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Comparative, collaborative, and integrative risk governance for emerging technologies

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Abstract

Various emerging technologies challenge existing governance processes to identify, assess, and manage risk. Though the existing risk-based paradigm has been essential for assessment of many chemical, biological, radiological, and nuclear technologies, a complementary approach may be warranted for the early-stage assessment and management challenges of high uncertainty technologies ranging from nanotechnology to synthetic biology to artificial intelligence, among many others. This paper argues for a risk governance approach that integrates quantitative experimental information alongside qualitative expert insight to characterize and balance the risks, benefits, costs, and societal implications of emerging technologies. Various articles in scholarly literature have highlighted differing points of how to address technological uncertainty, and this article builds upon such knowledge to explain how an emerging technology risk governance process should be driven by a multi-stakeholder effort, incorporate various disparate sources of information, review various endpoints and outcomes, and comparatively assess emerging technology performance against existing conventional products in a given application area. At least in the early stages of development when quantitative data for risk assessment remain incomplete or limited, such an approach can be valuable for policymakers and decision makers to evaluate the impact that such technologies may have upon human and environmental health.

Keywords

Synthetic biology; Biotechnology; Nanotechnology; Governance; Risk Assessment; Policy; Decision analysis; Regulations

Introduction

Emerging technologies, including the key enabling technologies, promise revolutionary benefits for humanity and the natural environment. However, some of them present uncertain risks along with uncertain or untested mechanisms for observation and monitoring. For example, the consequences of deploying certain applications deriving from nanotechnology or synthetic biology are yet very uncertain (especially if considering issues of biosafety and biosecurity) (König et al. 2016; Mukunda et al. 2009). Furthermore, as scientists and industry may not agree in either methods for assessing potential risks and consequences and data, various interpretations of the science may emerge, together with ambiguity and possible divergent perceptions of risks and benefits associated with the technologies (Renn et al. 2011; Falkner and Jaspers 2012). Next to technologies that have the capacity to fundamentally alter or even synthesize living organisms in complex socio-ecological systems and involve challenging issues of values and ethics, some emerging technologies may enhance applications of existing technologies involving new materials and processes (e.g., graphene or hydraulic fracturing) (Small et al. 2014; Linkov et al. 2014).

The pace of technology development is increasing, and will need regulators and other key stakeholders in industry and academia to continue to increase to meet increasing challenges to the status quo and to sustainability (Linkov et al. 2018). In part, this has led to public suspicion, sometimes mistrust, often unease, increasing vulnerability of objective valuations to misclaims made by interest groups and misguided individuals, tainting the well of public and consumer interest. As our world continues to develop technologically, so too must our ability to deal with a heterogeneity of knowledge and level of uncertainties (Scott-Fordsmand et al. 2014; Subramanian et al. 2014; Kuzma et al. 2008; Calvert and Martin 2009). Experts, policymakers, and regulators should design prospective, adaptive, and knowledge-based benefits and risks assessments and governance processes (Tait 2012).

Current practice relies upon risk assessment to quantify the risks of materials and technologies and upon management to control risks, typically by limiting exposure of humans and environmental receptors, are limited to acceptable levels. For mature and well-defined technologies, the current risk assessment/management approach has a long history of delivering valuable insight to regulators regarding how to establish best practices of policy and governance for various fields (Malloy et al. 2016; Seager et al. 2017; Shatkin 2008).

However, three features of the conventional approach hinder its effective application to emerging technologies. First, it typically requires substantial quantitative data regarding hazards, consequences, and exposure regarding the material or technology in question (Rycroft et al. 2018; Shatkin et al. 2016). Such data are often limited or unavailable due to the unique physical qualities of new materials as, for example, the unique and uncertain human health hazards that might occur within synthetic biology development (Epstein and Vermeire 2016). Second, it assumes that the potential consequences of using novel materials and technologies can be comprehensively cataloged (Hristozov et al. 2012, 2016). Emerging technologies such as synthetic biology and artificial intelligence intersect with complex biological, ecological, and sociotechnical systems, raising the specter of cascading effects and unpredictable outcomes. Given the limitations of current approaches to facilitate risk assessment of highly uncertain emerging technologies, a different approach is strongly desirable to balance development of innovative technologies with responsible use (see additional discussion for biotechnology in Vallero 2015). Finally, an innovation often challenges several policy areas that are used to operating in silos, whereas innovation may require more flexible, adaptive, and integrated approaches.

