The EU NANoREG project

A common European approach to the regulatory testing of nanomaterials

Overview NANoREG

Content

1 NANoREG at a glance

Title: A common European approach to the regulatory testing of nanomaterials

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Programme: EU FP7, NMP.2012.1.3-3 Regulatory testing of nanomaterials

Project duration: 42 months – start date: 1 March 2013

Budget: approx. 50 million euros, of which 10 million euros EU funding

Partners: around 63 partners from 14 countries including universities, research institutes, authorities, SMEs and industrial enterprises.

2 Objectives

NANoREG is a European approach to the regulatory testing of nanomaterials. The innovative and economic potential of the use of manufactured nanomaterials (MNMs) is nevertheless hampered by a limited understanding of the environmental health and safety (EHS) issues associated with it. While data on toxicity is consistently available, the relevance of this data for regulation is often unclear or lacks the necessary scientific basis. The increasingly short time to the market introduction of new MNMs calls for immediate measures by the regulatory authorities. NANoREG is the first FP7 project which is developing answers to the questions raised by regulatory authorities and legislators by:

I. using existing data, complemented with new knowledge
II. developing a toolbox with instruments for risk assessment, characterisation, toxicity testing and exposure measurements of MNMs
III. developing testing strategies for the long term which are adapted to the requirements for safe innovations using MNMs
IV. building a close collaboration between authorities, industry and science with the goal of developing efficient and practically applicable risk management approaches for MNMs and products containing MNMs.

The interdisciplinary approach involving close cooperation of the three main stakeholders (authorities, industry and science) helps reduce the risks arising from the use of MNMs in industrial products, articles in daily use and the entertainment sector.

NANoREG started off by analysing existing knowledge and data gathered by the OECD Working Party on Manufactured Nanomaterials (WPMN), the EU Framework Programme and other projects. A synthesis of the different needs of authorities in combination with existing and new knowledge aims to close current gaps.

To answer the regulatory questions, NANoREG has established liaisons with regulatory authorities, legislators and the scientific community in NANoREG partner countries, and is intensifying or establishing cooperation with selected industries and new enterprises. In addition, it is developing wider liaisons to global institutions for standardisation and regulation in countries such as the United States, Canada, Australia, Japan and Russia.

3 Work packages

1 – Scientific answers to regulatory issues
2 – Synthesis, supplying and characterisation of MNMs

3 – Determining exposure through life-cycle analysis
4 – Biokinetic and toxicity testing in vivo
5 – Regulatory risk assessment and testing
6 – Keeping pace with innovation – safe-by-design strategies
7 – Liaisons, dissemination, exploitation, communication
8 – Project management

4 Project structure

The project structure can be found at http://www.nanoreg.eu/.

5 Participants in Germany

Authorities: BMUB & UBA (funds for WP4 and 7, no project partners), BAuA (WP3, 4, 5, 7), BfR (WP4)

University: University of Leipzig (WP4, WP5)

Research institute: FhG ITEM (sub-contractor in WP4)

Industry: BASF (WP4)

6 Overview of results (October 2014)

6.1. 16 regulatory issues

At the start of the project, five regulatory questions seeking scientific answers were drawn up and submitted for comment and refinement throughout Europe. This led to 16 questions and sub-questions which were forwarded to the scientific work packages. The next step entails investigating which questions can be answered with the existing capacities and where additional resources are needed. The full list of questions can be downloaded on the project website at http://www.nanoreg.eu/ .

6.2. Guidance Document

The Guidance Document forms the basis for the joint scientific work of NANoREG. It contains standard operating procedures (SOPs) for different methods of sample preparation and analysis, in order to guarantee comparability of the results of the different partners and ensure a high scientific standard. Equally important in this context is an agreed format for saving and where necessary exchanging data. The ISA-TAB nano format was laid down as the project standard.

6.3. Selection of material

Based on a discussion of experts, 19 core nanomaterials were laid down as binding for reviewing the test guidelines for their applicability to nanomaterials. All these nanomaterials are industry relevant, for instance TiO2, SiO2, ZnO, CeO2 and BaSO4, carbon nanotubes (CNT) and nanofibrillar cellulose. Besides these mandatory substances, other nanomaterials are also admissible for the study in the context of specialised test methods. The project partner JRC is in charge of the nanomaterial sample repository and distributes the individual samples, which project partners can order online.