Minutes
20.3.2017/AV

EU NANOSAFETY CLUSTER MEETING
Task Force Meeting for establishment of an EC Risk Governance of Nanotechnologies

Time: Wednesday 1 March 2017, 10.30–15.30
Venue: Aula Magna Silvio Trentin, Ca'Foscari University of Venice, Venice, Italy

1. Welcome and introduction to the NSC workshop

Dr. Danail Hristozov, University of Venice and Dr. Keld Alstrup Jensen, National Research Centre for the Working Environment, Chair of the Workshop, welcomed the participants to the Task Force Meeting for establishment of an EC Risk Governance of Nanotechnologies. Dr. Jensen introduced the agenda and thanked the local organizers and the Finnish Institute of Occupational Health as Coordinator of the Cluster for supporting the organizing of the Workshop.

Session 1. Thought starters

2. Explanation of the needs of the EC action on nano-risk governance

Dr. Georgios Katalagarianakis, European Commission, described the status of the EC risk governance action and the preparations of the next H2020 work programme. Dr. Katalagarianakis informed that there will be four topics in the H2020 NMBP work programme 2018–20 related to governance, science-based risk assessment and regulatory aspects, and risk governance is one of them. International cooperation will be strengthened involving a close EU-US relationship with exploring the possibility of parallel calls.

Dr. Katalagarianakis brought up that engaging the civil society is the key challenge on the way to the governance of engineered nanomaterials, or anything else to that matter. Other challenges are improving the communication and listening to the needs of the market players. Dr. Katalagarianakis further discussed how governance has been defined in the past - stressing that governance is, above all, making choices for actions with a principle of precaution based on past experience and estimation of expected impact. The governance means, first, defining a goal or goals, then implementing policies towards the goal and taking action on information, communication, planning and feedback, and monitoring of the progress. Dr. Katalagarianakis pointed out that even if we will start with risk governance, the real target is the innovation governance.

Dr. Katalagarianakis presented the draft call text in the forthcoming H2020 work programme 2018–20 concerning *risk governance of nanotechnology*. A number of actions are proposed including the development of governance framework tools and the establishment of a sustained risk governance body.

3. **The Society for Risk Analysis – NanoSafety Cluster Round-table initiative on Risk Governance of Nanotechnologies, SRANSC^{RT}**

   Dr. Danail Hristozov introduced the Society for Risk Analysis (SRA) – NanoSafety Cluster Round-table initiative on Risk Governance of Nanotechnologies. The SRA is a multi-disciplinary international society open for all interested in risk analysis. It concerns risk analysis: risk assessment, communication, perception, management and policy. The background of the SRA are the various NanoSafety Cluster projects and the framework of the International Risk Governance Council and it offers an open platform for exchange of ideas and collaboration with regulators, insurance sector and industry.

   The Round Table Initiative was launched in July 2015 in SRA World Congress in Singapore. The objectives of the SRANSC^{RT} are to advance the nanotechnology risk science and policy through a dialogue addressing the gaps and pressing needs of data and tools. The end products of the activity are a white paper on risk perception, communication and governance of nanotechnologies, the SRA Conference in Venice on 1–3 March 2017 and publications. SRANSC^{RT} has organized webinars, round table events and workshops. The round table events have been organized in Singapore, in the USA and in Europe.

4. **The Society for Risk Analysis – NanoSafety Cluster white paper: Understanding tools to drive prevention-based risk governance of nanotechnologies**

   Dr. Igor Linkov, US Army Corps of Engineers and Dr. Benjamin Trump, Oak Ridge Institute for Science and Education, presented the views behind the SRANSC white paper. Dr. Trump started by describing briefly the change of risk perceptions from the 1970s to 2000s; with the need to move from quantifying risks and their mathematical expression to a wider, more holistic perspective.

   The SRANSC white paper was commissioned in July 2015 with the aim to move into the direction of risk governance. The white paper tends to focus in six most frequently used tool groups through literature analyses. The tool groups are: cost-benefit analysis, hazard/exposure assessment, life-cycle assessment, adaptive management, control banding and decision analysis. Strategies and methods are used to guide governance building.

   Dr. Trump described that the tool groups can be divided to two general frameworks: traditional, risk-based, and approaches centered on comparison. The literature analysis results show the domination of the traditional framework. According to the six tool groups, the traditional framework appears to dominate.

