

Assessing the Social Acceptability of New Technologies: Gaps and Tensions Between Science and Regulation

ARTICLE (RÉVISION PAR LES PAIRS / PEER-REVIEWED)

Danielle Tapin^{1,3}, Georges A. Legault^{2,3}, Johane Patenaude^{1,3}

Reçu/Received: 20 Jan 2014 Publié/Published: 8 Dec 2014

Éditeurs/Editors: Charles Dupras & Jean-Christophe Bélisle Pipon Évaluateurs externes/Peer-Reviewers: Michael Mehta & Todd Kuiken

2014 D Tapin, G A Legault, J Patenaude, Creative Commons Attribution 4.0 International License

Résumé

Les considérations éthiques concernant le développement de technologies font maintenant partie du champ de la bioéthique, concentrées en grande partie sur les interactions entre la science et le gouvernement pour établir le bien social. Depuis l'avènement des différentes formes de biotechnologies, l'analyse scientifique des risques a fait l'objet de diverses lignes de questionnement par rapport au rôle que la science quantitative joue dans la surveillance gouvernementale. Cela est d'autant plus important dans le débat actuel sur l'acceptabilité des nanotechnologies. Dans cet article, nous précisons d'abord les points forts et les limites de l'analyse scientifique de l'acceptabilité sociale des risques de la nanotechnologie. Ensuite, nous montrons les limites de l'adoption d'une approche empirique dans les sciences sociales et humaines pour prédire l'acceptabilité sociale d'une technologie. Nous soutenons que la reconnaissance des hypothèses sous-jacentes de ces deux approches quantitatives doit ouvrir une route à des approches plus réflexives par les sciences sociales et les sciences humaines.

Mots clés

bioéthique, éthique du développement technologique, biotechnologie, analyse scientifique des risques, acceptabilité sociale des risques, biotechnologie et bien social

Abstract

Ethical considerations regarding the development of technologies are now a standard part of the field of bioethics, focused in large part on the interactions between science and government in establishing the social good. Since the advent of different forms of biotechnology, scientific risk analysis has been subject to various lines of questioning relative to the role that quantitative science plays in government oversight. This is even more significant in the present debate on the acceptability of nanotechnology. In this article, we first specify the strengths and limitations of the scientific analysis of the social acceptability of risks in nanotechnology. Next, we demonstrate the limitations of taking an empirical approach in the social sciences and the humanities to predicting the social acceptability of a technology. We argue that recognizing the assumptions underlying these two quantitative approaches should open up a road to more reflective approaches by the social sciences and the humanities.

Keywords

bioethics, ethics of technological development, biotechnology, scientific risk analysis, social acceptability of risks, biotechnology and social good

Affiliations des auteurs / Author Affiliations

- ¹ Faculté de médecine et des sciences de la santé, Université de Sherbrooke, Sherbrooke, Canada
- ² Faculté de droit, Université de Sherbrooke, Sherbrooke, Canada
- ³ Institut interdisciplinaire d'innovation technologique (3it), Université de Sherbrooke, Sherbrooke, Canada

Correspondance / Correspondence

Johane Patenaude, Johane.Patenaude@USherbrooke.ca

Remerciements

Cette étude est actuellement financée par une subvention des Instituts de recherche en santé du Canada (IRSC: 43854)

Conflit d'intérêts

Aucun déclaré

Acknowledgements

This study is currently being funded by a grant from the Canadian Institutes for Health Research (CIHR: 43854)

Conflicts of Interest

None to declare

ISSN 1923-2799 1 / 1/12



Introduction

Bioethics is a very large field of research involving the study of multiple aspects of the impact of human activities on human health, environment and how people live together. Since the Second World War, bioethics has concentrated to a large extent on issues in research ethics and clinical ethics, while the ethical governance of activities in these two areas (i.e., human subjects research and clinical practice) has been attributed to research ethics and clinical ethics committees [1]. In a similar vein, since 2001, the ethics of technological development in Québec has been institutionalized in the form of a provincial oversight body, the *Commission de l'éthique de la science et de la technologie* (CEST). The CEST's mandate is to discuss publicly the social and ethical acceptability of certain technological advances such as genetic databases, genetically modified organisms (GMOs), and nanotechnologies [2]. In the process of addressing the bioethical aspects of technological development, this Commission reveals what Sheila Jasanoff [3] calls the pact between science and regulation that has governed the social acceptability of technology since the middle of the 20th century.

