

# 1. Introduction: the challenges of oversight for emerging technologies

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## 1.1 INTRODUCTION

We are in the midst of one of the greatest periods of scientific and technological innovation in human history. Scientific discoveries and technological developments are fueling explosive advances in biotechnology, personalized medicine and synthetic biology; applied neuroscience; nanotechnology; information technology and artificial intelligence; robotics; geoenvironment and other fields. Each of these emerging technologies promises almost unfathomable social and personal benefits. As a result, governments are actively promoting them, while researchers and the private sector are devoting enormous resources to their development. The result has been rapid and widespread commercialization, production and application. Yet each of these technologies also carries the possibility of significant risks to health, safety and the environment. And each entails other potential impacts that raise broader social, economic and ethical concerns.

To be sure, many of the issues raised by the current emerging technologies are generic: they attend every significant new technology. As Christopher Bosso argues, society must balance the potential benefits of every technological innovation against its potential risks and potential economic, social and personal impacts. Benefits, moreover, typically appear near-term and tangible – in the light of self-interest as well as natural optimism – while risks appear distant and intangible.<sup>1</sup>

Nonetheless, the current suite of emerging technologies poses challenges for regulatory oversight that are quantitatively, if not qualitatively,

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<sup>1</sup> Christopher Bosso, “The Enduring Embrace: The Regulatory *Ancien Régime* and Governance of Nanomaterials in the U.S.”, 9 NANOTECHNOLOGY LAW & BUSINESS 4 (June 2013).

greater than those posed by most earlier innovations.<sup>2</sup> These challenges stem from the breadth and power of individual platforms such as biotechnology, nanotechnology and synthetic biology. They also derive from the convergence of multiple technologies, such as the application of advanced information processing to enhance biotechnology or robotics, or the use of synthetic biological forms as “production facilities” for nanoscale fabrication,<sup>3</sup> producing even more powerful hybrids. Finally, the simultaneous development and introduction of so many complex technological platforms creates significant difficulties for oversight.

This volume considers the challenges for regulatory oversight posed by current emerging technologies, and proposes innovative models of governance for responding to those challenges. The governance innovations suggested by the contributing authors involve both modifications of traditional regulatory procedures and “governance” approaches to oversight that go beyond traditional regulation. As such, the volume makes a significant contribution to the evolving debate on oversight of emerging technologies.

This introductory chapter outlines and analyzes some of the major challenges to regulatory oversight, setting the stage for consideration of potential responses. To structure the analysis, the chapter uses as a point of reference the risk governance framework and related materials prepared by the International Risk Governance Council (IRGC).<sup>4</sup> While this volume focuses primarily on the regulatory system of the United States, the challenges discussed here and in the work of the IRGC arise in all countries affected by emerging technologies. Some chapters in the volume, moreover, expressly consider developments in other countries.<sup>5</sup> And many of the proposals advanced by the contributing authors are broadly applicable – at least in principle – across diverse economic and regulatory systems.

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<sup>2</sup> Braden Allenby, “The Dynamics of Emerging Technology Systems” (this volume, Chapter 2).

<sup>3</sup> LeRoy Paddock and Molly Masterton, “An Integrated Framework for Governing Emerging Technologies such as Nanotechnology and Synthetic Biology” (this volume, Chapter 4).

<sup>4</sup> IRGC, *An Introduction to the IRGC Risk Governance Framework* (2008), available at <http://www.irgc.org/risk-governance/irgc-risk-governance-framework> (accessed July 7, 2013).

<sup>5</sup> For example, Diana M. Bowman, “The Hare and the Tortoise: An Australian Perspective on Regulating New Technologies and their Products and Processes” (this volume, Chapter 8); Preben H. Lindøe, Michael Baram and John Paterson, “Reliance on Industrial Standards to Prevent Major Accidents in Offshore Oil and Gas Operations” (this volume, Chapter 12).

