Risk Governance in Nanotechnology

Article on the conceptual framework for risk governance in nanotechnology developed by the International Risk Governance Council

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Introduction to Risk Governance

Risk governance plays a very important role in smooth functioning of societies in developed nations. A robust framework that is legally, politically, financially and socially durable provides a strong platform for a well-regulated society that is able to offer its citizens a nurturing environment. Risk Governance covers almost all areas of human activity. It covers organisational activity of governments, businesses, educational institutes and the larger civil society. The scope of risk governance is defined and quantified by the various risks posed to society, the measures that can be implemented to remove the possibility of harm.

Risk has been defined as an uncertain consequence of an event or activities with respect to something that society values. Risk has two components – likelihood of potential consequences and the severity of the consequences. The analysis of risk not only covers physical consequences but also includes financial impact, economic investments, institutions, cultural heritage and psychological impact. There are four categories of risks based on their characteristics - simple, complex, uncertain and ambiguous.

The definition of a hazard differs from that of the risk though in practice it has been used interchangeably. Hazard essentially described the potential for harm. "*A hazard characterises the inherent property of a risk agent or related processes where a risk would describe the potential effect the hazard is likely to cause on specific targets such as the environment, eco-systems and human health."* Risks may be classified according to their origin such as physical agents, chemical agents, biological agents, natural forces, social – communicative, and complex hazards.

An integrated framework is essential that takes into account scientific, economic, and social aspects of all stakeholders concerned while analysing the risk and hazards. The International Risk

Governance council (IRGC)[1], an independent foundation, has prepared a platform for such a framework. The framework not only provides a factual and socio-cultural dimension but also encourages participation through its underlying fundamentals of good governance. The risk governance is conducted in four phases namely – 'pre-assessment', 'appraisal', 'evaluation and characterisation' and 'management'. Communication forms the core in the cyclic processing of the framework that is depicted in Figure 1.

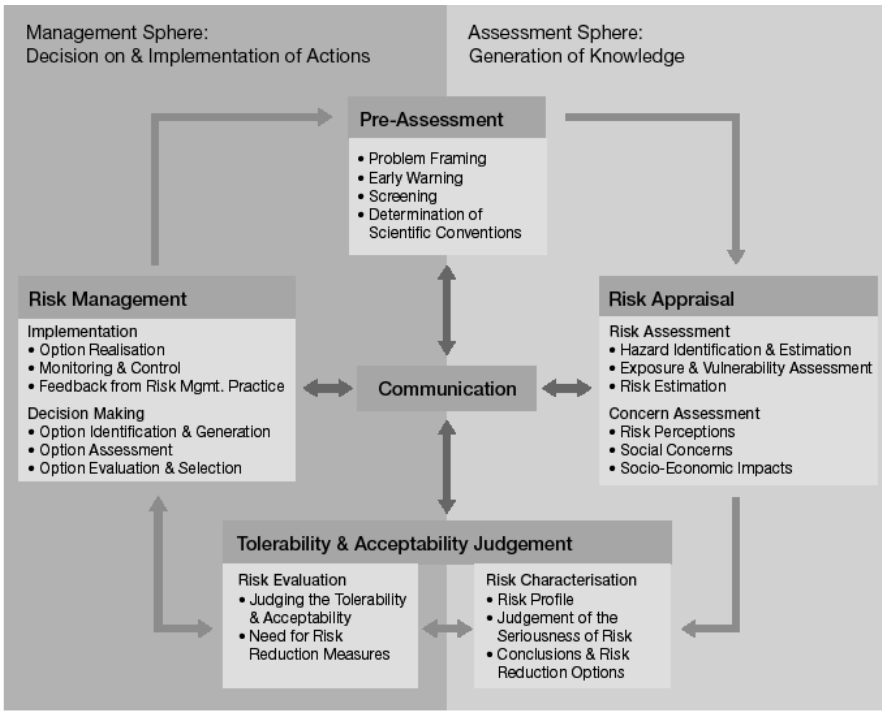

Figure 1 – IRGC Risk Governance framework (White Paper on Risk Governance – Towards an Integrative Approach p13)

With the growing interest and development of nanotechnology[2] and its applications within society, the framework needs to address a myriad of issues spanning different areas of knowledge. The IRGC has proposed a conceptual framework for nanotechnology. This framework takes into consideration the present regulatory scenario, international situation and the science-policy interface. The framework has been developed taking into account the four generations of nanotechnology products and their potential character. The framework also integrates risk-benefit

[1] IRGC is a public-private partnership in which governments, industry and academia can freely discuss such issues and, together, design and propose appropriate risk governance recommendations that have relevance to both developed and developing countries.

[2] Nanotechnology is the interdisciplinary technology that is concerned with materials, structures and devices fabricated with dimensions ranging between 1-100 nanometres (1 nanometre is a billionth of a metre).

assessment such as health, environmental and safety along with social and ethical issues from the societal perspective.

