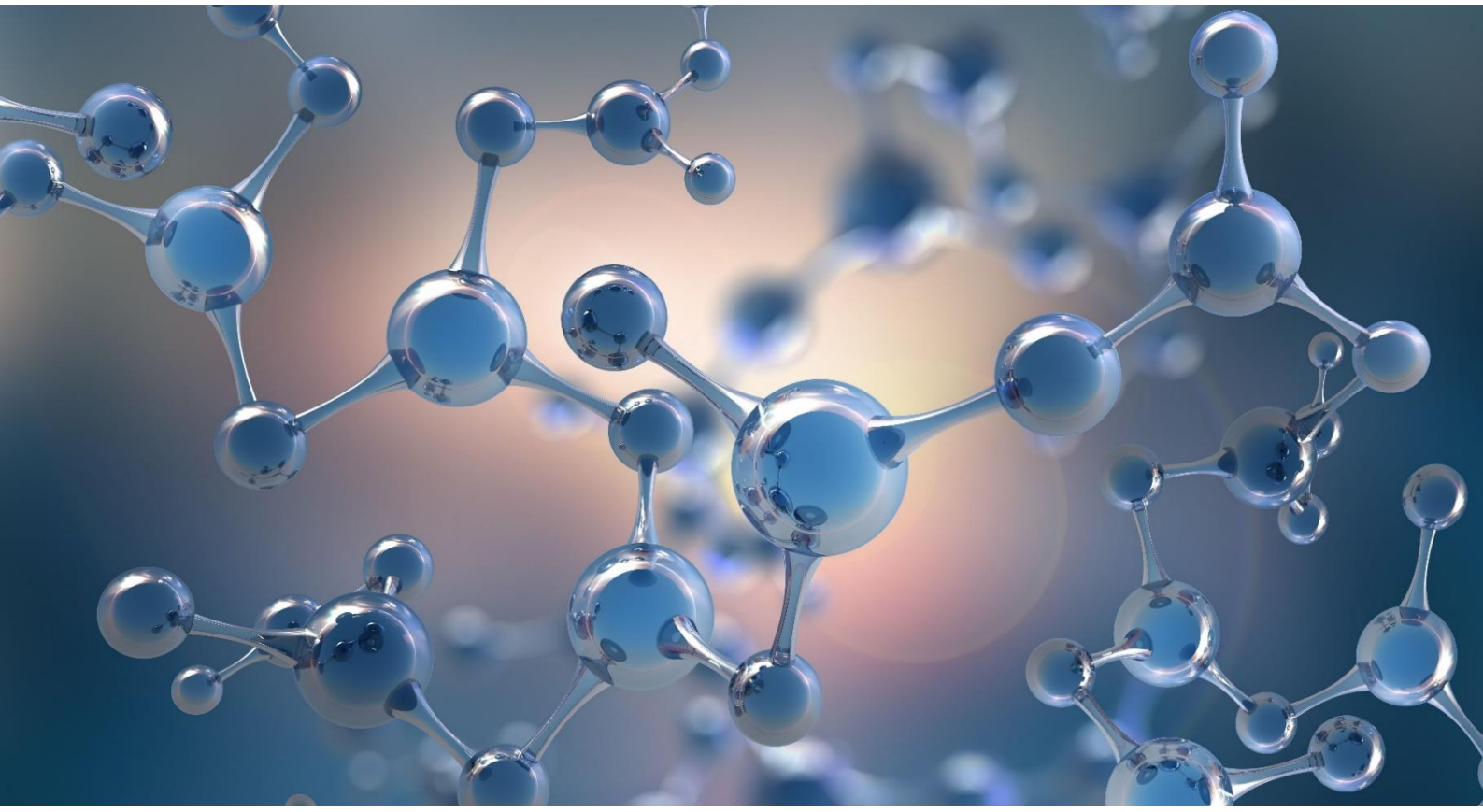
International Conference
How the world deals with materials on the nanoscale
22 and 23 June 2023 in Berlin

Conference report



Federal Ministry
for the Environment, Nature Conservation,
Nuclear Safety and Consumer Protection

in cooperation with

OECD
BETTER POLICIES FOR BETTER LIVES

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1 Conference opening

1.1 Welcome by the Federal Ministry of the Environment from the State Secretary Christiane Rohleder

Dear Mr Röttgen, Mr Machnig, Mr Lahl, Mr Diderich, Mr Dröll, Ladies and Gentlemen,

We are meeting here today at this international conference to mark the end of the German government's NanoDialogue. I am pleased that we are able to co-host the conference together with the OECD.

The driving force behind our ministry is and always has been to ensure the safety of people and the environment. This is why we also launched the NanoDialogue in 2006 in an effort to find a responsible way forward with nanotechnologies and nanomaterials, which were new at the time.

This remains a priority for me as nanomaterials have long since conquered the international market. Which is also the centrepiece of our conference – how do we deal globally with innovative materials that are so tiny, minuscule in fact?

The first day of the conference will feature best practice examples for governance. The German government's NanoDialogue, which many of you participated in, is one such example. Specific areas of application will then be covered on the second day.

I would like to take this opportunity to thank all the speakers for making the journey to Berlin. It is very important to me that we engage in dialogue internationally.

In a moment, we will reflect together on the German government's NanoDialogue, which was spearheaded by the Federal Environment Ministry. My predecessors were as proud of this initiative as I am. And I would like to tell you why.

For 16 years now, we have been organising in-depth exchange among stakeholders in the NanoDialogue to arrive at a common understanding of the opportunities and risks of nanotechnologies and their various applications. Since 2006, more than 300 people from non-governmental organisations, the scientific community, industry and public authorities have made voluntary contributions to this globally unique stakeholder dialogue.

I would like to express my sincere thanks to everyone who has contributed to these efforts.

Guided by the precautionary principle, this dialogue fostered a culture of innovation that focused on the responsible use of nanomaterials. Opportunities and potential risks were always viewed in tandem, thereby creating a platform for an objective exchange of views. We have learned a lot from this approach.

The international conference organised in cooperation with the OECD marks the conclusion of the NanoDialogue. But our ministry will of course continue to engage in scientific and socio-political dialogue on this issue. Let's take a brief look back together.

In 2006, when nanotechnologies were still quite new, the NanoKommission was convened to support their development with candid and fair discussions. At the time, there were many concerns and fears among the general public, but relatively limited knowledge. Working with its various subgroups, the NanoKommission drew up recommendations for the German government. These were presented at a public conference in early 2011.

One key recommendation was for REACH, the European Chemicals Regulation, to be adapted for nanomaterials. This has been achieved with great dedication on Germany's part. Since 2020, the information requirements under REACH have also applied to nanomaterials.

The format was then changed to two-day expert dialogues where experts discussed specific issues or fields of application. The goal of the responsible use of nanomaterials was rigorously pursued from the very first dialogue session to the very last. This included always considering the opportunities and potential risks in parallel. It was one of the key factors in our success. "How can risks be identified and minimised while simultaneously taking advantage of opportunities?" This has always been a central question.

The answer is: we need intensive interchange and cooperation in science, research and industry so that nanoscale materials are designed, used and disposed of responsibly everywhere. This is necessary if we want to establish robust laws and sound risk management.

And we also need the right methods because all of us know: valid measurement and test methods are the only way we can document the various aspects required to ensure safety for people and the environment and achieve sustainability. Internationally standardised measurement and test methods are the only way we can create effective measures to ensure safety for people and the environment. And they are the only way we can put innovation and investments on firm footing.

For us in the Federal Environment Ministry, it is of course particularly important that these methods can also be used for regulatory purposes. This is why we are devoting a lot of attention to the OECD processes in particular, and ISO also plays an important role for us.

But back to the NanoDialogue.

I am convinced that the success of this dialogue has contributed to the general level of acceptance for nanotechnologies and nanomaterials in Germany. Through this dialogue, stakeholders did not talk past one another, but with one another. It has created a platform where opposing viewpoints can be fairly expressed and misunderstandings resolved. And it has helped to develop an understanding of the different perspectives and courses of action.

But you can take my word for it: it was by no means a foregone conclusion that this dialogue process would be successful. It was a struggle for everyone involved, as our views were sometimes quite at odds at the beginning.

