

Foresight Study on the Risk Governance of New Technologies: The Case of Nanotechnology

Sheona A. K. Read,¹ Gary S. Kass,² Hilary R. Sutcliffe,² and Steven M. Hankin^{1,*}

Technology-led innovation represents an important driver of European economic and industrial competitiveness and offers solutions to societal challenges. In order to facilitate responsible innovation and public acceptance, a need exists to identify and implement oversight approaches focused on the effective risk governance of emerging technologies. This article describes a foresight study on the governance of new technologies, using nanotechnology as a case example. Following a mapping of the governance landscape, four plausible foresight scenarios were developed, capturing critical uncertainties for nanotechnology governance. Key governance elements were then stress tested within these scenarios to see how well they might perform in a range of possible futures and to inform identification of the strengths, weaknesses, opportunities, and threats for nanotechnology governance in Europe. Based on the study outcomes, recommendations are proposed regarding the development of governance associated with the responsible development of new technologies.

KEY WORDS: Foresight; future scenarios; governance; nanotechnology; new technologies

1. INTRODUCTION

Emerging technological developments represent an important driver of international economic and industrial competitiveness, and an important approach to resolving Europe's societal challenges (e.g., healthy aging, climate-friendly materials, sustainable energy solutions, etc.). However, running in parallel is the increased power of society to influence the trajectory of such technological developments. There is now considerable economic and political pressure to develop effective strategies to ensure that novel technologies deliver innovations in line with societal priorities and requirements. Failure to take account of both the actual and perceived societal preferences may result in barriers to innovation potentially asso-

ciated with negative public perception, as has been seen in the past with genetically modified foods, for example, where societal rejection has resulted in delayed or failed commercialization of many applications. An effective oversight system must, as a minimum, be able to assess and minimize the potential risks from a new technology in such a way that does not stifle innovation and develops public confidence.

In order to support the development of effective risk governance approaches for emerging technologies, this article describes a foresight study on the governance of new technologies, specifically focusing on nanotechnology as a case example. Nanotechnology is often viewed as one of the critical technologies of the 21st century, and has been identified as one of six key enabling technologies that are anticipated to act as significant drivers of innovation, technological and economic competitiveness, and societal developments in Europe over the next few decades.⁽¹⁾ However, uncertainties surrounding the potential risks of engineered nanomaterials and nano-enabled products pose a challenge to the development, uptake,

¹Institute of Occupational Medicine (IOM), Riccarton, Edinburgh, UK.

²MATTER, London, UK.

*Address correspondence to Steven M. Hankin, Institute of Occupational Medicine, Research Avenue North, Riccarton, Edinburgh, EH14 4AP, UK; steve.hankin@iom-world.org.

and exploitation of these materials. Over the past five years an international policy debate has emerged concerning appropriate mechanisms for the governance and regulation of nanotechnology.^(2,3) As such, consideration of this sector as a case study is of high value to informing the governance of new technologies in general.

This article first provides an overview of the governance landscape perceived for emerging technologies, with a focus on nanotechnology, which served as a primer for the development of foresight scenarios that were the subject of the dialogue-based stress testing exercise of the study. Following the stress testing and an analysis of strengths, weaknesses, opportunities, and threats, recommendations of relevance to policymakers, industry, and wider stakeholders are then proposed regarding the development of governance associated with the responsible development of new technologies.

2. CONTEXT

2.1. The Governance Landscape for Emerging Technologies

The governance landscape highlights the perceived underpinnings, issues, principles, and methodologies of governance for emerging technologies, drawing on the considerations of several recent reviews and publications.^(4–10) In order to summarize these visually, a mind-map has been developed (Fig. 1).

The mind-map has been divided into nine main themes or “nodes” defining the key considerations of the governance landscape. Each node further subdivides into a number of segments, in which the key features of that particular node are detailed, covering:

1. definitions and terminology—defining what is meant by the term governance in the context of emerging technologies and key terms commonly used within the context of governance, including norms, rules, and values;
2. purpose and principles of governance—considering the general principles and prerequisites of good governance;
3. drivers of governance—considering political drivers, social trends, and the role of the public, media, and NGOs, as well as economic, technological, environmental, and legal/regulatory factors;

4. scope and scale of governance—covering wider contextual factors surrounding the core risk governance framework, including organizational capacity, the actor network/value chain, social climate, political/regulatory cultures, and international context;
5. theoretical governance approaches—considering anticipative and/or reactive approaches, experimentalist and organizational learning, procedural, reflexive, and substantive approaches, the various rationales and paradigms of governance approaches, and risk governance models;
6. practical governance approaches—including practical tools for the assessment of new technologies, as well as processes, conditions, and vehicles required for the implementation of governance;
7. existing governance initiatives/projects—including a scan of international initiatives, and examples of completed governance projects and standardization activity;
8. new governance initiatives/projects—including examples of new governance initiatives/projects that apply across a broad range of emerging technologies; and
9. challenges of governance—including conflicts between norms, values, and context; governing governance; technology push and policy pull; absence of governance; framing of technologies; and harmonization of governance.

Key considerations of the governance landscape are described in further detail below.

The term governance in the context of emerging technologies describes the ways in which the research, development, application, and use of a technology is developed, steered, and controlled. Governance as an overarching philosophy does include compliance with mandatory regulation, but as a term it is generally used to also reflect adoption of more flexible approaches such as voluntary oversight initiatives developed by nonstatutory bodies in addition to compliance with “top-down” legislative approaches. Governance of emerging technologies strives for collaboration among a complex and dynamic network of national and transnational actors/agents, including politicians, regulators, industry/ business, nongovernmental organizations (NGOs), media, and the public. Moreover, governance is a complex interplay between a range of different actors with different motivations.

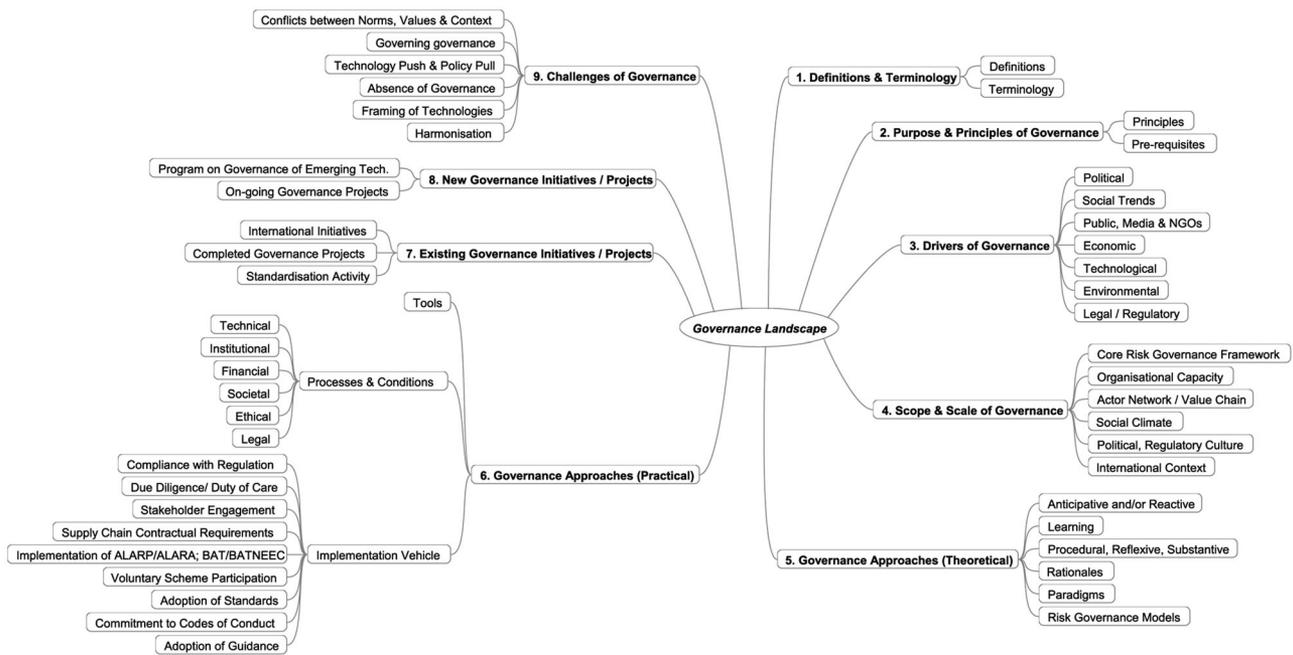


Fig. 1. The governance landscape for emerging technologies.

