

ProSafe

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Deliverable 4.3

Agreed call topics for the common call

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1 Description of task

Task 4.2 is addressing two main fields of activity:

1. Definition of common call topics
2. Harmonization of national regulatory orientated tasks

This Deliverable D4.3 only addresses the first of the two fields, giving an overview of the agreed call topics as well as public guidelines for the general call (as specified in the DoA).

With an approved process to elaborate common call topics, Task 4.2 delivers 3-5 topics for one transnational call, considering the following prerequisites:

- The call topics will mainly address safe-by-design approaches and their integration in industry's innovation processes.
- The calls will also be open for specific national needs in safety research to reduce risk of applications of nanomaterials and their integration in products, especially requirements of consumer and public organizations and socio-economic needs.

2 Description of work & main achievements

2.1 Summary

In the frame of T4.2, call topics for the ProSafe transnational call have been suggested, elaborated and consolidated. From the point of view of the European Commission, this work is crucial in the context of the further development of the safe by design approach and its implementation in industrial settings, because so far no dedicated funding for this type of promotion regarding safe by design activities has been available in European Framework Programmes.

Resulting from the work carried out and described here, four distinct call topics have been defined:

- Topic 1 - Integration of the NANoREG Safe-by-Design concept (SbD) in industrial innovation processes along the entire, or a part of, the value chain of a manufactured nano material or a nano inspired product
- Topic 2 - Gaining and collection of knowledge for the sustainable implementation of the NANoREG Safe-by-Design concepts (SbD) in industrial innovation processes
- Topic 3 - Social Science research in support of awareness and impact of the NANoREG Safe-by-Design concept (SbD) on nanotechnology innovations for the society
- Topic 4 - Development of methods and knowledge for a downstream approach as complement for existing products using the NANoREG Safe-by-Design (SbD) Concept.

Above this, general conditions for the call have been set-up, and guidelines for proposers and evaluators as well as a time-line for the call have been elaborated.

The preparation of this call has been successful. As a conclusion of this work it can be stated, however, that there is still a lack among the stakeholders regarding awareness of the existence of the safe by design concept, and that it is rather difficult to bring funding organisations on board for the funding of safe by design activities.

The follow up of the work described in this deliverable D4.3 will be performed and documented in D4.6 within T4.3, led by FCT.

2.2 Background of the task

The process for the definition of common call topics was inspired by the EC project office based on experiences made within the SIINN project (Safe Implementation of Innovative Nanoscience and Nanotechnology, GA 265799). The following instruments developed during the execution of SIINN were used by this ProSafe task:

- Liaison with the funding agencies to finance projects addressing the safe implementation of nanomaterials and nano technologies.
- Process to elaborate common topics for calls based on recommendations of an internal working group, consolidated with the ProSafe Consortium as well as potential funding partners.

2.3 Description of the work carried out

The following list gives a chronological overview of the activities and work carried out since project start, leading to the agreed call topics:

- **2015/February** - preparation of the drafts of the first two call topics by the responsible T4.2 partners ICP and TEMAS
- **2015/02/11-12** - presentation and discussion of the first draft call topics on the occasion of the kick-off Meeting Aix-en-Provence
- **2015/02/23** - preparation of a general overview of the common calls by Karl Hoehener (TEMAS), consolidation with Task Leader T4.2 (S. Tanasescu)
- **2015/03/10** - preparation of a ProSafe Common Call Fact Sheet for the acquisition of national funding agencies by Karl Hoehener (TEMAS), consolidation with Task Leader T4.2 (S. Tanasescu)
- **2015/03/13** - a first discussion of a possible collaboration in joint SIINN/ERA NET style calls on the occasion of the EU-US meeting with US funders, Venice: principle agreement on collaboration, suggestion by US funders to include a topic on socio-economic aspects
- **2015/05/07-08** - ProSafe T4.2 meeting and brainstorming regarding call topics during the SIINN final conference, Madrid: discussion of draft contents of call topics
- **2015/06/04** - preliminary publication of draft Joint Transnational Call
- **2015/06/12** - several activities with respect to the call at the EuroNanoForum 2015, Riga:
 - outlook of ProSafe with first Call of common projects (*Speaker: Tom van Teunenbroek, Ministerie van Infrastructuur en Milieu*)
 - first pre-announcement and brokerage event for the first ProSafe call (*Speaker: Dina Carrilho (FCT)*)
 - poster: Safe Innovation and the ProSafe Joint Transnational Call 2015 (Pre announcement)
- **2015/06/30 - 2015/07/01** - Call Committee meeting, Lisbon: further specification of call topics (including topic 3) as well as definition of the time-line for the call
- **2015/09/08** - internal T4.2 meeting at TEMAS with S. Tanasescu (Task Leader) for the discussion of call topics and definition of next steps
- **2015/09/09-10** - a conference for the first ProSafe Call was held during the 2nd ProSafe Consortium Meeting in Ispra, for the finalisation of the call topics. On this occasion, it was suggested and agreed to include another topic (topic 4) regarding alternative ways of implementing SbD approaches
- **2015/10/01** - TELCO with ECHA for the discussion of the call topics with regard to their relevance from the European regulatory view
- **2015/12/11** - telephone conference with Swiss and Austrian funding organisations for the clarification of their publication (TEMAS, FCT, FFG, CTI, BMVIT)
- **2016/02/04** - Second pre-announcement for the final draft ProSafe Joint Transnational Call on ProSafe Website, including topics 3 and 4
- **2016/02/16-17** - final overview of call at the 3rd Consortium Meeting in Dessau.

2.4 Results

As listed in the DoA, this Deliverable has two focal points: the actual agreed call topics, and first information on general issues regarding the call. In the following two sub-chapters the results regarding these two points are summarised.

2.4.1 Agreed call topics

The original suggestion for the call comprised two topics (with a focus on the implementation of SbD approaches in industrial contexts), which were then subsequently complemented by topic 3 (more focus on socio-economic aspects, by request from the US side), and topic 4 (more focus on complementary aspects to downstream evaluation, resulting from discussions with EC officials).

2.4.1.1 Topic 1 - Integration of the NANoREG Safe-by-Design concept (SbD) in industrial innovation processes along the entire, or a part of, the value chain of a manufactured nano material or a nano inspired product

Specific challenge: The real or perceived uncertainties surrounding the potential risks of Manufactured Nano Materials (MNMs) and their diverse applications, as well as a lack of regulatory clarity, have a negative effect on the development, uptake and exploitation of these materials and their application in industrial products. The implementation of SbD concepts in industrial innovation processes for MNMs and nano-inspired products is an instrument to reduce this negative effect.

SbD supports the inventory of the uncertainties at the earliest opportunity and provides instruments to diminish such uncertainties when assessing risk, and managing it through organizational and technical approaches, e.g. engineering-out related risks (hazard and exposure) to an acceptable level.

Successful implementation of nanotechnologies depends on the capacity to define and quantify acceptable risks. To do so, it is necessary to collect and/or generate reliable information about MNMs and the products containing MNMs, as well as their impact on the Environment and Human Safety along the respective value chain.

A balance between costs and benefits for exposure and hazard control is a key issue for the acceptance of the NANoREG SbD concept.

Scope: The objective of this call is the identification and reduction of uncertainties along with the respective risk levels of an MNM or a nano-inspired product through the implementation of the SbD concept as part of the industrial innovation process. Such implementation can take place in various stages of an innovation project, for example:

- From the start of an innovation project, at the beginning of the value chain of the corresponding nano material or nano product;
- During the implementation of an innovation project, in certain sections of the value chain of the corresponding nano material or nano product;
- During the market launch of a nano material or nano product.

Special case: The general assumption of ProSafe is that the required tools supporting the integration of SbD in the first stages of an industrial innovation processes are available. When this is not the case, a specific task for the development or adaption of the missing tool can be part of the proposal.

