

Chapter 9

An International Framework Agreement on Scientific and Technological Innovation and Regulation

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9.1 Introduction

In this chapter, I consider *international* action to help law and policy better keep pace with emerging scientific and technological innovations. I focus especially on addressing innovations that have the potential to create significant health, safety and environmental risks and/or to pose significant social, cultural and ethical challenges, even as they promise significant benefits. Prominent among these are Brad Allenby's "five horsemen of emerging technologies"¹ – nanotechnology, biotechnology, robotics, information and communication technology, and applied cognitive science, along with their increasingly powerful combinations – as well as synthetic biology. Even more challenging, of course, are the equally disruptive innovations that have not yet been introduced, or of which we are not yet aware.

In speaking of "international action," I do not mean to suggest that innovations like those just mentioned can or should be directly regulated, or otherwise addressed by law, at the international level. Direct international regulation is not a realistic option, in large part because the international legal system is relatively weak in all three of the institutional forms Gary Marchant identifies as collectively constituting "law:" "legislation, regulation, and judicial case law."² First, there is no global legislature capable of adopting statutory law. Second, there is no global Food and Drug Administration, Environmental Protection Agency or similar administrative organ capable of adopting effective regulatory law. To be sure, rough analogues of regulatory agencies exist among the "specialized agencies" of the United Nations system – e.g., the World Health Organization (WHO) – and other international organizations, such as the UN Environment Programme (UNEP). A few of those entities, including the WHO, have even been granted authority to adopt "regulations" applicable to states (that is, to nations), albeit in narrow circumstances and typically subject to

¹Brad R. Allenby, [Chapter 1](#), this volume, at [8].

²Gary E. Marchant, [Chapter 2](#), this volume, at [22].

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opt-out rights.³ Yet on the whole international organizations are so weak that they are hardly comparable to powerful domestic regulatory agencies. Few if any of them, moreover, have authority to adopt binding regulations applicable to private actors, including business firms and researchers. Third, in spite of a recent wave of judicialization,⁴ the international system still relies on courts far less than do domestic legal systems, especially in common law countries. What is more, tribunals such as the International Court of Justice have traditionally not observed principles of *stare decisis* that enable them to develop binding “judicial case law.”⁵

Given the limits on international legislation, administrative regulation and case law, we are left with the two traditional mechanisms of international law-making, customary law and treaties. Neither, unfortunately, is generally associated with the rapid action needed to deal with exponential rates of innovation.⁶ Customary international law is developed through the actual practice of states, as well as the subjective acceptance by states of regularities in practice as legally binding rules (“*opinio juris*”). Customary law has traditionally been based on gradual accretions of practice, and has thus been quite slow to develop, although there have been many recent efforts to expedite the process.⁷ Custom may also work best in areas that directly engage the state and respond to relatively simple rules, such as the breadth of the territorial sea or the immunity of diplomats. Formal treaty negotiations are also relatively slow and costly – although recent innovations in areas such as international environmental law have made the process considerably more flexible, as discussed further below. In addition, the treaty process has traditionally privileged diplomats and high executive officials over technical experts. In short, at least in their traditional forms, both mechanisms are even less well-suited than national law to the dynamic context of scientific innovation.

More precisely, then, the focus of this chapter is on international action to *coordinate national* law and policy in responding to scientific and technological innovations.⁸ Beyond merely coordinating, moreover, international arrangements can *steer* national actions in desirable directions. “Steering” (in contrast to “regulation” or

³See, e.g., Constitution of the World Health Organization, Art. 21–22.

⁴See Goldstein, Judith, Miles Kahler, Robert O. Keohane, and Anne-Marie Slaughter. 2001. Introduction: Legalization and world politics. In *Legalization and world politics*, eds. Judith Goldstein, Miles Kahler, Robert O. Keohane, and Anne-Marie Slaughter. Cambridge, MA: MIT Press.

⁵See, e.g., Statute of the International Court of Justice, Art. 59: “The decision of the Court has no binding force except between the parties and in respect of that particular case.”

⁶See Marchant, *supra*, at [19].

⁷Especially in rapidly developing areas such as human rights, advocates have sought to develop a more dynamic “modern” form of customary law by deemphasizing the accretion of state practice and instead emphasizing declarations of rules by states (which arguably reflect *opinio juris*) in fora such as the General Assembly, or even in multilateral treaties. See Roberts, Anthea Elizabeth. 2001. Traditional and modern approaches to customary international law: A reconciliation. *American Journal International Law* 95: 757.

⁸The introductory chapter by Gary Marchant, *supra*, implicitly assumes that legal responses to innovation will be national, and indeed focuses primarily on the US.

“coercion”) refers to the use of persuasion, incentives, peer pressure and other “managerial” forms of influence⁹; here it would be designed to move national actions not only toward greater uniformity, but also toward greater efficiency, effectiveness, legitimacy and public-interest orientation in form and content.¹⁰ Finally, international arrangements might *facilitate* speedier and better designed national legal and policy responses, especially in states with limited regulatory capacity.

I do not attempt to specify here the substantive content of international coordination, steering and facilitation – exactly which legal and policy responses international arrangements should encourage and support – or even the details of international organizations and procedures. Both inquiries are essential, but are parts of a larger project. Instead, I suggest here a general institutional framework for international coordination, steering and facilitation, consisting of two main elements. The first is an international “framework convention,” a particularly flexible type of treaty prominent in international environmental law and certain other fields. While negotiating a framework convention involves some of the same problems of delay and cost as any treaty process, the framework convention model is explicitly designed to be initially less demanding and easier to negotiate, while facilitating more detailed incremental and adaptive rule-making over time, as better information on risks and benefits is obtained. The second element is a set of international institutions and procedures to coordinate, steer and facilitate national action, which would be established by and operate under the authority of the framework convention.

Even under existing framework conventions, rule-making and implementation often engage actors beyond the participating states as such. The arrangements I propose would build on this experience by incorporating as essential parts of the regime actors operating at three levels of governance.¹¹ The first is the traditional “international” or inter-state level. Here the framework convention and its basic institutions and mechanisms would be created and managed by representatives of the “state parties.” The second is the “trans-governmental” level, which includes cross-national arrangements among executive agencies and officials, legislative bodies and legislators, and other units and individuals within national governments, rather than among “states” as such.¹² Here the convention would authorize and rely for rule-making and implementation on cooperation among national regulatory agencies, regulators and other relevant units and officials within “the state.” The third is the “transnational” level, which includes cross-national relationships among societal actors and organizations. Here the convention would empower and rely on cooperation among

⁹On the managerial approach, see Chayes, Abram, and Antonia Handler Chayes. 1998. *The new sovereignty: Compliance with international regulatory agreements*. Washington: Brookings.

¹⁰See, e.g., Wood, Stepan. 2002–2003. Environmental management systems and public authority in Canada: Rethinking environmental governance. *Buffalo Environmental Law Journal* 10: 129.

¹¹For a useful introduction to the three levels of governance identified here, see Pollack, Mark A., and Gregory C. Shaffer. 2001. Transatlantic governance in historical and theoretical perspective. In *Transatlantic governance in the global economy*, eds. Mark A. Pollack and Gregory C. Shaffer. Lanham, MD: Rowman & Littlefield Publishers, Inc.

¹²Slaughter, Anne-Marie. 2004. *A new world order*. Princeton, NJ: Princeton University Press.

private actors that have stakes in the issues of concern and can contribute to effective legal and policy responses. Two essential societal groups would be actors engaged in scientific and technological R&D and science- and technology-based business firms: these actors produce the innovations to which law must respond, are most knowledgeable about those innovations, and have the authority, access and information to produce meaningful compliance with legal rules on a day-to-day basis in the lab or factory. Other important societal actors are those potentially affected by innovations – e.g., workers and consumers – and representatives of the larger (transnational) society concerned with the social, cultural and ethical implications of innovations.

9.2 Benefits of International Coordination

Given the difficulties faced by even a highly-developed national legal system like the US in keeping pace with exponentially accelerating innovation, why should we consider introducing the additional complexities of international action? The value of international coordination, steering and facilitation arises out of two sources: the underlying problem of keeping pace with innovation, and the secondary problem of inconsistent or inappropriate national responses.

In terms of the underlying problem, keeping pace with emerging scientific and technological innovations depends crucially on information: legal and policy institutions require early warning of significant innovations; information on new technologies and their potential benefits, risks and other impacts¹³; means of assessing unclear data; even some degree of prediction.¹⁴ In all these areas, more information is better than less, and multiple social, cultural and ethical perspectives are more valuable than unitary, possibly myopic ones. International coordination, steering and facilitation can help states and societal actors produce and share information more effectively, while increasing the comparability of information and assessments from varied sources, e.g., in terms of nomenclature, metrology, indicators and presentation formats. International action can also enhance the diffusion of information from the first movers in an area of innovation to those at earlier stages of the technology life cycle. In addition, scientific and technological innovations can have significant cross-border effects: on the environment, human health or even national security in other states. International coordination helps guarantee a flow of information to affected states and societal actors – both about the effects themselves and about the nature and results of any control measures taken by the first-movers – improving their ability to respond in a timely and effective way.

