

ProSafe Final Report

3 August 2017

Grant Agreement number:	646325
Project acronym:	ProSafe
Project title:	“Promoting the Implementation of Safe by Design (PROSAFE)”
Funding Scheme:	
Date of latest version of Annex I:	30 November 2016
Period covered:	1 February 2015 – 30 April 2017
Coordinator:	Ministry of Infrastructure and the Environment
Scientific representative:	Tom van Teunenbroek
Tel:	+31 6 52740279
E-mail:	tom.van.teunenbroek@nanoreg.eu / pobox@nanoreg.eu
Project web site address:	http://www.h2020-prosafe.eu/

Table of Content

1. INTRODUCTION AND READING GUIDE	3
1.1 AIM OF THE PROSAFE FINAL REPORT	3
1.2 THE TWO PARTS OF THIS REPORT.....	3
1.3 READING GUIDE AND ADDITIONAL INFORMATION	3
2. CONTEXT, OBJECTIVES, CONCLUSIONS OF THE ACTION	4
2.1 ABSTRACT	4
2.2 WORK PERFORMED AND MAIN RESULTS.....	5
Coordination and collaboration (WP1)	5
Joint Document, Scientific conference and White Paper (WP5 + WP1)	6
Exploiting Synergies (WP2)	6
Streamlining data acquisition, collection and data management (WP3)	7
Liaisons with Member and Associated States (WP4)	8
Knowledge management, Dissemination and Exploitation (WP5)	9
3. IMPACT AND FOLLOW-UP	10
3.1 IMPACT OF MAIN PROJECT RESULTS AND IMPACT FOR SPECIFIC TOPICS	10
√ Joint Document	10
√ White Paper	10
√ Data management	11
√ Accessibility of information	11
√ Collaboration	11
3.2 IMPACT OF SPECIFIC DELIVERABLES	12
√ Work package 1: Global activities	12
√ Work package 2: Exploiting synergies	12
√ Work package 3: Streamlining data acquisition, collection and data (management)	12
√ Work package 4: Liaisons with Member and Associated States	13
√ Work package 5 Knowledge management, Dissemination and Exploitation	13
3.3 BEYOND PROSAFE.....	13
ANNEX I: PROSAFE TASK FORCE	15
ANNEX 2 LIST OF PARTNERS	15

