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TNO report

Literature review on risk governance at the company level

Date December 2011

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Number of pages 46 (incl. appendices)
Project name Literature review on risk governance at the company level
Project number 031.21201

Management Summary

Title	:	How to Organise Risk Governance at the Company Level Literature Review
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Date	:	1 December 2011

Summary

This literature review on Risk Governance is part of a TNO research programme on the safety of innovative substances and technologies in the workplace. The purpose of this review is to investigate how risk governance can be applied in the workplace when dealing with uncertainties regarding the (health) risks of these technologies, and with the related responsibilities. The review gives an overview of the current state of affairs of risk governance as a concept, and more specifically examines what is taking place in (workplace) practice. The review focuses more specifically on the relationship between risk governance and working with nanotechnologies. The review will be used as input and (scientific) background for future case studies to see if, and how, risk governance can be applied in workplace settings.
From the state of the art of (international) research into the concept of risk governance we can conclude that the concept is best known and most often referred to as the framework of risk governance presented by the International Risk Governance Council (IRGC) in 2005. This concept was developed and is used to analyse risks at the macro level, for example to analyse the BSE crisis or Hurricane Katrina. At the company level, risk governance is not yet explicitly addressed, for example as part of policies on occupational health & safety (OHS), despite the international and national process of deregulating responsibilities. However, some elements of a risk governance approach can be found in some (larger) companies. Current company practices, especially in the field of working with new, emerging technologies and substances (e.g. nanotechnology) can be seen at leading companies, such as the Nano Risk Framework of DuPont and the BASF Dialogue Forum Nano 2009/2010. Other measures taken at the company level to direct working safely with nanotechnology include the Nanosafety Guidelines of the Delft University of Technology, Stoffenmanager Nano and Handleiding Nano. A Swiss risk assessment matrix and a French Control Banding Tool are being used in other EU Member States. We have also noticed that leading companies like DSM, BASF and DuPont are starting to implement in-company codes of conduct or (parts of) the EU Code of Conduct on Responsible Nanotechnology Research & Development. Lots of ad-hoc measures are being taken in a fragmented way, and the precautionary principle is too often incorrectly understood as the equivalent of putting a moratorium in place. Altogether, the application of a wider approach to risks is still absent. Companies seem to be sticking to risk assessment and management in a rather traditional manner, and are disregarding the need to include concern assessment and concern management. The result is that barriers are thrown up that hinder the introduction of innovative technologies (e.g. nanoproducts).

The study of the literature implies that dealing with uncertainties (how can we govern our risks) will have to be given a more central place in society – not only at the macro level, but especially at the company and organisational level where national regulation and legislation (enforcement) can no longer be the guiding principle for the management of uncertain risks. In the case of nanotechnologies it has been estimated that the collection of all the scientific data needed to enable the traditional classical risk approach to be fully effective might take up to several decades, if it even proves possible at all. This demonstrates that we need to develop alternative approaches for dealing with uncertain, complex and ambiguous risks. As central elements of this approach, uncertainties will have to be explicitly addressed and discussed, and the (meaning of the) precautionary principle will have to be further elaborated and agreed upon. Moreover, when risks are increasingly uncertain and ambiguous, the active involvement of an even wider group of experts and stakeholders will be necessary.

It is recommended to stress and communicate the need for companies to adopt a wider approach to risk assessment and management which includes concern assessment and management as well, in order to reach a balance between the opportunities and risks of innovative technologies.

Some practical recommendations at the company level are, firstly, to re-frame the concept of risk governance at the company level, together with the companies: what does dealing with uncertainties mean in terms of company policy. Secondly, to look more closely – together with companies – at the phases as presented in the IRGC Framework: Pre-assessment, Risk Appraisal and Risk Management at several company levels (internal, external and with stakeholders in the company supply chain). Thirdly, to design (together with companies) a more explicit role for communication as positioned in the current risk governance model, in order to draw up guidelines and recommendations on how to implement risk governance. Fourthly, the implementation of the EU Code of Conduct on Responsible Nanotechnology Research & Development is an interesting first step and starting point for developing risk management (OHS) guidelines for risk governance together with companies in order to enable companies to deal with uncertainties and responsibilities. A further aim is to identify at the company level how and where the concept of risk governance can be linked to other company policies, such as corporate social responsibility, resilient engineering and sustainability. And finally, to develop practical tools and guidelines that complement current risk assessment and management tools for substances (e.g. Stoffenmanager and Stoffenmanager Nano), by adding elements of concern assessment (e.g. stakeholder involvement) and concern management (e.g. risk communication).

All these efforts will support companies in implementing a wider approach to the management of uncertain risks, thus preventing barriers to innovation.

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1 Introduction

Workplaces, like the rest of the world, have to deal with uncertainties more and more frequently. Take, for example, the uncertainties we have to face with the increase of new technologies, problems like BSE, asbestos, accidents in nuclear plants, genetically modified food, terrorism, developments in nanotechnology and natural disasters. These examples are similar in terms of uncertainty about the effects they cause. Other common features of uncertainties are: an uncertain knowledge base, unknown cause and effect, and involuntary exposure to the risk (if the situation is interpreted as a risk at all). The effects can be destructive for society and can easily cross borders.

Recently, in Europe we have witnessed the impact of problems regarding infection with the unknown strain 0104:H4 of the EHEC bacterium. In the first stage of this infection, mainly in Germany, it became clear that knowledge was not available and that individuals were not being exposed voluntarily. It was proof of total ignorance of the causes and sources of the infection, and therefore presented a situation that was uncontrollable for individuals. The most plausible suggestion (as a result of the earliest investigations) that infected cucumbers were the cause was taken as input for prevention. Anxiety in the whole of Europe led to extrajudicial measures that were somehow out of proportion (the destruction of lots of fruit and vegetables, with significant losses for businesses).

This example shows that dealing with uncertainty and uncertain risks is difficult. For politicians, for company management, and actually for society as a whole. Given that adequate knowledge and information is not available, and therefore is uncertain, society asks for certain answers and information. At the company level we face more or less the same dynamic. According to Occupational Health & Safety (OHS) policies, when working with new technologies and in the presence of new (not yet known) uncertainties, people first make a traditional risk analysis rather than accepting the uncertainties. This sounds reasonable, as acceptance of uncertainty is complex, unnatural and in some cases not desirable. However, the increase of uncertainties entering the workplace will require new OHS policies. As uncertainties are characterised by complex causalities, and often influenced by the whole of the company's safety chain, new decision-making processes and ways of communicating what to whom need to be taken into account.
The concept of risk governance was introduced in 2005 by the International Risk Governance Council as an integrated method for dealing with new risks and uncertainties in the management of (potential) risks that arise with the emergence of new technologies. This TNO literature review on Risk Governance is part of a TNO research programme on the safety of innovative substances and technologies in workplaces. The purpose of this literature review on risk governance is to investigate how risk governance can be applied in companies when dealing with uncertainties and responsibilities. The literature review gives an overview of the current state of affairs of risk governance as a concept, and more specifically examines what is taking place in (workplace) practice. The review focuses more specifically on the relationship between risk governance and working with nanotechnologies. Outcomes of the review will be used as input and (scientific) background for case studies to investigate whether and how risk governance can be applied in workplaces when working with nanotechnology.

The review will also try to identify relevant theories and research in the field regarding the application of risk governance in practical (workplace) settings. Finally, the review will determine whether or not there are gaps in research and knowledge regarding practical application in the workplace.

2 Scope of the review and research questions

In general, literature reviews are conducted to identify what has been researched and written recently concerning the field under review. But such reviews are also used to identify and determine whether or not there are gaps in knowledge and research.
Our aim for this literature review on risk governance is closely connected to this general idea behind conducting a review. Our main research questions are:

Q 1: What is the current state of affairs of (international) research into the concept of risk governance? And, more specifically:

Q 2: What research has been done into the application of risk governance in relation to health and safety policies in companies when working with new, emerging technologies and substances (e.g. nanotechnology)?

Q3. What current practices exist that can be related to risk governance (codes of conduct, etc.)?

The answers to Questions 1, 2 and 3 should provide a background for and help to add focus to further research within the TNO research on risk governance programme.

Literature has been searched in Pub Med (42 references) and Scopus (122 references).
Search strings: Risk Governance – Risk Management- Governance of New emerging risks – Risks – uncertainty management
In addition, existing contacts with and information from internet research groups working in the field and information on current and former projects have provided various reports and articles. Secondary references in the articles and reports retrieved provided useful publications as well.
The literature review on risk governance was carried out in the following steps:

(1) To find out what the current propositions defining risks and risk governance as characteristic aspects of modern societies are.
(2) To identify what has been written and researched (recently) about the subject of risk governance in general and in relation to substances, and more specifically in relation to nanotechnologies.
(3) To identify relevant theories and research in the field in relation to the application of risk governance in practical (workplace) settings.
(4) To determine whether there are gaps in research and knowledge regarding practical application in the workplace.

This literature review is an important starting point to further explore what risk governance can mean for workplaces. However, we would like to point out that a literature review does not stand on its own. In this report we will also analyse signals from society and companies in relation to risk governance that merit further research. We would therefore like the review to be seen as part of an iterative process (see figure 1).

Figure 1: Iterative process of the review on risk governance in workplaces

3 Risk Governance, definitions and state of affairs

In this chapter we will review the on-going development of risk governance as a global concept for managing risks. What are the main principles? And how are these principles used to intervene and prevent various types of risk?

3.1 World risk society 2011

The German sociologist Ulrich Beck introduced the term “World Risk Society” at the end of the 20th century, claiming that many of the technologies that are introduced (or are to be introduced) in a modern technological society entail risks that are characteristically different from the dangers in the past (Beck,1986). In his work, Beck characterised contemporary society as a society preoccupied with risk and with the distribution of risk. At the same time, he defined modern technological society as one that allows scientists, engineers and industry to develop and introduce all kinds of new technologies that have an (as yet) unknown impact on health and safety while simultaneously it is a society that fails to hold anyone accountable and liable for these side effects (organising irresponsibility). Beck’s work (1985, 1995) showed the need for reorganising the responsibilities that arise from new technologies and for involving many stakeholders.

In 2011, the use of new technologies is increasingly becoming a part of business and working processes. In the workplaces of today, work practices and processes are continuously changing due to further globalisation and shifting economic and social conditions. Globalisation refers to the process of increasing the connectivity and interdependence of the world’s markets, businesses and production processes by means of information technology. These changes have brought new risks. The increasing complexity of the supply chain is resulting in new risks of disruption, uncertainty about the quality of (semi-finished) products and safety problems related to used materials and chemicals. Moreover, foreign incidents and disasters have a swift and large impact on production processes. New (health and safety) risks and challenges are entering the workplace (cf. Houtman et al., 2008).

3.2 Terminology, meaning and characterisation of risk

The meaning of risk can be remarkably different and the risk terminology we found in the current literature is very broad, so that we can lists terms such as risk assessment, risk analysis, risk management, risk communication, risk regulation, risk governance, risk perception and risk acceptability. A number of definitions can be traced (From the final EU Risk Bridge report, 2009, pp. 10-16):

1. Risk

- The combination of the frequency (or probability) of an occurrence and the consequences of a specified hazardous event (JRC, 2000).
- The expected loss (of lives, persons injured, property damaged and economic activity disrupted) due to a particular hazard for a given area and reference period.
  Based on mathematical calculations, risk is the product of hazard and vulnerability (European Environment Agency).