## 1.2 CHALLENGES TO REGULATORY OVERSIGHT

### 1.2.1 Pacing

One of the major challenges posed by emerging technologies is the “pacing problem:” how can regulatory oversight arrangements keep pace with rapid scientific and technological innovation?<sup>6</sup> To be sure, technological innovation is a complex process, and not necessarily a rapid one. As Timothy F. Malloy outlines in Chapter 6, innovation can be seen as involving six stages: recognition of a need or opportunity; basic research; applied research; development; commercialization (including production of products and applications of technology); and diffusion, leading to widespread adoption.<sup>7</sup> Frequently, then, the innovation process spans substantial time periods. Current emerging technologies, however, are moving through these stages at an extremely rapid pace, “in many cases on exponential or near-exponential paths.”<sup>8</sup>

This pace is driven primarily by private economic incentives and first-mover advantages. But the process of innovation is accelerated by a range of governmental “push” and “pull” incentives,<sup>9</sup> motivated by perceived social benefits and a widespread innovation culture that views innovation as “the key ingredient of any effort to improve people’s quality of life.”<sup>10</sup> The result is a “tortoise and hare” problem:<sup>11</sup> technological innovation – the hare – is inherently fast and is further

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<sup>6</sup> See *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight* (Gary E. Marchant, Braden R. Allenby and Joseph R. Herkert, eds, 2011).

<sup>7</sup> Timothy F. Malloy, “Integrating Technology Assessment into Government Technology Policy” (this volume, Chapter 6). Malloy adopts the six-stage process introduced in Everett M. Rogers, *DIFFUSION OF INNOVATIONS* 132–50 (4th ed. 1995).

<sup>8</sup> Gary E. Marchant and Wendell Wallach, “Governing the Governance of Emerging Technologies” (this volume, Chapter 7).

<sup>9</sup> Malloy, *supra* note 7; Gregory F. Nemet, “Demand-Pull, Technology-Push, and Government-Led Incentives for Non-Incremental Technical Change,” 5 *RESEARCH POLICY* 700, 702 (2009).

<sup>10</sup> OECD, *The OECD Innovation Strategy: Getting a Head Start on Tomorrow*, available at <http://www.oecd.org/site/innovationstrategy/#d.en.192273> (accessed July 7, 2013).

<sup>11</sup> Jennifer Kuzma, “Properly Paced or Problematic?: Examining the Past and Present Governance of GMOs in the United States” (this volume, Chapter 9); Bowman, *supra* note 5.

accelerated by market and public incentives; governmental oversight – the tortoise – is by comparison inherently slow.

Consider the ideal oversight process formulated by the IRGC, designed “to enable societies to benefit from change while minimizing the negative consequences of the associated risks.”<sup>12</sup> The IRGC risk governance framework encompasses five interrelated phases that expand on the traditional categories of risk assessment, management and communication. “Pre-assessment” involves early warning of potential risks, framing those risks in terms of their technical characteristics and the issues perceived by stakeholders and society, and identifying potentially applicable analytical tools and regulatory frameworks. “Appraisal” comprises both a scientific risk assessment and a “concern assessment,” which analyzes stakeholder, social and cultural perceptions of potential risks. “Characterization” entails determining whether the likely risks are acceptable and identifying appropriate responses. “Risk management” includes identifying, evaluating and implementing measures to avoid, reduce or transfer risks. And “communication” is a two-way process, with oversight bodies informing stakeholders and society about risks and providing them with opportunities for voice throughout the process. Importantly, the IRGC framework goes well beyond scientific and material analysis of risks (for example, their measurable qualities and the probability of their occurrence) to incorporate social and psychological considerations in every phase. Thus, for example, assessment should consider the broader risk culture, as well as the ways in which different groups perceive risks and benefits “when values and emotions come into play.”<sup>13</sup>

This process, done properly, clearly requires substantial amounts of time. Organizing oversight around five stages makes the process inherently lengthy. Framing and appraisal require oversight bodies to gather and analyze extensive scientific and technical information. For some emerging technologies, it will be necessary to generate new data, and even to develop new testing methods and assessment models.<sup>14</sup> Framing and appraisal also require oversight bodies to identify stakeholders and potentially concerned social groups, as well as representatives of the public at large, and to gather and assess extensive information about their perceptions and concerns – an inherently time-consuming undertaking,

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<sup>12</sup> IRGC, *supra* note 4.

<sup>13</sup> *Id.* at 10.