¹³Currently, as Allenby notes, “the public (and, indeed, technologists outside of their particular specialties) get only impressionistic glimpses of emerging technologies in stories about particular events or experimental results.” Allenby, *supra*, at [9].

¹⁴Predicting the full range of impacts of a significant scientific innovation at an early stage is, of course, impossible. See Allenby, *supra*, at [7].

In terms of national responses, inconsistent national regulations are frequently a drag on economic activity, especially on international trade. The standard example is the conflict between the US and Europe over genetically modified foods (GMOs). From the US perspective, relatively strict European regulation functioned as a trade barrier. The US and other agricultural exporting countries challenged certain restrictions on GMOs by the EU and individual EU member states through the dispute settlement process of the World Trade Organization (WTO); in 2008 the US went so far as to request WTO authorization for trade sanctions in response to the EU's failure to implement the resulting decision.¹⁵ Economic conflicts like this can harm international relations more generally, interfering with welfare-enhancing cooperation in other areas. Inconsistent national regulation also hampers scientists, engineers and business firms who seek to collaborate across borders on research, development and commercialization.

Beyond merely reducing inconsistency, international action that incorporates an element of steering can help offset incentives that lead states to over- or under-regulate. Overall, the stronger incentives are probably to *under*-regulate, largely for competitive reasons. In highly dynamic fields such as the “five horsemen,” researchers and firms compete strenuously to discover, develop and commercialize scientific and technological innovations; governments compete almost as strenuously to support, finance and eliminate regulatory obstacles for national innovators: for the direct economic gains, the positive externalities innovation can create for other economic sectors, and national prestige. In terms of regulation, this is a classic Prisoner's Dilemma, akin to the well-known but controversial “race to the bottom” in areas such as worker rights and environmental protection.¹⁶ The incentives to under-regulate are enhanced when a technology creates negative trans-border externalities, passing some of the costs to others. In these situations, international steering can play a significant role in restraining national “defection.”

Apart from the stringency of regulation, it is widely recognized that states need encouragement (steering) and support (facilitation) to move toward “better regulation.” For example, the European Commission has adopted a comprehensive “better regulation” strategy to improve regulatory actions at EU level and within its member states.¹⁷ The aim of such efforts is to encourage regulatory approaches and instruments that are more efficient and flexible, less costly, more effective, and

¹⁵Arbitration between the parties on the appropriateness of US retaliation was suspended to give the EU a longer time to implement the decision. For a summary of the dispute settlement proceeding – European Communities – Measures Affecting the Approval and Marketing of Biotech Products, WTO Dispute DS291 – see http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm, visited 10 Sept 2009.

¹⁶See, e.g., Prakash, Aseem, and Matthew Potoski. 2006. The voluntary environmentalists: Green clubs, ISO 14001 and Voluntary Regulations 352–53 and sources cited (2006).

¹⁷See http://ec.europa.eu/governance/better_regulation/index_en.htm, visited 10 Sept 2009. EU member states, such as the United Kingdom, have empowered lead agencies to promote the better regulation agenda across the national government. See <http://www.berr.gov.uk/whatwedo/bre/>, visited 10 Sept 2009.

more appropriate in terms of their social, cultural and ethical impacts than traditional forms of legal action. Better regulation in one state not only helps that state deal effectively with local innovation risks, but also leads it to moderate any adverse trans-border effects. To the extent that better regulation programs lead states to rely on comparable regulatory techniques, moreover, they enhance international coordination.

Finally, many economies still classed as “developing” or “in transition” engage in sophisticated scientific and technological research on a large scale. The obvious example is China, “now a key global player in R&D in terms of absolute size as well as growth rates.”¹⁸ Yet many such states, and even some more advanced countries, lack the regulatory capacity to foresee and respond adequately to emerging risks. International institutions can facilitate effective and socially appropriate responses in these states (while reducing potentially harmful trans-border effects and incentives to under-regulate) by providing low-cost information, disseminating effective regulatory models, and granting other forms of technical and financial assistance. At the same time, such support can facilitate home-grown innovation within developing and transitional economies as well as the dissemination of appropriate innovations to them, helping to address the narrowing but still substantial North-South divide in science and technology.¹⁹

To be sure, states differ widely in their economic interests, “risk cultures,”²⁰ social relations, legal and regulatory systems, levels of development, capacities and other attributes. As a result, it is inevitable and often appropriate that states will respond to particular innovations with different forms and levels of regulation. For example, where the principal risk of an innovation is the disruption of traditional practices or ethical principles that vary across cultures, an international regime might appropriately stop at encouraging the exchange of information, assessments and cultural viewpoints; stronger efforts to promote uniform regulation would be counterproductive.²¹ Again, then, the goals of an international arrangement must be coordination, steering and facilitation – even true “harmonization,” let alone direct international regulation, is very unlikely and might be inappropriate.

Even in these limited terms, current international arrangements are far from adequate; indeed, their weaknesses are probably more severe than any of the domestic

¹⁸See OECD. 2007. Innovation and growth: Rationale for an innovation strategy 7–8, available at <http://www.oecd.org/dataoecd/2/31/39374789.pdf>, visited 10 Sept 2009.

¹⁹See World Bank, Global Economic Prospects 2008: Technology Diffusion in the Developing World (2008).

²⁰See International Risk Governance Council. 2008. An introduction to the IRGC risk governance framework 7, available at <http://www.irgc.org/The-IRGC-risk-governance-framework,82.html>, visited 10 Sept 2009.

²¹Some states might still have an incentive to under-regulate, e.g., to attract individuals seeking to access a medical technology that is restricted in their home states. Yet inconsistent national regulation could also be an effective sorting mechanism in these situations, allowing nations to regulate their own societies in accordance with their dominant cultural beliefs, while still allowing individuals that do not share those beliefs to access the regulated technologies. Thanks to Lyria Bennett Moses for suggesting these points.

problems discussed in other chapters of this volume. Most states and national regulatory agencies do not coordinate their responses to risky innovations at all. Many of the collaborative arrangements that do exist focus primarily on promoting innovation, not on analyzing or responding to risks or to social or ethical concerns; an important example is the effort by the OECD Directorate for Science, Technology and Industry to develop a strategy for promoting innovation in member countries.²² Steering is even more limited, with important exceptions such as the European Union better regulation agenda.²³ Most current arrangements emphasize streamlining or reducing regulation²⁴; when regulation is discussed, moreover, the focus is on current issues with immediate economic impact, not on emerging or future technologies and risks. Relatively modest efforts could significantly improve the international science and technology regime.

9.3 Uncertainty

The core feature of the “pacing law with science and technology” problem, whether at the national or international level, is its inescapable uncertainty: “Uncertainty is pervasive in risk regulation, by definition.”²⁵ Fundamentally, regulatory authorities must try to *anticipate future developments*, including the potential benefits, risks and other impacts of early-stage innovations. More specifically, at least three types of uncertainty frequently exist.

First, most innovations pose various forms of *technical uncertainty*, both static and dynamic, relating to the ultimate nature and scope of the innovation itself and its potential benefits, risks and impacts.²⁶ Second, many of the innovations discussed in this volume involve *normative uncertainty*: at least some individuals find it difficult to reconcile what they know of a technology with personal values or prevailing social norms; they may even find it difficult to determine which values and norms should apply.²⁷ Technologies for cognitive enhancement, radical lifespan

²²Early work on this strategy suggests minimal consideration of regulatory issues. See http://www.oecd.org/pages/0,3417,en_41462537_41454856_1_1_1_1_1,00.html, visited 10 Sept 2009.

²³See note 17, *supra*.

²⁴See, e.g., the OECD. 2005. Guiding principles for regulatory quality and performance, available at http://www.oecd.org/document/38/0,3343,en_2649_34141_2753254_1_1_1_1,00.html, visited 10 Sept 2009. A major tool of streamlining is regulatory impact analysis (RIA), which enables cost-benefit analysis of proposed regulations. See http://www.oecd.org/document/49/0,3343,en_2649_34141_35258801_1_1_1_1,00.html, visited 10 Sept 2009.

²⁵See OECD. 2006. Working party on regulatory management and reform, risk and regulation: Issues for discussion 7, available at <http://www.oecd.org/dataoecd/20/39/37551219.pdf>, visited 10 Sept 2009.

²⁶For example, the International Risk Governance Council, *supra* note 20 at 16–17, distinguishes *complex* problems (where the cause of particular observed effects is uncertain because many causal agents operate simultaneously) from *uncertain* problems (where the data on benefits or risks are insufficient or unclear).

