



Future-proof Nanomaterials

The Netherlands, 17-18 April 2018

Report of the Policy Conference 'A future-proof approach to nanomaterials'

June 7th, 2018

Summary

On 17 and 18 April, the Dutch Ministry of Infrastructure and Water Management and the National Institute for Public Health and Environment (RIVM) organised an international policy conference 'A Future-proof approach to Nanomaterials'. Representatives of the EU Member States and Associated countries, the European Commission, OECD and other international bodies and stakeholders attended the conference.

Important topics during the conference included possible adaptation of European legislation, development of test methods, availability of data in databases and anticipating potential risks from early on in the material design processes (Safe by Design approach).

The conference started with [a series of presentations](#). They served to set the scene on the world of possibilities of (new) nanomaterials, and the regulatory challenges regarding safety and health. The presentations on the issues and recommendations that resulted from the [NANoREG](#) and [ProSafe](#) projects served as starting point to discuss initiatives of the participants to further develop and implement the recommendations as listed in [the White Paper](#) on these projects.

During the second day, initiatives have been discussed among smaller groups in several rounds and elaborated into nine action plans. Alliances have been created that jointly take responsibility to implement these action plans.



17-18 April 2018 Policy Conference aboard the ss Rotterdam.

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Background

Two major EU funded projects, [NANoREG](#) and [ProSafe](#), coordinated by the then Ministry of Environment and Infrastructure of the Netherlands, focused on improving the risk management of nanomaterials.

In NANoREG over 85 institutional partners from EU member states, associated states, the Republic of Korea and Brazil collaborated in developing reliable, reproducible and relevant methods for testing and assessing the effects of nanomaterials on human health and environment in a regulatory context. The duration of the project was 48 months; the end date was 28 February 2017. The budget was approximately fifty million euro. Ten million was provided by the EU (FP7 programme) and forty million by member states, regions, partners and other sources.

In ProSafe, twelve organisations from nine EU member states and associated states collaborated to evaluate the results of a wide range of EU projects on Environment, Health and Safety research in the field of nanotechnology. They aimed to translate the evaluation results into building blocks and recommendations for regulatory actions thus adding considerable added value to the individual projects (“the whole is greater than the sum of its parts”). Additional activities focussed on: the examination and development of joint activities with global networks; exploiting synergies between NANoREG and other projects; streamlining data acquisition, collection and data management; widening the liaisons between member states and associated states across the EU. The duration of the project was 27 months; the end date was 30 April 2017. The budget was approximately 2.5 million euros.

The policy recommendations which were drawn from a detailed evaluation and analysis of the outcomes and results of the NANoREG and ProSafe projects culminated in the writing of a [White Paper](#). This was a major activity, firstly involving an evaluation by an international task force of experts, whose conclusions were summarised in a so-called [Joint Document](#), and which was presented at a [dedicated OECD conference](#), leading finally to the formulation of the White Paper. Important issues in the recommendations are the possible adaptation of European legislation, development of test methods, availability of data in databases and anticipating potential risks from early on in the material design processes (Safe by Design approach).

These recommendations gain strength when embraced by willing organisations. This needed a floor to debate and assess a coherent follow-up. Organisations involved in, or responsible for, nanosafety research and the regulation of nanomaterials, including the EU Member States, the European Commission, the OECD and other stakeholders should get together to raise the fire for a future-proof approach to nanomaterials. Therefore, the Ministry of Environment and Water Management of the Netherlands, together with the National Institute of Public Health and Environment (RIVM) initiated [an international policy conference](#) to discuss how to implement the recommendations laid down in the White Paper.

The focus of this conference was on ideas and experiences of the participants that could be further developed into initiatives, actions, and partnerships. The aim was to be as specific as possible and thus put forward a promising agenda for a future-proof approach of nanomaterials.

Technology development and recommendations

[The conference](#) started with three presentations intended to set the scene. [Dave Blank](#) highlighted recent and expected breakthroughs in nanotechnology research including experiments with safe-by-design. [Claire Skentelbery](#) explained the large potential of nanotechnology and stressed the importance of clear, stable and common legislation. [Georgios Katalagarianakis](#) gave an overview of the support given by the European Commission to invention and innovation of nanomaterials including safety.

[Tom van Teunenbroek](#) and [Aart Dijkzeul](#) introduced the [14 recommendations](#) identified in the White Paper, based on the results of the NANoREG and ProSafe projects. Participants were mostly supportive of the recommendations. The comments included the wish to first harmonise relevant definitions. Participants thought it would help to order the recommendations in a compelling storyline, but also to convert them into SMART actions. To bring the recommendations forward it was suggested to promote national initiatives and to build a community for exchange of knowledge, experiences and advice. It was remarked that research and policy priorities may change with new generations of nanomaterials. The lack of FAIR data, including those on exposure, remains a challenging issue. Generally, it was believed necessary to put a lot of emphasis on safe-by-design, but also retain and improve hazard-based regulation.



