Safe Design of Nanomaterials

Paving the way for Innovation
1 Foreword

Micro and nanotechnology will make a significant contribution to resolving major societal questions such as how to keep an ageing society healthy and how to keep our environment inhabitable in a changing climate. The basis for being able to provide this contribution lies in the creation of an open, dynamic and sustainable ecosystem for research and innovation with which the Netherlands can continue to play its leading role in the world, and can extend this role further, in micro and nanotechnology.

Attention to and action in Safe Design of Nanomaterials is quintessential for the innovation journey ahead. The NanoNextNL and TNO workshop on Safe Design is a first essential step in this journey together with researchers, companies and government.

Prof dr ing Dave Blank
Chair Executive Board NanoNextNL
2 Introduction

With its excellent scientific research and increasing business activities, the Netherlands has a unique position in nanoscience and -technology. This is not a mere coincidence but the result of a long term shared vision and innovation strategy. At the turn of the millennium, Dutch policy started to focus on nanotechnology, which resulted in the NanoNed consortium. In 2008 NanoNed together with other stakeholders presented the Strategic Research Agenda. The SRA has been the shared vision for several complementary consortia ever since: NanoNextNL (research and innovation), NanoLabNL (infrastructure), NWOnano (fundamentals) and High Tech Systems & Materials (application – as part of the Dutch Top Sector approach).

The positive effect of collaboration on innovation has been shown in numerous studies since the 1980s. This holds especially in emerging technologies in which both codified and tacit knowledge from different stakeholders (e.g. science and business) with different backgrounds (e.g. biology and physics) has to be combined. Nanotechnology is such an emerging technology in which more and more stakeholders are involved and new products are evolving. Innovation research into these settings has indicated major success drivers: governmental funding realises research into long-term, risky, expensive endeavours; a prime mover initiates network formation which is essential for (tacit) knowledge creation; collaboration and knowledge creation are stimulated by a shared vision and trust, and are further supported by agreements (e.g. IPR) and research organisations. These are the drivers that help stimulate innovation in nanotechnology in the Dutch Delta.

Emerging technologies such as nanotechnology are surrounded by uncertainties with regard to technological (im)possibilities, financial rewards and societal implications. Within the development and innovation process, clarity about the safety surrounding these new technologies is one of the most important conditions for acceptance of the technology. Particularly for nanomaterials, a subclass of the entire nanotechnology playing field, safety is an essential point of attention due to the uncertain risks. In the Netherlands this is recognised by all parties concerned. In the workshop ‘Safe Design of Nanomaterials’, which was organised on 10 May 2012 by NanoNextNL and TNO, the stakeholders took the first steps together towards an integrated policy for Safe Design of Nanomaterials.
Reader’s guide

This green paper is a summary of the workshop ‘Safe Design of Nanomaterials’ and an action agenda. In paragraphs 3 – 5, the substantive experts reflect on their contribution to the workshop. The 10 points of action which followed from the interaction between all participants during the workshop have been brought together in paragraph 6. The concrete follow-up actions which follow from this and will be picked up in the coming period are designated in paragraph 7.

Dr Rens Vandeberg
Senior Programme Officer Risk Analysis & Technology Assessment in NanoNextNL
3 Innovating safely: a question of cooperating more effectively?

In the development of a new technology, attention is in the first instance focused on the promise of new possibilities and opportunities. At the same time, the development of new products can also lead to new uncertainties surrounding the safety of those products. It is essential for societal acceptance and optimal use of economic potential that risks are mapped out and uncertainties surrounding the risks are dealt with effectively.

In many innovative technologies, the uncertainties about possible hazardous consequences have proven to be an important factor. Because of their innovative nature, information on undesirable effects has often been insufficiently available for too long. In addition to this, or as a consequence thereof, a number of technological developments may appeal to feelings of unrest, which can quickly lead to resistance and suspicion towards the technology. Questions also arise about liability, and whether or not to apply the precautionary principle. In the end, these questions can have an adverse effect on innovations.

Sustainable innovation or responsible implementation of a new technology are approaches which demand attention to incorporating the questions about safety for human beings and the environment at an earlier stage of the innovation chain. This already happens in the regular process of product development to some extent, but especially in the instance of new technologies, it is not clear whether regulation provides a comprehensive answer to the question of whether a product is safe.

There are various initiatives to achieve a change in this. One example of this is REACH, to obtain relevant information on safety for human beings and the environment for chemical substances which are currently on the market or are yet to be launched. The suitability of REACH for nanomaterials is still a matter of discussion between and within various stakeholder groups. Another approach is the so-called Safe by Design concept, where the functionality of a (nano)material and its toxicity are considered in an integrated way.
The Safe by Design concept does not actually sound like innovation. Indeed, it sounds rather obvious. A concept which is seen as self-evident by companies that develop projects, a concept seen as self-evidently being covered by regulation, by government institutions. To some extent, this is indeed the case, however new technologies and new types of products may lead to new risks, or existing test requirements may not be able to fully guarantee the safety of these technologies and products.