<sup>14</sup> For nanotechnology, for example, see Gary E. Marchant et al., “Big Issues for Small Stuff: Nanotechnology Regulation and Risk Management,” 52 *JURIMETRICS* 243–77 (2012).

and one for which new procedures may need to be adopted. Risk management involves identifying and evaluating a range of alternatives before selecting appropriate risk managers and management measures, and frequently entails actions to further international harmonization. Communication requires that authorities provide opportunities for meaningful stakeholder and public input. And all of these activities require exercises of judgment, not simple ministerial responses.

Even more important, the IRGC framework assumes that innovation will not outpace the risk governance process. Notions such as early warning, scientific and concern assessments, characterization and evaluation – indeed, even the choice of risk management measures – make sense only if the technology under consideration retains the same contours and remains at a similar level of development while those operations are being performed, or at worst evolves temporally in parallel to the risk governance process. If a technology changes form or diversifies into multiple forms, products and applications more rapidly than the process can be carried out, risk governance may never catch up.

Yet the IRGC assumption of parallel pacing is not satisfied on two counts: current technologies are “emerging” at an exponential pace, as noted above, while risk governance is slowed and hampered by systemic weaknesses in regulatory systems, as highlighted throughout this volume.<sup>15</sup> Many United States regulatory agencies – especially those with environmental responsibilities – are operating under outdated legislation, dating back as far as the 1970s. Such vintage statutes are often ill-suited to the issues posed by current technologies; for example, few provide for the kinds of societal input modern risk governance requires. In the current political climate, however, the chances that such legislation can be updated, or that new *sui generis* statutes can be adopted, are virtually nil. Exercises of regulatory authority also face strong opposition based on small-government and free-market ideologies and fear of the “nanny state.”<sup>16</sup> In addition, many regulatory agencies and other oversight bodies face declining financial resources – rather than the increased resources that well-structured risk governance on the IRGC model would require – both because of efforts to constrain regulation and because of severe budget pressures.

Many scholars, including several of the editors and contributors to this volume, have called for “governance” or “new governance” approaches to oversight, to supplement or substitute for formal governmental

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<sup>15</sup> For example, Marchant and Wallach, *supra* note 8.

<sup>16</sup> Bowman, *supra* note 5.

regulation.<sup>17</sup> Governance approaches rely on decentralizing regulatory authority among public, private and public-private actors and institutions; they also rely on softer forms of oversight, such as information disclosures, codes of conduct and certification mechanisms. Such arrangements can be adopted and revised more rapidly than formal regulations; they are also more easily adopted in anticipatory or experimental forms. Yet while governance approaches may help address the pacing problem, they have significant limitations: soft governance measures lack the enforceability of mandatory regulations; soft and private measures require voluntary participation, which may not be forthcoming (for example, the EPA's recent Nanoscale Materials Stewardship Program took several years to develop but produced very limited participation); and private codes of conduct may lack the legitimacy of public regulation, producing a lesser degree of public confidence and trust.<sup>18</sup>

### 1.2.2 Quality of Risk Governance

Apart from the sheer speed of their development and diffusion, the nature of current emerging technologies makes high-quality risk governance difficult to achieve. These technologies are protean: each technological family or platform includes numerous forms. For example, “nanotechnology” is not simply one discipline, or family of techniques, but rather a vast range of disciplines, including engineering, materials science, biotechnology, medicine, physics, chemistry and information technology.<sup>19</sup> Each technology also encompasses numerous products or applications, and potentially many more.<sup>20</sup>

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<sup>17</sup> See, for example, Gary E. Marchant, Kenneth W. Abbott, Douglas J. Sylvester and Lyn M. Gulley, “Transnational New Governance and the International Coordination of Nanotechnology Oversight,” in *THE NANOTECHNOLOGY CHALLENGE: CREATING LEGAL INSTITUTIONS FOR UNCERTAIN CHALLENGES* (David Dana, ed., 2012); Kenneth W. Abbott, Gary E. Marchant and Elizabeth A. Corley, “Soft Law Oversight Mechanisms for Nanotechnology,” 52 *JURIMETRICS* 279–312 (2012); Gregory N. Mandel, “Regulating Emerging Technologies,” 1 *LAW, INNOVATION, AND TECH.* 75 (2009); LeRoy Paddock, “An Integrated Approach to Nanotechnology Governance,” 28 *UCLA J. ENVTL. L. AND POL’Y* 251, 255 (2010).

<sup>18</sup> See Abbott et al., *supra* note 17.

