

Second joint transnational call (2013) within the ERA-NET SIINN on

"Safe Implementation of Innovative Nanoscience and Nanotechnology"

Submission deadline for proposals: 31st October 2013 at 12:00 (noon) CET

For further information contact the Call Office:

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1. MOTIVATION

The commercial application of manufactured nanomaterials (MNMs) products is increasing rapidly, but one important aspect, the safety of MNMs, still represents a barrier to their wide innovative use. Available data on the toxicological behaviour of MNMs is often scant, unreliable or contradictory. Therefore, the development of a consolidated framework to address nano-related risks and the management of these risks for humans and the environment, by investigating the toxicological behaviour of MNMs, is needed. R&D activities in the Member and Associated States of the EU in the area of nanoscience and nanotechnology (N&N) remain largely uncoordinated and fragmented, resulting in the sub-optimal use of available resources, such as human resources, research equipment and funding. Thus, international funding initiatives enabling researchers to pool knowhow, data and resources are called for.

In this context, the ERA-NET "SIINN" for research programmes on Safe Implementation of Innovative Nanoscience and Nanotechnology, launches the second transnational call for proposals. The following parties,

- Bundesministerium für Bildung und Forschung, Germany, hereinafter referred to as BMBF, and
- Bundesministerium für Verkehr, Innovation und Technologie, Austria, hereinafter referred to as BMVIT, and
- Service Public de Wallonie, Belgium (Wallonia), hereinafter referred to as SPW-DGO6, and
- Executive Agency for Higher Education, Research, Development and Innovation Funding, Romania, hereinafter referred to as UEFISCDI, and
- Fundação para a Ciência e a Tecnologia, Portugal, hereinafter referred to as FCT, and
- The Chief Scientist Office, Ministry of Health, Israel, hereinafter referred to as CSO-MOH, and

have decided to open a **Joint Transnational Call (JTC)** for funding multilateral integrated research projects focusing on five different topics related to the safety of manufactured nanomaterials. For details on the areas covered by each topic, please see section 2 (Call topics).

Please note that CSO-MOH (Israel) participates in one topic only:

	Topic 1	Topic 2	Topic 3	Topic 4	Topic 5
BMBF/Ptj (Germany)	ok	Ok	ok	Ok	ok
BMVIT/FFG (Austria)	ok	Ok	ok	Ok	ok
SPW-DGO6 (Belgium, Wallonie)	ok	Ok	ok	Ok	ok
UEFISCDI (Romania)	ok	Ok	ok	Ok	ok
FCT (Portugal)	ok	Ok	ok	Ok	ok
CSO-MOH (Israel)	not funding	not funding	not funding	not funding	ok

The call is opened simultaneously by the partners in their respective countries.



2. CALL TOPICS

The aim of the second SIINN Call is to close knowledge gaps with respect to EHS (Environment and Human Safety) issues in order to promote the rapid transfer of the results of nanoscience and nanotechnology research into industrial application by helping to create reliable conditions. The choice of the Call Topics reflects a comprehensive work effort by the SIINN Project Consortium where both external and internal documents have been consulted. Of special relevance is the ongoing SIINN internal work on roadmaps for the safe handling of nano-objects, safe processes, safe products and safe transportation of nano products addressing identified gaps.

The call is open to innovative transnational research proposals focusing on manufactured nanomaterials (MNMs) in the **five topics** described below. It is expected that successful proposals employ state-of-the art characterization methods and procedures where appropriate. Furthermore, projects that include development of innovative and improved characterization methods relevant for EHS issues are especially encouraged. Emphasis should be placed by applicants to aim for an integration of SMEs as partners in the project consortia and to keep possible benefits of the suggested research for SMEs in mind.

