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A RISK GOVERNANCE MODEL FOR NANOTECHNOLOGY: A REVIEW OF INTERNATIONAL GUIDELINES AND POLICY STATEMENTS

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Nanotechnology is acknowledged by the research and development community as the technology of the 21st century. Whether used for combating cancer or improving telecommunication, the scientific breakthroughs emerging from nanotechnology are significant, but it is also understood that they are not without risk. In the midst of understanding the implications of nanotechnology, it has become clear that we should not be misled about nanotechnology's impact on society. While there are many uncertainties, there is also much promise in that nanotechnology can impact many disadvantaged communities around the world. As is the case with other emerging technologies, a balance has to be found between the risks and the benefits. In this editorial, we examine the relevant international policy statements on nanotechnology and highlight how they provide guidance towards the management of the risks posed, in particular, those affecting human health.

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DEFINING THE CONTEXT OF NANOTECHNOLOGY: THE SCIENCE OF THE SMALL

Nanotechnology is an overarching term to describe a range of sciences and technologies that aim to manipulate atomic matter for precise purposes. Hailed as the next 'Industrial Revolution'[1], nanotechnology provides new avenues, in for instance, human biology and medicine entailing the monitoring, repairing, constructing and controlling of human biological systems at the cellular level by using materials and structures engineered at the molecular level.[2] Due to the "nano" qualities, properties of organic and inorganic matter such as size, shape as well as surface area, and solubility can be manipulated and applied very broadly.[3] Prime examples are applications of nanotechnology in medicine. For example, drugs can be delivered to targeted areas in the body with the use of adenoviruses- viruses used as vectors with near ideal nanosize properties and characteristics- thus eliminating many side effects associated with conventional pharmaceutical treatments.[4]

Whether developed for treating cancer or improving telecommunication these scientific breakthroughs are significant. However, it is also understood that they are not without risk. One danger lies in the engineering of nanoparticles where not much is known about the effects to human health particularly since there is little information on how nanoparticles differ in physical, chemical, and biological properties from their macro sized counterparts. [5,6] Despite these unknowns, the global proliferation of the nanotechnology industry has increased at an alarming rate. This unprecedented growth is often attributed to the commitment by the United States to heavily invest in nanotechnology research and development with the enactment of the *21st Century Nanotechnology Research and Development Act*[7] in 2003.

The ratification of this policy stimulated an unprecedented swell of research and development worldwide. A global survey conducted by the European Science and Technology Observatory shows that more than 150 companies are developing medical applications using a mixture of nano materials such as carbon nanotubes, various polymers and chemical substances.[8] According to more recent estimates by the United States National Science Foundation, the nanotechnology market could reach as much as 1 trillion dollars by 2011/12.[9] It is evident at this stage of nanotechnology research and development that the potential commercial benefits may be considered to outweigh the 'unknown' risks.

Given this context, the introduction of nanotechnology into society is expected to have a profound impact on human health. This potential impact is central to the nanotechnology debate and form the backdrop of this editorial. We will explore the theme of *risk governance* in international policy statements on nanotechnology.

A MYRIAD OF POSSIBLE RISKS TO HUMAN HEALTH

Although nanotechnology brings much hope and excitement for a wide range of areas, the potential risks to human health are widely documented. At this stage, it is known that nanoparticles and nanomatter occur naturally in our environment. They can also arise as by-products or be generated by chemical reactions of engineered nanomaterials.[10] Many argue that these engineered nanoparticles used to produce commercial goods will eventually be released into the environment and contaminate water and food sources.[11] On the other hand, there is the perspective that nanoscale materials are "smaller thus safer" or "just the same as regular matter but smaller". However, as exploration into the characteristics of nanoparticles advances, it is becoming apparent that this view is not necessarily accurate.