<sup>19</sup> Graeme A. Hodge, Diana M. Bowman and Andrew D. Maynard, “Introduction: The Regulatory Challenges for Nanotechnologies,” in *INTERNATIONAL HANDBOOK ON REGULATING NANOTECHNOLOGIES* (Graeme A. Hodge, Diana M. Bowman and Andrew D. Maynard, eds, 2010).

<sup>20</sup> For examples from nanotechnology and synthetic biology, see Paddock and Masterton, *supra* note 3.

As a result, risk governance must contend with pervasive uncertainty as to the future course of technological development, undermining the logical progression of the risk governance process. In addition, the breadth of these platforms and the range of their impacts – as well as the overlaps and interactions among platforms – make emerging technologies poor fits with existing statutory allocations of regulatory authority: these features greatly complicate the crucial phase of risk governance in which oversight or risk management responsibility is assigned to the most appropriate regulatory scheme and agency – or more likely divided among multiple schemes and agencies, or perhaps assigned to a newly created scheme or agency. In most regulatory systems, moreover, no meta-regulator, other than the legislature, has the authority to make such determinations.

Uncertainty also characterizes the risks and benefits of current emerging technologies.<sup>21</sup> As Mandel notes, “One of the greatest challenges facing emerging technology governance is scientific uncertainty concerning the potential human health and environmental impacts of a technology.”<sup>22</sup> For some technologies, such as synthetic biology, the implications are “not only difficult to predict but are fundamentally unknowable.”<sup>23</sup>

Broadly conceived, the risks posed by emerging technologies extend well beyond traditional health, safety and environment issues. They engage “different ideas and values about the role of technology in society, assurances of safety, and equal sharing of risks and benefits,”<sup>24</sup> and other elements of diverse risk cultures. They also encompass broader impacts on social, economic and personal life, sometimes raising difficult ethical issues. Examples include the possibility of significant life extension through genetic and nanoscale therapies; radical enhancement of human capacities through a range of technological interventions; creation of new life forms; intrusions on personal privacy through nano and

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<sup>21</sup> As Paddock and Masterton note, *supra* note 3, such uncertainty characterizes almost all new technologies; again, however, current emerging technologies appear unusually complex and uncertain.

<sup>22</sup> Gregory N. Mandel, “Emerging Technology Governance” (this volume, Chapter 3).

<sup>23</sup> Paddock and Masterton, *supra* note 3 (quoting Joy Y. Zhang, Claire Marris and Nikolas Rose, “The Transnational Governance of Synthetic Biology: Scientific Uncertainty, Cross-Borderness and the ‘Art’ of Governance,” 3 (BIOS, The London School of Economics and Political Science, Working Paper No. 4, 2011), available at [http://royalsociety.org/uploadedFiles/Royal\\_Society\\_Content/policy/publications/2011/4294977685.pdf](http://royalsociety.org/uploadedFiles/Royal_Society_Content/policy/publications/2011/4294977685.pdf) (accessed July 7, 2013)).

<sup>24</sup> Kuzma, *supra* note 11.

biosensors; and unjust economic and social outcomes due to differential access to valuable innovations.

Technologies characterized by this degree of uncertainty are particularly likely to produce deficiencies and failures in governance, what the IRGC calls “risk governance deficits.”<sup>25</sup> Deficits are especially likely in the early phases of the risk governance process, in which information is gathered and risks are assessed and appraised. IRGC observes that risk governance failures during these phases are frequently caused by lack of sufficient factual information or misinterpretation of available information; failing to consult or to properly assess the concerns, risk perceptions and risk attitudes of stakeholders and the public; and failing to consider “Black Swans” – potential factual or social impacts outside normal expectations. Diverse, uncertain technologies may also lead to deficits in risk management, such as failing to adopt appropriate strategies, anticipate the side effects of management measures, address long-term risks and manage conflicts.

In addition, IRGC argues that when new developments occur within complex systems, significant risks and risk governance deficits are more likely to arise; for example, unpredictable risks may emerge from chance variations, and non-linear effects may arise when unanticipated thresholds are crossed.<sup>26</sup> Emerging technologies are evolving within multiple complex systems: the “scientific-industrial complex” of technology promotion, research and development, commercialization and global markets; the highly politicized “regulatory system” of national and sub-national agencies, international institutions, and non-state actors and organizations exercising regulatory authority; the “attitudinal system” of public and stakeholder values, attitudes, social relationships and norms; and the social-ecological and earth systems in which health and environmental impacts unfold.