2.1. Over-arching aspects of nanosafety research (Topic 1)

Technical content/scope:

The scientific and technical objectives under this topic are summarized by (but not limited and not mandatory to) the following:

- Development of common synergistic strategies (research and/or implementation) for the understanding of both human health and environmental effects of MNM, building on existing knowledge from both fields
- Development of methods for the understanding of intrinsic properties of MNM, important for the grouping of materials with relevance for risk assessment of MNM (and possibly for regulatory or normative needs)
- The importance of surface modifications for surface reactivity and biophysical or other interactions (e.g. surrounding matrices); definition of relevant parameters, evaluation of their importance and how to measure them. Studies that can be useful for grouping of MNM for risk assessment are especially encouraged
- Release and subsequent fate of MNMs from different types of matrices in environmental or biological settings, with a focus on MNM in real-life applications

Expected Impact:

Availability of methods for the understanding and prediction of the importance of intrinsic and extrinsic properties of MNM for their interaction with surrounding matrices. Availability of results relevant for human health and environmental concerns, with a strong focus on real-life applications, including medical issues. New approaches for the grouping of MNM according to common properties and effects on human health and the environment. Highly interdisciplinary and broadly applicable research results otherwise not obtainable within national research funding.



2.2. Exposure assessment (Topic 2)

Technical content/scope:

The scientific and technical objectives under this topic are summarized by (but not limited and not mandatory to) the following:

- Consumer exposure assessment (including food and food packaging, pharmaceuticals),
 generating a corresponding list of the most widespread MNMs important for risk assessment
- Developing new tools for effective characterization of individual exposure to MNMs

Expected Impact:

Understanding and prediction of exposure mechanisms and kinetics with a strong focus on consumer exposure. Support and extension of existing knowledge for exposure assessments.

2.3. Toxicity mechanisms (Topic 3)

Technical content/scope:

The scientific and technical objectives under this topic are summarized by (but not limited and not mandatory to) the following:

- Toxico-kinetic modeling of the behavior in organisms of the most important MNM present in consumer products, using in silico and in vitro approaches, and giving input for in vivo studies and the interpretation of in vivo data
- Dose-response studies of toxicological properties including genotoxicity and development of appropriate dose concepts using "real life" particles from relevant applications, e.g. with functional coatings.
- Study of cellular signaling pathways activated by MNMs (e.g. transcription factor activation and translocation, kinase activation etc.)
- Developing and applying reliable test strategies by integrating various approaches in order to exclude cross-reactions and the interference of the MNMs with the test system
- Developing and applying reliable test strategies by integrating physiologically relevant barrier mechanisms
- Development of advanced surface chemistry characterization techniques, in particular techniques capable of detecting and specifying the interactions between biological molecules and the surface of NPs and MNMs

Expected Impact:

Understanding of the impact of physico-chemical properties and dose effects on toxicology of selected MNM (according to the importance of their presence in products), and establishing of standard-operating-procedures (SOP).

2.4. Environmental impacts of MNMs (Topic 4)

<u>Technical content/scope:</u>

The scientific and technical objectives under this topic are summarized by (but not limited and not mandatory to) the following:

 Environmental exposures assessment; predictions and analytical studies of diffusion, (bio)accumulation, and (bio)concentration of MNMs in both biotic and abiotic components of ecosystems (plants, animals, soil, water). A special emphasis should be placed on end-of-life



aspects of MNMs in different environments (waste streams, recycling...) as well as on the determination of the natural background.

- Investigation of MNM paths of uptake and subsequent tissue effects in appropriate environmental species.

Expected Impact:

Availability of robust systems for the evaluation of impacts of MNM on the environment during their life cycle including end of life considerations.

2.5. Effects of MNM on human health (Topic 5)

Technical content/scope:

The scientific and technical objectives under this topic are summarized by (but not limited and not mandatory to) the following:

- Uptake, cell-particle interactions, distribution and effects of administered/ingested MNM in normal and diseased cells/tissues
- Establishing validated tests with high acceptance potential for assessing the safety of MNMs based on biokinetic data and emphasizing dosimetry
- The validation of testing procedures which allow prediction of the hazardous properties of MNMs

Expected Impact:

Understanding of the overall effects of MNM and their pathways, with a focus on ingestion, on human health. Application of achieved results on a broad variety of MNM applications in real-life situations, including the medical sector. Availability of appropriate testing strategies.

General remarks

The research teams within a consortium should include investigators of complementary scientific disciplines and research areas necessary to address the proposed research aims. Proposals should contain novel, ambitious aims and ideas, combined with well-structured work plans. A single proposal may cover more than one of the topics above.