That this special format could evolve was also due to our competent yet neutral style of moderation which did not push a specific agenda.

Proof that together we have done a lot of things right is the praise we have received from both the environmental and nature conservation organisation in Germany called BUND, and the German Chemical Industry Association.

I would therefore like to take this opportunity to thank Ms Reihlen, Mr Jepsen and the entire team at Ökopol, who have successfully tackled this challenge.

I firmly believe that the continued success of the NanoDialogue is based on discussions as equals, listening to each other and taking each other seriously, both in terms of the opportunities and the risks.

I am very interested to hear how you view the dialogue from a scientific perspective.

If you ask me personally, the NanoDialogue's culture of innovation fostered by the precautionary principle will continue to help raise the level of acceptance of nanotechnologies in many fields of application.

Because innovation never stops. The solutions to the challenges of our time also need new materials, many of which are now nanoscale. At the same time, we want to prevent harm to people and the environment caused by known or future materials. And with as little animal testing as possible. We are also committed to this by the United Nations Sustainable Development Goals and the European Commission's Chemicals Strategy for Sustainability.

EU legislation defines nanomaterials as between 1-100 nanometres. But of course we also pay close attention to those material innovations that use the entire nanoscale starting from 1-1000 nanometres. After all, as we all know, the questions and challenges don't stop at 100 nanometres. And reliable measurement and testing is necessary in all areas where innovative nanoscale materials give rise to questions. This is also a recurring theme in international discussions at the OECD and other standardisation bodies.

It is good for us to keep an eye on this issue together at international level. This is the only way for regulations to keep pace with innovation. And only with appropriate regulation can we create a safe environment for people and reliability for long-term investments.

This is another reason why it is important that the principle of Safe and Sustainable by Design (SSbD) be applied consistently. Here I would also like to thank the European Commission, which has prioritised this principle, and also the OECD for its Safer Innovation Approach. We have all also discussed these issues in the NanoDialogue.

Ladies and Gentlemen,

You know the diverse fields of application for nanomaterials better than I do: from microelectronics to the automotive industry, from the medical sector to water treatment and various building products, nanoscale materials have the potential to contribute to solving environmental and socio-political challenges.

Transparency and communication are essential for the acceptance of new technologies and for their safe and sustainable use. Several examples from very different fields of application will be presented and discussed today and tomorrow.

Even beyond this final conference, our dialogue will continue with conferences, workshops and, of course, through my ministry's active involvement in other nanomaterial events.

We will also continue to share ideas within the framework of the OECD Working Party on Manufactured Nanomaterials, a long-standing international network that I very much value. The OECD chemicals programme is unique and plays a major role in the safe management of chemicals internationally.

The European Commission's Green Deal with its chemicals strategy for sustainability and a toxic-free environment is immensely important for the protection of the environment and human health at European level. Here, too, our ministry will continue to lend its full support.

Along the way, we will encounter ever new innovative materials that raise the question of safety and sustainability. Here, the concept of Safe and Sustainable by Design will be key.

I wish all of these projects every success. We owe it to the environment, ourselves and our children.

Last but not least, I would like to thank all the people who made these two days possible. I am especially grateful for the unwavering voluntary commitment we have seen from so many of you!

Now I hope you have candid discussions in the spirit of the NanoDialogue and wish you a wonderful evening in the Basilica of the Bode Museum today.

1.2 Welcome by the OECD

Bob Diderich, Head of the Environment, Health and Safety Division in the OECD Environment Directorate, welcomed the participants. He pointed out that the German NanoDialogue had made an important contribution to the OECD's work on nanosafety by identifying challenges and possible solutions for discussion at the international level. He also emphasised that the international work on standards was a constant challenge and that cooperation should be continued as a high priority. He considered the conference a good opportunity to reflect on the work of the past and to prepare for new challenges.

2 The NanoDialogue of the Federal Government

In a short overview lecture, the contents and structure of the NanoDialogue of the German Federal Government were presented. Afterwards, the moderator reflected with various stakeholders from the total of six dialogue phases on the topics, challenges and successes of the NanoDialogue from 2006 to today (time travel). Afterwards, the stakeholders discussed the questions from the audience. Mary Gulumian from South Africa presented her view of the NanoDialogue and Bob Diderich (OECD) concluded the conference block with his observations from the NanoDialogue discussion.

2.1 Overview of the NanoDialogue

On the initiative of the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, the Federal Government launched the NanoDialogue in 2006 by convening the NanoCommission. Representatives of industry, civil society organisations, science, authorities and ministries worked together in the NanoCommission. The NanoCommission met in two phases over a total of four years and published two reports. The NanoCommission's working groups which dealt among others with the topics of risk assessment and regulation, also published reports on their work.

The NanoCommission discussed fundamental questions on assessing the opportunities and risks of the use of nanomaterials. This included dealing with uncertainties due to a lack of information as well as possibilities to establish standards for the safe use of nanomaterials through voluntary commitments. The NanoCommission formulated research priorities to close knowledge gaps. In later years, there was also an in-depth discussion on regulatory instruments for nanomaterials.

The discussion format of the NanoDialogue was changed from 2011 onwards so that the discussion took place in two-day ExpertDialogues. Each of the ExpertDialogues dealt with specific topics on the application of nanomaterials. The participants consisted of experts from the stakeholders on the respective topics. A total of 14 ExpertDialogues took place.

In the early ExpertDialogues, topics from the NanoCommission were discussed in more detail and concluded (instruments for risk assessment, product register, guiding principles for sustainable nanotechnologies). In the later ExpertDialogues, specific areas of application were discussed, e.g. the food, medical, construction and automotive sectors. The topics of the tow last ExpertDialogues were "advanced materials" and "active nanoscale materials", both innovative materials with new properties.

In the NanoDialogue, opportunities and risks of nanotechnologies were always discussed in parallel, which contributed significantly to a trusting and constructive discussion. The stakeholders were open to listening to each other, learning from each other and respecting the different perspectives on the topic. In total, more than 300 people from ministries, authorities, scientific institutions, industry and associations took part in the dialogue.

2.2 Time travel through the NanoDialogue with stakeholders

In 2005, Uwe Lahl, as Head of the Department of Immission Control and Health, Plant Safety and Transport, Chemical Safety at the Federal Environment Ministry, and Matthias Machnig, then State Secretary at the Environment Ministry, developed the idea of the NanoDialogue. The experiences from the introduction of genetic engineering were a central reason for this: Mr Lahl said that the debate on genetic engineering had divided society, among other things, because only the risks and not the opportunities of the technology were discussed. At the time, Mr Lahl and Mr Machnig considered nanotechnologies to be just as explosive. Both saw the use of the potential of nanotechnologies, e.g. to increase resource efficiency or their possible contributions to electromobility, as being in danger and started the dialogue to have a knowledge-based and precaution-oriented discussion.

When the NanoDialogue began, the topic of nanotechnologies was still new and stakeholder dialogues that offered space for open and protected discussion were not widespread. The Ministry of Environment promoted the dialogue with the sentence "We need a commission that looks at the gos and the no-gos of the technology. And in that sentence, we had both sides of the issue covered", Mr Lahl elaborated.

The NanoCommission was supposed to be composed of people from all interest groups to enable a broad exchange. As it was intended to ensure that the work was based on solid knowledge and particular importance was attached to the participation of the scientific community. Mr Lahl reported that it was difficult to convince the environmental and consumer protection organisations to participate, as they had initially been sceptical about the Commission and its goal of discussing opportunities and risks on an equal footing. The industry, on the other hand, had shown great interest in participating.

Mr Kayser, a member of the first and second work phase of the NanoCommission and Senior Vice President of BASF SE said: "It is essential for the industry to have some predictability of future developments. Participation in the NanoCommission was also intended as a learning process in order to better understand the expectations and wishes of the stakeholders and provide data and information that suit these needs." He said a key challenge had been to build trust, open up to discussion and create transparency about the opportunities and risks of nanotechnologies, given the lack of information at the time. In this context, Mr Kayser also highlighted the merits of Mr Wolf-Michael Catenhusen, who was the State Secretary in the Federal Ministry of Education and Research at the time and moderated the discussions of the NanoCommission.