The aim of the Safe by Design concept is to develop new products where functionality and safety are tested in an integrated way. This integrated approach demands multi-disciplinary collaboration. This is more than a matter of sharing knowledge and pursuing the same objective. It is also a process in which it must be discovered what the motivation may be for different parties to participate, what the role of trust is, whether this can be a self-regulating system or whether leadership or responsibility is expected from a stakeholder. These process-oriented sides deserve more attention in Safe by Design projects, because it is a prerequisite for Safe by Design structurally being viewed as a concept rather than a project.

Dr Adriëlle Sips
Theme coordinator Risk Analysis & Technology Assessment in NanoNextNL, National Institute for Public Health and the Environment
4 Safe Design of Nanomaterials

Nanomaterials are a subset of the much larger class of natural and man-made particulate matter covering all sizes below 10 microns. The health effects of these materials have received increasing amounts of attention with the focus, in the beginning, on naturally occurring materials and industrial pollutants and, more recently, on engineered materials. Health effects of particulate matter have been registered on the cardiovascular, respiratory and immune system and include various types of inflammatory disorders and cancers. The primary cause of these effects is the oxidative nature of the particles themselves or the contaminants that adhere to them. In the case of nanoparticles, below ± 100 nm, there are two additional features that add to their potential to cause health effects, small size and altered physical chemical properties. Due to their small size they are able to freely permeate cell membranes and distribute themselves throughout all organs and remain there for extended periods of time. Their small size also results in an altered physical chemical nature such that material which is harmless as large particles can have an altered chemistry in the nano-state.

We do not currently know of any specific human disease or serious environmental impact attributable to engineered nanoparticles, however, there is experimental evidence for potential nanoparticle hazard. Currently, 6 base materials, Au, Ag, Zn/ZnO, Ti/TiO2 Silica and Carbon, constitute more than 90% of all manufactured nanoproducts and, while there are only about 1,000 commercial nanoproducts on the market today, the number is expected to grow to more than 100,000 in the next decade. They will undoubtedly be more diverse and complex in composition than today’s products. The increase in number and types of applications will herald the transition of nanotechnology from the discovery phase to a mature technology but bring with it new concerns of the environmental and associated health impacts of the materials themselves and new production technologies. During the discovery phase nanomaterials have been produced on a small, primarily laboratory scale and any potential threat to the environment or general health of the population has been minimal, but with the production of bulk, industry-scale quantities following traditional methods one can expect potential health and environmental hazards from the products and the accompanying by-products and waste streams. This does not, however, have to be the fate of a new, mature nanotechnology. It is, in principle, possible following the principles of green chemistry, to produce nanomaterials which are safe using methods that do not stress the environment, in other words materials which are safe by design.
Nanomaterials so produced will be made, as far as possible, from renewable resources that are safe for plant and animal life, using production methods that are safe for the workers and methods that minimise waste streams by limiting the number of synthetic steps and reaction intermediates and by incorporating as high a percentage of the starting material as possible in the final product. In cases where function requires the use of unsafe components, materials can be designed with properties enabling an efficient recovery and reuse at the end of their life-cycle.

Prof dr George Robillard

Director at Biomade Technology Foundation

Emeritus professor at University of Groningen
5 Safely handling nanomaterials

In 2009, the SER advice ‘safely handling nanomaterials in the workplace’ was drawn up. The health and safety of the employees working with nanomaterials in the workplace is central to this report. The guiding principle is that materials with uncertain or unknown risks, which include nanomaterials, must be treated as (extremely) hazardous materials. This means that work involving nanomaterials must be aimed at preventing or minimising exposure to employees.

The prevention or minimisation of exposure is ensured by means of the following hierarchy: elimination, substitution, containment, engineered monitoring solutions, administrative monitoring solutions, personal protective equipment. From the point of view of this hierarchy, it is essential to take safety into consideration in the design of nanomaterials.

Currently, there are only a few known examples of the development of nanomaterials where the risks have been reduced. Two examples are the use of coated titanium dioxide nanomaterials in sun creams and the use of shorter carbon nanofibres.

Insight into the toxicological risks is required for the design of safe nanomaterials. However, due to the fast development of new materials, it is extremely time-consuming to assess these materials via traditional risk assessments, where the risk assessment is based on a complete set of exposure and toxicity data. This data is often still lacking for nanomaterials and it is extremely time consuming to gather it (and also too expensive and possibly unethical due to the use of large numbers of laboratory animals. Society is therefore confronted with uncertain risks, which require a new approach. For the assessment of uncertain risks and how to deal with them, a dialogue is required between a large number of stakeholders which is shown in figure 1. Through the dialogue between different stakeholders, companies will gain an insight into the information that is required for acceptance by users and authorities, which will lead to
accelerated innovation in combination with responsible handling of the risks. With this in mind, the workshop Safe Design of Nanomaterials was set up with researchers, companies, branch organisations, and authorities, which led to 10 action points (see 6 Action points).

