NANOREG Report Summary

Project ID: 310584
Funded under: FP7-NMP
Country: Netherlands

Periodic Report Summary 1 - NANOREG (A common European approach to the regulatory testing of nanomaterials)

Project Context and Objectives:
Context and objectives
Nanotechnology is one of the six 'Key Enabling Technologies' (KETs), the European Commission identified in its 2012 Communication on this topic. KETs are regarded as crucial for ensuring the competitiveness of European industries in the knowledge economy.

A serious threat to the capitalization of the innovative and economic potential of Nanotechnology is the limited understanding of the Environmental, Health and Safety (EHS) aspects of nanomaterials (NMs).
The NANoREG project is aimed at the elimination of these uncertainties by (among others) identifying what EHS aspects are relevant from a regulatory point of view, carrying out the research to fill in the gaps and developing a framework and the NANoREG toolbox for testing the EHS aspects and for the assessment and management of the risks.

NANoREG basics
In the first 18 month reporting period, the most important basic conditions for the research and development (R&D) work have been fulfilled. The Questions and Needs of regulatory relevance (the "demand side" of the project) have been articulated. The gaps in knowledge have been identified and the NANoREG quality concept has been developed. In the regulatory context of the NANoREG project, this quality concept is essential to generate reliable, comparable and exchangeable EHS data. To meet these demands, the NANoREG Guidance Document sets minimum requirements for quality checks during toxicity testing by harmonizing key test conditions, provides benchmark data and limits the number of different NMs to be tested.

NANoREG R&D work
The work on synthesis, supplying and characterization of NMs has made good progress. Guidelines and SOPs for identification of NMs in a regulatory context have been evaluated, developed and tested among which procedures for number- and volume-specific measurements. Technical data sheets for NMs and reference data for batch dispersions have been produced.

Important steps have been set to identify the most critical exposure scenarios. The results of this activity once more make clear that there is a serious lack of reliable data on consumer and environmental exposure to NMs. The foreseen NANoREG activities on "release of nanomaterials" and "measurement of exposure" will fill these gaps (only) partially.

The long term-term inhalation study as well as other biokinetic, oral, dermal and inhalation toxicity studies are (in general) on target and produced the first preliminary results. The majority of these results, with exception to the HARN materials, show a low toxicity in contrast to the many in vitro effects reported on these substances.

Regarding the in vitro testing and the work on "the relevance of barriers" preliminary work has been done in order to harmonize activities and to assure the reliability of the results. Suitable methods for solubility measurements have been tested.
The work on safe by design resulted in a working document on a concept for Safe Innovation (including safe by design) and a draft report on lessons learned from drug development testing.
A relational database describing the potential relationship between physico-chemical characteristics and (eco)tox endpoints was designed. An online web-based tool for data entry was developed.

Collaboration and dissemination
With Brazil, South Korea and the Czech Republic, an agreement in principle has been reached regarding collaboration between these countries and NANoREG. On a bilateral basis, collaborations between NANoREG and several other (FP7) projects and international bodies like ECHA and OECD have been established or are under preparation. The collaboration with the National Coordinators and with Industry is developing well.

Overall progress

The NANoREG project is on track. The planning however is several months behind schedule. The top-down approach described in the DoW has been implemented successfully thus creating a good starting point for the R&D work. The prospect is that the goals of the NANoREG project will be achieved.

Project Results:

WP1
- Questions and needs of regulatory relevance have been identified (D1.1)
"Demand side" of the project established; R&D activities to focus on addressing them
- Gaps in knowledge identified (D1.2)
Focus in the needed R&D work in NANoREG
- Data platform (CIRCABC, NIWO) (MS5)
CMS available; contributes to efficient cooperation between partners
- NM web ordering system (NIWO)
Efficient centralised ordering and distribution system of NM samples to partners
- T1.3 overview matrix
Overview of how tasks are contributing to address the D1.1 questions