The current debate on the acceptability of nanotechnologies offers fertile ground for inquiry on the limits of a quantitative approach to determining the social acceptability of technologies. Since each technology assessment requires specific quantitative data, this paper will concentrate on the case of nanotechnology. At the present time, we are witnessing the dawn of a new technological revolution in which the promises offered by scientific advances are presented as a guarantee of collective enrichment. These promises of benefits, however, are accompanied by various risks, and this presents a challenge to those in government dealing with technological development and its regulation. The guestion that arises is how the benefits of nanotechnology will be distributed. Some applications may offer universal benefits, such as health-improving or life-saving medical treatments, but nonetheless be inaccessible to the poor due to their costs. Nanotechnology has the potential to offer solutions to pressing social challenges - such as water treatment, energy generation and environmental remediation - but the divide between rich and poor countries will only grow if these applications are not broadly shared [4]. What needs to change, according to Jasanoff, is the *culture* of governance within nations as well as internationally; and for this we need to address not only the mechanics but also the substance of participatory politics. The issue, in other words, is no longer whether the public should have a say in technical decisions, but how to promote more meaningful interaction among policy-makers, scientific experts, corporate producers, and the public [3].

Classical risk analysis examines potential impacts on human health and safety. But numerous questions arise in its application to emerging fields of innovation such as nanotechnology. As regards to risk analysis, we may wonder, on the one hand, what characterizes the scientific aspects of the analysis, and on the other hand, how it is possible to go from scientific analysis to a judgment about acceptability. In the first part of this paper, we take as a case study the risk analysis of nanotechnology in order to examine the strengths and weaknesses of using a risk analysis approach for measuring social acceptability. In the second part of this paper, we concentrate on the role played by scientific analysis in the social sciences and the humanities, particularly in psychosocial approaches to risk perception used for evaluating social acceptability. This will allow us to identify the challenges of integrating an E3LS approach (ethical, environmental, economic, legal, and social) to these questions.

Risk measurement and assessment in the natural sciences: Diagnosis and limitations

The introduction of new technologies or scientific and technical advances bring unquestioned benefits, but as stated by Jasanoff, they also generate new uncertainties and failures with the result that doubt continually undermines knowledge, and unforeseen consequences confound faith in progress. Moreover, the risks of modernity often cut across social lines and operate as a great equalizer of

ISSN 1923-2799 2 / 12



classes [3]. It is no surprise that potential risks from nanotechnology are at the heart of concerns associated with its acceptability. If we turn to the scientific paradigm advanced by the natural sciences, we observe that risk analysis is based on knowledge obtained in order to explain a phenomenon, for example, the behaviour of matter or energy. Risk measurement and assessment are based on quantifiable and observable criteria, for which it is ideally possible to establish a cause and effect relationship using data, probabilities, and proofs.

In Canada, current guidelines and notifications under Environment Canada regulation related to new substances such as nanomaterials depends on the data about toxicity and ecotoxicity available for carrying out conclusive risk assessments. A risk assessment comprises four components: 1) identification of danger, 2) assessment of the dose-response relationship, 3) assessment of exposure, and 4) characterization of the risks (estimate, zero-risk, modeling, uncertainties) [5-6].

In the case of nanomaterials such as carbon nanotubes, a risk analysis serves to identify the possible effects on human health or ecosystems (danger component). In the first instance, it aims to identify normal pathways of exposure (oral, respiratory, cutaneous), to define the duration of exposure, the dose, and to determine the absorption, distribution, biotransformation, and excretion of the nanosubstance and finally its toxicokinetics. In traditional toxicological studies, the aim is to establish a correlation between the observed effects and the quantity of the product to which an organism has been exposed in order to establish a dose-response relationship. But the scientific risk analysis of some nanoparticles comes up against certain limitations.

For example, in toxicological risk analysis, usually we associate the quantity of product absorbed with the adverse effects observed. But when nanoscale and non-nanoscale particles of the same chemical composition are present in equal concentrations, the results obtained during exposure to nanometric particles (<100 nm) are different than with the macroscale form. Non-nanometric particles or a non-nanometric fraction are constituted of fine particles or macroscale size particles that are over 100 nm in size, so are separated using an impactor. The US Environmental Protection Agency (EPA) uses the term "macroscale material". Nanometric material is equivalent to "nanoscale material" as used in EPA documents [7-10].

In the case of nanosized titanium dioxide, the quantity of nanoproduct that one is exposed to is no longer the only relevant parameter that must be linked to the effects measured, and this clouds the issue somewhat. For example, studies appear to link the effects observed to certain parameters such as solubility, mass, concentration, size and granulometry, surface properties, form, porousness, degree of aggregation, impurities in the synthesized nanoparticle, and the nanoparticle's hydrophobic features. Our review of the literature reveals numerous toxic effects linked to nanoparticles [10-11]. Moreover, the Council of Canadian Academies has emphasized that it is difficult to determine risk, given our limited knowledge of the potential toxic effects linked to the various physical and chemical properties of nanomaterials [12].

The Inspector General at the EPA issued a report on December 29, 2011 concluding that the "EPA does not currently have sufficient information or processes to effectively manage the human health and environmental risks of nanomaterials" [13-14]. The report further outlined that despite having "statutory authority to regulate nanomaterials," the EPA did not have the appropriate "environmental and human health exposure and toxicological data" to effectively regulate research and products in the area of nanotechnology." Corley [13-14] argues that the EPA should consult more regularly with nanoscientists and nanomanufacturers to gather data for the science-based approach to policy making that has been outlined by the White House in President Obama's June 2011 memo [13-14].