   Dr. Linkov continued the presentation by defining the governance and pointing out that tools are needed, but using of tools does not necessarily lead to good governance. There is also a need to consider non-risk considerations of cost, societal benefit, ethics, implications, etc. Dr. Linkov brought up the risk governance framework divided to risk based governance

and prevention based governance. He noted that the future EU projects have to decide how to address the risk governance. Dr. Trump and Dr. Linkov concluded that risk governance is a complex effort where more is needed than traditional tools to facilitate nanosafety governance.

5. Risk transfer for nanotechnology risk governance

Dr. Martin Mullins, University of Limerick, discussed how nanotechnology is approached from the insurance point of view. He noted that there are several communication challenges between different stakeholders, for example the concept of risk is defined differently by the scientists and the insurance side. Dr. Mullins added that the scientific community and the risk acceptance community should better understand what types of criteria are needed for insurance contracts and which the threats are in the insurance industry. The meaning of risk to the SME sector is important to be addressed, as well.

Dr. Mullins cited some perceptions of a few big insurance companies revealing that as concerns the new risks and especially nanotechnology, the biggest challenge in the insurance industry is the lack of data. According to the insurance companies it is difficult to find trusted sources to back their decision making**.**

Dr. Mullins pointed out that one aspect to be addressed is the perceptions of the courts e.g. concerning the concepts used. The logic of the legal systems should be understood by the scientific community. The connection between insurance industry and the regulators should be addressed as well.

6. A risk governance framework for current and future nanotechnologies

Dr. Vicki Stone highlighted the essential elements of governance in nanotechnologies. A governance framework structures the situation and the options available to a person who is e.g. entitled to make a decision, who is responsible, who is liable, etc. Different tools are required within the framework to help people to make right decisions.

Dr. Stone illustrated the framework with a diagram containing three parts: tools for risk management, regulatory framework and governance framework. She pointed out that the user has to be taken as a starting point; whether it is a SME, a major industrial corporation or something between. It has to be considered, what is the “audience” and their level of understanding; what their needs are; and whether they are concerned by their workforce or by the consumers of their products. The users’ needs, risk banding, risk mitigation and risk transfer are integrated in the decision support system (DSS).

The DSS and tools function within the context of regulatory framework consisting of different types of laws; public/regulatory, private, soft (e.g. OECD guidelines) and criminal laws.

Risk perception, how people see risks, is a key issue. In this connection also the influence of the mass media is important to be taken into account and how and on what basis or knowledge the media communicate risk to our target groups. The acceptance of the risks in the society depends also on the type of the product (medicine vs. cosmetics, for example).

Dr. Stone concluded that the model of likely human behaviour and decision making in individual, organisational, national and international level influence how the framework is used and interpreted. The governance framework systematically facilitate and incentivise good practice for different stakeholders.

It was queried from the audience what is the role of standardization in this context. It was concluded that everything done in standardization should be taken into account as well as existing regulations and guidelines in nanotechnology. They influence the regulatory framework.

Session 2. NanoSafety Cluster Task Force on Risk Governance of Nanotechnologies

Dr. Keld Alstrup Jensen introduced the topic of the afternoon session, i.e. the discussion on the understanding of risk governance and it elements. Presentations held in the morning session illustrate the situation at the moment. Dr. Jensen continued that the job for our task force is to define the key elements of the risk governance framework (RGF) and prepare a document with advice for the EC by the end of 2017.

To set the starting point, K.A. Jensen briefly presented the idea of the Systems-of-Systems Cooper-like stage-gate risk innovation governance framework for nanomaterials, which is currently under development in the H2020 caLIBRAte project. He discussed that there are many similarities and links to the risk governance framework presented by Dr. Vicki Stone earlier in the day.

Dr. Mullins pointed out that there exist different governance concepts and frameworks and their emphasis has changed in time. It should be defined what are the conditions, including conditions related to the mentalities, and the management tools to allow the governance to be implemented. The tools still are mainly of technical nature. It would be important to include practices and social, economic and political issues in the framework.

Dr. Katalagarianakis brought up that while science should remain one of the backbones of the governance, it is not enough. With the scientific tools we should be able to predict and speculate the future and be flexible in correcting and changing the tools and actions on the basis of constant evaluations even if the goal remains the same.

Dr. Stone requested whether multiple frameworks tailored to the needs of different stakeholders should be created. She pointed out that this would, however, be time consuming and costly.

