



## **NANOSAFETY CLUSTER MEETING**

**Time:** 14 September 2016; 12:30–16:00

**Venue:** Karolinska Institutet, Solna Campus, Hörsal CMB (CMB Lecture Hall) Berzelius väg 21, Stockholm, Sweden

### **Session 1: NSC Roadmaps and recent developments**

Chairs: Dr Nicolas Segebarth and Dr Éva Valsami-Jones

#### **1. Welcome and opening remarks**

The Coordinator of the NanoSafety Cluster, Dr Kai Savolainen from FIOH and Dr Bengt Fadeel from Karolinska Institutet welcomed the participants to the meeting. Dr Nicolas Segebarth gave the opening remarks on behalf of the European Commission.

#### **2. Update of the Roadmaps**

##### ***Closer to the Market Roadmap***

Mr Andreas Falk introduced the aims of the CTTM Roadmap which are to speed up the progress towards market implementation and to support the commercialization of nanotechnologies.

Mr Falk told that two bottlenecks have been identified: the lack of nanosafety management system and the lack of integration of nanosafety issues into industry process management systems. There are plenty of solutions suggested, such as sector specific nanosafety management systems; standardisation, training and certification; translation and encapsulation of the results of research in a battery of practical methods, strategies and tools for the management of nano-risks; and harmonized standards. The bottlenecks will be addressed with short term activities (2018–2020) such as reporting and networking activities and certification of methods.

As to the impacts of the CTTM, Mr Falk outlined, first, the improvement of efficacy of toxicology studies of NMs and certification of methods. In addition, it is important to provide industrial stakeholders and general public with appropriate knowledge on the risks of nanoparticles and NMs, which will overcome the existing lack of knowledge transfer in economic and societal terms. It is also crucial to integrate the nanosafety dimension and safety issues to the business plans of the relevant industry.

Reference: Closer to the Market Roadmap (CTTM), 2016 ([pdf](#))

Authors: Andreas Falk, Christa Schimpel, Andrea Haase, Benoît Hazebrouck, Carlos Fito López, Adriele Prina-Mello, Kai Savolainen, Adriënné Sips, Jesús M. Lopez de Ipiña, Iseult Lynch, Costas Charitidis, Visser Germ



### ***Nanobioinformatics Roadmap***

Dr Andrea Haase gave an introduction to the Nanobioinformatics Roadmap. She told that the first draft of the Roadmap will come out in the end of 2016 and the final version will be issued in the middle of next year. The Roadmap is a shared effort between EU and USA.

Dr Haase explained that the objectives of the Roadmap are, first, to be a vehicle for community interaction and resource to support different stakeholders. Further, to capture, preserve, and disseminate all publicly-available NM measurement data (experimental and computational), to take advantage of existing NM measurement results, to identify specific pilot projects to reach the first three objectives and to describe the way forward. Nanoinformatics processes and impact concerning both communities and individuals were presented as well as contributors, which include various data experts.

The outline of the document contains five sections: data gathering and data storage, data analysis, data accessibility and data exchange, current network and the roadmap itself.

The ***Regulatory Research Roadmap*** was not discussed due to the absence of Dr Vicki Stone.

### ***Integrating the roadmaps and updating the Research Roadmap (Strategic Research Agenda)***

Dr Kai Savolainen told that the aim is to integrate the Research Strategy Roadmap, the Regulatory Research Roadmap and the Closer to the Market Roadmap to one self-standing roadmap in order to support the EU Commission in its goal to generate a path from scientific discovery through innovations, with the support of regulations, to profitable products in the market.

Research Strategy roadmap was published in 2013 and it requires updating to meet challenges of Horizon 2020. Research priorities need to be clearly defined as shall the main messages in the two other roadmaps as well. A short version of all three documents should be generated in order to make them easy-to-use and their contents should be aligned with each other to enable their merger. A working group shall be established and a schedule defined to finalize the compilation work.

## **3. Update of NSC internal/external developments and discussion**

### ***Task Force (TF) on Safety: draft conclusions for High Level Group (HLG)***

Dr Éva Valsami-Jones introduced the purposes of the TF and the set of recommendations under preparation for the HLG. The recommendations are:

- FP research is essential for the further development of regulatory tools in advanced material safety. More international cooperation is recommended (e.g. CoRs, OECD, ISO).
- Scientific research should be better connected with regulatory needs.
- Safe-by design approaches and tools for advanced material development create new opportunities for innovation and market expansion. This should include all aspects,

not only hazard, but also e.g. exposure consideration and mitigation. They should be included in all calls for research.