Further considerations for proposals include that:

- OECD guidelines and high-level SOPs should be followed where appropriate. Improvements and further developments are appreciated.
- Projects have to provide a European added value compared to strictly national funding.
- Projects that strengthen standardization efforts are encouraged.
- Where appropriate, a link between fundamental properties of MNM and applications (e.g. medicine, materials, energy) should be strived for.
- The inclusion of more than one MNM, with a connection to real-life applications, in the studies is considered an advantage.
- Where appropriate, justification of suggested doses for in vivo and/or in vitro studies should be provided.
- Long-term studies are encouraged where appropriate since MNM exposure to both the general public and in occupational settings typically is characterized by low doses but over extended period of times.



- Researchers are encouraged to form consortia which combine research topics (e.g. consumer exposure assessment and toxico-kinetic modeling of relevant MNM). In combining research topics the application of research results by industry and regulators should be increased.
- The transnational character of ERA-NET projects represents an added value to the activities and this will be reflected in the evaluation, under the criterion Potential Impact.
- The projects should contribute to the formation and improvement of European networks in the field of nanosafety research. The participation in the meetings and activities of the European NanoSafety Cluster is expected.
- One of the major tasks of the ERA-NET SIINN is the provision of validated data on risk and toxicity behavior of manufactured nanomaterials. The participants of research projects funded by the SIINN ERA-NET are requested to supply relevant and validated data to a common database. In this context, the Joint Research Centre of the European Commission (JRC) offers the use of the database NANOhub which is set up according to the OECD recommendations on nanotoxicity data structures. Within the JRC NANOhub installations, a database for the projects funded in the framework of SIINN has been implemented. Funded consortia have to submit all relevant and validated data to this database. The participation in an appropriate training (webinar) by the JRC is mandatory for funded consortia.

3. MANAGEMENT BOARDS

Two boards, the Call Committee and the Evaluation Panel, will manage the evaluation process of the call with the support of the Call Office (set up at Foundation for Science and Technology, FCT, Portugal). The process includes the eligibility and relevance check of the proposals, the evaluation of the proposals and the final selection and award of research projects.

- The Evaluation Panel (EP) is a panel of internationally recognised scientific experts responsible for the evaluation of submitted proposals. EP members will not submit or participate in proposals within this call, and must sign a confidentiality agreement and a statement to confirm that they do not have any conflicts of interest.
- The Call Committee is composed of a representative from each participating country's/region's funding organisation. All decisions concerning the call procedures will be taken by the Call Committee. It will supervise the progress of the call and the evaluation of proposals. The Call Committee will make the final funding recommendation to the national/regional funding organisations regarding the proposals to be funded, based on the final ranking list provided by the EP. It accompanies the entire lifespan of the Call, evaluates the performance of the projects and resolves potential disagreements which may arise during the lifetime of the projects.

4. GENERAL REQUIREMENTS FOR PROPOSALS

Joint research proposals may be submitted by applicants belonging to one of the following categories (according to country/regional regulations):

- academia (research teams working in universities, other higher education institutions or research institutes)
- clinical/public health sector (research teams working in hospitals/public health and/or other health care settings and health organizations)



• enterprises (all sizes of private companies). Participation of small and medium-size enterprises (SMEs) is encouraged when allowed by national/regional regulations (please check with your respective national/regional funding organisation).

Consortia proposing a collaborative project must fulfil the following **eligibility criteria**:

- Each consortium submitting a proposal must involve a minimum of three independent partners from at least two regions/countries participating in the call.
- Applicants from countries whose funding organisations do not participate in the call may be
 part of a consortium if they are able to secure their own funding. Such partners must state
 the source of funding for their part in the proposal. These participants must have the funds
 and resources available prior to application.
- The coordinator of the proposal must be based in a country participating in the call.
- The majority (2/3) of partners and funding volume in a proposal must belong to countries participating in the call.
- The consortia must be balanced in terms of transnational participation. Therefore, it is mandatory that no more than 66% (2/3) of the total funding will be requested by partners from one country.
- The duration of the projects has to be between 24 and 36 months.

In addition, consortia are advised to follow these **recommendations**:

- Research should be focused on a clearly defined goal and, as such, the formation of consortia
 with between 3 and 7 partners is recommended. For EHS framework projects, the number of
 partners may be higher.
- The proposal should clearly show the specific contribution of each research consortium partner and the European added value of working together.
- The expected size of a project in terms of total funding is typically in the range of 0.3 to 1 M€.