- The uncertainty of the outcome, either a positive opportunity or negative threat, of actions and events. It is the combination of likelihood and impact, including perceived importance.
- The uncertain consequence of an event or an activity with respect to something that humans value. Such consequences can be positive or negative, depending on the values that people associate with them (Renn, 2005).

The concepts of probability, uncertainty and consequences appear in all the definitions. Nevertheless, they are slightly different: the first one, adopted within the glossary of the Major Accident Hazard Bureau of the Joint Research Centre of the European Commission, stresses the relationship between the probability and consequences of hazards in mathematical terms. The second one, adopted within an environmental assessment context, combines this with the concept of vulnerability, thus extending the characterisation of risk to the context involved. The third one, formulated in a policy-support document, avoids value judgments (i.e. risk is neither negative nor positive), stresses the element of uncertainty, refers to "likelihood" instead of "probability"[1] and introduces a fundamental element: the social perception of risk. The fourth one stresses this last element further and emphasises it by referring to human values.

2. Risk Assessment

- The overall process comprising risk analysis and risk evaluation, in which:
  - Risk analysis refers to the systematic use of information to identify sources and to estimate risk. Information can include historical data, theoretical analysis, informed opinions and the concerns of stakeholders.
  - Risk evaluation refers to the procedure, based on risk analysis, for assessing if the tolerable risk has been achieved (JRC, 2005).
- The procedure in which the risk posed by inherent hazards involved in processes or situations is estimated either quantitatively or qualitatively.
- A process intended to calculate or estimate the risk for a given target organism, system or (sub) population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system. The risk assessment process involves four steps: hazard identification, hazard characterisation (related term: dose-response assessment), exposure assessment and risk characterisation.
- The process of establishing information regarding the acceptable levels of a risk and/or the levels of risk for an individual, group, society, or the environment.

3. Risk Management

- The systematic application of management policies, procedures and practices to the task of analysing, evaluating and controlling risk (JRC, 2000).
- The decision-making process involving the consideration of political, social, economic and technical factors alongside the relevant risk assessment information relating to a hazard so as to develop, analyse and compare regulatory and non-regulatory options and to select and implement an appropriate regulatory response to that hazard.

Risk Management involves three elements: risk evaluation, emission and exposure control and risk monitoring.

[1] Likelihood: the chance that something will happen [noncount]; Probability: the chance that something will happen [count] (www.learnersdictionary.com/search/likelihood).

4. Risk communication

Risk communication is associated with environmental health decision-making on issues such as air pollution, hazardous waste sites, lead, pesticides, drinking water, and asbestos. Risk communication is also used to help promote changes in individual behaviour such as helping people to make informed decisions, for example about continuing to enjoy traditional foods while moderating consumption because of the presence of contaminants.
The National Research Council (NRC) defines risk communication as “an interactive process of exchange of information and opinion among individuals, groups, and institutions that raises the level of understanding of relevant issues or actions for those involved and satisfies them that they are adequately informed within the limits of available knowledge”. The definition includes “discussion about risk types and levels and about methods for managing risks”. Specifically, this process is defined by the levels of involvement in decision-making, actions, or policies aimed at managing or controlling health or environmental risks.
Risk communication can be seen as the process of exchanging or sharing information about risk between decision-makers and other stakeholders (JRC, 2000). An interactive exchange of information takes place about (health or environmental) risks among risk assessors, managers, news media, interest groups and the general public.

5. (Risk) Governance

(Risk) “Governance is the sum of the many ways individuals and institutions, public and private, manage their common affairs. It is a continuing process through which conflicting or diverse interests may be accommodated and co-operative action may be taken. It includes formal institutions and regimes empowered to enforce compliance, as well as informal arrangements that people and institutions either have agreed to or perceive to be in their interest” (Commission on Global Governance, 1995).

To better understand how governance and the management of risks can take place, we will first look at the three frameworks with which the different definitions of risk can be associated (Final EU Risk Bridge report, Van der Vlies et al., p. 12):

1. The natural/applied science domain, where risk is the result of the quantitative integration of the probability and effect of given factors.
2. The applied regulatory domain where risk is the result of the integration of both quantitative and qualitative factors (for example a major accident scenario in relation to its social environmental contexts).
3. The regulatory domain, where risk is not necessarily the object of quantitative estimations but is perceived as the consequence of events that have to be avoided.

Furthermore, in the management of risks it is also important to address the risk characteristics, as these characteristics have implications for how they should be handled. Four types of risks can be distinguished. Table 1 gives an overview of the specifics of the types of risk and of the management strategies and instruments that are currently being used.

Table 1: Type of risks, specifics and management strategies (according to White Paper by Ortwin Renn, p. 47)

Type of risk	Specifics	Management strategy	Instruments
Simple risk problems	Character and extent are well known	Routine-based (tolerability/acceptability judgment) Risk reduction	Applying traditional decision-making
Complex risks	Little insight into harmful effects	1. Risk-informed Risk agent and causal chain 2. Robustness-focused Risk absorbing system	Characterising available evidence (expert consensus, seeking tools). Improving the buffer capacity of the risk target through e.g. additional safety factors.
Uncertain risks	To realise less or to know nothing about changes and risks	Precaution based (risk agent) Resilience-focused (risk absorbing system)	Debate with stakeholders. Precautionary principle (As low as reasonably achievable; best available control technology).
Ambiguous risks	Opinions about risks differ; what is and isn't normatively acceptable	Discourse-based	Integration of stakeholder involvement in reaching closure. Emphasis on communication and social discourse.

3.3 Risk Governance, definition and meaning

3.3.1 What is governance

Since the end of the last century (the 1990s) the use of the concept of risk governance has been advocated for addressing general aspects of decision-making regarding new risks. Tait and Lyall (2006) see the transition from government to governance as a change from a top-down legislative approach to regulation ("powers over") to an approach "to set parameters of the system for self-regulation" ("powers to").
From "powers over" towards "powers to" means a difference in the process that entails:

- Permeable & flexible system boundaries.
- An increasing role for non-governmental actors in policy-making.

- Networks rather than hierarchies.
- Blurring of the boundaries between the public and private sectors.
- A state role that puts more emphasis on facilitating and coordination than on “command and control” mechanisms.
- More centred around “problem solving” than “problem bargaining”.
- Recognising statistical, methodological and epistemological uncertainty (the latter type of uncertainty refers to the acknowledgement that not everything about the relevant social and natural system is known and may even be ignored; the precautionary principle is often put into place to deal with uncertainties).

So, over the last twenty years we see in the social sciences literature an increased tendency in the policy-making process to involve other actors than just the government. Several forms of governance can appear; case studies on food safety and rural policies have shown 3 forms of governance (RIVM report Hajer et al., 2004).

1. Network governance. The core of this perspective is a decentralised concept of social organisation and governance. It can be used as an analytical model, where stakeholder involvement is used to investigate and to analyse, or as a steering model which can be seen as a normative, prescriptive approach.
2. Multi-level governance. From this perspective, the sharing of policy-making competencies takes place in a system of negotiation between nested governments at several levels (supranational, national and regional).
3. Deliberative governance is a more participatory form of governance. Deliberation can be seen as a way of (re)creating new patterns of collaboration.

Some authors differentiate between horizontal and vertical governance (Lyall and Tait, 2004). The horizontal level includes the relevant actors in decision-making processes within a defined geographical, functional or political administrative segment. The vertical level describes the links between these segments (like the relationships between the local, regional and national levels of institutions).

Current governance approaches are mainly focused on problem solving, where the government, civil society and the market are working together in several contexts. It should be noted that governance will not only be used in the context of problem solving. A more participatory (bottom up) approach to deliberately develop new solutions and alternative decision-making processes can help to improve implementation and to build trust.

3.3.2 Framework for risk governance

Risk Governance was first introduced by the International Risk Governance Council (IRCG, Ortwin Renn, 2005) as an integrative risk management concept and is mainly seen as useful for dealing with global uncertainties (Bijker, 2011) .

The IRCG frames Risk Governance as a methodology for handling risk that is comprehensive and context-sensitive. Risk Governance reflects the fact that decisions in modern society are no longer directed and taken by governments only, but are arrived at in networks incorporating all the parties concerned. The

application of such ideas to risks and risk-related decision-making is termed *Risk Governance* (IRCG White Paper, 2005).

Definition of Risk Governance: The identification, assessment, management and communication of risks in a broad context. It includes the totality of actors, rules, conventions, processes and mechanisms concerned with how relevant risk information is collected, analysed and communicated, and how and by whom risk management decisions are taken. (Renn, 2008)

In White Paper no. 1 (IRGC, 2005) the IRGC puts forward an integrated, analytical framework for risk governance that provides guidance for the development of comprehensive assessment and management strategies to cope with risks, in particular at the global level. The concept of risk governance comprises a broad picture of risk: not only does it include what has been termed “risk management “or “risk analysis”, it also looks at how risk-related decision-making takes place when several actors are involved.
The framework contains two innovations for looking at risks: the inclusion of the societal context and a new categorisation of risk-related knowledge.
The framework breaks down into **three main phases**: 1) pre-assessment, 2) appraisal and 3) management. Communication is positioned in the middle to enable and stimulate all activities in the process of organising risk governance (cf. figure 2).

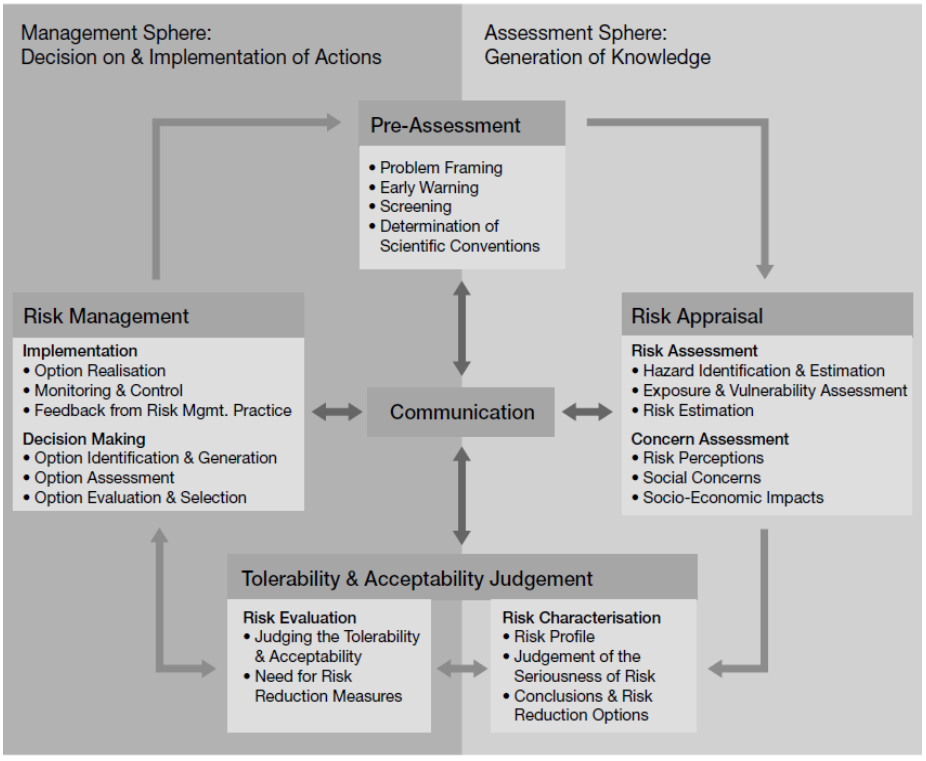

Figure 2: IRGC Risk Governance Framework (White Paper, IRGC 2005, p. 13)

In its White Paper (2005), the IRCG extensively describes the purpose and actions to be taken in all phases of the Risk Governance framework. In summary, the most important aspects are as follows:
The purpose of the **pre-assessment phase** is to capture both the variety of issues that stakeholders and society may associate with a certain risk as well as existing indicators, routines, and conventions that may prematurely narrow down, or act as a filter for, what is to be addressed as risk. What counts as a risk may be different for different groups and actors. Pre-assessment consists of four steps in order to provide the knowledge base for the decision as to whether or not a risk should be taken and, if so, how the risk can possibly be reduced or contained.

