievements of NANoREG project so far

In November 2016 NANoREG will release its Framework for the Safety Assessment of Nanomaterials, a major output of this EU FP7 flagship initiative. It will be available ahead of the ProSafe-OECD Scientific Conference 29th of November – 1st of December 2016 in Paris. Among others, it proposes forward-looking strategies aiming at making the nanomaterial safety assessment in the REACH context more practical and economically efficient. The NANoREG Toolbox is the second major output, expected end 2016. It, too, will be publicly available and exploitable. It supports the implementation of the Framework by listing methods, datasets, models, guidance documents, decision trees, etc., from within and beyond NANoREG. The tools are catalogued in relation to the Framework document topics.

The main results of the work package “Synthesis, supplying and characterization” comprise a suite of newly developed and / or tested standard operational methods, which address important characterization and testing end-points of MNM in a regulatory context. An improved framework for substance identification, categorization and naming of materials in REACH has been developed and proposed. The framework considers also chemically and structurally complex materials and identification of MNM. It is demonstrated that improvement and harmonization of characterization and test item preparation methods improves data quality considerably to a level where it is acceptable for implementation in a regulatory context.

The work package “Exposure through life cycle analysis” dealt with the identification of the most critical exposure scenarios during the life cycle of a product based on a model that took into account production volume and main NMs application domains. Methods were developed and tested to quantify the release of NMs, for selected processes during their lifecycle with special efforts focused on dust emission. Improved measurement tools and methods were then tested during a campaign of 20 field measurements. A series of comprehensively-monitored NMs exposure experiment were undertaken inside a large climate-controlled chamber to test quantitative and predictive exposure models. A reliable methodology has been developed and validated to determine the effectiveness of personal protective equipment (PPE) and engineering controls (ECs). Then a testing strategy based on mesocosms were developed to better mimic the effects and impact of exposure of ecosystems to NMs.

The in vivo studies performed in NANoREG work package “Biokinetics and toxicity testing in vivo” so far have not provided evidence that the nanomaterials studied possess different hazardous properties compared to their analogous bulk materials. The established regulatory standard tests proved to be adequate also for nanomaterials albeit mostly with some adaptation. There was some but no general evidence that the nanostructure may lead to a certain modulation of the hazard potency.

The work package “Advancement of Regulatory Risk Assessment and Testing” dealt with issues on accelerating the regulatory process. To that end, grouping and read-across possibilities for nanomaterials were explored and a strategy was developed to prioritise those nanomaterial applications that may lead to high exposure or high toxic potential and ultimately high risks for human health. Understanding dissolution properties for in vitro studies and biokinetic and toxicity behaviour of nanomaterials were investigated as well as the suitability in vitro methodologies on intestinal permeability and genotoxicity. The adoption of high throughput screening (HTS) and high content analysis (HCA) for NM toxicity testing allows the testing of large numbers of materials. It is recognized that certain analytical limitations and interferences should be overcome if in vitro is to become a real alternative to in vivo experimentation.

The work package “Keeping pace with innovation” has explored the applicability of various instruments to support Safe-by-Design. Recently. A so-called NANoREG foresight system was developed in order to timely gain insight into the extend regulations and guidelines will be prepared for innovative nanomaterials. This system will be further developed in NanoRegII. The impacts of recommendations for regulations with respect to environment and human health safety (EHS) are mostly effective on an international scale. Therefore, work package “Liaisons, Dissemination, Exploitation and Communication” was designed to establish liaisons with: a) selected global regulation and standardisation institutions, b) with national authorities for EHS legislation and regulation as well as with industry and the public, and c) to foster an active transfer of the NANoREG results to the relevant national stakeholders.

Facts and figures

- 87 partners from 19 countries (Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom, Brazil and South Korea) participate in the NANoREG project.
- The Budget for the NANoREG project is approximately 50 million euro of which 10.000.000 euro is contributed by the EU Framework 7 Programme.
- The project started on March 1st, 2013 and runs until February 28th, 2017 (48 months).

Contact

Project Coordination: Tom van Teunenbroek, Ministry of Infrastructure and the Environment, Den Haag, Netherlands, Tom.vanTeunenbroek@minienm.nl

Project Management: A.H.J. Dijkzeul, Ministry of Infrastructure and the Environment, Den Haag, Netherlands, aart.dijkzeul@minienm.nl

IPR Management: Karl Höhener, TEMAS AG, Arbon, Switzerland, karl.hoehener@temas.ch

For more details about NANoREG please visit the official project website www.nanoreg.eu.