Each transnational proposal must nominate a project consortium coordinator among the project partners. The coordinator must be from a Joint Call funding country/region. The project coordinator will represent the consortium externally and towards the Call Office and Call Committee, and will be responsible for its internal operational management (such as controlling, reporting, intellectual property rights issues and contact with the Call Office). Each project partner will be represented by one (and only one) project coordinator.

Please note that the inclusion of a partner in a proposal that is not eligible and cannot be funded could lead to the rejection of the proposal without further review unless the consortium remains eligible without the « non-eligible » partner. In this case, in agreement with the original consortium, the Coordinator of the project and with all funding organisations involved, a new proposal could be reviewed discarding the "non-eligible" partner. Whilst applications will be submitted jointly by research groups from several countries, national/regional groups will be funded by the national/regional funding organisation of their country/region that is participating in this JTC. The applications therefore need also to comply with the eligibility criteria of national/regional funding organisations. The project coordinator has to verify that all applicants of the consortium have contacted their corresponding national/regional contact point (funding organization) and confirmed eligibility with their respective funding organizations before submitting an application (see contact information of national/regional contact points on Section 9). A corresponding declaration has to be submitted to the Call Office as an appendix to the proposal.



5. SUBMISSION OF JOINT PROPOSALS

There will be a one-stage submission procedure for joint applications. One joint proposal document (in English) shall be prepared by the partners of a joint transnational proposal, and must be submitted to the Call Office by the project coordinator.

Furthermore, it has to be taken into account that Austrian, German, and Walloons applicants must submit additional national proposal/documents to their national funding organizations. Details of the corresponding requirements and procedures are described on Appendix B of the Guidelines for applicants. Please consult the respective national/regional funding organization or the respective national/regional contact point for further details.

Since receiving the national applications by the deadline of the Call is not an eligibility criteria, national applications will be requested directly by SIINN participating countries according to their deadlines which can be after the Call has closed.

Joint proposals (in English) must be completed and submitted to the submission website (http://www.siinn.eu) – it will be open from 18th June 2013 – no later than 31st October 2013 at 12:00 (noon) CET. Only the proposal templates provided on the SIINN web site (http://www.siinn.eu) will be accepted, and they must be completed following strictly the "Guidelines for Applicants". Further information on how to submit the proposals electronically is available in the "Guidelines for Applicants".

For the final funding decision of the national/regional funding organization, a national/regional application of the respective consortium partners may be required. Please consult the national/regional funding organization or the local contact point (LCP) for further details.

6. EVALUATION

6.1. Eligibility check of proposals

The Call Office will assess the proposals to ensure that they meet the call's eligibility criteria. The Call Office will forward the proposals to the national/regional funding organizations, which will perform a formal check for **compliance with their respective national/regional regulations.**

Please note that proposals not meeting the formal criteria or the national/regional eligibility criteria and requirements of the call **could be declined without further review.**

6.2. Evaluation of proposals

a. Reviewers

Each proposal will be allocated to at least two external reviewers and two evaluation panel (EP) members who fit the profile of the application. The reviewers are internationally recognized scientists chosen for their expertise and particular thematic orientations related to the topic addressed in the proposal.



b. Written evaluation

Reviewers will be asked to use a common evaluation form and give a score of 0 to 9 to each criterion for each proposal:

Criterion 0: Is the proposal within the scope of the call?

If the proposal is considered not to be within the scope of the call, only an explanation of why the proposal is out of scope is required.

Criterion 1: Scientific and/or technological excellence

- Soundness of concept and quality of the objectives
- Progress beyond the current state of the art
- Quality and effectiveness of the S/T methodology and associated work plan

Criterion 2: Implementation and Management

- Appropriateness of the management structure and procedures
- Quality and relevant experience of the individual participants
- Quality of the consortium as a whole (including complementarity, balance)
- Appropriateness of the allocation and justification of the resources to be committed (staff, equipment)
- Inherent safety and EHS assessment form life-cycle perspective if applicable.