In both dialogue phases of the NanoCommission transparency, benefits and risks, as well as how to deal with uncertainties and knowledge gaps about nanomaterials were discussed.

Mr Calliess, Professor of Public and European Law at the Free University of Berlin, described the task of the Commission as follows: "From a legal perspective, the task was to balance the responsibility of the authorities resulting from fundamental rights and the state objective of environmental protection, taking into account the precautionary principle, with the freedom of innovation. This is the only way to create the necessary trust in society."

Mr Röttgen, Federal Minister for the Environment at the time, saw this trust-building supported by the composition of the NanoCommission and the transparency about opportunities and risks. He said: "From a political point of view, it was obvious that the discussion needed to continue, and conclusions needed to be drawn, including whether legislation should be adapted to enable the opportunities of the technology and manage its risks." The Nano-Dialogue, he said, was a model for how objectivity and scientific knowledge could be brought into the political discussion.

Mr Calliess saw a central debate of the NanoCommission in understanding how to concretely apply the precautionary principle in the context of nanomaterials and which legal instrument was suitable for regulation. He said that although the EU chemicals regulation REACH was relevant, the discussion in the EU had not yet progressed to the point where adjustments could have been made for nanomaterials. Therefore, and due to the experience with asbestos, in the second work phase of the NanoCommission, the introduction of a nanoproduct register to ensure traceability of nanomaterials in products was discussed. Mr Röttgen emphasised that this could also have been a sensible measure to increase confidence in technological development, among other things because it would have made it possible to assign responsibility for risks to the actors.

Klaus-Michael Weltring, scientific director at the Nano-Bioanalytik-Zentrum Münster and managing director of the Gesellschaft für Bioanalytik Münster, explained that the mechanistic, cellular effect of nanomaterials in medicines was known due to the tests required for their approval. Therefore, uncertainties in the risk assessment of nanomaterials in medical applications had hardly been discussed in the NanoDialogue. However, the examination of the benefits of medicines was an interesting, additional assessment aspect that had not been considered in the discussion until then. In addition, the medical context had raised ethical questions for the NanoDialogue which, although not new in principle, had not yet been discussed for nanomaterials.

Kerstin Hund-Rinke, a scientist in the Department of Ecotoxicology at the Fraunhofer Institute for Molecular Biology and Applied Ecology, emphasised that the complexity of assessing risks of nanomaterials required interdisciplinary approaches and discussions. She described the process in the NanoDialogue as sometimes frustrating, especially in the early phases, due to the different use of language in the various disciplines: "I understood all the words that were said, but not always their meaning." However, over time the stakeholders learned a lot from each other and about each other, so that understanding became possible and very interesting conversations were held. In this way, more and more diverse and specific topics could be discussed in detail with the stakeholders in the ExpertDialogues.

Rolf Buschmann, an expert for technical environmental protection at the Bund für Umwelt und Naturschutz Deutschland (BUND), confirmed that participation in the NanoDialogue was controversial among NGOs, especially in the early phases. However, the initial mistrust had subsided over time and Mr Buschmann perceived the dialogue as a "win-win situation" for all participants. All stakeholders had jointly gained knowledge about the scientific and technical basis of nanomaterials in different applications as well as developed a common understanding of the precautionary principle. He also said: "The assessment of which risks can be tolerated must be communicated together with the benefits. In the NanoDialogue we did exactly that - examined the benefits and the risks, tried to find a balance and communicated this well."

The Federal States, which are responsible for the enforcement of the chemicals legislation in Germany, also took part in the NanoDialogue. The Federal States' work is coordinated by the Bund-Länder-Arbeitsgemeinschaft Chemikalien, a regular working group of the Federal States discussing enforcement issues of chemicals legislation (BLAC). Michael Cuno from the Ministry of Social Affairs, Health, Integration and Consumer Protection in Brandenburg and a member of the BLAC reported that the information about the NanoDialogue in the BLAC had contributed significantly to the opinion-forming about nanotechnologies in the federal states. In addition, the feedback from the BLAC in the NanoDialogue was a good opportunity to include questions on enforcement in the discussion.

Carolin Kranz, Head of the Nano Team at BASF at the beginning of the NanoDialogue and responsible for communication and political framework conditions, participated in the NanoDialogue from start to finish. As a manufacturer and user of nanomaterials, BASF never considered leaving the dialogue. Ms Kranz said: "The more we got involved in the dialogue, the more we were inspired by the dialogue and the experience of being able to create something together - not only the dialogue, but also other initiatives that were launched at that time". BASF had not only brought many years of experience with sustainability issues and dialogue, but also an attitude of listening and learning about stakeholder concerns.

Andrea Haase, Deputy Head of the Chemicals and Product Safety Department and Head of the Fibre and Nanotoxicology Division at the Federal Institute for Risk Assessment, represented all the higher federal authorities that participated in the NanoDialogue at the conference. She emphasised that the platform of the NanoDialogue could also be used by the authorities to maintain an open exchange among themselves and thus to jointly develop an understanding of the topic of nanomaterials. This was unique and very important also for the work in the OECD. In line with the progress of innovation, the focus would now be broadened from nanomaterials to advanced materials. The information and the comprehensive understanding of nanomaterials from the NanoDialogue would flow into this and be put to good use.

2.3 Questions and discussions on the NanoDialogue

After the time travel, Ms Haase, Mr Kayser, Mr Calliess, Mr Machnig and Mr Buschmann answered questions from the audience. The following aspects were discussed:

- In the NanoDialogue, stakeholders discussed various options for regulating nanomaterials. Although the REACH Regulation was supported by many as a regulatory instrument, it was obvious at the beginning of the dialogue that adaptations would take a long time[1]. Therefore, the stakeholders also discussed a separate "nano law".
- Legislation should not unnecessarily hinder innovation and the innovation principle should go hand in hand with the precautionary principle. This could be ensured, for example, via revision and/or sunset clauses in legislation, which could also lead to the withdrawal of existing provisions.
- The lack of data to assess potential risks from nanomaterials was a recurring theme throughout the NanoDialogue. Although many data gaps have since been closed, there are still uncertainties in the assessments. Therefore, data on nanomaterials and their uses must continue to be generated in order to verify their safety. However, there are always remaining uncertainties that need to be dealt with politically. Stakeholder dialogues have an important role to play here.

2.4 An international view of the German NanoDialogue

Mary Gulumian, Professor at Northwest University in South Africa, compared the German NanoDialogue with the parallel activities in South Africa. She described the NanoDialogue as a proactive response to the challenges posed by nanomaterials, in which the opportunities and risks were always discussed simultaneously. The cross-sectoral, interdisciplinary work had made structured results available to society and helped define research priorities.

Ms Gulumian reported that a strategy for the promotion of nano-research was adopted in South Africa in 2006. In addition, a nanotechnology platform had been established

[1] An adaptation of the REACH annexes to nanomaterials did not come into force until 2020.

to support safety research and risk assessment of nanomaterials in South Africa. These measures had significantly strengthened nano-research in South Africa. However, it had also become apparent that the commercialisation of nano-innovations was not working well, partly due to a lack of links between industry and universities and a lack of cooperation between stakeholders. The latter should now be remedied through greater stakeholder involvement, e.g. through workshops. Ms Gulumian reported that South Africa had particularly taken up the approach of cross-sectoral and interdisciplinary research as well as the high importance of stakeholder dialogue from the NanoDialogue.

2.5 Summary

Bob Diderich from the OECD summarised the time travel and discussions on the NanoDialogue: One of the initial dialogue goals - the avoidance of a societal divide - was achieved. Other successes were the involvement of a wide range of actors and the continuous, always parallel discussion of opportunities and risks of nanotechnologies and possible regulatory options. This enabled scientific findings to be used well in the sense of safe innovation.

Mr Diderich saw the central challenges of the dialogue in building trust and in finding a way to deal with uncertainties in the assessment of nanomaterials due to missing data. The Nano-Commission's approach of defining different levels of concern was a special feature that allowed prioritisation of the need for action. In the regulatory discussions, a balance was sought between the duty to protect humans and the environment and the right to innovation. The adaptation of REACH ultimately brought this discussion to an end.