Expected impacts:

- Consistent, applicable and scientifically sound implementation of the SbD concept in nano material and nano product specific value chains or parts of them;
- Balancing of benefits and costs in industrial innovation processes implementing SbD concept;
- Reduction of uncertainties with the respective risk levels of a nano material or a nano inspired product along the value chain or a part of it;

- Confidence in data and information generated by the implementation of SbD concept for the different stakeholders;
- Increased confidence in the safety of nano materials and nano-inspired products based on a transparent process, applying Standard Operating Procedures (SOP) and creating robust data.

2.4.1.2 Topic 2 - Gaining and collection of knowledge for the sustainable implementation of the NANOREG Safe-by-Design concepts (SbD) in industrial innovation processes

Specific challenge: The innovation processes in industry are well established. Uncertainties, risk and safety with respect to the development of Manufactured Nano Materials (MNMs) and nano-inspired products are usually not addressed in such processes. A concept for the use of SbD in such processes has been developed within the NANOREG project. This concept allows the recognition of uncertainties and risks as early as possible and to reduce them to reach an acceptable risk level. The professional, successful and cost effective implementation of the SbD concept in existing industrial innovation processes is therefore paramount for the safe development and application of nanotechnologies. Developing such knowledge and integration strategies is crucial for an easy and economic application of the SbD concept and for its sustainability. The development of knowledge and strategies for SbD integration in the industrial innovation process is one of the major challenges related to a multidisciplinary and harmonized approach of nano-safety operating procedures. In order to make sustainable use of such knowledge it will be necessary to build up pools of competence for the implementation of this knowledge. With respect to this, research centres and/or national/regional platforms dedicated to research, market follow-up, and dissemination of nanosafety need to be involved, so that they can act as service providers to industry.

Scope: The objective is to develop the necessary knowledge and strategies for an easy and cost effective implementation of the SbD concept in existing industrial innovation processes.

The acquisition of such knowledge should take place according to:

- Theoretical development of an implementation strategy for the SbD concept using a specific innovation project as model;
- Practical pilot implementation of the SbD concept in the selected innovation project;
- Finalization of a common “knowledge package” and strategy for future implementations.

Expected impacts:

- Solid knowledge base for future SbD implementation;
- Recommendations for training guidelines for the application of SbD;
- Guideline for the implementation of SbD in industrial innovation processes;
- Increasing the regulatory awareness of industry and improvement of timely and effective decision-making;
- Economic, well-balanced implementation of SbD in the selected innovation projects of nanomaterials or nano inspired products;
- Availability of knowledge pools.

2.4.1.3 Topic 3 - Social Science research in support of awareness and impact of the NANOREG Safe-by-Design concept (SbD) on nanotechnology innovations for the society

Specific challenge: The industrial innovation and development of nanomaterials and nano-inspired products require advances in socio-economic research to deal with societal impacts. SbD development will require understanding of socio-economic dynamics and exploration of social-political drivers, customs, and attitudes, both nationally and globally, in a multi-criteria analysis.

In order to understand and establish effective risk management strategies, public perceptions and attitudes concerning risks should be evaluated. The approaches and methodologies of risk managers should also be investigated to assess usefulness and effectiveness.

Incorporating and weighting real or perceived uncertainties surrounding the potential risks of Manufactured Nanomaterials (MNM) and their diverse applications will depend upon strong social behavioural and economic research to both understand current real or perceived risks and to develop appropriate risk management strategies.

Scope: The objective of this call is to evaluate risk assessment methodologies. Assess public customs and attitudes towards risks (real or perceived) of MNMs and to provide data on socio-political drivers.