²⁷Values and norms also differ widely between communities, even within a particular state.

extension and synthetic biology all create challenging problems of normative uncertainty, contributing to their “wicked complexity.”²⁸ Third, technical and normative problems create *political uncertainty* for legal and policy officials. At early intervention points in the life cycle of an innovation, policy-makers cannot be sure what regulatory measures will be effective against the likely risks, and what the costs and effects of alternative measure may be. Even more important, policy-makers cannot easily predict which if any interest groups or “value actors”²⁹ will oppose the innovation – as some activists oppose GMOs and nanotechnology³⁰ – or contest particular government responses, or how the general public will react. Without an understanding of the potential political costs and benefits, few policy-makers will willingly implement a meaningful regulatory response.

Given the centrality of information problems, an international arrangement must include certain essential elements:

- (a) It should steer states toward more extensive production, sharing and assessment of information about potential benefits, risks and impacts, and toward the adoption of comparable nomenclatures, metrology, indicators and methodologies.
- (b) It should promote technical, social and political learning and normative deliberation to overcome the three forms of uncertainty, both within and across states.
- (c) It should promote and facilitate the adoption of comparable, effective and efficient national regulatory frameworks, including both general science and technology policy and specific regulatory mechanisms.
- (d) It should be capable of relatively rapid action as problems appear, and flexible enough to recalibrate those actions as new information and understandings emerge.
- (e) Finally, it should encourage the participation and engagement of stakeholders, relevant epistemic communities and civil society, both within states and transnationally: to facilitate learning and deliberation, minimize political disputes, avoid regulatory capture, and further democratic principles.

These are challenging requirements given the difficulties of international legal action. The framework convention model is expressly designed to meet them at

²⁸See Allenby, *supra*, at [12]. The IRGC, *supra* note [20, at 16–17], refers to these as *ambiguous* problems, which involve “divergent or contested perspectives on the justification, severity or wider meanings associated with a given threat.”

²⁹See Abbott, Kenneth W., and Duncan Snidal. 2002. Values and interests: International legalization in the fight against corruption. *Journal of Legal Studies* 31 (1): Part 2, S141–78.

³⁰For example, the ETC Group proposes a “moratorium . . . on [nanotechnology] research involving molecular self-assembly and self-replication” as well as strong public oversight of all nanotechnology development; it recently sponsored a design contest for a universal “nano-hazard” symbol. <http://www.etcgroup.org/en/issues/nanotechnology.html>, visited 10 Sept 2009. As to GMOs, the ETC Group argues that “in the current social, economic and political context, genetic engineering is not safe, and involves unacceptable levels of risk to people and the environment.” <http://www.etcgroup.org/en/issues/biotechnology.html>, visited 10 Sept 2009.

the inter-state level. To fully meet these requirements, however, an international arrangement must incorporate “governance as well as government.”³¹ bringing into the regime the capabilities of public and private officials, experts and stakeholders; and adopting a broad understanding of “law” that includes public and private “soft law,” such as codes of conduct, guidelines and best practices.³²

9.4 A Framework Agreement on Scientific and Technological Innovation and Regulation

An international system to coordinate, steer and facilitate national responses to emerging innovations requires a “constitution.” To ensure the stability of the system, this should take the form of a treaty, the basic legal structure of international regimes. If treaty negotiations proved too costly or provoked strong resistance, states could set out the fundamental principles and procedures of the new system in a non-legally binding instrument, such as a declaration of an international organization; however, the treaty form offers significant advantages, discussed further below. The treaty should be structured as a framework convention to ease initial negotiations and provide for adaptive rule-making over time. We might call this the Framework Agreement on Scientific and Technological Innovation and Regulation (FASTIR) – a title whose acronym evokes the desire for speedy legal responses.

9.4.1 Innovation

As its title suggests, FASTIR could include arrangements to facilitate scientific and technological innovation within participating states. A possible basis for such arrangements might be the work of the Organization for Economic Cooperation

³¹Cf. Rosenau, James N., and Ernst Otto Czempiel, eds. 1992. *Governance without government: Order and change in world politics*. Cambridge: Cambridge University Press. For a recent application of governance theory to the regulation of business firms in areas such as worker rights, human rights and the environment, see Abbott, Kenneth W., and Duncan Snidal. 2009. Strengthening International Regulation through Transnational New Governance: Overcoming the Orchestration Deficit. *Vanderbilt Journal of Transnational* 42: 501. See also Mandel, Gregory N. 2008. Nanotechnology governance. *Alabama Law Review* 59: 1323.

³²On public soft law, see Abbott, Kenneth W., and Duncan Snidal. 2000. Hard and soft law in international governance. *International Organization* 54(3): 421. On private soft law, see Abbott & Snidal, Strengthening International Regulation, *supra*; Cashore, Benjamin, Graeme Auld, and Deanna Newsome. 2004. *Governing through markets: Forest certification and the emergence of non-state authority* (referring to norms of influential private institutions as “private sector hard law”); Kirton, John J., and Michael J. Trebilcock. 2004. Introduction: Hard choices and soft law in sustainable global governance. In *Hard choices, soft law: Voluntary standards in global trade, environment and social governance*, eds. John J. Kirton and Michael J. Trebilcock (defining soft law as relying “primarily on the participation and resources of nongovernmental actors in the construction, operation, and implementation of a governance arrangement”).

and Development (OECD). As mentioned above, the OECD has since 2007 been developing a general “innovation strategy” for its member states – virtually all of which are advanced industrial economies – as a way to promote sustained economic growth.³³ The OECD is due to complete its strategy in 2010; FASTIR could incorporate its major principles and establish mechanisms to promote them. FASTIR could also promote cross-border collaboration in research and development, another area in which OECD has done useful work.³⁴ Finally, FASTIR could incorporate mechanisms to promote indigenous innovation within developing countries, as well as the diffusion to such countries of appropriate innovations created in the North.³⁵

9.4.2 *The Framework Convention-Protocol Approach*

In this chapter, however, I focus not on encouraging innovation, but on mechanisms for responding to the potential risks and adverse impacts of emerging innovations through “regulation,” broadly defined.³⁶ As a “framework convention” FASTIR would have three principal functions relevant to regulation:

- First, it would establish the “pacing law with science and technology” problem as a legitimate issue of international concern,³⁷ while providing structures for ongoing international cooperation. As a “framework” convention, FASTIR would not itself address specific innovations or resolve specific issues; it would thus include few substantive obligations. It should, however, set forth agreed *objectives*, *principles* and *general commitments* to guide national and collective action over time, and should establish *institutions* and *procedures* to coordinate, steer and facilitate national legal and policy actions.

³³See http://www.oecd.org/pages/0,3417,en_41462537_41454856_1_1_1_1,00.html, visited 10 Sept 2009. See also Gault, Fred, and Susanne Huttner. A Cat’s Cradle for Policy. *Nature* 455: 462, 25 Sept 2008.

³⁴See http://www.oecd.org/document/10/0,3343,en_2649_34319_35044426_1_1_1_1,00.html, visited 10 Sept 2009.

³⁵Achieving these goals might require somewhat different approaches than those used in advanced economies, although certain approaches would be fruitful in both settings. See Sarah Box. 2009. OECD Work on innovation – A stocktaking of existing work. DSTI/DOC 2: 46–48, available at <http://www.oecd.org/dataoecd/14/32/42095821.pdf>, visited 10 Sept 2009. See generally World Bank, *Global Economic Prospects 2008*, supra note 19.

³⁶There have been many efforts to define “regulation” to encompass trans-governmental and transnational standards and procedures as well as traditional mandatory state regulation. For example, Julia Black, *Enrolling Actors in Regulatory Systems: Examples from UK Financial Services Regulation*, 2003 *Pub. L. (Spring)* 63, 65 (2003), defines “regulation” as “the sustained and focused attempt to alter the behavior of others according to defined standards or purposes with the intention of producing a broadly identified outcome or outcomes, and which may involve mechanisms of standard-setting, information-gathering and behavior-modification.”

³⁷Daniel Bodansky. 1999. *The framework convention/protocol approach framework convention*. Tobacco control technical briefing series, No. 1, WHO/NCD/TFI/99.1, p. 20, available at <http://www.who.int/tobacco/resources/publications/fctc/en/>, visited 10 Sept 2009.

- Second, it would establish procedures by which states could create detailed substantive agreements (“protocols,” “annexes” or other subsidiary instruments) when conditions became ripe for concrete international action. Such instruments could address specific fields of innovation (e.g., nanotechnology or synthetic biology) as well as cross-cutting issues (e.g., public input on ethical controversies). FASTIR would thus initiate – or at least facilitate – an incremental process of rule-making, enabling states and other actors to take more definitive, coordinated action as they gain sufficient information and understanding to overcome technical, normative and political uncertainty. This incremental process is known as the framework convention-protocol approach.
- Third, FASTIR would establish mechanisms to encourage and facilitate the acquisition and sharing of information on emerging innovations, as well as forms of dialogue and deliberation designed to produce deeper understanding of the risks, benefits and social and ethical implications of those innovations.