Overall, he concluded that the NanoDialogue was a good example and model of how new issues can be addressed and how progress can be made even in the absence of complete data on risks.

3 Legal requirements for handling nanomaterials

In this session of the conference, regulatory approaches to the safe handling of nanomaterials from different regions and countries were presented and discussed.

3.1 Management of nanomaterials in EU law

Andrej Kobe, responsible for chemicals and nanomaterials in the EU Commission's Directorate General for the Environment, gave an overview of the history of European regulation of nanomaterials. Important milestones were the EU Strategy for Nanomaterials (2004), two regulatory reviews (2008 and 2012), the proposed definition for nanomaterials (2011), and the adaptation of product legislation and the REACH Regulation (2018) to nanomaterials. The results of the NanoDialogue have been incorporated into the European discussions.

Mr Kobe explained that nanomaterials were regulated in the EU like other chemicals. However, the respective laws had specific requirements, e.g. for risk assessment, authorisation (active substances), notification or labelling. A nano register does not exist. Instead, the European Nano Observatory (EUON) provides information on (the applications of) nanomaterials.

Mr Kobe summarised that the EU had good legislation on nanomaterials, but there are still some challenges to be addressed, including the definition of nanomaterials, risk assessment and testing methods.

3.2 Toxic Substances Control Act: New review of nanomaterials

Alexandria Stanton is a senior chemist for the Toxic Substances Control Act at the US Environmental Protection Agency (US EPA) and presented on the regulation of nanomaterials in the United States together with Jim Alwood, Head of Risk Management in the New Chemicals Division at the US EPA.

Ms Stanton explained that the Toxic Substances Control Act (TSCA) was central to the regulation of nanomaterials, but that there were other, product-related regulations. TSCA divides chemicals into "new substances" that are not listed in the TSCA registry and "existing substances" that are. Companies that want to manufacture or import “new substances” must first provide the US EPA with available information about the material, its properties, and its uses through a notification. "Existing" nanomaterials would not need to be notified.

The US EPA reviews this "pre-manufacture notification" within 90 days. If potential risks are identified, the US EPA imposes risk mitigation measures. Mr Alwood added that often information for a sufficient assessment was missing and that the EPA would have to request it.

Mr Alwood informed that the US EPA had received 86 notifications of nanomaterials in total. A large proportion of these being metals and metal oxides as well as carbon-based particles with production quantities of less than one tonne per year. Mr Alwood used a case study to show the difficulties in examining notifications. He concluded the presentation by saying that the regulation of nanomaterials was already challenging due to their unique and diverse properties. In addition, the regulatory field was growing due to new standards, test methods and research, including on advanced materials.

3.3 Legislation and policy framework in the context of nanomaterials for agriculture and food in India

Alok Adholeya, Professor at the Indian Council for Research on International, Economic Relations (CRIER) and at the organisation Triindia, explained the role and content of the "Guidelines for the Assessment of Nanobased Products for Agriculture and Food". These guidelines contain the requirements and methods for the risk assessment of nanomaterials, which are to be used by regulators to develop appropriate legislation. The scope of the guidelines includes pesticides, fertilisers and agrochemicals, but also processing aids for food processing or feed containing nanomaterials.

Mr Adholeya explained that data on the identity of the nanomaterial contained, its physical-chemical properties and its human and environmental toxicity were needed for the product assessment. Depending on the type of product or application, different information was needed. All test methods are based on the OECD guidelines and guidance documents.

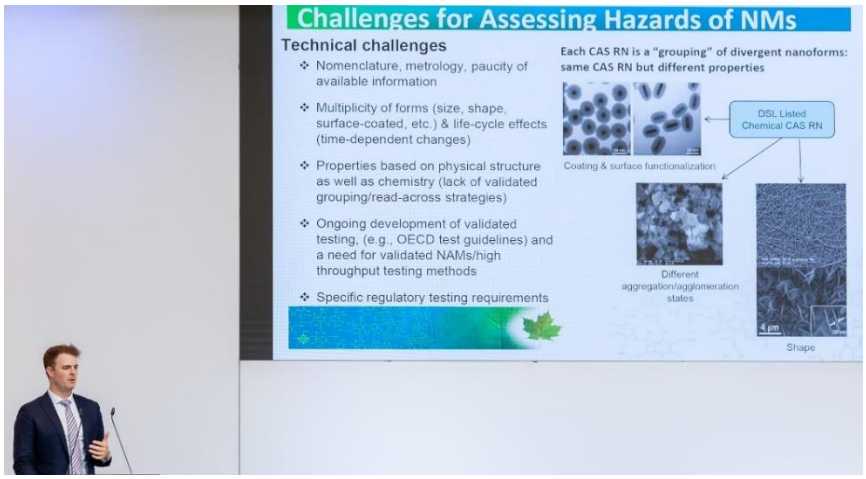
The guidelines are intended to support efficient translation of innovations into the market, Mr Adholeya explained. For the evaluation of products, different institutions have to cooperate and bring together expertise and experience in the fields of technology, economics, ethics, regulation and entrepreneurship. In this way, many products have already been developed for the Indian market and brought into use.

3.4 Challenges and "best practice" for risk assessment of nanomaterials in Canada

Djordje Vladisavljevic, Head of Nanotechnology at the Public Health Agency of Canada, presented the Canadian system for risk assessment of nanomaterials. In Canada, too, nanomaterials are divided into "existing" nanomaterials listed in the national register and "new" nanomaterials not yet listed. Companies placing "new" nanomaterials on the market are obliged to submit characterisation and risk assessment data to the authority, whereas this is not the case for "existing" ones.

Mr Vladisavljevic reported that Health Canada was assessing the risks of nanomaterials according to a guideline published in summer 2022. If potential risks were identified, Health Canada could impose requirements for risk reduction for a use. In total, about 150 "new" nanomaterials had been assessed so far and 53 "existing" ones had been prioritised for assessment. Health Canada had started with the assessment of zinc oxide and titanium dioxide.

Mr Vladisavljevic named the following challenges in the risk assessment of nanomaterials: lack of specific legal requirements, lack of data for "existing" nanomaterials especially on (eco-) toxicity, lack of validity of test results of one nanoform for other nanoforms, lack of knowledge about the mode of action of nanoparticles and uncertainties in exposure due to the increasing number of applications of nanomaterials. Intesive research would therefore still be necessary, especially for new test methods (New Approach Methods).



3.5 "Soft" regulation of risks in dealing with nanomaterials

Halila Faiza Zainal Abidin from the Ministry of Science, Technology and Innovation in Malaysia reported that her country had a large number of laws regulating chemicals. She criticised that this system lacked specifications for the structured collection and evaluation of information. In addition, the regulations overlapped and had gaps at the same time. There were no specific requirements or assessment tools for nanomaterials.

Ms. Zainal Abidin informed that in Malaysia, "hard" regulation allows for state action when there are hazards and risks, or a justified concern. This would be combined with "soft" approaches, especially with standards and norms developed in participatory processes. These are not binding and there are no sanctions for non-compliance. Ms Zainal Abidin added that there was also a national nanotechnology strategy and a nano-research programme, as well as a certification system for nanoproducts. These "soft" approaches would raise awareness of health risks posed by nanomaterials, build trust and promote innovation.

At the end of her presentation, Ms Zainal Abidin expressed the hope that communication on nanomaterials and data sharing between countries would improve.

3.6 Summary of the discussion

The speakers in this session reflected with conference participants on issues related to the assessment and management of risks from nanomaterials in the absence of data on their properties and applications. The audience affirmed that the lack of data hinders risk assessment and called for further research to fill the knowledge gaps. However, it was also questioned whether the authorities (can) make sufficient use of the existing studies at all.

Various aspects were mentioned as reasons for the lack of information:

- There is a (partial) lack of instruments to demand missing data from the industry.
- Not all actors work according to OECD methods, which is why test results are not comparable or cannot be used for regulatory purposes.
- Confidentiality requirements prevent the exchange of data.
- In the studies, nanomaterials are often not clearly identified and characterised. This also complicates the grouping of nanoforms.