Criterion 3: Potential Impact

- Addressing industrially relevant environmental, health and safety (EHS) aspects of nanoscale technologies
- Contribution to the development of a consolidated framework to address nanorelated risks and the management of these risks for humans and the environment
- Appropriateness of measures for the dissemination and/or exploitation of results
- European dimension of the research and the proposed solutions, necessity for transnational approach
- Transnational added value of the collaboration

c. EP meeting

The EP members will meet to discuss each proposal and, after consideration of the evaluation criteria, external reviews and their own discussions, the EP will identify the top-quality proposals recommended for funding and establish a ranking list.

6.3. Funding decision

Based on the proposals' ranking established by the EP and on available funding, the Call Committee will suggest the projects to be funded to the national/regional funding organisations.

Only high quality proposals will be funded. If the number of proposals considered to have high quality, as judged by the Evaluation Panel, corresponds to a total requested funding which is smaller than the committed funds, only part of the funds will be used.

Projects not recommended for funding by the Evaluation Panel will not be funded in any case.



Final funding decisions will be made by the national/regional funding organisations according to their legal frameworks and regulations.

The Call Office will communicate the final decisions to all project coordinators, as well as the comments of the reviewers.

7. FINANCIAL AND LEGAL ISSUES

7.1. Funding model

The JTC 2013 Funding Partners have agreed to launch a joint call, where each country/region funds only its national/regional component of the transnational research project. This means that each national/regional partner organization of a funded project is subject to the rules and regulations of their respective national/regional funding organisation. The funding rate within the call will be variable according to national/regional rules. Funding is granted for a maximum of 36 months according to national regulations. Eligible costs may vary according to the corresponding national/regional regulations of the respective funding organisation.

Prior to submitting a proposal, applicants must verify their eligibility and the rate of financial support with their national/regional funding organisation. It is mandatory for all applicants to contact their national/regional organisation (see local contact points, section 9).

7.2. Funding contracts

Each project includes several consortium members called research partners and one project coordinator. Each research partner/research institution will have a separate funding contract/letter of grant according to national/regional regulations with the appropriate national/regional funding organisations.

Changes to the composition of research consortia or to the budget cannot occur during the contract/letter of grant, unless there is an appropriate justification. Any changes have to be well justified and the relevant funding organizations will decide upon the proper action to be taken. The research partners shall inform the Call Office and the funding bodies of that project of any event that might affect the implementation of the project.

7.3. Research consortium agreement and ownership of intellectual property rights

The project consortium partners must agree on a **consortium agreement** (CA) for cooperation (addressing the issues given in "Guidelines for Applicants" on consortium agreements) before the official project start date. Upon request, this consortium agreement must be made available to the concerned funding organisations. This consortium agreement must be signed by all partners within three months of the official project start. Please note that national/regional rules may apply.

Results and new Intellectual Property Rights (IPR) resulting from projects funded through this JTC will be owned by the researchers' organisations according to national rules on IPR. If several participants have jointly carried out work generating new IPR, they shall agree amongst themselves (consortium agreement) as to the allocation of ownership of IPR, taking into account their contributions to the creation of those IPR as well as the European guidelines on IPR issues.



The results of the research project and IPR created should be actively exploited and made available for use, whether for commercial gain or not, in order for public benefit to be obtained from the knowledge created.

The funding partners shall have the right to use documents, information and results submitted by the research partners and/or to use the information and results for their own purposes, provided that the owner's rights are kept and taking care to specify their origin.

7.4. Database for SIINN funded projects

One of the major tasks of the ERA-NET SIINN is the provision of validated data on risk and toxicity behaviour of manufactured nanomaterials. The participants of research projects funded by the SIINN ERA-NET will be requested to supply relevant and validated data to a common database.

The Joint Research Centre (JRC) of the European Commission offers the use of the database NANOhub which is set up according to the OECD recommendations on nanotoxicity data structures. The use of NANOhub is free of charge.

Within the JRC NANOhub installations (http://www.napira.eu/), a database for the projects funded in the framework of SIINN has been implemented. For all research projects to be funded within the framework of the second SIINN call, it will be mandatory to submit all relevant and validated data created during the lifetime of the project to this database.

The participation in an appropriate training (webinar) by the JRC will be a mandatory prerequisite for funded consortia in order to be allowed to access this database.

8. RESPONSIBILITIES, REPORTING REQUIREMENTS AND DISSEMINATION

The coordinators of all the funded projects must submit **annual and a final** (within three months of the end of the project) **scientific progress project report** to the Call Office. All reports must be in English and use a common report form that will be provided. The research partners are jointly responsible for the delivery of the reports, and the Call Office will only accept reports delivered on behalf of the consortium, via the project coordinator.