To address this array of governance problems, oversight of emerging technologies must be flexible and adaptable in the face of uncertain

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<sup>25</sup> IRGC, “Policy Brief, Risk Governance Deficits: Analysis, Illustration and Recommendations” (2010), available at <http://www.irgc.org/risk-governance/irgc-risk-governance-deficits> (accessed July 7, 2013).

<sup>26</sup> IRGC, “The Emergence of Risks: Contributing Factors,” 5–6 (2010), available at <http://www.irgc.org/risk-governance/emerging-risk/irgc-concept-of-contributing-factors-to-risk-emergence/> (accessed July 7, 2013). Complex systems may, however, be more adaptable and resilient.

technological futures, risks and benefits;<sup>27</sup> resilient in the face of changing conditions and attitudes and possible surprises;<sup>28</sup> and robust in the face of threatening developments that have not been understood or anticipated.<sup>29</sup> These demands are not always consistent: for example, the decentralization of authority, multiple oversight bodies and soft measures of “new governance” may produce greater flexibility and resilience (especially through redundancy), but reduce robustness. More fundamentally, demands for adaptability, resilience and robustness place great stress on regulatory systems; as with the pacing problem, most systems fall far short.

### 1.2.3 Stakeholder Engagement

Numerous actors and organizations perceive themselves as having stakes in the benefits, risks and impacts of emerging technologies. These include scientific and technological researchers, business firms and industry associations, government officials, and civil society groups focused on issues from health, worker safety and environmental protection to privacy and economic justice. Private actors and organizations that engage in technology oversight through new governance arrangements have particular interests in the management of technological risks.<sup>30</sup> Societal groups with varying attitudes toward technology and risk also have stakes; in a real sense, so too do members of the general public, as consumers, as victims of potential risks or in other capacities. These actors increasingly demand information, transparency and voice,<sup>31</sup> and may challenge decisions in which they have not participated, making stakeholder engagement a necessity.

More fundamentally, as the IRGC risk governance framework suggests, neither technologies nor risks are exclusively objective, factual phenomena; they are in significant part socially constructed, based on subjective attitudes, understandings, values and cultures. Technologies

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<sup>27</sup> Mandel, *supra* note 22; Marchant and Wallach, *supra* note 8; Leon Fuerth, “Operationalizing Anticipatory Governance,” 2 PRISM 4, 31 (2011), available at <http://www.ndu.edu/press/prism2-4.html> (accessed July 7, 2013).

<sup>28</sup> IRGC, *supra* note 25, at 15; IRGC, *supra* note 4, at 17.

<sup>29</sup> *Id.* at 17. The IRGC recommends robustness-focused strategies where risks are “complex,” with the underlying causal relationships poorly understood; it recommends resilience-focused strategies where risks are “uncertain,” with technical data lacking or unclear.

<sup>30</sup> For examples from nanotechnology, see Abbott et al., *supra* note 17.

<sup>31</sup> Kuzma, *supra* note 11.

and risks for which attitudes and understandings vary widely are referred to as “ambiguous.” For example, certain individuals and groups may understand a technological application such as genetically modified crops as a radical innovation with unknowable and potentially dangerous consequences; others may perceive it as an extension of familiar processes, such as plant breeding.<sup>32</sup> Similarly, certain individuals and groups may perceive particular potential impacts as threatening or ethically repellent; others may find them neither threatening nor ethically troubling. Risk governance that does not identify and take into account the relevant attitudes and concerns will not succeed.

Finally, modern regulatory policy, including risk regulation policy, views public communication, input and participation as essential. To cite just a few examples, the 2012 OECD recommendations on regulatory policy – approved by the governments of all developed nations – call for “open government,” including transparency and communication, stakeholder engagement throughout the regulatory process, and open and balanced public consultations.<sup>33</sup> Executive Order 13563, issued in 2011, requires a regulatory process that “involves public participation,” including “the open exchange of information and perspectives among ... experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole.”<sup>34</sup> The Principles for Regulation and Oversight of Emerging Technologies, issued by the White House Emerging Technologies Interagency Policy Coordination Committee on March 11, 2011, calls for “ample opportunities for stakeholder involvement and public participation;” these procedures are “important for promoting accountability, for decisions, for increasing trust, and for ensuring that officials have access to widely dispersed information.”<sup>35</sup> And IRGC calls for “inclusive governance,” based on an appreciation of the contributions stakeholders can make to risk governance; it recommends engaging wider circles of stakeholders as the technical, social and ethical issues raised by particular technologies become more extensive.<sup>36</sup>

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<sup>32</sup> IRGC, *supra* note 4, at 8–10 (noting differences in the subjective “framing” of genetically modified crops and nanotechnology).