To properly perform these three functions, FASTIR should be a legally binding treaty. Even though it would lack concrete substantive obligations, its binding legal character would commit states to common principles, institutions and procedures; obligate them to develop and share information and assessments and participate in dialogue; and establish a firm basis for subsequent coordinated rule-making.³⁸

9.4.3 General Provisions

Two prominent framework conventions – the 1988 Vienna Convention for the Protection of the Ozone Layer and the 1992 United Nations Framework Convention on Climate Change (FCCC) – suggest certain general provisions that FASTIR should include. First, the agreement should enunciate basic *principles to guide future action*. Such principles would inform the ongoing dialogue among participating states and other actors, reduce the transactions costs of later negotiations, and help shape national actions – both directly, as states accept and internalize the principles, and indirectly, as other states and domestic interest groups pressure states to observe them.

Based on Vienna and the FCCC, participating states might commit to:

- i. cooperate in good faith to facilitate and coordinate the acquisition and sharing of information on and assessments of emerging scientific and technological innovations, beginning at the earliest possible stage of their development;

³⁸On the benefits of the framework convention-protocol approach, see *id.*; Abbott, Kenneth W., and Duncan Snidal. 2004. Pathways to international cooperation. In *The impact of international law on international cooperation*, eds. E. Benvenisti and M. Hirsch; Abbott, Kenneth W., Gary Marchant, and Douglas Sylvester. 2006. A framework convention for nanotechnology? *Environmental Law Reporter News and Analysis* 36: 10931.

- ii. cooperate in good faith to coordinate national regulatory actions (broadly defined), while recognizing that such actions may vary due to differing regulatory cultures and legal systems;
- iii. involve technical experts, researchers, workers, consumers and other stakeholders from the private sector and civil society, as appropriate, in assessing emerging innovations and framing and evaluating regulatory responses;
- iv. adopt, and cooperate to promote efficient, effective and appropriate forms of regulation that do not unduly hamper innovation or impose excessive costs, while protecting the public;
- v. minimize the impact of national regulatory actions on international trade and other forms of international economic activity³⁹;
- vi. take into account the special needs and circumstances of developing countries and economies in transition, in accordance with the principle of common but differentiated responsibilities; and
- vii. (perhaps most controversially) apply some form of the precautionary principle in dealing with potentially serious risks of early-stage innovations.⁴⁰

In addition, the agreement might include certain *general commitments*, especially regarding research and information sharing, collaboration and the general character of national regulatory procedures. Again drawing on Vienna and the FCCC, the parties to FASTIR should commit themselves to:

- i. promote and cooperate in scientific, technological, socio-economic, ethical and other forms of research on and assessment of emerging innovations, beginning at the earliest possible stage in their development, with the aim of reducing uncertainty as to their potential benefits, risks and social, economic and ethical implications⁴¹;
- ii. cooperate to fully, openly and promptly exchange information on and assessments of emerging innovations and their potential benefits, risks and other impacts (subject to protections for trade secrets and other sensitive private information), through mechanisms established under the convention and directly among themselves⁴²;

³⁹The WTO Agreements on Technical Barriers to Trade (TBT) and on the Application of Sanitary and Phytosanitary Measures (SPS) include useful formulations of such principles. For example, the TBT Agreement provides that (a) technical regulations should not “create unnecessary obstacles to international trade;” and that (b) while states should be free to adopt necessary regulations, measures should not be applied in ways that constitute “arbitrary or unjustifiable discrimination” between states or “a disguised restriction on international trade.” TBT Agreement, Preamble, para. 6.

⁴⁰See, e.g., FCCC Art. 3:3: “The Parties should take precautionary measures to anticipate, prevent or minimize the causes of climate change and mitigate its adverse effects. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures, taking into account that policies and measures . . . should be cost-effective so as to ensure global benefits at the lowest possible cost.”

⁴¹Cf. FCCC Art. 4:g; Vienna Art. 2:2(a).

⁴²Cf. FCCC Art. 4:h.

- iii. provide technical and financial assistance, individually and collectively, to developing country parties to assist them in gathering information on and assessing the benefits, risks and other impacts of innovations, sharing such information and assessments, and formulating legal and policy responses;
- iv. evaluate the environmental, health and safety risks and the social and ethical implications of scientific and technological innovations along with their benefits;
- v. shape national regulatory processes to facilitate the coordination of legal and policy responses to emerging innovations, subject to variations due to differing regulatory cultures and legal systems, and to share information on the consequences of various response strategies⁴³;
- vi. give adequate advance notice to other parties of legal and policy actions that might have adverse external consequences, e.g., on international trade, through mechanisms established under the convention, and consult in good faith regarding any such consequences; and
- vii. participate in good faith in the institutions and procedures the convention creates.

9.4.4 Host Institution

The heart of FASTIR would be the creation of institutions and procedures for the coordination, steering and facilitation of national regulatory actions. As treaty bodies, the core institutions would be inter-state in nature.

The initial structural decision would be the selection of an organization to host FASTIR and provide the administrative, financial and intellectual services needed to build and operate an effective operational regime. The convention could create a new, freestanding host institution, but for reasons of cost and efficiency it would be preferable to identify an existing organization that provides a good “fit” with the objectives and mechanisms of the agreement.

“Fit” turns on three major factors. First, membership in the host organization should be roughly congruent with the states that are expected or desired to participate in the convention; at the least, all the essential convention parties should be members of the organization. This is often a difficult problem for treaty negotiators, as the international system includes a limited supply of effective organizations from which to choose. If perfect congruence cannot be achieved, as is often the case, the convention can provide special arrangements for collaboration by non-members. Second, the host organization should have the authority, expertise and experience to engage in the legal and political working methods envisioned by the convention. For example, if the convention contemplates the adoption of legally binding protocols, the host organization should be authorized to develop binding instruments and have

⁴³Cf. FCCC Art. 4:g-h.

experience in doing so; it should not be a purely soft law institution.⁴⁴ Third, the fundamental principles of the host organization should be consistent with those of the convention.

The UN specialized agency with the most specific science policy mandate is UNESCO – the United Nations Educational, Scientific and Cultural Organization.⁴⁵ UNESCO has certain advantages as a host institution. It is a true multilateral organization, with over 190 members, so all FASTIR parties are almost certain to belong. It has adopted both treaties, such as the Convention Concerning the Protection of the World Cultural and Natural Heritage (1972), and soft law instruments, such as the Universal Declaration on Bioethics and Human Rights (2005) and the International Declaration on Human Genetic Data (2003). Its principles emphasize the exchange of information, capacity building in developing countries, and respect for individual cultures, all likely to be consistent with FASTIR.

Yet UNESCO also has significant weaknesses. First, it focuses primarily on the cultural, human rights and related aspects of scientific issues within its mandate, as reflected in its Declaration on Bioethics and Human Rights and its Universal Declaration on the Human Genome and Human Rights (1997). As a result, while UNESCO could add substantial value in assessing the social, cultural and ethical impacts of innovations, it may be too narrow to serve as a host organization. Second, UNESCO's current priorities are to build scientific and science policy capacities in developing countries, while promoting poverty alleviation and sustainable development.⁴⁶ It might be an uncomfortable fit for the industrial countries that dominate scientific innovation. Third, some UNESCO policies have been highly controversial: the US, UK and Singapore withdrew from the organization in the 1980s, and the US remained outside for nearly 20 years.⁴⁷ Recent reforms have moderated these controversies, but UNESCO may still retain unnecessary political "baggage."

The OECD may be a more suitable host, although it too has weaknesses. The members of the organization are the 30 leading industrialized states, so most essential FASTIR parties – the states that are most active in advanced scientific and technological research and development – are OECD members. To be sure, some states important for the convention – notably the BRIC countries⁴⁸ and other developing and transitional economies where research is developing rapidly – are not

⁴⁴The converse is also true, although that situation is less common: if the convention contemplates operating through soft law, it should not affiliate with an organization (such as the WTO) that focuses solely on hard law. See Abbott and Snidal, *Pathways*, supra note 38.

⁴⁵See http://portal.unesco.org/en/ev.php-URL_ID=3328&URL_DO=DO_TOPIC&URL_SECTION=201.html; http://portal.unesco.org/science/en/ev.php-URL_ID=5802&URL_DO=DO_TOPIC&URL_SECTION=201.html, visited 10 Sept 2009.

⁴⁶ http://portal.unesco.org/science/en/ev.php-URL_ID=5805&URL_DO=DO_TOPIC&URL_SECTION=201.html, visited 10 Sept 2009. A leading priority is gender equality. http://portal.unesco.org/science/en/ev.php-URL_ID=5157&URL_DO=DO_TOPIC&URL_SECTION=201.html, visited 10 Sept 2009.

⁴⁷See http://portal.unesco.org/en/ev.php-URL_ID=14606&URL_DO=DO_TOPIC&URL_SECTION=201.html, visited 10 Sept 2009.

⁴⁸Brazil, Russia, India and China.