Risk governance for emerging technologies

In this context, it is worth considering the recommendations from the International Risk Governance Council, which describes that risk governance sits as the confluence of all analyses and actions relative to the development of a given technology (Renn 2005). This includes (i) framing the technology in the context of its possible deployment and applications, benefits, and risks for various stakeholders, (ii) assessing those benefits and risks (including assessment of perception and concerns), (iii) evaluating other aspects that decision makers will consider before making decisions, such as the existence of specific economic, political or societal interests, or also certain issues of national security or ideology, that must be considered, (iv) identifying various risk management options, which can be combined to establish a strategy for the development (or not) of the technology, and (v) communicating about risk and benefits. As will be described below, the advantages of such a risk governance approach for emerging technologies are driven by several key factors, including the following: the collaborative nature of such an approach amongst multiple pertinent stakeholders, its ability to integrate various sources of qualitative, semi-quantitative, and quantitative information to assess such technologies, and the various criteria of risk, cost, benefit, social implications, and other considerations that are inherently valuable to any such governance decision.

A comprehensive approach to potential risks involved in the development of emerging technologies requires a collaborative effort among different stakeholders, as the problem-solving capacities of the individual actors within government, industry, academia, and civil society are limited and often unequal to the major challenges of governing uncertain risks (Kuzma 2015). Therefore, there is a need to engage these stakeholder groups in a continuous dialogue and coordinate a profusion of roles, perspectives and goals in the process of the development and implementation of safe guidelines and good practices consistent with recent scientific advancements (Schmidt et al. 2009). Such guidance may arise in the form of formal legal requirements, such as new laws or regulatory instruments, or less formally via voluntary participation within multi-party codes of conduct.

A comparative approach in risk governance is needed to address emerging technologies of this sort and to prove an environment that fosters responsible innovation (Renn et al. 2011; Linkov et al. 2013). This evolution in risk governance must overcome both institutional momentum and vested interests dedicated to the continuance of traditional approaches, a step outside our comfort zones effecting change in how we think about risk and its governance. Comparative risk governance differs from the conventional approach in several ways. First, it eschews a narrow focus on identifying and controlling quantifiable effects of new materials or technologies taken by conventional risk assessment and management (Canis et al. 2010). The approach should explicitly identify and address the trade-offs that must be made, by assessing the risks involved in a proposed new activity against other feasible alternatives, including safer designs that avoid or minimize risk by reducing the inherent hazard or exposure of the emerging material or technology itself. This idea is visually represented in Fig. 1, where disparate criteria such as cost, benefit, risk, and social utility are analyzed via relevant utility functions and then aggregated via a semi-quantitative metric. This is what the US chemical regulation aims to do when it pursues three policy objectives for assessing and regulating (i) the chemical effects on human health and the environment, (ii) the benefits of use and the availability of substitutes, and (iii) the effects on the economy and innovation. Further, the relation between trade-off analysis and sustainability has been considered in the US National Research Council report on Sustainability at the US Environmental Protection Agency (EPA) (NRC 2011).

Second, recognizing that comprehensive quantitative data will be either unavailable or involve too much uncertainty to be reliable, governance should not require the collection of absolute measures of acceptable risk. Instead, governance should be based on collaboration between policymakers, regulators, industrial developers, workers, experts, and representatives of society from multiple disciplines, in a manner that establishes safe guidelines and best practices consistent with recent scientific advancements and expected new developments (Renn 2005; Trump et al. 2017; Kuiken et al. 2014). Such effort requires assessment across a material's life cycle, including insight from laboratory researchers and workers involved in the initial production of a material who are particularly at risk, to safe containment and shipping, to consumer product safety, to proper end-of-life disposal.

Current practices for emerging technologies must emphasize proactive and adaptive approaches to risk management and governance whenever risk assessment is hindered by limited availability of experimental data and the state of development (Oye 2012; Tait 2009; Trump 2017; Cummings et al. 2017). Comparative approaches driven by expert opinion and stakeholder engagement may help overcome at an early stage the limitations of quantitative risk assessment approaches through:

i. an impacts analysis of technological substitution based on:

   a. a critical review of the risks potentially associated with an application of an emerging technology against a conventional technological application that it would replace,

   b. a review of how such a novel technology produces further economic, health, or social benefits and costs in lieu of the conventional alternative (Mohan et al. 2012),

   c. a review of the trade-offs between risks and between risks and opportunities, and an explicit and transparent communication about those trade-offs (Blaunstein et al. 2014; Yatsalo et al. 2016),

   d. considerations of other risk factors including social perception and the engagement of the public in an evaluation and decision-making process (Palma-Oliveira et al. 2017; Siegrist et al. 2007; Trump et al. 2015), as well as cost of development that may help or hinder continued research and maturation of the emerging technology, and

ii. a participative and deliberate decision process to monitor risks and impacts of the new technology and integrate feedback into review of initial assessment (and subsequent management decisions) (Cummings and Kuzma 2017).