Research exploring the impacts of manufactured nanomaterials and nanoparticles must incorporate responsible innovation, SbD and life cycle assessment. In addition to interdisciplinary collaboration among the physical sciences, the social sciences must also be engaged. Understanding social norms, behaviours, and socio-political actions requires data, tools, and methodologies of the social sciences. This call is especially interested in:

- How exposure will affect population changes, demographically and geographically
- How nanotechnology development might affect socio-economic disparities – within and among nations;
- What communication tools and methodologies might improve dialogue among various stakeholders including the public, scientists, policy makers, and industry;
- How quantitative data integration tools might contribute to formulating key questions for regulatory action and decision-making.

Expected impacts:

- Knowledge for determining factors about: how society perceives potential risks;
- Impact of critical socio-economic factors in the information frameworks of different stakeholders;
- Engaging population groups and other social-economical parameters that may impact MNM risk perception;
- Impacts of different weights for the social-economical parameters and integration in the SbD knowledge pool;
- Impact of the relevant holistic lines of evidence to support effective risk management measures in the MNM value chain, in a whole or part;
- Impact of the decision-making in the SbD process along the value chain taking in to account logic multi-criteria systems with the critical socio-economical information components.

2.4.1.4 Topic 4 - Development of methods and knowledge for a downstream approach as complement for existing products using the NANoREG Safe-by-Design (SbD) Concept.

Specific challenge: Looking at the value chain of a nano material or nano-inspired product from downstream, integrating a systemic view on R&D, materials and product development, processing, use and end of life, using the SbD concept for the improvement of the safety of nano materials and nano-inspired products. Projects under this top should mainly address existing nano materials and nano-products.

The results of this approach allows industries and insurance companies to obtain an overview of the existing risk potentials and the safety level of the respective material or product, even the existing regulations are not applicable (e.g. production volume, etc.) or not existing. The key element of this overview is the data and information dossier – as defined in the SbD concept – tuned for the different stakeholders and needs, such as EHS, etc.

This alternative route needs a concerted effort from industries and researchers along the value chains, generating a systematic view on the distribution and relative severity of risks, in order to prioritize them and the respective measures for reduction.

Scope: The objective of this topic is to setup projects aiming to evaluate safety and risks from the downstream side of a product development or an existing product, taking into account the following issues:

- application and complementing of the tools, instruments, data/information collection recommended for the SbD concept for the proposed downstream approach;
- spotting of possible risks along the entire value chain, especially seen as downstream approach to the value entire chain;
- appraisal of potentials and impacts about uncertainties and/or risks potentials along the value chain;
- prioritization of risks along the entire value chain with regard to the highest impact on risk reduction measures;
- definition and implementation of suitable risk reduction measures.

Expected impacts:

- knowledge about the systematic downstream approach to identify potential risks over the entire value chain of nano material or nano-inspired products, existing or under development;
- methods about the identification of the most efficient concepts for the reduction of the identified risks and prioritization of investments to reduce identified risks along the value chain;
- efficient and early-on reduction of most important risks along the value chain;
- adjustment and optimization of investments in risk management with respect to the achievable risk reduction;
- accelerated exchange of information among partners along value chains.
- monitoring the reduced risk potentials and the remaining ones as part of an “impact assessment” of this approach.

2.4.2 General aspects

Apart from the actual agreed call topics, this Deliverable is supposed to give a short summary of activities regarding general guidelines for the call - as far as preparatory work in T4.2 is concerned. Detailed information about administrative and other general aspects of the call will be elaborated in T4.3, and will be included in D4.6, to be delivered by partner FCT.

In the frame of work in T4.2, the following documents have been prepared:

- Preliminary Announcement: aim, scope, topics and general conditions for the call and the application (<http://www.h2020-prosafe.eu/prosafe/?p=187>)
- Guidelines for Applicants (so far in draft version, will be completed within T4.3 and included in D4.6), including:
 1. Definitions
 2. Registration
 3. Proposal submission
 4. Call topics 4
 5. Proposal structure and page limitations
 6. Eligibility criteria
 7. Eligibility check
 8. Evaluation criteria
 9. Funding recommendation and implementation
 10. Reporting requirements
 11. Special conditions
 12. Project start and consortium agreement
 13. Ownership of intellectual property rights
- Template for the technical description of the proposal (so far in draft version, will be completed within T4.3 and included in D4.6):
 1. Relevance – Contribution of the project to the goals of the 1st ProSafe Call
 - 1.1. Contribution of the project to the goals of the call
 - 1.2. Added value of the proposed transnational collaboration
 2. Scientific and/or technological excellence
 - 2.1. Description of the state of the art

