Minutes
7.12.2016/AV

NANOSAFETY CLUSTER MEETING

Time: Wednesday 9 November 2016, 14.00–18.00
Venue: Maison MINATEC, Meeting Room Titane 2
Address: Parvis Louis Néel, 38054 Grenoble Cedex 9

Session 1: Upgrading of NSC activities
Chairs: Mr. Andreas Falk and Dr. Kai Savolainen

1. Welcome and opening remarks

The Coordinator of the NanoSafety Cluster, Dr. Kai Savolainen from FIOH and Dr. Jean-François Damlencourt from CEA/PNS, organizer of the Nanosafe16 Conference, welcomed the participants to the meeting.

2. Opening remarks on behalf of the EC and what EC expects from NSC

Dr. Georgios Katalagarianakis thanked Dr. Kai Savolainen for a marvellous job in coordinating the Cluster in times of frequent governmental cuts. The cluster of projects is important for sharing a common EC culture and policy and it has established an important continuity in the nanosafety science across the projects. It is important to continue and strengthen the current activities such as the website and the newsletter and to build up the more recent activities such as Safe-by-Design subgroup, and skills and training activities. Two options for the future direction of the NSC were presented: a transformation of the Cluster or launching a risk governance body and further, a more complex innovation governance body.

Dr. Katalagarianakis highlighted several Cluster actions, which should continue or be strengthened such as community building, research policy and roadmaps activities, cross projects cooperation, cooperation with CoRs and other international cooperation, integrating scientific research with regulatory research and close cooperation with regulatory authorities and agencies, such as ISO-CEN and OECD.

3. Invitation to present views how to develop the coordination of the NSC

How FIOH has coordinated NSC
Dr. Kai Savolainen described how the Finnish Institute of Occupational Health (FIOH) has coordinated NSC since March 2011. The agreement with the Commission was renewed in 2015 until the end of 2018. FIOH announced in September 2016 that it will finish the NSC coordination when the NANOSOLUTIONS project ends at the end of March 2017. Dr.

Savolainen considered to be important that the new coordinator of the NSC is also a coordinator, or a key partner, of a large EU funded nanosafety project.

FIOH has supported the NSC coordination by 0.3 – 0.5 annual person years drawn from the Institute's budget. The coordination has not included the shaping of the contents of the NSC work as FIOH has considered its role to be a coordinator, not a leader. The practical work has included planning and supporting NSC activities, organizing meetings with the local host and documentation of the meetings. FIOH, together with the NSC, has established a Steering Group, participated in the work of the WGs and CoRs, and taken responsibility of designated NSC projects like the production of the "Nanosafety in Europe 2015–2025" (SRA). In addition FIOH has been active in preparing of the merging of the SRA, RRR and CTTM roadmaps.

Ideas for developing NSC coordination

Mr. Andreas Falk gave a presentation on how to develop the coordination of the NSC. NSC is an independent platform to support and speed up the development of safety and enabling tools to bring forward nanotechnology to the market and to the benefit of the society. Its strengths are scientific expertise and connections with regulators. It should, however, strive more for cross project collaboration and academia-market connection. According to Mr. Falk's vision, NSC should continue to be an independent platform, providing science-based excellence. It will develop, update and disseminate strategic documents; enable interaction beyond the individual project results, towards identifying comparable tasks in projects and collaborating to create synergy. NSC will strive for bringing the academia and market actors closer together. The coordination of NSC could have a time limit of 5 years with a possibility to be extended with another 5 years. Industrial innovation liaison (I2L) subgroup of WG9 is a good example of connecting academia and the market based on the safety activities of the projects.

