EU Brokerage Event on KET[1] in Horizon 2020

Workshop Session 7: EU-U.S. and International Cooperation
(NMBP 03-2016, NMBP 35-2016, NMBP 14-2017)

1 October 2015, 10.15 – 12.45 (2h30min)
Maison de la Région - 1 Place Adrien Zeller - 67000 Strasbourg

Organized by BILAT USA 2.0[2]

Objectives & Scope

The overall goal of this workshop is to exchange of knowledge on European and U.S. cutting edge research and innovation capacities on the following specific topics of the Nanotechnology based on the (draft) work programme 2016-2017 of the H2020:

- NMBP 03-2017: Innovative and sustainable materials solutions for the substitution of critical raw materials in the electric power system
- NMBP 35-2016: Promoting safe innovation through global consolidation and networking of nanosafety centres and strengthening the European nanosafety cooperation
- NMBP 14-2017: Regulatory Science Framework for assessment of risk-benefit ratio of Nanomedicines and Biomaterials

The workshop also aims to identify the common interests based on existing cooperation activities and facilitating new collaborations within the Horizon 2020.

Details of the topics are provided in the Annex I as they appeared in the (draft) Work Programme.

Agenda as well as information about the speakers are indicated in Annex II.

Expected Outcomes of the Workshop

- Increased knowledge of most recent research activities in EU and in the U.S. on the selected topics
- Increase visibility of existing projects and project ideas

[1] Focus on **K**ey **E**nabling **T**echnologies,- nanotechnologies, advanced materials, advanced manufacturing and processing

[2] BILAT USA 2.0 is a bilateral coordination activity to enhance and develop science, technology and innovation partnerships between the European Union and the United States of America. For more information: http://www.euussciencetechnology.eu/

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- Networking of EU and U.S. experts
- New EU-U.S. collaborations on selected topics within and outside of the H2020

Target group of the Event

The immediate target group is the participants of the Brokerage event. Furthermore, the workshop and presentations will be made public and widely distributed among the relevant stakeholders.

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ANNEX I

TOPICS[3]

- **NMBP-03-2016: Innovative and sustainable materials solutions for the substitution of critical raw materials in the electric power system**
- **NMBP-35-2016: Promoting safe innovation through global consolidation and networking of nanosafety centres and strengthening the European industry through cooperation in nanosafety**
- **NMBP-14-2017: Regulatory Science Framework for assessment of risk benefit ratio of Nanomedicines and Biomaterials**

NMBP-03-2016: Innovative and sustainable materials solutions for the substitution of critical raw materials in the electric power system

Specific Challenge: The ambition of the European Union to achieve a secure, competitive and sustainable energy system by 2050 has become a priority. The electric power system will play a pivotal role in the overall energy mix, with particular challenges to achieve a balance between electricity supply, conversion, transport and use of energy. Critical raw materials[4] (CRM) can become a bottleneck to the supply-chain of the different technologies used in the electric power system with implications for materials demand under different scenarios described in the EU Energy Roadmap 2050.

Even if recycling rates for some of these materials could be optimised to the highest possible extent, the overall increasing demand for CRM urges the roll-out of substitution-based solutions within the next decade.

This specific challenge is covered by the Priority Area "Substitution of raw materials" of the European Innovation Partnership (EIP) on Raw Materials.

Scope: Proposals should deliver innovative, sustainable and cost effective materials solutions for the substitution of (i) heavy rare earth elements used in permanent magnets; and/or (ii) CRM used in energy storage applications; and/or (iii) CRM used in catalysts for applications to generate electricity; and/or (iv) CRM in materials used in photovoltaic cells. Substitution of CRM in electronics or lighting applications is excluded.