The structured review of data on individual "new and existing" nanomaterials as part of the notification procedures in the EU, USA and Canada was seen by many as a good way of sifting through the current data situation. This would also include general information on the uses expected by those placing them on the market. Information on "existing" nanomaterials was also partly collected in surveys. However, the resulting knowledge about exposure patterns was very rough and subject to uncertainties.

On the part of the US EPA, it was noted that data uncertainties would be countered with restrictions on exposure. This would also be a motivation for the industry to generate new data. If data were available, the conditions for marketing would be adjusted if necessary.

It was also noted that the exchange between regulators in different countries and the comparison of assessment results for individual nanomaterials was helpful in questioning their own risk assessments. In addition, this would ensure that no safety aspects are overlooked overall.

The EU proposal of a definition of nanomaterials was questioned in the discussion. It would include materials in which the proportion of particles smaller than 100 nm is above 50 %. In Canada, however, the threshold would be 10 %. Mr Kobe explained that in the studies on reducing the percentage in the EU definition, hardly any effects on the range of materials covered had become apparent. In addition, there were no methods for precisely determining this percentage, which was why the definition is applied rather pragmatically and flexibly.

4 Governance of nanomaterials through supportive implementation measures and communication

In this session of the conference, it was presented how some actors support the implementation of legislation on nanomaterials through activities and projects.

4.1 Training, guidance and support for nanosafety implementation at global level

Georg Karlaganis, Senior Advisor at the United Nations Training Institute (UNITAR), presented activities at the global level in support of nanosafety that are jointly implemented by the UN and OECD.

Mr Karlaganis presented an e-learning course developed by UNITAR, the OECD and the US National Institute for Occupational Safety and Health (NIOSH) to provide basic knowledge on the safe handling of nanomaterials. The course could be used free of charge. He reported that eleven years ago, the International Conference on Chemicals Management (ICCM) had passed a resolution naming nanomaterials as an "emerging issue". UNITAR then launched pilot projects in various countries to help governments develop national strategies for dealing with nanotechnologies and implement appropriate measures. National meetings to raise awareness of nanotechnologies had been organised for more than eight years.

At the end of his presentation, Mr Karlaganis pointed out that the international work on nanomaterials should be continued and corresponding decisions should be taken at the upcoming World Chemicals Conference. This would also include questions of waste management within the framework of the Basel Convention.

4.2 Linking societal perspectives with business practice: concrete examples from France

Mathilde Detcheverry works for the environmental and consumer protection organisation AVICENN @VeilleNanos (France). She reported that AVICENN had tested various cosmetics, food, hygiene and health products as well as toys and paints for their content of nanoscale titanium dioxide, silica, iron oxide and silver. The product manufacturers were asked about the nanomaterials they contained, and samples were analysed in the laboratory.

Ms Detcheverry reported that nanomaterials had been found in 20 out of 23 products. Among other things, the detection of inhalable titanium dioxide in hairspray and of nanomaterials in food was a cause for concern. Some products were not correctly labelled, others contained unauthorised nanomaterials. Some product manufacturers had denied using nanomaterials despite laboratory evidence, while others had promised to remove products from the market.

Ms Detcheverry called for improving the level of knowledge about nanomaterials in authorities and companies and creating more transparency about nanomaterials in (concrete) products. She also called for better monitoring of the implementation of legal requirements.

In response to a question from the audience, Ms Detcheverry explained that although only a few laboratories could currently carry out such analyses, more laboratories would qualify for this in the future.

4.3 National strategy for the safe handling of nanomaterials in Sweden

Penny Nymark is an assistant professor at the Institute of Environmental Medicine, Karolinska Institute (Sweden). She presented experiences with the Swedish nanoplatform (SweNanoSafe), which was established as part of the implementation of the National Nano Strategy in 2016. The aim of the platform was to promote communication between different stakeholders, transfer knowledge and support national authorities in the safe handling of nanomaterials.

Ms Nymark named the "Council of Authorities" and its cooperation with a group of experts, which had been formed to ensure the quality of the council's work, as the greatest success of the platform. The communication between these two forums had been extraordinarily good and had led, among other things, to an alignment of the terminology of all participants. This had greatly facilitated the dialogue.

Ms Nymark informed about other activities in the framework of the national strategy/ nanoplatform, e.g. the publication of reports on the safe use of nanomaterials (many in English), workshops on various topics, e.g. on the concept of "Safe and Sustainable by Design", surveys to gather feedback on government activities from stakeholders and a national exchange forum. She reported that the dialogue between national authorities was seen as particularly valuable as it had not existed before. Feedback from the scientific community was that the programme, with its many opportunities and incentives, had significantly increased the contribution of science to the dialogue.

5 Evening event

On the evening of the first day, the conference participants had the opportunity to build contacts and network in a relaxed atmosphere in the Basilica of the Bodemuseum. The shared cultural experience brought together new interlocutors and thus laid the foundation for international contacts beyond the NanoDialogue. Mr Parzinger, President of the Prussian Cultural Heritage Foundation, received the group with a welcome speech and introduced the history of the building and the Foundation.

Mr Vorwerk, Deputy Director-General Chemical Safety, Environment and Health at the Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection, also welcomed the guests with a short speech in which he summarised some key points from the presentations and the discussions at the conference.

6 Standardisation of test methods

The second conference day began with presentations and discussions on the standardisation of test methods. The importance of test methods for the generation of new data and the safe handling of nanomaterials had already been frequently addressed on the first conference day.

6.1 The OECD's work on "safe and sustainable innovation" in nanomaterials

Mar Gonzalez, coordinator of the OECD Working Party on Manufactured Nanomaterials (WPMN), reported that the working group had benefited greatly from the German NanoDialogue. The WPMN began its work on adapting test methods to the specifics of nanomaterials in 2006.

Ms Gonzalez emphasised the importance of test methods, which, in conjunction with the OECD principle of mutual recognition of data, are the basis for reliable, harmonised and globally recognised information. She explained that various stakeholders from around the world cooperated in the development of the methods. The Nanosafety Cluster and other research projects had greatly accelerated the adaptation of test methods. The experience gained with nanomaterials would now be transferred to "advanced materials". The draft of a strategic approach for dealing with these materials should be published in autumn 2023. Case studies would also be planned to test its applicability. In parallel, an approach entitled "Safe and Sustainable Innovation" was being developed. Ms Gonzalez mentioned Integrated Assessment Approaches (IATA) and Novel Methods of Testing (NAMs) as other future topics.

In her conclusion, Ms Gonzalez underlined that cooperation to develop and adapt test methods remains central and requires funding. This would include validation in ring trials.

6.2 The Malta Initiative - OECD Test Methods for Nanomaterials

Thomas Kuhlbusch, Head of the Department of Hazardous Substances at the Federal Institute for Occupational Safety and Health (Germany), presented the Malta Initiative[2]. It was launched in 2017 with the aim of raising awareness that the OECD test methods for the assessment of nanomaterials needed to be adapted or newly developed so that regulation could keep pace

[2] Malta Initiative

with innovation. It was important to take into account the legal requirements from all regions of the world so that the methods would be adopted in legislation.

Three research projects funded by the EU Commission[3] and many industry projects had fed their results into the work. Mr Kuhlbusch presented that two other projects[4] were dedicated to OECD documentation standards. The OECD principle of mutual recognition of data was an important basis and strong motivation for all participants to work on the revision of test methods. Since 2017, 14 test methods had been revised; 13 projects were still ongoing. Based on the experience of this work, Mr Kuhlbusch recommended paying more attention to communication, speed of processes and accessibility and compatibility of data when adapting or developing test methods.

Mr Kuhlbusch reported that the Malta Initiative's position paper called for a European test method strategy that would, among other things, secure funding for the development and validation of test methods.

6.3 NanoMesureFrance: Entry point for reliable data for the French nanotechnology industry

Georges Favre, Director of the French Metrology Institute and Test Laboratory (LNE), and Francois Xavier Ouf, Research and Development Coordinator of NanoMesureFrance, reported on the NanoMesureFrance initiative. This should generate reliable and comparable test data,

[3] NanoRigo, RiskGone und Gov4Nano
[4] Nanomet und NanoHarmony

promote communication and the exchange of information between the actors as well as cooperation. The LNE would be well suited for coordination due to its neutral position towards the stakeholders. NanoMesureFrance started in 2022 with the creation of an association to implement the activities.