How to develop the coordination of the NSC

Dr. Flemming Cassee presented his views on how to develop the coordination of the NSC. The scope of the NSC would be to create a scientific basis to ensure the safe and responsible development of ENM, and to support the definition of regulatory measures and implementation of legislation in Europe. NSC focuses on a strong two-way communication with the stakeholders. Dr. Cassee considered that the progress of many activities is relatively slow due to the lack of funding and the interaction between WGs is virtually absent. For many members attending the Cluster meetings and participating in other Cluster activities are too expensive and time consuming. As improvements Dr. Cassee suggested better definition of specific tasks and reduction of the size of the tasks to more manageable and achievable in a shorter time frame. The tasks should focus on gathering information from existing and past projects to make cross project observations and comparisons. Larger activities should require funding. Awarding of the projects for their NSC activity by the DG RTD was suggested.

As the future aspects Dr. Cassee suggested discontinuing the WGs and establishing ad hoc task forces to address specific questions. CoR activity should continue. NSC could be led by a steering group with a rotating membership. Secretarial and organizational support and newsletter and website maintenance should have separate funding. Dr. Cassee's institute

RIVM is willing to lead the Cluster provided that there are a plan of action and funding in place.

It was commented from the audience that every EU nanosafety project has to allocate 2 % of its EU funding to NSC activities.

A vision for the NSC – governance and strategy

Dr. Iseult Lynch gave a presentation prepared together with Dr. Eva Valsami-Jones. She stressed the importance of stakeholder engagement in the Cluster meetings instead of the current business meetings, which could be organized virtually. Scrimmage model, which has successfully been used by some CoRs, could be introduced. The WGs should have more opportunities to work on specific tasks face-to-face. A new structure for NSC was introduced. The Steering Committee including WG Leaders, roadmap leaders and High Level Group (HLG) representative, would lead the Cluster and communicate with the EC.

Currently the WG activity relies essentially on voluntary contributions and individual enthusiasm. The 2 % allocation and individual project's contribution cannot be verified. The WGs and NSC website should better show the roles of the contributors in a transparent way.

Dr. Lynch introduced that University of Birmingham already has personnel in place for NSC coordination. Crucial for NSC development is an active and responsive Steering Committee, which works with Commission to establish task forces to address specific issues (e.g. roadmaps) and provide strategic guidance to WGs and project coordinators. Other key elements are close integration with HLG activities, platform for development of integrated response to ECHA and SCENIHR; clear guidance for projects how to contribute, greater transparency regarding the 2 % contribution, and up-to-date web platform.

NSC meetings should be developed to be more participatory, workshop-type encounters. In addition, a conference and stakeholder-specific events should be organized annually.

After the presentations the following points were discussed:

- A more effective use of face-to-face meetings to specific questions is important to develop the NSC activities. Meetings focusing on specific tasks would be most productive; e.g. standardization, research, etc.
- NSC meetings are currently not attended by industry, because relevant issues to them are not handled in the meetings. NSC needs proactive involvement from the people from individual projects, who have links to industry. NSC needs to learn a better dialogue with the industry.
- The lack of funding is effectively hindering the active working in the Cluster.
- Sharing of data is a big responsibility of the Cluster and has to be assured. Sustainability Task Force deals with the sustainability of the data resources.

Dr. Kai Savolainen summarized that three excellent, quite ambitious, visions have been presented on the future coordination of the NSC in addition to the excellent presentation by Dr. Katalagarianakis. Dr. Savolainen noted that the current Cluster is an informal group

of projects and organizations but even if informal, it has become visible around the world and internationally well known.

Dr. Savolainen suggested that the planning of the future coordination would be continued in the Steering Group meetings. He stressed that the Steering Group, however, is not the body which decides the future coordinator, but it can promote and facilitate the planning. The planning hopefully ends up in an unanimous agreement on the coordination so that a ballot is not needed.

4. Invitation to present views how to develop/restructure the NSC Working Groups

How to develop the work of WGs. A suggestion from WG3

Dr. Claus Svendsen presented the suggestion of the WG3. Currently there are 9 WGs working with similar objectives. Dr. Svendsen considered as one of the biggest challenge that the WGs do not have a meeting forum. There also is double work done between WGs and CoRs.