<sup>33</sup> OECD, Recommendation of the Council on Regulatory Policy and Governance (Annex, section 2), March 22, 2012, available at <http://www.oecd.org/governance/regulatory-policy/> (accessed July 7, 2013).

<sup>34</sup> E.O. 13563, Improving Regulation and Regulatory Review, January 18, 2011, 76 (14) Fed. Reg. 3821 (January 21, 2011).

<sup>35</sup> <http://www.whitehouse.gov/blog/2011/03/16/emerging-technologies-committee-lays-out-principles-guidance> (accessed July 7, 2013).

<sup>36</sup> IRGC, *supra* note 4, at 18.

Many regulatory statutes, schemes and agencies, however, lack strong provisions and procedures for stakeholder engagement. As Jennifer Kuzma notes, stakeholders and publics are normally limited to formal comment procedures once regulations have been drafted, and to *ex post* litigation if regulations are unsatisfactory.<sup>37</sup> This is a far cry from the ongoing engagement central to the IRGC process. Resource constraints also bind tightly here; active stakeholder and public engagement can be costly. At the same time, expansive stakeholder participation can delay the risk regulation process, and may even interfere with desired applications of expertise and judgment by risk managers. Where actors, organizations and societal groups view ambiguous technologies and risks with different understandings, concerns and values, moreover, consensus on risk governance measures becomes far more difficult to achieve. As in most areas of regulation, oversight bodies may be forced to make trade-offs between desired features.<sup>38</sup>

#### 1.2.4 Coordination

In a complex regulatory system, the quality and even the pacing of oversight can suffer when a multiplicity of actors exercise regulatory authority without sufficient coordination. With no meta-regulator to manage the system as a whole, substantive issues or aspects of the risk governance process can fall through the cracks: each oversight body focuses on a narrow set of issues, viewing novel risks as someone else's responsibility.<sup>39</sup> In addition, oversight regimes can overlap. In these cases, at best, duplication of efforts saps scarce resources from the governance system and creates additional costs for the targets of oversight. Duplication can also lead to competition among oversight bodies, consuming additional resources, distracting organizations from their assigned missions and leading to conflict that complicates efforts at coordination. At worst, duplication can produce conflicting standards, creating severe problems for agencies, targets and stakeholders.

Strong risk governance processes like the IRGC framework require a high degree of coordination. Responsibility for each phase of the process must be clearly and appropriately assigned. For example, IRGC strongly recommends that risk assessment and risk management responsibilities

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<sup>37</sup> Kuzma, *supra* note 11.

<sup>38</sup> On trade-offs as a characteristic problem of regulation, see Robert Baldwin, Martin Cave and Martin Lodge, *UNDERSTANDING REGULATION* 29, 32–5 (2d ed. 2012).

<sup>39</sup> IRGC, *supra* note 25, at 16.

be assigned to different bodies; both bodies should cooperate in other phases of the process, such as pre-assessment and communication.<sup>40</sup> IRGC also emphasizes that institutional responsibilities should be clearly assigned and accepted.<sup>41</sup> In its view, oversight bodies must take the broader institutional context into account:<sup>42</sup> gaps and overlaps resulting from dispersed and uncoordinated responsibilities are serious governance deficits that can undercut decision-making.<sup>43</sup>

Three types of coordination problem may plague governance of emerging technologies:

- First, governance of different forms, applications or impacts of a technology may fall to multiple governmental agencies. This is an almost inevitable product of the breadth of the current emerging technologies, as noted above. While bodies such as the Emerging Technologies Interagency Policy Coordination Committee can bring some order to such arrangements,<sup>44</sup> inter-agency coordination is a perennial problem.
- Second, governance of a technology may be multi-level, in the usual sense of involving multiple levels of government.<sup>45</sup> This is a particular problem within the European Union, where EU and national regulations and management bodies – and perhaps regional, local and international norms and agencies as well – often have overlapping jurisdictions and responsibilities.<sup>46</sup> It is less a problem in the United States, but oversight actions by state and local governments and any relevant international standards or international harmonization procedures add complexity to the oversight system.
- Third, a different multi-level governance problem arises when private and public-private bodies engage in oversight as part of new governance approaches. In the case of nanotechnology, for

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<sup>40</sup> IRGC, *supra* note 4, at 8.