In the **risk appraisal** phase of the framework a *risk assessment* is done. The risk assessment concerns the complexity, uncertainty and ambiguity of risks. It is a challenge to understand when and how one has to deal with what kind of risk category. The assessment seeks to link a potential source of harm, a hazard, with the likely consequences of the latter. Confirming the results of risk assessments can be extremely difficult, in particular when cause-effect relationships are hard to establish.

Risk characterisation and evaluation aims at judging risk acceptability and/or tolerability. Risk characterisation consists of scientific evidence based on the results of the appraisal phase. Risk evaluation assesses broader, value-based issues that also influence judgment and therefore extend beyond the risk itself, as the outcomes influence policy-making and the societal balance of risks and benefits.

The **risk management phase** designs and implements the actions and interventions to tackle risks with an aim to avoid, reduce, transfer or contain them. A risk management strategy can be drafted based on the dominant characteristic of each of the four risk categories (simple, complex, uncertain and ambiguous).

Risk communication is of major importance in the risk governance process throughout the handling chain. Risk communication is therefore centred on the model of risk governance (cf. figure 2). Risk communication should enable stakeholders and civil society to understand the rationale of the results and the decisions from the risk appraisal and risk management phases. Effective risk communication should foster tolerance for conflicting viewpoints, and create trust in the institutional means for assessing and managing risk and related concerns (White Paper, IRGC 2005, pp.11-15).

Risk communication has a dual function:
1. To establish a close communication link between all those involved in the pre-assessment and judgments of risks.
2. To communicate risk to the outside world. This requires extensive consideration of the viewpoints and agendas of the media, general public, etc., in order to bring across objective information on the risks. It should take into account that communication about acute risks needs a different approach than that for risks over a longer period of time.

Furthermore, it is important to consider that risk communication and trust are interconnected processes (Marjolein B.A. van Asselt & Renn, 2011) in the sense of:
- Sharing information.

- Building up and sustaining trust among the various actors.
- Involving people in risk-related decisions.

Given this current situation, the question arises of whether the concept of risk governance, which is seen as a new concept in the management of risks (as it looks into uncertain risks from a multi-stakeholder point of view) adds a new perspective to the assessment and management of uncertainties in workplaces. Currently, the concept of risk governance, based on the Risk Governance Deficits method (IRGC, 2009) is mainly used at the macro level. Several cases (on both a societal and a global level of analysis) have been analysed by means of the risk governance model, such as:

- The Bovine Spongiform Encephalopathy (BSE) Epidemic in the UK.
- Electromagnetic Fields: Mobile Phones and Power Lines.
- Fisheries Depletion and Collapse.
- Genetically Modified Crops in Europe: Decision nodes and incubation periods in generating a risk governance deficit.
- The Response to Hurricane Katrina.

(IRGC, 2009)

The conceptual as well as the normative basis for risk governance has been reviewed recently by Renn, Klinke and Van Asselt (Ambio 2011 40: 231-246) by looking into some basic lessons taken from various articles on understanding risk governance in practice. This analysis process led to some suggestions for changes to the risk governance framework as proposed by the IRCG (cf. figure 3).
Some interesting notions:

- The idea of risk governance is to support a paradigm shift that helps risk professionals to familiarise themselves with a broader concept of risk.
- Interdisciplinary risk estimation should be emphasised more, in order to frame risks in a more deliberative way.
- Governance is used in both a descriptive and normative sense. The ambition is to show that risk governance is similar to governance in general and provides a conceptual as well as a normative basis for dealing responsibly with uncertain, complex and/or ambiguous risks in particular.
- Deliberation and communication should be at the heart of the governance process. It is not sufficient that communication is organised but rather it needs to facilitate various actors from different backgrounds succeeding in interacting meaningfully in the face of uncertainty, complexity and/or ambiguity (cf. figure 3: A modified risk governance framework, based on Klinke and Renn, in press).
- The aim of communication is to provide a better basis for participation and decision-making, also in terms of trust and social support.
- Social learning is required in order to find ways to discuss uncertainty, complexity and/ or ambiguity.

Worth noting is the statement that risk governance advocates a paradigm shift in current risk management (Renn, Klinke and van Asselt, 2011). It draws attention to the fact that not all risks are simple. Uncertainties will increase in today's workplaces and most risks can therefore not be calculated as a function of probability and effect. Many risks require societal choices and decisions. This means that several actors should be included in the process of handling risks. Inclusion does not mean that various actors are simply `included`, but also that they play a key role in framing the risk.

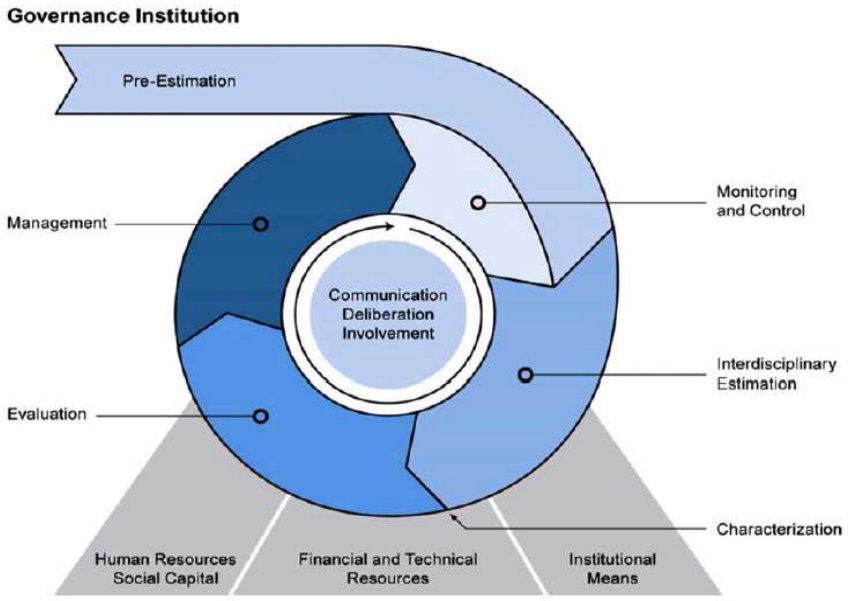

Figure 3: Modified risk governance framework (Renn and Klinke, in press)

In the EU Risk Bridge project (2009), global issues such as climate change , electromagnetic fields, radioactive waste and nanotechnology were also studied and reviewed comparatively from the perspective of risk governance.
Two interesting questions were answered during the project:

(1) What is the analysis of governance good for?

First, it provides risk managers with an indication of where to improve performance and where goals such as accountability, sustainability and fairness can be better achieved. Looking only into the heat of the debate as a thermometer of performance is often misleading.
Secondly, the review showed that some aspects of risk governance are systematically under-represented. In particular, the inclusion of judgments regarding tolerability and acceptability was unsuccessful. Thirdly, the comparative review can help risk professionals to learn from other cases. Having a common framework and identical phases greatly facilitates such learning (EU Risk Bridge report, 2009, p. 337).

(2) How does the IRCG framework function in practice?

In the Risk Bridge project, cases were deliberately studied from a bottom-up as well as a top-down approach. The IRCG framework is considered a top-down approach and was applied as a structural instrument for analytical purposes. It is precisely by combining the two (bottom-up and top-down) approaches that synergies can be found, as new perspectives and insights are developed, especially when starting up new practices. The IRGC approach should, therefore, not be applied as a rigid technocratic model or a blue print for risk governance processes.

The case studies conducted in the Risk Bridge project showed that the old linear government style (DAD: Decide, Announce, Defend) does not allow for different frames and cannot include new insights, developments and technologies.

For the implementation of good risk governance processes it is best to develop a step-by-step iterative (cyclical) management process, with feedback loops between framing, action planning, monitoring, evaluation and the inclusion of several stakeholders in the governance process (cf. for example, figure 3). Risk governance requires flexibility, so one should be aware not to connect risk governance to a rigid model (EU Risk Bridge report, p. 346).

3.4 Resilience engineering and risk governance

A white paper on resilience engineering for ATM (2009) states that the established approaches to risk and safety mainly focus on things that go wrong, more specifically areas like disasters, accidents and incidents. Traditionally, there is little or no focus on things that go right, despite the fact that these happen far more often than the things that go wrong. The focus of resilience engineering is on the whole set of outcomes, i.e. things that go right as well as things that go wrong. The aim of resilience engineering is not only to prevent things from going wrong, but also to ensure that things go right, i.e. to facilitate normal outcomes. The main purpose of resilience engineering is to develop methods and models to improve an organisation's ability to succeed under varying conditions, thereby enhancing both safety and daily operations. Resilience involves aspects like:[2]

- The ability to respond.
- The ability to monitor.
- The ability to anticipate.
- The ability to learn.

Risk governance is mainly aimed at identifying uncertainties within organisations and, even more importantly, in the entire safety and supply chain. We consider risk governance and resilience engineering to be complementary at the organisational level as important drivers to develop a learning organisation. Both concepts promote transparency and open communication in order to stimulate stakeholder- and public engagement and to enhance learning, support and acceptance.

3.5 Corporate social responsibility and risk governance

Corporate social responsibility (CSR) was defined by the European Commission as a concept whereby companies integrate social and environmental concerns into their business operations and into their interaction with their stakeholders on a voluntary basis. To be socially responsible means going beyond fulfilling legal expectations by also investing more in human capital, the environment and relations with stakeholders (European Agency for Safety and Health at Work, 2004). Safe and sound working conditions and good worker health are among the social responsibilities of companies and can be regarded as an integral part of CSR. Three aspects of the social dimension of CSR are: *internal aspects* like human resource management, health and safety at work (OHS), business ethics, compliance, organisational learning and employee participation; *external local aspects* such as local corporate citizenship that requires cooperation with business

[2] http://www.resilience-innovationlab.org/the-resilience-analysis-grid

partners, local authorities and local NGOs; and *external worldwide aspects* such as human rights, global environmental concerns, and safety and health at supply companies that require communication with consumers, investors, globally operating NGOs, etc.
CSR raises new issues for the managements of companies, such as the importance of broad stakeholder involvement and the adoption of innovative measures. Case studies (Zwetsloot, Starren, 2004) show companies that practice CSR have a clear interest in safety and health at work, as poor standards may harm their image.
An interesting observation in these studies is that companies that practise an active CSR policy are broadening their policy arena for health and safety.
The involvement of civil society, the mass media and NGOs is playing a more substantial role in this field. Obviously, CSR can be linked to risk governance, as business practices from the CSR point of view means acting responsibly towards people, the planet and profit (the so-called “3P’s”). Also, health and safety is an important dimension when companies need to project a positive image to the public and to potential employees as well as investors and stakeholders. Moreover, communication with stakeholders (internal, external, and within the supply chain) is paramount to the successful implementation of CSR.