- 2.2. Technical-scientific quality
- 2.3. Work plan
- 3. Potential Impact
 - 3.1. Expected impact of the results for potential utility of Safe-by-Design for stakeholders
 - 3.2. Reduction of uncertainty and risks along the value chain
 - 3.3. Dissemination and/or exploitation of results
 - 3.4. Ethical issues and safety issues
- 4. Implementation and Management
 - 4.1. Potential of the Consortium to realize the project
 - 4.2. Management capabilities and resources
 - 4.3. Description of the participants
- Guidelines for Evaluation (so far in draft version, will be completed within T4.3 and included in D4.6), including.
 - 1. Definitions
 - 2. Formation of the Evaluation Panel (EP)
 - 3. Assignment of rapporteurs and reviewers
 - 4. Registration of the reviewers
 - 5. Remote evaluation of the proposals
 - 6. EP meeting
 - 7. EP decision making (ranking list)
 - 8. Final consensus reports
 - 9. Minutes of the EP meeting
 - 10. Evaluation fees

The following final call and evaluation timeline has been decided and approved on February 12, 2016:

Date	Step
15 February 2016	Deadline for funding organisations to declare their participation in the Call
29 February 2016	Publication of the Joint Transnational Call
29 February 2016 – 14 March 2016	Funding organisations should send suggestions of reviewers to the Call Secretariat
From 15 March 2016	Send emails to possible reviewers to confirm their availability to participate in the evaluation process
20 May 2016	Deadline for submission of transnational proposals
23 May 2016 – 17 June 2016	Eligibility check by the Call Secretariat + Eligibility check by the funding organisations (deadline to inform the secretariat is 17 June 2016)
23 May 2016 – 3 June 2016	Provisional allocation of the proposals to the reviewers
21 June 2016	Final allocation of the proposals to the reviewers (on the basis of the eligibility results)
24 June 2016	Call Committee meeting (audioconference) to confirm eligibility results and approve the list of the reviewers to be officially invited.
27 June 2016	Official invitation sent to the reviewers
4 July 2016	Start of the remote evaluation
9 September 2016	Deadline for the submission of written individual evaluation reports by reviewers
14 October 2016	Deadline for the submission of draft consensus reports by rapporteurs (based on three individual evaluations)
26-27 October 2016	Evaluation Panel Meeting

Date	Step
27 October 2016 (Afternoon)	Call Committee meeting to select and recommend full proposals for funding
Middle November 2016	Final recommendation for funding by the Call Committee
From November 2016	Funding decision at national level. Start of national administrative procedures
January 2017	Earliest starting date of the funded projects

2.5 Evaluation and conclusions

Even though there was a substantial delay in the preparation of the call, the work is on track and the call will be launched based on a wide consensus among the stakeholders involved. The number of funding organisations is still a critical issue, but the minimum amount of partners has been reached.

3 Deviations from the work plan

The preparation and consolidation of the call topics as well as call documents, and therefore also the delivery of this Deliverable D4.3, has taken considerably longer than foreseen, the deviation of the timeline being motivated by the following:

- intense discussions until consensus about first two call topics, especially with regard to the eligibility of funding of basic and applied research
- the adjustment of call topics with US partners and EC
- the lengthy and difficult acquisition of the necessary minimum set of funding agencies for the call

The definitive publication of the call has now been set to February 29, 2016.

4 Performance of the partners

n.a.

5 References / Selected sources of information (optional)

n.a.

6 List of abbreviations (optional)

n.a.

7 Annexes (optional)

n.a.