FRAMING NANO

Governance in Nanoscience and Nanotechnology

FramingNano Project:

A multistakeholder dialogue platform framing the responsible development of Nanosciences & Nanotechnologies

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THE FRAMINGNANO GOVERNANCE PLATFORM

A NEW INTEGRATED APPROACH TO THE RESPONSIBLE DEVELOPMENT OF NANOTECHNOLOGIES

FINAL REPORT

February 2010

PROJECT CONSORTIUM

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The FramingNano Governance Platform

A New Integrated Approach to the Responsible Development of Nanotechnologies

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- FramingNano Mapping Study on Regulation and Governance of Nanotechnologies, January 2009 (FramingNano, 2009)
- FramingNano Report on the Delphi Consultation, March 2010 (FramingNano, 2010)

This and the other project reports can be downloaded free of charge from www.framingnano.eu.

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1 Executive Summary

There are massive expectations of nanotechnology with many claimed societal benefits. However, these are only likely to materialise if there is an accompanying governance system that addresses both the important issues related to their development and the needs for the sustainability and growth of applications.

In addition to the potential benefits, attention needs to be focused on the potential risks and concerns arising from the application of nanotechnologies as well as societal and transboundary implications. Because of the cross-cutting nature of nanotechnologies, effective governance requires a high level of interaction between those who develop, manufacture, sell and regulate nanotechnology-based products, as well as with representatives of civil society, in order to implement a proactive and adaptive framework capable of supporting the development of these novel technologies across clear boundaries.

The FramingNano project was launched in May 2008 with the aim of creating proposals for a workable governance platform and has been based on three essential pillars of activity:

- **Analysis** of existing and ongoing regulatory processes, science-policy interfaces, research on risk assessment, and governance in nanotechnologies;
- **Consultation** with all relevant stakeholders[1] to assess attitudes, expectations and needs, and to define a list of key issues be considered during the deliberative phase of the project;
- **Dissemination** of information on the governance of nanotechnologies, including proposals developed within the project in order to raise stakeholder awareness and obtain further input to the development of a governance platform.

The resulting FramingNano Governance Platform, as described in this report, has been proposed to the European Commission as a tool to support the responsible development of nanotechnologies at European level and beyond. The Platform provides proposals and guidance at four different levels:

- **Technical and organisational:** prioritising actions and research needs in relation to Environmental, Health and Safety (EHS) issues and Ethical Legal and Societal Aspects (ELSA), and defining the roles and responsibilities of the various stakeholders involved;
- **Communication and dialogue:** proposing means of effectively disseminating trustworthy information and channelling stakeholder views into European policy actions;
- **Institutional:** suggesting how to manage and sustain European policy for the responsible development of Nanoscience and Nanotechnologies (N&N), and indicating roles and responsibilities at the level of institutions;
- **International harmonisation:** identifying transboundary issues to be addressed at both EU and international levels.

[1] Relevant stakeholders were classified into four groups: Regulation & Control (government policy makers, regulator and standards agencies, lawyers); Research (academia, industry); Business (production, retail, insurance and finance, industrial/professional organisation); People (NGOs, consumer associations, social/ethical researchers, workers representatives)

Major Barriers and Challenges in Nanotechnologies Governance

The FramingNano Governance Platform focuses initially on the risks and societal concerns associated with nanotechnologies since these are key to defining a governance framework. Negative aspects must always however be balanced against those beneficial impacts that are the "positive drivers" of the development of nanotechnologies. Therefore, the broader concept of **nanotechnology-induced change** which includes benefits, risks and systemic effects, is used here to guide the proposed governance model.

The level and nature of uncertainties about potential risks (EHS) and societal concerns (ELSA) strongly depends on the "generation" of nanotechnology (e.g. simple/passive nanostructure vs. active/reactive nanostructures) and type of application. Most of the issues arising in relation to the responsible development of N&N are common to any emerging technology. The experiences of the past can therefore be useful in defining the governance needs of N&N for the future.

Nanotechnology is still a relatively "young" technology and the most pressing current issues concern mainly the possible harmful effects of (non-degradable) "free" engineered nanomaterials. However, potentially revolutionary (and beneficial) applications of N&N are under development, and the need to address these should already be anticipated.

There are still many knowledge gaps in relation to nanomaterials, and important challenges to the governance of nanotechnologies include:

- Insufficient scientific knowledge about the characteristics and behaviour of nanomaterials, including data on exposure and hazards;
- Lack of common definitions and a standardised nomenclature;
- Lack of standardized methodologies to assess and manage EHS issues;
- Difficulties for regulation to keep pace with scientific developments, new products and applications, and increasing commercialisation of N&N;
- Limited exchange of information amongst stakeholders along the value chain and beyond;
- Uncertainties about public acceptance, resulting from a lack of transparency about EHS and ELSA issues;
- Weaknesses in education with respect to N&N.

A number of technical, institutional and communication recommendations to address these challenges is summarised in Annex II.

A number of initiatives from governments, authorities, the scientific and industrial communities, and other stakeholders already exist or are being developed to address these problems (FramingNano Mapping Study, 2009). In terms of the assessment of the current regulatory situation, several main positions persist amongst stakeholders as follows:

- Nanomaterials are not new materials. The existing regulatory situation is adequate. If scientific evidence indicates the need for modification, the regulatory framework will be adapted.

- Specific guidance and standards must be developed to support existing regulations but the existing regulatory situation is generally adequate.
- Regulation should be amended (on a case by case basis) for specific nanomaterials and their applications. Above all, when a high potential risk is identified, a precautionary approach should be chosen.
- The existing regulatory situation is not adequate at all. Nanomaterials should be subject to mandatory, nano-specific regulation.

The aim of the FramingNano Governance Platform is to integrate these different positions and to promote a responsible development of nanotechnologies without hampering innovation and commercial growth. Regulations for N&N should support safety issues to the same degree as for non-nano materials and products, coping with a certain level of uncertainty which may remain due to the dynamic character of the evolution of the sector. The Platform, therefore, proposes an **adaptive and inclusive** approach in order to be able to address both current and future issues in nanotechnology governance.

The FramingNano Governance Platform

From the FramingNano project research it has been concluded that governance and regulation of nanotechnologies must be considered a dynamic affair which needs to be continuously adapted. This implies a continuous observation of the state-of-the-art knowledge on nanotechnology-induced change. Also, the relevant stakeholders and the interested public have to be meaningfully included in the definition of commonly accepted principles, criteria and values to be used for the assessment of these changes. The FramingNano Governance Platform therefore has a number of key objectives:

- **Raising awareness:** promoting an understanding of the huge impacts of nanotechnology-induced change and of the convergence of technologies at the nanoscale;
- **Defining commonly accepted rules:** developing a commonly-agreed assessment methodology that facilitates prioritisation and focus on the key issues of nanotechnology-induced change.
- **Advising:** reacting in a timely and adequate way to the data gaps and other challenges that the rapid development of N&N presents;
- **Anticipating and adapting:** the Governance Platform to trends and developments in nanotechnology-induced change, and towards a responsive, innovation-friendly framework;
- **Strengthening informed trust:** amongst all stakeholders where concerns related to nanotechnology-induced change emerge;
- **Establishing means of cooperation**: to fill emerging gaps related to access to nanotechnology-induced change on a global level.

The framework and structures envisaged to achieve these objectives should permit the establishment of a governance process that runs in a continuously-fed loop to provide a dynamic, sustainable governance model capable of coping with the present and future challenges of nanotechnologies (Figure 1).

Two key functions are proposed to put the Platform into operation: a **Deliberative Panel** and a **Decision Making Body** (Figure 2).

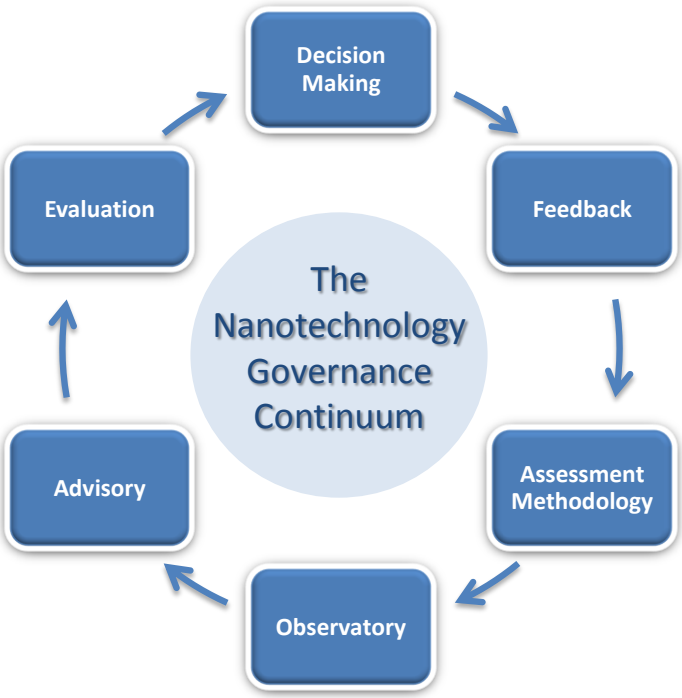

Figure 1: Overview of the process of the FramingNano Governance Platform (FramingNano Consortium 2009)

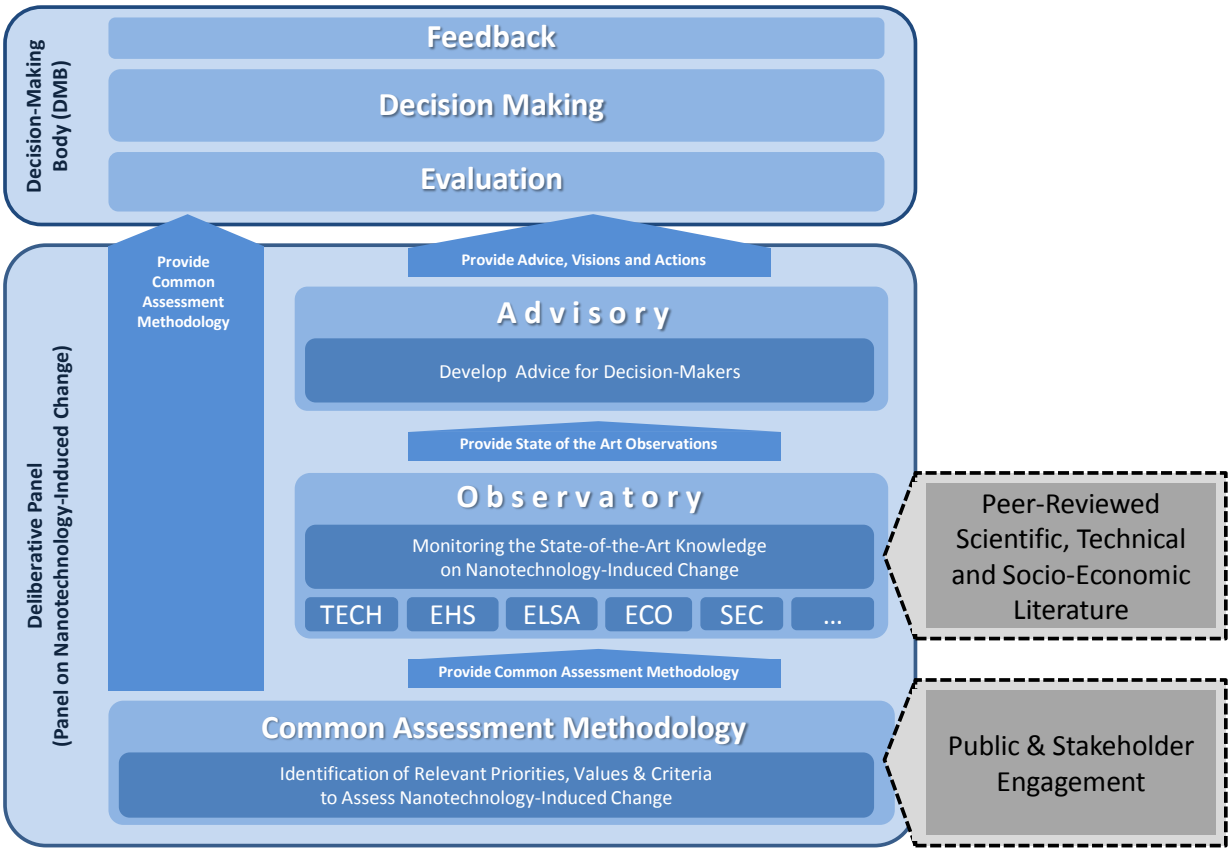

Figure 2: Overview on the proposed structure of the FramingNano Governance Platform (FramingNano Consortium 2009)

The Deliberative Panel

The Deliberative Panel[2] (on nanotechnology-induced changes) is proposed to be established as a structured, permanent group of experts responsible for

- engaging with key stakeholders and the public to develop a **Common Assessment Methodology** on nanotechnology-induced changes. This will make it possible to assess the state of the art and monitor such changes in the light of an integrated set of criteria (principles and values) and shape and adapt the Governance Platform as necessary.
- observing and assessing the state-of-the-art in developments and knowledge concerning nanotechnology-induced change (**Observatory function**); and
- translating this intelligence into visions, actions and recommendations on nanotechnology governance for decision-makers (**Advisory function**);

Examples of criteria that could be established in the context of the Common Assessment Methodology include: the identification of critical issues, how to determine appropriate risk-benefit judgements, EHS and ELSA priorities, and the societal desirability of different nanotechnology applications.

Since these values and principles are expected to be subject to change and refinement with the developments of nanotechnologies, this process must take place on an on-going basis.

The Panel's Observatory function would provide a continuous overview, assessment and summary of key developments and advancing knowledge in relation to nanotechnology-induced change, taking into account the criteria emerging from the Common Assessment Methodology and referring to the state-of-the-art scientific, technical and socio-economic information available.

The Observatory would need to have access to non public data, in particular those arising from industry, to explore ways to overcome constraints arising from the confidential character of business information and intellectual property rights (IPR), and rely on an open information archive and freely accessible database of scientific literature on nanoscience research.

In order to be able to function effectively, the Panel should comprise multidisciplinary experts in different nanotechnology fields from different countries, with backgrounds and functions in academia and research, business, public institutions and civil society organisations. To maintain trust it is of central importance that such experts are not restricted by conflicts of interest.

The input of laypersons is also important to ensure the widest representation of societal interests. The Panel would, therefore, also explore methods to effectively gather such opinions by considering, in the first instance, the outcomes of the different public engagement initiatives on nanotechnology-induced change that are currently in place at national, regional and worldwide levels[3].

To fulfil its observatory activities effectively, the Panel should ideally be structured into topic-related Working Groups (WG) focusing on specific issues related to nanotechnology-induced change, e.g.

[2] A relevant example is the International Panel on Climate Change (IPCC)

[3] The organisation of such initiatives is out of the scope of the Panel.

technological developments, economic impacts, EHS, ELSA and security. Certain issues could also be structured according to industrial sectors or applications.

Based on the outcomes of the Observatory and the input of the Common Assessment Methodology, the Panel would fulfil its **advisory function** by proposing models, visions and actions relevant for nanotechnology governance to the **Decision Making Body (DMB)**.

The Advisory function would remain with a restricted number of experts acting as steering/scientific committee guiding the development of the Common Assessment Methodology and the activity of the Observatory function, carried out by a larger group of experts.

Outputs of the Advisory could include, for example, advice on R&D and innovation policies, proposals for the coordination of R&D activities, suggestions for review and adaptation of national regulations or development of "soft law", best practices and guidelines, and methodologies for data sharing.

The Decision Making Body

The Decision Making Body (DMB) is proposed as a board which would be comprised of representatives of those existing institutions and competent authorities responsible for decision making in the different fields affected by nanotechnologies. These representatives would be brought together in order to share a common understanding of the transdisciplinary nature of nanotechnology-induced change and to channel the outputs of the Deliberative Panel into the relevant decision making processes. The DMB would meet on a regular basis.

Existing decision-making structures covering nanotechnologies are scattered widely amongst existing institutions at all levels of subsidiarity. Depending on the area of application (e.g. chemicals, foods, medical devices, pharmaceuticals, etc.), different governance initiatives and regulatory frameworks are applied or consulted (e.g. REACH or other application or product-specific regulations) and decision making is expected to take place within these existing frameworks as appropriate. These existing decision making structures must be included in the overall process of the Governance Platform and their corresponding responsibilities and accountabilities recognised in order to avoid unnecessary fragmentation of responsibilities and duplication of efforts.

The relevant decision makers are responsible for the evaluation and implementation of the visions, recommendations and actions proposed by the Deliberative Panel in their respective areas of competence. The overarching challenge for the DMB would be to **evaluate and decide** on recommendations and proposals related to nanotechnology governance, taking account of the principles and values emerging from the Common Assessment Methodology activities developed together with involved stakeholders and the broader public.

To maintain an effective and transparent evaluation and decision making process, the DMB should be subject to a **Feedback** function which makes its output available to the Deliberative Panel, allowing validation as to whether the decisions taken address the needs identified by the Commonly Assessment Methodology.

At the European level, both the Deliberative Panel and the DMB could report to the European Commission. While decisions are adopted at Member State level, policy implementation will remain under the responsibility of national Competent Authorities. It is desirable that the proposed Governance Platform be adopted at international level to facilitate cross-border trade and to assure

that a responsible development of nanotechnologies takes place worldwide. Depending on the level at which the Governance Platform will be implemented (European level, global), the Deliberative Panel and the DMB could be hosted by an existing European or United Nations structure, or an informal intergovernmental organisation.

It is important to note that the Governance Platform as proposed in this report and graphically depicted in Figure 2 should be regarded as a heuristic solution arrived at on the basis of dialogue with interested stakeholders and a deliberative process, rather than a definitive or "fixed" solution. The elements and processes described in the Platform, and depicted in Figure 1, are all considered vital for the governance and responsible development of nanotechnologies. However, while some suggestions on possible routes forward are offered, the way in which these elements can be integrated into existing structures, where they could be hosted, or whether or not completely new bodies need to be created, is ultimately a political decision and beyond the remit of this Project.

Likewise, implementing some of the recommendations of this report will have significant financial and organisational implications and, while this is recognised, the manner in which these aspects can be addressed in detail is also dependent on political decision.

In some ways, an analogy can be drawn in this respect with other processes like standardization, which is sometimes viewed by critics as a costly process involving many interested stakeholders but which, ultimately, is far less costly to society than the absence of such a process.

With regard to the timescale for adoption of the Governance Platform, implementation of the technical, institutional and communication-related recommendations summarised in Annex II would be the **short term, immediate** goal. These actions are an essential prerequisite to the adoption of a fully-fledged Governance Platform **in the short to medium term** at global (and not just EU) level, thereby supporting an effective international harmonisation of governance approaches.

In the **medium to long term**, key objectives would include the continuous optimisation and adaptation of the Governance Platform to face the challenges posed by emerging, and potentially revolutionary, applications of nanotechnologies so that full advantage can be taken of them.

The Governance Platform as proposed is considered to be an essential tool to translate the complex and major current and future challenges in nanotechnology governance, together with those presented by other converging technologies, into an opportunity and driver for growth for the benefit of the society as a whole.

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2 Introduction

2.1 This Report

This document is the final report of the FramingNano FP7 research project and contains the final proposal of the FramingNano Governance Platform which has been elaborated and refined during the project.

This report includes inputs and comments on the draft Governance Platform gathered during a restricted Expert Workshop and an International Conference, as well as additional detailed background information on the project methodology. The principal basis for the proposed Governance Platform derives from a two-stage Delphi consultation among interested nanotechnology stakeholders, the outcomes of a dialogue of a multi-stakeholder workshop. The conclusions and recommendations in this document represent the result of the entire research of the FramingNano project and the opinion of the FramingNano project consortium.

In the opening chapter of this report ("The FramingNano Governance Platform") the proposal for a Governance Platform is presented, which was the objective of the FramingNano project. In the following two chapters, "Outlining the Problem of Nano Governance" and "Stakeholder Opinions on Nano Governance", some of the research results which have been gained throughout the project on nanotechnology governance are reported in detail.

2.2 About FramingNano

The expectations on nanotechnologies are high, but it is widely shared that the benefits promised will fully materialise only if there is a governance system which addresses, in a timely manner, the potential risks and concerns associated with their development to allow growth and technology exploitation that leads to sustainable applications.

Given the nature of nanotechnologies, an effective governance approach will have to increase the level of interaction amongst those developing, producing, selling and regulating nanotechnology, as well as with civil society in general. First then it will be possible to promote a proactive and adaptive process capable of framing the development of these new technologies across known and accepted boundaries. The establishment of open, transparent, objective and trustworthy communication will also be necessary[4, 5].

The FramingNano project, a Support Action developed in response to a call under the Capacities - Science in Society area in FP7, started in May 2008 and aims to frame these interfaces into a workable platform.

As the most urgent discussions are about Environmental, Health and Safety (EHS) issues and Ethical, Legal and Social Aspects (ELSA) related to nanotechnologies, this project considers both risks and

[4] The importance of open governance of scientific research is underlined in the 2009 work programme for Capacities, Science in Society area, European Commission C(2008) 4566, 26 Aug 2008.

[5] A broad definition of principles of 'good governance' is provided in section 2.3.

concerns. The implications of "nanotechnology-induced change" have to be understood and "framed" or "guided" into an adaptive model of governance (Roure, 2008). Existing governance approaches need therefore to be analysed and further developed.

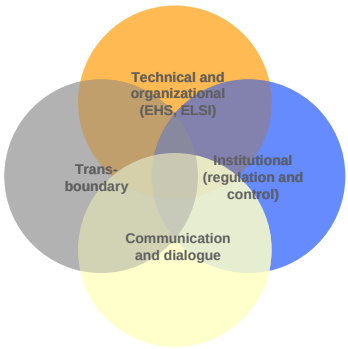
A broad process is considered vital to ensure that the diverse needs and expectations are adequately addressed to foster the definition of a set of social, political and technical criteria to shape a governance framework capable of assuring the responsible development of nanotechnologies.

The involvement of a broad variety of stakeholders is fundamental to begin a *"co-operative research process"* [6] allowing and facilitating:

- sharing of knowledge and expertise among science and technology researchers and society researchers, in order to help to integrate a societal perspective into the research and development (R&D) process of nanosciences & nanotechnologies (N&N), and to address science-society interactions as a system;
- increasing awareness of non-researchers (policy makers, civil society organization, general public) about N&N, *"building their capacities"* in order to understand, evaluate and manage N&N issues.

Also, as indicated by the European Commission[7], FramingNano considers *"aiming as much at the harmonious societal integration of new scientific and technological knowledge as to achieving the specific objective of the research itself."*

The main outcome of FramingNano is the proposal of a Governance Platform to the European Commission, to be adopted by all stakeholders to support a responsible development of nanotechnologies at the European level. The Governance Platform provides indication and guidance for actions over the coming years acting at four different levels:



- **Technical and organisational:** prioritising actions and research needs in relation to Environmental, Health and Safety (EHS) issues and Ethical Legal and Societal Aspects (ELSA), and defining the roles and responsibilities of the various stakeholders involved;
- **Communication and dialogue:** proposing means of effectively disseminating trustworthy information and channelling stakeholder views into European policy actions.
- **Institutional:** suggesting how to manage and sustain European policy for the responsible development of Nanoscience and Nanotechnologies (N&N), and indicating roles and responsibilities at the level of institutions;
- **International harmonisation:** identifying transboundary issues to be addressed at both EU and international levels;

[6] The paradigm of 'co-operative research' has been discussed in *"From Science And Society To Science In Society: Towards A Framework For 'Co-Operative Research"* - Report of a EC Workshop Governance and Scientific Advice Unit of DG RTD, DG Research and Tech. Dev., Brussels, 11/2005 (p. 9)

[7] FP7 Work Programme 2007, European Commission C(2007)563 of 26.02.2007

2.3 What is Governance in Nanotechnologies?

Governance of nanotechnologies is a term that is often used in the context of risk considerations. However, it is a very broad and also somehow vague term which addresses a number of elements and perspectives.

According to the European Commission, it originates from the need of economics (as regards corporate governance) and political science (as regards State governance) for an all-embracing concept capable of conveying diverse meanings not covered by the traditional term "government".

The European Commission established its own concept of governance in the White Paper on European Governance (Commission of the European Communities, 2001), in which the term "European governance" refers to the rules, processes and behaviour that affect the way in which powers are exercised at European level, particularly as regards openness, participation, accountability, effectiveness and coherence. These five "principles of good governance" reinforce those of subsidiarity and proportionality.

According to a *White Paper on Nanotechnology Risk Governance* (Renn, et al., 2006), principles of good governance include participation, transparency, effectiveness and efficiency, accountability, strategic focus, sustainability, equity and fairness, respect for the rule of law and the need for the chosen solution to be politically and legally realisable as well as ethically and publicly acceptable.

However, the concept of governance implies mechanisms, processes and institutions that go beyond state structures. Given the nature of nanotechnologies their governance requires collaboration and coordination between various institutions and stakeholders, and calls for the consideration of contextual factors such as institutional arrangements (e.g. regulatory and legal frameworks, coordination mechanisms such as markets, incentives or self-imposed norms), socio-political decision making, culture and perceptions (Renn, et al., 2006).

FramingNano focuses on governance of risks and concerns that have to be understood and “framed” or “guided”, since talking about risks (rather than benefits or opportunities) is instrumental to define a regulatory framework. Nevertheless, both benefits and opportunities are the necessary background of the debate and they always need to be balanced against each other. Moreover, in order to define a *responsible* framework of governance, the process must take into account societal issues together with technological drivers.

Based on the original plan and the assessment of approaches under consideration for the governance of nanotechnologies done by the project, the term governance, for *the purpose of the project activities*, has been related to the aforementioned set of topics: technical and organisational issues, institutional aspects, communication and dialogue, international harmonisation.

2.4 Major Challenges in Nano Governance

While applications making use of the novel properties of nanomaterials are increasingly being put on the market, the knowledge about nanotechnology-induced change with respect to potential health, safety, environmental issues and ethical, legal and societal aspects of these technologies lags behind.

It has clearly emerged that key building blocks are currently missing so that risk assessment and adequate risk management of manufactured nanomaterials and nano-related products is currently hampered by many uncertainties. While waiting for new data and risk assessment methodology to be developed and evidence-based rules to emerge, new products making use of such nanomaterials appear on the market with no or little regulation or nanospecific testing requirements in place.

In the abovementioned setting, a generalisation of risk assessment findings among different nanomaterials and applications is not meaningful; a strict case-by-case approach is therefore necessary (SCENIHR, 2009). However, considering a rapidly increasing number and variety of different nanomaterials in use, such case-by-case-approach will be inefficient over time, and means of categorising applications and nanomaterials according to their potential risk must be found.

Despite the admittedly large knowledge gaps and in the light of a precautionary approach, a *"wait and see"* attitude is not an adequate option. Since our knowledge will remain incomplete for some time, and very likely the quest for knowledge will never end (Brown, 2009), a model of nanotechnology governance must be developed and agreed on in order to provide means of dealing with those gaps and the evolving state of our knowledge. However, this model must also be capable of identifying what is already known and assemble this knowledge to be used efficiently.

The big challenge for regulators regarding these novel technologies is to ensure a certain level of safety without stifling innovation. The high level of scientific uncertainty surrounding EHS risks complicates the evaluation of the adequacy of existing and proposed regulatory responses, and regulations need to be flexible to accommodate newly emerging risks or insights while assuring the public that existing products on the market are safe, both for humans and the environment. Nanotechnology regulators on both sides of the Atlantic are keen to avoid a situation where scientific uncertainty amplifies risk perceptions by a sceptical public, as was the case in the early debate about genetically modified plants in food (Falkner, et al., 2009).

Key barriers to be overcome for the governance of a responsible development of nanotechnologies are:

- lack of knowledge concerning risks
- lack of commonly agreed and standardized methodologies to assess and manage nanotechnology-related risks
- inability of regulation to keep pace with scientific discovery, development and commercialisation of nanotechnologies and nano-related products
- public backlash, resulting from a lack of transparency about the development and use of nanotechnologies

The aforementioned barriers influence the design of the governance framework for nanotech-nologies and, together with their steady evolution, make an adaptive and prospective approach

indispensable. Nanotechnology governance must be regarded as dynamic affair to readily adapt to the evolution of knowledge, the applications under consideration and varying stakeholder attitudes.

Recent debates in the EU and elsewhere demonstrate that technological developments cannot take place independently from the expectations and needs of the society, but it has proven difficult to organise scientific developments according to public expectations. However, because much of the anticipated potential for nanotechnologies is still at the research stage, considerable uncertainties also exist regarding their societal impacts, and these uncertainties even grow bigger when the more "visionary" developments of nanotechnologies and their feasibility are addressed.

