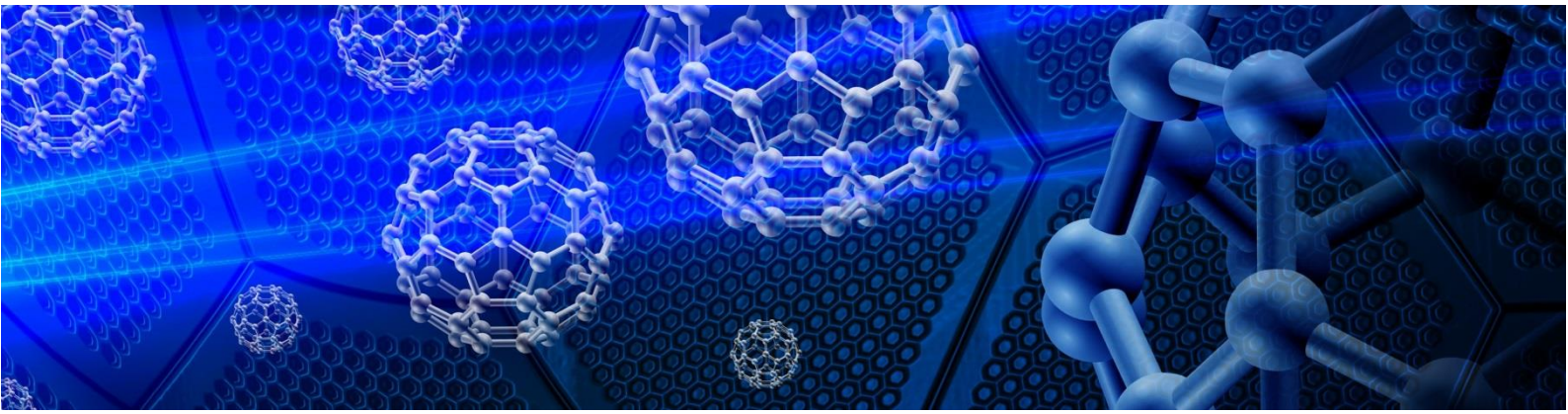


ProSafe

Promoting the Implementation of Safe by Design

Co-funded by the Horizon 2020 Framework Programme of the European Union
CSA ProSafe H2020-NMP-CSA-2014, Grant agreement number 646325

Background and project objectives

The capitalisation of the innovative and economic potential of nanotechnology is hampered by the uncertainty regarding the Environmental Health and Safety (EHS) aspects of nanomaterials and - linked to that - the regulation of these aspects.

A number of nanosafety projects try to limit these uncertainties by developing methods for testing the effects and assessing risks of nanomaterials in a regulatory context. In addition to this, several projects try to develop the concept of Safe by Design (SbD) as a way to incorporate the EHS aspects in an early stage of the innovation process in order to guarantee safety in the workplace, for consumers and the environment.

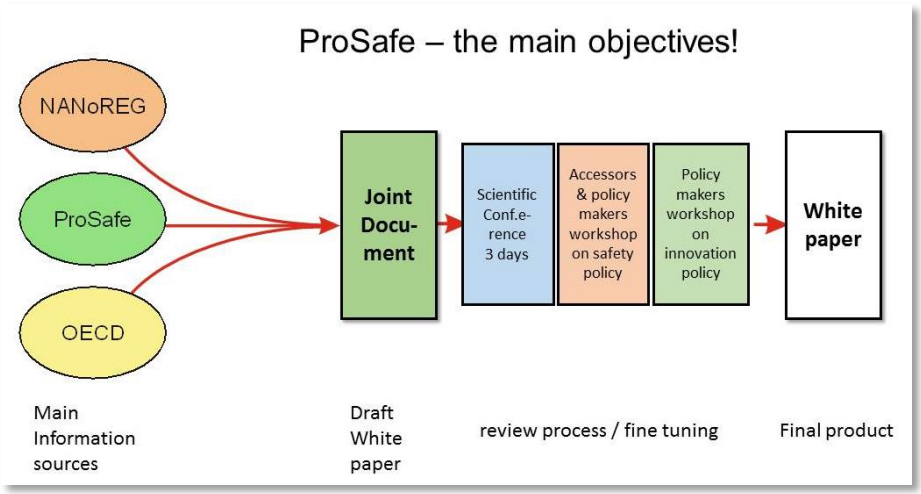
Evaluating and integrating the results of the most relevant EHS projects and translating them into building blocks for regulatory actions for the short and midterm, as well as for the long term, will add considerable added value to the individual projects ("the whole is greater than the sum of its parts"). The ProSafe project is aimed at creating this added value through two main products.

The main aims and resulting products of ProSafe are a White Paper, and an agreement on long term goals for EU-US collaboration. The FACTSHEET is about the White Paper and the related supporting actions.

White Paper

The philosophy behind the White Paper is that policy makers and regulators throughout the EU and beyond, should be stimulated and supported to take up and implement the results of NANoREG and similar actions such as WPMN SP1.