The US Food and Drug Administration (FDA) also has responsibility for regulating nanomaterials; however, the FDA regulates products and not technologies. Thus, the FDA regulates nanotechnology on a product by product basis – and different categories of products (e.g., drugs versus cosmetics)

ISSN 1923-2799 3 / 12



can have varying levels of regulatory oversight. For example, drugs receive more rigorous oversight from the FDA than do dietary supplements, regardless of the presence of nanomaterials in either category. Concerns about the FDA's categories for products – and specifically discrepancies in levels of regulation across categories – have increased over time among the public and scientists [13,14].

The assessment of environmental risks and risks to human health from nanotechnologies is based entirely on the knowledge of those scientific experts who will be responsible for establishing risk management from the results of calculated or modeled risk. Accordingly, if the scientific analysis cannot conclude that there is known risk or cannot determine dose-response, the potential risk will be deemed acceptable for society unless there is proof to the contrary. Moreover, such scientific analysis is often claimed to be capable of presenting the ultimate criterion for the acceptability of a risk, whether low or high risk [14]. But in what way does this ultimate judgment rest on a scientific analysis? Risk analyses often assume that the criteria for social acceptability reside only on matter of facts and not values [14]. But it is the government oversight that has implicitly set the standard of acceptability by giving to scientific experts the role of risk analysis.

In the absence of confirmation of a potential or real risk because the necessary probative data are currently nonexistent, recourse is made to the concept of substantive equivalents. It is assumed that it is possible to assess a risk based on a level of equivalence, by establishing a possible link between a substance's physical or chemical characteristics and reference data derived from a substance whose harmlessness has been demonstrated by means of a full toxicological assessment [15]. Yet, nanometric silver does not have the same properties as micrometric silver; so how are we to establish its equivalence and the uncertainties associated with it, in the absence of an accurate guide to assessment criteria relating to the equivalence or non-equivalence of a given material? The Canadian Environmental Protection Act (CEPA) [16] places nanometric silver on the same basis as silver of standard dimensions, regardless of their differences with regards to their physical or chemical properties. The same is true for titanium dioxide of nanometric dimensions. Regulation under CEPA [16,17], and the New Substances Notification Regulations (Chemicals and Polymers), identify targeted substances with a Non-Domestic Substances List (NDSL). A nanosized substance whose structure or molecular arrangement does not differ from that of the standard-sized form of the same substance is considered to be an existing substance. Existing nanomaterials are not targeted by the Regulation and do not have to be declared. Further, fullerenes are not on the original NDSL and are considered to be a new substance [5,6,17,18].

In November 2008, the EPA decided to classify carbon nanotubes as a new product. This meant that carbon nanotubes would have to be approved for use, whereas previously this was not required because they have the same chemical composition as graphite, a substance that had long since been approved. The introduction of nanoparticles in sun protection creams was considered by the FDA as a reduction in the particle's dimension and not as an addition of a new particle and thus did not require a new approval [11]. It appears that the same approach is being applied to the addition of nanoparticles to foods [19]. Their equivalence is assumed until the weight of probative data demonstrates proven risk. Substantial equivalence is not an empirical fact; it is a construct that limits to risk analysis by association. But if other risks are identified, then the substance becomes a 'new' substance. To ensure that nanoscale materials are manufactured and used in a manner that protects against unreasonable risks to human health and the environment, the EPA is pursuing a comprehensive regulatory approach under the Toxic Substances Control Act [10]. This four-pronged approach includes: Premanufacture notifications; a Significant New Use Rule; an information gathering rule; and a test rule. The information gathering rule and the test rule apply to certain nanoscale materials that are already on the market. The Significant New Use Rule will ensure that nanoscale materials receive appropriate regulatory review by the EPA in order to evaluate the intended use of these nanoscale materials and to take action to prohibit or limit activities that may present an unreasonable risk to human health or to the environment [20,21].

ISSN 1923-2799 4 / 12



Currently, particular attention is being paid to long thin carbon nanotubes, which seem to have features similar to the long thin asbestos fibres that are responsible for the appearance of mesothelioma in humans [8-10,22,23]. By analogy, the graphene that forms the structure of nanotubes is rigid and may have a biopersistence like that of asbestos [22,23]. Toxic effects similar to those of asbestos on lungs, that is, similar to mesothelioma, have been observed in various animal studies and have raised significant concern in the international scientific community. For the time being, however, these results cannot be extrapolated to humans [12,25,26]. Given this context of incomplete data on exposure and toxicokinetics for the majority of nanometric substances, it seems impossible to quantify the risks to workers in most situations, as reported by the Quebec-based *Institut de recherche Robert-Sauvé en santé et sécurité du travail* (IRSST) [11,27]. The three main federal agencies in the US that have taken on the task of developing nanotechnology regulations are the EPA, the FDA, and the Occupational Safety and Health Administration (OSHA); in addition, the National Institute of Occupational Safety and Health (NIOSH) – part of the Centers for Disease Control and Prevention (CDC) – has served a strong role in nanotechnology research and guideline development for workers exposed to nanomaterials [28].

