

FRAMING NANO

Governance in Nanoscience and Nanotechnology

FramingNano Project:

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

www.framingnano.eu

THE FRAMINGNANO GOVERNANCE PLATFORM

A NEW INTEGRATED APPROACH TO THE RESPONSIBLE
DEVELOPMENT OF NANOTECHNOLOGIES

EXECUTIVE SUMMARY

February 2010

PROJECT CONSORTIUM



The FramingNano Governance Platform

A New Integrated Approach to the Responsible Development of Nanotechnologies

Published under the FramingNano project as deliverable D3.2 for Work Package 3.

FramingNano is a Support Action (SA) funded under the Programme Capacities, in the area Science in Society, within the 7^o Framework Programme (FP7) of the European Commission (SiS-2007-1.2.3.2-CT, Project N. 217724)

Authors

Markus Widmer, Christoph Meili, The Innovation Society, St.Gallen (Switzerland)
Elvio Mantovani, Andrea Porcari, AIRI/Nanotec IT (Italy)

All the other partners of the Consortium and the FramingNano Advisory Board (FAB) Members have contributed to the preparation of the report.

Suggested Citation

Widmer, M., Meili, C., Mantovani, E., Porcari, A. The FramingNano Governance Platform: A New Integrated Approach to the Responsible Development of Nanotechnologies, February 2010.

© FramingNano Project Consortium 2010

Project Members



AIRI/Nanotec IT, Italy

www.nanotec.it

Elvio Mantovani, Andrea Porcari



The Innovation Society, Switzerland

www.innovationsociety.ch

Christoph Meili, Markus Widmer



The Institute of Nanotechnology, UK

www.nano.org.uk

Richard Moore



National Institute for Public Health & the Environment,
The Netherlands

www.rivm.nl

Adrienne Sips, Susan Wijnhoven, Cornelle Noorlander



Fondation EurActiv, Belgium

www.euractiv.com

Julian Oliver, Gary Finnegan



Technology Centre, Czech Republic

www.tc.cz

Jitka Kubatova

The full report can be downloaded from www.framingnano.eu.

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 stakeholders¹ to assess attitudes, expectations and needs, and to define a list of key issues to 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).

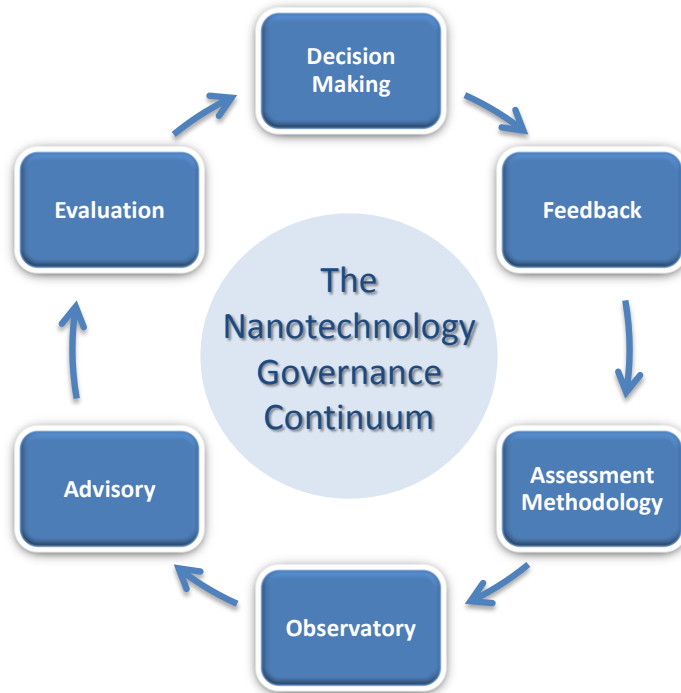


Figure 1: Overview of the process of the FramingNano Governance Platform (FramingNano Consortium 2009)