The White Paper will be a document that will provide building blocks for regulators and industry to address EHS aspects of Manufactured Nano Materials (MNMs) including evaluated methods for testing and assessing risks of nanomaterials and including Safe by Design (SbD).



The process of preparing this White Paper is aimed at creating a broad based platform of support, that is necessary to have any chance of success. The effort has to be supported at all levels of government, by regulators, legislators and scientists, and must also have the support of industry. It must also be accepted by the US and other non-EU players.

Commitment from the Member States (MS) and Associated States will be obtained by the process of "growing" NANoREG to NANoREG+, involving countries such as South Korea, Brazil as well as the EU MS not already in NANoREG. The scope is to disseminate and support the widespread adoption of principles and methodology which NANoREG embodies.

The ProSafe Strategic Policy Development Group will be a key part in this process, supporting the acceptance of the approach given in the White Paper. Furthermore international bodies will, as much as possible, be involved in the development of the White Paper and preceding Joint Document.

The Joint Document will be the integrated assessment of the results of NANoREG and other EU initiatives (such as other nanosafety projects like Marina, SUN etc.), as well as the relevant results for the OECD SP1. Scientific results will be presented, discussed and reviewed during a 3 day conference, and two later workshops for assessors and policy makers.

Supporting activities

- Foresight Study

As input for the White Paper, ProSafe will analyse and synthesise the understanding of what will come in the next 3-10 years for nanomaterial product development and its risk management. This foresight exercise will seek knowledge of experts who are currently preparing products (e.g. at stage-gate steps 3-5) as well as those developing exposure and hazard assessment methods relevant to their evaluation.

- Establishing standard approaches for (EHS) data management

To coordinate the development of tools allowing data sharing between databases and supporting toxicological model development for SbD and regulatory purposes, ProSafe will propose an approach for streamlining data acquisition and support a commonly-agreed database development based on ISA-TAB-NANO and a widely-agreed minimal ontology.

- Safe by Design

A novel safety culture will be developed by facilitating the incorporation of SbD as an integral part of the core research and development activities of nanomaterial, nano-implemented products, and the production of these materials and products, thereby supporting the reduction of risks.

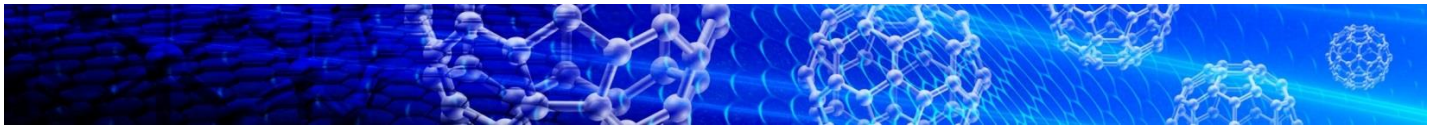
- Networking

Setting up or expanding networks with authorities, non-governmental organisations and industry aimed at the exchange of knowledge on nanosafety research and the harmonisation of SbD approaches. Definition of a common project call together with national funding agencies, for will and acceptance and further elaboration of the NANoREG safe innovation and SbD concepts.

Expected impacts

ProSafe is designed to have a major impact on the outcome of the NANoREG project and other nanosafety projects. It will:

- Strengthen and support the aims of NANoREG.
- Exploit synergy, mainly within all MS and AS but also world-wide, with activities aiming to support the implementation of SbD approaches to regulation. The action will lead to joint projects, twinned projects and global networks facilitating the goal of risk management and incorporating risk assessment in the early stages of material, product and process design.
- Combine efforts with those of the NANoREG project so that the expected datasets from the latter can be complemented and cross validated with similar datasets from other projects running globally in order to reach OECD - MAD (Mutually Accepted Data) status identifying and eradicating any inconsistencies.
- Evaluate and combine results and present them in such a way that they can be used as building blocks for a standardized approach of testing and assessing the EHS aspect of MNMs in a regulatory context.



Project partners

1. MINISTERIE VAN INFRASTRUCTUUR EN MILIEU (NL)
2. INSTITUTE OF OCCUPATIONAL MEDICINE (UK)
3. JOINT RESEARCH CENTRE – IHCP (EC)
4. CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE – CEREGE (FR)
5. ISTITUTO SUPERIORE DI SANITÀ (IT)
6. TEMAS AG TECHNOLOGY AND MANAGEMENT (CH)
7. NANOTECHNOLOGY INDUSTRIES ASSOCIATION AISBL (BE)
8. VENETO NANOTECH (IT)
9. UMWELTBUNDESAMT (DE)
10. FUNDACAO PARA A CIENCIA E A TECNOLOGIA (PT)
11. INSTITUTE OF PHYSICAL CHEMISTRY I. MURGULESCU (RO)

PROSAFE at a Glance

- **Grant agreement number:** 646325
- **Project start:** 1st Feb. 2015
- **Project duration:** 24 months
- **Project Coordination:**
- Tom van Teunenbroek, Ministry of Infrastructure and the Environment, Netherlands
- **Project management**:
- Aart H.J. Dijkzeul, Ministry of Infrastructure and the Environment, Netherlands
- PROSAFE CSA is funded by the H2020 Programme with € 2.512.612