[3] Nanotechnologies, Advanced Materials, Biotechnology, and Advanced Manufacturing and Processing DRAFT WORK PROGRAMME 2016-17

[4] The 2014 revision of the list of critical raw materials for the EU can be found at http://ec.europa.eu/growth/sectors/raw-materials/specific-interest/critical/index_en.htm

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In order to ensure the industrial relevance and impact of the research efforts, the cost effectiveness and commercial exploitation potential of the proposed solutions compared to state-of-the-art solutions currently available on the market should be convincingly assessed in the proposal. The sustainability of the materials solutions should be analysed through a life-cycle assessment. Recycling/reuse should be addressed.

Where relevant, proposals should contribute to the "Expert network on critical raw materials ". Refer to the part on 'Climate action, environment, resource efficiency and raw materials' of this Work Programme, topic SC5-17a-2016.

The implementation of this topic is intended to start at TRL 3 and target TRL 5.

In line with the objectives of the Union's strategy for international cooperation in research and innovation (COM(2012)497), international cooperation according to the current rules of participation is encouraged, in particular with Japan5. The quality of the international cooperation will be reflected in the evaluation of the proposal, under the criteria 'Excellence' and 'Impact'.

The Commission considers that proposals requesting a contribution from the EU between EUR 3 and 5 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

- A strongly reduced or completely eliminated CRM content in the proposed solution(s) while keeping up or improving the materials performance levels as specified in the relevant parts of the SET-Plan Integrated Roadmap and its Annexes, available at https://setis.ec.europa.eu/set-plan-process/integrated-roadmap-and-action-plan
- A risk mitigation strategy from future bottlenecks in the material supply-chain of energy technologies used in the electric power system;
- Contribute to achieving the objectives of the EIP on Raw Materials, In particular, a substantial contribution to the demonstration of substitutes in targeted applications of critical raw materials.

Type of Action: Research and Innovation action

5 Co-funding opportunities from the Japan Science and Technology Agency exist for Japanese partners. For more information, please consult http://www.jst.go.jp/sicp/announce_eujoint_03_GeneralInfo.html.

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NMBP-35-2016: Promoting safe innovation through global consolidation and networking of nanosafety centres and strengthening the European industry through cooperation in nanosafety

Specific Challenge: The rapid expansion of nanotechnology has brought the question of the safety of the emerging applications and the risk management measures. Considerable effort has been put by FP6 and FP7 projects for answering basis scientific and technical questions and will continue under H2020. There is a need to support regulatory aspects by providing the technology, skills and conventions necessary for implementation of existing rules and consistent development of new ones. This supposes developing the capacity to routinely assess and reduce risks in regulatory terms, both for toxicity and exposure, and the capacity to develop and implement safe-by-design processes and products with the aim of keeping risk level below pre-defined values.

Scope: The objective of this topic is to support safe innovation related aspects by providing the technology, skills, and processes, necessary for science-based best NanoSafety practices in industrial and commercial activities.

This objective is being addressed by excellence centres currently being established in several EU member states and globally. A wide variety of national and (EU) regional platforms and centres can be observed which are dedicated to research, market follow-up, dissemination of nanosafety. There is the need to consolidate and further develop these first initiatives so as to make available to industry and other stakeholders concerned an European-wide, up-to-date, science-based, organisational structure capable of managing risks and support safe innovation. It should also ensure providing scientific support to more general questions on product quality, technical approvals, counterfeiting, training and certification system for nanosafety at work and providing reliable information for the public.

The proposed CSA should aim at networking these platforms, including the nanosafety cluster, at European level and cooperate with third countries. The foundation and basis for the development of the European nano-network will be based on the interaction and adequate communication to generate a step-change in the risk management process. It may include work and resources specific to the participants or other public and private sources. The CSA can be used to pool resources and organise calls for market oriented activities which are of common interest for the platforms.

To ensure fast transfer of knowledge from basic research to market implementation, the proposed CSA should strengthen and support the Nanosafety Cluster activities, in particular those aiming at communication and outreach.