From recommendations to action plans

The participants were challenged to present existing initiatives that needed further elaboration or to formulate new initiatives that would help to progress the recommendations. Thirteen initiatives were proposed that subsequently were consolidated to nine action plans.

For each of these nine action plans, for the time being, a first contact is indicated to take the next step: to bring together partners for this initiative and among each other decide on who will lead the action, what will be the division of tasks and what will be the short and long-term planning.



Thirteen initiatives were proposed and consolidated to nine action plans.

The nine action plans in short:

A) Future types of nanomaterials

This initiative is an exercise to make subsequent inventories of foreseen future types of nanomaterials, define these types and further terminology, identify the challenges in risk assessment that would arise from these advanced materials and formulate how the risks of these materials can be adequately managed including through adopting new or adapting existing regulation.

First contact: Mar Gonzalez (OECD)

B) FAIR data

This initiative focuses on the generation and use of FAIR (Findable, Accessible, Interoperable, and Reusable) data. Make sure that in all call for tenders (on an EU level and on a Member State level (national calls) nanosafety data that are generated are FAIR (Procurement rules)

First contact: Ronald Flippi (NL)

C) Zero-effect data

This initiative would increase the accessibility of zero-effect data, that would be helpful for designing tests and increase the overall efficiency of testing. Data on physical and chemical properties and that are currently not published, could be made accessible by publication in an open access online journal. Original publications could be useful.

First contact: Claire Skentelbery (NIA)

D) Facilitation of Platforms

This initiative aims to strengthen the communication and cooperation between those involved with nanomaterials. Two different platforms were proposed:

- a platform of stakeholders, e.g. authorities, industry, NGOs, academia/scientists to ensure knowledge exchange in the field of nanosafety;
- a platform of policy-makers; in their activities they may invite and inform stakeholders.

First contact: Gregory Moore (SE)

E) Safe by Design

This initiative aims to bring Safe-by-Design from theory to common practice. It is proposed to explore a European definition of the concept, to determine drivers for implementation (such as incorporation in curricula, benefits to society), to make an inventory of Safe-by-Design experiences, develop a knowledge sharing platform on Safe-by-Design, etc.

First contact: Monique Bosman (NL)

F) REACH information requirements in relation to needs of nanomaterials

This initiative is to see whether REACH information requirements are applicable to and/or match to the needs of existing and next generation nanomaterials/advanced materials. This will be done via an informal working group that clarifies the issues. If possible, the findings will also be included in Council Conclusions on the REACH evaluation

First contact: to be decided; this is a great opportunity for one of the other participants to take the lead

G) Testing of Nanomaterials

This initiative provides an overarching structure and push needed for developments of testing NM. This includes, among others, an overarching structure for regulation, gap identification and accelerating testing guidelines and strategies.

First contact: Anke Jesse (DE)

H) Regulatory relevant research agenda

The aim of this initiative is to set a regulatory relevant research agenda (5y), drafted by a regulatory nano-cluster. The agenda should provide guidance with reference to regulatory needs. By means of the agenda, and the regulatory nano-cluster, expertise of EU-wide (include east) nanosafety know-how can be shared.

First contact: to be decided; this is a great opportunity for one of the other participants to take the lead

I) Definition of Nano

This initiative is meant to be the start of a process to support legal definitions (e.g. Nano Forms, Grouping). Abstract terms should be given more practical meaning: what parameters are relevant, what criteria are used for grouping, what is the underlying reason for grouping, etc.

First contact: Claire Skentelbery (NIA)

Possible follow up; next harbour?

Inspired by the facilitator of the Policy Conference, Peter Woodward, the conference created a momentum for bringing together the energy and the ideas for a future-proof approach for nanomaterials. It brought forward new actions and partnerships. Participants were eager for follow-up activities, which could be managed by a steering committee, including a next policy conference and regular communication on progress. This is seen as the main challenge for the host and the participants.

Participants suggested a next meeting in the second half of 2018, to exchange the progress made on the actions and to get more parties involved in these actions. The Netherlands will stimulate the organisation of a second meeting and share experiences of the Rotterdam conference.

Fortunately, already during the meeting, candidates for a steering committee have been identified: Anke Jesse (BMUB, DE), Alexander Pogany (BMVIT, AT), Rob Aitken (IOM, UK), Peter Kearns and Mar Gonzalez (OECD, FR), Claire Skentelbery (NIA, BE) and Juan Riego Sintes (JRC, BE) committed to a 'next step'. Also, it was suggested that this steering committee could connect in some way to the initiative to form nanoplatforms.