The societal dimension of nanotechnology research forms an integral part of the integrative, responsible and safe approach set out by the European Commission in the European Strategy for nanotechnology (2004), and developed further in the Action Plan on nanotechnology (2005) and its first (2007) and second (2009) Implementation Report. In these Commission communications it is clearly stated that nanotechnology must be developed in a responsible way, embedded within an exchange with the public and that enables interested people to reach their own informed and independent judgements (European Commission, 2008). A range of ELSA related initiatives are seeking to assess the relevant issues and to engage a wider public, to stimulate the broader societal dialogue which these and other studies call for. This discussion seeks to expose the technological goals and political decision making to societal expectations and concerns.

Finally, research, development and commercialisation of nanotechnologies is a worldwide affair, involving highly industrialised developed countries as well as emerging countries. An integrated governance approach for anticipatory and corrective measures that will have trans-boundary and global implications is advocated from many parts.

A more comprehensive overview on the problems challenging the governance of nanotechnologies is presented in the background chapters "Outlining the Problem of Nano Governance" and "Stakeholder Opinions on Nano Governance".

3 The FramingNano Governance Platform

3.1 Basic Assumptions

The main goal of the FramingNano Governance Platform is to enable the responsible development of nanotechnologies. The Governance Platform should facilitate the realisation of the benefits these technologies promise, while limiting their potential risks and remaining sensitive to public concerns and changes induced by nanotechnologies. The Governance Platform provides a framework of principles, procedures and responsibilities which indicate how to define and implement a model of responsible nanotechnology governance in Europe.

The European Economic and Social Committee (EESC) (European Economic and Social Committee, 2009) recommended that the European Community initiative on nanotechnologies further developed as to:

- ensure that there is a coherent and user-friendly framework into which the various Community regulations fit;
- set up a permanent European reference structure for N&N and nanomaterials, with a European focal point for promotion and coordination that also covers the risk assessment and prevention aspects;
- facilitate structured dialogue with civil society, on a sound and transparent basis, to provide a united European voice in this field, which is vital to our future on the global stage.

Overall, the governance framework is intended to provide means for addressing nanotechnology impacts on a more integrated level than the case-by-case approaches applied today. The Governance Platform therefore takes up the concepts and values which emerged in the last years which should underpin a model for an integrated, adaptive, inclusive and transparent process of nanotechnology governance. This will foster a continuous and trust-building dialogue between those involved in or affected by decisions in nanotechnology governance.

As indicated in section 2.2, the proposed Governance Platform is intended to act at four strongly interrelated levels: technical and organisational (EHS and ELSA), institutional (regulation & control), trans-boundary, as well as communication and dialogue. Referring to these areas, the FramingNano project research has led to the identification of principles and basic assumptions which have to be considered by the deliberative process of the FramingNano Governance Platform in the following areas:

- Responsible Development of Nanotechnologies: Principles in EHS and ELSA
- Communication: Public Dialogue, Information Sharing and Knowledge Transfer
    - Public Dialogue: Inclusiveness and Public Engagement
    - Information Sharing among Stakeholders
    - Knowledge Transfer: Education and Professional Formation
- Adaptive and Flexible Governance: Adaptive Regulation
- Creating Trust Between Stakeholders

These topics are discussed in brief in the following paragraphs, identifying some recommendations emerging from the project research and the FramingNano stakeholder consultations. Details and results of the corresponding FramingNano Delphi consultation are reported in the background sections ("Outlining the Problem of Nano Governance" and "Stakeholder Opinions on Nano Governance").

3.1.1 Responsible Development of Nanotechnologies: Principles in EHS and ELSA

3.1.1.1 Environmental, Health and Safety (EHS)

Over the past years it has become clear that all stakeholders agree on the need for a safe and sustainable implementation of nanotechnologies. It is also commonly agreed that the development of the scientific building blocks necessary to assess potential risks of manufactured nanomaterials is lagging behind the commercial application of these materials. As mentioned above, the resulting uncertainties are considered a major barrier for a sustainable and responsible development of nanotechnologies in the long term.

EHS issues of nanotechnologies were generally considered very important in the FramingNano consultation (see section 5.3.1), and at the present stage of development of nanotechnologies the focus is mainly on manufactured nanomaterials. Although there are some differences in the priority ranking given depending on the type of responding organization, topics such as standardized and validated test methodologies, risk assessment and safety in manufacturing and in the laboratory are generally considered central in a governance approach.

Some of the broad uncertainties in EHS which have been acknowledged in the FramingNano research include:

- missing common terminology and definitions
- methodologies to assess the effects of nanomaterials in the body and the environment
- metrology to reproducibly and reliably detect, quantify and characterise nanomaterials in their environment
- information on potential hazards of manufactured nanomaterials
- information on release and potential exposure routes of manufactured nanomaterials
- end of life issues of manufactured nanomaterials
- lack of standards
- adequate procedures in risk management

There seemed to be a consensus on the nature and extent of scientific gaps on EHS, but when it comes to decide how to deal with the existing gaps and how to prioritise actions in the light of limited resources, several opinions on how to set priorities in EHS issues emerged.

Overall, it can be concluded that on the basis of the current knowledge, sensible prioritisations must be made. It is therefore recommended, for example, to distinguish between "free" and "bound" nanomaterials, between "degradable" and "non degradable" or "soluble" and "insoluble" nanomaterials, and to focus on those nanomaterials where commercial relevance is given and/or

exposure is to be expected highest. On the other hand, as many of the necessary scientific building blocks for risk assessment are interdependent and need to be developed in a bottom-up process, a clear indication of EHS research priorities is necessary.

Recommendations on general principles and methodological aspects of EHS

- **Roadmap on EHS:** Define a clear and transparent roadmap (at EU or global level) on developments in EHS research, taking into account in particular the ISO roadmap in this field. The roadmap must be clear on priorities and actions to be taken (timeline, expected progress and results).
- **Observe:** Closely monitor developments in the field, through the establishment of specific observatory and assessment procedures (at least at EU level) on EHS developments.
- **Increase efforts:** Strongly increase (financial and human) efforts in research on building blocks for risk assessment of nano-related products, including instrumentations and validated analytical methods. Provide incentives for EHS research by considering these issues in public funding for non-risk research.
- **Agree on common terminology:** A commonly accepted terminology is pre-requisite to the organization, accessibility and understanding of new knowledge in nano-EHS.
- **Speed up standards development:** Mechanisms to facilitate participation to standards activities (ISO TC 229 and (national) mirror committees) must be explored in order to support work on standards (incentives and direct financial supports, for participation).
- **Use existing knowledge:** Explore the applicability of existing and newly developed knowledge and methods e.g. in order to identify critical materials and applications or for the protection of workers to manufactured nanomaterials (airborne nanoparticles).
- **Precautionary approach:** Many uncertainties on the hazards of the many different manufactured nanomaterials will persist for some time and make sound risk assessment difficult. Where the hazard cannot be properly assessed with current methodologies, a precautionary approach to minimise exposure should be chosen.
- **Best practices:** Develop, disseminate, and apply best available practices for the evaluation and management of risks, basing on a precautionary approach. Already existing public and private initiatives should be carefully examined.

3.1.1.2 Ethical, Legal and Societal Aspects (ELSA)

The importance of ELSA of nanotechnologies was widely recognised as discussed in the first FramingNano publication (FramingNano, 2009). However, apart from legal issues implicit in regulation which are closely related to the application of nanotechnologies, ELSA were considered to be of lower urgency by the stakeholders involved in the dialogue.

It turned evident that neither ethical issues nor societal concerns are clear-cut, also because they are expected to become more relevant with the potential uses or misuses of more distant, future (visionary) applications of nanotechnologies. Accordingly, they should be treated in a completely different way than risks related to safety[8], and it is understandable that stakeholder opinions on these issues are less well-defined than in the case of EHS, and that it is difficult to give these issues a clear order of priority.

[8] Further insights into possible approaches to ethical reflection on the development of N&N are provided by EU projects such as e.g. DEEPEN, NanoBio-RAISE and Nano2Life.

There is a consensus on the general principles and values which should guide the development of N&N, and these generally do not differ much from the ones indicated in the European Commission's Recommendation on a Code of Conduct for responsible N&N research (European Commission, 2008b). Particular emphasis is given to the principles of transparency and responsibility, which are closely related to the need for better information about the properties, behaviour, production and use of nano-related products in order to increase confidence in the safety of N&N.

Nevertheless, a clear understanding about the ways how to implement these principles seems missing, together with concrete responses to the ethical and societal concerns identified. This is underlined in the case of the EC Code of Conduct, where improved guidelines and indications of how to implement it are considered essential elements in enabling its widespread application.

Therefore, though the need to properly address the ethical and societal impacts of nanotechnologies has been rated important by stakeholders, there have been few or no clear indications for immediate needs and actions. The spectrum of the concerns related to ELSA (as identified in the previous phases of the project (FramingNano, 2009)) is ample and includes issues such as the impacts of nanotechnologies on medicine (e.g. through novel predictive diagnostics), on information and communication technology, on the security sector (e.g. privacy in relation to novel surveillance technologies), on energy technology and a sustainable economy, on novel nano-enabled foods, on animal testing and concerns about the global impact of nanotechnologies on poverty and on third world development.

It must also be noted that few (if any) of the issues identified are specific for nanotechnologies; many of them are rather specific to (novel) technologies in general, or sector-specific. However, nanotechnology may add new aspects to existing issues, widen their scope, or bring an 'old' issue to wider public awareness. Enough resources should therefore be dedicated to understand and define actions which translate agreed principles and values into concrete measures.

Recommendations on general principles and methodological aspects on ELSA

- **Responsibility, transparency, openness, social justice and accountability** have been identified to be key principles in the governance of nanotechnologies, and these principles must therefore be taken particularly into account for governance actions.
- **Risk-Benefit-Balance:** In order to determine an application's acceptance, risks must always be checked against the potential benefits, which, in turn, have to be compared with those provided by existing technologies. The extent at which the objective pursued can be stretched should be indicated.
- **Identification of ELSA:** Analysis should focus to single out specific issues and applications, so as to help gather concrete statements and opinions in order to anticipate and proactively address potential societal risks as well as benefits.

3.1.2 Communication and Dialogue

This section looks at three different aspects of communication. One is to establish and maintain a meaningful reflexive dialogue by including publics and stakeholders. The second is the communication of information on nanomaterials among stakeholders, e.g. along the value chain. The third aspect is about knowledge transfer, particularly by educating young people in science and technology:

- **Public Dialogue: Inclusiveness and Public Engagement**
- **Information Sharing among Stakeholders**
- **Knowledge transfer: Education and Professional Formation**

To be effective, some requirements, in terms of a general methodology and set of principles, should underpin any dialogue and communication initiatives amongst different groups of stakeholders. These are:

- Communication between the main stakeholders/players should be fostered
- Sufficient means of communicating, and pursuing communication should be provided, e.g. in the form of a publicly accessible platform
- Enhance communication of scientific findings and their interpretation in terms of risks rather than hazards
- Differentiate clearly between different risks, concerns, nanomaterials and applications
- Define clearly the priorities and actions to be taken (timeline, expected progress and results, failures and achievements)
- Pinpoint clearly roles, responsibilities and leadership for all stakeholders in the whole field of governance of nanotechnology
- Maintain the independence of those communicating with the public
- Make clear where there are uncertainties in what is known. However, the uncertainties should be seen in relation to what is already known and the fact that uncertainties are ubiquitous.

3.1.2.1 Public Dialogue: Inclusiveness and Public Engagement

Since the very beginning of the nanotechnology evolution, most stakeholders have agreed that the lessons from the rejection of genetically modified plants should be learned. This time, the broader public must be involved in an “inclusive” process of evaluating and balancing the benefits and risks of nanotechnologies. On the policy side, the aim is to elicit indicators of significant concern from non-involved members of the public (as opposed to stakeholder organisations) and hopefully also to promote a sense of involvement and trust.

Several initiatives on public engagement have been activated throughout Europe, both at regional and national level, and a clear commitment on this topic has been declared by the European Commission. In the case of nanotechnology the public has shown interest to be included in shaping the development of nanotechnologies. The Deepen FP7 research project therefore urged policy makers to be innovative in finding ways to ensure the public is given a say in the decision making

process, and encouraged them to explore different formats of public engagement (Davies, et al., 2009). Societal engagement was identified as central to bridging the gap between the development of nanotechnology and the involvement of society.

Even so, the EC has clearly committed itself to an inclusive approach, although the outcome of such process is connected with uncertainties. The Council of the European Union therefore invited the Commission *"to encourage public debate and foster public awareness"* (Council of the European Union, 2008), and the EESC recommended that *"structured dialogue with civil society be strengthened, on a sound and transparent basis, to provide a united European voice in this field, which is vital to our future on the global stage"* (European Economic and Social Committee, 2009).

However, the principle of inclusiveness has received rather an ambivalent rating throughout the project consultation. Inclusiveness is seen as a fundamental principle to build a proper level of trust and confidence, to take into account the concerns and ideas of the different players, and to distinguish between perceived and real risks. Many comments indicated that a model for responsible nanotechnology governance must provide means of including key stakeholders valued for their commitment to a constructive dialogue, while it is unrealistic to assume to involve the entire public in the process.

Stakeholders should be aware that public engagement is more than public dialogue. In line with recent EC policy, public engagement goes far beyond a "temperature sensing exercise" and allows to constructively taking up representative stakeholder opinions in the process of decision making in nanotechnology governance. Public engagement therefore requires an attitude that public opinions and concerns are genuinely taken into account in the process of governance. Public trust might become at stake when public engagement is preached but acceptance of nanotechnology is the real item on the agenda. In this case dialogues will be seen as no more than sophisticated opinion engineering or window dressing for fixed policies.

The FramingNano project has identified some key principles that should underlie public dialogue and the expected public inputs. Such process should lead us to find a commonly accepted agreement on a set of values and criteria on how to assess and decide in nanotechnology governance. These key principles should be taken up and integrated in the process of nanotechnology governance.

Recommendations on general principles and methodological aspects in Public Dialogue

- **Openness and adaptation:** policy makers, scientists, industry should communicate information in an interactive context with publics, and should also be open to changing their approaches in the light of what the 'lay' people have to say.
- **Follow-up:** people must be aware at the outset of what they can expect to happen in the policy process and get feedback on what actually happened. There should be a reasonable influence on the policy questions from the dialogue initiatives.
- **Learning curve:** Common and effective models of engagement should be developed, in order to avoid duplication and overlapping of activities. Awareness should be raised that a dialogue can first be started when all stakeholders in the process have reached a certain basic knowledge level. A clear learning curve and definition of the point when the dialogue can start must be defined.
- **Public information**: making available to the public clear and transparent descriptions of the approach to regulation and funding, anticipating benefits, costs, risks and uncertainties.

- **Meaning:** Methods should be found to include the public in the development of principles, values and criteria which guide the governing, assessment and decision making process on nanotechnologies. Public dialogue on nanotechnologies needs to be firmed and used to explore such criteria and values.
- **Trust, not engineered consent:** The creation of trust among the stakeholders and the public is key, not the engineering of consent. Policy makers, scientists or industry should communicate information in an interactive context with publics, and should also be open to changing their approaches in the light of what the 'lay' people have to say.
- **Differentiate:** Generalised statements on nanotechnologies are usually inadequate. In the communication, the stakeholders need to clearly differentiating between different risks, concerns, nanomaterials and applications.

In terms of inputs from public dialogue are expected:

- **Societal desirability:** Needs and advantages of existing and future N&N applications
- **Ethical concerns**: Wider ethical concerns related to use (and misuse) specific N&N applications[9]
- **Risk appetite**: Preferences about the level of tolerable risks (risk-benefit balance)
- **Values and Criteria** to be used to balance risks against benefits

3.1.2.2 Information Sharing Among Stakeholders

The transfer of data and knowledge among involved stakeholders is regarded as one of the key elements for dealing with uncertainties of EHS of nanomaterials. If proper tools are available, the efficiency of identifying, assessing, managing and communicating potential risks related to N&N can greatly be increased.

Three main levels of possible intervention have been identified during the project[10] :

1. **Inter-agency communication** among different (subject-specific) authorities, at regional or international level, and across application sectors
2. **Information exchange between industry and regulatory authorities**
3. **Data sharing along the value chain:** Knowledge transfer among those stakeholders producing data (industry, researchers) and those further along the value chain (producers, processors, consumers, recyclers.

There is a variety of initiatives on these three areas mainly on an informal basis (such as events and meetings among regulators and/or with stakeholders). Also some structured actions, such as voluntary/mandatory reporting schemes have been activated, so far however with a tepid response. Stewardship actions to improve risk management, cooperation and data sharing for manufactured nanomaterials have been prompted by single industries or by clusters of industries (the chemical industry has been particularly active). A central role in cooperation and data sharing is played by the

[9] Such as handling of information, privacy, food-related issues, military applications, global justice and equity, and the use of nanotechnologies for human enhancement.

[10] So far, the attention has been focused to manufactured nanomaterials, more than on nanotechnology in general, mainly because they are the "building blocks" of most of nano-related products.

Organization for Economic Co-operation (OECD) and by the International Organization for Standardization (ISO).

However, common and effective measures to ensure an effective interaction among regulatory agencies, industry and stakeholders in general are still missing, while it is acknowledged that N&N introduce materials with new properties which could currently slip through the net of regulation and control.

Authorities lack the necessary risk data to construct meaningful oversight options – on the other hand, the industry is often expected to have the necessary (but proprietary) data. In its report, IRGC recommend (IRGC, 2009) establishing systematic liaisons between government and industry to share risk information and promote socially responsible outcomes, and many problems of losing trust or public credibility in sectors such as food and cosmetics derive from unnecessary secrecy.

Knowledge transfer among stakeholders producing this data (industry, researchers) and those further along the value chain (producers, processors, consumers, recyclers) is an important aspect of communication. The definition of data disclosure procedures and making available to the public data and information on impacts of nanomaterials represent important issues to be considered in the governance platform. A balance must be found between the principle of public access to governmental information, particularly when related to risks to health or the environment, and the need to protect proprietary or sensitive data.

Regarding information of consumers and users of nanotechnologies, the "freedom to choose" for consumers seemed unequivocally accepted among all stakeholders. The closer the application is to the body of the user, the more important this freedom is usually rated[11] . However, the specific form of how to present such information to the consumer remains controversially discussed. It is seems, for instance, not clear at all whether labelling will allow consumers to make an informed choice, considering that the background information necessary to make such decision will not be on the product labels.

Recommendations on general principles and methodological aspects on information sharing along the value chain

- **Transparency**
- **Responsibility and accountability:** Ensure innovation takes place in a safe manner and with the proper level of (voluntary and mandatory) control and legislative intervention.
- **Avoid duplications:** Whenever possible, use/adapt already existing information requirements and procedures (including confidentiality settings) under existing regulations (e.g. REACH).
- **Improve knowledge:** Mechanisms and incentives should be provided to encourage stakeholders (researchers, industrialists, legislators) to develop and share data on the use of nanotechnologies along the value chain.
- **Adapt the MSDS:** Explore the possibility to adapt material safety data sheet (MSDS) to adequately represent the special properties of manufactured nanomaterials.

[11] This latter request has been (at least partially) answered by recent modifications of the EU Directive for cosmetics introducing labelling of nanomaterials in this sector. Also in the food sectors some rules related to labelling will probably be introduced.

- **Strengthen Industry /authorities partnerships**: Establish a permanent communication interface, with a strong effort to include also SMEs. Consider existing industry product stewardship actions and other mechanisms (such as Substance Information Exchange Forum (SIEF) under REACH, relevant OECD and ISO activities.
- **Inter-agency communication** needs to be strengthened by e.g. organising regular meetings (possibly on a formal base) among EU and national regulatory agencies (both cross-sectoral, and sector specific) to foster a common understanding and support the definition of common methodologies.
- **Confidentiality:** Explore methods to overcome the problem of confidential business information (CBI) and intellectual property in data sharing with industry.
- **Establish open data repositories** such as database on EHS, to enable industry and researchers to share data with regulators, consumers and other businesses on a commonly accepted (and standardized) methodology.
- **Standards:** Support standards and harmonisation activities (financial support to participation to standards work).

3.1.2.3 Knowledge Transfer: Education and Professional Formation

With increasing commercial importance, a growing number of people and professionals will get in contact with practical applications of nanotechnologies. The importance of strengthening commitment to provide adequate education at universities and at vocational schools in the areas of both basic and professional education is acknowledged by stakeholders, and the necessary teaching and learning materials need to be developed to support teachers in acquiring and mediating the necessary skills and knowledge on nanotechnologies.

Implementation of nanotechnologies in the basic and professional education curricula presents an opportunity to reach broad sectors of the society and ensure the building of a base of knowledge necessary to lead an informed discussion on nanotechnologies and their implications.

Recommendations on general principles and methodological aspects in education

- **School education:** Responsible development and application of nanotechnologies is based on an adequate education at schools and universities. Interdisciplinary education and training of teachers, including topics related to health and safety of nanotechnologies need to be addressed.
- **Professional education**: Nanotechnologies will gain increasing importance in our professional lives. Professional education should therefore apply at the stage of the education of professionals, in particular to strengthen the knowledge of professionals in the area of occupational safety and health (OSH).

3.1.3 Adaptive and Flexible Governance: Adaptive Regulation

With respect to a few years ago, when there were two mutually incompatible views toward regulation (a self-regulating "laisser-faire" model and the idea of a total moratorium), to date, the on-going reflections and the attitudes on regulation of nanotechnologies are broader and more articulated. However, there is a general consensus among scientists, policy experts, regulators and civil society organisations that there are some significant shortcomings in the application of the existing regulation to N&N.

Explicit regulations for nanomaterials and nano-related products are still rare. Nevertheless, it is agreed that nanomaterials and applications making use of nanotechnologies could either fall under the scope of existing regulatory schemes or be identified under regulation of all kinds of emerging technologies. For the time being, the identified shortcomings are therefore generally rather related to the implementation of the existing provisions in practice than to the scope of existing legislations. In synthesis, the shortcomings include:

- mandatory information reporting or safety evaluation requirements which are commonly triggered by mass (e.g. the annual production volume) instead of values taking account of the specific properties of nanomaterials
- the profound lack of (eco) toxicological data and standardised methodologies which prevents the development of meaningful data on risk assessment (such as occupational exposure limits)
- the lack of validated and standardised metrologies (instruments) to detect, characterise and quantify nanomaterials makes it difficult to determine actual exposure levels

These shortcomings and uncertainties affect most of the areas of legislation and sectors of applications related to nanotechnologies (FramingNano, 2009).

While the uncertainties on the potential risks of manufactured nanomaterials and nanotechnologies are expected to remain relevant and will not be fully answered within a short time, a governance framework must provide structures to deal with these uncertainties and provide means on how to find practical ways to come to commonly accepted decisions in risk governance based on meaningful stakeholder inclusion.

To avoid a sterile discussion becoming entangled in a never ending 'vicious cycle' (Risk Bridge, 2009), it is thus necessary to start a proactive and cooperative process among stakeholders to foster a dynamic regulatory situation, ready to adapt to the evolution of scientific knowledge and nanotechnology applications, but also to changing public attitudes. Essential elements are to

- improve the knowledge base on the production, use and commercialisation of nanomaterials and nano-related applications as well as related EHS issues
- apply the best available practices for the evaluation and management of risks, basing on a precautionary approach
- remain vigilant, defining concrete and effective measures to adapt/improve the regulatory situation, and monitor the effectiveness of their implementation.

The need for concrete measures to improve the level of implementation of N&N in the existing regulatory frameworks has been clearly underlined in the project consultation, and is backing the recent position of the European Parliament which asked the EC to report on the regulatory situation on N&N within 2011.

The level of confidence in existing regulations when dealing with nanotechnology depends both on the type of product considered and the legislative framework within which it has to comply (FramingNano, 2009). In regards of priority industry sectors and application areas, the attention seemed to be focused in particular on the following sectors: foods and feedstuffs, cosmetics, chemical substances, environmental protection, occupational safety and (apparently with lower urgency) to medical devices and pharmaceuticals. Products and applications resulting in close body contact or ingestion are generally rated highly in terms of priority. The areas of textiles, articles of daily use in general, products especially relevant to children (toys, products for babies), electronics, and agricultural applications also emerged to be sensible areas.

Voluntary measures ("soft" regulation) and "hard" regulation can be adapted in a combined approach, although some stakeholders have indicated fears that voluntary measures could be "abused" to delay or weaken mandatory regulations. In order to decide which form or regulation is applied best, the impact of hard law and soft law has to be assessed in the individual case (e.g. depending on the area of application). Therefore, proper structures to get such feedback on the impact and effectiveness of individual forms of rules need to be established within the governance framework.

Regulatory subsidiarity is an important element to be taken into consideration. It is important to pinpoint the tendency of European countries regarding regulation and legislation with respect to the directions coming from the European Commission (harmonisation at European level). Stakeholders generally indicated to prefer a European approach over individual national regulations, and they tended to favour international regulations at least in a second phase.

Regulatory stability is a concern which has repeatedly been underlined during the project analysis, mainly by opinions from industry, fearing that ever-changing and stricter regulatory requirements represent a barrier to innovation, commercialisation, and financial investment into new products and technologies.

In conclusion, a dynamic character of the governance framework will be necessary in the light of the many differences of the different sectors of application it must cover, the corresponding differences in how risks are handled and how regulation is applied, to adapt to future generations of nanotechnology-related products and applications expected to present additional or different challenges for nanotechnology governance and to take into account (changing) public attitude and responsiveness.

There should be a strong interaction between science on the one hand, giving the state of the art of the understanding, and governance and regulation on the other hand. These two parts need to be closely linked and updated in the idea of a dynamic approach.

Recommendations on general principles and methodological aspects on institutional issues; "hard" and "soft" regulation

- **Best practices**: Apply best available practices for the evaluation and management of risks, basing on a precautionary approach.
- **Remain vigilant**: defining concrete and effective measures to adapt/improve the regulatory situation, and monitor their effective implementation.
- **Support existing regulatory bodies**: existing bodies should oversee nanotech regulation, but they need to be equipped with the necessary financial and personnel capacity to take up this emerging issue adequately.
- **Support SMEs**: develop and make available tools and guidelines which support SME in handling N&N (e.g. nanospecific risk management systems) and fulfilling regulatory duties concerning N&N.
- **Combined approach:** support a combination of mandatory and voluntary measures.
- **Transparency and accountability**
- **Monitor effectiveness:** Provide mechanisms to monitor effectiveness of voluntary measures
- **Explore incentives:** careful design of independent control, increased stakeholder pressure, better publicity and benchmarks.
- **Benchmarks:** provide benchmarks and guidance to voluntary measures, in particular the EC code of Conduct, initiatives, to support and increase participation.

3.1.4 Creating Trust between Stakeholders

Trust in regulators and public authorities is considered crucial to gain public acceptance of a new technology. Consequently, the generation of trust among those directly involved in the governance process, and among those only affected by it, must be considered a central element in the process of creating a sustainable governance framework for nanotechnologies.

The current uncertainties and *"the delay and lack of reliable risk-related information have led to a loss of trust between public authorities, industry and non-governmental organisations"* (IRGC, 2009). This needs to be addressed by the governance platform which must promote trust-building processes among the stakeholders. Trust, however, cannot be created at will. It is the result of stakeholder perceptions deriving from a variety of factors defining good governance, such as enhancing transparency, providing meaningful ways of participation and respond to citizen's needs and concerns

The FramingNano stakeholder consultation particularly emphasized the important role and the expectations in policymakers and regulators. Public trust in the ability of public bodies to regulate N&N for good of society was of paramount importance. The concepts of inclusiveness, transparency, public understanding and trust, always tied to the value of social justice and where all interested stakeholders are included and invited to engage in the dialogue, were set against an out-dated concept of "engineered consent" which springs from the belief that public perception can be guided by spreading selected information.

3.2 The FramingNano Governance Platform Concept

Only if the broader impacts of nanotechnologies are well understood, appropriate measures, actions and strategies to manage these impacts can be developed. In order to be able to design an appropriate framework, intelligence of the quickly evolving state of the art of nanotechnology-induced change is required.

From the FramingNano project research it has been concluded that governance and regulation of nanotechnologies must be considered a dynamic affair which needs to be continuously adapted. This implies a continuous observation of the state-of-the-art knowledge on nanotechnology-induced change.

Even so, the relevant stakeholders and the interested public have to be meaningfully included in the definition of commonly accepted principles, criteria and values to be used for the assessment of these changes.