1. Introduction and Reading Guide

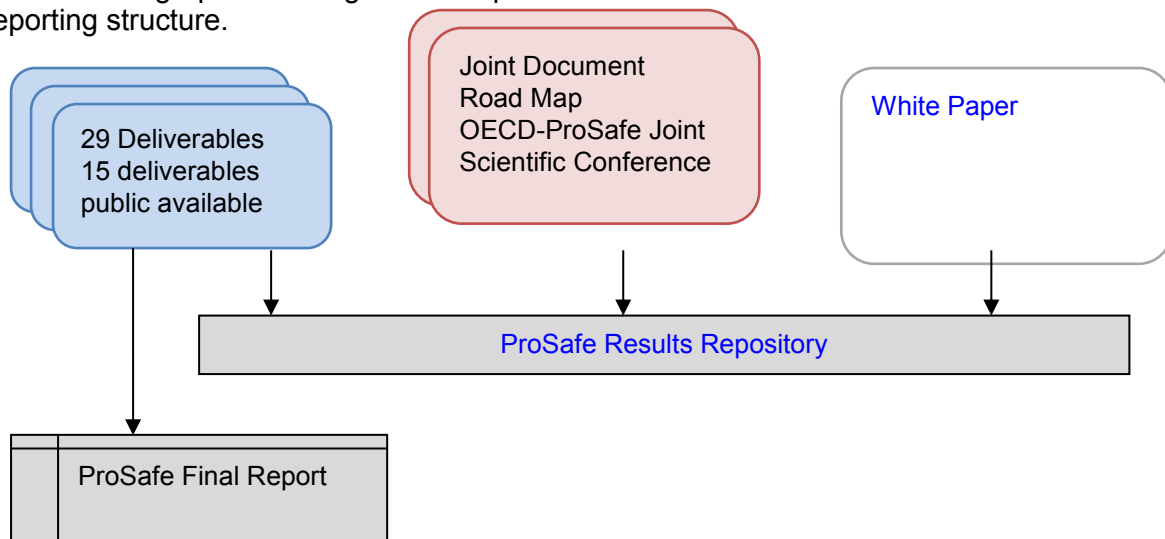
1.1 Aim of the ProSafe Final Report

The ProSafe Final Report informs interested parties on the results of the ProSafe project. At the same time it justifies the financial contribution to the ProSafe project by the EC and the involved member states. To this end we link the activities to the resources used and evaluate the implementation of the Description of Action. Finally yet importantly, we give an overview of our experiences regarding topics that also are of relevance for other H2020 projects, such as hurdles for collaboration and data logging.

1.2 The two parts of this report

The ProSafe Final Report is split in two parts. Part 1 is a public document. It gives a complete overview of the results of the project. The Final Report Part 2 reports on dissemination and project management including the use of resources. Part 2 is for internal use only.

All key ProSafe results are publicly available as of the end of the project. For detailed information on topics or deliverables a hyperlink to the ProSafe Results Repository is created. The graphic below gives an impression of the main elements of the ProSafe reporting structure.



1.3 Reading Guide and additional information

Section 2.1 summarises the context and overall objectives of the project. It gives information on the problems that are being addressed and the relevance of these problems for society. It also describes the overall objective of the project.

Section 2.2 provides a concise overview of the results of the project and their impact. It provides links to all relevant deliverables produced by the consortium.

Last but not least, chapter 3 elaborates the impact of the project.

To keep the size of the report within reasonable limits, the Final Report refers to documents available in the ProSafe Results Repository by means of a hyperlink. By clicking on the hyperlink, the document referred to, is directly available.

2. Context, objectives, conclusions of the action

2.1 Abstract

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). This limited understanding leads to uncertainty on how to judge the fitness for use of these materials in a regulatory context. This may have a negative impact on the investment climate and on societal appreciation (public perception) of products containing NMs and, thus, on possible applications of nanomaterials that can be economically beneficial, as well as sustainable. Examples are the use of nanomaterials in solar cells to make energy generation more efficient or, more in general, reducing the use of materials like minerals and the development of more efficient production processes.

Reducing and eliminating these uncertainties and developing ways to incorporate nanosafety into the design of nanomaterials is an objective of a great number of nanosafety projects funded by the EU or national authorities. The ProSafe project is aimed at coordinating and supporting part of these efforts by bringing together and, where possible, aligning the results of these projects. The main aims and resulting products of the ProSafe project are:

1. The [Joint Document](#) (JD): This document compiles the results of an extensive evaluation by a Task Force of independent senior experts of the results of NANoREG and other EU NanoSafety Cluster (NSC) projects and the results of the OECD sponsorship programme. The document served as a reference document for the OECD-ProSafe Joint Scientific Conference in November 2016. The Joint Document also serves as the technical annex to the EU policy-oriented White Paper.
2. The [White Paper](#): This document will come forward with recommendations for policymakers and legislators for measures to come to a more efficient and effective governance and regulation of nanomaterials, including evaluated methods for testing and assessing risks of nanomaterials, and including Safe by Design (SbD).
Contributing aims and activities for the White Paper are:
 - Analysis and synthesis of what will come in the next 3-10 years for nanomaterial product development and its risk management ("foresight study").
 - Establishing standard approaches for (EHS) data management.
 - Acceptance and further elaboration of the NANoREG safe innovation and safe-by-design concepts.