New scientific research reveals that materials at the nanoscale often exhibit very different physical, chemical, and biological properties than their macro sized counterparts.[12] Size, geometry, solubility are all properties that make the nanoparticle particularly sensitive to the complexity of

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toxic response.[13] These particles can enter the human body through nasal passages, skin, or intestinal tract, and can translocate through the human body via spinal fluids, neurons, and upper respiratory tract. A growing body of evidence suggests that acute exposure to nanomaterials activates the body's defense mechanisms such as inflammatory and oxidative stress responses, and innate and adaptive immunity.[14] Many scientists have also seen these particles settle in nasal passages, where they are taken up by the olfactory nerves and carried past the blood-brain barrier directly into the brain cells.[15] Other health effects of nanoparticles are suspected to not manifest for many years, which is believed to be the case for fourth generation nanotechnology products that are based on homogeneous molecular systems usually built from the 'bottom-up'.[16,17]

The complexity of nanoparticles is raised exponentially by the fact that they are malleable and can be 're-packaged' into other types of chemical composites to form completely new products. With the lack of validated measurement methods and reference data for determining the nature of engineered nanoparticles, we may never know all the effects of engineered nanoparticles.[18] At this moment, there are an estimated 50,000 types of nanomaterials; all exhibiting unique characteristics with various potential health effects. In light of this knowledge deficit, it has been suggested by scholars such as Simon Brown, professor at the Department of Physics and Astronomy at the University of Canterbury in New Zealand that policy makers focus on the real issue namely, the development of a *risk governance* strategy for what we do know and what we can anticipate.[19] In Brown's view, "[This is the way] to overcome this knowledge deficit and the 'paralysis by analysis' that we are currently experiencing."[20]

THE CONCEPT OF RISK GOVERNANCE

Initially mentioned in the report *Small Sizes that Matter: Opportunities and Risks of Nanotechnology* by the Organization for Economic Co-operation and Development (OECD) together with the Allianz Group[21], the *risk governance* model was re-worked into a working conceptual framework for nanotechnology by the International Risk Governance Council (IRGC), an independent and risk governance foundation[22]. The dominant characteristic of the *risk governance* model is the need to facilitate the interaction of key stakeholders and institutions for achieving specific desired goals.

Moving away from the traditional concept of government and its institutions; a *risk governance* model encompasses all the risk-relevant decisions and actions; is of particular importance in situations where the nature of the risk requires collaboration and coordination between various agencies and stakeholders (no single decision-making authority available); and calls for the consideration of contextual factors such as: (a) institutional arrangements (e.g. regulatory and legal framework and coordination mechanisms such as markets, incentives or self-imposed norms); and (b) socio-political culture and perceptions.[23] Other more prominent characteristics of the *risk governance* framework as presented by the IGRC involve the improvement of a knowledge base, the strengthening of risk management structures and procedures, and promoting stakeholder communication.[24]

As with all new technologies, the prevalence of uncertain consequences raises concern at the international level. It is this uncertainty that has led to calls for caution in the management of risks associated with nanotechnology, and a growing interest in the *risk governance* framework.

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REVIEW OF INTERNATIONAL POLICY STATEMENTS

We sought to examine how international governmental and non-governmental bodies at various jurisdictional levels address these risks. We did not include policy statements from consumer interests groups are active in this area. We conducted a policy scan of online resources using databases such as NIOSH[25], ICON[26], NELSI Global, OECD database[27] and Woodrow Wilson Institute-Project on Emerging Nanotechnologies[28] combined with catalogues addressing nanotechnology risk. Keywords such as nanotechnology, regulation, risk, human health, ethics, safety, governance, toxicity and policy yielded 13 policies directly addressing nanotechnology health risks, and 3 of those mentioned in great details the concept of *risk governance*.

The discussion that follows focuses on the results of the search addressing the theme of *risk governance* within the nanotechnology area.

RESULTS

The review yielded a range of policy statements from various jurisdictions primarily for Canada, the United States, the United Kingdom, Australia and France. Other relevant position statements and reports were also found from supranational government and non-governmental organizations such as the European Commission, the Organization for Economic Co-operation and Development (OECD) and the United Nations Educational, Scientific and Cultural Organization (UNESCO).

The most notable policy statement to first address the issue of risk is the *Nanoscience and Nanotechnology: Opportunities and Uncertainties* published in 2004 by the Royal Society and Royal Academy of Engineering.[29] In this statement, they express concern over the potential health hazards posed by free, manufactured nanoparticles and nanotubes. Accordingly, "all relevant regulatory bodies [should] consider whether regulations are appropriate to protect humans and the environment from the hazards outlined in this report […]."[30]

The policy statement underpins the relevant theme of risk and acknowledges the need for further investigation into the unknown health concerns. This sentiment is equally expressed by other governmental and non-governmental agencies such as the European Group on Ethics in Science and New Technologies[31], the Organization for Economic Co-Operation and Development (OECD)[32], the Swiss Re[33], and the International Risk Governance Council[34], and the Council of Canadian Academies[35].