What can we conclude about the strengths and limitations of scientific assessment of the acceptability of products emerging from the nanotechnologies?

- 1. Scientific assessment is based on facts that are subject to measurement, calculation, and estimation, that determine the nature and intensity of risks to human health and ecosystems. It can only establish known or real risks according to the limits of the methods used.
- 2. Scientific assessment cannot in principle reach a conclusive judgment regarding the acceptability of a risk; it can only inform the public about the intensity of the risks to which that public is potentially exposed.

But in delegating risk analysis to scientific experts, government oversight has implicitly accepted that the criteria for social acceptability are simply a matter of quantification [29-31]. The pact between government and science occults the imbedded value judgments behind quantification. The first value judgment concerns the degree of proof needed to conclude that there is a risk. Regulators act only on proven and known risks. Why not act when risks are probable as often demonstrated by scientific controversies? This is why we have seen in Europe appeals to the Precautionary principle. What is being acknowledged is the necessity to act even if there is uncertainty around the causal relationship. The second value judgment concerns the degree of risks that is socially acceptable. Only high level risks are taken into account to justify governmental action and these high risks are determined by scientific analysis. It is one thing to establish the level of a contaminant emitted from a source that a human can be potentially exposed to, but it is completely different to assess the cumulative effect of different sources of a contaminant in daily exposure. With this pact between natural sciences and regulation, the contributions of the social sciences and humanities are considered unimportant in determining the social acceptability of risks. Their role has been relegated to studies on risk perception and the social acceptance of risks [3,30].

Measures of risk perception and the assessment of social acceptability: Diagnosis and limitations

Since the psychosocial work of Slovic [34,36,37,39], those disciplines in the social sciences and humanities with an experimental nature have sought, like the natural sciences, to establish clear links between certain social factors and individuals' acceptance of risk. These "analyses of risk perception" seek to determine what factors influence people to accept a risk in performing an activity or buying a product. Such studies play a significant role in society when it comes to the social acceptance of new technologies. To the extent that it is possible to have knowledge of these social factors, such

ISSN 1923-2799 5 / 12



knowledge can be used as part of a strategy for developing new technologies so that they will receive public acceptance. As well, knowledge of this kind can be used in communicating the risks associated with technological development.

There exist two theoretical approaches to understanding human actions: the *explanatory approach*, which aims to identify factors that influence risk perception and the acceptability of risk; and the *descriptive approach*, which calls upon an understanding of variability in risk perception and acceptability based on a set of factors that come into play in individual analyses of impacts and acceptability [31,32].

Explanatory studies of a psychosocial (behavioural) nature examine individual psychological development and its interactions with a given social environment, and aim to account for risk perception and acceptability based on individual psychological factors such as living habits, personality traits, personal preferences, proximity to the risk, etc. [33,34]. Studies of a sociological kind (studies of social movements) that examine the social impact of representations (thoughts) and behaviours (actions) aim to account for risk perception and acceptability based on such sociological factors as disciplinary training, national culture, and confidence in systems of social regulation. These studies strive either to provide, based on factors of acceptability, explanations for the public's perception of certain risks in general (their greater or lesser degree of riskiness) or to define the links between the extent of a risk and perceptions of the acceptability of a technology, such as nanotechnologies.

Table 1 presents 19 factors that influence an individual's judgment about the acceptability of a technology. These psychometric factors are frequently used in studies of risk perception by Slovic and other risk perception researchers, and by different organizations around the world [34-37]. Each factor is to be read as constituting a graduated scale, going from maximum safety to maximum risk. For example, if I deliberately choose to live in a zone close to electrical pylons, I may not perceive the risk in the same way as I would if a company planned to put up a new power line in the area in which I am currently living.

Table 1. Factors of Predictability and Acceptability

Safe ++	Risk++
Voluntary exposure	Involuntary exposure
Natural	Industrial (artificial)
Familiar	Unfamiliar
Comprehensible	Incomprehensible
No media attention	Media attention
Benefits	No benefits
Equity	Inequity
Affects all people	Affects children
Unknown victims	Targeted victims
Individually controlled	Controlled by others
No dread-filled apprehension	Dread-filled apprehension
Few observable effects	Catastrophic
Moral	Amoral
Ordinary accident	Memorable accident
Certainty	Uncertainty
Long-term effects	Short-term effects
Scientific certainty	Scientific uncertainty
Reversible effects	Irreversible effects
Avoidable	Not avoidable

ISSN 1923-2799 6 / 12



Generally, the factors that tend to determine the level of concern are dependent on both the positive and negative effects a technology may have, and the values or emotions of an individual. Their evaluation of risk takes place in a complex decision-making process where objective and scientific knowledge is not the key factor in risk assessment or acceptance leading to differences in opinion about the acceptability of a risk [38,39].