- Nanosafety centres add to the capacity of the industry to develop and implement safe-by-design processes and products, as well as to the routine assessment and reduction of risks. Networking between the centres and regulation measures is required.
- Better communication and collaboration between material science and risk research is recommended.
- Intelligent testing strategies should be carried out with an interdisciplinary approach. Better integration between experimentation and modelling is recommended.
- Novel research needs to be supported such as development of state-of-the-art instrumentation for nanoscale analysis, omics tools, and in-silico informatics approaches.
- A mechanism for longer-term support for research should be established through cooperation between the EC and member states to ensure continuation of research beyond the lifetime of individual projects.
- Collaborative projects and networks co-funded across member states create excellent synergies in research and Europe-wide market adoption and implementation (ERA-NET). These should not be lost in future funding frameworks.
- Efficient bridging between the research and standardisation has to be ensured.

Dr Nicolas Segebarth expressed a wish that in Task Force's future work the scope of recommendations could be widened to recommendations for policy actions with an influence far beyond the Framework Programme.

The ***NanoDefine NSC synergies – outcomes & next steps*** was not discussed due to the absence of Dr Rune Karlsson.

#### ***Sustainability Task Force (TF): Nanoinformatics and data resource sustainability***

Dr Barry Hardy introduced the Task Force background and infrastructure. The TF aims at identifying practices, models and structures for supporting sustainability for NSC resources and to develop community infrastructure activities aligned within NSC. Further, the TF identifies opportunities for community and network funding and joins and aligns with open commercial approaches. Dr Hardy continued by presenting the portal for eNanoMapper applications and data, which forms a simple and easy entry point that guarantees a sustainability for at least 5 years beyond the project's life time. New initiatives include e.g. the EU–US NanoEHS workshop to be held on 24.10.2016 in Germany. As next steps the TF is going to engage in data practice guidance and data sharing guidance, ontology evaluation, contribution to roadmaps, Open Data initiatives, and elaboration of service model.

Dr Hardy concluded that community is a key ingredient to long term sustainability success. This should involve both centralised approaches to certain problems (e.g., open standards, ontology on common concepts), but also a distributed approach supporting variations in scientific cultures, needs and activities from different sub-sectors of the community. Around such a composite dialogue and set of relationships, including active development of



common understanding and responding to stakeholder needs, and obtaining true commitment, practices and resources have the better chance to be sustained. This will be a key success factor of a sustainable "Knowledge Infrastructure" for the NSC, and needs to involve people interacting around ideas, methods and data, in an increasingly higher quality approach to an emerging scientific discipline.

Dr Nicolas Segebarth pointed out that the data sustainability is going to be compulsory for all FP projects as well as Open Data policy; every data produced in the EU funded projects will be Open Access.

#### ***Open Data & NSC activities***

Dr Egon Willighagen discussed how Open Data can help the activities of the NanoSafety Cluster. Dr Willighagen started with presenting the NanoSafety Cluster database in eNanoMapper project and the NANoREG data. Several examples of Open Data archives and repositories in Europe were presented. These include Figshare, Zenodo, ELIXIR, OpenAIRE, EUDAT, etc. Commission web-site Digital single market includes several Open Data Portals maintained by public administrations. Linked data forms an important approach for data management.

In the NSC research data management it is important to take into account the legislation concerning data sharing and copyright protection. The use of Open Data requires clear copyright statements, full provenance of where the data comes from and an open licence or waiver. The importance of CLW (Copyright statement and Licence or Waiver) was discussed in more detail. Dr Willighagen concluded that there is a clear need to fund a research data infrastructure itself among the NSC community which is cheaper with Open Source solutions. Plenty of solutions exist for Research Data Management but scalable, distributed approach is needed. All stakeholders must take their responsibilities concerning early and clear intellectual property agreements and CLW.

Nicolas Segebarth informed the audience that a new policy initiative concerning risk governance will be launched on nanosafety field. Georgios Katalagianakis will introduce the initiative to NSC in the next NSC Meeting in Grenoble in November. In nanosafety research field there are structure, organization and decision making processes already well in place but how to measure the progress is a question to be addressed.