Norms and values vary across different contexts, both between cultures (e.g., Eastern and Western, commercial and *blue-skies* research) and between issues. This may result in conflicts in opinion and appropriate or desired approaches for governance. A key challenge around governance is the extent to which the various rules and institutions of governance align with each other, thus either mitigating or exacerbating conflicts between jurisdictions and traditions in different cultures and different sectors. Harmonization between jurisdictions is a major challenge and one of the reasons why the pace of developing multilevel governance is slow, and why governance regimes vary around the globe both between and within jurisdictions such as the European Union and the United States, but also within the European Union and within member states for different technology sectors. Nevertheless, one of the key purposes of governance is to act as a safeguard in society and to provide opportunity for the improvement in health and well-being, and to ensure human rights and the environment are protected.

There are a broad range of emerging approaches or “vehicles” for the demonstrable implementation of governance of new technologies. These approaches range from “hard” approaches such as compliance with regulatory and legislative frameworks, to “soft” voluntary-based approaches such

as the adoption of standards, codes of conduct, and guidance. It is worthwhile noting that the hard approaches tend to be relatively fixed and take a long time to develop, whereas the soft approaches can be updated relatively easily in light of new knowledge.

However, organizations, countries, and regions are likely to have a variety of different attitudes and approaches to these principles, processes, and conditions. This is linked to the political and social climate, which includes such key variables as the willingness to accept risk, the relative tolerability or acceptability of different levels of risk from different sources in different contexts, and the extent to which the governance of science and technology is considered necessary and trusted by numerous publics. There has been much concern regarding the social amplification of risk, created by the interplay between values-driven NGOs and headline-hungry media.

Hence, framing is a critical challenge in developing approaches to governing new technologies. In essence, framing a technology is a way to describe how a technology is perceived and discussed. It may be described as a “breakthrough” or as a “novel” technology, or it may be described as an extension of existing practice. It is necessary not only to understand these framings, but also who is using them and why they are doing so. In many instances

it is the narrowness of framing (either of the technology or its governance) that creates contention and conflict. For example, genetic modification is framed (by some) as an example or extension of plant breeding, with governance framed as a health, safety, and environmental risk issue. For others, it is framed as “un-natural” with governance framed as ethical issues such as “tinkering with nature” or imposing unnecessary risks on people who cannot exercise choice. The way in which a new technology is framed influences public perception. This is one of the factors determining why some new technologies become the focus of much public concern, while others are adopted without much attention.

2.2. The Nanotechnology Governance Landscape

Building on the considerations of the aforementioned governance landscape for emerging technologies, nanotechnology-specific aspects perceived for consideration with governance have been further developed. The nanotechnology governance landscape, summarized visually in a mind-map (Fig. 2), gives consideration to:

1. purpose of nanotechnology governance;
2. challenges facing nanotechnology governance;
3. existing nanotechnology governance approaches.

Key elements of the nanotechnology governance landscape are discussed in further detail below.

2.2.1. Purpose of Nanotechnology Governance

Nanotechnology governance to date typically focuses on the management of risk. It is only relatively recently that experts have started to consider how the regulatory and promotion aspects of innovation might be better integrated.⁽¹¹⁾ Risk governance is traditionally concerned with minimizing the risks of harmful effects of nanotechnologies and is thus a back-end response to innovation. Conversely, innovation governance is aimed at purposefully influencing technological choices, such that innovation is directed to socially agreed purposes, benefits, and priorities.⁽¹²⁾

Building trust and confidence among all stakeholders, including the public, is considered to be essential to gain acceptance and ensure continued development of a new technology.^(13–15) Trust and confidence cannot be created at will, however,

and are the result of stakeholder perceptions deriving from an effective governance system and recognized trustworthiness bestowed by stakeholders. There have been calls for an inclusive governance approach, which facilitates meaningful stakeholder dialogue and stakeholder involvement.⁽¹⁶⁾ An effective and integrated governance approach must facilitate the realization of benefits (focused around meeting societal goals, not just economic competitiveness), while at the same time limiting the potential risks posed and remaining sensitive to public concerns and changes nanotechnologies may induce.⁽¹⁷⁾ While open and transparent discussion and stakeholder involvement is acknowledged as a vital part of the governance process,⁽¹³⁾ it is important to note, however, that stakeholder engagement will not necessarily deliver consensus, as has been demonstrated with the genetically modified foods case where the routes by which stakeholders’ perspectives could be factored into decision making were not well established. Indeed, consensus around value-laden issues among diverse populations is a most unlikely outcome.

Ensuring the safe and sustainable development of nanotechnologies is widely agreed to be essential⁽¹⁷⁾ and an effective governance approach would ideally enable a safe, sustainable, and society-focused technology to be developed, without stifling innovation—indeed, safety, sustainability, and meeting societal goals could be the source of innovation, providing stimulus to innovation for specific challenge-led purposes.⁽¹⁸⁾ This presents a challenge, however, given the potential lag time between the generation of knowledge on the potential environment, health, and safety risks of nanomaterials, and the pace of commercialization of nano-enabled products.⁽¹⁹⁾ The resulting range of uncertainties are considered, by some, to be a major barrier to the sustainable and responsible development of nanotechnologies in the long term.

A crucial prerequisite for governance of emerging technologies is reliable information about the network of agents that are involved.⁽²⁰⁾ In addition, to support governance there is a clear need to develop and nurture relationships between members of the actor network to ensure strong risk communication along the value chain. Effective governance will require a high level of cooperation, coordination, and communication between various institutions and stakeholders, including those who develop, manufacture, market, and regulate nano-enabled products, as well as representatives of civil society, in

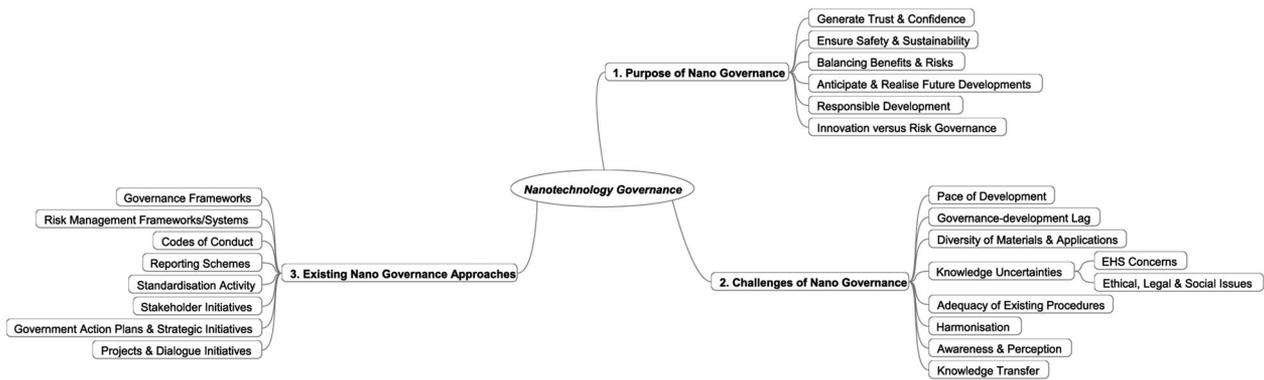


Fig. 2. Nanotechnology-specific aspects for consideration with governance.