The JD was prepared based on a review of approximately 1,000 published articles and research reports by nine internationally recognized nanomaterial experts. The two key criteria used for the evaluation of the documented research were *reliability* and *relevance*, as defined by the OECD. The nine areas of concern studied in this report are: (1) physicochemical characterisation, (2) exposures through the life cycle, (3) fate, persistence and bioaccumulation, (4) exposure modelling, (5) ecological effects and biokinetics, (6) human health effects and biokinetics *in vivo*, (7) human health effects and biokinetics *in vitro*, (8) (Q)SAR modelling of nanomaterials and (9) risk assessment. For each of the areas of concern specific recommendations on the most appropriate protocols of regulatory relevance were identified, while gap analyses revealed specific high priority areas for further regulatory relevant research. A detailed list of all procedures and data sets that are ready for regulatory consideration and possible use are identified in the JD itself.

The key findings of the JD, and associated research gaps have been discussed during the OECD-ProSafe Joint Scientific Conference in November 2016. Critical comments and suggestions from conference delegates and participants are included in the final version of

the JD. A number of papers, related to the areas of concern as mentioned above, will be published in a special issue of the NanoImpact journal.

The [ProSafe White Paper](#) '*Towards a more effective and efficient governance and regulation of nanomaterials*' rests on the efforts and results of the FP7 project NANoREG and the H2020 project ProSafe. Both projects were driven by the need to reduce the uncertainty regarding the regulatory assessment of the EHS aspects of nanomaterials.

The White Paper recommends adjustments to the REACH annexes, aimed at making the current regulation better suited to nanomaterials. It includes proposals for further harmonisation of test methods by the OECD and proposals for a more efficient use of the results of nanosafety projects, by improving the data management infrastructure. For the longer term, the White Paper sketches possibilities of innovation of risk assessment, the potential of promising approaches like QSARS to predict the EHS effects of nanomaterials, and Safe by Design as a way to include safety aspects of nanomaterials in the process of developing nanomaterials and their future applications.

The implementation of the recommendations will make the current legislation better applicable to nanomaterials, will reduce the uncertainty for industry with respect to the regulatory requirements and will reduce industry compliance costs and efforts. This is especially important for SMEs.

It is up to the EU Member States, the European Commission and international harmonising bodies to decide on the implementation of the White Paper recommendations.

2.2 Work performed and main results

Coordination and collaboration (WP1)

ProSafe contributed to the accession of several new partners to the NANoREG project, thus expanding NANoREG's research capacity and filling gaps in specific knowledge and experience of the NANoREG Consortium. The implementation of the collaboration agreements between those new partners and the NANoREG Consortium was also supported by ProSafe.

Contacts between representatives of the US Nano Initiative and the EU during the meeting of the Society of Risk Analyses in Washington have resulted in rough contours for a common EU – US research programme for the mid- and long-term. These contours encompass the following topics:

- Reference materials and standards.
- Data management; curation, big data; mining of existing data.
- High Throughput Screening and new testing techniques.

At this moment it is unsure whether the funds for these promising future topics can be unlocked on US as well as EU side.

A Non-Disclosure Agreement was concluded with five partners from US, South-Africa and Australia to involve them in the work of NANoREG Work Package 3 on exposure. Among others they reviewed and contributed to several NANoREG WP3 deliverables. Collaboration with CEINT – Duke University has been established focussing on data management, curation and collaboration with the US-nanoinformatics program, as to determine a strategic planning for data standardization, templates and guidance documents for data harmonization between Europe and the US.

Joint Document, Scientific conference and White Paper (WP5 + WP1)

The ProSafe Joint Document summarises the results of an evaluation of the regulatory relevance of methods for testing and assessing nanomaterials. This evaluation was carried out by a group of experts that covered the most relevant scientific fields of nanosafety on the basis of the “ProSafe roadmap for reviewing data, protocols, report and guidance notes for regulatory relevance”. The draft JD was discussed during a three-day scientific conference co-organised by ProSafe and the OECD. The conference was attended by about 180 experts and policy makers from all over the world. It was concluded that there is a need to continue to work towards the further harmonisation of test methods in order to create a solid base for testing nanomaterials and to fulfil the conditions for mutual acceptance of data.