Dr Esther Zondervan
*Researcher Risk Analysis & Technology Assessment in NanoNextNL, TNO*
6  Action points

The 10 action points formulated during the workshop Safe design of nanomaterials are:

1. Setting up Safe Design Platform with all relevant stakeholders as a meeting point, sounding board and initiator, with a focus on priorities where perception also plays an important role. The platform coordinates and initiates the establishment of standards, regulation and maps out the playing field. The platform is focused on safe design issues and sets out a roadmap for issues that arise before and after!

2. Generating clarity on the critical end points in terms of toxicology, which have to be tested to reach a verdict.

3. Drawing up a guidance protocol to facilitate safe design (experience from drug development). For economic reasons, this protocol must be applicable in practice (not too strict).

4. Publishing both positive and negative results. The development process should be brought under confidential organisations which are able to safeguard the publication of both.

5. Bringing together, disclosing and making a database accessible of safe design concepts from various domains of applications (with an advisory function). Design of a start page ‘safe design’ like the substance manager.

6. More attention for risk assessment in the R&D process by the training of and communication between HSE and R&D manager (and marketing manager?) to raise awareness, expertise and cooperation.

7. Development of fast and cheap tests which can be used for fast screening of various nanomaterials by means of a pyramid approach.

8. Developing a broad perspective in which the exposure and toxicological risks are brought together for the entire chain (manufacturers, suppliers, downstream users, etc.) in the area of safe design approach. This means that risks can be reduced in the design stage, for every phase in the chain. For this approach, transparency in Material Safety Data Sheets is essential.

9. Positioning a leading ministry as the responsible organisation, that places the safe design issue and the impact on human beings, the environment and society in an accepted implementing body.

10. Organising multi-disciplinary teams with a knowledge of consumers, legislation, technical issues, etc., for the introduction of safe design concepts within companies.
7 Follow-up actions

Roadmap
Following on from the Workshop Safe Design and the action points that arose, NanoNextNL has taken the initiative to draw up a Roadmap Nano Safe Design. This roadmap concretizes aims and actions in order to achieve them and structurally unites stakeholders in this ambition. Science, business and government are represented in the Roadmap.

Safe Design and Risk Assessment & Technology Assessment
Explicit attention will also be given to safe design within risk assessment during the Topic Meeting Risk Assessment & Technology Assessment of NanoNextNL in cooperation with RIVM on 9 November 2012.

Publications
Safe Design is of importance to all stakeholders in nanomaterials. During the workshop, various parties already came together. To draw more attention to and increase the size of the network, the outcomes of the workshop will be distributed more widely by means of publications in (trade) magazines.

Demo
TNO is currently working on a demo case ‘safe design of quantum dots’. TNO is also looking for companies that want to work together on a new demo case.
8 Contact information

For questions, comments or ideas about Nano Safe Design, the workshop, NanoNextNL or TNO, please contact:

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Appendix I – NanoNextNL and TNO

The Nano Safe Design workshop on 10 May 2012 was organised by NanoNextNL and TNO.

About NanoNextNL

NanoNextNL is a consortium of over one hundred companies, universities, knowledge institutes and university medical centres, which is aimed at research into micro and nanotechnology. The total sum involved for NanoNextNL is 250 million Euros, half of which is contributed by the collaboration of more than one hundred businesses, universities, knowledge institutes and university medical centres and the other half by the Government of the Netherlands.

www.NanoNextNL.nl

About TNO

Netherlands Organisation for Applied Scientific Research (TNO) is a research organisation with a staff of 4,500 employees, mostly researchers and consultants in many technological fields of interest. The TNO mission is to connect people and knowledge to create innovations that boost the sustainable competitive strength of industry and well-being of society. In the field of nanomaterials, TNO is working on the development and characterisation of new nanomaterials, the risks of nanomaterials (toxicity, exposure and communication) and life cycle assessment.

www.TNO.nl
10 Appendix II – Participants

Agentschap NL
Deining Maatschappelijke Communicatie
DSM Ahead B.V.
FME
GL Plastics
Holland Colours
KWR
Ministerie van EL&I
Ministerie van EL&I
Nanocyl
Nano-FM B.V.
NanoLabNL
NanoNextNL
RIVM
Solvay
SZW
Tata Steel
TNO
Umicore
Universiteit Utrecht
Van Gansewinkel
VION Food Nederland
VVVF
Wetsus

Safe Design of Nanomaterials – Paving the way for innovation (2012); Action plan and green paper.