One of the challenges has to do with regulation and the need to (re)build trust in science. Like with the debate over genetically modified (GM) foods, labeling is likely to become a key issue with nanotechnology. Consumers in North America and Europe rejected and boycotted GM foods; they had little confidence in the technology that was introduced, as they felt that the (economic) benefits were all going to the promoters. Consumers decided to control the health risks by choosing not to eat GM foods; they would not hand over the control to the government or GM foods promoters, because they did not trust them [40]. A dialogue with the public is essential. We need to communicate probing scientific data, discuss potential environmental, economic, ethical and health issues in the case of nanotechnology applications if we do not want to repeat the controversies related to the introduction of GM foods into the market [40].

In light of these factors, we can see that, just like GMOs, nanotechnologies present certain significant risk perception factors: "Involuntary exposure", "Industrial (artificial)", "Unknown", and "Scientific uncertainty". What is it that leads a person finally to decide to adopt a product that incorporates nanotechnologies? It is very hard to predict these behaviours, given that in the course of arriving at a judgment of acceptability, an individual may assign different weight to these 19 factors.

Clearly these sociological studies on perceptions of the risks and acceptability of nanotechnology can reveal the degree of acceptance a technology may incur at a given moment and establish trends towards acceptance for the medium or long term. Nevertheless, industrial or environmental incidents such as Bhopal or Chernobyl that appear to discredit a given technology can alter the perception of risk and acceptability [33,39]. The level of acceptance calculated depends on social context, and context has only to change for the public to go from acceptance to rejection.

Other psychosocial studies have dealt with factors that make it possible to discriminate between scientific experts' risk perception and that of ordinary people. Table 2 shows the ten factors that are taken into account by Siegrist [33].

Table 2. Laypeople's and Experts' Perception of Nanotechnological Hazards

Risk Dimension Study

- 1. Probability of health effects
- 2. Dreaded risks
- 3. Voluntary exposure to risk
- 4. Exposed individual's level of knowledge about the risk
- 5. Secondary health effects
- 6. Personal control over risk
- 7. Confidence in the regulatory agencies
- 8. Development is ethically acceptable
- 9. Benefits to the public
- 10. Opinion regarding the technologies offered

There is an assumption that is widespread in scientific and government circles, to the effect that the "ordinary person" harbours irrational fears about the risks of technology, whereas scientists bring objective judgment to bear on risk [2,41-44]. It is thus no surprise that in this table, four factors relate to perceptions about impacts on health.

ISSN 1923-2799 7 / 12



These analyses also take into account four other factors, including freedom to choose risk and opinions regarding the technologies (whether one is a technophile or a technophobe) [45,46]. The last of these factors, confidence in the regulatory agencies, may seem surprising at first glance. However, it is sufficient to consider the role that governments assign to experts in determining risks and their acceptability to recognise the significance of this factor. Is should not be surprising, in light of the mad cow and contaminated blood episodes, that a segment of the public is dubious about the trustworthiness of regulatory agencies. Moreover, given the limitations of scientific risk analysis, and faced with the scientific uncertainty that surrounds nanotechnologies, it is legitimate to wonder whether we should not revisit the model of the cognitive deficit between experts and ordinary people that is assumed in these analyses: this would take into account the significance of the way scientific uncertainty plays out in our individual and social choices. Brown [47] presents a new cognitive deficit model that is emerging with the development of the new technologies, this one between experts. This new deficit model relates to gaps in scientific knowledge or in probative data and the uncertainty that flows from these.

What can we conclude from the role played by those areas of the humanities and social sciences with an empirical approach to studying social acceptability? These approaches to analysing risk perception take into account that risk perception is emotional and therefore must be understood in order to have a rational approach to risk acceptance. The main objective is to understand the emotional factors that may hinder the acceptance of products and technologies in order to act upon them. This approach is coherent with the pact between science and regulation where technological development is considered only as market driven. The final judge of social acceptability of a product is the consumer or end user: if he buys it then he accepts it. Social acceptance is a wager of social acceptability [3,48].

Conclusion

Ever since states began to intervene to ensure a degree of public safety by controlling certain risks by means of government agencies, they have conferred a heavy responsibility on scientific analysis: not just the responsibility for identifying and measuring risks, but also for determining their social acceptability. In light of the introduction of GMOs in consumer products and now nanotechnologies, the question must be asked: What can science really measure when it comes to the social acceptability of a technology? Our aim here has been to show that government oversight of nanotechnology, as with any other technology, has delegated to scientific experts the value judgment on social acceptability. The final judgment is based on the scientific methods of risk assessment (known risk, substantive equivalence, analogy). Social acceptance of risk has also been the realm of empirical risk dimension studies focused on risk perception. By knowing the supposed variables of risk perception and acceptability, communication strategies can address both risk management and technology acceptance. The empirical approach assumes that science can measure the good since it can manage risks in society. Government oversight of technology has hidden the value judgments imbedded in the weighing of social benefits against social and environmental harms and effects on individual health.