order to promote a proactive and adaptive process. Orienting research and development toward “grand challenges” is therefore a critical strategy in ensuring sustainable development as a key outcome of scientific advances and technological development.⁽¹⁸⁾

Various established tools can be used in nanotechnology governance, including technology assessment (TA), value-sensitive design (VSD), and risk assessment, along with vehicles such as codes of conduct, reporting schemes, standardization, and stakeholder dialogue. TA refers to a number of techniques that can be used to study and anticipate positive and negative implications of a new technology for society and inform decision making regarding development, deployment, and governance of new technologies. VSD is an approach that seeks to provide theory and method to account for human values in a principled and systematic manner throughout the design process of a new technology.⁽²¹⁾ VSD is intended to bridge the gap between technical design considerations and ethical concerns. Risk assessment involves identifying and exploring the types, intensities, and likelihood of the consequences related to a hazard or threat.⁽⁴⁾ The process of delineating and justifying a judgment about the tolerability or acceptability of a given risk is one of the most controversial parts of dealing with risks. The ALARP principle is a powerful risk management strategy that aims to reduce the risk to “as low as reasonably practicable.” The key question in relation to this principle is what constitutes reasonably practicable. In essence, for a risk to be ALARP it must be possible to demonstrate that the cost involved in reducing the risk further would be grossly disproportionate to the benefit gained.⁽²²⁾ Considered together, these culminate in a discourse on “responsible develop-

ment,” a term often invoked by both government and industry.^(12,23–25) Responsible development offers an overarching framing of the governance of nanotechnology as fundamentally defined by its capacity to “enable” research and development while balancing any negative consequences.⁽²⁶⁾ The emerging discourse of responsible development and its embodiment in various codes represents an observable trend toward reflexive, responsible, and socially robust governance, not only for nanotechnology but for emerging technology in general.

Given the anticipated increase in complexity and significant technical and social uncertainties of future generations of nanotechnologies, many stakeholders have highlighted the need for a more anticipatory approach to nanotechnology governance.^(17,27–30) Such an approach would act to anticipate and realize future developments, while also identifying and reacting to potential risks.⁽³⁰⁾ However, an anticipatory approach to governance faces significant challenges, most notably in terms of the necessary scale and support, organization, and engagement of stakeholders from the serendipity of innovation processes and outcomes and our limited ability to anticipate. Nevertheless, such an approach could have the benefit of “future-proofing” a range of emerging technologies such as synthetic biology, as well as future generations of nanotechnology.

2.2.2. Challenges Facing Nanotechnology Governance

The development and commercialization of nanotechnologies and nano-enabled products is occurring at an increasingly rapid pace and product innovation and manufacturing processes are likely to

change frequently. The diverse nature of nanomaterials and nano-enabled applications means they cut across a number of sectors and regulatory jurisdictions⁽³¹⁾ and can pose a significant challenge to governance through regulation,^(28,32–34) creating difficulties for traditional approaches. There is a risk of governance lagging behind and a need exists for a flexible, adaptable, and dynamic approach with the ability to keep abreast of changes in the technology and landscape.

Another key characteristic of nanotechnologies that will make governance challenging is the wide range of uncertainties in relation to their environmental, health, and safety (EHS) risks.^(15,28,32,35,36) These uncertainties range from “simple” uncertainties (known unknowns) such as measurements and metrology to “ignorance” (unknown knowns and unknown unknowns) regarding risks yet to be identified from technologies yet to be developed. The prevalence and variety of uncertainties suggests that an effective governance approach should include an appropriate precautionary element.⁽¹⁵⁾ Another area of uncertainty that poses a significant challenge to governance of nanotechnologies is in relation to the ethical, legal, and societal issues (ELSI), known as “value uncertainty.” There is now widespread agreement that it is better to address the long-term EHS and ELSI issues related to nanotechnologies early with broad stakeholder input, rather than having to adjust and respond to developments after they have occurred.⁽³⁷⁾ However, this should not be taken to mean that “addressing” these issues early will eliminate them or eliminate controversy should an adverse risk become manifest. Rather, “addressing” such concerns would seek, where possible, to forestall them but where not, other mechanisms and institutions (such as liability and compensation regimes) would be introduced to “manage” the situation should a risk occur.

Many experts acknowledge that performing risk assessment for engineered nanomaterials is a challenging task, not only due to significant scientific uncertainty and lack of data, but also due to the need to take into account a wide range of different materials and their diverse properties and applications.⁽³⁸⁾ Risk assessment of more complex second- to fourth-generation nanotechnologies will undoubtedly present even more challenges.⁽²⁸⁾ It is broadly agreed that “dynamic developments need a dynamic framework”⁽¹⁷⁾ and regulators increasingly need to anticipate (even if they cannot reliably predict) future technological developments and estab-

lish frameworks that offer flexibility and adaptability to ensure long-term effectiveness.^(3,39)

A number of recent regulatory and policy reviews^(2,31) have highlighted the need for greater international cooperation and harmonization in addressing the aforementioned uncertainties. However, current regulatory efforts are primarily focused at the national and regional level; the international dimensions of nanotechnology governance are still limited,⁽³⁾ although dialogue is evident in attempting to progress matters, for example, between the United States and Canada⁽⁴⁰⁾ and between the European Union and Brazil.⁽⁴¹⁾ A number of activities are also progressing that may better facilitate harmonized governance, including the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), which Europe has implemented through the Classification, Labelling and Packaging (CLP) Regulation (EC No 1272/2008).⁽⁴²⁾ It may thus be more realistic to expect global governance functions to be progressed, for example, through activities of the Organization for Economic Co-operation and Development (OECD) and/or the International Organization for Standardization (ISO), and to be built in a flexible, step-by-step, approach.

Another important challenge relates to the public’s awareness and perception (actual and perceived) of nanotechnologies, which has the potential to impact on governance, future investment, and development of the nanotechnology industry.⁽⁴³⁾ A number of recent research initiatives and consumer polls^(44–48) have indicated that public awareness of nanotechnologies remains low but generally positive (on the back of general pro-science and technology perception) and there is, therefore, a risk of public rejection as has been seen in the past with the case of genetically modified foods, for example.⁽¹⁵⁾ The prospect of unfounded public rejection suggests that there is a need for improved knowledge and good risk management and communication, such that governance tools must be identified and implemented *explicitly* to consolidate and increase public confidence in the industry.

Lastly, a critical challenge facing the governance of nanotechnologies concerns the limited exchange of information among stakeholders along the value chain.⁽¹⁷⁾ A number of difficulties concern the transfer of knowledge among stakeholders in the supply chain, for example, how to communicate in a situation of uncertainty: such uncertainties prevent authorities from implementing clear rules and regulations and pose significant challenges in

communicating clear messages regarding whether certain applications of nanotechnology are to be considered “risky” or “safe.”