The underlying basic assumptions, identified in section 3.1, indicate how to deal with the present and future governance challenges related to a responsible nanotechnology development in a prospective, adaptive and inclusive way. This is suggested to be done by establishing a set of capacities and assigning responsibilities by:

- engaging with the public and stakeholders to agree on a **Common Assessment Methodology** on nanotechnology-induced change. The resulting values and principles will underlie decision making in nanotechnology governance. This will allow stakeholders to elaborate views, contribute to an informed debate and exert concrete influence in governance and policies of nanotechnology development.
- establishing an **Observatory** which continuously overviews and evaluates the relevant stakeholders, developments and the advancing state-of-the-art knowledge about nanotechnology-induced change and impact assessment, taking into account the principles and values which emerge from the Common Assessment Methodology.
- implementing an **Advisory** which pro-actively assesses emerging trends and developments on the basis of the Observatory and proposes visions and actions concerning nanotechnology governance.
- evaluating and deciding on the proposed visions and actions within the existing decision making structures, but taking into account the inputs and guidelines resulting from the public engagement under the process of defining a Common Assessment Methodology on nanotechnology-induced change (**Evaluation and Decision Making**) .
- implementing a orderly feedback function which transparently documents the decision making process, makes the results available to the Observatory, the public and the stakeholders, and which allows to validate whether the decision making process meets the criteria established in the Common Assessment Methodology (**Feedback**).

If these capacities and responsibilities are set up in an interconnected and continuous way, the resulting process of nanotechnology governance will be **1) adaptive or "self-corrective"** as it provides a framework which allows that new information on or new issues of nanotechnology-induced change are taken up according to the concerns, priorities and principles of the stakeholders,

2) inclusive as the relevant stakeholders and the interested public are meaningfully engaged in the definition of commonly accepted principles, criteria and values to be used for the assessment of nanotechnology-induced change and therefore have a say in defining the basis which underlies decision making in nanotechnology governance, and **3) transparent and trust-building** in terms that the decisions in nanotechnology governance are based on a commonly accepted assessment methodology which is open for on-going public revision.

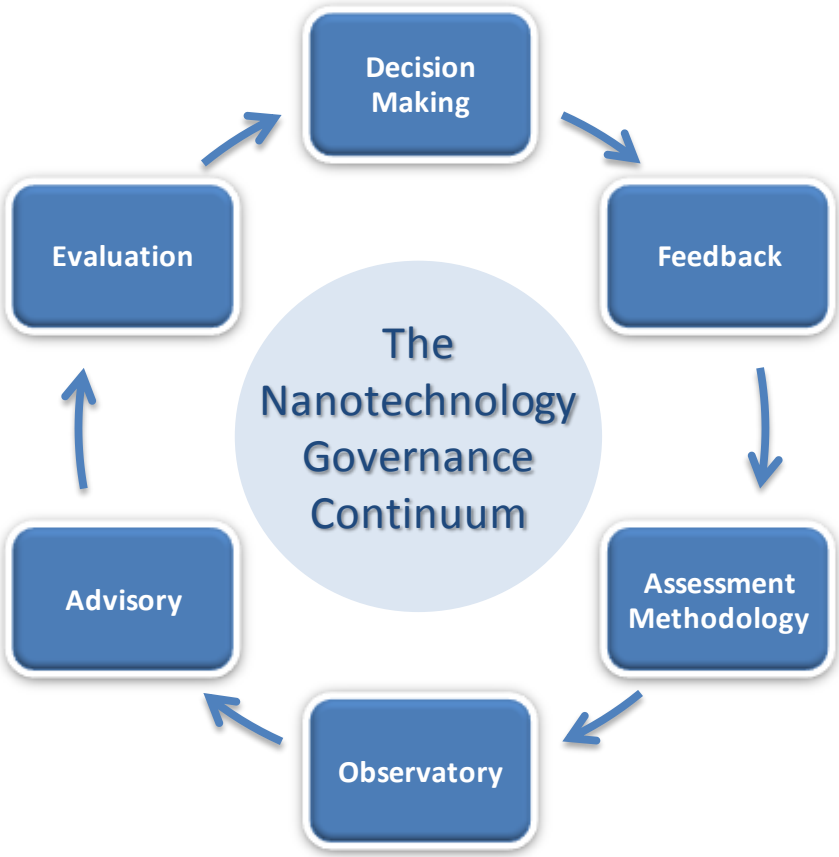


Figure 3: Overview of the process of the FramingNano Governance Platform (FramingNano Consortium, 2009)

The framework and structures envisaged to achieve these objectives should permit the establishment of a governance process that runs in a continuously-fed loop to provide a dynamic, sustainable governance model capable of coping with the present and future challenges of nanotechnologies (Figure 3).

The governance model process is proposed to consist of five key elements: “Common Assessment Methodology”, “Observatory”, “Evaluation”, “Decision Making” and “Feedback”. These elements are linked in a loop to reflect the continuous, adaptive and flexible approach to nanotechnology governance proposed by the Platform.

3.2.1 Structure of the FramingNano Governance Platform

The implementation of a continuous nanotechnology governance process will allow addressing present and future challenges in nanotechnology governance in a prospective, adaptive and inclusive way.

The continuous process of nanotechnology governance (as introduced in section 3.2 and Figure 3) is proposed to be put into operation by implementing two key structures which underpin the proposal of the FramingNano Governance Platform: a **Deliberative Panel** and a **Decision Making Body.** The proposed elements of the FramingNano Governance Platform are represented in Figure 4 and further detailed in the following paragraphs.

3.2.1.1 The Deliberative Panel

The Deliberative Panel (panel on nanotechnology-induced change) is proposed to be established as a structured, permanent group of experts responsible for observing, assessing and advising on the impacts of nanotechnologies and of convergence at the nanoscale.

The Deliberative Panel will monitor the on-going developments and the state-of-the-art knowledge concerning nanotechnology-induced change (**Observatory *function***), and it will translate this intelligence into visions, actions and recommendations on nanotechnology governance towards decision makers, thereby advising them on appropriate measures in the governance of nanotechnologies (**Advisory *function***).

Nanotechnologies shall be developed and used for the good of society. However, it is not necessarily evident what risks the public is willing to take in exchange for certain benefits of nanotechnologies, (e.g. in nanomedicine or nanotechnology-enabled diagnostics).

One of the key challenges for the Panel consequently consists in directing its attention towards those issues which are identified to be of particular relevance, urgency, controversy or the like by the affected stakeholders. The Panel is therefore engaging with stakeholders and the public to elaborate a **Common Assessment Methodology.** Such methodology will provide an integrated set of values, criteria, priorities and principles which should, according to the stakeholders, underlie the assessment of nanotechnology-induced change and the decision making in nanotechnology governance.

Examples of criteria that could be established in the context of the Common Assessment Methodology include

- the social desirability of different nanotechnology applications;
- EHS and ELSA priorities to be considered in the research and governance process;
- the level of tolerable risk taking in regards of the expected benefits of individual applications;
- particular values and criteria to be considered in the assessment process of nanotechnology-induced change.

The values and criteria determined through the Common Assessment Methodology will allow a prioritisation of the existing and emerging issues of nanotechnology-induced change and will provide

guidance to decision makers by specifying a framework for normative qualification of the available knowledge and the knowledge gaps to be addressed by the Panel.

The Panel will coordinate and support the development of the common assessment methodology. This ensures a more deliberative and inclusive approach to policy making process and nanotechnology governance in general. As the public and a variety of stakeholders will be affected by decisions in nanotechnology governance, such normative dimensions of nanotechnology-induced change need to be assessed in a multi-stakeholder approach rather than just in, e.g., scientific circles. Therefore, a transparent procedure of public engagement must accompany the ongoing "calibration" of the assessment methodology according to the preferences of the stakeholders and the public. This process must provide means of short term as well as systemic, long term approaches to nanotechnology-induced change assessment.

Since these values and principles are expected to be subject to change and refinement with the developments of nanotechnologies, this process must take place on an on-going basis.

The challenge for the Panel's **Observatory function** would be to provide continuously updated intelligence about the state-of-the-art knowledge of nanotechnology-induced change, to identify and assess the large field of stakeholders (whether actively engaged in nanotechnology research, development or governance or only "affected") and to evaluate their roles (interests, concerns, agenda). The Observatory may be seen as a monitoring and early warning / early listening system, which provides the best available information relevant to understanding nanotechnology-induced change for the development of appropriate measures and actions and for the use of decision makers.

In the process of identifying, assessing and condensing the relevant issues for the Advisory, the Observatory will follow the principles, values and criteria provided by the Common Assessment Methodology. This ensures that issues are taken up based on the priorities and concerns of a broad range of stakeholders (including the public).

In order to be able to function effectively, the Panel should ideally be structured into different topic-related Working Groups (WG) focusing on specific issues related to nanotechnology-induced change, e.g. technological developments (TECH), environmental health and safety (EHS), ethical, legal and societal aspects (ELSA), security and defence (SEC), economic impacts (ECO), etc. Certain issues could also be structured according to industrial sectors or applications. The list of issues (and the allocation of WGs) is not exhaustive and is expected to be subject to changes over time, and the Observatory will direct its attention to those issues which are of identified to be of particular relevance in the Common Assessment Methodology.

In general, the Observatory should be able to rely on open information archives. One recent to such an archive is given by the FP7 project ICPC NanoNet which aims to establish a freely accessible, open publication database on scientific literature on nanoscience research (Nano Archive). In the first place, peer-reviewed literature should be considered, but also "grey literature" could be taken into account. Moreover, in order to avoid IPR and CBI issues for the contributing industry, such database could be based on properties of nanomaterials rather than on the characteristics of nano-products.

However, as the state of the art of science and technology cannot be defined by academia only, a critical task of the Observatory is to ensure the inclusion of all relevant inputs, which most importantly also includes data and information arising from industry. The Panel will need to explore

ways to overcome constraints arising from the confidential character of business information and intellectual property rights (IPR).

Based on the outcomes of the Observatory and input to the Common Assessment Methodology, the Panel will fulfil its **advisory function** by proposing models visions and actions relevant for nanotechnology governance to the Decision Making Body (DMB).

The Advisory would provide advice on how to adequately react in a timely and responsible way to the gaps and challenges that the rapid and dynamic development of nanotechnologies present to regulators, decision-makers and other stakeholders involved, based on principles and values from stakeholder input. It would indicate means of how to adapt the current governance framework to transformational technologies converging at the nanoscale, towards a predictable and innovation friendly framework.

The Advisory function would remain with a restricted number of experts acting as steering/scientific committee guiding the development of the Common Assessment Methodology and the activity of the Observatory function, carried out by a larger group of experts.

Outputs of the Advisory could include, for example, advice on

- best practices and guidelines to be implemented in international / national law
- coordination of EHS research & development
- actions to adjust international/national regulations
- improvements of soft regulation / voluntary measures
- early warning / early listening issues
- methodology for data sharing
- indications for responsible R&D and innovation policies

In order to be able to function effectively and to understand the impacts of nanotechnology and of convergence at the nanoscale, the Panel should comprise multidisciplinary experts in different nanotechnology fields from different countries, with backgrounds and functions in academia and research, business, public institutions and civil society organisations. A majority of opinions need to be expressed and different schools of thought should have the occasion to participate in the Panel.

It will be of central importance that these experts are not restricted by conflicts of interest and that they are regarded as fully independent and unbiased; otherwise, its work will not be trusted.

The input of laypersons is also important to ensure the widest representation of societal interests. The Panel would, therefore, also explore methods to effectively gather such opinions by considering, in the first instance, the outcomes of the different public engagement initiatives on nanotechnology-induced change that are currently in place at national, regional and worldwide levels. The organisation of such initiatives, however, is out of the scope of the Panel.

3.2.1.2 The Decision Making Body

The Decision Making Body (DMB) is a board which would be comprised of representatives of those existing institutions and competent authorities responsible for decision making in the different fields affected by nanotechnologies. These representatives would be brought together in order to share a common understanding of the transdisciplinary nature of nanotechnology-induced change and to channel the outputs of the Deliberative Panel into the relevant decision making processes. The DMB has a threefold responsibility:

- evaluate the proposed visions and actions (taking into account the Common Assessment Methodology) (**Evaluation**)
- decide on the proposed visions and actions (**Decision Making**)
- give feedback on the decision making process and the results (**Feedback**)

Existing decision-making structures covering nanotechnologies are scattered widely amongst existing institutions at all levels of subsidiarity. Depending on the area of application (e.g. chemicals, foods, medical devices, pharmaceuticals, etc.), different governance initiatives and regulatory frameworks are applied or consulted (e.g. REACH or other application or product-specific regulations) and decision making is expected to take place within these existing frameworks as appropriate. These existing decision making structures must be included in the overall process of the Governance Platform and their corresponding responsibilities and accountabilities recognised in order to avoid unnecessary fragmentation of responsibilities and duplication of efforts.

The relevant decision makers are responsible for the evaluation and implementation of the visions, recommendations and actions proposed by the Deliberative Panel in their respective areas of competence. The overarching challenge for the DMB is to **evaluate and decide** on recommendations and proposals related to nanotechnology governance, taking account of the principles and values emerging from the Common Assessment Methodology activities developed together with involved stakeholders and the broader public.

At the **Evaluation** stage, the actions and recommendations for nanotechnology governance resulting from the deliberative process are evaluated and judged according to the terms of reference of the Common Assessment Methodology (principles, priorities, values, criteria, etc.) which has been derived from the corresponding public engagement process.

Based on the Evaluation, the **Decision Making** can take place. It would be essential for the national competent authorities (governments, regulators) to participate in the DMB, and the relevant decision makers would be responsible for the implementation of the visions, recommendations and actions proposed by the Deliberative Panel in their respective areas of competence. The DMB could meet on a regular basis, e.g. in the context of a conference on nanotechnology-induced change.

To maintain an effective and transparent evaluation and decision making process, the DMB should be subject to a **Feedback** function which makes its output available to the Deliberative Panel, allowing validation as to whether the decisions taken address the needs identified by the Commonly Assessment Methodology.

3.3 Implementation of the Governance Platform

The issue of where to host the Deliberative Panel and DMB is ultimately a political one. Depending on the level at which the Governance Platform will be implemented (European level, global), the Deliberative Panel and the DMB could be hosted by an existing European or United Nations structure, or an informal intergovernmental organisation.

At the European level, both the Deliberative Panel and the DMB could report to the European Commission. While decisions are adopted at Member State level, policy implementation will remain under the responsibility of national Competent Authorities. It is desirable that the proposed Governance Platform be adopted at international level to facilitate cross-border trade and to assure that a responsible development of nanotechnologies takes place worldwide.

Recent developments indicate that the International Conference on Chemicals Management (ICCM) under the Strategic Approach to International Chemicals Management (SAICM) of the UN Environment Programme (UNEP) is on the way to be established as the first international forum to discuss such issues on a truly and entirely global level. It is a multi-stakeholder approach, which includes governments and non-governmental organisations.

The regular International Conference on Chemicals Management (ICCM) is part of SACIM's action plan. At the second ICCM meeting in May 2009 in Geneva, nanotechnology and manufactured nanomaterials were discussed as an emerging policy issue, and the Conference agreed to include adding the issue of nanotechnology and manufactured nanomaterials to the Global Plan of Action on the agenda for the third session of the Conference. This forum might be a suitable place to decide on global issues of nanotechnology governance.

Alternatively, the International Dialogue on Responsible Research and Development of Nanotechnology could be considered as the hosting organisation. This dialogue is of informal nature, aiming to facilitate good governance in nanotechnology and at a development of nanotechnology that corresponds to the needs of society as a whole. In this respect this dialogue wants to be inclusive, involving all countries and stakeholders interested in the responsible and sustainable development of nanotechnology. Issues such as global approaches in nanotechnology governance, inclusiveness, societal engagement and coordinated observatories have been discussed during the 3rd International Dialogue taking place in Brussels in March 2008 which has been organised by the European Commission.

Related examples and comparable concepts or precursors of the proposed Governance Platform and its modules are described in Annex I: Precursors and Examples for the Governance Platform.

With regard to the timescale for adoption of the Governance Platform, the implementation of the technical, institutional and communication-related recommendations summarised in Annex II is the **short term, immediate,** goal. These actions are an essential prerequisite to the adoption of a fully-fledged Governance Platform **in the short to medium term** at global, and not just EU, level, thereby ensuring an effective international harmonisation of procedures.

In the **medium to long term**, key objectives will include the continuous optimisation and adaptation of the Governance Platform to face the challenges posed by emerging, and potentially revolutionary, applications of nanotechnologies so that full advantage can be taken of them.

The Governance Platform as proposed will help to translate the complex and major current and future challenges in nanotechnology governance, together with those presented by other converging technologies, into an opportunity and driver for growth for the benefit of the society as a whole.

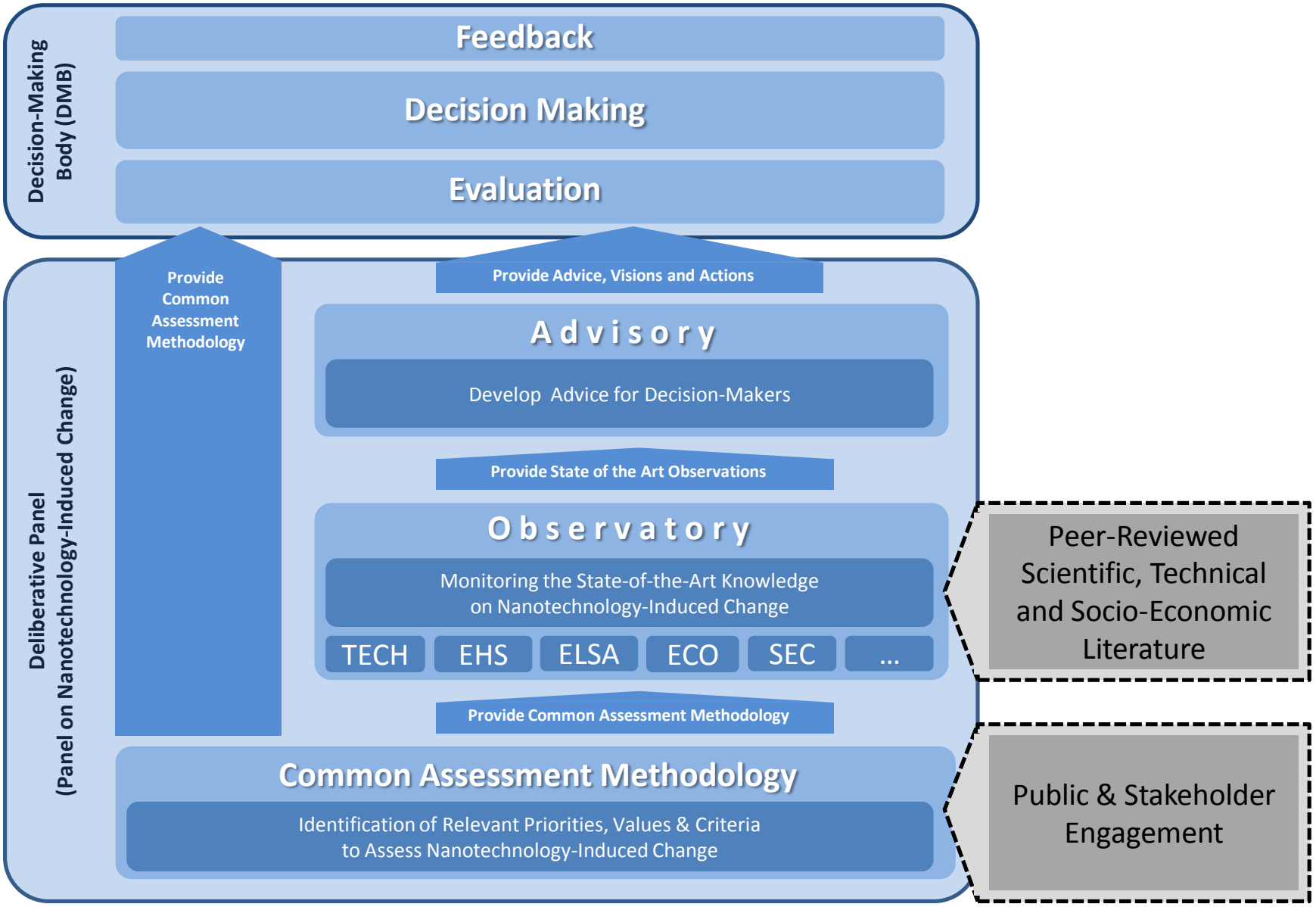


Figure 4: Overview on the structure of the FramingNano Governance Platform (FramingNano Consortium 2009)

Background Parts

The following parts of this report contain detailed background information which was acquired during the entire FramingNano project and which formed the basis for the deliberative process resulting in the proposal for the FramingNano Governance Platform.

4 Outlining the Problem of Nano Governance

4.1 Nanotechnologies: An Issue of Overarching Impact

Nanotechnologies are seen amongst the most innovative and pioneering technologies of our time. Currently, products making use of nanotechnologies and/or manufactured nanomaterials are making their way to the shelves of the stores thanks also to the fact that nanotechnologies can be implemented in existing products and processes, improving their functionality.

As a consequence of the increasing number of nanotechnology-related products that refer to practically all industrial sectors, concerns about potential risks associated with them are raising. At the moment this concern is linked to use of manufactured nanomaterials/nanoparticles and their effects on environment, health and safety (EHS). Ethical, legal and social aspects (ELSA), though important, are presently more in the background. Of particular concern to toxicologists and workplace hygiene experts are especially the non-degradable and insoluble nanoparticles which have been shown to be able to enter the body through various pathways and exhibit interactions that have previously not been observed.

A new field of science, called nanotoxicology, is emerging, which deals with effects and mechanisms of action of nanoparticles on the cellular level and in organisms. Of particular concern to toxicologists are, besides potential short-term effects, eventual harmful effects on humans and the environment over the long-term. This makes it an especially delicate issue, since such effects are difficult to investigate and only manifest after a long time when considerable exposure might already have happened.

These fears have led to a vivid discussion about the balance of benefits and risks of manufactured nanomaterials in recent years. From the course of previous technology debates such as, e.g. nuclear power or genetically modified organisms (GMO) in Europe, it became evident that multiple factors can dampen the sustainable and successful development of a new technology such as late identification of EHS risks as well as missing or late inclusion of the affected stakeholders. It is therefore generally perceived that the acceptance of a technology by the broad public is of utmost importance and a precondition for a sustained development of nanotechnologies.

The awareness about the potential risks of nanotechnology risks has dramatically risen in recent years, not only among researchers, but also within the industry, among lawmakers, regulators, environmental advocates and (to some limited extent) the broader public alike. It has become clear to (most) stakeholders with interests in nanotechnologies that just one major incident with a relation to nanotechnologies anywhere in the world could trigger international reactions that might not remain restricted to the specific application it originated from.

Since so many stakeholders are in some way affected by or concerned about nanotechnologies, it has become evident that some sort of inclusive approach is necessary for the dialogue on issues of governance and regulation regarding manufactured nanomaterials. In the course of the ongoing debate, various stakeholder groups have issued differing calls for adequate risk governance and

regulation, and questions arose as which regulatory or policy instruments are most effective and appropriate for managing the potential risks associated with nanotechnologies.

4.2 Challenges of Dealing with the Uncertainty

While applications making use of the novel properties of nanomaterials are increasingly being put on the market, the scientific knowledge about potential health, safety, environmental, ethical, legal and societal effects of these technologies considerably lags behind.

In order for a responsible development of nanotechnologies to work, risk assessment procedures should be established and the results should subsequently be implemented into risk management. To come to sensible decisions in risk management, stakeholders need to be able to identify nanomaterials, know the different types of hazards involved, estimate release and exposure, and detect and measure the nanomaterials in the corresponding surroundings.

> How to apply adequate oversight when the state of scientific knowledge is not adequate is one of the basic dilemmas in developing and applying 21st-century oversight mechanisms. In most cases, the science related to risk will be primitive and uncertain, but the potential risks will be serious enough so that lack of oversight will not be an acceptable option (Davies, 2009).

The key uncertainties include the agreement on definitions and the development of adequate metrology and methodology to detect, quantify, characterise and assess nanomaterials:

I) Uncertainties about **terminology and definitions**. Since there exists no standardised definition of "nano", different scientific and regulatory definitions of nanotechnologies and nanomaterials are used depending on the regulatory subject and sector of application, rendering communication complicated. Since "nanotechnology" as a single technology does not exist but rather represents an imaginary set of possibilities and promises to take influence at the level of atoms and molecules, a characterisation of what is "nano" in the individual case has to be included to be clear.

> A definition of nanoparticles based on their non-bulk size-dependent properties is needed to better focus future research efforts in nanotoxicology, and to compare the results of studies performed on particles of identical composition (Auffan, et al., 2009).

II) Uncertainties in **metrologies and methodologies** to (reproducibly and reliably) characterise and test nanomaterials and their effects in the body and the environment. Existing analytic methods may not necessarily be appropriate for determining the distribution, partitioning and persistence of nanomaterials and nanosystems under various conditions. Although SCENIHR concluded that "currently available OECD guidelines for the testing of chemicals are likely to be adequate to detect potential hazards of manufactured nanomaterials as well" (SCENIHR, 2007), the existing instruments for the detection, characterisation and in situ monitoring of nanomaterials, as well as common test procedures and risk assessment strategies will have to be validated and possibly adapted in terms of their appropriateness for use with manufactured nanomaterials. Maynard et al. therefore in 2006 proposed to develop within one year the necessary strategic programmes that would enable relevant risk-focused research (Maynard, 2006)[12].

[12] Maynard et al. proposed to

- "develop instruments to assess exposure to engineered nanomaterials in air and water, within the next 3–10 years"

The lack of a commonly accepted and validated standardised approach in terminology, nomenclature, test strategies and other methodologies represents a huge challenge in the process of initiating a coordinated, meaningful and timely assessment of nanomaterial risks. As long as scientific studies remain difficult or impossible to compare among each other, the evolving nanomaterial risk database will remain fragmentary, and the synergistic effect of standardised tests will complicate communication and a common approach in risk assessment.

4.2.1 Ramping Up Risk Assessment

Some specific hazards have been identified in the context of risk for human health and the environment (SCENIHR, 2009). For some nanomaterials, toxic effects on environmental organisms have been demonstrated, as well as the potential to transfer across environmental species, indicating a potential for bioaccumulation in species at the end of that part of the food chain.

Even if a specific scenario is determined hazardous, for a risk there must be an exposure. Specific gaps exist on the level of hazard estimation and exposure assessment. For instance on detection and measurement of nanoparticles at the workplace and in the environment, the estimation of the amounts of nanomaterials present in products on the market plus the potential release of nanomaterials from these products into the environment. Finally, information on the uptake, distribution and possible modification of nanomaterials in the environment and within the body, as well as understanding and predicting the precise cause-and-effect chain of nanomaterials interacting with organisms and tissues is missing.

I) Hazards have been observed by scientists for various nanoparticles, but it has so far been impossible to systematically identify causality between the observed hazards and specific physical and chemical properties. Transformation from dose-response relationships to safe no-effect levels or thresholds is hardly possible. For nanomaterials, mass is not a good measure for description of the effects. Characteristics as surface and number of particles appear to be a better measure. Apart from short-term toxicity and exposure, long-term issues have been reported to be evenly or even more critical. Finally, there is almost no epidemiologic data available of effects after constant, but low exposure to certain nanomaterials.

II) Exposure related information is also reported to be scarce, which can mainly be attributed to the fact that currently the presence and characteristics of nanomaterials in the work place and in the environment cannot yet be measured and assessed reliably, and to the fact that the missing information on where possible sources of emission might be found. In addition, hardly any information is available on the concentration and form of the nanomaterials in the products and the potential release of them out of these products.

In abovementioned context, a generalisation of risk assessment findings among different nanomaterials is not meaningful; a strict **case-by-case approach** is therefore necessary (SCENIHR, 2009).

- "develop robust systems for evaluating the health and environmental impact of engineered nanomaterials over their entire life, within the next 5 years"
- "develop and validate methods to evaluate the toxicity of engineered nanomaterials, within the next 5–15 years"
- "develop models for predicting the potential impact of engineered nanomaterials on the environment and human health, within the next 10 years"

4.2.2 Adapting the Regulatory Framework

The big challenge for regulators of nanomaterials and technologies is to ensure a certain level of safety without stifling innovation and be sure of social acceptance of the technology (Bowman, et al., 2009). However, the high level of scientific uncertainty surrounding EHS risks complicates the evaluation of the adequacy of regulatory responses, and regulations need to be flexible to accommodate newly emerging risks while assuring the public that existing products in the marketplace are safe. Nanotechnology regulators on both sides of the Atlantic are keen to avoid a situation where scientific uncertainty amplifies risk perceptions by a sceptical public, as was the case in the early debate about genetically modified food (Falkner, et al., 2009).