The International Risk Governance Council (IRGC) is an independent foundation based in Switzerland whose purpose is to help in the understanding and management of important, emerging global risks. It does so by identifying and drawing on the best scientific knowledge and – by combining it with the understanding of experts in the public and private sectors – developing fact-based risk governance recommendations for policy makers. In 2005, the IRGC decided to address the risk governance of nanotechnology as an emerging technology that both offers potentially enormous benefits and presents significant challenges to government, industry and society at large. The IRGC's project is to integrate risk/benefit analysis on environmental, health, and safety issues with ethical, legal and social considerations and was made possible through financial support provided by the US EPA and Department of State, the Swiss Agency for Development and Cooperation and the Swiss Reinsurance Company (Swiss Re) [4].

ISSN 1923-2799 8 / 12



The IRGC has identified three significant deficits. First, reliable technical data on risks is not yet available; second, the public does not know enough about the novel technology or risks to have an opinion; and third, few studies have been conducted to take into account and evaluate public preoccupations. These deficits will make judgments about acceptability or tolerability difficult. If the knowledge within scientific/industrial communities is not appropriately shared with regulatory agencies, civil society and the public, risk perception/management may not be based on the best available knowledge, innovative opportunities may be lost, and public confidence in transparency and accountability may erode. In order to develop a system that will both manage risks and be acceptable to the public, policy makers must first define and characterise the technology in the context of current strategies for dealing with anticipated risks and the concerns about the technology that are being raised by society. The IRGC stresses that it is important to better understand what impact the technology is likely to have on society, by conducting a thorough assessment of the technical risks and evaluating how the public perceives those risks. Policy makers must also evaluate whether those risks are acceptable according to societal values (acceptability judgement), and then design a risk management system that evaluates all these inputs through a multi-stakeholder dialogue and decision-making [4].

The Commission de l'éthique, de la science et de la technologie du Québec (CEST) was asked in 2004 by the Ministère du Développement économique, de l'Innovation et de l'Exportation to present a position statement to help elaborate a strategic approach for the development of nanotechnologies in order to take into account ethical and social aspects related to the introduction of nanotechnologies in national and international markets [2]. In its examination of the ethical issues of nanotechnology, the CEST first noted that the responsible management of nanotechnology development turns on three fundamental premises: establishing a nomenclature specific to nanoscience and nanotechnology, developing nanometrology to establish international standards, and continuing to conduct research and disseminate research findings [2]. After explaining these premises, the CEST first raised a number of ethical concerns related to nanotechnology-derived products, specifically those associated with health, the environment, and safety. It then explored the broader ethical questions raised by the development of nanotechnology as well as other emerging technologies, such as biotechnology and genomics. The issues raised included governance, economic activity, and citizenship. The CEST argued that it was important to be aware of all of these concerns and to intervene as early as possible so that these emerging technologies can realize their potential to the benefit – and not the detriment – of society and the public. The CEST's position statement comprises the assessment of scientific, legal and ethical implications of nanotechnology. In its ethical assessment of nanotechnology, the CEST is upholding principles such as the protection of health and the environment, as well as respect for many values such as dignity, liberty, the integrity of the person, respect for the person, quality of life, respect for privacy, justice and equity, transparency and democracy [2].

The approaches described by the CEST and IRGC are examples of the types of comprehensive assessments needed to address the concerns associated with the introduction of novel technologies in our society. Within the broader context, then, bioethics as a reflective practice of our activities is now addressing the fundamental question of the ethical dimensions of our technological development and opens a new challenge for interdisciplinary approaches in the humanities and social sciences for clarifying ways to ensure a responsible development of novel technologies [49], such as GMOs, nanotechnology and robotics.

List of References

- 1. Faden, R. (2004). <u>Bioethics: A field in transition</u>. *Journal of Law, Medicine & Ethics*, 32(2): 276-278.
- 2. Gouvernement du Québec, Commission de l'éthique de la science et de la technologie. (2006). Avis Éthique et nanotechnologies : Se donner les moyens d'agir. Québec, QC.