2.2.3. *An Overview of Existing Nanotechnology Governance Approaches*

Three prominent governance frameworks have been applied in the context of nanotechnology, namely, the International Risk Governance Council (IRGC) Risk Governance Framework,^(19,31) the FramingNano Governance Platform,⁽¹⁷⁾ and the Responsible Care[®] Global Charter.⁽⁴⁹⁾ While these frameworks facilitate several desirable attributes for an optimal governance framework (such as the use of best available technology, flexibility and versatility, and stakeholder engagement), there remains some question as to whether these frameworks, in their current form, facilitate foresight and provide sufficient means/detail for effective implementation. In addition, several risk management frameworks/systems have been developed, including the Nano Risk Framework,⁽⁵⁰⁾ CENARIOS[®],⁽⁵¹⁾ and AssuredNano[™], yet there is limited evidence in the public domain to suggest that they sufficiently facilitate the engagement of stakeholders along the value chain or provide foresight.

Several voluntary codes of conduct for nanotechnology have been developed, including the European Commission Code of Conduct for Responsible Nanosciences and Nanotechnologies Research,⁽²³⁾ the Responsible NanoCode,⁽⁵²⁾ the BASF Nanotechnology Code of Conduct,⁽²⁵⁾ and the Bayer Code of Good Practice on the Production and On-Site Use of Nanomaterials.⁽⁵³⁾ While offering flexibility and versatility, the main limitation with these codes is that they are considered only to provide principles (in some cases supported by examples) and lack sufficient detail for effective implementation.

Current mandatory and voluntary reporting schemes, such as the French Decree for Mandatory Reporting on Nanomaterials⁽⁵⁴⁾ and the Australian National Industrial Chemicals Notification and Assessment Scheme,⁽⁵⁵⁾ are valuable in terms of gathering information on nanomaterial properties, production volumes, and uses. However, these schemes do not in themselves contribute an effective governance approach.

Standardization activities in the nanotechnology field are taking place at both a national and international level, involving a broad range of interests and organizations. At the forefront of these activities is

the International Organization for Standardization (ISO), the European Committee for Standardization (CEN), the British Standards Institution (BSI), ASTM International, and the Organization for Economic Co-operation and Development Working Party on Manufactured Nanomaterials (OECD WPMN). A recently published British Standard⁽⁵⁶⁾ provides some clarity on the fundamental requirements for delivering effective governance of organizational performance, albeit not specifically for emerging technology. Nanotechnology-specific standards to date have focused on terminology and nomenclature, metrology and instrumentation, test methodologies, and science-based health, safety, and environmental practices.

In addition, a number of stakeholder initiatives (e.g., the Woodrow Wilson Centre Project on Emerging Nanotechnologies, and the Center for Nanotechnology in Society-Arizona State University), government strategic initiatives (e.g., the European Nanosciences & Nanotechnologies Action Plan for Europe, and the U.K. Nanotechnologies Strategy), projects, and dialogue initiatives (e.g., FramingNano, NANOETHICS, and NANODIODE) have or are being undertaken in relation to nanotechnology governance. While undoubtedly contributing to knowledge in the field, the majority of these activities have not been aimed at the development of a practical governance framework and there remains limited evidence of any significant outputs penetrating the field and being widely adopted by stakeholders.

The considerations of the governance landscape were used to inform and support the foresight study.

3. FORESIGHT STUDY METHODOLOGY

3.1. Development of Nanotechnology Foresight Scenarios

Building on the development of the governance landscape, further insights into the major factors influencing the governance of nanotechnologies were sought through informal dialogue with 27 stakeholders from a diverse range of backgrounds within Europe, including industry (11), government (6), academia (6), and NGOs (4). In order to make sense of the wealth of insights emerging and set them in context for the development of the foresight scenarios, the totality of the issues were borne in mind throughout a process of formulating a “focal question” and “sub-questions” that captured the

essence of the research. The focal question was defined as: *What might affect the governance of nanotechnologies in Europe in the next 20 years?*

Sub-questions were explored with a view to determining the “critical uncertainties” (i.e., the most important and most uncertain factors that could affect the answer to the focal question), specifically: *What might be the development trajectories for nanotechnologies? To what extent might the anticipated benefits become manifest? To what extent might the anticipated risks become manifest? What styles of governance might affect the development of nanotechnologies? How may stakeholders’ values, attitudes, and perceptions affect the development and governance of nanotechnologies?*

Three “critical uncertainties” were identified that capture the most important and uncertain issues, each of which could have a number of alternative future conditions but the plausible range of conditions for each is set out below:

1. The style of governance
 - Mandatory, formal, reactive, closed. The process of making laws, regulations, and decisions is formal and narrow, characterized by a clear focus on codified and statutory (and industry standard) requirements that prescribe action in response to challenge.
 - Managed, anticipatory, open. This style is characterized by regulations and decisions that seek to identify, as far as reasonably practicable, risks and opportunities that may emerge and involves broad stakeholder involvement and participation in the making of laws.
2. The scope of governance
 - Fragmented, nano-specific regulation. The focus is clearly on nanotechnologies by virtue of risks and benefits purported to arise from particular size-related properties and from a fragmentation across countries or sectors.
 - Harmonized, generic regulation. There is no specific focus on “nano” sized-related risks and benefits; these are integrated within generic laws or sector-based regimes.
3. Perception of public perception
 - Erroneous perception. Public attitudes are perceived erroneously as not accepting of nanotechnologies in products.
 - Accurate perception. Public attitudes are perceived correctly as accepting of nanotechnologies in products.

Combining these critical uncertainties identified eight potential foresight scenarios (Table I). It is apparent that some combinations are less plausible than others; for instance, where stakeholders accurately perceive that the public is accepting of nanotechnologies in products, it would be highly unlikely that the governance of nanotechnologies would be fragmented and nano-specific. The less plausible scenarios were of limited value to the study and were not developed further. The four plausible scenarios selected for further development and consideration were titled as follows: “Nano-Phobia Phobia,” “Size Still Matters,” “Nano for Growth,” and “Open Channels.” These four scenarios were expressed as short narratives that describe plausible pictures of how the governance landscape for nanotechnologies may look and feel in 20 years’ time (i.e., by the year 2034) (Appendix 1). As with any scenarios, these are not projections, forecasts, or predictions; rather, they set out distinct possible futures that could occur. Many other scenarios are plausible; however, the four scenarios map out a series of divergent futures that cover a wide range of possibilities.

3.2. Testing Key Elements of the Governance Landscape

The next stage of the foresight study involved “stress testing” (also termed “wind-tunneling”) key elements of the governance landscape within the foresight scenarios to see how well each element might perform in the range of possible futures. This was facilitated through a workshop, attended by 17 stakeholders from a diverse range of backgrounds within Europe, including business/industry (9), civil society/academia (6), and regulatory/governance (2).

The following four key elements of the governance landscape, stemming from the identified practical governance approaches (Fig. 1), were tested to see how well they might “perform” in the foresight scenarios: (1) social and ethical assessment, TA, and VSD; (2) health, safety, and environmental risk assessment; (3) adoption of standards; (4) commitment to codes of conduct. These particular elements were selected as they represent the most practical, tangible, and realistic tools currently available and being used in the field of nanotechnology governance for stress testing within the scenarios.

Through a process of dialogue, which naturally reflected the experience and expertise of the stakeholders taking part, opinion was sought on how

Table I. Potential Foresight Scenarios Derived from Combining the Three Critical Uncertainties

Perception of Public Perception	Critical Uncertainties		Titles of Plausible Scenarios
	Style of Governance	Scope of Governance	
Erroneous perception of nonacceptance	Mandatory, formal, reactive, closed	Fragmented, nano-Specific	Nano-Phobia Phobia
		Harmonized, generic	–
	Managed, anticipatory, open	Fragmented, nano-specific	Size Still Matters
		Harmonized, generic	–
Accurate perception of acceptance	Mandatory, formal, reactive, closed	Fragmented, nano-specific	–
		Harmonized, generic	Nano for Growth
	Managed, anticipatory, open	Fragmented, nano-specific	–
		Harmonized, generic	Open Channels

robust each element would be, with groups being asked to reach a position on the relative performance of each element, along a scale from: *strongly, moderately, or weakly negative (poor) performance; neutral performance; to weakly, moderately, or strongly positive (good) performance*. The pooled ratings were compiled to produce an overall assessment of the performance of the governance elements across the set of scenarios in the form of a scenario/strategy matrix.