OECD members. In 2007, however, the OECD began a significant enlargement, inviting Russia as well as Chile, Estonia, Israel and Slovenia to begin discussions on membership and adopting a “road map” for negotiating their accession. It also offered “enhanced engagement, with a view to possible membership,” to Brazil, China, India, Indonesia and South Africa.⁴⁹ Some of these countries are also observers in OECD working parties that are considering specific emerging technologies. In addition, the OECD operates extensive outreach programs through its Centre for Co-operation with Non-Members. It sponsors ten “global forums” including non-members that address transnational problems; two new global forums, on biotechnology and the knowledge economy, are currently being created. Nonetheless, as critics such as the ETC Group argue, the structure of the OECD does not fully incorporate the views of developing countries that would feel the effects of any environmental, economic or other adverse consequences created by risky innovations.⁵⁰ To address this problem, FASTIR should provide adequate mechanisms for participation and input from concerned states not members of the OECD.

OECD working methods are also suitable. Most generally, the organization’s work is driven by research and analysis⁵¹; it has a large expert staff, and is among the world’s leading sources of economic and social data and forecasts as well as analyses of economic and social policy. National government experts provide, review and disseminate most of this information. The OECD is also familiar with trans-governmental and transnational policy-making. Most of its work is done in some 200 specialized committees and expert groups, in which representatives of national government agencies, staff and external experts share policy experiences, lessons learned and best practices, aiming for policy coordination.⁵² It also receives regular input from the private sector and workers through the Business and Industry Advisory Committee (BIAC) and the Trade Union Advisory Committee (TUAC), as well as other civil society links.⁵³ Finally, while the OECD relies primarily on soft law, including model treaties, best practice recommendations and guidelines, it also adopts and implements binding legal instruments, including conventions⁵⁴ and mandatory decisions.⁵⁵

⁴⁹“OECD invites five countries to membership talks, offers enhanced engagement to other big players,” 16 May 2007, available at http://www.oecd.org/document/33/0,3343,en_2649_34487_38603809_1_1_1_1,00.html, visited 10 Sept 2009.

⁵⁰ETC Group, Nanogeopolitics 2009: The Second Survey (draft July 2009), at 1, 10, http://www.lawbc.com/other_pdfs/00048599.PDF, visited 7 Sept 2009.

⁵¹See http://www.oecd.org/pages/0,3417,en_36734052_36761681_1_1_1_1,00.html, visited 7 Sept 2009.

⁵²See http://www.oecd.org/pages/0,3417,en_36734052_36761791_1_1_1_1,00.html, visited 7 Sept 2009.

⁵³See http://www.oecd.org/pages/0,3417,en_36734052_36761800_1_1_1_1,00.html, visited 7 Sept 2009.

⁵⁴For example, the Convention on Combating Bribery of Foreign Public Officials in International Business Transactions.

⁵⁵For example, the Code of Liberalisation of Capital Movements, adopted as a binding decision of the OECD Council.

Finally, the OECD already addresses significant aspects of science and technology policy,⁵⁶ including innovation,⁵⁷ international research collaboration,⁵⁸ nanotechnology⁵⁹ and biotechnology⁶⁰; the fundamental principles it follows in these fields are largely consistent with those animating FASTIR. To be sure, the economic and market orientation of the organization raises a note of caution. As noted above, OECD work on scientific and technological innovation has focused on developing incentives and appropriate market structures for innovation, access to global markets for products of innovation, and similar issues, as well as enhancing public support for R&D; in its work on innovation, the OECD has devoted little attention to the regulation of risks and other adverse impacts.⁶¹ In terms of regulatory policy, moreover, the OECD has been at the forefront of efforts to streamline regulation,⁶² promote regulatory impact assessment procedures,⁶³ and reduce administrative burdens.⁶⁴ However, the same OECD department that addresses regulatory policy has also considered risk regulation, and its work in that area has strived for balance.⁶⁵ Given its other advantages, the economic orientation of the OECD should not disqualify it as host for FASTIR.

9.4.5 Treaty Institutions

FASTIR would establish treaty bodies through which the state parties could take action under the convention. I merely sketch these institutions here, as their specific structures and functions would derive from the activities assigned to them.

The core institution of a framework convention is a *Conference of the Parties (COP)*. The COP is not simply the state parties meeting as a group, but an institution with its own authorities and decision-making procedures. The COP is typically authorized to promote agreed actions, such as information exchange and regulatory coordination. In addition, as the ultimate authority under the convention, the

⁵⁶See http://www.oecd.org/department/0,3355,en_2649_34269_1_1_1_1_1,00.html, visited 7 Sept 2009.

⁵⁷See note [33] *supra*.

⁵⁸http://www.oecd.org/department/0,3355,en_2649_34319_1_1_1_1_1,00.html, visited 7 Sept 2009.

⁵⁹http://www.oecd.org/site/0,3407,en_21571361_41212117_1_1_1_1_1,00.html, visited 7 Sept 2009.

⁶⁰http://www.oecd.org/department/0,3355,en_2649_34537_1_1_1_1_1,00.html, visited 7 Sept 2009.

⁶¹http://www.oecd.org/document/50/0,3343,en_41462537_41454856_41488882_1_1_1_1,00.html, visited 10 Sept 2009.

⁶²See note 24 *supra* and accompanying text.

⁶³*Ibid.*

⁶⁴http://www.oecd.org/document/43/0,3343,en_2649_34141_38227179_1_1_1_1,00.html, visited 7 Sept 2009.

⁶⁵http://www.oecd.org/document/23/0,3343,en_2649_34141_37551127_1_1_1_1,00.html, visited 7 Sept 2009.

COP adopts budgets, procedural rules and reports, establishes subsidiary bodies and makes similar administrative decisions. Most importantly, the COP is charged with continuously reviewing the adequacy of the convention's rules and procedures in light of advancing scientific knowledge, information on party compliance, and evidence of the convention's effectiveness. If the convention is judged to be insufficient in any of these areas, the COP may recommend – or even adopt – modifications.

The COP is supported by specialized committees and other *subsidiary bodies*. These may include traditional standing committees such as budget and administration; committees for particular fields of innovation, such as nanotechnology or synthetic biology; and a committee to supervise implementation and compliance.⁶⁶ Perhaps most significantly, modern conventions typically establish a scientific and technical committee to advise the COP, coordinate research collaboration, promote technical activities by participating states, assess the impact of the convention, and undertake similar important tasks.⁶⁷ If states adopt specific protocols under the framework convention, each would create its own Meeting of the Parties (MOP), analogous to COP for the parties to that protocol; a protocol can create its own subsidiary bodies or share those of the convention. Finally, the convention normally establishes a *secretariat*, which may be the host institution or may be housed there. The secretariat is responsible for day-to-day administration, but may also have considerable substantive influence, e.g., by analyzing information, consulting with experts and civil society, proposing modifications, promoting compliance, and controlling technical and financial assistance.

Finally, FASTIR should provide for *relations with other institutions*. Institutional relationships are particularly important in this case, for two reasons. First, FASTIR would rely on government agencies and officials and on a range of non-governmental actors (e.g., researchers, business firms, civil society organizations) to carry out much of its work. The convention should authorize relationships with such actors and organizations, and direct the COP and secretariat to establish and manage those relationships. Second, FASTIR – and hence the range of potential protocols – would have a very broad scope, extending over many aspects of scientific and technological innovation and regulation. It therefore faces a substantial risk of overlap or even conflict with other international agreements: many environmental treaties, for example, provide for regulation of technologies, scientific and technological research, technology transfer, information sharing and related matters.

One approach to institutional relationships – widely followed, but formal and narrow – is to authorize relevant international organizations and treaty secretariats, as well as qualified non-governmental organizations, to participate as “observers”

⁶⁶For example, FCCC Art. 10, “Subsidiary Body for Implementation.”

⁶⁷For example, FCCC Art. 9, “Subsidiary Body for Scientific and Technological Advice.” Some organizations with functions similar to those of FASTIR have elaborate structures of advisory and operational committees and other bodies. An interesting example is ICANN, the Internet Corporation for Assigned Names and Numbers. See <http://www.icann.org/en/structure/>, visited 9 Sept 2009.

in meetings under the convention.⁶⁸ Because FASTIR would initiate a high level of trans-governmental and transnational engagement, however, an approach that enables more extensive, informal cooperation would be more valuable. For example, the Convention on Biological Diversity (a similarly broad agreement which operates to some extent as a framework convention) directs its COP to contact the institutions of relevant treaties “with a view to establishing appropriate forms of cooperation with them.”⁶⁹ Even more broadly, the FCCC directs its COP to “seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies.”⁷⁰

9.4.6 Expedited Procedures

Finally, as a crucial part of the framework convention-protocol approach, FASTIR would establish procedures for collective action when the convention parties determine that action is required in a particular area. As noted earlier, this might be a specific field of scientific or technological research; a group of such fields; or one or more cross-cutting issues relevant to many areas of scientific and technological innovation.