ISSN 1923-2799 9 / 12



- 3. Jasanoff, S. (2003). <u>Technologies of humility: Citizen participation in governing science</u>. *Minerva* 41, 223-244.
- 4. International Risk Governance Council. (2007) Policy Brief, <u>Nanotechnology Risk Governance:</u> Recommendations for a global, coordinated approach to the governance of potential risks. Geneva.
- 5. Government of Canada, Environment Canada. (2007). <u>New Substances Program Advisory Note 2007-06: Requirements for nanomaterials under the New Substances Notification Regulations (Chemicals and Polymers)</u>. Ottawa, ON.
- 6. Government of Canada, Environment Canada. (2005). <u>Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers</u>. Ottawa, ON.
- 7. Maynard, A.D. & Kuempel, E.D. (2005). <u>Airborne nanostructured particles and occupational</u> health. *Journal of Nanoparticle Research*, 7: 587-614.
- 8. Oberdörster, G.; Maynard, A.; Donaldson, K.; Castranova, V.; Fitzpatrick, J.; Ausman, K.; Carter, J.,; Karn, B.; Kreyling, W.; Lai, D.; Olin, S.; Monteiro-Riviere, N.; Warheit, D.; Yang, H. (2005). Principles for characterizing the potential human health effects from exposure to nanomaterials: Elements of a screening strategy. Particle and Fibre Toxicology, 2(8): 8-42.
- 9. Oberdörster, G.; Oberdörster, E.; Oberdörster, J. (2005). Nanotoxicology: An emerging discipline evolving from studies of ultrafine particles. Environmental Health Perspectives, 113(7): 823-839.
- 10. Oberdörster, G.; Stone, V.; Donaldson, K. (2007). <u>Toxicology of nanoparticles: A historical perspective</u>. *Nanotoxicology*, 1(1): 2-25.
- 11. Institut de recherche Robert-Sauvé en santé et sécurité du travail. (2010). <u>Les nanoparticules de synthèse : Connaissances actuelles sur les risques et les mesures de prévention en SST</u>, Rapport IRSST # R-646 (2nd Edition). Montréal, QC.
- 12. Council of Canadian Academies (2008). <u>Small is Different: A Science Perspective on the Regulatory Challenges of the Nanoscale</u>. Ottawa, ON.
- 13. Corley, E.A; Youngjae, K; Dietram, A.S. (2013). <u>The current status and future direction of nanotechnology regulations: a view from nano-scientists</u>. *Review of Policy Research*, 30(5): 488-511.
- 14. U.S. Environmental Protection Agency Office of the Inspector General. (2011). *EPA Needs to Manage Nanomaterial Risks More Effectively*. (Report No. 12-P-0162). Washington, D.C.
- 15. Chenel, V. (2011). <u>Analyse du principe d'équivalence en substance en tant que concept directeur pour l'évaluation de l'innocuité des végétaux génétiquement modifiés</u>. M.A. Thesis, Sherbrooke: Université de Sherbrooke.
- 16. Government of Canada. (1999). Canadian Environmental Protection Act. Ottawa, ON.
- 17. Government of Canada. (2005). *New Substances Notification Regulations (Chemicals and Polymers)*, S.O.R./2005-247. Ottawa, ON.
- 18. Government of Canada, Environment Canada. (2007). *Notification. Evaluating New Substances*. Ottawa, ON.
- 19. Government of Canada, Environment Canada. (2007). <u>Domestic Substances List CEPA Section 71 Notices</u>. Ottawa, ON.
- 20. Mantovani, E.; Porcari, A.; Meili, C.; Widmer, M. (2009). *FramingNano Report: Mapping Study on Regulation and Governance of Nanotechnologies*. Rome, Italy: AIRI/Nanotec IT, The Innovation Society.
- 21. US Environmental Protection Agency. (2012). <u>Control of Nanoscale Materials under the Toxic Substance Control Act</u>. Washington, D.C.
- 22. Donaldson, K.; Murphy, F.A.; Duffin, R.; Poland, C.A. (2010). <u>Asbestos, carbon nanotubes and the pleural mesothelium</u>: A review of the hypothesis regarding the role of long fibre retention in the parietal pleura, inflammation and mesothelioma. *Particle and Fibre Toxicology*, 7(5): 1-17.
- 23. Krow, C.M. (2012). Nanotechnology and asbestos: Informing industry about carbon nanotubes, nanoscale titanium dioxide, and nanosilver. *IEEE Nanotechnology Magazine*, 6(4): 6-13.