Annex 1 - Programme Policy Conference

Day 1 - Tuesday 17 April 2018

12:00 – 13:00	Registration - Lunch
13:00 – 15:00	<p>Welcome, introductions, aims, agenda, process</p> <ul style="list-style-type: none"> ▪ Dutch Ministry of Infrastructure and Water Management ▪ Peter Woodward, <i>Independent Facilitator, Quest Associates</i>
	<p>Nanotechnology in our lives – opportunities and challenges</p> <ul style="list-style-type: none"> ▪ An exciting and brave new world – Prof. Dave Blank, <i>Invited Speaker, Member of the Advisory Council on Science, Technology and Innovation</i> ▪ Emerging challenges - Dr. Claire Skentelbery, <i>Invited Speaker, Director General of Nanotechnology Industries Association (NIA)</i> ▪ Sharing experiences on policy challenges and responses
15:00 – 15:30	Coffee and Tea break
15:30 – 18:00	<p>Nanotechnology – The policy challenge and solutions</p> <ul style="list-style-type: none"> ▪ Georgios Katalagarianakis, PhD <i>Invited Speaker, European Commission DG Research & Innovation</i> ▪ Presentation of Drs. Tom van Teunenbroek, <i>Coordinator NANoREG and ProSafe</i> <ul style="list-style-type: none"> - NANoREG and ProSafe research programme and methods - Regulation journey related to Nanotechnology ▪ Presentation of Ing. Aart Dijkzeul, <i>Project Manager NANoREG and ProSafe on behalf of the Ministry IenW</i> <ul style="list-style-type: none"> - Present White Paper Recommendations ▪ Table discussion on recommendations and Q&A for clarification Polling in response to the recommendations ▪ Identification of leaders of key initiatives <p>Closure of the Conference Day 1</p>
19:00 – 20:00	Reception for all participants – aboard the ss Rotterdam
20:00 – 22:00	Dinner for all participants, aboard the ss Rotterdam, hosted by the Dutch Ministry of Infrastructure and Water Management

Day 2 - Wednesday 18 April 2018

08:30 – 09:00	Welcome – Coffee - Tea
09:00 – 10:30	<p>Welcome and plan for the day</p> <ul style="list-style-type: none"> ▪ Embracing the challenge inspiring case study of good practice in nanomaterials regulation ▪ Collaborations for momentum Participants propose key initiatives to take forward White paper recommendations <p>Participants choose initiatives to explore</p>
10:30 – 11:00	Coffee and Tea break
11:00 – 13:00	Initiative leaders pitch their approaches and invite comments and participation to raise value and momentum. End with next steps plans with a view to future steps.
13:00 – 13:50	Lunch
13:50 – 16:20	<p>Building momentum for change Feedback key messages from initiatives What is this telling us? discussion with panel</p> <p>Further messages and long term visions Table groups invited to identify</p> <ol style="list-style-type: none"> 1) additional recommendations to ensure momentum 2) a radical idea to embrace nanotechnology in a safe way <p>Feedback to plenary with sounding board panel</p> <p>Summary of next steps and closing remarks</p>
16:20 – 18:00	Conference close and Farewell reception

Annex 2 – ProSafe White Paper Recommendations

A summary of the Recommendations as used during the conference:

1. Accelerate adapting the existing OECD chemicals test guidelines for applicability to nanomaterials.
2. Identify which data sets and descriptive test guidelines are lacking, specifically for nanomaterials, and develop these guidelines.
3. Implement a project in which properly characterized nanomaterial(s) is tested using approved testing methods evaluating all relevant types of toxicological effects.
4. Enforce open access to all relevant characterization and toxicological information.
5. Guarantee the long term storage, free access, quality assessment and comparability of research data on nano materials.
6. Coordinate future publicly funded nanosafety research to produce results relevant for regulation.
7. Set Occupational Exposure Levels for which applicable standardised derivation method exists.
8. Legally define the term nano material.
9. Harmonize groupings and principles for grouping across different institutional settings.
10. Add physical characteristics and surface chemistry to the information requirements.
11. Exempt nano materials from general information requirements that are not relevant for their risk assessment, but add those requirements that are of specific relevance.
12. Ensure that tests are designed to produce information that is fully relevant for risk assessment purposes.
13. Determine Mode-of-Action and Adverse-Outcome-Pathways specifically for nano forms which are representative for large groups of chemical substances.
14. Design, test and implement an approach that allows for the appropriate risk assessment for advanced materials, especially those produced in low volumes.

Annex 3 – Representation

Below a list of EU Member States, Associated countries, and International Organisations represented during the Policy Conference

Countries	NGO's	Industry	international organisations
Austria	CIEL	Solvay	EC
Belgium		CEFIC	ECHA
Bulgaria		NIA	JRC
Denmark			OECD
Estonia			
Finland			
Germany			
Ireland			
Italy			
Romania			
Spain			
Sweden			
Switzerland			
The Netherlands (host)			
United Kingdom			