Initially, the convention would have to establish procedures by which the state parties could identify and define specific areas or issues on which action should be taken. A wide range of approaches is possible. At one extreme, the FCCC prescribes only minimal procedures for initiating rule-making: any party may propose an amendment for action by the COP; the COP may adopt any protocol it wishes.⁷¹ In practice, the COP has used its broad authority to create a rule-making process, still highly flexible, managed by the COP Bureau (akin to an executive committee) with support from the secretariat and advice from specialized committees.⁷² At the other extreme, the International Labor Organization (ILO) administers a complex, two-year (“double discussion”) legislative process that involves several ILO bodies and requires consultations with governments, workers and employers.⁷³ For FASTIR, the general approach of the FCCC, including authority for the COP to develop detailed procedures, might be best.

⁶⁸For example, UNFCCC, Art. 7:6.

⁶⁹Convention on Biological Diversity, Art. 23:h.

⁷⁰FCCC, Art. 7:l.

⁷¹UNFCCC, Art. 15–17.

⁷²http://unfccc.int/essential_background/convention/convention_bodies/bureau/items/3431.php, visited 8 Sept 2009.

⁷³http://www.ilo.org/global/What_we_do/InternationalLabourStandards/Introduction/creation/lang-en/index.htm; International Labor Standards Handbook of Procedures, section I, [http://www.ilo.org/ilolex/cgi-lex/pdconv.pl?host?status01&textbase=iloeng&document=18&chapter=29&query=\(%23docno%3D25200602A\)+%40ref&highlight=&querytype=bool&context=0](http://www.ilo.org/ilolex/cgi-lex/pdconv.pl?host?status01&textbase=iloeng&document=18&chapter=29&query=(%23docno%3D25200602A)+%40ref&highlight=&querytype=bool&context=0), visited 8 Sept 2009.

The convention would then have to prescribe procedures for final action. Ideally these would be faster and less costly than the interstate negotiations needed to create a new treaty; in particular, Vienna and the FCCC each authorize the COP to take action by voting rather than by more time-consuming negotiation and agreement. The COP might act by adopting “protocols” – such as the well-known Montreal and Kyoto protocols – which set their own requirements for entry into force (e.g., minimum number of parties, national formalities). Vienna and the FCCC also authorize the COP to adopt amendments to the convention, “annexes” containing scientific, technical and administrative information, and amendments to protocols and annexes. The ozone regime in particular has made ample use of these procedures, repeatedly expanding its coverage of ozone-depleting substances and tightening its production and consumption limits and phase-out schedules as new information has become available.

In the remainder of this chapter, I sketch less formal modes of action the convention might also establish.

9.5 Information

For states to deal effectively with rapidly emerging innovations, they must establish processes that guarantee the production and sharing of early stage information on innovations and their potential benefits, risks and other impacts. In addition, to deal with the three types of uncertainty described above, states must have mechanisms to assess information as it emerges – in a technical sense, an economic, social and political sense, and often a normative sense. Even if we focus only on international efforts to coordinate, steer and facilitate national processes and to share the results across borders, these are challenging problems requiring institutional creativity. The ultimate solution – both domestically and internationally – will almost certainly require the engagement of all three levels of governance.

At the *transnational* level, FASTIR might first encourage states to establish domestic procedures that engage their scientific and technical communities, private sector and civil society in producing information, assessing it from multiple perspectives, and sharing the results.⁷⁴ It should also encourage them to adopt at least roughly similar procedures, subject to the many social, political and other differences among them, and to develop and use harmonized nomenclatures, indicators and other analytical tools. This form of steering could be accomplished through the adoption of principles or commitments, discussions in the COP or relevant committees, or efforts by the secretariat. The FASTIR parties could also fund technical assistance to help states with limited capacity to design and implement such procedures.

⁷⁴The 1998 Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters provides for rights of public participation in certain types of governmental decisions relating to the environment, and might be relevant to the procedures discussed here in states that have ratified that convention. See <http://www.unece.org/env/pp/welcome.html>, visited 10 Sept 2009.

FASTIR should also establish its own transnational information procedures. The core function of these mechanisms would be to encourage and promote the sharing of information across borders. Information sharing alone, however, would leave the assessment of innovations to individual states.⁷⁵ On the theory that multiple perspectives lead to better informed assessments,⁷⁶ FASTIR should go further, aiming to produce truly transnational assessments. For example, its scientific and technical advisory body could be tasked not only with traditional “vertical” functions such as reviewing the effectiveness of the convention and advising the COP, but also with “horizontal” functions such as sharing information and formulating common technical assessments, drawing on participating experts and the scientific communities they represent. FASTIR might establish similar transnational advisory bodies that represent technologically sophisticated business firms and civil society stakeholders, including workers, consumers and other concerned groups. Each body could share information and formulate collective assessments as well as advising the COP. Assessing social, cultural and ethical implications would be particularly challenging, as it requires normative deliberation; a multi-stakeholder body, broadly representative of societies and cultures, that brings together scientific and technological innovators and the stakeholders likely to be affected by their innovations would be best positioned to carry out this responsibility.

This level of private engagement would be unusual in an international institution, but it is essential in a regime devoted to ameliorating diverse forms of uncertainty. And it is not unprecedented. A similar approach has characterized the “transatlantic regulatory cooperation” (TRC) arrangements established by the US and the EU since the mid-1990s.⁷⁷ In addition to promoting cooperation among government agencies, TRC established people-to-people “dialogues,” spanning the two polities, to advise government negotiators on regulatory issues. The most influential has been the Transatlantic Business Dialogue⁷⁸; its views have largely set the TRC agenda. Others include the Transatlantic Consumer Dialogue⁷⁹ and a now nearly moribund Transatlantic Labor Dialogue. These Dialogues have somewhat different purposes than the bodies suggested here, but they indicate that it is feasible to incorporate non-state actors into international regimes.

Trans-governmental networks would be effective ways to share information, not only on innovations, but also on government interventions attempted or contemplated; consultations among officials could produce better informed regulation and avoid or address many international regulatory externalities. Trans-governmental

⁷⁵A commitment to share information and assessments was suggested above as an element of the convention.

⁷⁶See p. 130, *supra*.

⁷⁷For a history of these efforts, see Ahearn, Raymond J. Congressional research service, CRS report for congress – Transatlantic regulatory cooperation: Background and analysis, Oct. 22, 2008, available at <http://fas.org/sgp/crs/misc/RL34717.pdf>, visited 10 Sept 2009.

⁷⁸<http://www.tabd.com/>, visited 10 Sept 2009.

⁷⁹http://tacd.org/index.php?option=com_frontpage&Itemid=1, visited 10 Sept 2009.

networks would be equally effective at harmonizing nomenclatures and methodologies. They would allow regulators to share lessons learned on issues such as procedures for gathering early stage information on innovations, the conduct of technology assessments, the management of stakeholder and public input, and other governance issues. They could even encourage regulators to share and compare their assessments of risks and impacts, with the possibility of reformulating them based on peer input.

US-EU TRC programs have relied predominantly on trans-governmental approaches. For example, the 2005 Roadmap for US-EU Regulatory Cooperation⁸⁰ provided explicitly for collaboration on sectoral issues among agencies such as the US FDA, the EU DG Enterprise and Industry Pharmaceuticals Unit, and the European Medicines Agency; the US National Highway Traffic Safety Administration and the DG Enterprise and Industry Automobile Unit; and the US Consumer Product Safety Commission and DG Health and Consumer Affairs.⁸¹ FASTIR could either establish permanent networks of regulators from the most relevant agencies or could establish a mechanism for creating ad hoc networks as issues arose.

Finally, at the *inter-state* level, international agreements contain many procedures for information-sharing and collaboration that can serve as models. The FCCC provides a good illustration.⁸² This framework convention commits all state parties to develop, publish and share information on their greenhouse gas sources and sinks (using comparable methodologies developed by the COP) and on national mitigation measures; it further commits them to cooperate in scientific, technological, socio-economic and other research and to fully, openly and promptly exchange information.⁸³ Parties agree to support international research programs and networks, and to strengthen national research capabilities.⁸⁴ And the FCCC directs the COP to facilitate information exchange, coordinate national measures and develop comparable methodologies.⁸⁵

⁸⁰http://ec.europa.eu/enterprise/regulation/better_regulation/docs/docs_conference_EU_US_260106/2005_roadmap.pdf, visited 10 Sept 2009.

⁸¹For a recent summary of progress in these and similar initiatives, see Transatlantic Economic Council Report to the EU-US Summit 2008, available at <http://www.eurunion.org/partner/summit/Summit2008-06-10/2008EU-USSummitDeclar-6-10-08.pdf#page=16>, visited 10 Sept 2009.

⁸²In addition to the provisions discussed here, the FCCC directs its secretariat to cooperate with the Intergovernmental Panel on Climate Change (IPCC), a body established by the World Meteorological Organization and UN Environment Programme in 1989. The IPCC provides comprehensive periodic reviews of the state of scientific knowledge on climate change, its impacts and possible responses; it functions as an independent international source of information and assessment. This chapter, however, considers only mechanisms to encourage national governments and agencies to produce and share information.

⁸³FCCC Art. 4:1. See also Art. 12.