The coordinators and/or national group leaders might be asked to present the results of their projects at an **intermediate and/or a final status symposium**.

Any publications resulting from the funded projects must acknowledge the SIINN ERA-Net and the respective participating funding organisations, and one copy must be sent electronically to the Call Office.

If required, participants submit financial and scientific reports to their national/regional funding organisations, according to national/regional regulations.

9. SIINN CALL OFFICE, LOCAL CONTACT POINTS (LCP) AND FURTHER INFORMATION

The Call Office of the second SIINN Call is set up at FCT (Foundation for Science and Technology), Portugal, to assist the Call Committee and the national/regional funding bodies during the implementation of the call and the follow-up phase until the funded research projects and all



reporting requirements have ended. The Call Office will be responsible for the administrative management of the call. It will be the primary point of contact referring to the call procedures between the research consortia, the funding organisations and the peer reviewers. The project coordinator will be the person contacted by the Call Office during the application procedure, so he/she must forward this information to the other participants.

It is mandatory for all applicants to contact the national/regional contact person for any questions regarding the call (please see local contact points below).

Local contact points (LCP)

Country/ Region	Institution	Website	LCP
Germany	Jülich PtJ	www.ptj.de	Dr Rainer Hagenbeck +49 2461 61 5741 ptj-siinn@fz-juelich.de
Austria	FFG	www.ffg.at/nano-ehs	Dr Margit Haas +43 57755 5080 Margit.haas@ffg.at
Belgium Wallonia	SPW-DGO6	recherche- technologie.wallonie.be/f r/menu/ressources/progr ammes/les-era-nets.html	Dr Cédric Volcke +32 479 67 01 31 (mobile) +32 81 33 45 48 cedric.volcke@spw.wallonie.be
Romania	UEFISCDI	www.uefiscdi.gov.ro	Mihaela Manole +40.21.302.38.63 mihaela.manole@uefiscdi.ro
Portugal	FCT	http://www.fct.pt/apoios/cooptrans/eranets/siinn/index.phtml.en	Dr Carlos Pereira Dr Dina Carrilho +351 213924397 +351 213924381 Carlos.Pereira@fct.pt Dina.Carrilho@fct.pt
Israel	CSO-MOH	www.health.gov.il/resear ch-fund	Prof Avi Israeli +972 2 5082163 avii@moh.health.gov.il



Eligibility of beneficiary institutions for the participating organisations of the JTC 2013

		Eligible ben	Eligible beneficiary institution			
Country/Region	Institution	Academia	Clinical /public health	Company		
Germany	BMBF/PtJ	Yes	Yes	Yes		
Austria	BMVIT/FFG	Yes	Yes	Yes		
Belgium-Wallonia	SPW-DG06	Yes (1)	No	Yes		
Romania	UEFISCDI	Yes	Yes	Yes (1)		
Portugal	FCT	Yes	Yes	Yes		
Israel	CSO-MOH	Yes	Yes	No		

(1) The eligibility of academia, companies and institutions is subjected to different conditions in each country/region. Further details regarding the eligible beneficiaries and other national eligibility criteria and requirements are available on the "guidelines for applicants". Please contact the local contact point for specific information.

It is mandatory for applicants to contact their local contact points for further information.

Funding Commitment of the countries participating in the call

The total envisioned budget for this Call is about 4,520,000 €. Projects will be funded for a period between 24 and 36 months.

The expected financial commitment from the respective the participating countries for the entire funding period up to which national funding is possible are set as follows:

BMBF (Germany)	2 000 000 €
BMVIT (Austria)	500 000 €
SPW-DGO6 (Belgium, Wallonia)	1 000 000 €
UEFISCDI (Romania)	500 000 €
FCT (Portugal)	400 000 €
CSO-MOH (Israel)	120 000 €
Total	4 520 000 €



Call Timeline

Date	Step
20 May 2013	Call pre-announcement
18 June 2013	Publication of the joint call
31 October 2013	Deadline for submission of proposals
March 2014	Final funding decision at national/regional level
After March 2014	Start of national/regional administrative procedures
Fall 2014	Start of funding/projects