Possible horizontal aspects addressed by topic:

This topic is part of the open data pilot

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In line with the objectives of the Union's strategy for international cooperation in research and innovation (COM(2012) 497), international cooperation according to the current rules of participation is encouraged, in particular with Brazil, South Korea and the United States of America. The quality of the international cooperation will be rewarded in the evaluation of the proposal.

The Commission considers that proposals requesting a contribution from the EU between EUR 1 and 2 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts. No more than one project will be funded.

Expected Impact:

An independent science based EU nanosafety reference platform for all stakeholders in nanotechnology that collates information into a comprehensive and accessible European network portal and providing a solution to the problem of data accessibility and transferability, by removing barriers which currently limit knowledge distribution.

The CSA should mark progress for Guidance to market actors (industry, safety service providers, and public authorities), best practice, standards, technical approvals, environment protection, and operational certification systems.

The platforms network should prepare a European Hub to provide services and support for stakeholders (e.g. industry, governments, researchers etc.) to create in a sustainable way marketable, societal approved products and goods.

Involvement of highly renowned actors in the research field and from leading stakeholders from regulatory bodies, standardization bodies, into a seedless dialogue.

Significant research outputs efficiently disseminated to national and international communities

Type of Action: Coordination and Support Actions

NMBP-14-2017: Regulatory Science Framework for assessment of risk benefit ratio of Nanomedicines and Biomaterials

Specific Challenge: The application of nanotechnology and nanobiomaterials has great potential to advance medicine for the benefit of citizens. However, the use of these new technologies poses considerable challenges for assessing the quality, safety and efficacy of the novel nanomedicines and medical devices.

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Scope: Proposals should advance the field of medical regulatory science and practice through the development and validation of science based regulatory knowledge and standardisation of innovative technical tools and methods. The intention is to lead to a new and better methodology for pre-clinical and clinical evaluation and help to take appropriate stock of and to apply innovative scientific advances as and when they occur. As relevant, the proposed activities should address sex and gender specific aspects[6].

Proposals should focus on the development of new regulatory standards and tools that are based on scientific principles that already have a Proof-of-Concept at the laboratory scale.

Where appropriate, proposals should make use of the opportunities for obtaining scientific advice from medical regulatory bodies to support the qualification of innovative development methods.

International cooperation and participation of Member States funding programmes with complementary funding is encouraged to facilitate development of new regulatory science on the global scale.

Established methods, including related equipment, should be brought to Technology Readiness Level 6 and beyond, whereas those based on new concepts are expected to reach TRL 5.

This topic is suitable for international cooperation.

The Commission considers that proposals requesting a contribution from the EU between EUR 5 and 8 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

No more than one action will be funded.

Expected Impact:

- To reduce the cost of pre-clinical and clinical development for new medical products and therapies, that are based on the application of nanotechnology and nanobiomaterials;
- To reduce the time for innovations to reach the patients;
- To provide a set of tools for more informed risk assessment and decision making;
- To improve standardisation of regulatory practice at the European and international level;
- To establish a close collaboration among regulators, industry, science and patients with regard to the knowledge required for appropriate risk management, and create the basis for common approaches, mutually acceptable datasets and risk management practices;

[6] *See definition of the 'gender dimension approach' in the introduction of this Work Programme part.*

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- To establish a European Consortium for the Advancement of Regulatory Science in Biomaterials and Nanomedicines, involving industrial, medical, academic, regulatory and patient representative stakeholders;
- To identify within the consortium critical issues for innovative products and establishment of an action plan for further studies;
- To establish links with existing European Infrastructures active in the field, along with relevant European Research Networks;
- To elaborate an action plan for a better integration of the European Union with other regions of the world.