### **Session 2: NSC Working Group activities**

Chairs: Dr Sergio Moya, Dr Iseult Lynch and Dr Éva Valsami-Jones

#### **4. Enhancing stakeholder engagement in the NSC**

Dr Iseult Lynch discussed how to engage the stakeholders more effectively. Stakeholder engagement is one of the initial goals of the NSC. Dr Lynch questioned if these goals still are relevant or should they be updated. In connection with the NanoSafety Cluster annual conferences, which are at a planning stage, also an annual stakeholder event could be organized. The Joint Conference 2017 in Malaga will be a first step to that direction. Various

stakeholder groups should be handled individually, preferably in face-to face meetings, because their needs differ from each other.

It was discussed whether the goals of the NSC should be changed even more radically in connection with the coordinator change of the NSC. The discussions on updating the goals of the NSC and organizing stakeholder fora should be continued.

## 5. Brief reporting on the recent WG activities

### *WG 1 Materials*

Dr Sergio Moya introduced the goals of the WG1. WG1 provides a forum for discussion and coordination of characterization, definition, classification and grouping of nanoparticles and nanomaterials. Further, WG1 helps to identify what set of properties/metrics are needed for the proper description of nanomaterials and to define reference materials for nanosafety studies.

WG1 has contributed to two meetings in 2016, which are the 2nd NSC Synergy Workshop in Brussels and Joint NANOSOLUTIONS - NanoMILE workshop in Stockholm. As current activities WG1 will continue to review literature on ENPs to identify which physical chemistry properties are priority for risk assessment of ENPs, to compile the list of characterisation techniques that are under validation with the aim of being established as reference methods, and to promote discussion among the participants in the WG and with other WGs and within the larger scientific community on issues related to materials.

### *WG 2 Hazard identification*

Dr Flemming Cassee gave an overview of the WG 2 activities. He informed that collecting information and data via the WIKI has been discontinued. Also the collecting and sharing protocols via the SNC website has not been an easy task because of the lack of contributions from the members. A check list for doing in vitro studies has been generated and is available from the NSC website and the ones for ecotoxicology/marine biology are under development. The WG has contributed to NSC Self Evaluation which is awaiting publication and to the scientific programme of the Nanosafety Forum for Young Scientists in Visby. The WG has participated in the joined WG2 and Cost MODENA workshop held in May 2015 and contributes to a publication entitled Nanomaterials vs Ambient Ultrafine Particles: an Opportunity to Exchange Toxicology Knowledge. A peer reviewed publication will appear in Environmental Health Perspectives in October 2016. Other activities of WG2 include the updating the NSC Compendium and NSC website and contributing to a special issue of Toxicology and Applied Pharmacology entitled The First Decade of Nanotoxicology: Achievements, Disappointments and Lessons. In addition, facilitated by COST MODENA, WG2 members organized a workshop in May 2016 in Tallinn, Estonia about in vitro and in vivo particle dosimetry for nanomaterials, also in connection with US collaborators Dr Phil Demokritou from Harvard University and Dr Owen Price from ARA, North Carolina.

#### *WG3 Exposure*

Dr Claus Svendsen introduced the main objective of the WG3 which is to encourage sharing of project methods, techniques/results/data through various means and activities. During the last 12 months WG3 has actively participated in various workshops jointly organized by EU nano-projects. Other activities include a measurement campaign on release, exposure and dermal deposition and a related peer reviewed publication being written, and harmonisation of exposure data collection and sharing using NECID database as a shared structure to collate and share exposure data. A review of risk management measures (RMM) along the lifecycle of nano-enabled products has been done. A list of future initiatives was presented including many joint meetings, finalizing the above mentioned publication and contribution to CEN TC 137 WG3 standardization of methodology.

#### *WG4 Database*

Dr Egon Willighagen introduced the recent activities of the WG4, which include updating the overview of the database with caLIBRAte project. Linked data is one of the most important task of the WG and it concerns linked data between NSC resource, eNanoMapper, and third-party databases. WG4 is discussing a use case with the NECID project. The WG has monthly teleconferences, minutes of which are online on the WG webpages. The WG mailing list includes some 100 participants.