Mr Favre and Mr Ouf reported that the first activities of NanoMesureFrance would be to survey the need for (support for the application of) methods to characterise and test the properties of nanomaterials.

The results of the surveys would be discussed in a workshop in the next step. In addition, an interface would be created between industry and authorities to the OECD standardisation activities. NanoMesureFrance would act as an "independent third party" and aim to become the sole entry point in France for the harmonisation, validation, standardisation and dissemination of methods and the accreditation of laboratories.

6.4 Discussion

The session was concluded by an intense discussion about the standardisation of test methods. In response to the question of how the development or adaptation of test methods could be accelerated, various aspects were highlighted:

- The development time of test methods has already been significantly reduced. Some methods could be revised within three years, partly because knowledge of OECD procedures has improved.
- The revision of the guidelines does not require validation, so they can be completed more quickly.
- The work, including the processes preceding standardisation, must be prioritised and well planned. In addition, sufficient time for discussions and funding must be considered in the planning.
- The development time of a test method also depends on the interest of the organisation leading the process.
- There will be an increasing demand for "new approach methods". In the future, completely new methods will have to be developed and validated (again).
- Although the procedure for validating test methods has been improved, there is still potential for optimisation.

In the discussion, it was noted that authorities should (be able to) only use data generated according to OECD methods. This was contradicted by the argument that the entire state of knowledge, also from non-standardised studies, could be taken into account in the regulatory risk assessment. Study results that were carried out according to the rules of "Good Laboratory Practice" (GLP) and OECD test methods would already be weighted more heavily than other information.

On the one hand, it was noted that science is essential for the standardisation and validation of test methods. On the other hand, basic research should not be neglected, as it can also contribute to the identification of new risks and exposures. Other studies and methods than those of the OECD were also necessary for this. It was also emphasised that the qualification of laboratories was important. There is a high demand for laboratories that can analyse nanomaterials (in products), e.g. in food.

One participant reported that the recognition of data was difficult if test methods were not revised for nanomaterials. The OECD WPMN should discuss how this can be remedied and how companies can be supported in this regard.

It was discussed that the specifications for sampling and sample preparation differed from country to country. Therefore, the results of product analyses would differ significantly. A reference was made here to an ongoing research project on nanomaterials in food, which could provide findings on food that could possibly also be transferred to the analysis of cosmetics. In addition, the OECD guideline on sample preparation would be revised.

When asked why the guidelines on "Good Laboratory Practice" have not been updated, the answer was that this principle is timeless and independent of the substances examined. Therefore, there has been no need for updating so far. However, with the emergence of new test methods (NAM), adjustments might become necessary.

7 Safeguarding water as a resource

7.1 Technology development for water purification - experience in the safe handling of nanomaterials

Paul Westerhoff, Professor at the Department of Environmental Engineering at the University of Arizona (USA), presented research projects on the purification of drinking water and wastewater coordinated at the Engineering Research Center for Nanotechnology Enabled

Water Treatment (NEWT). He said that the aim of the research was to develop efficient, decentralised, nano-based purification systems that can be operated with (significantly) reduced use of chemicals, energy consumption and waste generation. Mr Westerhoff explained that the systems should be flexible and adaptive for different types of water. Technologies used would include: substrate-bound optical fibres to destroy biofilms, nanoscale catalytic layers to destroy chemicals, e.g. PFAS, and (ceramic) membranes.

Mr Westerhoff presented the results of stakeholder surveys, which identified that the safety of cleaning systems was a very high priority. Lack of confidence in the safety of the products could hinder market access. Therefore, the nano-based cleaning systems would now be tested and certified by the National Hygiene Foundation. A simple method for standardised measurement of the release of nanoparticles had been developed specifically for this test. In the following discussion, the developed test method was explained in more detail.

7.2 Reducing wastewater pollution in Colombia

Johann F. Osma, Secretary General of the Network of Nanosciences and Nanotechnologies at the University of the Andes (Colombia), began his presentation by stating that the preservation of biodiversity was a high priority in Colombia and that strict legal requirements for wastewater treatment therefore existed.

Mr Osma presented a project in which waste from a leather dyeing factory was used as a substrate for nanostructures to remove the dyes from the dyeing factory's wastewater. He showed the results of another project in which waste from cocoa cultivation was equipped with nanostructures to remove cadmium from wastewater. There were projects that had developed purification technologies to separate water from oil using fungal enzymes and bacterial proteins after accidents in the oil industry, he said. For drinking water purification, Mr Osma presented a system for destroying active pharmaceutical ingredients using microcapsules loaded with nanostructures and enzymes. All the research presented would be carried out in cooperation between industry, universities and the government.

In the discussion, there was strong support for the principle of using waste for wastewater treatment. In response to the question about international (research) cooperation, Mr Osma said that there was some, e.g. in chocolate production, but that there was also a large reliance on national resources. Overall, both the industry and the government attach great importance to "green chemistry".

8 Implementation of product safety

8.1 Development of secure, energy-saving data storage

Mitsugu Uejima, General Manager of Zeon Corporation (Japan), explained how his company uses carbon nanotubes (CNTs) to manufacture energy-saving data storage devices, implementing the concept of "Safe and Sustainable Innovation".

Mr Uejima explained that Zeon had developed a method to produce high-purity, long, single-walled CNTs and operated a manufacturing plant in Japan. He informed that these CNTs were considered to be of low concern as tests had shown that they were only irritating to eyes and had a medium aquatic toxicity. The CNTs had initially been used for optimising existing products, e.g. increasing the conductivity, durability and/or heat resistance of rubber.

Mr Uejima further reported that Zeon expects to save up to 40% of energy by using CNT-based data storage in the "green data centres of the future". Non-volatile, nano-based storage technologies were faster and denser, he said. They would consume virtually no energy in standby mode and significantly less energy in work mode than conventional storage.

Mr Uejima explained how Zeon optimises the production of CNTs in terms of energy consumption and occupational health and safety, among other things. Their CNTs would be degraded to CO_2 and would therefore not pose a permanent problem to the environment.

8.2 Studies on the nanosafety of locally available nanoproducts

Helme Helan is Deputy Director of the National Nanotechnology Centre at the Ministry of Science, Technology and Innovation in Malaysia. He presented a project that included a market analysis of nanoproducts in the Malaysian market, (eco-) toxicity tests of the nanomaterials they contain, studies on their fate in the environment and life cycle assessments (LCA). A total of 424 products with and without "nano-claims" from the fields of health, agriculture, energy and electronics had been examined. Mr Helan reported that in a case study on a product with silver nanoparticles, no risks were identified. LCA had been used to describe the environmental impacts of the product. In cases where the investigations indicated risks to humans and/or the environment, the companies were contacted. In the case of incorrect or misleading labelling, the authorities had withdrawn the products from the market.

Mr Helan said in his outlook that the information from the studies would be stored in a database in the future and, provided the permission of the manufacturers, would be published. In parallel to the study, he said, the ministry had set up a certification system for nanoproducts.

8.3 Overview of potential risks from nanomaterials in consumer products and ways to address them

Sean Kelly is the Interim Director General and Project Manager of the Nanotechnology Industries Association (NIA). He presented the results of a survey on nanoproducts in the UK market and the associated safety issues that the association had carried out in 2022. Cosmetics, toys, textiles and personal protective equipment (including face masks) had been examined.

Mr Kelly informed that a total of 613 products with "nano-claim" had been identified, of which 280 were available to the general public in the United Kingdom (UK). In more than 50 % of the products, the identity of the nanomaterial contained could not be determined. Nano-titanium dioxide, nano-silver and bisoctrizole had been found most frequently. A hazard profile had also been established for these substances.

Mr Kelly summarised that the project showed, among other things, that the number of nanoproducts had doubled in the last ten years. He said it was difficult to verify nano-claims because the identity of the nanomaterials in the products was often impossible to determine. The data needed to create hazard profiles for individual materials was often not available. Product manufacturers should therefore always keep themselves up to date with regard to the materials used. It had also been shown that many companies would not produce nanoproducts for the consumer market, partly because of the discussion about nanosafety and the high costs and low profit margins.