The results of the “stress-testing” exercise can be represented by a scenario/strategy matrix in which the columns represent the different scenarios and the rows represent response options. This helps to ensure that all options are tested systematically in all scenarios before a judgment of relative value can be made. In this way, stress testing is an analytical rather than a decision-making tool that helps users to gain an impression of the nature and level of risk or opportunity involved for each response.

As stress testing is based on the assumption that there is always room for improvement in the design of strategic options, this process can be applied iteratively to search for aspects that are more robust across the scenarios.^(57–59) The outcomes from such considerations determine to a large degree the relative flow of effort and resources that set the direction of the organization. Thus, if a risk is identified that is regarded as too significant to ignore, then resources might flow toward mitigating (or adapting to) that risk. By the same token, if an opportunity is identified that looks too good to ignore, resources might flow toward pursuing that opportunity.

Given that resources and effort are constrained in most organizations, and risk appetite varies between organizations, choices have to be made regarding where resources flow. This underpins the point that the strategic design process is effectively one based on deciding what to do more of, what to do less of, and what to do differently.

3.3. Analysis of Strengths, Weaknesses, Opportunities, and Threats

An analysis of the strengths, weaknesses, opportunities, and threats (SWOT) of the nanotechnology governance landscape was then undertaken to complement the governance landscaping and outcomes of the stakeholder stress-testing exercise. Specifically, it was sought to identify: current strengths of the nanotechnology governance landscape; current weaknesses of the nanotechnology governance landscape; future opportunities for the nanotechnology governance landscape (over the next 20 years); future threats facing the nanotechnology governance landscape (over the next 20 years). Strengths and weaknesses can be considered to be internal factors, determined by the current nature of the governance landscape itself. In contrast, opportunities and threats can be considered to be external factors, determined by the social, political, and economic climate of the wider world. Focusing on four to five key strengths, weaknesses, opportunities, and threats, the outcome of the SWOT analysis was arranged in a conventional matrix format suggesting how the strengths of the current nanotechnology governance

landscape might be exploited to capitalize on future opportunities and counter future threats, and how the weaknesses of the current nanotechnology governance landscape might be tackled to capitalize on future opportunities and enable future threats to be countered.

4. OUTCOMES OF THE FORESIGHT STUDY

4.1. Relative Performance of Each Governance Element

The consensus performance ratings reported by each group are summarized in the form of a scenario/strategy matrix (Table II) and graphically (Fig. 3). Overall, a clear picture emerges in which the vast majority of the elements of the governance landscape tested in the scenarios perform either neutrally to positively across the scenarios, with 14 out of 16 performing neutrally or positively. Poor performance was recorded in only two instances (social and ethical assessment in “Nano for Growth” and commitment to codes of conduct in “Nano-Phobia Phobia”). This suggests strongly that, on balance, the key elements of governance for nanotechnologies in Europe over the next 20 years throw up few significant risks and a number of good opportunities.

It is possible to classify the governance elements according to their overall performance, ranging from “solid core” elements through “contingent” elements to “weak marginal” elements. From the results outlined above, it was clear that there is a good opportunity to pursue the adoption of standards as a solid core element of the governance landscape for nanotechnologies in Europe, looking out over the next 20 years. The picture was not as clear for the other elements of the governance landscape, where variable or highly variable performance was recorded.

Risk assessment performed either neutrally or positively but did not perform particularly strongly in any scenario. This suggests that this element of governance would face few risks over the next 20 years and there would be an opportunity to pursue it as part of a core strategy, although there may be a need to find ways to strengthen its performance should certain scenarios come about. Maintaining a watching brief on how the future unfolds and being able to adapt risk assessment appropriately would help to ensure that risk assessment remained a worthwhile approach. Social and ethical assessment performed moderately positively in all scenarios except

for “Nano for Growth,” suggesting that a contingency plan would be required to help bolster performance should this scenario come about. However, in no scenario did this element of governance perform particularly well and it seemed to be tolerated in most scenarios rather than embraced. Commitment to codes of conduct demonstrated the most complex and highly volatile response to the differences embodied in the four scenarios. Codes of conduct were seen to perform poorly in a highly regulated scenario because they would be, to a large extent, redundant where activities were mandatory.

4.2. Enhancing the Governance of Nanotechnologies in Europe

The SWOT analysis for the nanotechnology governance landscape identified a number of key strengths, weaknesses, opportunities, and threats of the nanotechnology governance landscape. A range of strategic options have been identified, summarized in a matrix format (Fig. 4.), suggesting how the strengths of the current nanotechnology governance landscape might be exploited to capitalize on future opportunities and counter future threats, and how the weaknesses of the current nanotechnology governance landscape might be tackled to capitalize on future opportunities and enable future threats to be countered.

In terms of current *strengths*, it was notable that many governance initiatives have been developed in a timely manner, early in the development of nanotechnologies, and designed using good practice models to be inclusive, transparent, flexible, and, in many cases, adaptive to changing circumstances. Governance initiatives are evolutionary, building on the lessons of the past (e.g., asbestos, genetic modification) and a precautionary approach appears to be in-built in most mechanisms.

In terms of current *weaknesses* of the nanotechnology governance landscape, it was considered that the implementation and effectiveness of governance mechanisms is patchy. Most approaches are not being used in a systematic way by actors in the value chain, which may lead to disillusion among stakeholders about the effectiveness of governance. Many of the existing initiatives lack the necessary detail to be implemented at an operational level, and there is a significant lack of robust and relevant data on nanotechnology risks available to inform decision making. While a number of organizations have taken the lead in nanotechnology governance, followership

Table II. Consensus Performance Ratings for Each Governance Element in Each Foresight Scenario

		Nanotechnology Foresight Scenario			
		Nano-Phobia Phobia	Size Still Matters	Nano for Growth	Open Channels
Key element of the governance landscape	Social and ethical assessment, technology assessment, and value sensitive design	Positive <i>(weakly)</i>	Positive <i>(weakly)</i>	Negative <i>(moderately)</i>	Positive <i>(weakly to moderately)</i>
	Health, safety, and environmental risk assessment	Neutral	Positive <i>(moderately)</i>	Positive <i>(weakly to moderately)</i>	Neutral
	Adoption of standards	Positive <i>(strongly)</i>	Positive <i>(moderately)</i>	Positive <i>(moderately)</i>	Positive <i>(moderately to strongly)</i>
	Commitment to codes of conduct	Negative <i>(strongly)</i>	Neutral	Neutral	Positive <i>(strongly)</i>