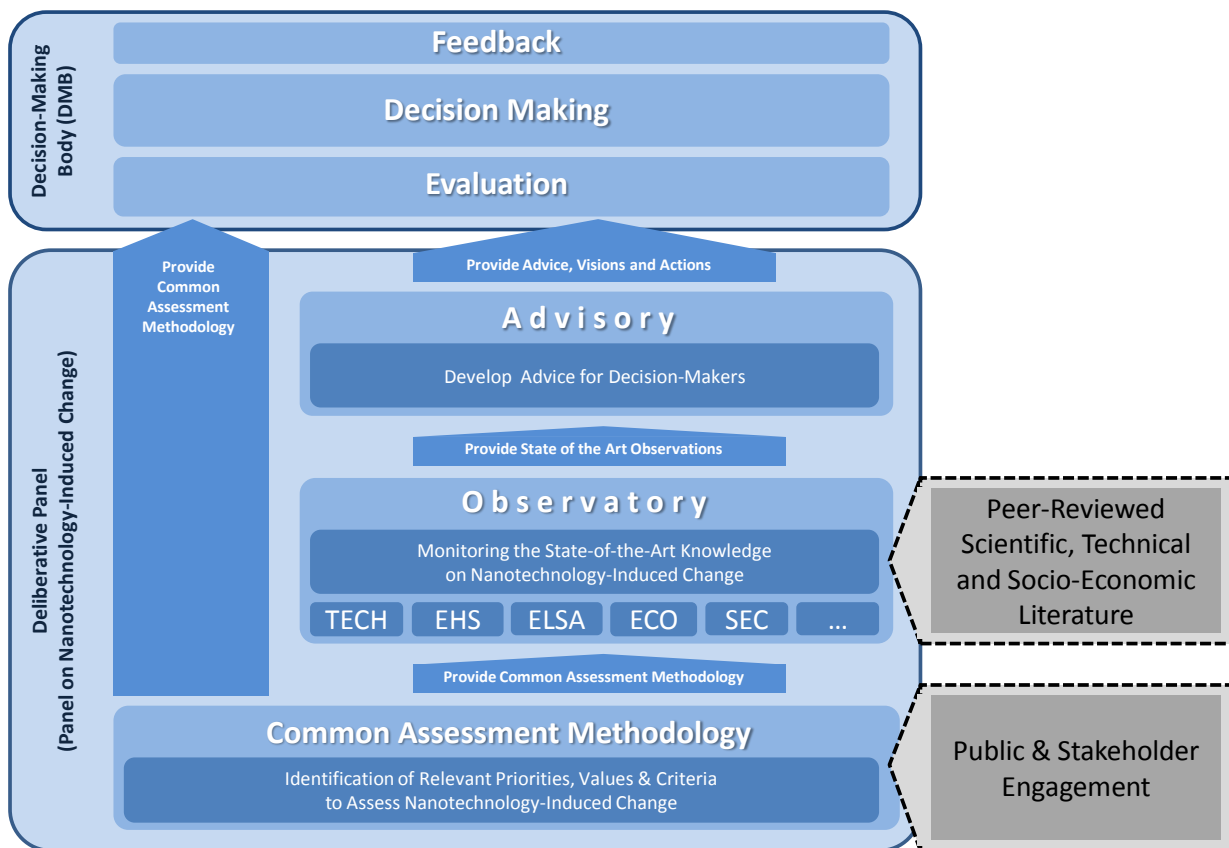


Figure 2: Overview on the proposed structure of the FramingNano Governance Platform (FramingNano Consortium 2009)

The Deliberative Panel

The Deliberative Panel² (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 levels³.

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.

Annex: 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**

FramingNano Advisory Board (FAB) Members

- **Prof. Jim Bridges**, Dep. of Toxicology and Environmental Health, University of Surrey (UK) and Chair of the Scientific Committee On Emerging And Newly Identified Health Risks (SCENIHR), European Commission
- **Dr. Donald M Bruce**, Managing Director - Edinethics, United Kingdom
- **Dr. Sergio Iavicoli**, Director - Department of Occupational Medicine, National Institute of Occupational Prevention and Safety, Italy
- **Prof. Georg Karlaganis**, Head of Department - Federal Office for the Environment, Switzerland
- **Dr. Gernot Klotz**, Executive Director Research and Innovation Department - European Chemical Industry Council (CEFIC), Belgium
- **Dr. Françoise Roure**, Senior National Adviser - Ministère de l'Economie, des Finances et de l'Emploi, (France) and Deputy Chair of the OECD Working Party on Nanotechnology

Other reports published under the FramingNano project

- The FramingNano Governance Platform – A New Integrated Approach to the Responsible Development of Nanotechnologies, Full Report, February 2010
- FramingNano Report on the Delphi Consultation, March 2010 (FramingNano, 2010)
- FramingNano Mapping Study on Regulation and Governance of Nanotechnologies, January 2009 (FramingNano, 2009)

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