9 Examples of medical uses

9.1 Nanomaterials in medicine - opportunities and experiences

Achim Aigner, Professor and Head of Clinical Pharmacology at the University of Leipzig (Germany), gave an overview of medical applications of nanomaterials. He explained that a central property of nanomaterials for medicine was the ability to overcome barriers between organs or cells and thereby transport pharmaceuticals. Examples of such "nano-carriers" were liposomes or polymeric particles of different shape, composition and size. However, the right combination of active ingredient, carrier and the corona - a molecular layer that attaches itself around the particle in the biological system - must be taken into account for the effectiveness of the overall system. Therefore, tests on the organism are of great importance.

Mr Aigner explained that there were other medical applications of nanomaterials besides targeted drug delivery, e.g. cell therapies that could replace viral approaches to genetically modify patient cells, or so-called theranostics, which combines diagnosis and therapy of diseases. He also presented research on therapies using "small interfering RNA" (siRNA). These siRNA led to an inhibition of the production of (problematic) proteins through the targeted degradation of certain RNA.

Mr Aigner emphasised that the use of nanoparticles makes sense in many areas of medicine. He said it was a great success that so many systems were already being used in clinical practice.

9.2 Use of nanotechnologies for mRNA vaccines

Patrick Baumhof, Senior Vice President Technology at CureVac SE (Germany), explained how mRNA vaccines work and presented different lipid-based nano-carriers developed by CureVac.

Mr Baumhof informed about the structure and function of the genetic code (DNA). The messenger RNA (mRNA) is a copy of parts of this information, is transported out of the cell nucleus and then used as a template for the production of proteins. This natural process would be used in mRNA vaccines.

Lipid-based nano-carriers are important for transporting the mRNA in the body. They prevent the degradation of the mRNA in the body before it can fulfil its function. In the target cell, the mRNA released by the nano-carrier leads to the formation of proteins, which in turn trigger the immune reaction.

CureVac had tested various lipid-based nano-carriers for their suitability to transport mRNA. Mr Baumhof presented various challenges in the manufacturing processes of the particles. In its trials, CureVac was able to show that nano-carriers increased the efficacy of mRNA vaccines.

Mr Baumhof distinguished three medical applications of mRNA: preventive vaccines, cancer vaccines that are used against tumours and molecular therapies that use mRNA to produce proteins that the body could not otherwise make itself.

9.3 Key challenges in the manufacture of lipid-based delivery systems - A case study on Covid vaccines

Lars Geiger, General Director Project Management Drug Substance of Evonik Operations GmbH (Germany) gave further insight into the challenges of manufacturing nano-carriers for active pharmaceutical ingredients. Evonik supports the pharmaceutical industry with the (joint) development of transport systems.

The central challenge in the development of the carrier system for the mRNA of the Covid vaccine was to increase the production volume from laboratory scale to a technical scale without compromising quality and within a short time. The purity of the lipids was particularly critical for the quality, among other things because they could also interact with the mRNA and thus deactivate the active substance. However, the analyses showed that the final product contained less than 0.3 % impurities.

Mr Geiger informed that two production plants and several hundred people had been involved in the development of two critical lipids. After only three months, the carrier system for the mRNA had been ready to be passed on to the customers. Since the vaccine had to be approved, marketing then took a while.

10 Take Home Messages and Conclusions

The conference concluded with a panel discussion reflecting on the presentations, discussions and findings of the two conference days. The panel included: Mar Gonzalez, Coordinator of the OECD Working Party on Nanomaterials (WPMN), Peter Dröll, Director for Prosperity at the European Commission's Directorate-General for Research and Innovation, David Azoulay, Managing Attorney of the Centre for International Environmental Law and Peter Wick, Head of the Particulate Research Laboratory at EMPA.

In the opening round, Peter Dröll summed up that the Nano-Dialogue had brought together the right people at the right time to link the national discussion with the European and also global level. This networking was also important to spread approaches such as the EU Green Deal or the concept of "Safe and Sustainable by Design". Mr Dröll was impressed by the many activities, including those to develop test methods.

Mar Gonzalez emphasised that the topic of "communication" and "stakeholder dialogue" had played an important role in many presentations and discussions during the two days of the conference. Comprehensive communication was central to the success of research and innovation and should be further strengthened in the future. Another important message from the conference for her was that feedback from companies on the feasibility of legal requirements, especially in the area of testing methods, needed to be heard and taken into account more.

David Azoulay found it important for (further) confidence building to look realistically at and communicate both the successes of the past and the questions that have not yet been answered or only partially answered, such as

the lack of data. He saw the EU regulation as insufficient and inadequately implemented and therefore called for a change in the legal basis. In this context, he said, one would have to say goodbye to the assumptions that "innovation basically means progress" and that "regulation always hinders innovation". In his view, regulation should rather be understood as an instrument that gives direction to innovation.

Peter Wick emphasised the need for dialogue, especially in the case of transdisciplinary challenges and in the context of emerging technologies such as artificial intelligence and "big data". A dialogue should work out what benefits a new technology could have for society and where its limits would lie, he said. Mr Wick also pointed out that future decisions must be based on reliable data collected using standardised methods. This also required thinking about how the next generation of scientists could be won over to underpin the (risk) discussion with facts.

In the further discussion on the panel and with the audience, it was commented, among other things, that the past had shown, e.g. on the topic of climate protection, that regulation can promote innovation. After the phthalate bans, the number of patents for alternatives had increased significantly; this would be a sign of innovation. However, innovation would not always be easy to evaluate. It was also said that societal need should guide the direction of innovation. Medicines or technologies for (waste) water treatment, for example, were more necessary than cosmetics. Other voices stated that the industry's ability to innovate had generally declined and that regulation was blamed for this. This raised the question of what a "smart" regulation could look like and what significance the precautionary principle could have in it.

The audience commented that the presentations on the use of nanotechnologies in medicine had been very helpful, as they had clearly shown the opportunities for society. Unfortunately, in connection with the development of the Covid vaccine, the central role of nanomaterials had not been emphasised.

The example of the Covid vaccine was also used to discuss whether innovation was controllable or not. Some expressed concern that the "breakthrough" of mRNA vaccines had already been preceded by a long period of "uncontrolled" basic research. The pandemic had opened up a new field of application, the urgency of which had "steered" and extremely accelerated research. Others countered that there was no desire to steer innovation.

Regarding data availability and data management, it was asked whether an "increase" in data would really go hand in hand with an increase in trust. New information often produced new questions, which in turn produced a new need for information. Handling huge amounts of data also required procedures that are trustworthy.

Instead of (just) "more data", we would need more transparency about data gaps and evaluation uncertainties. In addition, concepts would be needed to decide what data should be collected or generated for what purpose. Mr Kobe informed that the EU was already creating data rooms in various areas, e.g. for "Advanced Materials", where data could be collected and shared. These data rooms would be central to future progress, but were more difficult to create than expected.

In the final round of the panel, it was emphasised that this conference was very much in the tradition of the NanoDialogue and had shown that stakeholder communication is important for fully grasping an issue. A change of perspective would contribute to a better understanding of issues and stakeholders and thus to better decisions.