The JD was finalised in March 2017. It gives an impressive overview of the state of the art of methods and strategies to test and assess the risk of nanomaterials and their regulatory relevance. It is one of the building blocks for the ProSafe White Paper. A number of papers related to the areas of concern mentioned above will be published in a special issue of NanolImpact.

The White Paper comes forward with recommendations for policy makers and regulators aimed at a more effective and efficient governance and regulation of nanomaterials. The main focus of these recommendations is on the application of REACH to nanomaterials, since this regulation has the broadest coverage. But also other topics are addressed, such as the harmonisation of test methods, quality of nanoEHS data, the infrastructure for advanced information management, Safe by Design and innovation of risk assessment. Important building blocks for the document are the previously mentioned JD, the [NANoREG Regulatory Framework](#), including the proposal for a “new approach towards nanospecific prioritisation and risk assessment”, and several NANoREG deliverables. A draft of the White Paper has been distributed for written consultation in June 2017. The final version will be published in September 2017.

Resulting documents	
ProSafe roadmap for reviewing data, protocols, report and guidance notes for regulatory relevance (Annex 1 to Joint Document)	U
Deliverable 5.06: Major international conference	U
Deliverable 5.08: Joint Document	U
Deliverable 1.04: White Paper (available as of September 2017)	U

Exploiting Synergies (WP2)

The Synergy Scan of nanosafety projects (Task 2.1) has resulted in an comprehensive overview of EU and non EU-funded or industry-led projects that contribute to the implementation of Safe by Design (SbD). Most of the initiatives appear to be indirectly connected with SbD itself, since their main aim is to provide and transfer knowledge, for instance in the form of data, protocols, etc. to SbD. A further refinement was aimed at understanding which information needs to be extracted and provided to enable the adoption of SbD, and to foster its implementation in a regulatory perspective. The information, compiled in a spreadsheet dataset, has been – and still can be – used as input for projects further elaborating on the Safe by Design concept.

The attempt to get insight in future applications of nanomaterials and national strategies in relation to nanotechnology was not successful. It proved to be difficult to identify specific trends and timelines of appearance on the market of new products and applications (D2.02 Report on Forward thinking and scanning trends and developments).

The evaluation of the equipment needs for implementing appropriate risk assessment and management procedures was incorporated in the Delphi Poll (see below). The experts participating in the Poll tended to say that the need is more pressing to develop methods to assess exposures from actual uses of NMs, rather than toxicity assessment methods at present. However, comments in the forum also indicated that this attention to exposure assessment methods does not rule out a need for development of new toxicity assessment methods. These methods should be focussed on the results of exposure assessments of actual uses of NMs in products. In addition to sequencing methods development starting with the general class of real-world exposures, an instrumentation “class” is emerging that combines data analytics with a capability to generate multiple measurements across forms, time scales, and sampling points.

Foresight about whether technical methods will be ready to support Safe by Design (SbD) risk management approaches, for use of manufactured nanomaterials (MNMs) in the R&D pipeline, was gained by means of a Delphi forum process. The forum process used a multi-stakeholder expert steering group, two web surveys, and a discussion panel workshop as interaction and feedback points. The overall process took 18 months and included detailed participation by over 250 experts in Europe and North America. This approach provided useful information about prevailing opinions of experts and it provided useful experience on what works to understand such a complex risk management challenge. The results of the Delphi forum process are extensively described in D2.03: Report on Foresight exercise.

Resulting documents	
Deliverable D2.01 Synergy Scan report	↓
Deliverable D2.02 Novel "nano risks" and possibilities for efficient risk assessment	↓
Deliverable D2.03 Report on Foresight exercise	↓

Streamlining data acquisition, collection and data management (WP3)

A comprehensive mapping exercise of contemporary nanoEHS database developments and related implementations at both EU level and beyond was performed. Information from EU-funded projects and beyond on database development and implementations has been collected, collated and fleshed out with information from the literature and interactions with other ongoing developments and topical activities. The resulting deliverable 3.1 provides a complete landscape of data management in nanoEHS initiatives. The Landscape reveals shortcomings and gaps in the basic requirements for an improved approach to nanoEHS data management. Critical recommendations for improvement, essentially directed at funding agencies. The information has been used for the other tasks within WP3.