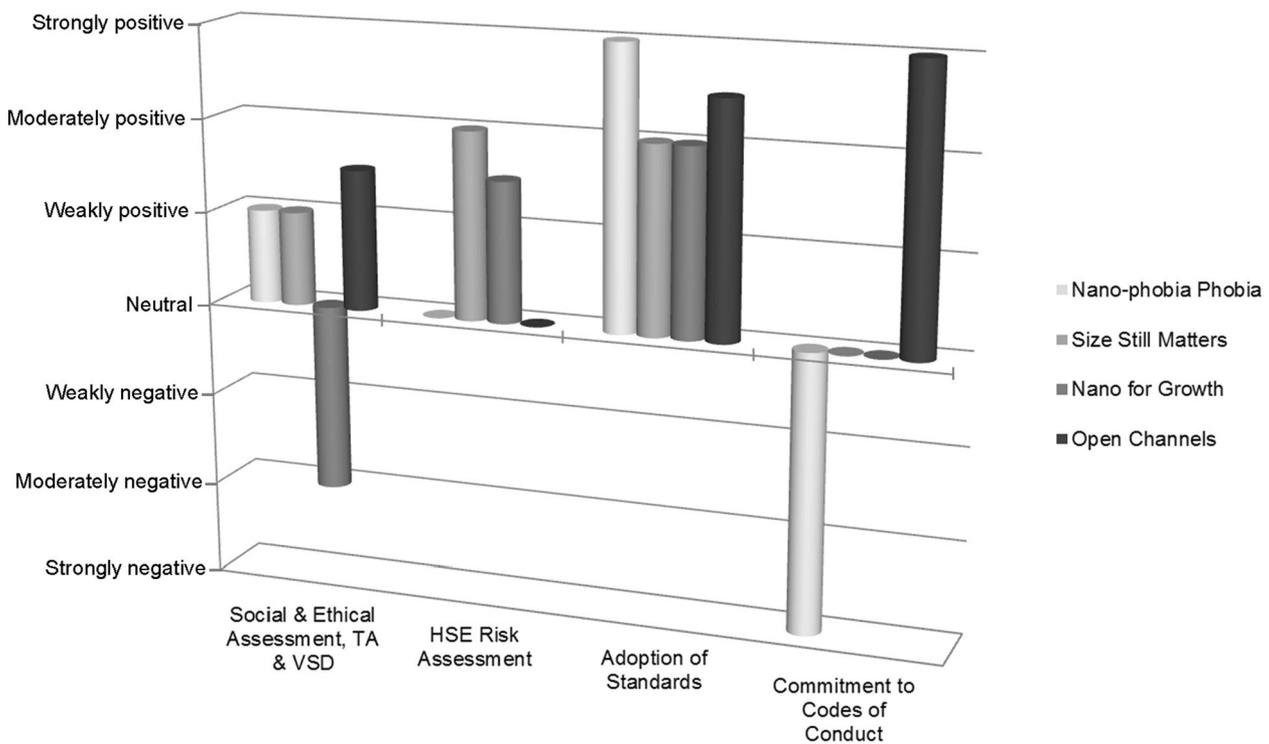


Fig. 3. Relative performance of each governance element in each foresight scenario.

among the business community is not widely evident at present. Lack of disclosure about the use of nanomaterials is considered as demonstrating a fundamental weakness of governance and a lack of consensus among stakeholders about what constitutes effective and optimal governance has the

potential to result in conflict and instability. The current landscape is not “formally” adaptive, but represents a novel system that hasn’t had time to evolve, due in part to a lack of experience and knowledge, and a lack of learning and memory, which sustains higher costs.

External factors (future) Internal factors (current)	OPPORTUNITIES: Broader participation, more inclusive fora for debate and deliberation; Existing frameworks and momentum towards governance; Greater focus on governance itself and/or nanotechnology; Evidence of effectiveness of governance; High profile negative event.	THREATS: Broader participation/inclusiveness Fragmentation of governance regimes worldwide; Evaporation of interest in governance and/or nanotechnology; Evidence of ineffectiveness of governance; Discovery of new hazards/risk pathways that the system cannot cope with.
STRENGTHS: Inclusive; Adaptive (in part); Designed to be open, transparent and facilitate disclosure; Evolutionary (builds on experience); Precautionary.	Focused, managed, streamlined participation; Collaborative research/evidence gathering; Evolve existing frameworks openly, inclusively and visibly reflecting broader sustainability agenda, including anticipation; Preparedness for the negative event (avoid only being reactive).	Focused, managed, streamlined participation; Develop process and operational guidance/tools; Demonstrate value and effectiveness, (need evidence that it works); Anticipatory and responsive approach; International-level consensus with coordination/championing.
WEAKNESSES: Impractical at operational level; Not 'formally' adaptive; Lack of business followership; Lack of robust and relevant data to inform decision making.	Convert existing frameworks into operational tools (including anticipation, VSD, TA, socio-economic assessment and risk assessment); Build adaptive capability into existing frameworks (including anticipation); Promotion/awareness raising of governance itself (what it means, what it includes, what it can achieve, what benefits it can bring); Research into effectiveness (e.g. multi-stakeholder evaluation of current frameworks through research collaboration with a specific focus on what works and does not work at an operational level). Evaluation must cover the broad-scale sustainability agenda; Preparedness for the negative event; Assured bonds/shared liability.	Develop process and operational guidance/tools; Formalise adaptive approach and build capability; Evidence gathering on effectiveness of governance (including dissemination/knowledge exchange and brokering) and practical operational application; Mandate (threat of) participation in governance; Incentivise participation in governance (through, for example, threat of mandatory governance, financial incentive, reputation incentive, supply chain pressure, value chain pressure etc.); Academic and applied research into new hazard and risk pathways and dissemination/knowledge exchange and brokering; Funding stream for developing operationally-focussed tools.

Fig. 4. Matrix Summarizing the Main Considerations of the SWOT Analysis for Nanotechnology Governance.

Future *opportunities* for nanotechnology governance (over the next 20 years) were considered to include increasing convergence of knowledge on governance good practice from nanotechnology and other emerging technologies, which has the potential to lead to greater clarity of purpose and practice. Growing clarity of purpose in mandatory regulation may focus greater attention on the benefits provided by various voluntary governance mechanisms, and growing clarity on the speculated risks of nano-materials may boost the ability of governance to deliver societal confidence. In addition, the current weaknesses of the governance landscape may serve

to stimulate a greater focus on governance and increasing focus on the broad sustainability agenda may stimulate interest in governance and benefit assessment methodologies in particular. Empowerment of society in shaping technology trajectories may result in an increased demand for governance and decreased conflict, thus serving to strengthen the power of governance.

Future *threats* facing the nanotechnology governance landscape (over the next 20 years) were considered to include broader participation and inclusiveness, which has the potential to slow the process of governance to such an extent that

governance is undermined or made too complicated. Continued disparity about the effectiveness of governance between stakeholders/jurisdictions could result in an undermining of its ability to deliver societal confidence, with disparity about the values underpinning governance having the potential to result in a governance stalemate. Fragmentation of governance in terms of frameworks, sectors, jurisdictions, and stakeholder confidence has the potential to damage the effectiveness of governance. The discovery of new hazards or risk pathways that a governance framework cannot cope with has the potential to undermine confidence in governance and demonstrate ineffectiveness. Evaporation of interest in governance and/or nanotechnology also poses a threat.

To utilize the outcomes of the stress-testing exercise and the SWOT analysis, the concept of “strategic foresight” is proposed as a means of enhancing the governance of nanotechnologies, facilitating navigation through the landscape, and steering future development. Strategic foresight uses inputs, forecasts, alternative futures exploration, analysis, and feedback to produce or alter plans and actions. A consideration of possible scenarios and pathways (desirable and actual) is important to realizing a vision. The concept of applying strategic foresight tools and techniques to the strategic development of emerging technologies, especially where there are profound or “deep uncertainties” about how the future may unfold, can be depicted conceptually (Figs. 5 and 6).

First, in the “map” or “chart” of the futures (Fig. 5) the dark area represents the zone or area of *implausible* futures (i.e., those future states that could not feasibly come about as we look at them in 2015). The white area represents the zone of *plausible* futures that might occur. Within this, a very broad range of futures could be envisaged (e.g., Scenario *i*), with the four “compass point” scenarios (i.e., Scenario N, E, S, W) and boundary between dark and white zones delineating the zone of plausible futures.