New technologies and substances entering workplaces not only influence traditional OHS policies but also have consequences for CSR, as traditional work becomes increasingly influenced by:

- Other involved parties (especially NGOs).
- The involvement of ethical issues.
- The social impact of products.
- A stronger link with human resource management (such as addressing the meaning of work and a correct work-life balance).
- A broader geographical perspective.
- Non-regulatory, private initiatives.

Especially in the non-regulatory field, for example in the increasing use of nanomaterials in workplaces, voluntary initiatives will increase (cf. figure 4).

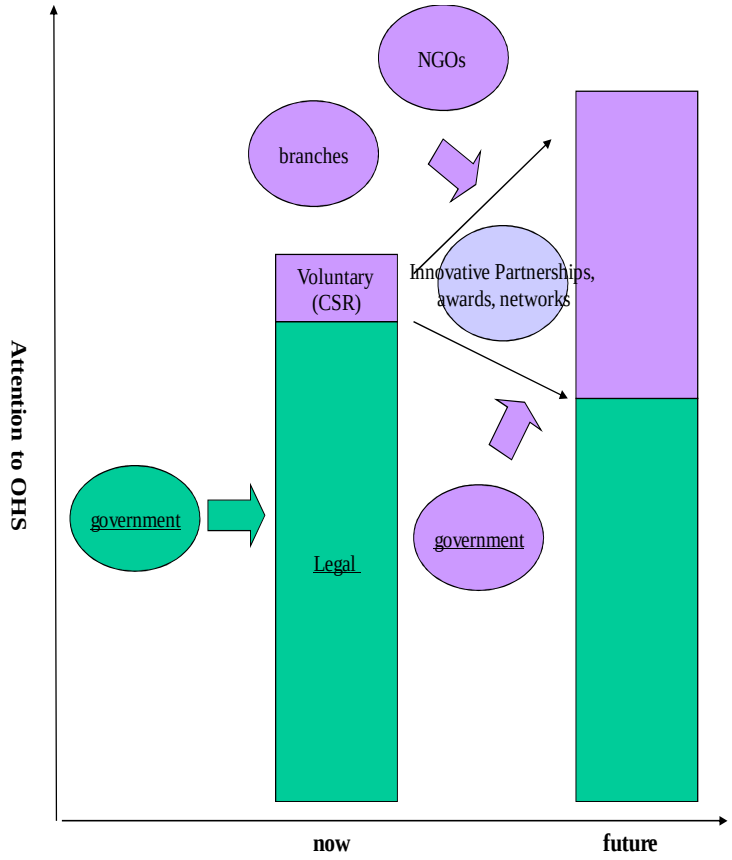

Figure 4: Increase in future non-regulatory arrangements (Starren, Zwetsloot, 2004)

3.6 Risk governance at company level

The global developments referred to above have shown that in the use of new technologies and substances it is becoming necessary to look beyond traditional methods of risk management at the company level. Employers, employees, government and society as a whole are increasingly aware of the fact that absolute safety is not possible. Moreover, in today's society we actually have to deal with risks and the safety paradox (Beck,1986). Working with new technologies and substances brings with it more and new uncertainties we have to deal with, in daily life and in the workplace. But the way in which we communicate about risks and uncertainties at the level of society as well as at a community and company level has also been undergoing enormous changes. Risk communication is no longer expected to be linear (as it used to be – from experts and government – top-down) but needs to fit into the world of Web 2.0 given that citizens have easy access to knowledge and information through social media and the internet. The use of several social media (twitter, Facebook, LinkedIn) makes it easy to share the latest information and not to be dependent on experts. Ways of organising upstream communication need to be further explored.

Moreover, societal changes and new (emerging) risks urge companies to build their own resilience against systemic risks by, for example:

- Conducting risk audits, which include contingency and disaster management plans.

- Stress testing for low-probability disaster scenarios.
- Examining and enhancing industry codes of conduct.
- Working with governments to monitor risk aggregation and educate society and workers to ensure the nature of risks is understood.
- Developing and using methods to involve major stakeholders in decision-making processes involving uncertain risks.

Some (new) risk problems are more than just making a calculation (risk = exposure, hazard or chance; the traditional risk approach). Uncertainties and different perceptions can lead to balancing the ambiguity of risks in society with the various interests of stakeholders, which are at stake as well. This implies that dealing with uncertainties (how can we govern our risks) will have to be given a more central place in society – not just at the macro level, but especially at the company and organisational level, whereas national regulation and legislation (enforcement and compliance) can no longer be the guiding principle for the management of uncertain risks. For example, in the case of nanotechnologies it has been estimated that the collection of all scientific data needed to enable the traditional risk approach might take up to several decades, if it even proves possible at all. This demonstrates that, in addition, alternative approaches to dealing with risks need to be developed. As central elements of this approach, uncertainties will have to be explicitly addressed and discussed, and the (meaning of the) precautionary principle will have to be further elaborated and agreed upon. Moreover, when risks are increasingly uncertain and ambiguous, the active involvement of an even wider group of experts and stakeholders will be necessary (cf. Box 1).

Box 1: Aspects of an Inclusive Decision-Making Process (IRGC 2005)

- There has been a major attempt to involve representatives of all key stakeholders.
- There has been a major attempt to empower all actors to participate actively and constructively in the dialogue.
- There has been a major attempt to co-design the framing of the issue in a dialogue with these different groups.
- There has been a major attempt to generate a common understanding of the magnitude of any possible risks (based on the expertise of all participants) as well as the potential risk management options, and to include a plurality of opinions that represent the different interests and values of all parties involved.
- There has been a major effort to conduct a forum for decision-making that provides equal and fair opportunities for all parties to voice their opinion and to express their preferences.
- There has been a clear connection between participatory decision-making bodies and the political implementation level.

4 Risk Governance and Nanotechnology

Nanotechnology is an emerging technology in workplaces. This chapter describes the current situation regarding nanotechnology in workplaces. We have been studying the literature on and research into ideas about and ways in which Risk Governance can be applied to nanotechnology. In this chapter we will review the very latest developments in this field.

4.1 Uncertainties caused by the rapid upswing of nanotechnologies

Nanotechnology encompasses research into and the application of nanomaterials, i.e. new materials with at least one dimension of less than 100 nanometres (Brun et al., 2009). The novel aspect of nanomaterials is the fact that they are intentionally produced (engineered) and manipulated such that they get very specific, desired properties. This is what distinguishes nanomaterials from naturally occurring or unintentionally produced ultrafine particles, such as volcanic ash or diesel motor emissions. Indications from toxicity testing show that nanomaterials may possess a specific toxicity that distinguishes them from similar substances on the non-nano scale, and that they may cross borders in the body that non-nano substances do not cross (Kosk-Bienco et al., 2009; Brun et al., 2009; Gezondheidsraad, 2006).
In an extensive expert consultation meeting of the European Agency for Safety and Health at Work, the risks posed by nanoparticles were by far the highest, and were agreed to be an “emerging chemical risk” related to occupational safety and health (Brun et al., 2009). Nanoparticles and the products that contain them are appearing in more and more workplaces at an increasing pace, although the variety of major applications in end-products is still rather limited and is focused on coatings and cosmetics (Borm et al., 2007; Pronk et al., 2011; Brun et al., 2009; Cornelissen et al, 2010). Nanotechnology is expected to grow rapidly, and in fact already *has* over the last 10 years (Brun et al., 2009).
At the same time, however, neither the probability of exposure to nor the hazards (toxicity) of nanomaterials are well-defined at the moment (Brun et al., 2009). Thus, the actual risks are accompanied by many uncertainties. According to one of the gurus of nanotoxicology, Andrew Maynard, it is not to be expected that this knowledge gap will be bridged soon. On the contrary:

“Quantitative toxicology and risk assessment are unlikely to keep pace with the accelerating development of emerging sophisticated materials [including nanomaterials], *meaning there will be a **growing** knowledge gap between the materials being produced and the knowledge needed to ensure their safe use”* (Maynard, et al., 2010).

The authors further add to this conclusion:
“Bridging this gap will require new approaches to evaluating risk and making decisions in the face of potential risks where there is incomplete information on exposure, hazard and response” (Maynard et al., 2010).

Within the framework of various national programmes as well as EU programmes (of which the 6th and 7th Framework Programmes are the most important) considerable resources have been allocated to study the potential health risks of occupational exposure to nanomaterials (Brun et al., 2009). In addition, international

bodies such as ISO, OECD and WHO have taken up the issue (WHO, 2010; ISO 2011, OECD, 2011). However, investments in nanotechnology development still by far outweigh investments in risk research (Brun et al., 2009). Nanotoxicologists point out that a common toxicological mechanism may play a role in certain aspects. This is mainly based on the nanoparticles' large surface area and consequently large surface reactivity, giving rise to oxidative stress and a range of diseases resulting from this. At the same time, however, individual nanomaterials should be evaluated on the basis of their own specific properties (Brun et al., 2009). The health risks of nanotechnology in general do not exist.
Moreover, it has been estimated that a full risk assessment of nanomaterials on a case-by-case basis would cost up to 1.2 billion euros, and would take 34 to 53 years to be fully implemented (Von Schomberg & Davies, 2010).

Gaps in regulation
Several drawbacks are preventing the implementation of current OHS regulations specific to the case of nanomaterials, and/or the development of additional regulations where needed (Vogelezang-Stoute et al., 2010). The most pressing need is an internationally agreed definition of nanomaterials which was (as of July 2011) still lacking (Ministry of I&M, 2011). The European Commission has made attempts to arrive at an agreed definition, but stakeholder consultations have not yet resulted in an agreement (Liden, 2011; RIVM, 2011).
The European Commission concluded that generally, the current regulatory framework is sufficient to deal with the risks of nanotechnology (EC, 2008). However, there are several issues to deal with (Vogelezang-Stoute, 2010; EC, 2008):

- The question of whether nanomaterials should be treated as new substances in the REACH regulation (while the chemical formula remains the same).
- Whether the current threshold of 1 tonne for inclusion into the REACH regulations should be dropped for nanomaterials, because their weight is often negligible, while the particle numbers present may be significant.
- As long as Occupational Exposure Limits cannot be defined on the basis of a health risk assessment, and as long as it is not known which metrics to use (e.g. weight or particle number) implementing an OHS regulation is difficult. In some countries, such as the Netherlands, the UK and Germany, initiatives have been started to develop and use temporary nano reference values based on precaution (Dekkers and De Heer, 2010).
- Due to the existing thresholds based on weight and a lack of classification on the basis of health risks, nanomaterials are often not yet stated on Material Safety Data Sheets, thus hampering companies' OHS policies.
- Similarly, the labelling of products that contain nanomaterials is not obligatory in most cases. However, the latest amendment to the Cosmetics directive is an exception, as it encompasses the obligatory labelling of nanomaterials in cosmetic products.
  Regarding the labelling issue, several authors have questioned the usefulness of labelling in all circumstances, as this may give rise to unnecessary fears in some cases (Johnson, 2011).