The work on methods for data logging, ontology and linking databases has been executed in close collaboration with FP7 eNanoMapper and NANoREG and was very fruitful. It resulted in the development and adoption by the NANoREG project of templates based on the of ISA-TAB-Nano logic for logging of experimental nanoEHS data. These templates are now available for the whole nanosafety community (NSC in Europe, and they have been further developed by Duke University and others in the US).

ProSafe also paved the road for the transfer of NANoREG experimental data to the NANoREG – eNanoMapper database in order to make this set of “good quality data” available for other parties. Noteworthy to mention that caLIBRAte and NanoReg² will build on this data set.

The ontology work was mainly led by eNanoMapper at EU NSC level, with full collaboration from ProSafe WP3 (and NANoREG).

WP3 also concludes (in D3.4 and D3.1) on recommendations to the European Commission on how to bring forward and improve data management in nanoEHS research funding.

The collaboration with Duke University (US) has a great potential for a further transatlantic collaboration in the field of data management (data entry, curation, exchange, etc.).

Resulting documents	
Deliverable D3.01 Landscape of databases useful to EHS assessment of nanomaterials - Gaps and overlaps review	↓
Deliverable D3.02 ISA-TAB-Nano database system established and adopted within the Nanosafety Cluster	↓
Deliverable D3.03 Minimal ontology and naming convention for nanosafety data	↓
Deliverable D3.04 Report on available database linking tools	↓

Liaisons with Member and Associated States (WP4)

Liaisons and contacts with different stakeholders of the Member States, Associated States and Third Countries have been established. However the interaction with this group (under the umbrella of the Strategic Policy Development Group) has been limited due to the fact that concrete results of the NANoREG and ProSafe projects only became available at a late stage of the ProSafe project.

To stimulate collaboration and information exchange in the field of Safe by Design, a transnational call was developed in collaboration with funding agencies of several countries. The call comprised four topics with focus on the Safe by Design concept developed within the NANoREG project and their integration in industry's innovation process. The result of this activity fell rather short of the expectations; eventually only one project was selected for funding.



The work on "Harmonization of national regulatory-oriented protocols, procedures, data and Safe-by-Design approaches" has resulted in an impressive "state-of-the-art document" (D4.04) that lists what is required to implement a SbD approach in terms of protocols, tools, datasets, etc. next to what is already available and to what needs to be – further – developed. The latter has been input for the NanoReg² project. The SbD concept developed by NANoREG has been complemented with "preparation of industry for regulation". Within NanoReg² the SbD concept will be combined with Regulatory Preparedness (regulators being prepared for innovation) into the NanoReg² Safe Innovation Approach (SIA).

The activities aimed at promoting the SbD approach for industrial innovation processes focussed on a dialogue with industry during business meetings. On top of that, the SbD approach was communicated to industry during seminars, workshops and by means of newsletters and email contacts.

Resulting documents	
Deliverable D4.03 Agreed call topics for the common call	↓
Deliverable D4.04 Inventory of the harmonized national regulation oriented task	↓
Deliverable D4.07 Report on Funded Projects for the joint call	↓

Knowledge management, Dissemination and Exploitation (WP5)

Apart from the already mentioned activities regarding the Joint Document and the ProSafe-OECD Scientific Conference, work package 5 focussed on providing the consortium with basic provisions for the project partners, like document templates, the ProSafe web site, a dissemination strategy and an exploitation strategy. Following up on the last mentioned task, several newsletters and press releases have been issued.

Resulting documents	
Deliverable D5.03 Project website	
Deliverable D5.05 Press releases during the project	

3. Impact and follow-up

The first section of this chapter describes the impact of the main project results (the Joint Document and the White Paper) and the impact regarding data management and accessibility of information. The second section provides a concise overview of the impact of some other specific deliverables. Information on (possible) future actions following up on the results of the project is presented in section 3.3.