Pre- Assessment: Four Generations of Nanotechnology Products

Nanotechnology is expected to become pervasive, and so will both the benefits and risks. The first generation of nanotechnology products incorporates passive nanostructures (fixed functionality) for instance scratch resistant nanostructured coatings for paintwork. The second generation will have active nanostructures, i.e. functionality will change in response to external stimuli. Examples include sensors that can detect and respond to changes in environmental conditions, and targeted cancer therapies. The third generation will be integrated nanosystems that combine active sub-systems, for example artificial organs built from nanoscale and evolutionary nanobiosystems. The fourth generation is expected to be based on heterogeneous molecular systems that are built from the bottom-up, rather than manufactured using top-down fabrication methods. This could include for example nanoscale gene therapies and molecules designed to self-assemble.

In order to simplify the potential impact of this rapidly growing interdisciplinary technology the four generations of nanotechnology products have been classified into two frames of reference for developing risk strategies and managing risks. The first frame includes the first generation of nanotechnology products. The second frame of reference includes the remaining generations of nanotechnology products. This classification provides decision makers with a suitable framework to assess and manage any risks that exist or may arise in the future as shown in table 1.

	Nanotechnology Product Generation	Product Characteristics
Frame 1	First	Passive Nanostructures
Frame 2	Second	Active Nanostructures
	Third	Integrated Nanosystems
	Fourth	Molecular Systems

Table 1: Four generations of Nanotechnology Products Classified into Two Risk Governance Frames

Risk Appraisal

Risk appraisal for frame one includes the evaluation of the hazards, exposure and risks with respect to product development. At present our knowledge of the environmental, health and safety risks posed to society by nanomaterials is limited. Hazards have been characterised into areas such as toxicity, ecotoxicity, carcinogenicity, volatility, flammability, persistence and accumulation in cells. Exposure routes are classified into oral, dermal, and respiratory uptake of nanomaterials during production, transport, decomposition or waste disposal. Risks have been classified into human health, explosion and ecological risks. Political and social risks have been raised in relation to the direction and level of development of nanotechnology research. There is a further risk that any education gap between different stakeholders could result in innovation opportunities being lost. The risk appraisal for frame two is considered to be even more difficult due to the incomplete understanding of the physical, chemical, and biological effects of nanostructures. The risk associated would be transformative and assessed as the technology develops.

Risk Evaluation and Characterisation

The third phase is the characterisation and evaluation of nanotechnology knowledge in relation to the two frames of reference. Risk Knowledge has been categorised into simple, complex, uncertain or ambiguous based on whether the method of evaluation was scientific (evidence based) or societal (value based). Simple Risks have clear cause-effect relationships for materials and their impact. Complex Risk refers to the difficulty in identifying the causal links and their effects. There is insufficient knowledge about the cause and effect relationship and their implications of the technological developments. Uncertain knowledge refers to the incompleteness of knowledge, with the available knowledge relying on uncertain assumptions, assertions and predictions. Ambiguous knowledge has variable interpretations though it largely denotes a lack of proper understanding of the phenomena and their effects.

Frame one knowledge has been considered to be complex for passive nanostructures with minimal impact on societal issues. Within the second frame of products, the knowledge associated with active nanostructured products has been deemed uncertain due to the lack of substantial risk related know-how. The knowledge associated with integrated nanosystems and molecular systems has been considered as ambiguous with the lack of clarity over the scientific, technological development and their impact on society.

Risk Management

The risk management strategies presented in the final phase, aim to tackle the hazards to society by setting out measures for avoiding, preventing, reducing, transferring or self-retaining risks. This will require an evolutionary approach given that nanotechnology is interdisciplinary, its applications spanning over different sectors and its development is taking place across the world.

For passive nanostructures, risk management strategies include developing testing methods and identifying the best metrics for toxicity and ecotoxicity. Other strategies such as development of relevant nomenclatures, novel processes and products would standardise the process of technology development. Nanotechnology products will require pre-market testing for health and environmental impact, life cycle assessment and consideration of secondary risks. In order to deal with exposure risks, nanomaterial monitoring methodologies need to be developed along with methods for reducing exposure (for example through the use of protective equipment). The institutional risk management strategy emphasises the need for systematic liaison between industry and government, and the need for transparency in decision making in R&D and investment. For instance, non-proprietary information on test results, impact assessment and their interpretation should be made available in the public domain. The above-mentioned strategies are also valid for frame two products. The knowledge gaps related to frame two products requires a proactive and participative approach to respond to new developments to address issues arising in the future.

Risk Communication

The good practice approach to risk communication between all relevant stakeholders would involve objectively stating information about benefits and the non-intended side effects of nanotechnology. The international disclosure of risk information by large multinational companies, and an integrated risk communication programme for scientists, regulators and industrial developers would facilitate the development of new products and their acceptance by society at large. The global nature of technology development would require involvement of all nations, encouraging public-private partnerships, sharing of standards and best practices.

Concluding Remarks

The challenges presented by risk governance in nanotechnology are not dissimilar to earlier technologies, such as genetically modified food and nuclear power. Nanotechnology, due to its interdisciplinary nature, may present a very unique opportunity for governance as Mihail Roco Chairman of the National Science and Technology has mentioned: “While nanotechnology has specific characteristics, we acknowledge that some of the governance gaps and recommendations could apply to many technologies and not only to nanotechnology, particularly in the case of risk communication and social issues.”

The challenge for policy and decision makers from various organisations and nations is gargantuan. Reviewing and adapting current legislation, cooperation and co-ordination between various stakeholders and upstream public engagement remain the main hurdles to be crossed. The litmus test for governance remains the agility of its responsiveness.

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