In 2006, the Dutch Health Council concluded that the best way of stimulating nanotechnology and the nanosciences would be to carefully deal with the risks, and that risk governance as defined by the IRGC may offer the opportunities to do so (Gezondheidsraad, 2006).

Case: a coatings supplier and a customer in a deadlock
An SME manufacturer of self-cleaning coatings that contain nanoparticles got in contact with a company that is responsible for the maintenance of train carriages. They offered the company an interesting business case: the nano-coating would considerably reduce the required cleaning frequency. Moreover, the nano-coating was less susceptible to wear caused by UV radiation. Unfortunately, the potential client refused to use the nano-coating, because it perceived the government's stated precautionary approach as being a ban on nanomaterials until all the risks would be fully known. Consultants provided assurances that the current control measures applied when spraying coatings (e.g. full-face respirators) would be sufficient. However, complete certainty could not be given. The maintenance company therefore persisted in its refusal as long as it could not be supplied with a written licence to operate from the Labour Inspectorate, for example.

´Late lessons from early warnings´
In 2001, the European Environmental Agency published the report entitled Late Lessons from Early Warnings, in which a number of cases were described of technologies that caused untold damage because early warnings about safety problems had been ignored. The lessons outlined in that report were applied to the nanotechnology case by Foss Hansen and co-workers (2008). The authors feared that "*we are still in danger of repeating old, and potentially costly, mistakes*". In order to prevent this, they defined a number of general recommendations:

- Facilitate learning (prevent institutional ignorance caused by monodisciplinarity).
- Stay in the real world (don't be too optimistic about controls, and use workers' and users' information about real world situations).
- Consider wider issues (if the predicted pros of nanotechnology do not come true or if the potential cons (risks) are not investigated but later prove to be significant, public trust may be lost).
- Retain regulatory independence (of stakeholders).
- Avoid paralysis by analysis: do not continue asking for more information as a substitute for action, but act on what we know now.

4.2 The IRGC risk governance framework applied to nanotechnologies

As early as in 2006, the IRGC's risk governance framework was applied to the nanotechnology case in an extensive paper (Renn & Rocco, 2006). The authors stated that the existing concerns about risks connected with nanomaterials, along with the relatively low level of information on nanotechnology that is available, and low public trust in industry and the government may lead to an increasing risk of "poor public perception". Furthermore, the existing regulatory uncertainty is hampering industrial innovation.
The authors point out that four generations of nanotechnology should be distinguished, each bringing about different levels of complexity, uncertainty, and ambiguity. Two risk governance frames were defined. The first frame only applies to the first generation of nanoproducts, passive nanostructures. Issues of complexity and uncertainty dominate here, and less so issues of ambiguity. The second risk government frame applies to nanoproducts of the 2nd, 3rd and 4th generations, i.e. active nanostructures, systems of nanosystems and molecular nanosystems, respectively. In these types of nanoproducts, which are partly to be expected only in the distant future, the level of ambiguity is much higher, thus necessitating a risk government frame more tailored to those types of issues (Renn & Rocco, 2006).

Some of the other major issues raised in the paper include:

- Avoid the general term “nanotechnology” in debates. This may discredit the entire area of nanotechnology research and applications if an incident were to occur with only one specific material or application.
- Do not perform risk assessments alone, but add concern assessment to the decision-making process.
- Voluntary agreements and codes adopted by industry may sustain public confidence in industry, and in new technologies in general.
- Public awareness is stimulated by trust through open dialogue and action, rather than media hype and stigmatisation.
- Governments will need internationally operating companies as well as NGOs in order to design effective regulation, because of the information lag that government representatives have.
- A major conflict between several NGOs and industry still lies in the question of how much precaution is required when applying nanomaterials.

It was indicated that the IRGC risk governance framework may provide “an orientation for developing a best practice approach to risk governance for emerging technologies” (Renn & Roco, 2006). The authors provided a number of recommendations for several types of stakeholders, including academia, industry, government, NGOs and international organisations. However, a truly practicable approach still remains to be defined.

4.3 Lessons from former public debates on nanotechnologies

As part of the European Commission’s Nanotechnology Action Plan, which deals with taking the opportunities nanotechnology offers while stimulating responsible development, an EC Communication Roadmap on Nanotechnology has been defined (EC, 2010). The aim is to involve all major stakeholders in a continuous dialogue on the opportunities and potential risks of nanotechnology in order to arrive at the desired responsible nanotechnology without hampering innovation.
In this paragraph we will report on a number of studies and practical experiences with public dialogues, which enable us to draw a number of interesting conclusions. Most dialogues focus on the general public but nevertheless many lessons learned may be applicable to dialogues within the framework of occupational health and safety as well.

Ten lessons

In a literature study and a series of interviews with stakeholders involved in the Dutch Nano debates (i.e. 24 NGOs), 10 Lessons for a Nano Dialogue were distilled (Hansen et al., 2008):

General lesson:

1. Distinguish between the risk issue and the broader debate on the impact of nanotechnology.

Lessons regarding the risk issue:

2. Tackle the risk issue. A lack of initiative on the part of authorities threatens the legitimacy of the Nano debate.
3. Involve civil society organisations in policy making.
4. Provide clear information on Nano products, risk policy and uncertainties.

Lessons regarding the wider Nano dialogue:

5. Take care in defining a broadly supported public agenda.
6. Connect to existing discussions.

7. Facilitate the involvement of small civil society organisations that do not have many resources of their own.
8. Be open to the agenda of civil society organisations.
9. Inform citizens on the societal aspects of nanotechnology.
10. Involve citizens on a small scale (e.g., in focus groups or panels).

It was observed that nano discussions are not entirely new and that they also revive existing issues. It was expected that it will take many years of research before reliable risk assessments can be made. Nanotechnology was regarded as a test case for good governance: how can authorities, science, businesses and society as a whole steer the developments, if at all? The Dutch Health Council has adopted the risk governance model of the IRGC (Gezondheidsraad, 2006). In the Dutch Cabinet Vision on Nanotechnology (2006) risk governance is explained and complemented with the policies described in the document “Nuchter omgaan met risico’s” (TK 2006a).
However, up until now, ethical issues have mainly drawn the attention of social scientists and only a small group of policy makers. The same holds true for governance issues, including public participation.
Practically all the Dutch NGOs interviewed regard the *precautionary principle* as important, just like transparency regarding the use of nanomaterials (i.e. labelling) and a broad social dialogue. None of the Dutch respondents were in favour of a moratorium on nanotechnology (Hansen et al., 2008).
All the Dutch NGOs reported to have insufficient capacity to actively follow the Nano dossiers. Their members had, as yet, hardly any questions on nanotechnology issues. The desires most often mentioned by NGOs (all 3x) were: regulations that prevent the marketing of products from which NPs can be freely distributed, activities to raise awareness, capacity building of NGOs, and transparency by companies. The authorities should take responsibility (while authorities in the Netherlands tend to shift responsibility to industry). Authorities should ensure there is an active interaction with stakeholders and a thorough risk communication with the public.
A number of international developments were described in the report as well. The international NGOs that are leading the nano debate were Greenpeace, Friends of the Earth and the Canadian ETC Group. ETC and Friends of the Earth International advocate a moratorium, while Greenpeace does not. However, all the environmental NGOs were of the opinion that a strict interpretation of the precautionary principle is needed.
Regarding existing Codes of Conduct, the EU Code of Conduct for Nanotechnology Research, the Responsible Nanocode (CEFIC), the Nano Risk Framework of DuPont and Environmental Defence, and BASF’s Code of Conduct were identified. It was stated that industry codes are aimed at achieving public acceptance by showing responsible development, proactive implementation of their own standards (before regulation is developed), and stakeholder involvement.
Finally, a number of results from public debates abroad were cited. In a USA survey, 60% of the citizens had little faith that managers of nanotechnology companies would protect the public. In Germany, citizens appeared to trust consumer organisations very much (92%), but industry not that much (32%) and politicians even less (23%).
One general conclusion of the study was, that *ignorance among the public results in a high sensitivity to negative information*. However, awareness of the issues is low, and for NGOs it appeared to be complicated to get the nano issue on the agenda.

The public does not have specific opinions on nanotechnology, but general attitudes towards technology, being either (generally) beneficial or (generally) risky. The NGOs stated that the authorities should take responsibility. They expect clear directions from them. However, authorities tend to shift responsibility to industry, at least in the Netherlands. Finally, it was stated that "*Trust in the messenger is crucial*" (Hansen et al., 2008).

International workshop on National Nano Debates

National experiences with nanotechnology debates were exchanged at an international workshop in 2010 (Anonymous, 2010). Societal dialogues are meant to reinforce democratic control over the development and use of technology. However, generally, there seems to be little enthusiasm to take part in public nano dialogues in most of the countries. The problem seems to be the lack of practical experiences; people do not yet know what nanotechnology really means. It was felt that the results of public dialogue are predictable. No matter what the issue, the outcome is that innovation should not be stopped, that authorities should regulate risks, and that citizens should have freedom of choice. Nevertheless, responsibility demands not only transparency from industry and researchers, but also citizenship from individual citizens and NGOs (i.e. responsible contributions to the debate).
NGO representatives stated that for them, a public dialogue is just one option; campaigning is another option. It was also stated that scientists and policy makers try to rationalise and quantify risks. *The subjective perception of risks among the public is disregarded by them too often*. Important questions to be asked include: who benefits from nanotechnology, who is affected, and what values are at stake. Furthermore, the historic context is regarded as being important. Previous debates affect the current one on nanotechnology. However, the nanotechnology dialogue seems to be less controversial than nuclear power, for example, and less framed.

Conclusions from the Dutch Broad Public Nano Debate

Recently, a review of 35 small-scale public dialogue projects on nanotechnology was carried out, which included a baseline questionnaire as well as an effect measurement survey (Nijkamp et al., 2011). The major conclusions and recommendations from this review were:

- Inform citizens well on the latest developments. Citizens regard good information as being more important than avoiding all risks.
- Provide openness regarding the risks. The more information, the more trust citizens have.
- Pay more attention to the potential (environmental) benefits of nanotechnologies.
- Young people can be reached well by providing training packages to schools and teachers.
- Keeping the information supply up to date deserves ongoing attention.
- Informing stakeholders should be accompanied by activities aimed at shaping and exchanging opinions.
- Small-scale focus groups and workshops are much more effective than the internet for dialogue.
- Concrete, actually existing nanoproducts should be discussed instead of nanotechnology in general.
- Stakeholders with different values and interests should be involved to stimulate discussion.

The main message distilled from the surveys and public discussions with citizens was: go ahead responsibly with nanotechnology (i.e. no stopping of or a moratorium on innovation). Citizens feel that the authorities should keep the responsibility for regulating nano risks. In addition, citizens *do* desire information on nanotechnology. Most concerns exist about food and cosmetics applications.