<sup>41</sup> *Id.* at 13.

<sup>42</sup> *Id.* at 20–1.

<sup>43</sup> IRGC, *supra* note 25, at 16.

<sup>44</sup> For discussions of inter-agency coordination mechanisms, see Mandel, *supra* note 22; Kuzma, *supra* note 11; Joshua W. Abbott, “Network Security Agreements: Communications Technology Governance by Other Means” (this volume, Chapter 11).

<sup>45</sup> Liesbet Hooghe and Gary Marks, “Unraveling the Central State, But How? Types of Multi-Level Governance,” 97 *AMER. POL.SCI. REVIEW* 233–43 (2003).

<sup>46</sup> IRGC, *supra* note 4, at 21.

example, current and recent programs that engage in soft or non-legally-binding forms of oversight have been sponsored by international organizations (for example, OECD working party on health and safety implications of manufactured nanoparticles); national agencies (for example, NIOSH recommended exposure levels for workers); multi-stakeholder public-private partnerships (for example, Responsible NanoCode); and private organizations dominated by business (NanoSafety Consortium for Carbon), researchers and civil society (Foresight Institute Guidelines), and business-civil society collaborations (Environmental Defense-duPont Nano Risk Framework).<sup>47</sup> Communication and other relationships between public regulators and non-state organizations are often weak, and traditional inter-governmental mechanisms are inapplicable.

In all these settings, the need for inter-institutional coordination is strong, but is often not satisfied.

### 1.3 OVERVIEW OF VOLUME

The editors asked the contributing authors to consider these and other problems relating to the oversight of emerging technologies, and to propose ways to respond to those problems. The result is a rich set of empirical examples, analyses and recommendations. This section provides a brief overview of the contributions of succeeding chapters.

Part I considers general issues of risk regulation and technology oversight. Braden Allenby begins by analyzing the complexity of technological systems – as illustrated by the railroad and its co-evolving clusters of technologies and social/political institutions – and the dynamics of technological change. Allenby argues that today’s technologies – especially the “Five Horsemen” of nanotechnology, biotechnology, robotics, information technology and applied cognitive science – are not only revolutionary in scope, scale and speed of innovation; they constitute a fundamental shift in the state of the earth system.

Gregory N. Mandel focuses on the delicate problem of managing risks while still ensuring beneficial innovation, in the fields of biotechnology, nanotechnology and synthetic biology. He argues that one-size-fits-all command-and-control regulation is an ineffective response to this problem, and recommends a more flexible “governance” approach that

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<sup>47</sup> Abbott et al., *supra* note 17.

maintains sufficient governmental oversight to generate public confidence. Mandel's suggested strategy uses the uncertainty created by an emerging technology as an incentive to bring stakeholders together, early in the life of the technology, to agree on and implement a regulatory approach; the approach chosen will necessarily evolve over time in an iterated process.

LeRoy Paddock and Molly Masterton build on earlier work recommending an integrated governance system for nanotechnology, extending that approach to synthetic biology. They call for an adaptive system of government regulation that encourages experimentation and learning and continually adjusts risk management measures based on lessons learned. In addition, Paddock and Masterton recommend a multi-faceted governance approach that simultaneously deploys information disclosure mechanisms, codes of conduct, civil liability and public dialogue.

Marc A. Saner argues that governance should extend beyond methods for controlling emerging technologies, especially where those technologies are changing faster than regulatory agencies can foresee or adapt, and where they raise difficult ethical issues. In such cases, governance should also incorporate social adaptation mechanisms, as is done in the area of climate change. Saner argues that a focus on adaptation enables holistic thinking, facilitates experimentation, helps ensure maximization of benefits, and allows for valuable action if decisions on oversight are deadlocked. In addition, a focus on adaptation may improve control approaches by accepting their limits.