Dr. Svendsen proposed a new structure, in which one of the main tasks of the WGs would be the organization of scientific meetings, collaboration of researchers across EU projects and sharing of project methods, techniques and results. Data resource sustainability, stakeholder involvement and setting future research priorities, could be taken care of by task forces. The new structure of the NSC would consist of a Steering Group formed by coordinators of the current EU projects, WG Leaders and EC project officers. CoR activity would continue and the WGs could be aligned with the CoRs.

The operation of the US-EU Communities of Research (CoRs)

Dr. Mark Wiesner gave an introduction to the operation of the US-EU CoRs. There are 7 CoRs active with relatively small funding for operation. The coordinator of the activity is Ms Stacey Standridge, who now has a new boss, President-Elect Mr. Donald Trump. Dr Wiesner brought up that under current circumstances it is very difficult to predict the future of the US National Nanotechnology Coordination Office and the joint US-EU CoR activity. The current activities of the CoRs include annual meetings, phone/video conference meetings (in some groups), scrimmages and preparing joint publications. The level of activity varies a lot between the CoRs some of them being extremely active. There is surely overlapping work with the WGs but the US-EU communication and discussion created around the CoR activity is extremely important in spite of the lack of resources.

In the end of his presentation Dr. Wiesner listed the challenges the US-EU cooperation should address: tests for product safety, data platforms and ensuring scientific input into regulatory activities. Finding more resources would be essential. One idea would be to engage CoRs as writers of Call for Proposals.

How to align the work of CoRs and WGs

Dr. Kai Savolainen started with noticing that the development of WG's has been discussed for a long time because most of the WGs have not been very active. A shortage of

commitment has been due to the lack of human resources and designated funding. The question has been raised whether the WG topics should be aligned with the CoR topics to avoid overlapping work. As a basis for further discussion, Dr. Savolainen presented a scheme which compares the WGs and CoRs and shows their parallel topics and similarities.

5. **Merging of the Research Roadmap (SRA), Regulatory Research Roadmap (RRR) and Closer to the Market (CTTM) Roadmap; Next steps**

Dr. Kai Savolainen introduced the goals for the merging; the documents require updating, they will be aligned to prepare one brief stand-alone document, which provides a meaningful path from scientific discovery, through supporting regulations, to economically beneficial innovations and marketable products, in order to support the safety and responsible use of ENM and nanotechnologies at all stages of the process. Dr. Savolainen introduced briefly the three documents to be merged.

Dr. Savolainen concluded that a working group shall be established for compilation of the document. The work is estimated to be ready in spring 2017. The document will be circulated among the whole NSC before handing over to the Commission.

Session 2: Launch of the EC risk governance action
Chairs: Dr. Georgios Katalagarianakis and Dr. Jean-François Damlencourt

6. **Nanosafety research policy in the EU Nanosafety Cluster and risk governance**

Dr. Georgios Katalagarianakis, European Commission, introduced the EC risk governance action. The governance was defined as converting knowledge into choice and choice into action towards a goal. For governance it is essential to define a goal and to implement policies towards the goal with information, communication, planning and feedback, and progress monitoring actions.

As to the information actions, the first requirement is that the agents collect their own information, convey the existing information to all other agents, and inform about their current work and what may be expected next. Several projects and organizations address this issue well but the common action is weak. There are problems as to data quality, data collection storage and curation. As to the communication actions, the agents must give the information out in a form, which is comprehensible at different levels, e.g. authorities, stakeholders, civil society and public. Open access and open data policy for this has already been established and open access publication is compulsory, while open data access is still in a pilot phase.

The principle in planning and feedback is that the governance structure seeks to parallel the addressed paradigm to similar well studied paradigms of the past, and to anticipate or speculate on the future. The policy and roadmaps exist or are in progress but many other

forms of implementation are still weak. There is a gap between scientific and regulatory level.