ISSN 1923-2799 10 / 12



- 24. Shvedova, A.A.; Kisin, E.R.; Mercer, R.; Murray, A.R.; Johnson, V.J.; Potapovich, A.I.; Tyurina, Y.Y.; Gorelik, O.; Arepalli, S.; Schwegler-Berry, D.; Hubbs, A.F.; Antonini, J.; Evans, D.E.; Ku, B.K.; Ramsey, D.; Maynard, A.; Kagan, V.E.; Castranova, V.; Baron, P. (2005). <u>Unusual inflammatory and fibrogenic pulmonary responses to single-walled carbon nanotubes in mice</u>. *American Journal of Physiology Lung Cellular and Molecular Physiology*, 289(5): 698-708.
- 25. Handy, R.D. & Shaw, B. J. (2007). <u>Toxic effects of nanoparticles and nanomaterials:</u>
 <u>Implications for public health, risk assessment and the public perception of nanotechnology</u>. *Health Risk & Society*, 9(2): 125-144.
- 26. Magrez, A.; Kasas, S.; Salicio, V.; Pasquier, N.; Seo, J.W.; Cello, M.; Catsicas, S.; Schwaller, B.; Forro, L. (2006). Cellular toxicity of carbon-based nanomaterials. Nano Letters, 6(6): 1121-1125.
- 27. Institut de recherche Robert-Sauvé en santé et sécurité du travail. (2008). *Les effets sur la santé reliés aux nanoparticules*. Rapport IRSST # R-558 (2nd Edition). Montréal, QC.
- 28. Marchant, G.E.; Sylvester, D.J.; Abbott, K.W. (2007). Nanotechnology regulation: The United States approach. In G. Hodge, D. Bowman, & K. Ludlow (Eds.), *New Global Frontiers in Regulation: The Age of Nanotechnology* (pp. 189-211). Cheltenham, UK: Edward Elgar Publishing.
- 29. Jasanoff, S. (1990). *The Fifth Branch: Science Advisers as Policymakers*, Cambridge, Mass.: Harvard University Press.
- 30. Jasanoff, S. (2007). <u>Designs on Nature: Science and Democracy in Europe and the United States</u>. Princeton University Press.
- 31. Jasanoff, S. (2011). <u>Constitutional moments in governing science and technology</u>. *Science Engineering Ethics*, 17(4): 621-638.
- 32. European Commission. (2012). Commission Staff Working Paper, Types and uses of nanomaterials, including safety aspects. Accompanying the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the Secondary Regulatory Review on Nanomaterials. Brussels.
- 33. Siegrist, M.; Keller, C.; Kastenholz, H.; Frey, S.; Wiek, A. (2007). <u>Laypeople's and experts' perception of nanotechnology hazards</u>. Risk Analysis, 27(1): 59-69.
- 34. Slovic, P. (1999). <u>Trust, emotion, sex, politics, and science: Surveying the risk-assessment battlefield</u>. *Risk Analysis*, 19(4), 689-701.
- 35. Bontempo, R.N.; Bottom, W.P.; Weber, E.U. (1997). <u>Cross-cultural differences in risk perception: A model-based approach</u>. *Risk Analysis*, 17(4): 479-488.
- 36. Slovic, P.; Finucane, M.L.; Peters, E.; MacGregor, D.G. (2004). Risk as analysis and risk as feelings: Some thoughts about affect, reason, risk, and rationality. Risk Analysis, 24(2): 311-322.
- 37. Slovic, P.; Malmfors, T.; Krewski, D.; Mertz, C.K.; Neil, N.; Bartlett, S. (1995). <u>Intuitive toxicology</u>. II. Expert and lay judgments of chemical risks in Canada. *Risk Analysis*, 15(6): 661-675
- 38. Sandman, P.M. (1994). *Quantitative Risk Communication: Explaining the Data* [DVD]. Newton Centre, MA: Sandman.
- 39. Covello, V.T.; Sandman, P.M.; Slovic, P. (1988). *Risk Communication, Risk Statistics, and Risk Comparisons: A Manual for Plant Managers*. Washington, DC: Chemical Manufacturers Association.
- 40. European Agency for Safety and Health at Work (EU-OSHA). (2012). <u>Risk Perception and Risk Communication with Regard to Nanomaterials in the Workplace</u>, European Risk Observatory, Literature Review, EU-OSHA, Luxembourg.
- 41. David, K. & Thompson, P.B. (2008). What can Nanotechnology learn from Biotechnology?

 Science and Ethical Lessons from the Debate over Agrifood Biotechnology and GMOs.

 Academic Press (Elsevier), Oxford (UK).
- 42. Davis, J.J.; Coleman, K.S.; Azamian, B.R.; Bagshaw, C.B.; Green, M.L.H. (2003). <u>Chemical and biochemical sensing with modified single walled carbon nanotubes</u>. *Chemistry A European Journal*, 9(16): 3732-3739.

ISSN 1923-2799 11 / 12



- 43. Houdebine, L.-M. (2002). <u>La transgénèse et ses applications médicales</u>. *Pathological Biology*, 50(6): 380-387.
- 44. Royal Society (The) & The Royal Academy of Engineering (2004). *Nanoscience and Nanotechnologies: Opportunities and Uncertainties*. London, UK.
- 45. Boisseau, P., & Loubaton, B. (2011). Nanomedicine, nanotechnology in medicine. Comptes Rendus Physiques, 12(7): 620-636.
- 46. Jones, R. (2009). It's not just about nanotoxicology. Nature Nanotechnology, 4: 615.
- 47. Brown, S. (2009). The new deficit model. Nature Nanotechnology, 4: 609-611.
- 48. Boissy, P.; Chenel, V.; Patenaude, J. (2014). L'acceptabilité et l'adoption de la télémédecine par les personnes atteintes d'affections de longues durées : perspective sur les enjeux technologiques, sociaux et éthiques. *Revue de l'Electricité et de l'Electronique* (REE), No spécial: Les applications TIC à la lutte contre la dépendance, 24-32.
- Patenaude, J.; Legault, G.-A.; Beauvais, J.; Bernier, L.; Béland, J-P.; Boissy, P.; Chenel, V.; Daniel, C.-E.; Genest, J.; Poirier, M.-S.; Tapin, D. (2014). <u>Framework for the analysis of the impacts of nanotechnologies and their ethical acceptability: basis of an interdisciplinary approach to assess novel technologies</u>. *Science and Engineering Ethics*. DOI 10.1007/s11948-014-9543-y, Epub 13 April 2014.

ISSN 1923-2799 12 / 12