Although the lagging of risk research behind commercial exploitation of a new technology can be explained by the emerging nature of any new technology and that business interests as the main driver to commercially push a technology, the existing uncertainties in identifying, assessing and quantifying risks related to nanotechnologies remain a huge challenge to those in charge of oversight, control and ensuring a certain level of safety to consumers, employers and the public. Current regulatory systems are designed on the basis of **quantitative cause-and-effect-relations**, clear thresholds and accepted levels of risk taking. However, many of the necessary prerequisites to build such evidence-based regulations for manufactured nanomaterials to control their manufacture, processing, use and disposal are (at least in parts) not available yet.

In many current regulatory systems such as those for chemical substances under REACH and TSCA, regulatory requirements and triggers are established referring to **mass based thresholds** and annual production volumes. Due to their tiny size, nanoparticles possess a multiplicatively increased surface in relation to their volume and mass, which is connected to an increased chemical activity. It is feared that due to (still) low production volumes of many manufactured nanomaterials, they will slip through the regulatory net and remain unregulated. The existing mass or volume parameters have therefore widely been acknowledged to be inadequate in the case of nanomaterials for regulatory purposes.

Among the regulatory issues under discussion, it has been suggested to review existing regulatory frameworks regarding their ability to allow **identification of manufactured nanomaterials** for regulatory purposes (whether they are able to distinct nanomaterials from non-nanomaterials and therefore apply specific rules, if necessary) and whether the current mechanisms of distinguishing and treating different chemical substances are also appropriate for the “new” class of nanoscale substances. The necessary adaptations of current regulations (e.g. in chemicals legislation) are currently under debate in the USA and in the EU. Under REACH, however, the distinction between “new” and “existing” chemicals, as being made by many other regulatory systems, has largely been eliminated and all chemicals have to be registered, tested and updated regularly.

While some regulatory systems in the cases in which the scientific evidence is not conclusive (“uncertainty“) allow referring to a “precautionary approach” to warrant regulatory actions, new models for risk governance have been sought and are currently discussed as alternatives or complements to existing regulations. Such approaches encompass **voluntary measures in nanotechnology risk governance** such as codes of conduct, risk management systems or data reporting programs. Nevertheless, it remains unclear to what extent such voluntary systems might fill the gap that is left open by traditional regulations, and at what price, i.e. concerning the question

whether all or just few players would participate, and to what extent such voluntary efforts would be transparent and trustworthy.

Industry advocates have claimed that strict and early regulations in the nanotechnology sector bear the risk of unnecessary overregulation and therefore, by burdening immense costs to industries, **innovation and financial investment might be hampered**. On the other hand, it is also clear that regulatory uncertainty might hamper innovation and restrain financial investments to this sector. Here, too, authorities and regulators need to find the right balance and the appropriate instruments to support innovation while at the same time preventing unexpected damage from materialising. Nevertheless, as long as the "true risks" of nanotechnologies and their applications cannot at least be roughly estimated and included into the risk portfolios and insurance policies of companies, the risk transfer mechanism through insurance companies will be interrupted.

In the light of the predominant lack of super ordinate regulatory frameworks which would explicitly address nanotechnologies, some nations and even municipals have begun to implement individual programmes and measures on their own initiative, sometimes also encompassing more stringent regulations. However, it has been criticised that allowing the development of a **patchwork of individual solutions** on the national and municipal level leads on the one side to a complicated regulatory situation (which is difficult to cope with for manufacturers) and also leads to a need for later adaptation, which is resource intensive.

4.2.3 Uncertainties in Future Projections of Nanotechnologies

Just as the prospected benefits of future nanotechnologies are likely to increase with time, so the impacts on our lives are also expected to grow. One widely referenced projection classifies different nanotechnology "generations" of applications according to their character. First generation one applications are commonly referred to as "passive nanostructures" which involve e.g. nanostructured or ultra-thin surface coatings (Renn, et al., 2006) which among others enable the manufacturing of nanostructured coatings, polymers and more reactive catalysts (Falkner, et al., 2009). Second generation applications include evolving function nanostructures such as, e.g., reactive nanostructured materials, which may lead to nanoparticles for targeted drug delivery systems. Both first and second generation nanotechnologies are currently in the research and/or development and commercialisation stage. Third and fourth generation nanotechnologies are expected to be materialised in the more distant future and deal with integrated nanosystems (e.g. artificial organs built from the nanoscale) and molecular nanosystems (molecule by molecule design or self-assembling nanostructures).

In the nature of rapid technological change and unpredictable commercialisation paths, the uncertainties about the impacts of nanotechnologies increase beyond the second generation of this model. As applications move towards more complex domains where bio-, information and nanotechnologies converge, and the scope of innovations increases, societal concerns will move into more contentious moral and ethical terrains. As technologies converge, a shift may be from risk to underlying ethical values (Satterfield, et al., 2009). Future generations of nanotechnologies are therefore expected to exacerbate the governance challenge. For example, the contentious areas of human enhancement has no EC regulatory framework.

4.2.4 Ethical, Legal and Broader Societal Impacts of Nanotechnologies (ELSA)

As recent discussions in the EU and elsewhere demonstrate, developments in science and technology cannot take place independently from the expectations and needs of the society. However, because much of the potential anticipated for nanotechnologies is still at the research stage, considerable uncertainties also exist regarding their societal impacts, especially the more "visionary" developments.

ELSA studies of nanotechnologies have therefore tended to be anticipatory, encompassing a broad range of topics including the values and goals which drive the research and its priorities, as well as issues more specific to the emerging applications. The enabling character of many nanotechnologies means that they tend to give important new dimensions to existing issues, more than they raise completely new ones.

Taking examples from various areas of nanotechnology, issues include the social impact of a predictive approach to medicine, based on rapid and widespread diagnostic tools; issues of privacy and surveillance, prompted by the potential of tiny monitoring devices; novel nano-enabled foods; justice and equity in access to the benefits of nanotechnologies, the risk-benefit balance for consumer products using nanoparticles, military uses and human enhancement potential. Legal aspects include liability, to what extent new regulation is required, voluntary or mandatory controls.

The societal dimension of nanotechnology research forms an integral part of the integrative, responsible and safe approach set out by the European Commission in the European Strategy for nanotechnology (2004), and developed further in the Action Plan on nanotechnology (2005) and its first and second Implementation Report (2007). In these Commission Communications it is clearly stated that nanotechnology must be developed in a responsible way, within an open dialogue that involves the public and that enables interested people to reach their own informed and independent judgements (European Commission, 2008c). A range of ELSA initiatives are seeking to assess the relevant issues and to engage wider publics, to stimulate the broader societal dialogue which these and other studies call for. This discussion seeks to expose the technological goals and political decision making to societal expectations and concerns.

4.2.5 Public Engagement

This commitment of the EC, and some particular member states such as the UK, Germany, France and the Netherlands, to wider stakeholder and public interaction on nanotechnologies has resulted in considerable funds spent on dialogue processes in several countries, e.g. through the Nanotechnology Engagement Group in the UK (Gavelin, et al., 2007), or the study on what consumers want to know about nanotechnologies in Germany (Grobe, et al., 2008). Different initiatives on public engagement, such as the recent Deepen project, have shown that the public has an interest to be included in shaping the development of nanotechnologies and urged policy makers to be innovative in finding ways to ensure the public is given a say in the decision making process.

Since the very beginning of the nanotechnology evolution, most stakeholders have agreed that the lessons from the GMO debate should be learned and this time the broader public must be included in an **"inclusive" process of debating** the benefits and risks of nanotechnologies. Formerly public communication was seen as a one way process by which people were given 'objective facts' about the technology, and it was expected that this would lead to its general acceptance. After the GMO

debate, it has become more generally recognised that many other factors than scientific information affect the way lay people view new technologies. Most engagement now adopts a more inclusive approach, which imparts information but presents it as part of a two-way dialogue which aims to hear from public views and reactions. On the policy side, the aim is to elicit indicators of significant concern from non-involved members of the public (as opposed to stakeholder organisations) and hopefully also to promote a sense of involvement and trust. The latter depends on the extent to which policies are open to adaptation, which may vary considerably. If not done sensitively, engagements may risk being seen as mere window dressing for policies which were not prepared to be changed. Engagement should be done if people are made aware at the outset of what they can expect to happen in the policy process and get feedback on what actually happened.

Various studies show that at the present time, the public does not have a strong awareness of the nature and potential benefits and risks of nanotechnologies. Typically, in response to broad presentations about nanotechnologies, people see potential benefits but also express concern at risks from nanoparticles, as well as wishing to be more included in setting policy priorities (e.g. Gavelin, et al., 2007). Relatively little engagement has been done on more specific issues, so far. Thus while the public has been included in some sort of basic discussion on nanotechnologies and their risks and benefits, there has been limited engagement on **fundamental and broader ELSA implications** which must also be considered by a Governance Platform. Of particular importance are issues such as technological enhancement of physical and cognitive abilities, manipulation of living organisms at the level of living cells, nanotechnology in relation to food, issues of data privacy, and on issues such as access to and distribution of nanotechnology knowledge among different groups of the world population. The dialogue on these topics usually takes place mainly at an expert level which is so far not easily accessible by the public.

A number of studies have noted public concern about the potential of nanotechnology to exacerbate global inequities. There is a wide **gap in levels of control and power** among the countries who are promoting and implementing nanotechnology, and those who will be impacted by it (Renn, et al., 2006). It is expected that some nanotechnologies might exacerbate the friction between developed and developing countries, especially the poorer ones, whose priorities and urgent needs are marginalised by ‘high tech’ goals targeted at markets of those rich enough to afford to pay. It is now a question of urgency in nanotechnology development how such inequitable development could be prevented and how the knowledge and potential applications of nanotechnologies can take into account already this grossly uneven global context.

4.2.6 Knowledge Transfer and Education

Other deficiencies can be identified in the approaches to education and the dissemination of knowledge. As nanotechnologies gain increasing commercial importance and penetrate our daily lives, an ever larger number of people will be in contact with nanotechnologies and will be using them in their professional practice.

Despite the increasing importance of nanotechnologies for research and development and many areas of our daily lives, however, there are only very few practical **teaching aids and learning materials** available to support teachers in mediating the necessary skills and knowledge. Nevertheless, implementation of nanotechnologies in the basic and professional education presents an opportunity to reach broad parts of society and ensure the transfer of certain basic knowledge

which is necessary to lead an informed discussion on nanotechnologies and their implications. Existing initiatives and projects which could fulfil an educational purpose are NanoSMILE (developed under the EU FP6 project Nanosafe2), nano&me or the Swiss Nano-Cube project (under development).

In terms of the technical communication and the **transfer of knowledge** among stakeholders in the supply chain, significant deficits have been identified. Nanotechnologies and manufactured nanomaterials introduce a new category of substances which are not explicitly covered by the existing systems and therefore currently slip through the net. Nevertheless, nanospecific information on the properties and potential risks needs to be available along their life cycle in order to correctly handle nanomaterials. The current **material safety data sheet (MSDS)**, the standard tool to transfer information on the risks and the appropriate handling of chemical substances, needs to be adapted for nanomaterials.

The transfer of safety information between companies (manufacturers), regulators (authorities) and the public outside the requirements of the MSDS is often hampered by claims of **confidentiality of data**, retaining the development or disclosure of data due to (legitimate) confidentiality reasons. Although the appointment to the confidentiality of data is not a problem generic to nanotechnologies only, in the current situation of a lack of reliable and validated data on the safety of manufactured nanomaterials it is expected to hamper the progress in the validation and the development of additional health and safety data on manufactured nanomaterials significantly. It has therefore been suggested to put the requirement to disclose safety relevant information in legally enforceable terms and make those who hold the proprietary information legally responsible of those working with the nanomaterial. The need to keep confidential such information is however advocated, in particular by industry people.

Public authorities are facing various “uncertainties” in regards of nanomaterials which prevent them from implementing clear rules and regulations, and which essentially render them incapable at this time to communicate clear messages of whether certain applications of nanotechnology are to be regarded “risky” or “safe”. **Communication in a situation of uncertainty** represents a new challenge to regulators and authorities, and their traditional role of defining rules and penalties based on (scientific) evidence is complicated in the case of manufactured nanomaterials as such evidence is only fragmentary at best or inconsistent. Regulators have therefore been looking for alternative approaches to fulfil their statutory duties. It is currently under debate whether the current regulatory frameworks are of the necessary flexibility to allow such alternative approaches to conventional regulation, and whether such approaches are sufficiently effective to replace conventional regulatory processes.

The Organization for Economic Co-operation and Development (**OECD)** takes a central role in the process of coordinating information exchange and data development between the developed nations, for example by coordinating the international efforts to generate toxicity data on 14 nanomaterials currently in use (see section 4.2.7 and section 5.6.3). While the OECD represents the foremost and major multi-national institution with a direct link to national policymaking engaged in the nanotechnologies development issue, other institutions of more informal or voluntary character such as the United Nations Environmental Programme (UNEP) and the International Organization for Standardization (**ISO**) are also deeply engaged or have recently announced an increased engagement in this area.

4.2.7 Coordination, Cooperation and International Harmonisation

The research, development and commercialisation of nanotechnologies involves many nations globally, from industrially highly developed countries to emerging countries, and also many developing countries have indicated interests in nanotechnologies or launched their own research and development initiatives. The roles of the different countries in the nanotechnology development chain are diverse and depend on their development status. It is therefore argued that an **integrated governance approach for anticipatory and corrective measures** is necessary for an emerging technology that will have trans-boundary and global implications (Renn, et al., 2006).

Coordination of policy at national and international levels may be significantly challenged by the increasing list of government departments and agencies involved with nanotechnologies. Traditionally, regulatory organisations and measures are **fragmented by the area of jurisdiction** (subject), type of regulation (product, process, etc.), intervention levels and national and international harmonisation of assessment and management procedures (or the lack thereof)[13]. This however makes it difficult to implement life-cycle considerations for chemicals and products, and in particular concerning nanotechnologies which are used in a variety of sectors, applications and industries, such fragmentation of regulatory authorities and controls makes it difficult to implement a consistent regulatory framework. In addition, the fragmentation increases the need for inter-agency coordination, communication and cooperation.

As the dispersal of nanomaterials and evolving nanostructures may not be confined or containable within certain areas or countries there is the potential for **risks to cross international borders**. However, there is no **international framework** at this time yet which would allow addressing the risk governance of nanotechnology on a global level and which would provide means of enhancing consistency in such issues among the nations. Nevertheless, the topic has been taken up within the series of informal International Dialogue meetings on Responsible Research and Development of Nanotechnology (March 2008 in Brussels), and within the Strategic Approach to International Chemicals Management (SAICM), International Conference on Chemicals Management (ICCM), second session in May 2009 in Geneva as an emerging issue. **Differences in national regulations** and their application may make it difficult for companies to manufacture standardised products and use standardised production processes, and the significantly new properties and issues of nanotechnology may allow for the transfer of risk, as when products are developed in a country with weaker controls and exported worldwide (Renn, et al., 2006).

Although several **international institutions and programmes** have been established with the intention to foster standardisation, co-operative development of health and safety data and harmonisation among involved nations (e.g. through OECD or ISO programmes on nanotechnologies, see section 5.6.3), such approaches usually do not have a focus on coordination of regulatory issues, and many current national and international systems may be inadequate for coping with the unique properties of nanomaterials. Existing international agreements dealing with the health hazards of materials tend to establish moratoria on well recognized and highly toxic pollutants only, and

[13] This situation is clearly underlined by the EESC opinion that reports: *"The EESC points out that, just as there are many disciplines and many sectors involved [in nanotechnologies], there is a similarly large number of relevant Community legislative and regulatory instruments (more than 90). The transparency of Community legislation and its ease of understanding by the public may be undermined by its complexity"* (European Economic and Social Committee, 2009).

therefore cannot serve as models for establishing international proactive risk management programs for nanotechnology where hazard information is only just emerging (Murashov, et al., 2009).

4.3 Dynamic Developments Need a Dynamic Framework

The increasingly rapid pace of nanotechnology development and commercialisation has obviously come into conflict with the lagging of the development of health and safety data and the necessary validation and potential adaptation of the current regulatory frameworks. It is uncertain whether the established governance systems are actually capable of adequately handling nanotechnologies and the corresponding applications within their frameworks, and it is thus feared that nanotechnologies and nanomaterials may cause damage to health and the environment before appropriate strategies based on quantitative risk assessment can be implemented. This may be conceived as one of the main reasons why many stakeholders call for the implementation of a precautionary approach in order to avoid such damage from accumulating, and in order to prevent that public backlash on nanotechnologies in general would lead to reactions similar to those observed with genetically modified organisms in recent years.

The current uncertainties about the potential risks of applications of nanotechnologies and the highly dynamic developments represent a particular challenge to regulators. Current governance and regulatory systems represent learned knowledge and experience from bulk and micro technology, and the adaptation of these regulatory systems is a reactive process which might leave workers and the public unprotected in the meantime. Nevertheless, a lot of information is currently already available and being developed as the emerging technology rapidly evolves and new safety and health information is generated under a large number of research initiatives. Regulatory agencies and politicians are facing the pressure to provide “just in time” decisions on nano risk governance under a lack of scientific evidence.

On the other hand, however, complete understanding of the mechanisms of risks does not need to be established prior to initiating appropriate measures to reduce potential risks. While the hazard side of risk still suffers from fundamental uncertainties which prevent many stakeholders from establishing sensible rules and measures, the exposure side of risk represents a good point to attack and many existing principles are well established and applicable for nanomaterials. In this light, rather than to wait until scientific evidence on hazards and mechanisms of harm will be clarified, establishing early measures regarding exposure mitigation seem very well possible already today.

Nevertheless, such early measures must be designed to be flexible and adaptable in the light of considerable scientific evidence expected to be evolving during the next decades. Even so, under such dynamic circumstances as represented by nanosciences and nanotechnologies, public perception and acceptance of certain areas of nanotechnologies might change – a factor that has to be taken into account in the design of governance measures.

As our knowledge about the characteristics and impacts of nanotechnologies, nanomaterials and the corresponding applications will increase and it can be expected that an adaptation of the regulatory approaches as well as the governance framework will certainly be necessary and should be provided.

To assure that a governance framework is dynamically adapted to the state of science and technology, keeps pace with progress of research and development and takes into account (changing) public attitude and responsiveness, it needs to be determined to what extent an

appropriate governance approach can be based on existing, conventional approaches and principles, or whether a novel approach needs to be developed and implemented. The proposed Governance Platform will therefore also suggest means to align the current governance framework towards an adaptation of the regulatory tools and procedures according to the evolving scientific knowledge and potential changes in the public perception.

5 Stakeholder Opinions on Nano Governance

The following sections of this report serve the purpose of summarising and aggregating the comments and opinions which have been collected during the two-staged FramingNano Delphi consultation and those comments which emerged during the FramingNano Multi-Stakeholder Workshop in Brussels on the 26th of February 2009 and the FramingNano Expert Workshop in St.Gallen on the 29th/30th of October 2009.

The opinions and comments collected within the FramingNano consultative phase are put in relation to further opinions found in the literature and in other stakeholder opinion gathering processes[14]. This should widen the focus of the opinion gathering process and enable us to identify issues of common agreement or potential controversy.

Since the main methods of opinion gathering have been Delphi consultations and expert workshops, the resulting answers are mainly of qualitative character. Any statistical interpretation of the results will therefore not be meaningful. While statements from external sources (e.g. from the literature) are labelled with the name and organisation of origin, comments from participants of the FramingNano activities are anonymous and therefore referenced to with indication of the type of organisation only.

This section is divided into five broader sections which allow the allocation of the opinions and comments gathered in the consultative phase of FramingNano to broader topics. This disposition also loosely follows the challenges identified and briefly outlined in section 2.4 above.

5.1 Principles Underlying Governance and Regulation

Good governance of nanotechnologies is often referred to as being underpinned by a number of fundamental principles. These principles are underlying the European code of conduct for responsible nanosciences and nanotechnologies research (European Commission, 2008b) and include

- **meaning**: N&N research activities should be comprehensible to the public. They should respect fundamental rights and be conducted in the interest of the well-being of individuals and society in their design, implementation, dissemination and use;
- **sustainability**: N&N research activities should be safe, ethical and contribute to sustainable development and should not harm people, animals, plants or the environment;

[14] One such source of reference is a Delphi exercise from Germany, which has been conducted by the Federal Institute for Risk Assessment (BfR) in 2006. In this study, 100 experts were invited to indicate and estimate potential risks of nanotechnology applications in foods, cosmetics, surface coatings and textiles. One third of the participating experts were from industries, one third from scientific institutions and one third from institutions engaged in the risk research area of nanotechnologies (BfR, 2009).

Another valuable source is the report by the Responsible Nano Forum ("A Beacon or just a Landmark?") which includes many expert statements on the issue of nanotechnology governance and regulation (Responsible Nano Forum, 2009).

- **precaution**: activities should be conducted in accordance with the precautionary principle so as to avoid any negative environmental, health and safety impact;
- **inclusiveness**: transparency and respect for the legitimate right of access to information, and openness to all stakeholders;
- **excellence**: applying the best scientific standards, including standards underpinning the integrity of research and standards relating to Good Laboratory Practices;
- **innovation**: governance of N&N research activities should encourage maximum creativity, flexibility and planning ability for innovation and growth;
- **accountability:** researchers and research organisations should remain accountable for the social, environmental and human health impacts that their N&N research may impose on present and future generations.

Recently, the European Economic and Social Committee (EESC) released an opinion (European Economic and Social Committee, 2009) regarding the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on regulatory aspects of nanomaterials (Commission of the European Communities, 2008), where the EESC stated that it supports the principles set out in the code of conduct on nanotechnologies and considers them also to be valid for the revision of the European legal and regulatory framework for N&N.

The above and some other principles[15] have been presented to Delphi participants both in the first and the second Delphi consultation in order to learn their opinion on the relevance and priority of the corresponding principles. The results are summarised in the following paragraph.

5.1.1 Weight of Principles

The principles considered by the Delphi respondents the most important (scores 4 or 5 of 5) for the governance of nanotechnology were, in descending order:

- Transparency (37/40)
- Health & Safety at Work (37/40)
- Public Safety (36/40)
- Scientific integrity (36/40)
- Responsibility (35/40)
- Openness (34/40)
- Environmental protection (33/40)
- Sustainability (32/40)
- Accountability (31/40)

[15] Flexibility, meaning, excellence, innovation, ability to adapt / promote innovation, ability to promote self-regulation and protection of intellectual property.

- Maintaining the quality of science (30/40)
- Providing legal certainty (29/40)
- Precautionary principle (29/40)

Overall, all principles received high ratings, and individual comments have been made on many different list items. Obviously, both EHS (e.g. health and safety at work, environmental protection) and ELSA principles (e.g. transparency, accountability) have received similarly high ratings.

The lowest ratings in terms of the number of respondents indicating an importance of 4 or 5 were attributed to

- Protection of intellectual property (16/40)
- Ability to promote self-regulation (16/40)
- Inclusiveness (17/40)
- Excellence (18/40)
- Meaning (19/40)
- Innovation (20/40)

In particular, in the case of the "protection of intellectual property", the responses indicated a highly inconsistent opinion of the stakeholders on this issue. On the other hand, "inclusiveness", which is considered a fundamentally important and much discussed principle among many stakeholders, received strikingly low ratings.

The strongest agreement from respondees regarding "responsibility", which is a key aspect of governance and has correspondingly been rated very high, was with the statements concerning:

- responsible development in terms of EHS issues (39/40)
- responsible development in terms of the means of supporting the participation of key stakeholders (33/40)
- responsible development in terms of ELSI issues (32/40)
- responsible development in terms of providing suitable tools for communication (31/40)
- taking a visionary view in terms of long-term planning in relation to societal needs (31/40)
- responsible development in terms of developing methods/tools to support risk governance (30/40)
- responsible development in terms of providing a suitable framework for oversight (30/40)

Especially the high approval of the item "supporting the participation of key stakeholders" stands in contrast to the overall low rating for the principle of "inclusiveness" above. Broader inclusiveness seems to be viewed therefore with some ambiguity, maybe pointing to the fact that although many stakeholders consider it sensible to "support the participation of key stakeholders", they take a realistic view about the broader public's interest (so far) to participate in inclusive processes about nanotechnology governance.

Regarding any specific actions which were proposed by the stakeholders for individual principles, "communication" was mentioned often. One respondent mentioned pro-active communication,

another labelling, and a third stakeholder pointed to the important role of communication and education tools involving the broader public.

5.1.1.1 Precautionary Principle

A precautionary approach advocates taking action even when a chemical poses only a possible threat to human health or the environment, rather than waiting for complete scientific proof of cause and effect to evolve. This may prevent damage in the phase during which new information is developed.

REACH explicitly declares that its provisions are underpinned by the precautionary principle (REACH Article 1(3)), a point that is often advocated by NGOs. This commitment supports the paradigm of a pro-active, precautionary approach instead of a "wait-and-see attitude". In the SCENIHR Public Consultation on Risk Assessment of Nanotechnologies, a strong precautionary approach was one of the main policy points brought forward by the participants (Bontoux, 2009).

The proactive approach in terms of regulating or governing the responsible development of nanotechnologies is currently hampered by the prevalent uncertainties which render an efficient, science and evidence based regulatory approach practically impossible. In such cases, the application of a precautionary approach suggests to take action before scientific evidence has completely emerged, in order to protect human health and the environment.

According to the European Commission, the precautionary principle should also underlie the risk assessment process, in that if there is uncertainty over scientific evidence (for example, conflicting or little data), the assessment should normally be based on the evidence that gives rise to the highest concern (worst case scenario) (European Commission, 2004).

A "lack of a precautionary approach" when regulating nanomaterials is emphasized by the FramingNano Delphi panels, especially in relation to vulnerable population groups such as children and infants.

> We believe that there is an urgent need for regulatory action to avoid a "nano disaster": More and more consumer products are hitting the market, in many cases without potential risks being sufficiently clarified and although there is a clear indication for substantial risks for some nanomaterials, such as with CNTs (policymaking body).

> [Main gaps in current national or European legislation concern the] [n]on-consideration of the precautionary principle, especially in relation to vulnerable population groups such as children and infants (NGO).

Nevertheless, the precautionary principle has not been one of the principles which have been rated highest among the Delphi participants (see list under section 5.1.1). This might surprise in consideration of its inherent relevance in the case of manufactured nanomaterials where sound scientific knowledge is still largely missing.

5.1.2 The Role of Policymakers and Regulators

Much the same as with the current knowledge on information regarding nanomaterials in trade, in the early phase of technology development, regulators and others are often unable to base potential regulatory decisions on an accredited state of science and technology that describes the expected impacts of manufactured nanomaterials on human health and the environment upon certain levels of exposure. This may particularly be attributed to a lack of practical long-term experiences with

manufactured nanomaterials, and the only slowly increasing scientific evidence which is complicated by the need to balance conflicting research findings.

Unsurprisingly, however, especially at this stage of technology development which is characterised by uncertainties, regulators often face considerable pressure to become active through a growing number of early-adopting industry players which engage in the new technology, and various NGOs which call for adequate control of any potential hazards.

Traditionally, policy makers and regulators (public authorities) are considered responsible to ensure a certain (agreed) level of safety to the public. However, with the implementation of REACH, the burden of proof about the safety of chemicals, including nanomaterials, has shifted from the authorities to those who make available the products. Businesses and industries, in fact, are largely held responsible to ensure that their products are safe, and they are required to inform public authorities about new findings which would require an updated risk assessment.

Most of the stakeholders in the FramingNano Delphi exercise basically agreed that policymakers and regulators are held responsible for the regulation of nanotechnologies.

> [Policymakers should] acknowledge that the chemical, physical, etc. properties of nanomaterials are newly discovered properties […] and exercise control from there to protect the workers manufacturing/handling such nanomaterials (public authority).
>
> Policymakers are responsible for the necessary regulatory framework, implementation and control (NGO).
>
> We need regulatory agencies able to strongly control industry and business and to stop activities if dangers are suspected (academia).

Even so, the role of policy makers and regulators has been extended to also involve the definition of a general research strategy and allocation of the necessary funding.

> Policymakers should also ensure that funds are available for research institutions and foundations to fund independent research that could either validate or reject the EHS information generated by industry, business, etc., and to explore scientific issues not yet realized (academia).

There have also been a few comments which clearly indicate that some stakeholders hold policy makers responsible to ensure a clear, transparent, and foreseeable governance framework.

> Policymakers should create a […] regulatory environment where industry, business and professional organizations are encouraged to […] generate EHS information on nanomaterials and publicly disclose information […] (academia)
>
> Stakeholders would like to see clarity on priorities, what action will be taken by when with what expected result and progress […] [This] requires clear leadership, communication and transparency (NGO).