#### *WG5 Risk*

Dr Janeck J Scott-Fordsmand presented WG5 work plan 2016. The WG continues integrating and coordinating risk assessment across the EU and US through a phone meeting together with database/modelling CoR, and is preparing a workshop in 2016 leading to a common framework. Four major phone conferences are going to take place in 2016–17 in addition to regular phone meetings within the risk CoR and with other CoRs. The risk CoR chaired a workshop at the US-EU CoR meeting in June 2016 involving stakeholders and social scientists with the main focus on risk and risk communication. The future work of WG5 include further implementation of long term risk paradigm, integrating roadmap with new project outcome e.g. fate, effect, risk models and governance; and coordinating with CoR activities.

#### *WG6 Modelling*

Dr Robert Rallo gave a progress report on WG6. Coordination of ongoing initiatives includes internal coordination between other NSC WGs, specifically WG4, WG5 and WG8, between EU Projects and Cost Actions (e.g. MODENA) and with European Materials Modelling Council (EMMC). External coordination concerns US-EU CoRs. In order to foster dissemination and sustainability of research results, the WG prepares an inventory of models and tools, reference dataset and guidelines. A book on Computational Modelling has been published in 2016.

In the future the new leadership after the end of FP7 projects has to be considered. To align the NSC WGs with the US-EU CoR structure an integration of WG4 and WG6 has been

proposed. A preliminary document concerning materials modelling for toxicity has been published in collaboration with EMMC.

#### *WG7 Dissemination*

Dr Alex Rinkus gave a summary of the NSC Survey, which objective was to evaluate effectiveness of NSC dissemination activities. On the basis of the Survey it was concluded that NSC-members would like more internal dissemination activities to increase networking and information-sharing across the Cluster and with EC and targeted external dissemination that facilitates individual or face-to-face networking. The Malaga Conference will be a “test event” for a NanoSafety Cluster Conference which is planned to be held in 2018.

Future activities of WG7 include the implementation of the Survey results. WG7 subgroup Training is promoting participation in upcoming training events and focusing on PhD students and young scientists. Subgroup Standardisation is available for implementation of the nanoSTAIR approach to identify and orientate possible New Work Item Proposals (NWIPs) and clustering initiatives around selected SOPs. Upcoming activities include developing guidance for bringing results to standardization and improving information on the website.

#### *WG8 Systems Biology*

Dr Bengt Fadeel described recent and forthcoming contributions of the WG to various meetings, such as Conference on Systems Biology in Nanosafety Research in November 2015, Joint NANOSOLUTIONS and NanoMILE Workshop in September 2016; NanoTOX 2016 Congress in June 2016; Modelling and Systems Biology session at the 2<sup>nd</sup> Nanosafety Forum for Young Scientists in September 2016, and IUTOX Congress in October 2016.

The workplan includes standardization activities aiming at good working practices in systems biology in nanosafety research and sharing and promoting the use of consistent protocols for omics studies through collection of SOPs. WG8 members will also contribute to the roadmap on nanobioinformatics.

#### *WG9 Safe by Design and Industrial Innovation*

Éva Valsami-Jones introduced the aims and objectives of the newly established WG9. As recent EU funded projects have a dedicated “safe by design” component, it has deemed important to facilitate discussion and integration of ideas, approaches and data from these projects. The focus areas of the WG are regulation and standardization, and industrial innovation.

The WG9 sub group Industrial Innovation Liaison (i2L) will serve as a cross linking body with the European Pilot Production Network. The recent activities of the i2L include collecting contact details of nanosafety-responsible persons in on-going projects and supporting feedback gathering for REACH review by a questionnaire. The comments for the REACH review will be provided to ECHA. Further activities include a meeting at the NanoSAFE





Conference in Grenoble and support of the upcoming Safe-by-Design Event to be organized in Bilbao in 2017.

#### **6. Next NSC meeting**

Next NSC meeting will be organized in Grenoble in connection with NanoSAFE16 Conference. The exact date and venue will be confirmed later and announced via the Community mailing list and Cluster website.

*The presentations of the meeting are available on the Cluster website*  
<http://www.nanosafetycluster.eu/nsc-meetings/nanosafety-cluster-meeting-stockholm-2016.html>

*The list of participants is available by request ([info@nanosafetycluster.eu](mailto:info@nanosafetycluster.eu)).*