This is a realistic approach to reviewing the risks and benefits associated with an emerging and potentially disruptive technology in a manner that accounts for both physical (e.g., health and environment), economic, and social outcomes. The approach requires the willingness of the public and private actors and their engagement on knowledge-based adaptive assessment and decision processes where new expert judgment and stakeholder opinions data are analyzed and integrated as it arises (Linkov et al. 2011; Wood et al. in press). If necessary, best practices for technology governance would shift, based upon experimentation and testing and integrating feedback into revisions of the early decisions. Combining risk characterization with quantitative risk assessments require new techniques such as integrating narratives in scenario construction, using stakeholder engagement methods for calibrating expert judgments and applying recursive methods of data generation and analysis such as cross-balance impact analysis (Mandel and Marchant 2014).

Expert elicitation has been a valuable tool for potential environmental risks associated with nanotechnologies (Trump et al. in press). The National Research Council Red Book provides a risk framework for integrating empirical information with scientific judgment (NRC 1983;

Small et al. 2014). Indeed, the U.S. has followed this framework for numerous comparative risk applications, including regulation of particulate matter, nuclear waste, and food safety. Uncertainty is particularly large when assessing the life cycles of the vast majority of chemical compounds (Csiszar et al. 2016; Malloy et al. 2016; Seager and Linkov 2008). Since risk is a function of both hazard and exposure, much of the uncertainty associated with new chemicals entering the marketplace is due to the paucity of reliable information regarding the toxicity, and even greater uncertainty about the frequency and extent of an individual's contact with a specific compound given typical utilizations of that chemical (e.g., cosmetics, cleaning products, etc.) and individuals' use patterns compared to the intended use (Grieger et al. 2009; Wilson and Schwarzman 2009; Ferson and Sentz 2016; Linkov et al. 2017).

Discussion

Such efforts to develop new approaches for governing risks involved in emerging technologies must adopt a holistic perspective of the elements of technology governance. Alongside analytical components of risk assessment, other elements should include active horizon scanning and anticipatory review of emerging technologies, methodological aspects of safe-by-design approaches, effective risk communication and engagement with publics on key issues regarding traditional technology risk (e.g., health implications), as well as non-traditional risk considerations (e.g., ethical/moral considerations, cost, social impact) (Gronvall 2018). This process should also work within the given framework of the jurisdiction at hand, where risk governance in the United States, European Union, and elsewhere must account for the unique institutional, political, and research environments that influence regulatory decision making and policymaking (Malsch et al. 2018).

Ultimately, a risk governance approach for emerging technologies will assist with the risk-based approaches utilized by regulators and other risk assessors by accounting for a broad view of comparative assessment of emerging and conventional technologies (Tervonen et al. 2009). The approach will help with early-stage guidance for emerging technologies like synthetic biology by generating information about expert perceptions of technological risk, benefit, time to development, ethics, cost, and various other considerations that all influence how a technology may assist with economic, medical, environmental, and social wellbeing (Bates et al. 2015). Such an approach inherently requires a collaborative effort between various stakeholders for an emerging technology's governance, where input from industry, workers, academia, government, non-governmental institutions, and civil society at large will not only help evaluate the benefits and risks of an uncertain technology, but also address public wariness to adopt and utilize such technologies as they enter the marketplace.

This approach may open new opportunities to improve public trust on regulation as informed guidance. A significant dividend of the approach is to facilitate an anticipatory and adaptive style of governance for emerging technologies, where governments would be increasingly able to perceive the impacts and applications of enabling and emerging technologies on the horizon, while iteratively improving risk assessment for such technologies as quantitative guidance becomes available (Mandel and Marchant 2014; Trump et al. 2017). This approach is expected to offer a broader set of evidence-based considerations than traditional risk assessment/management, supporting democratic decision making on governing the emerging technologies.

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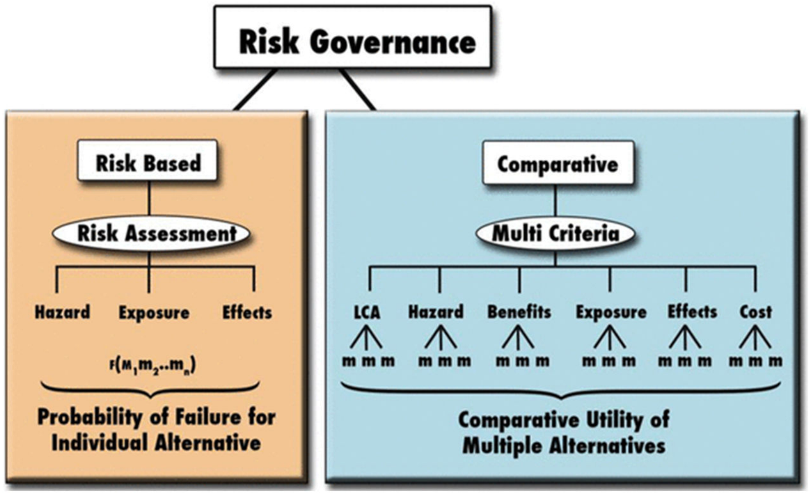

Fig. 1.

Differentiation of a traditional ‘risk-based’ and a ‘comparative-based’ approach to risk policy and governance for emerging technologies