3.1 Impact of main project results and impact for specific topics

√ *Joint Document*

The Joint Document gives an impressive overview of the state of the art regarding testing and assessing the effects of nanomaterials in a regulatory context. It identifies the available methods that are sufficiently robust to be applied in a regulatory context. It also comes forward with recommendations regarding the further development and harmonisation of test methods.

It gives guidance to all involved stakeholders in regulating and governing the risks of nanomaterials, on whether a given method makes sense or not. Furthermore, it gives direction to future harmonisation activities in OECD and other harmonising bodies.

The impact of the Joint Document is substantial. Partly, due to its content and partly due to the development process of this document. To start with the latter, the analysis covers an immense number of publications and has been carried out by renowned experts. The draft results have been discussed and reviewed during the 3-days OECD-ProSafe Joint Scientific Conference that was attended by 180 scientists from all over the world.

The “ProSafe roadmap for reviewing data, protocols, reports and guidance notes for regulatory relevance”, which forms the basis for the Joint Document, sets a standard for the evaluation of methods for testing and assessing the risks of nanomaterials. The applicability of this roadmap goes beyond the ProSafe project. It can be used more in general to evaluate the quality and regulatory relevance of data used in nowadays risk assessment of nanomaterials.

The conclusions and recommendations provided in the Joint Document have been used as building block for the White Paper.

√ *White Paper*

The [White Paper](#) integrates the main NANoREG outcome (Framework and Toolbox), the ProSafe Joint Document and the results of numerous other projects. It provides recommendations for regulators and policymakers aimed at a more efficient and effective governance and regulation for use of nanomaterials. The recommendations cover the following fields:

- Adjusting REACH and its annexes and Guidance Documents to make it fitter for nanomaterials, with respect to information requirements, categorisation and methods for testing and assessing the risks of these materials.
- The quality of nanoEHS data; recommendations in the White Paper follow up on the Joint Document with respect to harmonization and a more stringent evaluation of the quality of data to be used for risk assessment of nanomaterials.
- Safe by Design approach; the White Paper addresses some of the dilemmas linked to this approach, such as its role in a regulatory context, the lack of data, etc.
- Advanced data management; the recommendations in the White Paper on this topic deal with standardization of data logging, opening up results of nanosafety projects, the

accessibility of nanoEHS data, data curation (see further considerations on data management later in this section).

- Harmonised occupational exposure limits.
- Innovation in risk assessment aimed at “keeping pace with innovation”.

Most of the recommendations are formulated as a concrete action including the addressee(s) of the action.

The impact of the recommendations will strongly depend on the position Member States will take with respect to the proposed actions. This is further elaborated in section 3.3.

√ *Data management*

Together with the NANoREG project and the eNanoMapper project, ProSafe has given a boost to the awareness that for an efficient and effective nanosafety research, an advanced system of data management is key. This includes the necessity to i) open up all experimental nanoEHS data generated in – at least – government-funded nanosafety projects, ii) cater for standardised logging of these data and a sustainable infrastructure for developing and maintaining ontology, iii) provide long-term storage of and access to data, and iv) enable data curation.

It is to be expected that the example given by NANoREG, eNanoMapper and ProSafe with respect to opening up all generated information, to standards for data logging, nanoEHS ontology and transferring all data to a public accessible database will inspire other nanosafety projects to do the same. It also is to be expected that the recommendation in the White Paper to take more structural measures in this field will be followed up by Member States and the EC, thus creating even more impact.

The agreement between caLIBRAte, NanoReg² and NANoREG on data management – uploading, curation and sharing – also sets the example for the nanosafety community that exchange of information during and after a project duration is possible and beneficial.

√ *Accessibility of information*

The ProSafe Consortium partners decided to make all relevant results publicly available (ProSafe General Assembly in March 2017). The decision followed the example set by NANoREG. It is based on the conviction that open access to results of nanosafety projects is critical to the effectiveness and efficiency of nanosafety research. It is the only way to build on the results of previous projects. To carry out this decision, the ProSafe Results Repository has been created with a strong connection to the NANoREG Results Repository.