Progress monitoring means continuous follow-up, critical review of field operations and conditions, goal review, re-scheduling and revision of planning. Progress monitoring is the most difficult but also the most crucial part of the governance. It requires marked competences, skills and team work.

Dr. Katalagarianakis suggested that the Cluster would now start a transformation phase to the direction of risk governance, and from that proceed to innovation governance.

Dr. Danail Hristozov informed the audience about Society for Risk Analysis – NSC round table initiative, which started two years ago. Four workshops/round tables have been organized so far, first in Singapore, two in the USA and one in Venice. The aim of the activity is to prepare a roadmap white paper and a peer-reviewed journal article. Dr. Hristozov also informed about the SRA Policy Forum: Risk Governance for Key Enabling Technologies, to be held in Venice on 1-3 March 2017.

The following points were brought up during discussion:

- There are also threats involved in open access in the form others taking advantage from others work.
- Closer collaboration with the industry is needed and this can be started with a small group to see the challenges and resources needed.
- There are different layers; first, there is a need to develop and restructure NSC activities and develop risk governance; the innovation governance is a third layer, which brings the activity closer to the market.

It was also suggested that the governance issue could be dealt with by a task force activity. Dr. Eva Valsami-Jones, Dr. Kai Savolainen and Dr. Keld Alstrup Jensen expressed their willingness to join this kind of activity, if established. Reaching the regulators was mentioned as an important aspect of the activity. Dr. Katalagarianakis brought up that a scope and the partnership have been agreed; the schedule could be discussed in a future NSC Meeting. One option for this would be in connection with the SRA Policy Forum in Venice. Dr. Katalagarianakis suggested that Dr Keld Alstrup Jensen would be the first contact person and Dr. Eva Valsami-Jones another contact person for further planning.

It was agreed that a NSC Meeting on the topic of risk governance will be organized in Venice on 1.3.2017.

Dr. Barry Harry brought up that the WG4, Database WG, would prefer not to be integrated with WG6 Modelling and WG 8 Systems biology, but is very willing to continue close interaction with other WGs.

It was agreed that Dr. Eva Valsami-Jones and Dr. Flemming Cassee will lead the further planning of the future coordination of NSC. A plan will be presented at the next NSC Meeting

to be organized in Malaga. Dr. Katalagarianakis pointed out that the plan should include risk governance.

7. Any other business

Dr. Georgios Kalatagarianakis informed that an agreement has been made with South-Africa concerning nanosafety and a mission is going to be organized to South Africa during 2017 to identify the possibilities for cooperation in nanosafety. The maximum size of the delegation is 10 persons.

It was agreed that those who like to participate in the mission shall contact Dr. Keld Alstrup Jensen (kaj@arbejdsmiljoforskning.dk).

8. Next meetings and upcoming events

- Industrial Workshop on Safe-by-Design (SbD), 24–25 April 2017 in Bilbao, Spain. The workshop is organized by the H2020 projects NANOGENTOOLS, NanoReg 2, caLIBRAte, EC4SafeNano, NanoFase and NanoMILE. The aim of the workshop is to disseminate the knowledge on SbD to companies, promote the acceptance and uptake of SbD by them and also allow the H2020 projects to learn more about industrial stakeholder needs. A flyer of the event will be distributed soon. Further information: Dr Sean Kelly, NIA.
- A CoR meeting in Birmingham on 5–9 September 2017. Further information: Dr Iseult Lynch, UoB.
- The next NSC Meeting will be organized in Malaga in the context of the Joint Conference 2017, 7–9 February 2017, with the topic of choosing/appointing a new coordinator. The exact date and time is to be agreed.
- The following NSC Meeting after Malaga will be organized in Venice on 1 March 2017 with the topic of risk governance.

9. Closing of the Meeting

The Coordinator, Dr. Kai Savolainen thanked everybody for an active participation and closed the Meeting at 18.00.

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

The list of participants is available by request (info@nanosafetycluster.eu).