WP2
- Web ordering system is operational
All partners use the same NMs. Contributes to comparability of test data
- Technical data sheets completed
Test data can be linked to characteristics of the NMs
- Guidance Document and SOPs developed for partners
Test data obtained within the project will be more reliable and comparable
- A probe-sonicator calibration protocol was developed and implemented
Qualification using this protocol enables harmonization of test dispersions used in toxicology studies
- Benchmark data SOPs/NMs available
The reference data make it possible to check the quality of the batch dispersion used for toxicological testing
- Important milestones for measurement of NM for the EC definition has been reached
Number- and volume-specific measurement procedures address directly a key regulatory question

WP3
- D3.1: Gap analysis report, identifying the critical exposure scenarios within the key value chains
Reveals poorly documented areas concerning exposure to NM, especially consumer and environmental exposure
- Selection of four dustiness testing methods to be used by all partners involved
Harmonization for effective use of resources
- A mesocosm network was developed by all partners involved
Covers continental as well as coastal/marine exposure situations
- A 2-box dispersion model was developed and is under validation
Consolidation of the set of modelling tools

WP4
- Cooperation between partners for 'multi-partner' tasks established and additional synergisms established
Well-grounded fundament to achieve the aims WP4 established
- Materials selected
Fundament to achieve the aims WP4 established
- First and or pre-experiments carried out
So far, no evidence for a specific or particular concern in nanomaterials' toxicity detected

WP5
- International activities on grouping and read-across have been compiled and developments are followed
Increased international cooperation and harmonisation in optimising scarce resources
- Suitable methods for solubility measurements have been tested
Agreed methods and later development of standard operating procedures
- In vitro models are being developed and tested among partners
Reliability of results between laboratories increase confidence in results
- Ag-ion release is size dependent
The ion-release property can be used for grouping and read-across purposes

WP6
- Review on Horizon Scanning Techniques and their contribution to a safe innovation concept
Common understanding of the role of Horizon Scanning in a safe innovation concept; up till now restricted to partners within the task
- Working document on a concept for Safe Innovation (including SbD)
Conceptual idea addresses regulatory and technical aspects; has formed pivotal input to NANoREG II proposal and will form a main linking pin between NANoREG and NANoREG II
- MS23: first draft of report on lessons learned from drug development testing
Common understanding of Safe by Design within NANoREG and how this relates to discussions on this topic outside

NANoREG
- Web based tool for identifying relationships between phys chem characteristics and (eco)toxicity endpoints
Tool facilitates linkage several data systems (NANoREG, NANoREG II)
- Literature review and design of appropriate testing programme to identify the impact of phys-chem characteristics (especially surface characteristics) towards toxicity endpoints
Improved view on validity of test results, improved view on relevant concepts grouping

Potential Impact:
According to the DoW, the overall impact of the NANoREG project is to supply solid answers to questions and requirements of regulatory and legislation authorities, and also to generate new insights and possibilities for innovators and industries. This will be achieved through representative tests and case studies along the value chain of nanomaterials. The outcome is a frame work and specific tools covering the value chain. This approach has two routes:
•The generative route (describes the hazard and exposure analysis as part of an R&D or Innovation process, bottom-up and includes safe(r) design measures). Here, two processes, a) product design and b) EHS risk estimations and reduction, are running simultaneously. The expected impact will be a product with significant lower risks for humans and the environment.
•The market control route (top-down). A set of instruments and the sample preparation for the market control route will have a significant impact on market control processes and the safety of consumers for "un-known" product origin, and the workplace inspection.

On top of that, the NANoREG project has and will have an impact on the awareness in the “Nano-safety community” that standardisation, quality control and exchangeability of EHS data of nanomaterials, are a prerequisite for an effective and efficient cooperation within this community.

For a more detailed overview of the impact of already achieved results, please see the following chapters were for each work package, the most important results and their impact are listed.

List of Websites:
www.nanoreg.eu

Related information

Result In Brief	European regulatory standards for nanomaterials

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Subjects

Scientific Research

Information source: SESAM

Last updated on 2015-04-22
Retrieved on 2017-06-07

Permalink: http://cordis.europa.eu/result/rcn/161199_en.html