Just like for *data management* (see above), the example set by NANoREG and ProSafe will probably inspire other nanosafety projects to do the same. Implementation of the recommendations on this White Paper topic by EC and Member States will strongly contribute to the impact of ProSafe in this field.

√ *Collaboration*

The ProSafe project gave an additional boost to collaborations already started within the NANoREG project. The new collaborations comprised the exchange of data, the review of scientific work on exposure and data management, curation and collaboration with the US-nanoinformatics program. The NANoREG National Coordinators, of whom most also participated in the ProSafe Strategic Policy Development Group, have played – and will play – an important role in the science- and policy-oriented dialogue regarding nanosafety at EU level and beyond.

3.2 Impact of specific deliverables

This section describes in a concise way the impact of results not yet mentioned in the previous section.

√ *Work package 1: Global activities*

Results	Impact
<i>Great number of organisations have been informed on the ProSafe Project</i>	The ProSafe project and its aims and activities are known to a broad group of scientists and policy makers. This is beneficial for the platform of support for the results of the project as they will condense in, among others, the Joint Document and the White Paper
<i>Inventory of available or relevant experience and data</i>	Basis for selection of potential organisations to involve in NANoREG or ProSafe processes
<i>Collaboration between the Greek organisations FORTH and NCSR and NANoREG has been established</i>	Additional R&D capacity and expertise for the NANoREG project; broader support for the outcome of NANoREG and ProSafe
<i>Collaboration between US organisations and NANoREG Work Package 3 on exposure</i>	Additional expertise and data will contribute to the results of several NANoREG tasks
<i>Collaboration on data management between ProSafe, eNanoMapper and Duke University (CEINT)</i>	Securing data management for the near future via the database infrastructure developed by eNanoMapper
<i>White Paper</i>	A consolidated way forward for risk assessment of nanomaterials in the EU

√ *Work package 2: Exploiting synergies*

Results	Impact
<i>D2.01 Synergy Scan report</i>	Identification of relevant initiatives that can contribute to the implementation of SbD as an alternative or complimentary approach for safety assessment of NMs
<i>The regulatory questions from NANoREG have been mapped to data needs and types of measurement tools implied</i>	Improvement of questions for second round of the Delphi Poll
<i>Outcome of the Delphi Poll</i>	useful input for the ProSafe White Paper

√ *Work package 3: Streamlining data acquisition, collection and data (management)*

Results	Impact
<i>Landscape of databases useful to nanoEHS – Gaps and overlaps review</i>	Detailed landscape of nanoEHS databases availability and usability in view of potential inter-linkage; forward-looking advices
<i>Promotion of the data logging strategy and templates released by the NANoREG project, and of a real database-linking approach</i>	Promotion of a community-wide approach to the ISA-TAB-Nano logic and related minimal ontology in collaboration with eNanoMapper The 'news' has been concretely recorded by US nanoEHS stakeholders (e.g. NanoWG, CoR) and at EU NSC level

√ *Work package 4: Liaisons with Member and Associated States*

Results	Impact
<i>Liaisons with the different Stakeholder Groups of the MS, AS and selected Third Countries by establishing the Strategic Policy Development Group (42 members from 20 countries)</i>	By exploiting synergy, mainly within all MS and AS, but also world-wide, with activities aiming to support the implementation of Safe by Design approaches to regulation
<i>Definition of the call topics of the first Joint Transnational Call</i>	Good basis for the Transnational call; focus regarding the results of national calls
<i>Launch of the first ProSafe Joint Transnational Call for which 4 countries have committed to participate</i>	Limited as explained in section 2.2
<i>Inventory of topics for harmonisation</i>	Insight in requirements and availability of tools for assessing the risks of NMs and in how Safe by Design contributes to focussing R&D activities.