Type of Action: Research and Innovation action

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ANNEX II

AGENDA

Opportunities for U.S.-EU Cooperation within H2020
Work Programme 2016-2017

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Opening Remarks	• **Kai Savolainen, Moderator,** Finnish Institute of Occupational Health • **Berna Windischbaur**, Representative of the BILAT USA 2.0 • **Lisa Friedersdorf**, U.S. National Nanotechnology Coordination Office, National Nano Initiative
NMBP 03-2016 Innovative and sustainable materials solutions for the substitution of critical raw materials in the electric power system	• **Dimitri Niarchos,** Director of Research, Coordinator of the REFREEPERMAG Project • **George Hadjipanayis,** University of Delaware, Department of Physics and Astronomy
NMBP 35-2016: Promoting safe innovation through global consolidation and networking of nanosafety centres and strengthening the European nanosafety cooperation	• **Martie van Tongeren**, Institute for Occupational Medicine, Edinburgh, UK
NMBP 14-2017: Regulatory Science Framework for assessment of risk-benefit ratio of Nanomedicines and Biomaterials	• **Scott McNeil**, U.S. Nanotechnology Characterization Laboratory • **Susanne Bremer Hoffmann,** Institute for Health and Consumer Protection (IHCP), JRC, Ispra, Italy.

[7] Focus on **K**ey **E**nabling **T**echnologies,- nanotechnologies, advanced materials, advanced manufacturing and processing

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List of Speakers and BIOGRAPHIES

Name of the Speaker	E-mail	Involved Topic
Kai Savolainen	Kai.Savolainen@ttl.fi	Welcoming Remarks , Moderator
Martie van Tongeren	Martie.VanTongeren@iom-world.org	**NMBP 35-2016**: Promoting safe innovation through global consolidation and networking of nanosafety centres and strengthening the European nanosafety cooperation
Lisa Friedersdorf	lfriedersdorf@nnco.nano.gov	Welcoming Remarks
Scott McNeil	mcneils@mail.nih.gov	**NMBP 14-2017:** Regulatory Science Framework for assessment of risk benefit ratio of Nanomedicines and Biomaterials
Dimitris Niarchos	d.niarchos@inn.demokritos.gr	**NMBP 03-2017:** Innovative and sustainable materials solutions for the substitution of critical raw materials in the electric power system
Susanne Bremer Hoffmann	Susanne.BREMER-HOFFMANN@ec.europa.eu	**NMBP 14-2017**: Regulatory Science Framework for assessment of risk benefit ratio of Nanomedicines and Biomaterials
Berna Windischbaur	Berna.windischbaur@ffg.at	Welcoming remarks as organizer of the workshop on behalf of BILAT USA 2.0 Project

KAI SAVOLAINEN

Prof. Kai Savolainen is Research Professor and the Director of the Nanosafety Research Centre of the Finnish Institute of Occupational Health (FIOH) since January 1, 2011 with main responsibility to lead nanosafety research with an aim to increase safety at workplaces where nanomaterials/nanotechnologies are being used. The work includes leading of the centre, assuring appropriate external research funding from external sources for the activities of the centre, applying and coordinating funds for large EU consortia funded from EU RTD framework programmes, emphasize implementation of the work in workplaces and enterprises in Finland and beyond, serve stakeholders in Finland and abroad (employer organization, labor unions, regulators, decision makers), dissemination information and promote dialogue on safety of engineered nanomaterials and nanotechnologies, and effectively network with partners in Finland, in the EU and globally.

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LISA FRIEDERSDORF

Dr. Lisa Friedersdorf is the Deputy Director of the National Nanotechnology Cooperation Office. She has been involved in nanotechnology for nearly twenty years, with a particular interest in advancing technology commercialization through university-industry-government collaboration. She is also a strong advocate for science, technology, engineering, and mathematics (STEM) education, and has over two decades of experience teaching at both the university and high school levels. Prior to working with the NNCO, she was the Managing Director of the Institute for Nanoscale and Quantum Scientific and Technological Advanced Research (nanoSTAR) at the University of Virginia, where she fostered a campus-wide nanotechnology community, facilitated new collaborative research opportunities, and built external awareness of University capabilities and accomplishments in the field.