It is feasible to mark on this chart where the current situation (i.e., “now”) might be found within the zone of plausible futures. In this hypothetical case, “now” is located close to Scenario W, but with some influence from all others in the zone of plausible futures. Thus describing the current situation would show that it has many features in common with Scenario W, although some aspects of the other scenarios would also be apparent.

Having marked “now,” the next stage is to locate on the chart where the desired future or “vision” might be located. In this case, the vision is located close to Scenario E, but again with some minor aspects of the other scenarios, particularly Scenario N. As such, the influence of Scenario W would be very small. In describing the vision, it would look similar to Scenario E, although some hints of aspects of the other scenarios would also be apparent to various degrees. It is axiomatic that a vision must be credible and thus must sit within the zone of plausible futures. Unless the vision coincides precisely with “now,” there will be some distance between where the situation is now and the desired future. Unless it is left to fate, some action will be needed to bridge the gap between “now” and the “vision.” This is represented on the chart in two ways: first as the desirable pathway to the vision—traveling the shortest distance between now and the vision. The journey is, of course, not instantaneous and will take time. The chart shows how this pathway is split into five-year time-steps from 2015 to 2040. The second journey is by a more winding path, where changing circumstances, some beyond the control of the traveler, but others as a result of deliberate choices, mean that each time-step might take the traveler in a direction that deviates from the desired pathway. This is denoted on the chart as the “actual pathway towards the vision.”

The distance between the actual path and the desired pathway is shown, at each time-step, by dotted lines. It is thus apparent that the effort required to return from the actual pathway to the desired pathway may continue to increase unless corrective action is taken that allows the traveler to adapt to changing circumstances on the journey. Without such adaptations, the pathway might well be a “random walk,” which, by 2040, could place the traveler anywhere within the white area of the chart—reaching the vision by this means would be highly improbable and would come about purely by chance.

Strategic foresight utilizes tools that can help in the planning of the journey toward the vision (Fig. 6). It ensures that the journey is purposeful, directed, and with deliberate actions, but also that it is adaptive to changing circumstances and, potentially, to changing goals. Having set out the vision and tested its robustness in a range of scenarios using stress testing/wind-tunneling, the next step is to establish the conditions necessary to achieve the vision—the milestones or way-markers on the journey. These are determined using back-casting techniques that ask, on a decadal basis, what needs

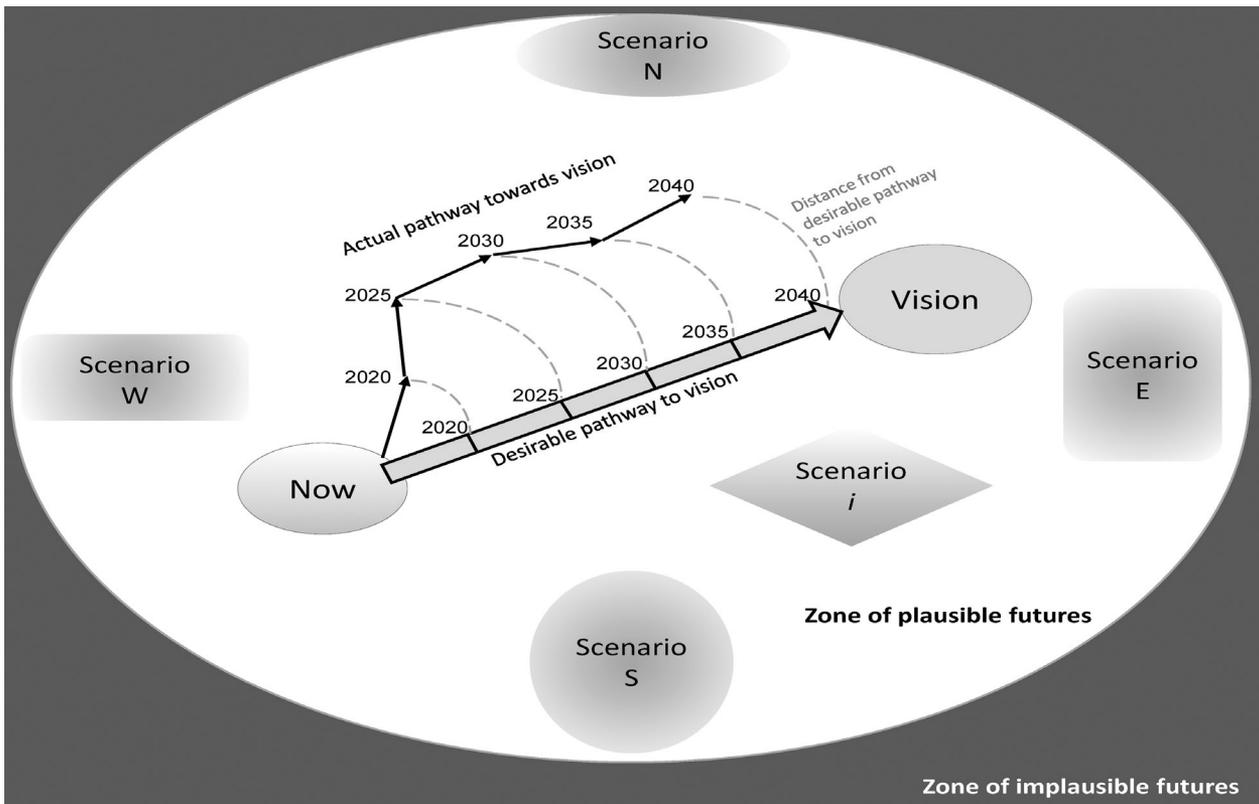


Fig. 5. Conceptual diagram outlining the space where strategic foresight can be used to navigate a pathway to the desired vision for governance.

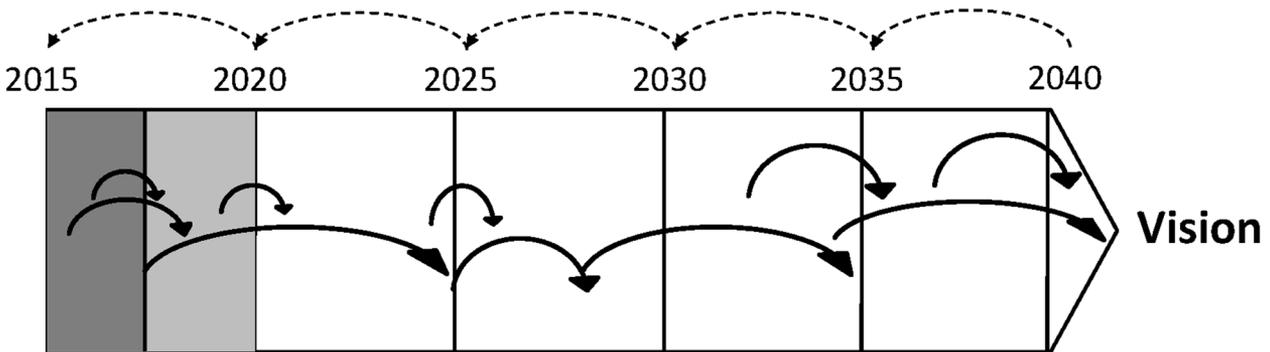


Fig. 6. Conceptual representation of strategic foresight. First, the conditions necessary to reach the *vision* are scoped by “back-casting” (dashed arrows). The actions and approaches (solid arrows) required to achieve the overall necessary conditions *en route* to the *vision* are developed through “road-mapping,” setting out the strategic direction for implementation through corporate governance plans in the near- (dark gray) and medium-term (light gray); multiple arrows denote adaptations to changing conditions, from monitoring, horizon scanning, and iterating scenarios.

to have happened or be in place by a certain date in order to realize the vision. This then casts back to the present day where the plan can then begin to look forward, using road-mapping to set out the actions and approaches required to achieve the necessary

conditions or arrive at the milestones/way-markers. These should be set out in an “itinerary” or statement of strategic direction or strategic intent.