Nanotechnology, however, is intricate.[36] Defining as well as distinguishing between nanoparticles with different risk issues is thereby difficult.[37] Many policy statements recognize these challenges. For example, the European Group on Ethics in Science and New Technologies recommends that, "more research into [health] and safety of nanoproducts is required [,] and that without strategic risk research public confidence in nanotechnologies could be reduced through real perceived dangers."[38] The Comité Consultatif National d'Éthique pour les Science de la Vie et de la Santé argues that there are major consequences for not properly assessing the health risks of nanoproducts, and that it is imperative that we address with urgency the development of a measurement system.[39]

It was in a 2006 white paper, however, that the IRGC first presented a *risk governance* framework consisting of two separate frames of risk appraisal (risk-benefit assessment and risk perception) within a roadmap for the future development of nanotechnology.[40] These frames are based on the level of complexity of nanoproducts, the evolution of the products and the social and ethical consequences of these products. According to the IRGC, "Frame 1 is concerned with the relatively simple, passive or merely reactive nanostructures with steady behaviour and Frame 2 with more complex and / or evolving-active nanostructures and nanosystems, some of which could utilise fundamental molecular elements or biostructures as their building blocks."[41]

 ISSN 1718-9306

The Swiss RE in their 2004 publication entitled *Nanotechnology: Small Matter, Many Unknowns* go one step further and highlight the various requirements for a successful risk management strategy.[42] They argue that the activity of risk communication is lacking. The Innovation Society, on the other hand, proposes the development of definitions, standards, best practices and a coordinated effort at the international level.[43] The OECD and Allianz Group add the requirement of open access.[44] Finally, the 2007 report by the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), makes reference to the importance of incorporating public accountability and transparency as well as public education on the ethical and social issues emanating from consumer-based nanoproducts into *risk governance* models and frameworks.[45]

CONCLUSION

We set out to review a range of policy statements addressing the theme of *risk governance* for nanotechnology. In addition to this goal, we found that the idea of *risk governance* is contingent upon the establishment of international health and safety standards; the development of appropriate metrology and terminology tools; the communication of the relative risks; and the development of transparent and accountable risk policy.[46] There is much concern that without a *risk governance* framework, contradictory regulatory regimes in various jurisdictions will encourage nanotechnology research and development companies to work out of countries where there is little restriction and safeguards for health safety, particularly as global competition for nanotechnology products increases. This occurrence may well compromise the health of workers and consumers in these as well as other international jurisdictions.[47]

The *global risk governance* model at this moment provides a potential framework for initiating the activities required for building a *risk governance* strategy at the international level. To summarize the *risk governance* framework builds communication channels between industry, governments and academia, bridges private and commercial interests with research and development, and provides adequate support by building an evidence base. With proper direction, this model can also strengthen management structures and processes through an international body which can put in place tools and guidelines for minimizing health risks.

The success of this model, however, lies in its ability to stay apace with the nanotechnology industry. Its longevity will depend upon the uptake of its policies by participating jurisdictions. The potential benefits of the *risk governance* model are the integration and assessment of health risks and the ethical, legal and social concerns which often form the parameters for discussing the social impact and consequently the future acceptance of this emerging technology.

As we continue to build our knowledge about the health risks of nanoparticles, several international governmental and non-governmental agencies argue that a *risk governance* approach is required to safely convey and manage the known and unknown risks associated with nanotechnology. In fact, since the completion of this work, there has been a steady increase in the amount of policies considering *risk governance* as a potential framework for risk oversight. Currently, governments are unable to set up new regulatory structures within their own jurisdictions to match the pace of innovation in the nanotechnology field, and without appropriate research evidence, this task is made even more difficult.[48] Persistent scientific uncertainty is also limiting the effectiveness of existing regulatory frameworks. A global *risk governance* model including the creation of an international regulatory agency is therefore an option worthy of consideration and discussion.

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 ISSN 1718-9306

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