The responses emphasized the important role of and the expectation in policymakers and regulators. Public trust in the ability of public bodies to regulate NS&T for good of society was rated highly important by 3 out of 4 Delphi participants; a fact that has also been confirmed by other surveys.

5.2 Barriers to Responsible Development

A broad range of barriers have been mentioned in the two Delphi consultations and during the FramingNano Multi-Stakeholder Workshop which contribute to hamper a responsible development of nanotechnologies.

In the first Delphi panel, stakeholders were given a list of barriers which they were asked to rate according to their impact. While there was a spread of opinions concerning the importance of the listed issues as barriers, there was a discernible trend to consider the strongest barriers (scores 4 and 5 of 5) to be, in descending order:

- Lack of standards or other voluntary tools (28/40)
- Lack of agreed common risk management methodologies (including risk assessment) (26/40)
- Lack of knowledge of the sector amongst those responsible for its governance (25/40)
- Lack of knowledge concerning nanotechnology risks (23/40)
- Inability of regulation to keep pace with scientific discovery/development (21/40)

Obviously, the well-known knowledge gaps in methodologies, risk assessment, risk management and standardisation were rated highest. In the second Delphi panel, stakeholders were asked to further precise their opinion on barriers to responsible development by providing individual comments. The following list summarises a selection of them.

- Lack of characterized nanoparticles (regulatory authority).
- Lack of characterization tools for both quantitative and qualitative analysis. If you can't measure it, you can't control it (regulatory authority).
- Lack of sufficient funds to speed up risk assessment research as so overwhelmingly much of the EU nanotechnology research budget is used for R&D. Independent and well financed research is necessary for informed judgments and decisions in weighing of risks (NGO).
- Fear of public backlash, resulting in lack of transparency about the use of nano, which in turn will erode trust (NGO).
- The lack of knowledge [...] of the research workers and users is the most important barrier to the responsible development of nanotechnologies (academia).
- 1. Lack of conscience and common sense by the users of nanotechnology. 2. Lack of knowledge of nanotechnologies by those responsible for public media (industry).
- Economical interests, which can be in contrast with a regulation of the entire matter (academia).
- Lack of political will among key decision-makers and stakeholders to face the challenge and initiate what is needed to bring us on the path of responsible development of nanotechnology (academia).

5.3 Priorities in EHS and ELSA Issues

In this section, stakeholder opinions and observations on general environmental health and safety (EHS) issues as well as ethical, legal and societal aspects (ELSA) regarding manufactured nanomaterials will be presented and discussed.

5.3.1 Environmental Health and Safety Issues (EHS)

It is commonly agreed, both in the scientific literature and among governments and regulators, that the science to identify and explain potential risks of manufactured nanomaterials is ways behind the commercial application of nanomaterials in processes and products. These uncertainties are considered a major barrier for a sustainable and responsible development of manufactured nanomaterials over the long term.

Speaking at the FramingNano multi-stakeholder workshop in Brussels, a representative of the EU Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) noted that nanomaterials are "difficult to handle" and "unpredictable in their behaviour", but he also made clear that "not all nanomaterials are toxic" on the other hand.

> In vitro studies indicate the possibility for cell damage but the relevance of such work for risk assessment is limited. It is impossible to extrapolate what happens in cell culture to real world risk (public authority).

The above statement puts the current uncertainties regarding nanomaterial risk assessment in a nutshell. While some of the most important challenges regarding the risk assessment of nanomaterials have briefly been outlined in section 2.4 above, this section will not further elaborate the various knowledge gaps, but provide stakeholder opinions and comments on how to best address the uncertainties and on how to set meaningful priorities.

Many sources in the literature have previously identified the various knowledge gaps regarding risk research, building blocks for nanomaterial risk assessment and risk management (e.g. Meili, et al., 2007). Although there has evolved a broad consensus among experts on the nature and extent of these gaps and how they could best be filled in principle, if it comes to decide how to deal with the remaining gaps and how to prioritise actions with limited resources available, many gap analyses remain rather vague.

5.3.1.1 Dealing with the Uncertainty – Status Quo and Beyond

There is a broad consensus among scientists, policy experts, regulators and civil society organisations that some very significant gaps in the understanding of potential nanomaterial risks exist to date. It is also commonly agreed that the incompleteness or possible inadequacy of many of the scientific building blocks essentially prevents stakeholders from performing comprehensive risk assessment on manufactured nanomaterials as of today.

> The repercussions of not understanding the toxicology and ecotoxicology early enough can distort the debate about a technology (Hilary Sutcliffe in (Responsible Nano Forum, 2009)).

Consequently, it seems reasonable to conclude from the current debate that these uncertainties may hamper both nanotechnology developments in general, but also influence societal acceptance of these technologies a lot.

> The public and NGOs simply expect that products on the market are adequately tested for safety across the lifecycle. When they find there are gaps, that we can't even measure nanomaterials adequately in some areas etc., they are rightly concerned (NGO).

In a report on the occasion of the fifth anniversary of the publication of the well-known Royal Society & Royal Academy of Engineering report about the opportunities and uncertainties of nanoscience and nanotechnologies (RS & RAE, 2004), a number of renowned experts expressed their view on

what has changed since 2004, and what recommendations in the report might still be equally relevant today (Responsible Nano Forum, 2009). Although the contributors to the report point to the many activities in the field of nanosciences and nanotechnologies since the initial release of the report, they seem to have had a hard time to indicate concrete accomplishments which would have resulted in a rephrasing or rearranging of the initial recommendations.

> Yet despite all this activity, it's harder to pin down how much concrete progress has been made (Dr Andrew Maynard in (Responsible Nano Forum, 2009)).

More precisely, while the identification of gaps has received a lot of attention in the past few years, it seems more difficult to identify concrete progress in eliminating the gaps identified. This of course has to be assessed in the context of the complexity of the issues, and in the light of the many even very basic uncertainties that exist, but it has critically been mentioned that

> [p]eople in government seem to spend a lot of time and effort acknowledging gaps and problems […]. Of course we need a coherent plan, but it appears like nothing happens beyond lots of talking about strategy (Dr Rob Reid, Scientific Advisor at Which? in (Responsible Nano Forum, 2009)).

> [T]oo much effort is being spent by too many desperate parties on defining strategies instead of completing work tasks. This may be money driven though, as it is easier to talk about something than complete practical tasks! (Unattributed pharmaceutical company statement in (Responsible Nano Forum, 2009)).

It seems therefore to become a relatively widespread appraisal among involved stakeholders that too much time and money is spent on strategies and planning, while accomplishments on the practical side of the identified work remain rare. Concluding on this, it is definitely necessary to go one step forward now from the identification of gaps towards concrete coordination of the efforts and eventually solving the problems which have thoroughly been identified.

> This lack of knowledge has created a degree of uncertainty that will only be overcome with the publication of a body of rigorous risk assessments, particularly of nanomaterials in commercial use now, which account for the full life-cycle of the materials in question (Unattributed international organization in (Responsible Nano Forum, 2009)).

> The emphasis shifts now to the hard work of differentiating, with some predictability, those nanoparticles or nanoparticle applications that are relatively benign from those that will require closer scrutiny or control (Dr Kristen M. Kulinowski, Rice University, in (Responsible Nano Forum, 2009)).

It is often argued that concrete efforts in risk assessment and control are currently made impossible by the lack of definitions, standards and methodology (scientific building blocks for risk assessment). However, regarding the state of knowledge, not all stakeholders agree on the assumption that current knowledge is insufficient to be able to effectively assess and control the risks that manufactured nanomaterials may present in practice.

According to an OECD workshop on risk assessment of manufactured nanomaterials held on September 16-18, 2009, speakers expressed their belief that there may be more environmental, health and safety data than people realize for some nanomaterials. The aim of the workshop was among other issues to identify possible approaches for risk assessment based on the current state of knowledge. Eileen Kuempel, a senior scientist with the National Institute for Occupational Safety and Health (NIOSH), at this workshop said that

> standard methods for hazard and risk assessment using toxicology data are available and appear feasible (Eileen Kuemper, NIOSH, at the OECD Workshop on Risk Assessment of Manufactured Nanomaterials in a Regulatory Context, Washington DC).

A similar opinion has been brought in during the FramingNano Multi-Stakeholder Workshop in Brussels by one representative of a regulatory authority. He said that the timing of developing a Governance Platform for nanotechnologies is ripe though he acknowledged there are several gaps in current knowledge which will take time to fill. On the other hand, however, he pointed out that

> sufficient data already exists to allow regulation of nanotechnologies. […] In the meantime we can't just wait to legislate; we can't cross our fingers and hope nothing happens. We can easily generate regulations today based on the data we have right now (regulatory agency).

Moreover, in the 2009 report "A beacon or a landmark?" (Responsible Nano Forum, 2009), Prof Anthony Seaton from the Edinburgh Institute of Occupational Medicine in his personal views expressed that current understanding of nanomaterial risks is sufficient to implement sensible and pragmatic measures to protect researchers and workers.

> [...] [e]ven though there is insufficient yet known to enable us to predict which nanoparticles might entail real rather than theoretical risk, […] it is not necessary to know for sure that something is dangerous before taking action to reduce risk (Prof Anthony Seaton from Edinburgh Institute of Occupational Medicine, personal view, in (Responsible Nano Forum, 2009))

Seaton implicitly points to the necessity to apply a precautionary approach to face the current uncertainties about risk assessment of nanomaterials, and refers to the fact that regulations are never imposed with complete understanding of the risks, which is particularly true for emerging technologies which are characterised by high innovation dynamics and the rapid commercialisation of new products based on this technology. On the other hand, pro-active and precautionary preoccupation with risks that have not been demonstrated before is a new approach which might not always fit very well into the existing (regulatory) structures.

> Never before has the introduction of a new technology been attended by an effort to understand and forestall hazard before any adverse consequences have been demonstrated […] (Prof Anthony Seaton from Edinburgh Institute of Occupational Medicine, personal view, in (Responsible Nano Forum, 2009)).

On the other hand, however, too much proactivity in engaging in regulation might also prove inappropriate since, as one Delphi respondent put it, establishing unenforceable regulations (e.g. due to lack of knowledge on testing and monitoring procedures) are not feasible in the long run as trust in regulatory authorities to cope with new technologies has been identified as a key factor in the shaping of public perception.

> A regulation that cannot be applied by absence of reproducible tests and adequate, efficient market monitoring, creates a long lasting lack of trust. So, a general declaration stating that the actual regulatory framework is, in principle, appropriate, does not respect the principle of responsibility and its translation in "duty to care / duty to protect".

In the governance debate, it seems therefore appropriate to carefully distinguish between the many open questions that science poses regarding the risks of nanomaterials *in general*, and those questions that have to be answered in order to be able to *control the risk* and implement a sensible regulatory framework which is able to reliably identify and adequately handle those nanomaterials which pose a threat to workers, the public and the environment.

> Methods of protection of workers and consumers from airborne nanoparticles are understood, allowing regulators information on which to base guidance [...] (Prof Anthony Seaton from Edinburgh Institute of Occupational Medicine, personal view, in (Responsible Nano Forum, 2009)).

While scientists are interested in understanding the mechanisms of toxicity on the most fundamental level (basic research), policy makers and regulators are dependent on more practice-oriented information in order to be able to control the risks and propose sensible measures and regulations. This may for example mean that the exact details of the toxicity mechanism of a certain nanomaterial might not necessarily be fully understood in order to establish regulations, if it is well known how exposure to this substance can effectively be prevented on a precautionary basis.

In the light of this assumption, it seems prudent at this point to identify and prioritise the questions that need to be answered in the specific regulatory context, and to be aware of what is already available.

5.3.1.2 Setting Priorities in EHS Issues

It has been mentioned in the FramingNano Delphi consultation that simultaneously engaging in all of the identified knowledge gaps and research subjects would overload existing (research) capacities by far. On the other hand, thorough and comprehensive risk assessment has clearly been assumed by others.

The participants at the FramingNano Delphi consultations were asked to indicate priority areas of research into the EHS issues. One participant of the Delphi panel indicated that in the light of scarce resources, a sensible prioritization should focus on safety issues where exposure is to be expected highest.

> In general, the focus should be on ensuring safety where exposures are most likely or already happening, and on limiting exposure and less on risk assessment (academic).

As risk is a combination of hazard and exposure, and the hazards of manufactured nanomaterials are currently not yet determinable on a general scientific basis, this exposure focused approach would not only be sensible in the light of scarce resources, but it would also circumvent many the existing gaps in the determination of hazards of many nanomaterials.

Further means of prioritization that have been mentioned were commercial relevance of the nanomaterial, and the distinction between “free” and “bound” nanoparticles.

> Priority of research should be focused on those nanoparticles that are already (frequently) used in products available on the European market, e.g. nanosilver (NGO).

The “commercial relevance” approach is also followed by the OECD in defining a list of 14 commercially highly relevant (only one being important for research mainly) nanomaterials where exposure could be expected. Regarding a prioritisation of efforts in terms of the nanomaterials investigated, the major source of concern regarding potential risks of nanotechnology is "free" manufactured nanomaterials during their entire life cycles (FramingNano, 2009), which is consistent with many other literature sources (e.g. Meili, et al., 2007).

In the first and the second Delphi panel, participants were asked to identify, rank and comment on needs concerning EHS issues. The list given in the survey encompassed items commonly mentioned in the context of the EHS debate of nanotechnologies, including

- hazard identification
- information on exposure routes

- risk assessment
- safety in manufacturing
- availability of safety data (e.g. as envisioned under REACH)
- release of nanomaterials into the environment
- risk management processes
- availability of standardized test methods
- end of life (e.g. waste stream) issues
- product safety testing
- public perception of safety
- safety in the laboratory
- availability of means of characterization
- standardized nanotechnology terminology
- labelling of nanomaterials and nanoparticles along their lifecycle

Respondents generally considered all of the EHS issues listed important, although there were some differences in the priority ranking given depending on the type of responding organization. Topics such as standardized nomenclature and test methods, risk assessment and safety in manufacturing and in the laboratory were generally rated highly. Almost all stakeholders consider the identified EHS issues to be important and to be addressed in a Governance Platform.

In the context of a further prioritization of the list items, it became evident that considerable interdependencies exist between the various list items. One regulatory authority in place of many others concluded that the availability of standardized nanotechnology terminology, means of characterization and standardized test methods were preconditions to be able to commence with hazard identification and risk assessment and, thereafter, the other listed priorities.

> Taxonomy is a pre-requisite to the organization, accessibility and understanding of the new knowledge in nano-EHS (regulatory advisor).

Furthermore, for example, "hazard identification[16]", "information on exposure routes", the "availability of means of characterization" and the "availability of standardized test methods" represent prerequisites to perform any reasonable form of risk assessment, and any sensible risk management process would be based on information about the safety in manufacturing and risk assessment. Even so, the basic technical elements such as "standardized nanotechnology terminology" and the "development of methodologies for the characterization and hazard identification of nanomaterials" represent basic prerequisites for the development or implementation of the more conceptual approaches such as life-cycle considerations, safety in manufacturing and the laboratory or risk management processes.

Many of the above items such as the lack of validated and standardised methodologies to identify, measure, characterise nanomaterials at the workplace, in products and in the environment have

[16] For detailed reference please consult the original FramingNano Delphi questionnaires, which are attached to (FramingNano, 2010).

been identified as triggers which currently hinder efficient risk assessment for manufactured nanomaterials. The above groups (classification added by the editors) may be regarded as consecutive steps in the risk assessment chain which build on each other, with the communication and transfer of knowledge task overlaying all of them as a task which is not limited to a certain stage of development.

However, as the following statements by respondents of the Delphi indicate, there is not necessarily a consensus among the stakeholders regarding the point of the chain of prerequisites for risk assessment where priority actions should best be set:

> Opinion 1 (methodology level): First of all, **test methodology** should be available to have an idea of human and environmental exposure (Other: Consultant) [emphasis added]

> Opinion 2 (hazard identification level): The most important item at this stage is **hazard identification**, as it cannot be assumed that current knowledge has identified the real dangerous effects of nanomaterials and related processes (academic) [emphasis added]

> Opinion 3 (risk assessment level): I think that **safety in manufacturing and in the laboratory** should be prioritised [...] [emphasis added]

Although all of these elements represent important and necessary pieces of a puzzle which will ultimately lead to being able to perform a sensible risk assessment on manufactured nanomaterials, it seems unclear whether a strict bottom-up approach is necessary (from definitions to risk assessment) or whether certain elements in the chain can be developed in parallel or ahead of the others.

Lack of knowledge concerning nanotechnology risks was viewed as a major barrier to the development of the technology, and the inability of regulation to keep pace with scientific developments might also stand in the way of responsible development in this area.

Further EHS issues (in a wider sense) considered important by respondents of the second Delphi panel included issues from a broad variety of areas, mostly complementing or further detailing the topics already mentioned in the given set of EHS priorities above. Bringing them in a systematic order may be used to emphasise the various knowledge gaps in the chain of scientific evidence necessary in order to determine hazards and exposures and eventually perform risk assessment of manufactured nanomaterials. The following arrangements have been made by the editors while the comments are extracted in unchanged form from the Delphi surveys.

5.3.1.1 The Role of Taxonomy, Nomenclature and Definitions

Agreed definitions and a common terminology are needed in order to make progress in the ongoing debate on nanotechnology, according to several experts who gathered in Brussels for the FramingNano Multi-Stakeholder Workshop.

> We need good definitions for what we are debating. At the moment, part of the problem is that people are discussing different things when it comes to nanotechnology. There are different interpretations when it comes to nanoparticles and I have the impression that regulators and innovators have different ideas on this (academics).

The issue of agreeing on definitions and terminology has been discussed in a regulatory context during the LSE conference on transatlantic regulatory cooperation in London in September 2009. It has become clear that for the purpose of enhancing the comparability of scientific data, scientific

definitions need to be clear and very sharp, but that on the other hand, for regulatory purposes and depending on the area regulated, regulatory definitions may need to be formulated differently. While one form of a nanomaterial might intentionally be explicitly considered in the regulation of cosmetics, it might not be of concern in the regulation of chemical substances.

One stakeholder pointed to the possibility to develop “running definitions” for food safety which define nanomaterials as those with dimensions smaller than 500 nm.

> We have found that restricting the definition only to particles smaller than 100 nm is not helpful in practice. Some entities are larger than 100 nm but exhibit nanoscale properties (regulatory authority).

This discrepancy between definitions has recently become obvious with the adaptation of the Novel Food Regulation and the recast of the Cosmetics Directive in the European Union, which contain different definitions of what a nanomaterial for the individual regulation’s purpose is, and which also vary from the current ISO definitions for nano-objects (ISO, 2009).

The Delphi panel did not identify any new or previously unnoticed elements, indicating that among the participating stakeholders, there is a consensus on the steps that are necessary to eventually be able to perform sound risk assessment on manufactured nanomaterials.

5.3.2 Ethical, Legal and Societal Aspects (ELSA)

Policy makers are challenged to make decisions on further priorities of publically funded research and on regulations. In order to respond to the society's concerns it is of crucial importance to enter into a dialogue on benefits and risks of nanotechnology, including ethical, legal, societal aspects (ELSA) of nanotechnologies, also involving great parts of the public and basing on informed judgement. ELSA issues therefore go beyond EHS issues and cover, as mentioned before, a large spectrum of topics such as privacy, acceptance, human health, access, liability, regulation and control.

ELSA research has been established as a tool to expose technological and policy goals to the wider understanding to be gained from ethical reflection, social research and legal assessment. These fields can offer important insights to policy makers for responding to these needs of responsible governance of nanotechnology research (Hullmann, 2008). Along with public engagement exercises, they can also help in identify expectations and concerns of the wider European public. This ethical and societal dimension of nanotechnology research forms an integral part of the integrative, responsible and safe approach followed by the European Commission.

5.3.2.1 Key ELSA Implications Identified in the Delphi Panels

At first the debate on the potential risks of nanotechnologies and, in particular, of manufactured nanomaterials has predominantly focused on health, safety and environmental aspects. But increasingly since 2004, much work has begun to emerge on ethical, legal and societal issues (e.g. EU FP6 projects Nano2Life, NanoBio-Raise, Deepen). Spending on ethical, legal and social issues is supposed to be in the region of 3% to 5%, but in practice, it is much lower, according to one participant at the FramingNano Expert Workshop in Brussels. This reflects a failure to appreciate the importance of ELSA in research funding.

With a strong relation to the EHS aspects, the legal issue of regulation has probably received by far the most attention from all of the identified ELSA aspects regarding nanotechnologies. Nevertheless, understanding emerging trends in public perceptions of nanomaterials is critically important for those who regulate risks.

> We need to ensure that we have a regulatory process that ensures that all recognized possible ELSI issues are systematically considered from time-to-time although they might not be relevant to begin with (academia).

Stakeholders' views of the relative urgency and importance of various ELSA issues have been gathered in the Delphi consultation.

There was a notable majority in particular (29/40 agreeing with 10 "don't knows" and only 1 disagreement) that nanotechnology would make an important contribution to the future economy. Also scoring high levels of agreement were that nanotechnology would raise important ethical questions for society (26/40) and that nanotechnology has the potential for serious criminal or military misuse (24/40).

A substantial number of respondees expressed doubts that nanotechnology would contribute towards a fairer society (17) although 22 respondees did not think it would have negative consequences for the labour market. While 19 respondents expressed doubts that nanotechnology would benefit all levels of society, 21 at the same time considered it would have an overall positive impact on society. 19 respondents considered that nanotechnology would revolutionize manufacturing.

The responses to the section on ELSA implications of nanotechnologies in general received a greater proportion of "don't knows" than some other questions.

Certain other ELSA issues were identified in the comments by different respondents:

- transparency over research and testing and over the use of nanotechnologies and nanomaterials in products
- appropriate product claims
- use or misuse of novel nanotechnology applications in criminal or military activities
- responsiveness of companies to sharing information with workers (occupational safety)
- benefits to society
- rights to access information in relation to intellectual property
- benefit of nanotechnologies over existing technologies
- effect on existing technology/production (e.g. impact on farmers)
- effects on the labour market
- responsiveness of companies to [public] concerns
- impact of technological solutions on our attitudes to food and diet
- views about what is natural and unnatural, natural and scientific
- differing perceptions of safety
- contribution towards third world development

- reduction or increase in animal testing
- privacy in relation to monitoring devices
- enhancement of human performance and human machine interactions
- discrimination to technology benefits
- increased personal responsibility in relation to novel diagnostics.

Compared with more systematic expert evaluations of ethical issues, this list is only partial. For example there are numerous other issues in nanomedicine - like a shift from symptomatic towards more predictive medicine from nano-enabled diagnostics and its effect on doctor-patient relationships, the remote monitoring of chronic patients, the degree of patient or doctor control in devices which combine monitoring and therapy, equity in relation to expensive high tech treatments, etc. There would be many more ELSA issues in different products and sectors. It has been striking that the list of priority ELSA items identified was very similar for all sectors considered (food and feedstuffs, cosmetics, chemicals, environmental protection, occupational safety, medical devices and medical products).

It is widely recognised that few if any issues identified are specific for nanotechnologies. Many of them including e.g. security concerns, data privacy, etc. are rather technology-or sector- specific than strictly nanospecific. However, nanotechnology may bring out new aspects of existing issues, widen their scope, or bring an 'old' issue to wider public awareness.

Lessons learned and experience from other debates, like GMOs and stem cells, can be valuable in promoting nanotechnology debate.

Regarding the benefits on the ethical, legal and social aspects of nanotechnologies, in the FramingNano Delphi consultation, responses overall indicated that there was a notable majority in particular agreeing that nanotechnology would make an important contribution to the future economy, and many considered it would have an overall positive impact on society. Fewer respondents considered that nanotechnology would revolutionize manufacturing.

On the other hand, the negative impacts, however, scoring levels of agreement were high that nanotechnology would raise important ethical questions for society and that nanotechnology has the potential for serious criminal or military misuse. Furthermore, a substantial number of Delphi respondents expressed doubts that nanotechnology would contribute towards a fairer society, and many expressed doubts that nanotechnology would benefit all levels of society.

This nuanced view correlates with some recent public engagement studies which show a generally positive view of the potential of nanotechnologies in many fields, while also recognising that significant risks may be need to be addressed (Gavelin, et al., 2007, Grobe, et al., 2008).

Focusing on the risk side only, all listed ELSA issues[17] have some importance with slightly stronger agreement that protection of personal data, privacy and limits to personal freedom are particularly important.

In qualifying their responses some stakeholders considered that:

[17] Please consult the questionnaires attached in (FramingNano, 2010) for reference.

- it is difficult to answer yes or no to such questions as ELSI issues are not so clear-cut
- any scientific advance, i.e. not just nanotechnologies, have a potential for misuse
- it is not yet clear how some nanotechnologies will manifest themselves in practice

In response to the identified concerns (and many others), sufficient resources and capabilities for conducting concern assessments along with risk assessments to identify concerns in a timely and early manner have been requested elsewhere (Renn, et al., 2006).

5.4 Opinions on Regulation

The regulatory sector, as a consequence of the novel properties of manufactured nanomaterials, has been identified as an area that should be considered for the control and use of the technology. A regulators' role traditionally involves setting thresholds (define the level of tolerable risks) and determine clear rules for exemptions. In order to fulfil these expectations, regulators need a sound database and a profound level of knowledge to establish reasonable rules; it is commonly agreed that this prerequisite is not met today regarding the availability of scientific data about the potential risks of manufactured nanomaterials (see sections 4.2 and 5.1). Nevertheless, it is also argued that policy-making cannot be placed on hold until risk assessments are complete (see e.g. Corley, et al., 2009, and section 5.3.1.1 above).

As one important aspect at the interface between the EHS and the ELSA debate, the on-going discussion on the adequacy of current regulatory options as well as the identification of opinions on possible ways to "adapt" or "fix" these regulatory frameworks have been a main focus of the Delphi investigations under FramingNano. In the public discourse, it has been questioned whether the existing regulatory frameworks, tools and procedures are adequate to handle nanotechnologies and nanomaterials as an emerging technology, or whether new laws, regulations or entirely novel approaches would be necessary.

> I would prefer to keep minimum government intervention in nanotechnology governance. Hence, other than ensuring the nano material of the same chemical identity will be considered as a new chemical (which will then be subject to all the existing legislative control), no new legislative control is needed […] (Regulatory/standards body).

> We need regulatory agencies able to strongly control industry and business and to stop activities if dangers are suspected (academia).

5.4.1 General Considerations

5.4.1.1 Grouping Stakeholders by Opinion

The claims concerning regulation of manufactured nanomaterials differ depending on the respective stakeholder. They range from a moderate claim to review whether the existing legal frameworks are appropriate to effectively handle manufactured nanomaterials (this approach has been the predominant perspective of governments and governmental authorities so far), to a radical call for a moratorium on nanotechnology research and product marketing until the risk situation has been clarified (the position of some non-governmental organisations).

In order to provide better overview, the FramingNano mapping study (FramingNano, 2009) has analysed diverging stakeholder opinions on regulation and governance of nanotechnologies and identified four broader opinion groups. Each of these groups represents a general view on regulation.

Table 5-1: Positions of stakeholders with respect to regulation of N&N

Position / Opinion	Policy makers	Business	Researchers	CSOs
The existing regulatory situation is adequate. In the case that scientific evidence indicates a need for modification, the regulatory framework will be adapted.	+	+		
Specific guidance and standards must be developed to support existing regulations when dealing with N&N, but the existing regulatory situation is generally adequate.	++	++	++	
Regulation should be amended (on a case by case basis) for specific N&N, above all when a high potential risk is identified. A precautionary approach is envisaged.	++	+	++	+
The existing regulatory situation is not adequate at all. Nanomaterials should be subject to mandatory, nano-specific regulations.				++

Nevertheless, it has emerged in the FramingNano process that some long-standing boundaries between industry, policy makers and environmentalists are dissolving, and, accordingly, stakeholders are increasingly difficult to "categorise".

> Traditional roles are blurring: businesses are going green, NGOs are becoming more businesslike – and are selling their services – governments are outsourcing work to agencies, and academics have become entrepreneurs (industry).

In particular, several industry statements have indicated that traditional positions, e.g. against any regulation of nanotechnologies, is considered in a much more differentiated way that it might be expected from previous debates.

This gives rise to the conclusion that in the governance process of nanotechnologies, clear-cut stakeholder positions depending on their sector cannot be assumed and communication has therefore to be adjusted to this fact.