⁸⁴*Ibid.*, Art. 5.

⁸⁵*Ibid.*, Art 7.

9.6 Steering National Regulatory Systems

As a framework convention, FASTIR would not set the terms for the regulation of specific technologies or risks; that would be the function of subsequent protocols. Nonetheless, FASTIR could include an important, though more general, substantive component: principles and mechanisms designed to steer national institutions and procedures toward desirable *approaches* to technology regulation, and to facilitate implementation of those approaches in states with limited regulatory capacity. Agreed principles and procedures would also make it easier to coordinate national regulatory actions.

9.6.1 Science, Technology and Policy-Making

A major focus of these efforts should be the production and handling of scientific and technological information relevant to regulation. Especially when innovation is dynamic, effective and legitimate regulation requires institutions and processes that provide timely and appropriate scientific input into policy-making and that guarantee the integrity of that input. Currently, even some advanced states lack well-developed institutions and processes for scientific policy-making, while those that exist are far from comparable. Here again, modest international efforts could produce significant benefits.

In terms of institutions, for example, the United Kingdom Parliament is advised by the Parliamentary Office of Science and Technology (POST), which aims to provide “independent, balanced and accessible analysis of public policy issues related to science and technology.”⁸⁶ POST also engages in “horizon-scanning to anticipate issues of science and technology that are likely to impact on policy.”⁸⁷ POST and similar organizations advising other European legislatures, including the European Parliament, have formed the European Parliamentary Technology Assessment (EPTA) network “as an aid to the democratic control of scientific and technological innovations.” In addition to enhancing each member’s own work, EPTA can undertake joint technology assessments.⁸⁸ In the US, in contrast, although Congress created the Office of Technology Assessment (OTA) in 1972 to provide “objective and authoritative analysis of complex scientific and technical issues to aid in policymaking,”⁸⁹ it terminated funding for OTA in 1995.⁹⁰

⁸⁶http://www.parliament.uk/parliamentary_offices/post.cfm, visited 10 Sept 2009.

⁸⁷Ibid.

⁸⁸<http://www.eptanetwork.org/EPTA/about.php>, visited 10 Sept 2009.

⁸⁹Knezo, Genevieve. Congressional research service, “Technology assessment in congress: History and legislative options,” CRS report for congress RS21586, May 20, 2005, at 1. OTA is explicitly credited as the inspiration for EPTA. <http://www.eptanetwork.org/EPTA/about.php>, visited 10 Sept 2009.

⁹⁰Knezo, supra note 89, at 1. The Government Accountability Office (GAO) has been granted temporary authority to conduct technology assessments on a pilot basis, and proposals to make

In the executive branch, both the UK and the US have government science advisers: in the UK, the Government Chief Scientific Adviser (GCSA) in the Government Office for Science⁹¹; in the US, the Director of the Office of Science and Technology Policy (OSTP) in the Executive Office of the President.⁹² Here too, however, the UK has introduced potentially worthwhile innovations. For example, since 2002 it has created a network of Chief Scientific Advisers based in a wide range of executive departments; each Adviser is charged with supporting the use of scientific evidence in policy-making, ensuring the quality of scientific inputs, and making its department a better consumer of science.⁹³ In addition, the government has adopted a common code of practice for scientific advisory committees⁹⁴ as well as common guidelines for executive departments and agencies on the use of science in policy-making.⁹⁵

In terms of process, perhaps the most significant issue is guaranteeing integrity in the supply and use of scientific and technological information. In the US during the administration of President George W. Bush, many scientists and other critics challenged the integrity of the policy process, charging that scientific input was manipulated for political ends.⁹⁶ Such interference must clearly be avoided if emerging innovations are to be properly understood and regulated. President Barack Obama has responded strongly to these critiques, charging the Director of OSTP with “the responsibility for ensuring the highest level of integrity in all aspects of the executive branch’s involvement with scientific and technological processes.”⁹⁷ More concretely, the President has instructed the Director to “develop recommendations for Presidential action designed to guarantee scientific integrity throughout the executive branch;” those recommendations are to reflect stated principles, including

that arrangement permanent or to create an agency similar to OTA have been regularly introduced. *Ibid.*, at 3–6.

⁹¹<http://www.chiefscientificadviser.ie/>, visited 10 Sept 2009

⁹²<http://www.ostp.gov/>, visited 10 Sept 2009.

⁹³House of Commons, Science and Technology Committee. “Scientific advice, risk and evidence based policy making: Government response to the committee’s seventh report of session 2005–06,” First special report of session 2006–07, HC 307, Feb. 27, 2007, at 2.

⁹⁴Government Office for Science. Code of practice for Scientific Advisory Committees, December 2007, available at http://www.dius.gov.uk/partner_organisations/office_for_science/science_in_government/strategy_and_guidance/~media/publications/F/file42780, visited 10 Sept 2009

⁹⁵HM Government. Guidelines on scientific analysis in policy making, October 2005, available at <http://www.berr.gov.uk/files/file9767.pdf>, visited 10 Sept 2009

⁹⁶See, e.g., 2004 Union of concerned scientists statement on restoring scientific integrity to federal policy making, available at http://www.ucsusa.org/scientific_integrity/abuses_of_science/scientists-sign-on-statement.html, visited 10 Sept 2009; 2008 Union of concerned scientists statement on scientific freedom and the public good, available at http://www.ucsusa.org/scientific_integrity/abuses_of_science/scientific-freedom-and-the.html, visited 10 Sept 2009.

⁹⁷Memorandum for the Heads of Executive Departments and Agencies, “Scientific integrity,” March 9, 2009, available at http://www.whitehouse.gov/the_press_office/Memorandum-for-the-Heads-of-Executive-Departments-and-Agencies-3-9-09/, visited 10 Sept 2009.

the appointment of science and technology officials based on expertise and integrity rather than political considerations, and reliance on scientific processes such as peer review.⁹⁸

International cooperation on these issues has been very limited. The OECD regularly considers a variety of science and technology policy issues, including innovation as a spur to economic growth,⁹⁹ public sector research,¹⁰⁰ and international cooperation in basic research¹⁰¹; but it has not attempted to steer or coordinate national policy in the areas considered here. FASTIR could make an important contribution by enunciating principles and developing recommendations, best practices, guidelines, or even binding rules on the sources of scientific and technological information and analysis, the integrity of that information, and its appropriate use by legislators, regulatory agencies and executive policy-makers.

9.6.2 Regulatory Practice

A second focus area should be the promotion of good regulatory practices. Steering and facilitation in this area would encourage more efficient, effective and legitimate responses to innovations, and would increase the harmonization of national regulatory procedures and techniques, easing coordination of specific regulatory actions. By improving poor regulatory practices in particular states, these efforts could combat the emergence (or persistence) of “risk havens” – states with sufficient scientific and technological capacity to produce or consume risky innovations, but without the governance capacity to regulate appropriately – as well as the broader competitive incentives to under-regulate.

FASTIR could draw from existing international programs on regulatory practice. One useful building block might be the “Better Regulation” strategy implemented by the European Commission since 2002, expanded in 2005 as part of the revised “Lisbon Strategy” to stimulate economic growth and employment.¹⁰² Better Regulation is said to be motivated in part by the need to respond to rapid technological change¹⁰³; however, its principal goal appears to be reducing the economic burdens of regulation.

⁹⁸Ibid.

⁹⁹http://www.oecd.org/document/7/0,3343,en_2649_34273_1911303_1_1_1_1,00.html, visited 10 Sept 2009.

¹⁰⁰http://www.oecd.org/about/0,3347,en_2649_34293_1_1_1_1_1,00.html, visited 10 Sept 2009.

¹⁰¹http://www.oecd.org/department/0,3355,en_2649_34319_1_1_1_1_1,00.html, visited 10 Sept 2009.

¹⁰²Communication from the Commission to the Council and the European Parliament – Better Regulation for Growth and Jobs in the European Union, COM/2005/0097 final, 16 March 2005.

¹⁰³European Commission, Better Regulation – Simply Explained (2006), at 4, available at http://ec.europa.eu/governance/better_regulation/documents/brochure/br_brochure_en.pdf, visited 10 Sept 2009.

Better Regulation has five major components: (1) assessing the economic, social and environmental impacts of proposed regulations (regulatory impact assessment)¹⁰⁴; (2) assessing the “red tape” and other administrative burdens of proposed regulations; (3) consulting with stakeholders; (4) considering alternatives to mandatory regulation, including non-binding recommendations, directives that allow national flexibility rather than uniform regulations, co-regulation (entrusting the achievement of regulatory goals to private parties), and self-regulation; and (5) simplifying existing regulations.¹⁰⁵ The Commission applies these measures at EU level and encourages member states to do so domestically.