MARTIE VAN TONGEREN

Dr. Van Tongeren is Research Director at Institute of Occupational Medicine, which is a UK based leading provider of health and safety solutions to industry, commerce, public sector and professional bodies. His main research projects include development and application of tools to estimate current and past exposure to various chemical and other agents (including nanomaterials) in the work environment and the home for chemical risk assessment and epidemiological studies.

Research Interests:

Exposure Science, Epidemiology, Risk Assessment, Exposure Modelling, Nanotechnology

SCOTT MCNEIL

Dr. McNeil serves as the Director of the Nanotechnology Characterization Laboratory (NCL) for Leidos Biomedical Research and Frederick National Laboratory for Cancer Research, where he coordinates preclinical characterization of nanotech cancer therapeutics and diagnostics. At the NCL, Dr. McNeil leads a team of scientists responsible for testing candidate nanotech drugs and diagnostics, evaluating safety and efficacy, and assisting with product development -- from discovery-level, through scale-up and into clinical trials. NCL has assisted in characterization and evaluation of more than 300 nanotechnology products, several of which are now in human clinical trials. Dr. McNeil is a member of several working groups on nanomedicine, environmental health and safety, and other nanotechnology issues. He is an invited speaker to numerous nanotechnology-related conferences and has several patents pending related to nanotechnology and biotechnology. He is also a Vice President of Leidos Biomedical Research.

Prior to establishing the NCL, he served as a Senior Scientist in the Nanotech Initiatives Division at Leidos where he transitioned basic nanotechnology research to government and commercial markets. He advises industry and State and US Governments on the development of nanotechnology and is a member of several governmental and industrial working groups related to nanotechnology

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policy, standardization and commercialization. Dr. McNeil's professional career includes tenure as an Army Officer, with tours as Chief of Biochemistry at Tripler Army Medical Center, and as a Combat Arms officer during the Gulf War. He received his bachelor's degree in chemistry from Portland State University and his doctorate in cell biology from Oregon Health Sciences University.

DIMITRI NIARCHOS

Dr. D. Niarchos, is an internationally recognized materials scientist and Director of Research of the National Center for Scientific Research "Demokritos" as of May 9th 2005. He received his B.Sc (1972) and Ph. D (1978) from the Department of Physics of the University of Athens, Greece. He became a Post-Doctoral Fellow of the University of Chicago in 1979 and in 1981 was appointed as Assistant Professor at the Physics Department of the Illinois Institute of Technology, Chicago Illinois until 1985, then returned to Greece as a scientist at the Institute of Materials Science of the NCSR "Demokritos". In 1994 he was elected as Director of the Institute of Materials Science and from 1996-1999 as Vice President of the Center. He also has been Associate Professor of the University Joseph Fourier- CNRS-Lab Lois Neel, Grenoble France in 1989. His Scientific activities cover a wide span of the materials science and are summarized below: Nanostructured Magnetic Materials, Superconducting Materials, Magnetic MEMS , Left-Handed Magnetic Materials, Combinatorial Magnetic Materials synthesis, Energy .He is currently the Project coordinator of "Magnetic and Supercoducting Materials".

SUSANNE BREMER HOFFMANN

Susanne Bremer-Hoffmann, Dr. rer nat, holds a PhD degree in Biology obtained from the Charite University Hospital Berlin in Germany for her work on the development of immunotherapies against leukemia. After post-doctoral research at the Federal Institute for Risk Assessment in Germany, Susanne joined the Institute Research Centre (JRC) of the European Commission. Susanne became a team member of the European Centre for the Validation of Alternative Methods (ECVAM) in 1995 where she was involved in formal validation studies of toxicological in vitro tests detecting embryotoxicity and endocrine disruption and their regulatory acceptance at the OECD. She collaborated in several FP6 and FP 7 projects including the public/privat partnership initiative"SEURAT-1". In 2014 Susanne Bremer-Hoffmann joined the Nanobiosciences Unit of the same Institute and is currently participating in the establishment of the European Nanocharacterisation Laboratory.

Contact

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