5.4.2 Adequacy of Existing Regulatory Systems

5.4.2.1 Agreement and Disagreement with the Existing Regulatory Framework

The adequacy of existing regulations in order to safely handle manufactured nanomaterials has long been controversially discussed, and various stakeholder groups have issued diverging statements. Above all, many have requested to review existing legislations, and many governments have

promised to do so. In June 2008, the European Commission in a Communication to the European Parliament stated that:

> Overall, it can be concluded that current legislation covers to a large extent risks in relation to nanomaterials and that risks can be dealt with under the current legislative framework. However, current legislation may have to be modified in the light of new information becoming available […] (Commission of the European Communities, 2008).

The conclusion confirming that the existing regulations in principle cover manufactured nanomaterials has emerged as a dominant theme in the regulatory debate, although it has not remained unchallenged. Some kind of "regulatory stalemate" has resulted from this conclusion. It has been argued that existing regulations in principle cover nanomaterials, but adaptations may be necessary on the level of implementation. However, such adaptations were deemed impossible at the time due to the weak scientific database available, e.g. in order to determine new thresholds or levels of tolerable risk. Illustrating this at the example of the Swiss Federal Council, many governments similarly concluded that

> [o]nly when the methodological foundations and well-grounded risk assessments of synthetic [manufactured] nanomaterials are available, can additional statutory framework conditions for the safe handling of synthetic nanomaterials be developed (EDI, 2008).

These views have been confirmed by another Delphi exercise which has been carried out in 2006 in Germany among 71 nanotechnology experts (BfR, 2009) led to the conclusions that 50% of respondents were positive on the question whether existing rules such as REACH are sufficient whereas 32% expressed concerns that there was considerable need for action. The editors of the Delphi study added that the adequacy of current regulations was mostly supported by business representatives whereas other expert groups had a different overall opinion. On the other hand, however, while not saying that rules are completely inadequate to deal with nanomaterials, 64% of the experts stated that the existing regulatory framework needs to be adapted to nanomaterials and 21% of the experts thought it was necessary to introduce new (dedicated) nano-regulations.

Overall, the nanotechnology experts indicated that existing regulations are in principle adequate, no new nano-regulations need to be established and existing regulations should be adapted to the needs presented by the new properties of nanomaterials.

As an important milestone on the European level, however, in April 2009 the Members of the European Parliament upon initiative of the Committee on the Environment, Public Health and Food Safety overwhelmingly adopted a report to the Commission in which the Members of the Parliament requested quick and thorough action to adapt REACH in terms of its adequacy to handle manufactured nanomaterials (European Parliament, 2009c). Therein, the MP disagreed with the Commission's view that current legislation covers in principle the relevant risks relating to nanomaterials. The MP stated that

> […] in the absence of any nano-specific provisions in Community law, with the Commission's conclusion that current legislation covers in principle the relevant risks relating to nanomaterials, when due to the lack of appropriate data and methods to assess the risks relating to nanomaterials it is effectively unable to address their risks. (Commission of the European Communities, 2008)

and

> [...] as long as current legislation does not contain any nano-specific provisions, and as long as data and methods to adequately assess the risks of nanomaterials are missing, better implementation of current law alone cannot bring about the necessary level of protection. (Commission of the European Communities, 2008)

Consequently, the Parliament called on the Commission to review all relevant legislation within two years to implement the principle "no data, no market" [...], and to ensure that legislative provisions and instruments of implementation reflect the particular features of nanomaterials to which workers, consumers and/or the environment may be exposed. The European Parliament indicated that such review is not only necessary to adequately protect human health and the environment, but also to provide certainty and predictability to economic operators as well as public confidence.

More specifically, the new approach specified by the European Parliament to explicitly consider manufactured nanomaterials in regulations has recently influenced the update or the EU legislation on cosmetics (European Parliament, 2009b) and the development of the new Novel Food Regulation (European Parliament, 2009a), which both contain provisions and requirements specifically and explicitly taking reference to manufactured nanomaterials.

Although nanomaterials are indeed covered by the general scope of the existing legislative frameworks (which has not been challenged in the FramingNano consultations), it seems often unclear whether current regulations are actually applicable when it comes to specific nanomaterials and their diverse applications.

> Regulatory reviews have tended to focus on whether nanotechnologies and their applications are caught within the remit of existing provisions, the problem with this approach however is that it overlooks the question of regulatory effectiveness. […] The more pressing matter now is gaining insights into how those provisions operate [...]. (Dr Elen Stokes, Prof Robert Lee and Lori Frater, University of Cardiff, in (Responsible Nano Forum, 2009))

These rather critical comments, however, do not go as far as those by J. C. Davies in the US, who wrote the first version of the Toxic Substance Control Act (TSCA):

> The current oversight system was designed to deal with the problems of steam engine technology in the context of a pre-computer economy. It was based on assumptions that most problems are local, that programs can be segmented and isolated from each other, that technology changes slowly and that all the important problems have been identified (Davies, 2009).

These and many other points of criticism lead Davis to conclude that an entirely new oversight agency needs to be established for nanotechnologies and nanomaterials; while his proposal is the basis for discussion so far, recent developments in the US indicate that indeed the US chemicals legislation TSCA as a core element of nanomaterial oversight and control will undergo profound reform under the current Obama administration[18]. For a more detailed view on the issue of regulatory institutions, please see section 5.4.2.1.

In Europe, criticism to the existing chemicals legislation is addressed on a less fundamental level. The main problems identified in the course of the FramingNano process are

- the requirements to perform safety evaluations are triggered by mass (e.g. the annual production volume) instead of surface or particle number related values.

[18] See e.g. “Essential Principles for Reform of Chemicals Management Legislation” from September 29th, 2009, on the EPA website under http://www.epa.gov/oppt/existingchemicals/pubs/principles.html.

- the profound lack of (eco) toxicological data which prevents development of meaningful data on risk assessment.
- and that no risk thresholds and occupational exposure limits can be established with existing methodologies.

The Delphi respondents generally agreed that current regulations are at least partly insufficient in terms of safety provided, in terms of provisions for nanotechnology, in terms of guidance for effective implementation and even in terms of scope.

> The current regulations address chemicals, not nanomaterials. If and where nanomaterials behave like homogeneous chemicals, the regulations are adequate. However, for the most part, nanomaterials cannot be treated like chemicals, and the current regulations are not adequate (regulatory agency).
>
> We cannot regulate nanomaterials as if they were bulk materials. Nanomaterials or nanoparticles cannot be equivalent as other materials which have no specific nanostructure inside (NGO).

The overall assessment derived from responses of the two Delphi consultations is backing the recent position of the European Parliament which clearly spoke in favour of nano-specific adaptations and provisions in existing legislations (European Parliament, 2009c). Most Delphi respondents indicated that current regulation does not address or only partially address the needs that nanotechnologies present, both nationally and in the EU, with only a small number regarding current legislation as entirely adequate (FramingNano, 2010).

However, in the FramingNano Mapping Study, it was also found that the level of confidence in existing regulations when dealing with nanotechnology strongly depends both on the type of product considered and the legislative framework to which it has to comply (FramingNano, 2009). This issue is approached in the next section.

5.4.2.2 Priority Materials, Applications and Product Categories

Much like in the case of hazard based regulatory priority setting, which is currently hampered by many uncertainties and knowledge gaps, regulatory priority setting based upon actual or expected exposure to nanomaterials remains complicated as the identification of priority areas for regulation based on reliable economic data is spoiled by uncertainties about the true impact of nanotechnology enabled products on the market (OECD STI Working Paper 2009/7, 2009). Due to a lack of specific statistical coverage of nanotechnologies, regulators and public agencies are often left in the dark regarding

- which kinds of nanomaterials are (most) produced and sold and under what conditions and to whom; and
- how many workers are potentially exposed to what nanomaterials and how the environment might be exposed

Nevertheless, several OECD projects are currently being undertaken in order to support policy makers with a sound statistical framework regarding the commercial impact of manufactured nanomaterials. A first paper on the analysis of nanotechnology based in statistics and indicators has been presented in June 2009 by the OECD Directorate for Science, Technology and Industry (OECD STI Working Paper 2009/7, 2009), but further efforts will be necessary to be able to use such sources to support policy makers in regulatory priority setting.

In their 2009 report on regulatory aspects of nanomaterials, the European Parliament stated that it considers it particularly important to address nanomaterials explicitly within the scope of at least legislation on chemicals (REACH, biocides), food (foodstuffs, food additives, food and feed products from genetically modified organisms), relevant legislation on worker protection, as well as legislation on air quality, water quality and waste" (European Parliament, 2009c). Regarding amendments of worker protection legislation, the MP request to ensure that nanomaterials are only used in closed systems as long as it is not possible to reliably detect and control exposure. Also, the MP have identified that it is necessary to specifically amend waste legislation[19] to adequately address nanomaterials (European Parliament, 2009c).

In the FramingNano Delphi consultation, participants were asked to indicate which areas should be subject to regulatory provisions and in what priority. Above all, respondents generally considered regulatory provisions a suitable way to overcome most of the EHS issues previously identified (see section 5.3.1).

In regards of priority industry sector and application areas, responses of the first Delphi consultation indicated several sectors where legislative activity is needed:

- foods and feedstuffs
- cosmetics
- chemical substances
- environmental protection
- occupational safety

While respondents of the second Delphi panel mostly agreed with this priority list, during the FramingNano Stakeholder Workshop in Brussels in February 2009, provisions concerning nanotechnology in chemical substances and food were deemed inadequate by more than half of the respondents, with somewhat less concern about cosmetics, medicinal products and environmental protection. A lower level of concern was expressed over medical devices and occupational safety (FramingNano, 20010).

If compared to the expected growth rates, however, the highest expectations where projected by German experts in the area of surface coatings (BfR, 2009). Nanoproducts in textiles and cosmetics were expected to grow only moderately, while the experts expected big difficulties to market nanotechnology applications in the food sector.

Foods and feedstuffs

One industry representative said that it was understandable that the public might be uneasy with having new technologies used in their food.

> If you feel in control of the risks, you are more comfortable with it. We understand the request for more data is high on everyone's agenda (industry).

[19] List of waste established by Decision 2000/532/EC, waste acceptance criteria in landfills in Decision 2003/33/EC, emission limit values for waste incineration.

On the other hand, however, experts in the German Delphi indicated that they did not expect considerable markets for nanoproducts in the food sector (BfR, 2009), and one Delphi respondent noted that his organization had held a citizens' conference which provided some insight into public thinking. He said a survey of German newspaper coverage over the past 10 years revealed no major concern on nanotechnology, with the exception of those articulated by lobby groups on foods and cosmetics.

> Concern has been expressed by NGOs but not by citizens in Germany. [...] Citizens will accept nanotechnology, except in the areas of food and cosmetics (public authority).

Cosmetics

Typically, cosmetics have been mentioned by Delphi participants together with foods and feedstuffs as examples of highly relevant, close-to-consumer applications of nanotechnology.

> In particular the area of cosmetics is open to deep dangers, because the controls in this area are not very stringent. Moreover, cosmetics are used […] by the entire population […] day-after-day for the entire life, and the effects of accumulation (in the body but also in the ecosystem) are not known (academia).

Chemicals and materials

In the German survey (BfR, 2009), the experts indicated a high level of concern regarding health effects for 30 nanoproducts. These included silver particles in paintings for mould-infested walls, in soaps and in food supplements, halamids for antimicrobial equipment, carbon nanotubes for conducting fabrics, metal particles as antistatic enhancer, titanium dioxide in sunscreens.

On the other hand, the experts did not find it necessary to implement regulatory action regarding nanoparticulate titanium dioxide, zinc oxide and silica. These materials are well known and the experts do not expect systemic exposure upon dermal application of these substances.

Nanoproducts containing fullerenes have raised concerns among the experts, although they expected no such products on the market in Germany. Nevertheless, the possibility to buy such products over the internet might make regulatory measures necessary (BfR, 2009).

Besides fullerenes, the use and possible accumulation of nanosilver due to increasing use have been mentioned as concerning. Regarding potential environmental effects of such material release, it was feared that such materials exhibit effects in sewage plants.

In the context of a recent scientific hearing on the risk assessment of nanotechnologies by the European Commission DG SANCO, respondents among others expressed special concern regarding specific issues such as Carbon Nanotube (CNT) effects, genotoxicity testing, altered tissue distribution of nanomaterials and environmental toxicity (de Jong, 2009).

Medical devices and medicinal applications

Some respondents have raised concerns over the low level of concern expressed towards medical applications of nanotechnologies in the first FramingNano Delphi consultation.

> It is curious that medical products were at a low level of concern considering their current problems in reservoirs and other waterways (regulatory agency).

> [...] In these applications, great attention is necessary since the nanoparticles would circulate in the blood. I would not consider as lower the level of concern for this sector (public authority).

Ethical aspects have almost uniquely been mentioned in the Delphi responses in the context of medical devices. This on the one hand may be explained by the fact that in this sector some future applications of nanotechnologies with high ethical controversy have already been described. On the other hand, it seems equally safe to say that, although several academic and non-governmental organisations participated in the FramingNano surveys, that these issues are currently not regarded of utmost priority.

One Delphi participant mentioned that in the area of nano-medicine, the traditional balance between impacts and advantages in therapeutic choices is followed, and therefore this sector is not regarded as a priority area for regulatory activities.

Others

Besides the priority areas identified above, Delphi responses also indicated that the areas of textiles, articles of daily use in general, products especially relevant to children (toys, products for babies), electronics, and agricultural applications are important to be considered priority areas.

These categories broadly confirm the assumption that product and application categories which are connected to close body contact or ingestion are generally rated priority areas by most stakeholders.

At the workplace, inhalation of nanoparticles, safety of carbon nanotubes and long term exposure have all been mentioned as topics which need urgent action.

The end of life topic has been brought forward in different contexts. Many stakeholders have expressed concerns about missing lifecycle considerations in general, and in specific in the area of electronics.

5.4.2.3 Better Implementation of Existing Provisions Regarding Nanomaterials

Very often in the debate about the adequacy of the regulatory system regarding nanomaterials, the general scope and adequacy of regulatory approaches (such as, e.g., REACH in Europe) are not challenged, but rather the implementation of the existing provisions in practice.

The Delphi participants considered the implementation of current regulatory provision regarding manufactured nanomaterials to be hampered by a series of factors including

- mandatory information reporting requirements or safety evaluations are commonly triggered by **mass based thresholds** (e.g. a chemical's annual production volume in kilograms per year per manufacturer). Since many manufactured nanomaterials are produced or imported in small volumes, it is expected that they may not trigger such testing requirements. The community is discussing surface area or particle number based thresholds for nanomaterials instead of mass.

- the **lack of validated and standardised methodologies** (tests) to assess (eco)toxicological effects of nanomaterials makes it impossible to determine safe levels of exposure (no effect levels) and therefore determine (occupational) exposure limits which would serve as a threshold for regulations.

- the lack of **validated and standardised metrologies (instruments) to detect and measure nanomaterials** at the workplace, in products and in the environment makes it difficult to determine actual exposure levels and would therefore hamper the enforcement of legal provisions.

Particularly for small and medium enterprises (which represent an important part of the rising nano-industry in Europe and elsewhere) it is often difficult and costly to know how to fulfil the existing regulatory duties, not to speak to undertake extensive research on how to best handle manufactured nanomaterials based on the latest state of science and technology.

It has therefore repeatedly been proposed to develop and make available tools and guidelines which support such SME in making the right decisions regarding safety of manufactured nanomaterials in the production process. This has been proposed to be done, e.g., by providing guidelines dealing with the implementation of the various information and recommendations already available. In the German Delphi, the experts mostly supported measures to develop such guidelines (BfR, 2009).

> The simple cause-and-effect approach for single events should be replaced by a proactive corrective approach with adaptive management for a system which is disturbed by given events[20].

A recurring issue in the FramingNano consultation regarding better implementation of existing provisions concerned the fostering of the development of non-animal testing strategies, which is one of the priorities in EU policy and REACH. The issue of animal-free testing is of particular importance regarding the expected increase in chemical testing according to the requirements under REACH.

The promotion, development and validation of non-animal test methods and the development of non-animal testing strategies making use of advances in toxicogenomics, bioinformatics, systems biology, epigenetics and computational toxicology to evaluate changes in biologic processes using cells, cell-lines or cellular components is a priority issue of the European Union, and the Commission funds research into alternative testing methods and strategies in partnership with industry and cooperates within OECD on this issue. The Commission's JRC is also active in the development and assessment of alternative methods (European Commission, 2009).

Some animal welfare organizations are particularly active in the context of manufactured nanomaterials, as they seem to fear that the imminent threat of a need to test many manufactured nanomaterials in the near future will lead to a considerable increase in *in vivo* animal testing. This is an obvious conflict between societal emphasis on safety versus reduction of *in vivo* testing.

Some NGO active in animal protection argued in the FramingNano Delphi panels that safety testing strategies for nanomaterials should go beyond the provisions of EU Regulation 1907/2006 (Article 25) which lay down that tests on vertebrate animals should only be undertaken as a last resort. The development of an emerging technology such as nanotechnology should be taken as an opportunity to develop and implement a tiered non-animal testing strategy to test the human health and environmental safety of nanomaterials.

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[20] Roco, M.C. (2005b) "The Emergence and Policy Implications of Converging New Technologies Integrated from the Nanoscale," *Journal of Nanoparticle Research*, Vol. 7 No. 2-3, pp. 129-143.

According to the proponents of animal free toxicity testing, modern procedures such as computation (in silico) toxicity estimations and modelling should be used to comply with the goal of REACH to reduce animal toxicity testing.

These ambitions point towards a tiered non-animal testing strategy. As these groups argue, not only ethical, but also scientific aspects speak against using sentient animals for the testing of nanomaterials. It is recommended to take advantage of the revolutions in biology and biotechnology, toxicogenomics, bioinformatics, systems biology, epigenetics, and computational toxicology. In the area of nanomaterials, where validated test methods (as compared to conventional chemicals) so far do not exist,

> […] scientific and political efforts should set out to develop a non-animal testing strategy from the beginning (NGO).

Similarly, in the public consultation on risk assessment of nanotechnologies in September 2009, a number of NGOs asked for a ban on (in vivo) animal testing (Bontoux, 2009).

Overall, it became obvious that some specific NGOs are highly active in the debate on the abatement of animal testing, and these NGOs also make animal testing a subject of discussion in the context of nanotechnologies. Therefore, this issue has to be considered of high public relevance.

5.4.2.4 Subsidiarity in Regulation

Participants have been asked to indicate consensus or absence of consensus with the suggestion to regulate nanotechnologies and nanotechnology products at the European level or even beyond as opposed to individual national approaches.

The overall response to this question clearly indicated that respondents preferred a European approach as the primary step, although some expressed concerns that it might be “rather difficult” to achieve.

> Governance must be envisioned at the European level. There is no possible subsidiarity here (research: academia).

> These items must be addressed at least at a European level (enlarged also to near-Europe countries) (academia).

Nevertheless, many participants, although favouring the European approach as compared to national approaches, indicated that an international approach would be even better, and that later transfer of the regulations to an international level would be favourable.

> […] [I]nternational would be better still, but don’t know how that is doable (NGO).

> At first yes, then [it] should be extended to the international level (national agency).

Areas were an international approach would be particularly sensible, according to the Delphi participants, were environmental protection, education in nanotechnology at universities, and provisions on the generation and disclosure of information on nanomaterials, and on limitations of international property rights and patents.

Some concerns have been raised by a representative of an industry and of a NGO who indicated that the regulation of nanotechnologies on a higher level would be important, provided that the consideration of handling the regulatory issues on a higher level does not delay lower-level legislation and control.

> A pan-European approach to setting national legislative and regulatory frameworks is important as long as it does not delay the debate and ultimate implementation (industry).
>
> [T]his aim should not postpone EU wide legislation, implementation and control which have first priority […] (NGO).
>
> I fear that efforts to harmonize the regulatory approach worldwide would take forever and eventually led to the adoption of an insufficient regulatory approach due to special interests similar to what is currently going on in the field of climate change (academia).

Regarding the concrete approach to develop regulation at the corresponding level, several participants mentioned that a model approach could be suitable to start from. However, their opinions were divided on whether the model should be set on national or European level already.

> First a "model" should be developed for one country with e.g. most experience within the field of nanotechnology and risk […] assessment (regulatory authority).
>
> […] [W]e need to start with a combination of a strong European effort to address these issues along with a regulatory environment that is sensitive, alert and reactive to international efforts in the field (e.g. Canada, California, Massachusetts) which can then be used to address issues at the international level (OECD, WTO, G20) (academia).
>
> A master set of legislative actions, policies, safety guides etc. should, however, be developed, which could be used in the separate countries as templates, and with existing supranational agencies providing the forum for debate (industry).

Regulatory subsidiarity is certainly an important element to be taken into consideration. It is important to pinpoint the tendency of European countries regarding regulation and legislation with respect the directions coming from the European Commission (harmonisation at European level). However, in the present Delphi consultation, participants generally disapproved of a strictly subsidiary regulatory approach.

In conclusion, the participants of the FramingNano Delphi consultation clearly favoured a European approach over individual national regulations, and they tended to favour international regulations at least in a second phase. This raises questions about how such international approaches could be developed and agreed on and what institution would be responsible.

5.4.2.5 Institutional Issues Regarding Oversight and Regulation

Once it is clear at what level (national, European, international) regulations of nanotechnologies should be envisioned (see section 5.4.2.4), the question of what institution or authority should be responsible for the development and implementation of these regulations remains to be answered. Options range from implementing a new supranational multidisciplinary nano-agency to dedicating the implementation and rule-setting process to existing, national institutions on the basis of their authoritative competences.

An interesting perspective comes from the US, where J. Clarence Davies, who, as mentioned before, wrote the original version of what became the Toxic Substances Control Act (TSCA) and served as Assistant Administrator for Policy, Planning and Evaluation at the US EPA, describes the challenges that the US regulatory agencies face regarding nanotechnologies.

> Since 1980, the capability of the federal agencies responsible for environmental health and safety has steadily eroded. The agencies cannot perform their basic functions now, and they are completely unable to cope with the new challenges they face in the 21st century (Davies, 2009).

According to his arguments, the US federal regulatory agencies suffer from under-funding and bureaucratic ossification which prevents them from dealing adequately with the potential adverse effects of the new technologies. He concludes that "new thinking, new laws and new organizational forms are necessary" (Davies, 2009).

> An adequate oversight system must, at a minimum, be able to assess potential risks from a technology, minimize the chances that the risk will occur and maintain surveillance to identify risks that do occur (Davies, 2009).

The thought Department of Environmental and Consumer Protection would provide an integrated oversight, host a research and assessment section and a monitoring function. Those three elements and functions would facilitate integration as it would incorporate existing agencies for environmental protection, occupational safety, geological survey and others, and create new parts to cover risk assessment, monitoring and statistics.

The thought agency would strictly focus on product regulation, as compared to current mixed approaches on chemicals and products. This new focus would make sense in the light that oversight should encompass the life cycle of the product, and that it is a product's very specific properties that account for potential health and environmental effects, while the material properties would be covered by the workplace regulations.

Davies argues that regulators will most certainly never be able to rely on a sound basis of knowledge to base regulations on; therefore, a special emphasis must be laid on after-market monitoring and reacting to emerging issues.

> Because of the complexity of new technologies and the rapid pace of invention and adoption, the science will probably be inadequate to fully identify all the risks a new material or product will pose. For this reason, even more than in the past, it will be necessary to establish requirements and systems for identifying adverse effects of a product after it is in commercial use (Davies, 2009).

What according to Davies and many others seems to be particularly true for the US oversight system is maybe not that wrong for Europe too. Integrated approaches, trans-border trade, and complex problems that are not locally restrained, may all be used to characterise nanotechnologies.

However, Davies' considerations reflect a view where governments are expected to bear the additional responsibilities in relation to the development and market introduction of nanotechnologies, while in Europe under REACH, more responsibility is placed on industries and businesses that have to ensure that only safe products are on the market.

Asked about the need for new regulatory institutions, exclusively dedicated to nanotechnology issues, Delphi respondents mainly considered unnecessary to provide funding for a new regulatory institution, neither at national nor at international level (FramingNano, 2010). When asked to express agreement or disagreement with the statement that existing authorities should bear the task of overseeing the implementation of regulations addressing nanotechnologies or products containing nanomaterials, the majority of respondents indicated that existing authorities should oversee the implementation of regulations, at least in the beginning.

> A new supranational agency is not desirable (industry).

Although most participants expressed strong favours for a coordinated approach in regulation and a harmonisation of the regulatory approaches within Europe and on the international level, they

indicated no willingness to assign the tasks of regulatory oversight and control of implementation to a newly created agency.

There have, however, also been other opinions, indicating that the creation of new agencies may be necessary.

> This [existing authorities] is the only choice to begin with. However, new entities should evolve as more information on how and what to regulate becomes available (regulatory agency).

> A new nano-agency similar to ECHA [should be responsible for the implementation of national / international regulations] (academia).

> The structure of a European agency co-operating with national authorities, in accordance with the structure of operation of ECHA and the national authorities responsible under the REACH system, seems appropriate to regulate nanomaterials (NGO).

One respondent mentioned that the focus should not be mainly on bodies and institutions, but rather on the tools which are needed to govern nanotechnology development and commercialisation.

> Implementation can be focused or shared between existing bodies. There is a need of a body of reference for observing, reviewing, assessing, communicating and managing tools of common interest and implanting sanctions according to an international agreement (regulatory advisor).

This comment puts particular relevance on the need of a co-ordinated approach to develop tools and measures to govern the risk of manufactured nanomaterials, rather than concentrate the whole oversight on an international level.

The key points against involving existing authorities to oversee the implementation of regulations addressing nanotechnologies have been indicated in the overburdening of existing authorities with new and complex, multidisciplinary tasks, the lack of the necessary funding and in the lack of collaboration between authorities and other stakeholders.

> Existing bodies are for most cases overburdened and underfunded and have enough problems dealing with what they are suppose to deal with (cosmetics, chemicals, environmental protection) and adding regulation of nanomaterials (i.e. regulation of “the next industrial revolution”) to any one or more of these bodies would just overburden these bodies even more (academia).

> [P]rovided that additional resources are allocated and also close collaboration between authorities and researches/experts take place (regulatory authority).

In conclusion, many participants of the Delphi consultation have overall spoken in favour of regulatory oversight on the level of existing (national) authorities, though some have brought forward concerns that existing authorities are able to fulfil this task due to, among other reasons, inadequate resources. Coordination and harmonisation at a higher (European or supranational) level is in any case advocated.

This position is generally shared in Europe and is somehow in disagreement with signals from the US where there are doubts whether the existing public authorities such as US EPA will be able to effectively handle the additional burden of overseeing and regulating nanomaterials under the current budget and staff conditions and seems to favour a new regulatory body.

On the other hand, responses have also indicated that coordination and harmonisation needs to occur on a higher (European or supranational) level.

5.4.2.6 Regulatory Stability

Regulatory stability is a concern which has repeatedly been mentioned during the FramingNano project by industry representatives, fearing that ever-changing and stricter regulatory requirements represent a barrier to innovation, commercialisation, and financial investment into new products and technologies.

At the FramingNano Multi-Expert Workshop in Brussels in February 2009, one participant representing the chemical industry was critical of how regulators change the rules while companies are developing new products.

> It takes five to seven years to bring a product to market, but the policy cycle is four to five years. If the goalposts are constantly moved, it is difficult for industry to respond. For example, just a few years ago biofuels were encouraged. Industry invested but was then told to stop due to the food crisis (industry).

Nevertheless, in the background of the debate about the risks of manufactured nanomaterials, and the corresponding scientific uncertainties, some industry representatives have also argued that some stable and dependable regulation as such would not necessarily represent more of a barrier to innovation, research and development than the immanent "threat" of regulation or unsteady (changing) regulatory frameworks would.

5.4.3 The Role of Voluntary Measures in Nano Governance

Voluntary measures in nano governance have emerging in recent years as a complement to existing mandatory regulatory approaches. They are often described as critical interim measures to fill the current risk management gap before our knowledge of the emerging technology and the associated risks matures are developed.

> Voluntary risk management approaches as a complement to existing regulations may not be as protective for workers as government risk management regulations are, but may be a critical interim measure to fill the current risk management gap before our knowledge of the emerging technology and the associated risks matures (Murashov, et al., 2009).

These measures might, beyond the harmonisation of standards in multinational companies, also help to reduce risks and sustain public trust and confidence. On the other hand, however, voluntary approaches may not be as protective for workers as government risk management regulations are, and concerns have been raised concerning transparency, enforcement and control.

In the first Delphi round, participants were asked to name voluntary measures that they consider particularly relevant to nanotechnology. The following list was collected:

> CENARIOS Certifiable Nanospecific Risk Management and Monitoring Standard (TÜV SÜD / Innovation Society, Germany / Switzerland) (TÜV SÜD Industrie Service GmbH, 2008).
>
> Code of Conduct for Nanotechnologies (Swiss retail trade IG DHS, Switzerland) (IG DHS, 2008).
>
> Nano Risk Framework (Environmental Defense - DuPont) (Environmental Defense/DuPont, 2007).