Dr. Jensen mentioned that this focus on the stakeholder perspectives is also considered in the caLIBRAte project. In the caLIBRAte approach, four broad stakeholder sectors are defined: Industry, Consumers/NGOs, Insurance, and Regulators/administrators. These groups are then stratified and may require different tools and approaches depending on at which level you are in these stakeholder sectors. However, it is clear that caLIBRAte will not be able to conclude this work. We are starting the next generation governance. It was

discussed that the stakeholder groups should also include Service Providers (ourselves) as we support all stakeholder sectors.

Furthermore, the following points were highlighted in the discussions:

- Do we need target specific RGFs? Different end-users and sectors need governance.
- The psychological side has to be taken into account; how to measure emotions and how to handle the results. We have methods and tools for that, e.g. surveys.
- A risk governance body needs a framework with phases, functions and cycles; the body has to be able to continuous assessments. This requires capacity and relevant networks. Research on risks are needed.
- Value-associated issues should be taken into account. The governance is a value-driven activity; how to provide possibilities for innovations without compromising issues related to health.
- Who is going to govern on behalf of whom - the RGF should be designed according to that.
- The governance should be extended to monitor already very early phase of the innovation chain to identify where the risks emerge. Gathering feedback is important.
- Who is the receiver of the governance information; whom we need to convince?
- The RGF includes several options; the decision making process of an individual, safety-by-design, regulatory decisions and decisions on the products can be taken into account in different categories.
- The whole production chain has to be taken into account including the production itself and the product for end-users.
- A good governance includes also ethics. As to ethical culture, the SMEs are one of the most challenging targets.
- Globalization should be addressed; the scope can not only be what is produced in our own countries when the safety-by-design and risks of nanomaterials are considered. However, not even EU member states are consistent, there is a big variation of models and schemes in EU countries.
- Governance can have different actions according to different stakeholder, industry, regulators, insurance, customers, etc. We also need to take into account the service providers to the industry.
- We need to increase trust and reliability. We need to address source reliability e.g. in the web; distinguishing real risk and fake/phantom risk. In the insurance sector the decision making is extremely quick. It needs a mechanism, which is simple and quick to adopt. One solution could be a trustworthy network they can consult.
- Training and education should be a part of the governance.
- As concerns the regulators, are there other regulators than those described in the diagram; regulators of devices like electronic devises, for example? Who's governing that?

Dr. Jensen concluded that according to the discussions the RGFs presented can be used as a backbone for the document to be produced.

Dr. Katalagarianakis summarised that the EC is going to publish the work programme topic in the end of this year and spend about 10 million euros to fund the activity next year in order to create a sustainable risk governance body with a risk governance framework.

It was agreed that the draft call text will be circulated among the Meeting participants for comments. The deadline for the comments was set on 3.3.2017.

Dr. Linkov brought up strengthening the collaboration with the International Risk Governance Council (IRGC), which currently acts at the University of Lausanne in Switzerland (https://www.irgc.org/). The Council has made good success in risk governance and has a very strong scientific board of leading scientists in the field. Dr. Katalagarianakis pointed out that we need fresh and future oriented thinking in the complex field of nanosafety, where there are five distinct regulatory fields coping with great challenges.

Dr. Vicki Stone brought up that those delivering the RGF and networking effectively are not necessarily the same people who develop the framework. They could be consultants or government regulatory experts. Dr. Katalagarianakis added that we have to have an operative system able to act quickly when needed.

Dr. Jensen concluded that the nature of the risk governance body will be further discussed after the RGF has first been planned further. He reminded also that the H2020 call text shall be considered a priority at the moment.

Dr. Jensen also pointed out that due to the many participants, he found it not suitable to discuss the agenda point on the draft work plan of the Task Force in this Meeting. Dr. Jensen suggested that the speakers of the Meeting would form a core group for further Task Force activities. Those willing to join the TF were requested to contact Dr. Jensen by email. The suggestion was accepted.

It was informed that Dr. Iseult Lynch from the University of Birmingham, the forthcoming coordinating organization of the NSC, will be the operative secretary for the time being; after the coordination of the Finnish Institute of Occupational Health ends in March 2017.

Dr. Jensen thanked the participants for fruitful discussion and wished everyone a good Conference in Venice in the coming days.

The Meeting was finished at 15.30.