4.4 Lessons from four EU FP6 projects on nanotechnology governance and debate

A review of the European Commission's DG Research describes the lessons from four EU-projects on nanotechnology and governance (Von Schomberg and Davies, 2010). The EC believes that public policies need to be responsive to evolving public opinion. Nano governance should be seen in its historical context: How did stakeholders behave in previous cases? The early involvement of stakeholders is crucial. In the case of regulating new technologies, the power of governments is limited due to their dependency on the knowledge and cooperation of stakeholders. Promoting (voluntary) codes of conduct is one of the government's few options in the early stages. Furthermore, the authors refer to the EC's Code of Conduct and the Precautionary Principle in their introduction (cf. section 4.5). Subsequently, results and conclusions from five EU projects were described.

The DEEPEN project dealt with the ethics and narratives underlying the public dialogue on nanotechnology. It was stated that nanotechnology governance has to be made more robust and that responsible development is needed. Past experiences with unforeseen consequences (e.g. Softenon) has made the public critical about the potential benefits of new technologies. The policy response has been to promote public engagement: an open, two-way dialogue with the public. Current efforts to do this with nanotechnology are impressive. For the first time there is public policy debate on a technology that is at such an early stage. A body of work has been built. Generally, the public seems to be cautiously enthusiastic about the potential benefits, but concerned about regulation, and uneasy about potential unforeseen effects. People have feelings of powerlessness, a lack of choice and a lack of control. What is needed is to restore public trust by increasing the transparency and accountability of scientific governance – answering questions such as: "Who is looking after the long term?" and "Who will be responsible if things go wrong?" (Von Schomberg & Davies, 2010).

Key recommendations from the DEEPEN project were: 1. Understand the complexity of public attitudes; 2. Engage with enduring public narratives; 3. Public engagement is difficult; 4. Be innovative in engagement practices.
The issue of enduring public narratives was explained: "Concerns about nanotechnology form part of a larger context of concerns about technological society in general (…) and of a much wider sense of anxiety about technologies' effects on our lives". Concerns are structured by enduring stories ("narratives") that are a source of responses to a new technology. E.g. "Opening Pandora's box" or "Messing with nature". Policy makers need to acknowledge how strongly people feel about these issues.
Further to the conclusions described above, the DEEPEN project partners state that current society shows "*organised irresponsibility"*: it allows technologies to be developed and introduced, without the means to hold anyone accountable. Standard repertoires were seen in interviews with industry and NGO

representatives. Chemical companies are concerned about the lack of trust in industry, while NGOs mention the need for concern and precaution. Recent initiatives for Codes of Conduct, and the willingness to discuss these, provide an opportunity to open up these standard repertoires. A key feature of a code is that it creates a public space where a subscriber to the code can be called to account by the other subscribers. Codes of Conduct and proactive third parties may be seen as soft governance structures. What is important is not whether these are effective, but whether they stimulate critical reflection…" (A. Rip in Von Schomberg & Davies, 2010).

The FRAMINGNANO project dealt with designing a Governance Platform for nanotechnology, enabling an open, international, multi-stakeholder dialogue. The starting point for the project was the recognition that even if there are clear cause-effect relations (which is not the case) and knowledge thereof would develop rapidly, knowledge about the effects (of nanotechnology) will inevitably remain dominated by a high degree of uncertainty. Public acceptance can vary greatly with respect to the balance of risks and benefits, and application (e.g. food vs. coatings). Previous cases (e.g. GMOs) have learned that information from industry alone is often seen as biased. Interactive, bidirectional communication is crucial in gaining public confidence. Businesses should be made aware that proactive behaviour helps to avoid burdensome, impractical regulatory actions (Von Schomberg & Davies, 2010).
One of the activities in the project was an in-depth analysis of existing and proposed initiatives for nano regulation and governance (Mantovani et al., 2009). Another important feature of FRAMINGNANO was that it brought together stakeholders from different categories in a series of workshops. In a Delphi Consultation process, 377 stakeholders from a large variety of organisations in many EU member states were consulted. However, only 40 responses were received (Moore, 2010). No less than 33 of these 40 stakeholders were of the opinion that current legislation is insufficient to control the potential risks originating from the use of nanomaterials. However, the majority of the stakeholders thought that it was not necessary to design entirely new regulations. Instead, a combination of adapting existing regulations and introducing voluntary measures would be the best way (Moore, 2010). Furthermore, the authors observed that the extreme positions of a few years ago, i.e. either laissez-faire or a moratorium, no longer apply (Von Schomberg & Davies, 2010).
Various stages in a dialogue on new technologies were identified in the FRAMINGNANO project. In the first stage, the involvement is sought of active stakeholders who are able to make informed contributions to the debate. In the second stage, non-active stakeholders who may be affected by the new technology are also contacted (firstly via the NGOs).
The dialogue on nanotechnology should foster communication between the main players, differentiate between different risks, provide clarity on priorities and actions to be taken, pinpoint responsibilities and make these transparent, and maintain the independence of those communicating with the public. Interventions that are needed were distinguished at three levels: 1. data sharing along the value chain, including labelling; 2. data sharing between industry and regulators (notification), and 3. inter-agency communication (international).

"Data is not necessarily the source of trust". The REACH-principle "No data – no market" may be substituted by "No trust – no market". (One of the stakeholders consulted in the FRAMINGNANO project; Moore, 2010).

The authors identified a lack of convergence on models for engagement, duplication and overlap of activities, and a lack of clarity to the public on how the results of public engagement are taken up and used in practice as problems that might hamper the dialogue. Finally, it was concluded that what is still absent is how to implement the principles defined, and how to respond concretely to concerns. More resources were thought to be needed for defining concrete measures (Von Schomberg & Davies, 2010).
One of the deliverables of the FRAMINGNANO project (www.framingnano.eu) was the design of a proposed structure for a governance platform as presented in figure 4 (Widmer et al., 2010). The proposed platform seems to be an EU-wide activity, which appears to be hard to translate into a practical approach at the company-level.

The NANOPLAT project had a similar aim to FRAMINGNANO, i.e. establishing a permanent deliberative platform on nanotechnologies. The project partners put forward that "we are (perhaps) more sceptical towards science than ever before". Therefore, a more permanent form of deliberation is needed for enabling collective responsibility. The main idea behind the concept of governance is to involve stakeholders in taking responsibility for the dialogue with political authorities. The main elements in this process are openness, participation, accountability, effectiveness and coherence. It was proposed that an alternative to consensus may be tolerated consensus, i.e. agreement on different positions.
The project partners identified over 60 deliberative processes in the field of nanotechnology – national and international – between 2004 and 2010. Thus, a large number of online initiatives are already running, and building synergies is needed. A problem that was identified was that not all stakeholders have the resources needed to play their expected part. For nanotechnology, this might even be the case for almost all the stakeholders.
The elements that are needed for establishing a deliberative platform are an *independent* promoting institution, a more permanent responsibility (instead of a project), and continuous stimulation of the debate to keep the participants interested.
As stated before, however, public debate raises expectations: what will happen with our input? Therefore, the activities should be more closely linked to the decision-making process.

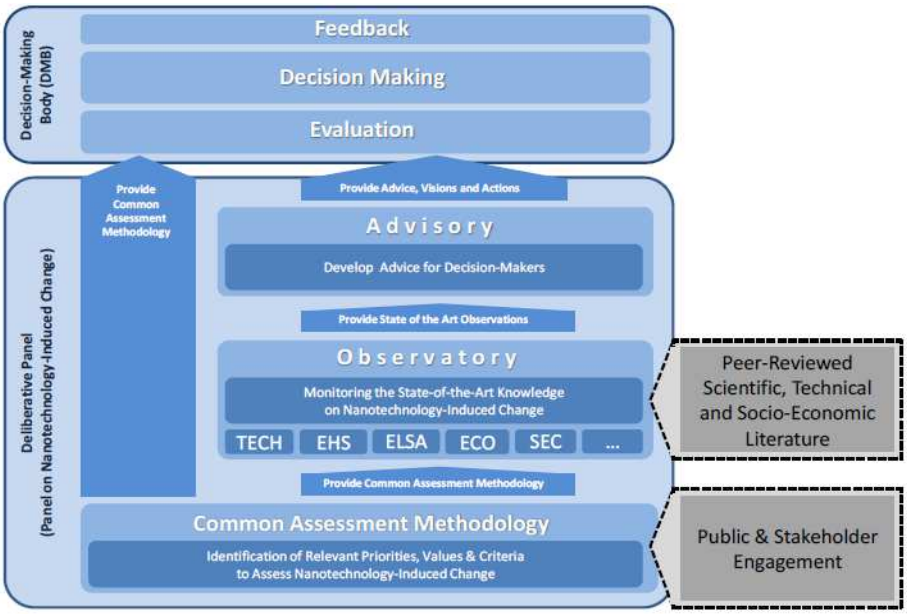

Figure 5: Overview of the proposed structure of the FRAMINGNANO governance platform (Widmer et al., 2010).

The NANOCAP project supported NGOs and trade unions in developing balanced position statements on nanotechnology. A key element in the project was the *precautionary principle*. Central in this is a demand for transparency regarding the use of nanomaterials, the “no data – no exposure” principle (instead of the more extreme “no data, no market” variant), and obligatory notification. The current practice is the opposite of precaution: collective experimentation.
What is needed are practical solutions for companies to put a precautionary approach into practice. Building blocks for a precautionary approach include the “No data, no exposure” principle, notification, exposure registration, transparent risk communication, nano reference values (temporary occupational exposure limits), early-warning systems, and a ban on “nonsense” products. Good practice guidelines should be validated. Furthermore, amended regulation was preferred to voluntary measures such as codes of conducts.
Mutual trust can only be realised by complete openness about nanomaterials and about where knowledge is currently lacking. Hazard information is already partly present, but exposure information is absent. However, product development is not going to wait for scientific evidence of safety or harm (which may in fact never become available).

Feelings of powerlessness and a lack of choice and control among the public (or workers) lead to concerns (DEEPEN project).

“Scientists take the credit for penicillin, but society takes the blame for the bomb.” (Ravet, ’75/Rip, ‘10).

4.5 Current governance tools

A number of governance tools are already available that provide building blocks for nanotechnology risk governance. These include the Precautionary Principle, Codes of Conduct published by the European Commission and industry, the (in the Netherlands) important advice of the Social Economic Council (SER, 2009) and various risk management tools.

4.5.1 The role of the Precautionary Principle

Virtually all publications and communications on nanotechnology and health risks refer to the precautionary principle (e.g. Brun et al., 2009; Kosk-Bienco, 2009; SER, 2009; EC, 2008, Hansen, 2008, Vogelezang-Stoute, 2010, EEB, 2008; Von Schomberg & Davies, 2010; Nijkamp et al., 2010).
The precautionary principle was included in the 1992 Maastricht Treaty, recognising that "Scientific risk assessment cannot provide the full basis for risk management decisions (…) leaving open opportunities for decision-making partly based on ethical issues and particular (…) interests" (Von Schomberg & Davies, 2010).
First of all, it has to be recognised that there is no fixed definition of the precautionary principle and no agreement on the extent to which and the way in which it should be applied. There are strong variants (a moratorium) and mild variants (assessing all the potential benefits and risks) of the precautionary principle (Nijkamp et al., 2010). One concise and practical definition of the precautionary principle was provided by Bijker (2010):
"The precautionary principle implies *taking measures*, because there are well-grounded indications that harm may be done, even though there is as yet insufficient scientific evidence." Thus, the precautionary approach does not mean putting a stop to innovation, for example, but rather taking action (Bijker, 2010). An example of an application of the stronger variant of the precautionary principle is the "No data, no market" principle of REACH. Furthermore, in the NANOCAP project a number of building blocks for the implementation of the precautionary principle in the case of nanotechnology were proposed (see above).