Precautionary Matrix for Synthetic Nanomaterials (Federal Office for Public Health FOPH, Switzerland) (Höck, et al., 2008).

Guidelines

PD 6699-2:2007 Nanotechnologies: Guide to safe handling and disposal of manufactured nanomaterials (British Standards Institution BSI) (BSI, 2008).

Further initiatives and concepts were mentioned from the literature, including

OECD Chemicals Governance Model

IRGC clover concept (iterative four-field process)

IRGC 2008: Risk Governance of Nanotechnology Applications in Food and Cosmetics

IRGC white paper no 2 Nanotechnology Risk Governance

The Institutionalised Transparency and Accountability Process (ITA) (Karita Research, Wenergy) (Andersson, et al., 2008).

Kjell Andersson and Clas-Otto Wene, The Institutionalized Transparency and Accountability Process for clarity in policy making. Karita R: 08:01, ISBN 978-91-976858-1-8

Action-Plans of several countries (e.g. Germany, Netherlands, Switzerland)

5.4.3.1 Agreement and Disagreement with a "Combined Approach"

The concept of a "combined approach" was introduced to the Delphi participants and includes a combination of voluntary measures and mandatory legislation, as a complement to mandatory rules or legislation only.

Under the current circumstances of uncertainty, national and international regulatory agencies have come to the first conclusion that existing regulatory frameworks are in principle adequate to cover manufactured nanomaterials, and as a second conclusion, that early regulation of manufactured nanomaterials is not a feasible option in consideration of the many gaps in our knowledge on the nature and possible handling of such risks.

On the other hand, according to various stakeholder surveys, a moratorium on nanotechnologies is not deemed reasonable either, and therefore a middle course between commercialising nanomaterials and products with unclear risk profiles, and halting all nanotechnology related research and development has to be sought.

> [T]o address the growing divide between regulatory guidance and commercialization, proactive, voluntary measures by industry must continue and expand. They must demonstrate more clearly how potential risks are being mitigated […] (Lynn L. Bergeson, Bergeson & Campbell PC, in (Responsible Nano Forum, 2009))

Several governments have opted to foster the implementation of voluntary programs, arguing that this is the only viable proportional option for the time being. Approving this approach, in the German Delphi panel, the majority of experts involved considered voluntary self-commitments as sensible and regarded workplace safety assessments the most important for such self-commitments (BfR, 2009). Many stakeholder responses in the FramingNano Delphi exercise also clearly indicated a high level of agreement with voluntary approaches (FramingNano, 2010). The discussion did, however, also lead to critical comments on voluntary approaches in general:

> [...] we have learned that voluntary measures do not work. They may enhance regulatory approaches, but mandatory regulation is necessary to get any kind of result. Otherwise, it's just a feel-good way for risky practices and practicers to buy time (regulatory agency).

Stakeholders were asked in the context of the first FramingNano Delphi consultation to express consensus or absence of consensus on such a combined approach. In the second Delphi consultation, participants were asked to rate the adequacy of such a combined approach for different sectors of applications of nanotechnologies.

The adequacy of voluntary measures besides mandatory regulation has been discussed controversially in the literature and during the Delphi panels. Nevertheless, a combination of legislation and voluntary measures received majority backing at the FramingNano Multi-Stakeholder Workshop. The responses of the first Delphi consultation suggest that the majority of respondees consider a combination of legislation and voluntary measures (72.5%) a feasible way forward.

> A combination of voluntary measures and legislation are needed for now, and hard legislation is absolutely necessary (public authority).

The responses suggest that a majority (31 of 40) consider that voluntary measures offer the possibility to increase safety and trust amongst stakeholders. On the other hand, 25 or 40 respondents indicated that current methodologies, e.g. risk assessment procedures and tools such as standardized definitions, are currently insufficient to support voluntary measures.

On the other hand, industry self-regulation and voluntary measures have been accused of serving the interests of industry above that of society by, for example, circumventing market forces by having variable standards of enforcement and of lacking the accountability and legitimacy of government regulation (Bowman, et al., 2009). Others fear that these measures could be used as a way to delay or avoid mandatory regulations. For example, one Delphi respondent and the Civil Society-Labor Coalition argued that

> […] voluntary regulations have often been used to delay or weaken rigorous regulation and should be seen as a tactic to delay needed regulation and forestall public involvement (Civil Society-Labor Coalition, 2007).

> If codes of practice are used to delay or subvert appropriate regulation then a combined approach is actually counterproductive. This has happened in many areas in the past to the detriment of the sector or issue. Some voluntary initiatives are designed for that reason (NGO).

In this context, a majority of the 40 participants of the first FramingNano Delphi consultation are against voluntary measures and codes of practice alone (62.5% against vs. 35% in favour). In the first Delphi round, however, a majority of the respondents (25 of 40) considered that voluntary measures do not hinder or delay the development of necessary mandatory regulations.

In regards of the adequacy of a combined approach in specific application sectors, stakeholders of the FramingNano Delphi consultation have been split. Even in the area of foods and feedstuffs and cosmetics, where we would expect a stronger favour towards mandatory rules, some regarded a combination of the latter with voluntary measures fully appropriate while others expressed the opinion that such approach would not be appropriate. Overall, no sector was identified where stakeholders were unanimously in favour or against a combination of voluntary measures and legislation.

The aspect of voluntary measures serving as "interim measures" until regulations based on sound science can be developed has also been brought forward.

> However it is essential that the right regulation is in place, this takes time. Voluntary initiatives have a role in the interim (NGO).

Additionally, certain voluntary measures have been described to include areas which may not be legislated but which also demonstrate responsible approaches.

> They help articulate expectations in a way which regulation sometimes is not able to do and helps rally multiple sectors around a shared understanding of responsible behavior (NGO).

In conclusion, stakeholders have taken a down-to-earth stance on voluntary measures and implicitly suggest that if such measures are considered, attention has to be paid to careful design of incentives and consideration of issues of transparency and accountability. Almost all responses indicated that the stakeholders considered mandatory legislation a viable element for certain areas, whether in combination with voluntary measures or alone. However, control and transparency have also been rated important and should explicitly be ensured when fostering or promoting such voluntary measures.

5.4.3.2 EC Code of Conduct on Responsible N&N Research

Stakeholder responses to the first FramingNano Delphi consultation indicated that the great majority of stakeholders were aware of the European Commission Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research (CoC). However, there was also a high level of uncertainty about possible actions to be taken with respect to the implementation of the principles and recommendations of the CoC within the member countries.

A European Commission official expressed disappointment at how EU member states have responded so far to a code of conduct on nanotechnology. Speaking at the FramingNano Multi-Stakeholder Workshop in Brussels, he said that the Commission had done significant work on nanotechnology issues but this had not always been reflected in countries across Europe (FramingNano, 2010).

> The Commission started work on this very early but has been disappointed by the response from member states, particularly by inaction concerning the code of conduct (policymaking body).

Having a voluntary code is critical if dialogue is to be maintained between industry, policy-makers and NGOs, he suggested.

One FramingNano Delphi participant supported this comment and suggested much wider engagement and promotion of the EU CoC among Member countries.

> The European Commission needs to communicate and engage much more widely about this initiative. They have simply put it out there and done nothing. Member states need to take it on board, promote it internally (NGO).

> This has been criticized by some parties as being toothless but a voluntary code ensures the cooperation of stakeholders (policymaking body).

The promotion of the CoC currently seems unsatisfactory to many stakeholders. One participant recommends letting member states know that their commitments and efforts regarding the CoC will

be made public. Further comments on incentives for voluntary measures will be discussed in section 5.4.3.3.

It is mentioned in the literature that voluntary nano-codes have weaknesses including a lack of explicit standards on which to base independent monitoring, as well as no sanctions for poor compliance. Similarly, one respondent of the Delphi panel mentioned that

> Purely voluntary measures will not be sufficient in the future. Third-party verification of these measures will become more important (research: industry).

Nevertheless, the authors of a paper on voluntary nano-codes conclude that "it is likely that nano-codes will become the "first cut" of a new governance regime for nanotechnologies" (Bowman, et al., 2009).

Regarding measures to improve knowledge and the implementation of the European Recommendation on a Code of Conduct for Responsible N&N Research, the following points have been proposed:

- Implement an internet homepage with answers to the most frequent questions, provide a platform for stakeholders to exchange experience with the implementation of the CoC.
- Organise regular meetings of different stakeholders to present models, problems and solutions regarding the implementation of the CoC.
- The effectiveness of a Code of conduct is related to its effectiveness in achieving its aims, which is critically linked to its independence, verification, profile in its arena, the publicity it gets, the support of key organisations, and pressure from key stakeholders.

In addition to these "soft measures", some respondents have also suggested mandatory rules to force the implementation of the CoC.

- Products based on nanotechnology should receive authorisation to go to the market only after having verified that a responsible code of conduct is followed by the stakeholders in the whole process of production. (government agency)
- Mandatory legislation requiring industry to implement a CoC. (academia)
- Use it in the forms for EC proposals. (research consortium)

However, such mandatory enforcement would strongly change the character of a voluntary measure. Similarly, one respondent put it like this:

> If a voluntary measure includes penalties, then it's not quite voluntary. Who would volunteer for punishment? (regulatory authority).

Considering the high level of "don't knows" amongst stakeholders in relation to their intentions with regard to implementing the EC CoC on responsible NS&T research, the responses to this question suggested a strong need for further stakeholder guidance regarding the CoC.

> Similarly the Responsible Nano Code, mainly for businesses, needs to communicate and engage more widely, particularly through the production of its benchmark or use of its evaluation framework (NGO).

5.4.3.3 Incentives and Disincentives

Incentives and disincentives are important factors governing the success or failure of voluntary measures. It is commonly agreed that voluntary measures lacking both incentives to participate (some kind of reward) and disincentives not to participate (penalties of some form for those not participating) are unlikely to become successful.

From a retrospective point of view, two governmental attempts to install and promote voluntary data reporting schemes on manufactured nanomaterials have allegedly not fully lived up to the expectations of the promoting authorities. While the fist of its kind, the Voluntary Reporting Scheme (VRS), launched in 2006 by the Department of Food and Rural Affairs (Defra) in the UK, has yielded only 13 submissions in two years, the second attempt by the US EPA in 2008 received 29 submissions on 123 different nanomaterials in one year, although it was expected that a much larger variety of materials is on the market already[21]. It has been argued that these early voluntary approaches lacked the incentives which would render participation for stakeholders more attractive (Hansen, 2009).

In the literature, various studies have been concentrating on identifying criteria which voluntary measures must fulfil in order to be accepted as a real alternative to mandatory regulation. It is usually acknowledged (see, e.g., Hansen, 2009) that key elements of successful voluntary programs are

- incentives to participate for the stakeholders
- agency guidance and technical assistance to implement the measure or compensate for expenses
- signed commitments and periodical reporting in order to create some accountability despite the missing mandatory character
- transparency both in design, reporting and evaluation.

In past voluntary environmental programs, it seems that the “threat of regulatory intervention” used in combination with unbiased technical- and non-technical information support, progress reports, and favourable publicity has been outstanding incentives for participants (Hansen, 2009).

In terms of increasing the promotion to adopt voluntary measures among the stakeholders, the responses of the Delphi consultation also led to the identification of a number of ideas regarding incentives, penalties and supporting tools.

- implement independently controlled certification systems (compare with organic food certification systems) and labelling
- increase visibility and publicity of the initiatives
- publication of a benchmark
- provide examples of good practice
- increase pressure by investors, insurers and NGOs

[21] It appears that approximately 90% of the different nanoscale materials that are likely to be commercially available were not reported under the Basic Program (US EPA, 2009).

As the majority (27 of 40) of the Delphi respondents indicated that voluntary measures would only be effective if rewards or penalties would be applied, it has been suggested to introduce sovereign penalties to motivate stakeholders to participate in voluntary measures:

- introduce rules to require positive evaluation in the project proposals on the use of voluntary measures during the proposed work (see also section 5.4.3.2)
- penalise intentional risk taking and EHS negligence.

However, by introducing penalties, it was argued that the voluntary character of a measure becomes at least questionable.

Broad participation in existing voluntary measures may be regarded as a key parameter from the point of view of a regulator. Unless the majority of stakeholders take part, a voluntary measure may still fulfil a signal purpose or serve as an example of best practice, but any purpose of guaranteeing a certain level of safety and therefore replacing any mandatory rules is questionable.

In the context of the European Code of Conduct on responsible nanosciences research, the FramingNano consultation has revealed that participation has so far been disappointingly limited, and that there is a lack of mechanisms to evaluate and compare performances among participants. Some participants make a lack of efforts to make the Code better known responsible for the apparent failure regarding widespread implementation.

5.5 Public Dialogue, Communication and Education

This section looks at three different aspects of communication. One is to establish and maintain a meaningful reflexive dialogue by including publics and stakeholders. There is also knowledge transfer, particularly by educating young people in science and technology, and finally the communication of information on nanomaterials along the value chain.

Public participation and deliberation is widely acknowledged as a key element of responsible development. A variety of initiatives have been undertaken with the purpose of involving the broader public and many stakeholders involved in some way with nanotechnologies. Many of the dialogue events also served the purpose to gather insights into the public's perception of benefits and risks of nanotechnologies. Such exercises can provide policymakers with a basis to develop governance models which could result in a broader acceptance within the society.

Several initiatives on public engagement have been activated throughout Europe, both at regional and national level. The EC has clearly committed itself to an inclusive approach, although the outcome of such process is connected with uncertainties. The Council of the European Union therefore invited the Commission "to encourage public debate and foster public awareness" (Council of the European Union, 2008), and the EESC recommended that "structured dialogue with civil society be strengthened, on a sound and transparent basis, to provide a united European voice in this field, which is vital to our future on the global stage" (European Economic and Social Committee, 2009).

It is also widely acknowledged that both the factual and the socio-cultural dimensions of risk need to be considered if risk governance is to produce adequate decisions and results. The factual dimension comprises physically measurable outcomes and discusses risk in terms of a combination of potential

– both positive and negative – consequences along with the probability of their occurrence. The socio-cultural dimension, on the other hand, emphasises how a particular risk is viewed when cognitions, associations, values and emotions come into play (Renn, et al., 2006).

5.5.1 Public and Stakeholder Dialogue

5.5.1.1 Concerning the Value of Nanotechnology Studies and Stakeholder Inclusion

Earlier and meaningful inclusion of researchers, industry, government, technology users, public and all interested stakeholders is important for a responsible development of nanotechnologies in particular because these technologies will affect many stakeholder groups and industry sectors due to their enabling and multidisciplinary character.

The principle of inclusiveness includes raising the awareness of all stakeholders of the complex and multi-faceted issues surrounding the governance of N&N, gather stakeholder inputs into the dialogue so as to facilitate mutual understanding and ensure *"transparency and respect for the legitimate right of access to information"*[22]. Appropriate models of action and interaction should be developed to this end, and they should be differentiated depending from the stakeholders and situation considered.

Considering a relevant case such as the area of food and cosmetics, in its report on risk assessment for this area, IRGC concluded that "it seems prudent to include major stakeholder groups in the phase of risk evaluation and in the design of risk reduction measures. [T]his would necessitate a neutral platform which could be used as a foundation for this dialogue between regulators, industry and civil society" (IRGC, 2009). Such approach is particularly recommended for the most revolutionary applications where the scientific uncertainty is high and the societal acceptance of risks is unclear.

The importance of a broader societal inclusion is also underlined by a recent resolution agreed on at the Conference on a Strategic Approach to International Chemicals Management (SAICM/ICCM2) of the United Nations Environmental Programme (UNEP), where the participating country representatives agreed to recommend governments to foster public dialogue on nanotechnologies.

> *Recommends* that Governments and other stakeholders begin or continue public dialogue on nanotechnologies and manufactured nanomaterials and strengthen the capacity for such engagement by providing accessible information and channels of communication (SAICM/ICCM2).

It seems also clear from the responses to the Delphi panels that all stakeholders should be involved in some way in the debate and that they all carry (individual) responsibilities. Some comments also indicated that stakeholders attached importance to a reinforcement of the interaction among different disciplines and stakeholders, since some issues are best dealt with in multi-stakeholder groups.

Although nobody seriously questions the importance of stakeholder dialogue, some have expressed concern that many of the studies and reports have not taken nanotechnology governance very far.

[22] EC Code of Conduct for responsible nanosciences and nanotechnologies research

Correspondingly, regarding “inclusive governance”, opinions in the FramingNano consultation were split and ranged from "inclusive governance is less helpful” to “societal engagement is the key point to ensuring effective nanotechnology governance” (FramingNano, 2010). During the FramingNano Multi-Stakeholder Workshop in Brussels one respondent observed that

> [w]e need to break the deadlock of ritualistic debates. […] Each social dialogue should build on previous work rather than starting from scratch each time (public authority).

One industry representative added that stakeholders must try to avoid asking the same questions and should try to learn from the research of others.

> Let’s look at what has been done in the past. Let’s build on previous work (industry).

Whilst these observations have a valid point, further clarification is needed where the problems lie and what the solutions might be. For example, nanotechnology engagements deal with difficult and unfamiliar technical questions, which take time to understand. They are likely to entail going over the same ground, especially if new people come. However, if established stakeholders understand the issues but simply disagree, then there could be a more intractable problem.

The portrayal of stakeholder dialogue as an opinion gathering process would be widely challenged. There is an equally strong view that engagement of relevant stakeholders is an integral part of decision making and democratic accountability. It needs to be made clear at the outset of any dialogue event what are identified as the tasks for research and regulation, so that those participating can be ensured that the outcomes of the event will have a reasonable influence on policy questions in practice. From the various comments and opinions gathered during the FramingNano project, it seems therefore safe to conclude that many stakeholders support inclusive processes, and that a clear learning curve must be observable.

5.5.1.2 Public Dialogue

Communication with and from the general public (as opposed to stakeholder organisations), takes many forms, as varied as market research on consumer opinions, studies of public perceptions, and two-way public engagement consultations. Many studies show that publics are still not at all familiar with nanotechnologies (e.g. Gavelin, et al., 2007; Grobe, et al., 2008). In response to information given in focus group and similar settings, publics usually give a favourable view of nanotechnologies as likely to produce worthwhile benefits, but also register concerned about the risks involved, even in medical applications. According to Satterfield et al., „benefit optimism should be tempered because a large proportion of sampled publics have suspended judgement, which suggests that judgements are malleable as yet.” Engagements with publics to date also observed some wider ethical concerns, include the handling of information, privacy, food-related issues, military applications, global justice and equity, and the use of nanotechnologies for human enhancement. This suggests that as more specific nanotechnology applications emerge, there will be a particular need to explore certain areas with a view to their societal desirability, or otherwise, and thus of their governance, such as surveillance, food and enhancement.

The knowledge of the public about nanotechnologies, perceived risks and benefits, as well as factors influencing the risk perception have also been subject to a variety of psychometric studies and surveys among nanotechnology experts and laypeople. From areas as diverse as GMOs and nuclear waste, it has been well established that the way lay people understand and frame risks can be very

different from expert evaluations. Understanding emerging trends in public perceptions of nanomaterials is also critically important for those who regulate risks (Satterfield, et al., 2009), as they should take up public concerns.

> Perception is critical for a number of reasons: because human behaviour is derivative of what we believe or perceive to be true; because perceptions and biases are not easily amenable to change with new knowledge; and because risk perceptions are said to be, at least in part, the result of social and psychological factors and not a 'knowledge deficit' about risks per se (Satterfield, et al., 2009).

Other important factors are the personal beliefs and values of people, how they associate and compare unfamiliar issues with other questions, their experience of governance and their trust in regulators, scientists, government, etc.

One of the chief lessons learned from the GMO crisis in Europe has been to abandon the 'information deficit model' of a one-way process of informing the public about new technologies. It is now widely accepted that more dialogical approaches are needed. Policy makers, scientists or industry should communicate information in an interactive context with publics, and should also be open to changing their approaches in the light of what the 'lay' people have to say. Such engagement exercises on nanotechnologies are underway in several EC countries.

But this still raises the question, noted by several speakers at the FramingNano workshop in Brussels of deciding *what* information to communicate and *how* and *when* to share it with the public. This will be important to earning public trust in nanotechnologies. One workshop participant told the FramingNano multi-stakeholder workshop in Brussels that meaningful public engagement is essential to the future nanotechnology. She warned against attempting to coerce the public into backing the science as experience suggests this tactic is doomed to failure.

> What we should strive for is not the engineering of consent but trust. […] Hoping for passive "acceptance" by the public is out of step with modern theories of reflexive government (policymaking body).

> History has demonstrated that attempts to engineer risk perceptions with education campaigns may backfire if the benefits are oversold or the risks downplayed (Satterfield, et al., 2009).

An example illustrating successful engagement, resulting in an increase of the public's ability to judge on nanotechnology applications, was given during the FramingNano Multi-Stakeholder Workshop.

> In my region, we gave people three months' exposure to information on nanotechnology and they came back with very sensible conclusions. The public needs more information. It's understandable that people don't want to "eat nanomaterials" but the public is nevertheless capable of weighing risks against benefits. The question is how do we arrange accessibility of to data and make it understandable (policymaking body).

As was also pointed out at the Multi-Stakeholder Workshop, the public will not be satisfied with information alone. Of itself, data is not necessarily a source of trust. Much depends on their trust or suspicion of the person or organisation mediating the information, how it fits with their existing perceptions and values, who is saying contrary things, what their friends and family think, and so on. Citizens are not merely consumers. While some regulators may say 'no data, no market', citizens might say 'no trust, no market'.

Responses from the Delphi exercise identified a number of communication areas where priorities are seen:

- making available to the public clear and transparent descriptions of the approach to regulation and funding, and to anticipating benefits, costs and risks
- making clear where there are uncertainties in what is known
- making available to the public information on who has the responsibility to regulate and support nanotechnology
- making available to the public a range of scientifically informed opinions of the technology, i.e. pros and cons
- foster communication between the main players, provide enough means to organize this communication
- enhance the ability to communicate scientific findings and their meaning and take a greater effort to differentiate

A similar problem of deciding what to communicate, to whom and in what form is also relevant in the debate about declaration and labelling of nanomaterials in consumer products. For opinions on the declaration issue, see section 5.5.2.2.

5.5.2 Information Sharing

The transfer of data and knowledge among involved stakeholders is regarded as one of the key elements which, if proper tools are available, greatly increase the efficiency of identifying, assessing, managing and communicating potential risks related to manufactured nanomaterials.

At the Conference for a Strategic Approach to International Chemicals Management (SAICM/ICCM2) in May 2009, the delegates adopted several strategic recommendations on nanotechnologies and also pointed to the necessity for a common approach in communication and transfer of health and safety information along the value chain and among stakeholders.

> [The Conference] encourages the wider dissemination of human health and environmental safety information in relation to products containing nanomaterials, while recognizing the need to protect confidential business information […] (SAICM/ICCM2, 2009).

Governments and intergovernmental, international and non-governmental organizations, including the private sector, are requested, subject to available resources, to facilitate access to relevant information and to share new information as it becomes available.

Several comments in the Delphi consultation have also pointed to the need for open and accessible information databases regarding nanomaterial risks. Information sharing is commonly rated very important, and it is pointed out that mechanisms need to be established to enable industry and researchers to share data with regulators, consumers and other businesses on a commonly accepted (and standardised) basis in order to enhance comparability.

> Many groups work at academic level on the assessment of nanoparticle toxicity, often finding different and contrasting results. It would be necessary to establish protocols and to favor a collection of results (public authority).

5.5.2.1 Data Sharing Along the Value Chain

Data sharing along the value chain is an essential element of information transfer from those manufacturing the nanomaterials to those using and eventually disposing or recycling the products

with incorporated nanomaterials. If one step in this information chain is disrupted, all subsequent links in the chain are lack the necessary information to implement adequate health, safety and environmental provisions.

The standard tool for data sharing along the value chain is the material safety data sheet (MSDS) which contains standardised information on environmental, human health and safety data of the respective material. While the MSDS represent a well-practised and reliable basis for the disclosure and transfer of such information about conventional (non-nanoscale) chemicals along the value chain, concerns have been raised regarding its adequacy for manufactured nanomaterials, since no information explicitly allowing the identification and characterisation of the nanoform of a chemical substance need to be included in the MSDS.

Consequently, the request to require in the MSDS the integration of information which allows the identification of nanomaterials and would give an overview on the expected hazards under certain circumstances has been a recurring issue in the FramingNano Delphi consultation.

> A specific legislation [should be adopted] to acknowledge that the novel chemical and physical properties of the material in the nanoform […] should be included and provided in the MSDS of the material […] (regulatory agency).

5.5.2.2 Labelling of Manufactured Nanomaterials

One of the topics which have recently been most controversially discussed is the recurring request for mandatory labelling or declaration of nanomaterials in (consumer) products. Although this is often debated in a regulatory context in the light of the requests to make labelling mandatory by legislation, it is also a communication issue.

Missing mandatory declaration of nanomaterials (e.g. through Material Safety Data Sheets, labelling or declaration) along the value chain in most sectors makes it difficult for downstream-users, processors, consumers, recyclers and oversight institutions to identify nanomaterials, apply proper safety measures and determine priority areas for regulatory action.

Although several industry and market surveys have been undertaken so far in order to identify the most common nanomaterials and applications of nanotechnology currently in use and on the market, such surveys have only provided a locally limited and very contemporary picture. Due to the fact that new products and applications continuously enter the market, the corresponding market must be regarded highly dynamic.

In a public consultation on risk assessment of nanotechnologies, the received feedback indicated that many manifested a strong wish to know what products are on the market, and therefore called for compulsory registration of nanomaterials as voluntary registration schemes had failed according to many of the respondents (De Jong, 2009).

The main reason behind the declaration claims, as it has e.g. emerged in the German expert Delphi panel, is that for consumers it is particularly important in the case of nanomaterials to be free to choose whether to buy nanoproducts or not. The closer the application is to the body of the user, the more important this freedom is usually rated (BfR, 2009).

Although the “freedom to choose” for consumers also in the FramingNano Delphi consultation seemed unequivocally accepted among all stakeholders, the specific form of how to present such information to the consumer is controversially discussed. Branding products with a ‘nanotechnology’

label might not be useful given the wide variety of goods that would be grouped together, as multiple speakers at the FramingNano Multi-Stakeholder Workshop in Brussels stated.

Even so, one respondent added that labels tend to suggest that there is reason to be concerned, maybe even if there is no hazard.

> We looked at labeling and found that if you label products with 'nano' you imply that all nanomaterials are similar. It also implies that you are communicating a hazard (policy advisor).

One Delphi participants from a health ministry said that France is not in favour of labelling goods as 'nanotechnology' because it does not provide much information.

> For us, it is not informative but we are convinced that if a list of [nano] ingredients is mandatory, each nanomaterial should be identified separately including size and surface area (public authority).

Mandatory labelling of nanomaterials in products might therefore be interpreted as a means of ensuring better market overview and ensuring freedom to choose or avoid nanomaterials; however, it will not necessarily allow consumers to make an informed choice, as the background information necessary to make such decision on an informed basis will not fit on product labels.

5.5.2.3 Avoid Duplicate Research and Testing

In the context of research prioritization, it is often mentioned the issue of duplication of research which should be avoided at all costs in order to maximise the output of data from the available research funding.

On the one hand, maximising the output per research dollar seems sensible. However, regarding the often controversial results of many toxicity studies in nanosciences and nanotechnologies, it seems necessary to have some amount of duplication in order to increase the certainty of the corresponding findings. Also, in the light that the scientific publication system of impact and citations will not favour duplicate publications, it seems somewhat exaggerated to fear duplicate research that much. Nevertheless, coordination of research on the highest possible level in order to provide as quickly as possible the most important scientific building blocks necessary for risk assessment is very reasonable in any case.

> In order to avoid duplicate testing also in the area of nanomaterials, the provisions on data sharing laid down in REACH should also apply to all nanomaterials regardless of the piece of legislation they are covered by (NGO).

Another issue in this context concerns duplicate research among industry stakeholders (businesses) and publicly funded institutions. In the FramingNano deliberative process, industry representatives have repeatedly assured that the industry takes its responsibility seriously and does what is necessary to ensure safe products on the market. Nevertheless, such data is often not making its way from the laboratories of the companies to the scientific and public communities; a fact that is often justified with the status of the data as confidential business information (CBI). It seems therefore reasonable to assume that some research which is done by companies will be repeated by publicly funded research groups due to the fact that it is often not known what has already been done.