Timothy F. Malloy focuses on government policies that promote new technologies, which often fail to take into account health, safety and environmental risks, social impacts and other unintended consequences, as illustrated by the case of the fuel additive MBTE under the Clean Air Act. Malloy analyzes a range of governance deficits that lead to unanticipated consequences. In response, he calls for government to integrate precaution with promotion. More specifically, he recommends the incorporation of technology assessment procedures that consider societal implications at the legislative stage of technology promotion.

Gary E. Marchant and Wendell Wallach emphasize the coordination problem in technology governance, especially where multiple public, private and public-private bodies engage in soft governance initiatives. Governance schemes like these are typically created in piecemeal fashion, and often operate independently. To address the problem that there is normally no meta-regulator to induce cooperation among diverse initiatives, Marchant and Wallach call for the establishment of "issue managers" for each technology of concern. An issue manager would collect information, promote coordination, provide a forum for stakeholders and

manage communication. After consideration of possible models, the authors propose a “governance coordinating committee” structure that would actively engage governmental and non-governmental stakeholders.

Part II of the volume considers country- and technology-specific governance issues and developments. Diana M. Bowman presents an Australian perspective. The governments of Australia and the state of Victoria, in particular, have aggressively regulated or mandated a range of technologies; these range from seat belts and motorcycle helmets to *in vitro* fertilization, embryo research and genetically modified foods. Bowman concentrates on the limits of government intervention, highlighting the resistance to activities that raise the specter of a “nanny state,” recent moves to limit intervention through regulatory reviews and the “better regulation” agenda, and Australia’s less aggressive response to nanotechnology. Her chapter contains a rich array of examples from the Australian regulatory experience.

Jennifer Kuzma uses the “tortoise and hare” metaphor to review the history of regulatory efforts to keep pace with the rapidly evolving technology of genetically modified crops. She finds that oversight largely succeeded in keeping pace temporally with technological developments, through a series of oversight mechanisms. However, many stakeholders find the resulting oversight system insufficient to ensure health and environmental protection in the long term, as well as insufficiently transparent and participatory. Kuzma thus argues for “proper pacing,” in which oversight both keeps pace and remains responsive to potential harms and public demands for information and voice.

Rachel A. Lindor and Gary E. Marchant explore innovative regulatory programs being implemented by US agencies for molecular diagnostics. These products represent a technology transition from a simple, inexpensive medical assay to a much more complex, expensive test that now plays a central role in directing medical interventions and prediction. The regulatory framework established for the old model of diagnostic tests does not fit the sophisticated new technologies. With no statutory changes imminent due to the inertia of the legislative process, two US agencies are experimenting with innovative new approaches for the regulation and reimbursement of molecular diagnostics within the pre-existing legal framework. This example demonstrates the potential for creative innovation within existing legal frameworks.

Joshua W. Abbott examines a traditional regulated industry – telecommunications – that is also marked by rapid technological change. He focuses on an oversight procedure used in the review of license applications for foreign-owned communications networks to deal with potential national security, law enforcement and similar risks. This procedure

is designed primarily to deal with the coordination problems raised by such broad policy concerns. The Federal Communications Commission defers to the Executive Branch, which exercises its oversight responsibility through ad hoc interagency teams. In addition, applying a new governance technique, interagency teams sometimes negotiate voluntary network security agreements with applicants; terms of these agreements become conditions of FCC licenses.

Preben H. Lindøe, Michael Baram and John Paterson examine risk regulation of offshore oilrigs and platforms. They first compare the regulatory approaches of the United Kingdom and Norway, which moved to performance-based rules following a series of accidents in the 1970s and 1980s, with that of the United States, which continued to impose technically detailed prescriptive regulations. They then examine the ways in which all three countries are rethinking their approaches in the light of the 2010 BP Deepwater Horizon Prospect disaster. Their analysis focuses on factors such as political and legal culture, social values and industrial-labor relations.

Gary E. Marchant draws overall conclusions regarding innovative governance models for emerging technologies in the concluding chapter of the volume. He concludes that there are no “golden bullets” that provide a perfect solution to the governance challenges of emerging technologies, but that the types of innovative governance described in this volume are helping us to muddle through.