4.5.2 European Commission's Code of Conduct on Nanotechnology Research

In 2008, the European Commission's Code of Conduct on Responsible Nanosciences and Nanotechnologies Research was published (EC, 2008). Member states are called on to implement the code. The EC Code of Conduct implies that risk assessment should have been performed before public funding is provided for a research project involving nanotechnology. The Code assigns responsibilities to all actors beyond governments and advocates their active involvement and collective responsibility (Von Schomberg & Davies, 2010). The Code defines a number of general principles:

- Meaning (nanotechnology research activities should be comprehensible to the public).
- Sustainability (the activities should be safe, ethical and contribute to sustainable development).
- Precaution (the activities should be conducted in accordance with the precautionary principle).
- Inclusiveness (governance of the activities should be guided by the principle of openness to all stakeholders).
- Excellence (the activities should meet the best scientific standards).

- Innovation (the activities should encourage maximum creativity, flexibility and planning for innovation and growth).
- Accountability (researchers should remain accountable for the effects of their research).

Furthermore, it is stated that "*good governance of N&N research should take into account the need and desire of all stakeholders to be aware of the specific challenges and opportunities raised by N&N. A general culture of responsibility should be created in view of challenges and opportunities that may be raised in the future and that we cannot at present foresee.*" Aspects stressed – among others – are the need for an open, pluralistic forum for discussion, easily accessible information, and the sharing of best practices.
Furthermore, the EC Code points out that "*Given the deficit of knowledge of the environmental and health impacts of nano-objects, Member states should apply the precautionary principle (…)".*
What is important is the active identification of knowledge gaps. Problematic in the nano case is that there is not yet a shared understanding of how we might define the acceptability of possible risks, and how to weigh them against potential benefits.

Inventory of voluntary measures in nano risk governance
In September 2008, an international Nano Regulation conference was held, which was sponsored by a number of insurance companies (Meili et al., 2008). Here, a large collection of voluntary measures in nano risk governance was presented, both national and international. The collection was made – and extended after the conference – within the framework of the NanoCode project (Mantovani et al., 2010). The initiatives presented included Codes of Conduct, industry Product Stewardship programmes, Guidance materials (e.g. from the German VCI), dialogue activities and national action plans. The full survey can be found at www.nanocode.eu.

Implementation of the EU Code of Conduct
Within the framework of a Support Action under the 7th Framework Programme, stakeholder consultations were undertaken to evaluate opinions on the EU Code of Conduct as well as on its level of implementation (www.nanocode.eu). Over 400 stakeholders were consulted. The major conclusions were that the awareness and implementation of the Code remain very limited, and that it had not been actively communicated and disseminated by the Commission (Meili et al., 2011). This lack of implementation was confirmed by other researchers, who noted that: "The current EC Code fails to be appreciated as an invitation to dialogue between N&N researchers and decision makers, but is rather seen as an imposition from above with the purpose of controlling the researchers' work (Kjolberg & Strand, 2011).
On the other hand, in the NanoCode survey, many stakeholders indicated that the Code's principles have been implicitly adopted by other means, e.g. internal codes. In fact, 62% of the stakeholders stated that their organisations apply other codes of conduct, principles or guidelines (Meili, 2011). Regarding the EU Code itself, various problems and questions were addressed, such as:

- The question of whether N&N still deserves its own code, or whether its scope should be extended to emerging technologies in general.
- The principles in the Code are too broad and unspecific, and it is hard to derive from it the concrete and verifiable actions that are needed to implement it.

- Parts of the Code gave rise to resistance, in particular the accountability principle. It was felt that individual, fundamental researchers could not be held accountable for the use of technologies. Furthermore, it is not clear who needs to do what to be accountable.
- There is a lack of pressure to implement the Code; incentives or penalties are needed, e.g. implementation as a precondition for receiving funding.

Concerning this last issue, one of the stakeholders stated that “If non-compliance is not tolerated, a voluntary measure is not the tool of choice – not even with incentives” (Meili, 2011). In order to enhance and facilitate implementation, the project partners of the NanoCode project have developed a set of practical criteria that can be used to self-assess the level of implementation of the Code: the Codemeter. In addition, it was recommended to establish an official EU Code of Conduct Information Platform. However, the authors recommend that a number of fundamental issues should be resolved (such as the resistance to the accountability principle) before the implementation of the Code is further stimulated. All the recommendations were reported in a Master Plan on the “issues and options on the path forward with the EC Code of Conduct” (Meili, 2011).

The government should define a set of good practices instead of a Code of Conduct (Dutch SME during the NanoCode stakeholder consultation; Bennet & Chi, 2010).

Nobody is interested in the Code, but might be in its consequences for their products (another Dutch SME during the NanoCode stakeholder consultation; Bennet & Chi, 2010).

4.5.3 Dutch Social Economic Council advice of 2009

In the Netherlands, the advice of the Social Economic Council to the Minister of Social Affairs and Employment - “Dealing safely with Nanoparticles on the Work Floor” (SER, 2009) – has played a central role in the discussion on nanotechnology governance. The Council represents employers’ and workers’ organisations.
The basis of the advice was that substances that have uncertain or unknown health risks, such as nanoparticles, should be treated as being very dangerous substances. Thus, policies and measures should be aimed at preventing or minimising exposure. The application of the precautionary principle was deemed necessary. Companies should apply the precautionary principle to obligatory risk inventories and action plans. As no health-based occupational exposure limits (OELs) can be provided as yet, according to the Council this implies that employers should aim at *preventing* exposure to nanoparticles, and if that is not possible, at keeping the exposure *as low as possible*. In order to help companies implement the precautionary principle, good practices and additional guidance should be developed. Furthermore, temporary OELs (reference values) should be established, and the possibilities of notification obligations, an obligatory statement of nanomaterials in Material Safety Data Sheets, labelling, exposure registries for workers and early warning systems (health monitoring) should be investigated.
As a result of this advice, several tools have been developed in the Netherlands (see below), which are currently being developed further.

4.5.4 Industry Codes and Position Papers

BASF's Code of Conduct Nanotechnology (www.basf.com)

One of the first companies to manufacture nanomaterials, BASF, has developed a Code of Conduct as well as internal safety guidelines and an external nanodialogue process. The Code of Conduct contains – among other things – the following main principles regarding the potential risks of nanotechnology:

- *The protection of human life (…) is a fundamental principle for our company.*
- *We identify sources of risk for its employees and eliminate these using appropriate measures.*
- *In the event of any health hazards, we take immediate action.*
- *We take risks seriously and work continuously to identify potential (…) health risks.*
- *We are actively engaged in the on-going development of a scientifically based database for the assessment of potential risks.*
- *We actively debate the opportunities and risks of nanotechnology with partners from all areas of society.*
- *Wherever existing legislation and guidelines have not yet taken developments in nanotechnology into account, BASF contributes constructively to drawing up legislation.*
- *BASF only markets products if their safety (…) can be guaranteed on the basis of all scientific information and technology.*
- *We provide our customers and logistics partners with information (…).*
- *Economic considerations do not take priority over safety and health issues.*
- *We are committed to transparency and to an objective and constructive public debate.*
- *We disclose new findings to the authorities and the public immediately.*

CEFIC statement on Responsible Production and Use of Nanomaterials

The European Association of the Chemical Industry (CEFIC) published this statement as an application of its Responsible Care programme to nanotechnology. CEFIC states that "companies and chemical associations actively participate in the debate around the safety of nanomaterials and the need to adopt risk analysis and risk management according to the precautionary principle as developed by the European Commission." Furthermore, the six core principles of the Responsible Care Global Charter are mentioned and applied to the nanotechnology case:

- *Continuously improve the environmental, health and safety knowledge and performance of our technologies, processes and products over their life cycles so as to avoid harm to people and the environment.*
- *Use resources efficiently and minimise waste.*
- *Report openly on performance, achievements and shortcomings.*
- *Listen, engage and work with people to understand and address their concerns and expectations.*
- *Cooperate with governments and organisations in the development and implementation of effective regulations and standards, and to meet or go beyond them.*
- *Provide help and advice to foster the responsible management of chemicals by all those who manage and use them.*

Furthermore, national and company-specific codes and guidelines on the responsible production, handling and use of nanomaterials are cited, including

those of BASF, Bayer, Du Pont, Nanocyl HSE, the Carbon Nanotubes Producers (PACTE), UIC, VCI (Germany) and Federchimica).

DSM´s position paper on nanotechnology (www.dsm.com)
The chemical company DSM has issued a position paper on nanotechnology, which contains the following main points:

- *DSM regards nanotechnology as a very promising help to realise our major aim: to make peoples life healthier, more sustainable and more pleasant.*
- *By means of risk analyses, taking into account known as well as potential risk factors, the risks of nanotechnology will be mapped and subsequently reduced.*
- *A proper exchange of information with our suppliers, employees and clients in the entire supply chain is a major prerequisite for a safe use of nanomaterials.*

Position paper CRO Forum/ Swiss Re
The so-called CRO Forum, a group of 9 large international insurance companies, has published a Nanotechnology Briefing and Position Paper (CRO Forum, 2010). It was observed that “nanotechnology presents the insurance and risk management industries with significant challenges and opportunities. Central to these are the relatively unknown environmental, health and safety exposures (…)”. It is stated that this uncertainty has a direct impact on the potential effectiveness of risk management, the availability of insurance risk transfer products, and the ability of insurers to establish suitable reserving practices (CRO Forum, 2010).
The insurance companies indicate their willingness to cooperate with other nanotechnology stakeholders to close the knowledge gaps, and to enable proprietary risk assessments. “The insurance industry’s primary interest is to promote risk awareness, risk management and above all, insurability” (CRO Forum, 2010).

Nano Risk Framework – Du Pont and EDF
In close cooperation, the chemical company Du Pont and the environmental NGO Environmental Defence Fund have developed a Nano Risk Framework.[3] The framework offers guidance regarding the key questions an organisation should consider when developing applications for nanomaterials, and on the critical information needed to make sound risk evaluations and risk management decisions. The framework allows users to address areas of incomplete or uncertain information by using reasonable assumptions and appropriate risk management practices. In addition, the framework offers guidance on how to communicate information and decisions to stakeholders.[3] One of the novel aspects is that the framework recommends the development of so-called “base-sets” of information on specific nanomaterials in specific applications. The actual framework consists of six steps:

1. Describe material and application.
2. Describe three lifecycle profiles (properties, hazards and exposure).
3. Evaluate risks.
4. Assess risk management.
5. Decide, document and act.
6. Review and adapt.