5.5.3 Education and Professional Formation

With the increasing commercial importance of applications of nanotechnologies and the penetration of such application into our daily (professional) lives, increasing numbers of professionals will get in

contact with practical applications of nanotechnologies and will need specific knowledge on these in order to e.g. to apply adequate protective measures, or correctly dispose wastes containing nanomaterials.

It is feared that a gap may develop between the need to handle emerging nanotechnology issues and the ability of public understanding and professional development to responsibly take advantage of the new technology (Renn, et al., 2006). Businesses using nanotechnology face a significant challenge in using this developing technology responsibly as there are numerous technical, health and safety uncertainties – and it is not clear how a responsible business can address them effectively. Despite the increasing importance of nanotechnologies, there are only very few practical teaching aids and learning materials available to date which support teachers to mediate the necessary basics.

The serious gaps in terms of education and implementation of nanosciences and nanotechnologies into professional formation have been addressed by the European Economic and Social Committee (EESC) in their recent opinion to the European Commission (European Economic and Social Committee, 2009):

> The EESC believes that robust action is needed in the area of interdisciplinary education and training and that this should include risk evaluation and prevention, backed up by infrastructures of excellence.

Several comments gathered in the FramingNano Delphi consultation further support this perspective and also indicate a clear need for action in the area of education and professional formation.

> Responsible research and application of nanotechnology must be (and can be only) based on the adequate education in schools and universities (research institution).

> Provisions for nanotechnology education in schools and universities are insufficient. Responsible people = educated people! (academic researcher).

In response to these needs, a few initiatives have recently begun to explore this new area. E.g., a webpage called nano&me[23] by the Responsible Nano Forum points to the public in general and provides balanced information on a very broad variety of topics on nanotechnologies in order to stimulate a debate.

Within the internationally unique pilot project „Swiss Nano-Cube“[24], the Swiss Government partly funded the development of a national information and learning platform dedicated to the topics of micro- and nanotechnologies for vocational schools, secondary schools as well as higher professional schools. Swiss Nano-Cube will be developed until the end of 2011 and will specifically address the needs for teaching aids on the secondary school level and in professional education, and will lead to the development of a learning and teaching platform providing educational modules and for individual professions.

Current developments as well as the many comments by Delphi participants on education indicated the strong need for strengthened commitment in the area of (professional) education at universities and vocational schools. Such engagement is considered both as a means of disseminating certain basic knowledge on nanotechnologies, but also in order to disseminate job-related information on a responsible use of nanotechnologies on the job which can then be shared with others.

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[23] www.nanoandme.org

[24] www.swissnanocube.ch

5.6 International Cooperation and Harmonisation

As awareness of EHS risk is growing and an ever greater range of commercial applications of nanotechnologies is entering international trade, demand for international coordination of regulatory responses is likely to rise (Falkner, et al., 2009).

> There is a need to avoiding divergence of new regulatory measures in a common marketplace, which is a very actual risk as such (regulatory advisor).

National institutions tend to be earlier in identifying and managing technology risk than national or supranational institutions – a fact that is currently confirmed in the US where local authorities have already implemented individual provisions which go beyond federal laws. Although such attempts can be regarded as valuable "case studies" which deliver inputs on how to best design regulations on the higher level, these approaches largely follow domestic imperatives and do not necessarily take into account the need for internationally coordinated political responses (Falkner, et al., 2009). Furthermore, later harmonization of diverging regional or national approaches to a federal or supranational legislation is cumbersome and costly.

5.6.1 Transatlantic Regulatory Cooperation

The issue of transatlantic regulatory cooperation has been subject to investigations in an EC-funded project which was concluded with the Conference on Transatlantic Regulatory Cooperation in London in September 2009 and a final report[25] (Falkner, et al., 2009b).

In the past, the EU and U.S. have cooperated in international efforts to harmonise risk regulation, through bodies such as the Organization for Economic Cooperation and Development (OECD) and the World Trade Organization (WTO). Where successful, such efforts have sought to promote high levels of protection while still enabling scientists and industries to operate freely in the transatlantic economic space. But differences in legislative frameworks, regulatory cultures, and societal risk perceptions have at times contributed to a divergence of regulatory responses (Falkner, et al., 2009).

Based also on expert surveys and interviews, the authors identified three areas where ameliorated transatlantic regulatory cooperation would be overall beneficial, thereby presenting some recommendations.

1. scientific building blocks for risk assessment
2. knowledge gaps
3. consumer labelling and ethical concerns in risk management.

Regarding 1, the report states that scientific uncertainty is a key challenge in developing an effective regulatory response to potential risks of nanomaterials, and that creating the scientific basis is an urgent task that is best done internationally coordinated for greater regulatory convergence. Developing common practices and internationally agreed, standardised tools and procedures in risk assessment are therefore key elements to more effective, harmonised regulations (Falkner, et al.,

[25] *Regulating Nanotechnologies in the EU and US*, funded by the European Commission, accomplished by a project consortium consisting of London School of Economics, Chatham House, the Environmental Law Institute and the Project on Emerging Nanotechnologies.

2009b). As a result, regulators (and other stakeholders) can be expected to be able to more fully exchange information across the borders and internally.

In terms of 2, the project refers to those gaps which are not related to definitions, metrology and methodology, but rather uncertainties about the presence of nanomaterials in commerce, about the potential toxic effects of certain nanomaterials. To overcome these gaps, the authors recommend to, as a matter of priority, significantly increase funding for research into EHS risks of nanomaterials. They especially point to the fact that greater transatlantic cooperation "would give a greater sense of strategic directions to existing research efforts". The existing gaps in the knowledge about nanomaterials actually in commerce should be closed by data gathering through strengthening mandatory reporting requirements.

Consumer labelling and ethical concerns (3.) have been identified to be of lower priority compared to the development of the building blocks for risk assessment, particularly because differences across the Atlantic in risk management priorities might, according to the report, lead to greater obstacles in a harmonisation attempts. Diverging consumer labelling requirements, however, as they are currently proposed in the new EU Cosmetics Regulation, might present potentially conflicting implications on international trade obligations.

The report concludes that of first priority, the ongoing work on creating scientific building blocks for risk assessment needs to be stepped up and expanded, mostly through providing appropriate support to the OECD, if it is to produce results in a timely fashion. Even so, it is recommended that better information sharing of EHS risk-related data on nanomaterials should be explored (Falkner, et al., 2009b). The authors therefore also recommend firming existing informal links between regulatory agencies across the Atlantic as an informal tool of exchange and learning.

While the exploration or informal communication and learning and some coordination and cooperation seem already to be established between the US and the EU, more formal "treaty-based harmonisation" of nanotechnology legislation between these two countries was identified to be of little interest among the interviewed stakeholders (Falkner, et al., 2009b). The authors therefore conclude that "there is no immediate need for negotiating an international regulatory regime on nanomaterials". Notwithstanding the importance of transatlantic cooperation in an attempt to harmonise the regulatory approaches, it is considered by many actors necessary that this co-operation is extended to the other big players to assure, among the other things, a common ground to an affective responsible development of nanotechnologies and avoid problems in the circulation of goods.

Regulatory cooperation between nations however does not mean that the same process of adaptation of the current regulatory frameworks be necessary everywhere. While the EU aims to incrementally adjust existing laws and regulations to cover emerging risks associated with nanotechnologies, in the US a revisiting process of TSCA is currently under way which may lead to a fundamental reforming of TSCA. As national regulations are a result of traditions and basic values of the corresponding nations, international harmonization of regulation is better described by a process of approaching and dialogue rather than an identical common endpoint.

5.6.2 Standardisation

Standards are essential for cross-disciplinary and cross-national communication, for the interoperability of applications, effective regulation, research cooperation and data-sharing, for the commercialisation of applications and for transborder trade.

The International Organization for Standardization (ISO) TC 229 Nanotechnologies is the technical committee dealing with nanotechnologies and has 32 participating countries (and 10 observers) many liaisons to other (national) standards bodies and six international organisations contributing to its work. The committee has so far published two standards: ISO TS 27687 Terminology for nano-objects – nanoparticle, nanofibre and nanoplate; and ISO/TR 12885 – Nanotechnologies - Health and safety practices in occupational settings relevant to nanotechnologies; and has nearly 40 projects under development, with many more to come, in four "horizontal areas": terminology and nomenclature; measurement and characterisation; health, safety and the environment; and materials specifications.

The vital role of standards in the emerging debate on nanotechnology risk assessment cannot be overestimated. Written Standards provide agreed ways of naming, describing, specifying, measuring, testing, managing and reporting things. Standardisation therefore goes hand in hand with agreeing on definitions, developing instruments and test strategies and validating procedures for risk assessment of nanomaterials. Ideally, standardisation would ensure that once suitable procedures and definitions for nanotechnologies have been found, all stakeholders will stick to these.

> Nearly everyone agrees that standardization, either European or international, is one of the most pressing issues in the development of nanotechnology. [...] At the moment, the process is slow, bureaucratic, under-funded, fragmentary and uncommunicative (Prof Geoffrey Hunt, St. Mary's University College, London, in (Responsible Nano Forum, 2009)).

A global effort is required for the terminology used for nanotechnology to be standardized, according to a leading expert of international standards committees for nanotechnologies. He said that the International Organization for Standardization (ISO) can only make substantial progress on nanotechnology if its members are willing to tackle this difficult subject.

> People believe standardization is something that happens somewhere else. In practice, the membership of ISO proposes, write and authorize the standards. Unless we receive support from members, it won't happen (standardization body).

According to this participant, standardization is a rigorous process which takes around three years to produce a full consensus standard. These standards are reviewed regularly and are voluntary in nature.

The role of the ISO is central. ISO enjoys a high degree of legitimacy among regulators and stakeholders, its standards are recognised in international trade law. Therefore, developments under ISO have maximum reach among stakeholders.

However, although widespread recognition of standards, once they are set up, is a primary goal of standardisation, several issues makes this unlikely to happen. First, standards are often not available for free. They are copyrighted and subject to considerable costs (e.g. ISO standards). Second, sticking to standards is voluntary. The result is that

> [m]ost nanotechnology research publications ignore international standards in terminology (Prof Geoffrey Hunt, St. Mary's University College, London, in (Responsible Nano Forum, 2009)).

And third, incentives to participate in standardisation efforts are limited by the fact that funding of such efforts is often minimal.

> Experts sitting on vital standardisation committees are volunteers and provided with no real incentive to do this vital work except for the support provided by their employers (Prof Geoffrey Hunt, St. Mary's University College, London, in (Responsible Nano Forum, 2009)).

Standardisation has clearly been identified as one of the most important issues in the context of a responsible development of nanotechnologies, and many respondents have mentioned the key role of standardisation as a parallel process to the development of definitions, metrologies and methodologies. Standardisation fulfils a vital function in agreeing on common procedures and making individual achievements available to all stakeholders in a centrally coordinated manner. However, the problems that standards are liable for costs and participation in the standardisation process is burdensome have also been mentioned.

5.6.3 The Role of the United Nations and the OECD

Genuine multilateral nanotechnology governance initiatives are still rare and have just begun to emerge. The United Nations Industrial Development Organisation's International Centre for Science and High Technology (ICS UNIDO) has hosted a few dialogue projects (Falkner, et al., 2009), and the WHO's Intergovernmental Forum on Chemical Safety (IFCS) has issued in 2008 the "Dakar Declaration", which calls for more international cooperation in risk assessment, information sharing, and for the development of a Global Code of Conduct. Furthermore, while being of informal nature, the International Dialogue on Responsible Research and Development of Nanotechnology aims to facilitate good governance in nanotechnology and at a development of nanotechnology that corresponds to the needs of society as a whole. In this respect this dialogue wants to be inclusive, involving all countries and stakeholders interested in the responsible and sustainable development of nanotechnology. Issues such as global approaches in nanotechnology governance, inclusiveness, societal engagement and coordinated observatories have been discussed during the 3rd International Dialogue taking place in Brussels in March 2008 which has been organised by the European Commission.

Recent developments indicate that the International Conference on Chemicals Management (ICCM) under the Strategic Approach to International Chemicals Management (SAICM) of the **United Nations Environment Programme (UNEP)** is on the way to be established as the first international forum to discuss nanotechnology governance issues on an entirely global level.

UNEP has adopted a Strategic Approach to International Chemicals Management (SAICM) in its 2006 International Conference on Chemicals Management (ICCM) that calls for the "sound management of chemicals" and also focuses on the implementation and coherence among international instruments and programmes. At the second session of ICCM in May 2009, nanotechnology and manufactured nanomaterials were subject to discussions under the agenda point of emerging policy issues (SAICM/ICCM2, 2009). Many representatives drew attention to the fact that while nanotechnology could offer significant benefits in economic, social and cultural terms it posed both environmental and health risks and therefore justified a precautionary approach. There was also general agreement on the importance of information-sharing between and among governments and other stakeholders

and synergies with other organizations. In that context, many applauded the work of the OECD, although one representative said that it was not sufficiently inclusive of developing countries and another that it did not facilitate participation by civil society. The Conference agreed to include the issue of nanotechnology and manufactured nanomaterials to the Global Plan of Action on the agenda for the third session of the Conference.

The SAICM approach is a multi-stakeholder approach, which includes governments and non-governmental organisations. Under the SAICM programme, a Global Action Plan on chemicals management is envisioned, and several representatives expressed support for a proposal to complement the Global Plan of Action by including specific activities on nanotechnology and manufactured nanomaterials, which will be discussed during the third session of the Conference (SAICM/ICCM2, 2009).

Most recently, the OECD, in related work, will be collaborating with the United Nations Institute for Training and Research (UNITAR) on regional events on nanotechnology, by explaining the human health and environmental safety aspects of nanotechnology at their regional meetings.

The **Organization for Economic Co-operation and Development (OECD)** provides an overarching structure for sharing information on nanotechnologies through two groups, the Working Party on Manufactured Nanomaterials (WPMN) and the Working Party on Nanotechnology (WPN). The Working Party on Nanotechnology (WPN) was established in March 2007 to advise upon emerging policy issues of science, technology and innovation related to the responsible development of nanotechnology. Based on the activities of 2007-2008 to quantify nanotechnology and to identify key policy issues of concern to countries, the 2009-2010 activities are dedicated to focus on policy advice and dissemination. The main goals of the WPN include

- development of a statistical framework for nanotechnology (definitions, indicators and statistics)
- case studies to explore national policy systems regarding nanotechnology
- addressing policy issues in policy roundtables
- explore with some companies in depth the challenges and possible policy actions in selected sub-areas and/or applications
- examining the potential contribution of nanotechnology to addressing global challenges such as the environment, water, health, climate change, agriculture and/or energy
- facilitate international research collaboration and scientific co-operation in nanotechnology

Therefore, many points of interest in the debate on regulation and governance of nanotechnologies are discussed in the OECD WPN at international level.

To evaluate the member countries' regulatory challenges regarding the safety of nanomaterials, OECD's Chemicals Committee (CC) decided to consider them in some detail. As the OECD states that unlocking nanotechnologies' full potential "will require a responsible and co-ordinated approach to ensure that potential challenges are being addressed in parallel with the development and use of technology", the (OECD) in 2006 established a "Working Party on Manufactured Nanomaterials" (WPMN). This group will focus on the implications for the safety for human health and the environment of the use of nanomaterials (focussing on testing and assessment methods). Projects

from the WPMN among others focus on information exchange on national regulatory programs and voluntary schemes, with a goal of identifying recommended approaches and elements to establish a successful information gathering programme. The OECD is also coordinating international efforts to generate toxicity data on 14 nanomaterials currently in use (OECD, 2008).

The stakeholders contributing to the two-stage Delphi panels overall also acknowledged the key role, efforts and approaches made under the OECD and ISO. In general terms, their role is primarily seen in fostering communication and harmonisation.

> OECD and ISO play a key role in facilitating international communication and dialogue and should focus on exploring new EHS-frontiers in the field […] (academia).

> [Supranational organization such as OECD and ISO can contribute to] [e]fficient exchange of experience/scientific results and rapid adaption of the current law according to new findings (regulatory authority).

> They can act as messengers and give momentum to the implementation, review, approval and dissemination phases in the separate countries (industry).

However, it has also been argued that supranational organisations which function with voluntary participation mechanisms such as the OECD (see e.g. the OECD sponsorship programme for the safety testing of a representative set of nanomaterials[26]) shift the burden of testing nanomaterials from those who would actually be required to do so by law to those volunteering for it, and that such organisations lack the legitimacy to issue regulations at a global scale.

> [T]he carrying out of this work should not be based on whether the member states voluntarily sign up to do it or whether stakeholders and researchers voluntarily devote their time to do it. Too much of the work that they currently do is focused on collecting information that producers should be generating by law (academia).

Another respondent has similarly pointed to a certain restriction of their role.

> The role [of supranational organisations] should be restricted to obtain a consensus on the methodology of quantity the workers' exposure to nano-material and standardize such methodology, the terminology and the instruments used in such measurement (government).

International governance of nanotechnology risk as it exists today has been described as "limited mostly to scientific and technical standardisation and coordination efforts by the leading nanotechnology countries in the OECD, with a few other forums having emerged to consider broader governance challenges" (Falkner, et al., 2009). A broader international nanotechnology risk agenda does not exist yet, and other international bodies with a potential interest in this area are only beginning to explore the challenges or define their potential roles.

Much of the work of the two OECD workgroups on nanotechnology do is driven by regulators and experts from leading nanotechnology countries in Europe and North America. Given the "OECD's nature as an exclusive industrialised country organization with a reputation for weak inclusion of stakeholders and lack of transparency" (Falkner, et al., 2009), it is questionable whether its work can be extended to become the basis for a more comprehensive and inclusive global governance framework. In this respect, the UN and the respective recent developments also represent a possible frame for increased supranational cooperation.

> UN can establish treaties with guidelines for individual nations and nation-based entities (regulatory authority).

[26] OECD Sponsorship Programme website http://www.oecd.org/document/47/0,3343,en_2649_37015404_41197295_1_1_1_1,00.html

While the ISO and the OECD can presently be regarded as the two central institutions fostering supranational standardisation and cooperation

> [t]he OECD enjoys broad legitimacy in promoting coordination on the building blocks for risk assessment and is thus a central institution in the context of transatlantic regulatory convergence. At the same time, more political energy and resources need to be invested in the OECD process on order to speed up its work (Falkner, et al., 2009b).

The FramingNano Delphi consultation revealed various opinions on the harmonization question.

> I do not think that "…it is necessary to harmonize the regulatory approach worldwide…", but I do think that international cooperation is needed, [...] so that countries that are considering adopting new legislation […] can learn from countries or regions that already have adopted such measures (academia).

> A harmonised approach is necessary, especially for companies with a global presence (industry).

Institutions potentially capable to coordinate national / European approaches on an international level have been indicated to be the OECD and the United Nations (WHO, GATT/WTO working groups).

> I would suggest a UN program, since the OECD is too concentrated with economic development versus human health and environmental protection (individual scientist).

While a high level of coordination is generally perceived favourably by the stakeholders, some expressed concerns about the partly exclusive nature and the informal character of the existing approaches under the OECD.

> An ongoing, inclusive, international dialogue on governance issues is absolutely necessary. The informal, existing one is a far too fragile one and must find the ways to secure its existence soon by formalizing it under a UN Convention (regulatory advisor).

One NGO respondent indicated that the structure of a European agency co-operating with national authorities, in accordance with the structure of operation of ECHA and the national authorities responsible under the REACH system, seems appropriate to regulate nanomaterials, and another respondent doubted that a supranational agency is "necessary, practical or effective".

Further opinions on the topic of regulatory subsidiarity and regulatory institutions may be found under section 5.4.2.4 and section 5.4.2.5.

5.6.3.1 Inclusion of Developing Countries

According to current developments it seems not unsubstantiated to fear that nanotechnologies could contribute to exacerbating the shear between developed and developing countries even more. On the other hand, some non-industrialised countries have expressed plans to engage in nanotechnologies research and development. Assuming that such countries will mainly engage in the production of raw nanomaterials, proper health and safety provisions are vital.

The FramingNano research revealed that in the context of cooperation, coordination and societal concerns, many stakeholders would regard increased inclusion of developing countries important.

> A much more proactive policy of engaging developing countries is needed not only from NGOs but also from government (Dr David J. Grimshaw, Practical Action, UK, in (Responsible Nano Forum, 2009)).

Many Delphi respondents have indicated that they regarded “contribution towards third world development” as an important ELSA issue, and one respondent pointed to the importance of the principle of non-discrimination so that developing countries have a right to access information.

The OECD represents the foremost institution for international cooperation in terms of identifying and assessing nanotechnology risks.

> The OECD serves an important function as a forum for coordination among leading industrializes countries, but its work should be complemented by the development of international governance capacity in other areas, and there should be greater inclusion of developing countries (Falkner, et al., 2009b).

Nevertheless, participation in the OECD is limited to industrialised countries, and no developing countries are represented within this organisation. It needs therefore to be reconsidered whether it will be favourable to develop the scientific basis for risk assessment in a limited and somewhat exclusive circle such as the OECD while other countries equally depend on that knowledge. On the other hand, if the information developed among the OECD countries is made freely accessible to all stakeholders, this problem is mitigated.

Annex I: Precursors and Examples for the Governance Platform

In this section, a number of existing organisations and approaches are presented which were discussed during the deliberative phase of the FramingNano Governance Platform as potentially helpful to discuss the structure and procedures of the proposed Governance Platform.

Deliberative Panel

The **International Panel on Climate Change (IPCC)** is a successful example of the observatory approach. IPCC started in 1989 and is a scientific intergovernmental body belonging to the United Nations. The IPCC it is the leading body for the assessment of climate change.

The IPCC is open to all member countries of the United Nations World Meteorological Organization (WMO) and the United Nations Environmental Program (UNEP). Government delegations of all member countries are invited to attend the Plenary sessions of the Panel during which all main decisions are taken. Authors, contributors, reviewers and other experts are selected by the Working Group Bureaus from nominations received from governments and participating organizations or identified directly because of their special expertise reflected in their publications and works. They work on a voluntary basis. The composition of lead author teams for chapters of IPCC reports shall reflect a range of views, expertise and geographical representation.

Assessment reports are the main product; they provide a comprehensive picture of the present state of understanding of climate change. Summaries for Policy Makers summarise the "lowest common denominator" resulted by the discussions in the Plenary Session; the core scientific findings are thereby reflected and endorsed by governments. However, the IPCC does not advocate or comment on government decisions and policies; its reports are policy-relevant, but not policy-prescriptive. Nevertheless, it provides policymakers with an objective source of information.

Observatory

ObservatoryNANO is an FP7 research project to study opportunities and risks in various technology sectors. Its primary aim is to support European decision-makers with information and analysis on developments in nanoscience and nanotechnology. It will collate and analyse data regarding scientific and technological (ST) trends (including peer-reviewed publications, patents, roadmaps, and published company data) and economic realities and expectations (including market analysis and economic performance, public and private funding strategies). The ST and economic analysis will be further supported by assessment of ethical and societal aspects, impacts on environment, health and safety, as well as developments in regulation and standardisation.

The **NanoTrust Dossiers** by the Institute of Technology Assessment of the Austrian Academy of Sciences in brief set out state-of-the-art information on possible health and environmental risks and on societal aspects of nanotechnologies.

The **CENARIOS 360° Risk Monitoring** approach includes a procedure for a broad assessment of the state-of-the-art of the knowledge about potential risks and impacts of specific nanomaterials and applications. In the monitoring, the available scientific, technical and socio-economic literature is scanned for upcoming trends and issues which require attention in the risk management of the corresponding nanotechnology applications.

A valuable example of authorities/industry cooperation with an observatory function is an event called **Authorities Dialogue** established in 2007 in the German speaking parts of Europe. Once a year, public authorities and organisations involved in nanotechnology governance convene to discuss current issues such as, e.g., "Governance of nanomaterials: Communication and dialogue with the stakeholders in practice" (topic of the November 2009 session in Vienna). Through this forum, representatives of different authorities and jurisdictions informally share opinions and gain insights into urgent issues of nano governance, while not being stymied by translation problems.

The project **Nano Archive** is part of the ICPCNanoNet project, funded by the EU under FP7 for four years from 1st June 2008. It aims to provide wider access to published nanoscience research and opportunities for collaboration between scientists in the EU and International Cooperation Partner Countries. The electronic archive of nanoscience publications is freely accessible to researchers around the globe, making research papers and other scholarly publications widely available, thereby

- reducing access barriers to research output from nano scientists and researchers across the globe
- ensuring records are readily searchable and retrievable by providing an Open Archives Initiative Protocol for Metadata Harvesting compliant service,
- bringing together material currently distributed across different institutions.

Advisory

The **Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)** provides opinions on questions concerning emerging or newly identified health and environmental risks and on broad, complex or multidisciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health and related issues not covered by other Community risk assessment bodies. In contrast to only observing, the SCENIHR (and the other scientific committees of the EC) provide opinions and recommendations to policymakers.

European Commission Framework Programme's Expert Advisory Group (EAG) on Nanotechnologies, Materials Science and Engineering and Production Systems (NMP). The mandate of the Expert Advisory Group (EAG) is to provide advice to the European Commission (EC) throughout the Framework Programme (FP) on the overall strategy and management and to ensure it meets the requirements of the European Research Area (ERA) for industrial technologies.

Common Assessment Methodology

The **European Citizen's initiative (ECI)** is one of the key democratic innovations of the Lisbon Treaty. The ECI, which enables one million citizens who are nationals of a significant number of Member States to call directly on the European Commission to bring forward an initiative of interest to them in an area of EU competence, would enable European citizens and civil society organisations to directly influence the political agenda of the EU for the first time in history[27] (Commission of the European Communities, 2009). This model of public engagement could analogously be considered in the governance of nanotechnologies.

[27] The ECI is planned to be operational in early 2011.

Annex II: Principles and Recommendations for the Governance Platform

The following table lists key principles and recommendations to be addressed in order to support the principles and future implementation of the FramingNano Governance Platform.

Technical and organisational level: **Environment, Health and Safety (EHS) Aspects**
• **Roadmap on EHS (EU or global level)**
• **Observe and monitor** developments in the field
• **Increase efforts in research on building blocks for risk assessment** (financial and human)
• **Define standardised terminology**
• **Speed up standards development** by exploring mechanism to support work on standards
• **Use existing knowledge** to evaluate and manage EHS issues, in particular at the workplace
• **Use a precautionary approach** where the hazards cannot be properly assessed
• **Develop, disseminate and apply best available practices**

Technical and organisational level: **Ethical Legal Societal Aspects (ELSA)**
• **Responsibility, transparency, openness, social justice, accountability and independence of expertise** are key principles for governance actions
• **Apply commonly accepted risk-benefit balances** to determine an application's acceptance
• **Identify, anticipate and proactively address ELSA** of specific issues and applications

Communication level: **Public Dialogue**
• **Openness and adaptation** of policy makers, scientists, industry to public concerns and opinions
• **Follow-up** of dialogue initiatives and uptake in the policy-making process
• **Learning curve on public dialogue and engagement**
• **Public information** on regulation and funding, anticipating benefits, costs, risks and uncertainties
• **Inclusiveness**
• **Trust, not engineered consent**
• **Differentiate** between different risks, concerns, nanomaterials and applications.

Communication level: **Information sharing along the value chain**
• **Transparency, responsibility and accountability** to ensure the proper level of (voluntary and mandatory) control and legislative intervention
• **Avoid duplications** whenever possible, use / adapt already existing requirements / procedures
• **Provide mechanism to improve knowledge,** develop and share data along the value chain
• **Explore the possibility to adapt the MSDS** (material safety data sheet) to nanomaterials
• **Strengthen industry /authorities partnerships**, with a strong effort to include SMEs
• **Strengthen inter-agency communication** among EU and national regulatory agencies
• **Explore methods to overcome confidentiality issues in data sharing**
• **Establish open data repositories** among industry, researchers, regulators and consumers
• **Support standards and harmonisation activities**
Communication level: **Education**
• **Address school education about N&N** (teacher training and teaching materials including EHS & ELSI)
• **Strengthen professional education** particularly in the occupation safety and health (OSH) area

Institutional level: **Hard and soft regulation**
• **Increase support to existing regulatory bodies** to deal with N&N
• **Apply best available practices** for the implementation of existing regulations to N&N
• **Remain vigilant:** adapting / improving the regulatory situation, monitoring implementation
• **Support SMEs** in handling N&N (nanospecific risk management systems) and fulfilling regulatory duties concerning N&N
• **Combined approach:** support a combination of mandatory and voluntary measures
• **Provide mechanisms to monitor the effectiveness of voluntary measures**
• **Explore incentives for voluntary measures** (e.g. independent control, better publicity)
• **Provide benchmarks and guidance for voluntary measures, in particular for the EC Code of Conduct**

Annex III: Literature

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