Impressions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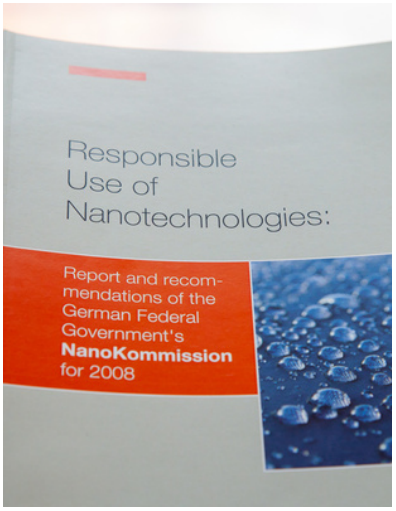
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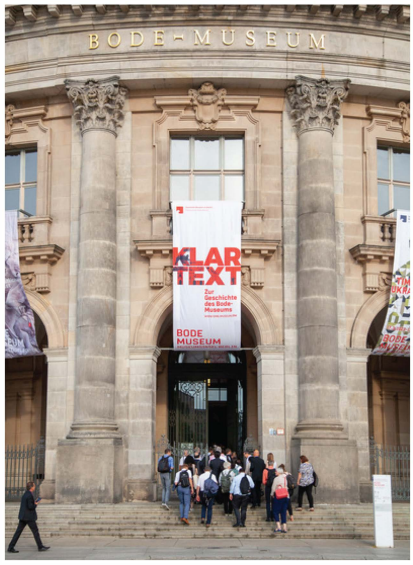
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Berlin 22/23 June 2023:
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Conference programme

INTERNATIONAL CONFERENCE

HOW THE WORLD DEALS WITH MATERIALS ON THE NANOSCALE

Responsible Use and Challenges

Programme

22-23 June 2023
Venue: Tagungswerk, Lindenstraße 85, 10969 Berlin

On invitation from the German Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection and in cooperation with the OECD

Federal Ministry
for the Environment, Nature Conservation,
Nuclear Safety and Consumer Protection

in cooperation with

OECD

Thursday, 22 June 2023

Opening

10:30 **Welcome by the Federal Ministry for the Environment**
Christiane Rohleder, State Secretary, Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection (BMUV), Germany

10:50 **Welcome by the OECD**
Bob Diderich, Head of the Environment, Health and Safety Division at the Environment Directorate of the OECD

11:00 **Introduction to the meeting and housekeeping**
Daan Schuurbiers, de Proeffabriek, The Netherlands

The German NanoDialogue

11:10 **More than 16 years of NanoDialogue of the German Federal Government**
Antonia Reihlen, Ökopol GmbH, Germany

11:25 **The NanoDialogue - time travel through 16 years of stakeholder discussions**

Matthias Machnig, Economic Forum of the German Social Democratic Party, Germany

Uwe Lahl, BZL Kommunikation und Projektsteuerung GmbH, Germany

Martin Kayser, BASF SE, Germany

Norbert Röttgen, Member of the German Bundestag, Germany

Christian Calliess, Free University of Berlin, Germany

Peter Markus, Ministry for the Environment, Nature Conservation and Transport of the Bundesland North Rhine Westphalia, Germany

Kerstin Hund-Rinke, Fraunhofer Institute for molecular biology and applied ecology, Germany

Rolf Buschmann, Friends of the Earth Germany, Germany

Carolin Kranz, BASF SE, Germany

Klaus-Michael Weltring, Society for Bioanalytics Münster e.V., Germany

Michael Cuno, Ministry of Social Affairs, Health, Integration and Consumer Protection, Brandenburg, Germany

Andrea Haase, Federal Institute for Risk assessment (BfR), Germany

12:40 **Questions from the audience**
Daan Schuurbiers, de Proeffabriek, The Netherlands

13:00 **Sharing an international perspective on the German NanoDialogue**
A bird's-eye view of achievements and future directions of NanoDialogue from the perspective of particle toxicology: Valuable lessons to be learned".
Mary Gulumian, North West University, South Africa

13:20 **Closing remarks on the NanoDialogue**
Bob Diderich, Head of the Environment, Health and Safety Division at the Environment Directorate of the OECD

13:30 - 15:00 Lunch break and networking

Managing nanomaterials via legal requirements

15:00 **Governing nanomaterials under EU regulation: chemicals, but particular**
Andrej Kobe, European Commission, Directorate-General for Environment, European Commission

15:20 **Toxic Substances Control Act New Chemicals Review for Nanomaterials**
Alexandria Stanton, Jim Alwood, Environmental Protection Agency (EPA), United States of America

15:40 **Legislation and policy framework in India around nanomaterials for agriculture and food**
Alok Adholeya, Translational Research & Innovations (TRI), India

16:00 **Challenges and best practices for risk assessment of pre- and post-market nanomaterials in Canada**
Djordje Vladisavljevic, Health Canada, Canada

16:20 **Regulating risk of nanomaterials through soft law approach**
Halila Faiza Zainal Abidin, Ministry of Science, Technology and Innovation (MOSTI), Malaysia

16:40 **Discussion**
Daan Schuurbiers, de Proeffabriek, The Netherlands

17:00 - 17:30 Coffee break

Managing nanomaterials by supporting implementation and communication

17:30 **Training, guidance and support for the implementation of nano safety at the global** scale
Georg Karlaganis, United Nations Institute for Training and Research (UNITAR)

17:50 **Connecting societal perspectives with business practices: concrete examples from France**
Mathilde Detcheverry, AVICENN @VeilleNanos, France

18:10 **National strategy for safe handling of nanomaterials in Sweden**
Penny Nymark, Karolinska Institutet, Sweden

18:30 **Final discussion**
Daan Schuurbiers, de Proeffabriek, The Netherlands

19:00 Invitation to dinner

Friday 23 June 2023

9:00 **Introduction to the day**
Daan Schuurbiers, de Proeffabriek, The Netherlands

Standardisation and test methods

9:15 **How consensus driven standards help the nano-dialogue from the inception**
Denis Koltsov, International Standardization Organisation (ISO), Switzerland

9:35 **OECD work to support safe and sustainable innovation of nanomaterials and advanced materials**
Mar Gonzalez, OECD Working Party on Manufactured Nanomaterials (WPMN), France

9:55 **The Malta Initiative, OECD Test Guidelines and European research projects**
Thomas Kuhlbusch, Federal Office for Occupational Safety and Health (BAuA), Germany

10:15 **NanoMesureFrance: A single entry point for structuring the French nanomaterials industry around reliable data**
Francois Xavier Ouf, Georges Favre, Laboratoire national de métrologie et d'essais (LNE), France

10:35 **Discussion**
Daan Schuurbiers, de Proeffabriek, The Netherlands

10:45 - 11:15 Coffee break

Examples of securing water as a resource

11:15 **Technology development for water purification and lessons learnt on the safe use of nanomaterials**
Paul Westerhoff, Arizona State University (ASU), United States of America

11:35 **Pollution reduction in wastewater in Colombia**
Johann F. Osma, University of the Andes, Colombia

11:55 **Discussion**
Daan Schuurbiers, de Proeffabriek, The Netherlands

Ensuring Product Safety

12:10 **Nanosafety studies on locally available nano-products**
Helme Helan, Ministry of Science, Technology and Innovation (MOSTI), Malaysia

12:30 **Inventory of potential risks from nanomaterials in consumer products and approaches to address them**
Sean Kelly, Nanotechnology Industries Association (NIA), Belgium

12:50 **Discussion**
Daan Schuurbiers, de Proeffabriek, The Netherlands

13:00 - 14:00 Lunch break

Ensuring Product Safety (cont.)

14:00 **Development of next-generation memory for energy saving and improved safety - safe and sustainable design in practice**
Mitsugu Uejima, Zeon Corporation, Japan

Examples of medical applications

14:20 **Nanomaterials in medicine - benefits and lessons learnt**
Achim Aigner, University of Leipzig, Germany

14:40 **Key manufacturing challenges for lipid-based delivery - Case study for covid vaccines**
Lars Geiger, Evonik, Germany

15:00 **Use of nanotechnologies for mRNA vaccines**
Patrick Baumhof, CureVac SE, Germany

15:20 **Discussion**
Daan Schuurbiers, de Proeffabriek, The Netherlands

Conclusion

15:30 **Take-home messages**
Peter Dröll, European Commission, Directorate-General for Research and Innovation, European Commission

Mar Gonzalez, OECD Working Party on Manufactured Nanomaterials (WPMN), France

David Azoulay, Center for International Environmental Law, Switzerland

Peter Wick, Swiss Federal Laboratories for Materials Science and Technology (Empa), Switzerland

15:55 **Closing the Conference**
Anke Jesse, Laura Gross, Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection (BMUV), Germany

16:00 End of the Conference

Responsible for the NanoDialogue of the Federal Government:
Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection

Design of the Dialogue
Division C II 6 - Nanoscale Advanced Materials, OECD Chemicals Policy

Head of Division: Dr Anke Jesse

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