[3] www.nanoriskframework.com

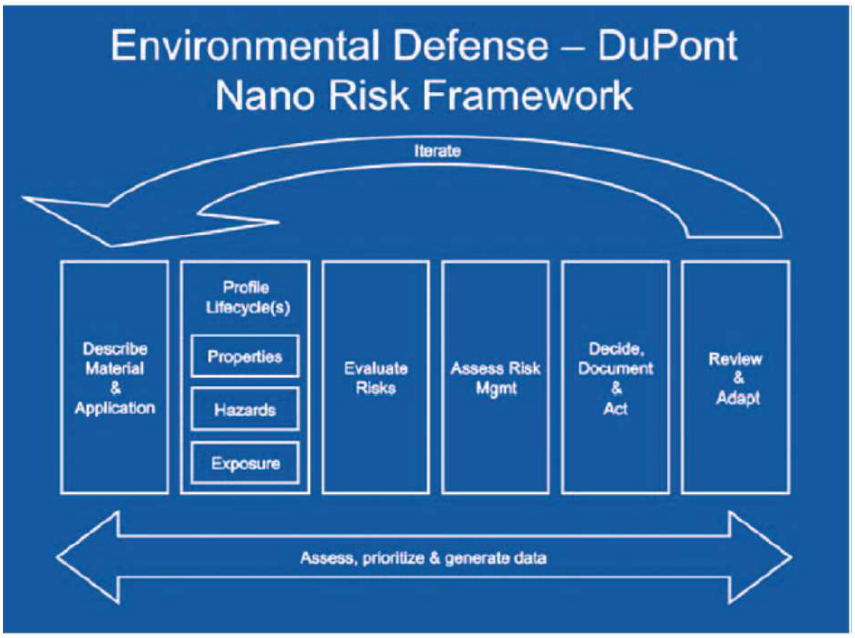

Figure 6: Nano Risk Framework of DuPont and Environmental Defence.
The full framework including a number of case studies are available for download.[4]

ETUC resolutions

The European Trade Union Confederation (ETUC) has adopted two resolutions on nanotechnologies and nanomaterials. The first resolution was adopted in June 2008 (ETUC, 2008), and calls for:

- The use of the precautionary principle.
- At least 15% of European public nanotechnology research budget to be allocated to health and environmental aspects.
- All research projects to include health and safety aspects as a compulsory part of reporting.
- The Commission to adopt a definition of nanomaterials not restricted to objects below 100 nm.
- Nanoproducts not to be produced unless the risks are known or a precautionary approach has been applied *and made transparent to the workers*.
- Full compliance with Reach's "no data, no market" principle.
- An adaptation of the thresholds applied in REACH, and a Chemical Safety Report to be required for all nanomaterials.
- An amendment of the Chemical Agents Directive such that control measures should not only been taken when risks have been proven, but also when risks are still *unknown*.
- Material Safety Data Sheets clearly stating whether nanomaterials are present.
- Member state authorities to set up national registers on the production, import and use of nanomaterials.
- The involvement of workers' representatives in voluntary industry initiatives such as Codes.

In December 2010, a second resolution was adopted. In this resolution, the “no data, no market” principle was substituted by the somewhat more realistic “no data, no exposure” principle as long as the implementation of the precautionary principle is concerned. This means that exposure should be prevented as long as crucial data is absent, e.g. by performing processes in closed systems (ETUC, 2010). Additionally, the 2nd resolution calls for the establishment of registries of worker exposure to nanomaterials, accompanied by health surveillance systems. Furthermore, most principles set out in the first resolution were reaffirmed.

4.5.5 The role of risk management tools

In several countries, preliminary risk management tools have been developed or are still under development in order to support companies in performing their risk assessments. Currently, the best-known tools are the Stoffenmanager Nano Module,[4] the Control Banding Nanotool[5], and the Handleiding veilig werken met nanomaterialen.[6] All of these tools enable the user to make a qualitative estimation, or prioritisation, of the (potential) risks of working with nanomaterials, and point the user to classes of control measures. Additional tools include, in the Netherlands, the Nanosafety Guidelines of the Delft University of Technology and, in other member states, a Swiss risk assessment matrix and a French Control Banding Tool (Brouwer,2011). Currently, within the framework of an ISO working group on the assessment of nanotechnology health risks, an attempt is being made to develop a harmonised recommendation on what tool(s) should be used (Van den Aker, 2011).[7]

Another approach that is currently being tested in a Dutch pilot project is the use of temporary precautionary reference values in combination with exposure measurements, as long as fully health-based occupational exposure limits cannot be developed yet (Dekkers & De Heer, 2010). However, measuring exposure to nanoparticles in a reliable way is still problematic (http://www.nano-device.eu/).

The current tools have in common that, obviously, they are based on current knowledge, which is limited in many aspects regarding both hazard and exposure. Therefore, the outcomes are still uncertain, and issues of governance remain.

Case: Enforcement of nanotechnology risk assessment and uncertainty

As a result of the many uncertainties that are still connected to both the hazard and the exposure potential of nanomaterials, the current risk assessment tools that are available in the Netherlands gave varying results in similar circumstances in a number of cases. This gave rise to a sense of uncertainty among both companies using nanomaterials and risk assessment tools and the Labour Inspectorate, which has the task of enforcing that companies carry out reliable risk assessments. Questions arising among companies included: How to carry out risk assessment for nanomaterials, which measures to take, and how far should precaution go? Questions arising at the Labour Inspectorate included: Which tool to recommend? Which risk assessment can be accepted as a suitable one? And what can really be demanded from companies? The Labour Inspectorate feared that many companies might get confused and would approach the Inspectorate for definitive answers. However, for the moment, a single truth does not exist.

[4] http://nano.stoffenmanager.nl
[5] http://www.ioha.net/assets/files/ICOH2009_CBNanotool_DMZ.pdf
[6] www.fnv.nl/media/pdf/94924/Handleiding_veilig_werken_met_Nanomaterialen_en_-producten.pdf.
[7] http://www.nen.nl/web/Normshop/Nieuwe-normen-Nanotechnologie.htm

4.5.6 Current implementation of nanotechnology risk assessment at the company level

In late 2010 and early 201, the Dutch Labour Inspectorate carried out a preliminary inspection project among 43 companies and research institutes at which nanomaterials or nanoproducts are handled. First of all, it turned out that it was difficult to find companies and organisations to inspect, as there is no register of companies using nanomaterials, and many companies themselves do not even know if they handle such materials (Boonstra, 2011). During the inspections themselves, it appeared that 37 out of these 43 organisations had not yet carried out a risk assessment specific to activities that may result in worker exposure to nanomaterials. Most of the organisations tried to assess the health risk of some of the activities and most of them took some control measures as well. However, these activities had a non-structured, ad-hoc character. Generally, not all nanomaterials and activities were covered. Moreover, 35% of the organisations did not inform the employees of the health risks of nanomaterials and the measures that should be taken (AI, 2011). Only 30% of the inspected companies that produce products that contain nanomaterials informed their clients about this fact. The reason for not informing clients was the fact that it is not yet obligatory (AI, 2011).

Informing stakeholders: the Nanosmile website
The website www.nanosmile.org was established within the framework of the FP7 Nanosafe2 project. The website contains five thematic modules: Precautions, Metrology, Health, Environment, and Governance. Each module contains information at three levels: Discover (for the general public) , Explore (to study) and Know-how (professional best practices). In the Governance module, a model is presented that shows the elements that contribute to the responsible development of nanotechnologies:

The Nanosmile website will be gradually extended in the future.

5 Conclusions

What are the main conclusions we can put forward from our review?
Looking back to the research questions with which we started this review, we can make the following conclusions:

1. From the current state of affairs of (international) research into the concept of risk governance:
   - The concept of risk governance is best known and mainly referred to as the framework of risk governance, presented by the IRGC in 2005.
   - This concept was developed and is used to analyse risks at the macro level, for example, to analyse the BSE crisis, or Hurricane Katrina.
   - At the company level, only some elements of risk governance are present at some (mainly larger) companies, e.g. the involvement of certain stakeholders and attempts to better communicate the risks. An overarching risk governance approach is not working yet, despite the international and national process of deregulating responsibilities.

2. What research is been done on the application of risk governance in relation to health and safety policies in workplaces when working with new emerging technologies and substances, e.g. Nanotechnology?
   - Current practices – generally involving only certain elements of a risk governance approach – can be found especially at leading companies, such as the Nano Risk Framework of DuPont, or BASF's Dialogue Forum Nano 2009/2010.
   - There are several opportunities to make risk governance more explicit, for example, in connection with corporate policies on Corporate Social Responsibility, Resilient Engineering and sustainability.

3. What current practices can be found in the literature that can be related to risk governance? (codes of conduct, etc.)
   - The application of a wider approach to risks is still absent. Companies seem to be sticking to risk assessment and management in a rather traditional manner, and are disregarding the need to include concern assessment and concern management. The result is that barriers are thrown up that hinder the introduction of innovative technologies (e.g. nanoproducts).
   - Leading companies like DSM, BASF and DuPont are starting to implement either company codes of conduct or elements of the EU Code of Conduct on Responsible Nanotechnology Research and Development.
   - Risk assessment and risk management practices implemented at the company level include, for example, the Nanosafety Guidelines of the Delft University of Technology, Stoffenmanager Nano and Handleiding Nano (in the Netherlands), and in other member states the Swiss risk assessment matrix and the French Control Banding Tool of ANSES. However, these do not yet seem to provide sufficient answers to all uncertainties.
   - Many ad-hoc measures are taken in a fragmented manner. The precautionary principle is too often incorrectly understood as the equivalent of putting a moratorium into place.

6 Recommendations and discussion

Uncertainties, and several differing perceptions of risk can lead to ambiguity regarding risks on the part of society. This implies that dealing with uncertainties (how can we govern our risks) will have to be given a more central place in society –not just at the macro level, but especially at the company and organisational level, whereas national regulation and legislation (enforcement) can no longer be the guiding principles for the management of uncertain risks. For example, in the case of nanotechnologies it has been estimated that the collection of all scientific data needed to enable the traditional risk approach might take up to several decades, if it even proves possible at all. Consequently, the uptake of innovations seems to be hindered. This demonstrates that, in addition, alternative approaches for dealing with risks need to be developed. As central elements of this approach, uncertainties will have to be explicitly addressed and discussed, and the (meaning of the) precautionary principle will have to be further elaborated and agreed upon. Moreover, if risks are increasingly uncertain and ambiguous, an active involvement of an even wider group of experts and stakeholders will be necessary.

We will therefore recommend for TNO:

- To stress and communicate the need for companies to adopt a wider approach to risk assessment and management which also includes concern assessment and management, in order to reach a balance between the opportunities and risks of innovative technologies.
- To re-frame, together with companies, the concept of risk governance at the company level: what does it mean for us to deal with uncertainties.
- Together with companies, to look more closely at the phases Pre-assessment, Risk Appraisal and Risk Management at several levels (internal, external and stakeholders in the supply chain) and examine the role of communication in the current risk governance model in order to draw up guidelines and recommendations on how to implement risk governance (i.e. the necessary wider approach to risk management).
- To be involved with the implementation of the EU Code of Conduct on Responsible Nanotechnology Research & Development, as a starting point to develop (together with companies) a risk management (OHS) guideline for risk governance. This will support the ability of companies to deal with uncertainties and responsibilities.
- To identify at the company level how and where the concept of risk governance can be linked to other company policies, such as corporate social responsibility, resilient engineering and sustainability.
- To develop practical tools and guidelines that complement current risk assessment and management tools for substances (e.g. Stoffenmanager and Stoffenmanager Nano), by adding elements of concern assessment (e.g. stakeholder involvement) and concern management (e.g. risk communication). This will support companies in implementing the wider approach to the management of uncertain risks, thus preventing barriers to innovation.

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