√ *Work package 5 Knowledge management, Dissemination and Exploitation*

Results	Impact
<i>ProSafe website elaborated</i>	Project information publicly available
<i>D5.02 Definition of the exploitation strategy</i>	Systematic dissemination of the main project results to relevant target groups
<i>Dissemination activities by means of dedicated newsletters and organisation of meetings</i>	Relevant target groups like the NanoSafety Cluster, Industry, etc. informed on the ProSafe project.

3.3 Beyond ProSafe

It would be a waste of public money to stop with the current final results. It is important to build on NANoREG and ProSafe foundations to further increase impact and, thus, to increase the return on investments for both projects.

However, responsibility for building on these foundations remains with the nanosafety community and its funders. During the ProSafe review meeting with EC representatives in May 2017, three initiatives deserving further exploration have been agreed upon.

The first initiative is related to the involvement of the EC's internal InterService Group Nano and, for example, DG Environment, DG Research and Innovation and DG Health and Food Safety to discuss the ProSafe White Paper and its recommendations on the REACH annexes and guidance documents, nanoEHS testing programme, etcetera.

During this same meeting a prescribed data infrastructure and mandatory opening up of deliverables and experimental data could be discussed, too.

The second initiative encompasses the formation of a NanoSafety Cluster regulatory task force. The aim of this task force should be to bridge the worlds of the policy makers/regulatory parties, such as OECD, ECHA, NIOSH, etc., with the scientists, concerning nanoEHS data and nanosafety research in general. This NSC task force could be a continuation of (part of) the NANoREG community as it has been developed in the past four years.

Finally, it would be beneficial if policy makers of EU Member States discuss and decide on the recommendations laid down in the White Paper.

The initiative for this discussion should be taken by the EC or one or more Member States. ProSafe has no bearings on this.

Annex I: ProSafe Task Force

Name	Role - Expertise
Klaus Steinhäuser	Chair of the Task Force
Phil Sayre	Co-chair of the Task Force
Günter Oberdörster	human health effects and biokinetics, <i>in vivo</i>
Barbara Rothen-Rutishauser – succeeding Agnieska Kinsner	human health effects, <i>in vitro</i>
Anders Baun – succeeding Frank von der Kammer Supported by Jerome Rose	fate and environmental exposure
Thomas Kuhlbusch Supported by Susan Wijnhoven	human exposure
Bernd Nowack	fate modelling
Anders Baun succeeding Teresa Fernandes	environmental effects and biokinetics
Greg Lowry	physicochemical characteristics
Enrico Burello	computational methods
Agnes Oomen	methods for risk assessment

Table 1 Overview of members of the Task Force

Annex 2 List of partners

The table below gives an overview of partners involved in the ProSafe Consortium.

1	MINISTERIE VAN INFRASTRUCTUUR EN MILIEU	Min I&M	Netherlands
2	INSTITUTE OF OCCUPATIONAL MEDICINE	IOM	United Kingdom
3	JRC -JOINT RESEARCH CENTRE- EUROPEAN COMMISSION	JRC	Belgium
4	CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE CNRS	CNRS CEREGE	France
5	ISTITUTO SUPERIORE DI SANITA	ISS	Italy
6*	INTERNATIONAL LIFE SCIENCES INSTITUTE EUROPEAN BRANCH AISBL	ILSI	Belgium
7	TEMAS AG TECHNOLOGY AND MANAGEMENT	TEMAS	Switzerland
8	NANOTECHNOLOGY INDUSTRIES ASSOCIATION	NIA	Belgium
9*	VENETO NANOTECH SOCIETA CONSORTILEPER AZIONI	VN	Italy
10	Umweltbundesamt	UBA	Germany
11	Fundacao Para a Ciencia e a Tecnologia	FCT	Portugal
12	Institutul De Chimie Fizica Ilie Murgulescu	IPC	Rumania
13	ECAMRICERT SRL	ER	Italy
14	RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU	RIVM	Netherlands

* Partners in grey font terminated their participation before the end of the project.