However, it is critical to recognize that changing circumstances mean that the pathways may need to

be altered and the ability to adapt should be built into the journey plans. Thus alternative routes, some short term and some longer term, may need to be followed. It is also possible that the desired destination may change as circumstances change. Being able to act in such an adaptive way requires monitoring of progress, horizon scanning for changing circumstances, and further iterations of scenarios and plans as the journey unfolds. From these considerations, recommendations have been identified to enable an optimal governance framework to be developed further and ultimately be realized.

5. CONCLUSIONS

This foresight study on the governance of new technologies, using nanotechnology as a case example, has presented the principal features of the governance landscape and a series of scenarios and pathways as a prelude to identifying in more detail where current approaches lie in the governance landscape and establishing consensus on the optimal approach(es).

From the findings of the scenario consultation element of the research, it can be seen that actions to strengthen voluntary initiatives in the governance landscape for nanotechnologies might comprise encouraging the adoption of standards, use of risk assessment and social and ethical assessment, and an effectiveness review and adoption of codes of conduct.

An aggregation of the critical outcomes from the SWOT analysis has been used to inform the development of a number of suggestions for policy actions and research, considering the strengths and weaknesses of the current nanotechnology governance landscape that might be exploited to capitalize on future opportunities and counter future threats.

Initial pragmatic actions to *encourage* the adoption of governance approaches, where there is uncertainty about the implementation ability/capacity, effectiveness, and value, which nevertheless could be explicitly incorporated into current policy (necessarily with an accompanying program of awareness-raising to facilitate commitment), include:

- encouragement, through policy adaptation or development, that due consideration be given to the demonstration of the basic principles of governance, through the use, or consideration, of relevant approaches and

tools highlighted in the governance landscape; this may be achieved, for example, through adoption of the recommendations of the BSI's code of practice for delivering effective governance;⁽⁵⁶⁾

- encouraging an anticipatory and responsive approach in governance;
- preparedness for a negative event;
- incentivizing participation in governance (e.g., financial incentive, reputation incentive, supply chain pressure, value chain pressure, threat of mandatory governance, etc.);
- mandating demonstration of the adoption of governance approaches.

However, prior to necessarily *mandating* governance, again where there is uncertainty about implementation ability/capacity, effectiveness, and value, actions considered essential for the further development of nanotechnology governance include:

- evidence gathering on effectiveness and value of governance (including dissemination/knowledge exchange and brokering) and practical operational application, via a multi-stakeholder evaluation of current frameworks with a specific focus on what works and doesn't work at an operational level; the evaluation should cover the broad-scale sustainability agenda, and consider the value of existing hazard and risk data (scientific and commercial, academic and applied) as well as emerging evidence;
- evolving existing frameworks openly, inclusively, and visibly reflecting broader sustainability agenda, including anticipation;
- developing governance processes, operational tools (including anticipation, VSD, TA, socio-economic assessment, and risk assessment), and necessary guidance for effective implementation.

These conclusions would benefit from a degree of international-level consensus with coordination/championing, and may only be possible with a funding stream for support.

6. RECOMMENDATIONS

The interaction of stakeholders, including the general public, NGOs, and civil society groups, as well as policymakers, academia, and business, is likely to be an important component of the delivery of optimal governance. Regarding a stakeholder-

based *process* to implement the aforementioned actions, it is considered essential that a coordinated underpinning multistakeholder initiative is developed to *clarify, test, and implement* a *vision* of optimal governance, considering different governance approaches in the context of overall mandatory and voluntary pathways, and to understand if and how current initiatives may contribute. This process could consider the effectiveness of existing governance approaches in relation to an optimal approach considering the current and potential economic and political context for nanotechnologies, content and process strengths, and weaknesses and implementation and communications challenges, in the context of the growing “responsible innovation” agenda.

Specific suggested recommendations with the objective of *clarifying* the *vision* for optimal governance include:

- mapping out plausible futures, determining the current situation facing stakeholders concerned with governance and where they want to be in the future;
- establishing the degree of consensus on the level at which sustainable governance for new technologies is needed and can be most effective, ranging from *ad hoc* implementation of principles by individual organizations through to a global harmonized compliance-based approach;
- identifying the requirements of an adaptive governance approach and stress testing the principles and practices, examining whether they are able to anticipate, respond, and adapt in relation to changing external conditions (e.g., societal, technological, economic, environmental, and political);
- demonstrating the utility of knowledge on hazards and risk pathways, both in an academic context and an applied context, and how this can inform decision making in a governance context;
- identifying proactive measures to prepare for the occurrence of a negative event in order to ensure that the broader market for all products utilizing a new technology are not unduly affected by an isolated incident;
- formalizing the requirements of an adaptive governance approach and developing the capability needed to operationalize it.

Once the optimal governance requirements have been clarified, a process of *testing* the robustness of the components, principles, and practices should be developed. Specific suggested recommendations with the objective of *testing* the *vision* for optimal governance include:

- expanding the scope of wind-tunneling/stress testing of the nanotechnology scenarios and the SWOT analysis to encompass a wider range of elements of the governance landscape, potentially in more scenarios and possibly with inclusion of more strengths, weaknesses, opportunities, and threats, and involve a wider stakeholder engagement process, perhaps across Europe (and maybe wider), with a broader range and greater number of stakeholders;
- identifying the actions and approaches required to achieve the *vision*, considering the gaps between the current and desired pathways, and test how optimal governance may anticipate, respond, and adapt in relation to changing external conditions (e.g., societal, technological, economic, environmental, and political changes);
- exploring and developing generic scenarios for new technologies, using the demonstrated methodology from this initial study, to frame the scenarios and test elements of governance in more detail;
- evaluating systematically the effectiveness of existing governance approaches, identifying whether approaches provide sufficient means/detail for effective implementation, facilitate engagement of stakeholders along the value chain, and provide a means to establish legitimacy of emerging technologies; such an evaluation should gather evidence of utilization from stakeholders, consider aspects such as dissemination, knowledge exchange, and brokering, and cover the broad-scale sustainability agenda;
- back-casting to identify the actions and approaches required to achieve the *vision*, which are defined and implemented through a roadmap, considering the financial, social, and political cost of bridging the gaps between the current and desired pathways.

Once the optimal governance requirements have been clarified and tested, a process of *implementing*

the *vision* should be developed. Specific suggested recommendations with the objective of supporting the *implementation* of the *vision* for optimal governance include:

- developing a governance “road-map,” outlining the steps to be taken to deliver a robust anticipatory and responsive governance process supported by practical, operational guidance and tools; this should be accompanied by a “business case” for the optimal governance approach, demonstrating a clear understanding of the operational requirements of the optimal governance approach and its value to companies in a variety of sectors and company sizes;
- developing activities to encourage focused, managed, and streamlined stakeholder participation in governance, for example, by organizing events and dialogue to promote and raise awareness of governance among stakeholders, providing information on what governance means and includes, what participation can achieve, and the benefits it can offer;
- clarifying and developing good practice guidance for different actors involved with governance at different stages in the value chain, including existing frameworks and codes of conduct with operational tools (e.g., VSD, TA, social and ethical assessment, risk assessment), and the adoption of standards.

While the scope and representativeness of the study was limited, opinions nevertheless provide some insight on the range of interests involved in the governance of nanotechnologies in Europe. The analysis presented here, if taken at face value, provides an indication of the issues arising, albeit not as a full or definitive assessment of the risks and opportunities, that face the future governance of nanotechnologies in Europe over the next 20 years.

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SUPPORTING INFORMATION

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APPENDIX 1. Nanotechnology Foresight Scenarios