Better Regulation clearly resembles the US regulatory review procedure conducted since 1981 by the Office of Management and Budget (OMB), first under President Reagan’s Executive Orders 12291 and 12498, and since 1993 under President Clinton’s Executive Order 12866,¹⁰⁶ as well as various OMB guidance instruments.¹⁰⁷ However, the European Commission notes two significant differences: OMB has focused heavily on cost-benefit analysis of proposed regulations, whereas Better Regulation calls for a broader analysis of alternatives; and OMB considers only administrative regulations, whereas Better Regulation also covers European measures equivalent to legislation.¹⁰⁸ On the first point, the Obama administration may again change course: it has directed OMB to make recommendations for a new executive order on regulatory review; those recommendations are to address elements such as “the role of cost-benefit analysis; . . . distributional considerations, fairness, and concern for the interests of future generations; . . . methods of ensuring that regulatory review does not produce undue delay; . . . [and] the role of the behavioral sciences . . .”¹⁰⁹

Two other existing programs are also relevant. First, since 1995 the OECD has developed principles for good regulation and regulatory reform; it applies those principles to its member states through peer review and disseminates them to non-members.¹¹⁰ The current Guiding Principles for Regulatory Quality and Performance were adopted in 2005.¹¹¹ They emphasize competition, efficiency, deregulation and open trade, with the goal of enhancing economic growth and productivity, and call for regulatory impact assessment. As noted above, the

¹⁰⁴The economic aspect was strengthened in 2005. See Communication, *supra* note 102, at section 2:A.

¹⁰⁵See Communication, *supra* note 102.

¹⁰⁶E.O. 12866, “Regulatory Planning and Review,” 30 Sept 1993, 58 Fed. Reg. 51735, 4 Oct 1993.

¹⁰⁷For example, Office of management and budget, circular A-4, “Regulatory analysis,” 17 Sept 2003, available at http://www.whitehouse.gov/omb/assets/regulatory_matters_pdf/a-4.pdf, visited 10 Sept 2009.

¹⁰⁸Communication, *supra* note 102, at 15. On cost-benefit analysis, see Circular A-4, *supra* note 107, at 2–3.

¹⁰⁹Memorandum for the Heads of Executive Departments and Agencies, “Regulatory Review,” Jan. 30, 2009, 74 Fed. Reg. 5977, 3 Feb 2009.

¹¹⁰http://www.oecd.org/about/0,3347,en_2649_34141_1_1_1_1_1,00.html, visited 10 Sept 2009.

¹¹¹<http://www.oecd.org/dataoecd/24/6/34976533.pdf>, visited 10 Sept 2009.

OECD has also considered issues of risk assessment and management.¹¹² Second, US-EU TRC programs have focused on avoiding barriers to trade created by disparate regulatory processes, especially product standards, testing and certification.¹¹³ The 2002 Guidelines on Regulatory Cooperation and Transparency¹¹⁴ encourage regulators to consult before such regulations are adopted.¹¹⁵ The 2005 Roadmap¹¹⁶ establishes dialogues among regulators on specific products, as well as cross-cutting dialogues. An OMB-European Commission dialogue has helped the agencies understand their respective approaches to regulatory review, but has produced little harmonization.¹¹⁷

Unfortunately, while all of these programs help to constrain excessive regulation and adverse impacts on trade, and some, such as Better Regulation, encourage flexible alternatives to command-and-control regulation, none of them seems well designed for the challenges posed by dynamic scientific innovation. National programs like Better Regulation and OMB review, moreover, differ in significant ways. Thus, while FASTIR could build on these programs, it would be necessary to modify them to address the unique problems of dynamic innovation: e.g., by encouraging the appropriate use of scientific information and assessments; ensuring balanced consideration of potential benefits, risks and other impacts along with regulatory burdens; and providing tools for rapid action in case of emerging threats.

9.6.3 *Trans-governmental Dialogue*

Both science and technology policy and good regulation are appropriate areas for a trans-governmental approach. Beyond traditional regulatory bodies such as environment or food and drug agencies, trans-governmental arrangements could be extended to legislators and to specialized actors such as science advisors and members of scientific advisory committees.

Many of the international norms and programs on science and technology policy and regulation just discussed have been created through trans-governmental

¹¹²http://www.oecd.org/document/23/0,3343,en_2649_34141_37551127_1_1_1_1,00.html, visited 10 Sept 2009.

¹¹³A major goal of TRC was to negotiate mutual recognition agreements that would obviate disparate product regulation. However, only three sectoral agreements were adopted. See Ahearn, CRS Report, *supra* note 77.

¹¹⁴http://ec.europa.eu/enterprise/regulation/better_regulation/docs/docs_conference_EU_US_260106/GUIDELINES_EU-US_FINAL.pdf, visited 10 Sept 2009.

¹¹⁵The 2006 Best Cooperative Practices distill lessons for such consultations. http://trade.ec.europa.eu/doclib/docs/2006/july/tradoc_129223.pdf, visited 10 Sept 2009. In spite of TRC, some major regulations, such as the EU REACH program for chemicals, were adopted without the contemplated notice and consultation. Ahearn, *supra* note [77].

¹¹⁶Note 80 *supra*.

¹¹⁷See http://www.whitehouse.gov/omb/assets/regulatory_matters_pdf/draft_sg-omb.pdf, visited 10 Sept 2009.

deliberations – e.g., in the OECD Working Party on Regulatory Management and Reform and Working Group on Technology and Innovation Policy. Others rely on trans-governmental deliberations to achieve their ends – e.g., through the sectoral US-EU regulatory dialogues and the cross-cutting OMB-Commission dialogue. However, virtually all of these bodies are composed of officials with a single mandate and viewpoint. Thus, the OECD Working Party is made up of “officials responsible for cross-cutting and horizontal regulatory reform policies,”¹¹⁸ while its Working Group is composed of “officials responsible for science, technology and innovation.”¹¹⁹ Such institutions are likely to produce understandings skewed to their particular interests and modes of thinking, without adequate consideration of competing concerns and approaches. FASTIR could make an important contribution by establishing balanced trans-governmental bodies that could consider potential tradeoffs among regulatory approaches; identify best practices in the use of scientific information for policy-making and in appropriate, timely and effective regulation; promote those practices through broad consultations, technical assistance and peer review; and facilitate their widespread adoption by governments.

9.7 Regulatory Action

When it becomes necessary to coordinate concrete regulatory measures (broadly defined) aimed at particular innovations, risks or other impacts, all three levels of governance should once again be engaged.

At the *transnational* level, FASTIR could follow an approach a co-author and I call “transnational new governance:” promoting and orchestrating the development and implementation of self-regulation and voluntary codes of conduct among the private actors responsible for developing and commercializing scientific and technological innovations, alone and in cooperation with concerned stakeholders. This approach would draw on the knowledge and capacities of those actors, making them part of the overall regulatory system, not mere targets of regulation.¹²⁰

As Brian Rappert’s chapter makes clear, professional codes of conduct have for the most part failed to address regulatory issues such as those considered here, and have been weakly implemented and enforced.¹²¹ Outside of the professions, however, considerable progress toward self-regulation and voluntary multi-stakeholder codes has already been made, especially in industries and areas of scientific and technical activity where the risks are perceived to be substantial. These include the

¹¹⁸http://www.oecd.org/about/0,3347,en_2649_34141_1_1_1_1_1,00.html, visited 10 Sept 2009.

¹¹⁹http://www.oecd.org/document/7/0,3343,en_2649_34273_1911303_1_1_1_1,00.html, visited 10 Sept 2009.

¹²⁰Public orchestration of private regulatory activity like that suggested here reflects the New Governance model of regulation. See Abbott & Snidal, *Strengthening International Regulation*, note 31, *supra*.

¹²¹Rappert, [Chapter 8](#), this volume. Professional codes have begun to grapple with somewhat similar problems concerning the ethics of research.

chemical industry,¹²² biological research – which many fear could be misused for destructive purposes such as biological weapons or terrorism¹²³ – and nanotechnology.¹²⁴

In the latter field, for example, the Foresight Institute developed its Guidelines for Responsible Nanotechnology Development – applicable to scientific and technological researchers, business firms and even government policy-makers – over several iterations beginning in 1999, through workshops and other interactions among members of the nanotechnology development community.¹²⁵ The current Guidelines focus on the riskiest area of nanotechnology research, autonomous replicators, but also state broader principles of responsible development; separate guidelines apply to researchers, firms and policy-makers. In addition, the Nanotechnology Industries Association, in collaboration with the Royal Society and Insight Investment, and subsequently with the UK government-sponsored Nanotechnology Knowledge Transfer Network, adopted the Responsible NanoCode in 2008. The NanoCode consists of broad strategic principles that apply throughout the product life-cycle, supplemented by concrete examples of good practice in implementing each principle; good practice guidelines allow for the benchmarking of individual organizations' performance. The founding partners of the NanoCode are themselves widely representative, and the multi-stakeholder working group that developed the Code engaged in extensive consultations.¹²⁶ Public authorities such as the European Commission have also begun to promulgate voluntary nanotechnology codes.¹²⁷

FASTIR could encourage the adoption of appropriate self-regulatory and other voluntary codes; facilitate their adoption and implementation; provide an international imprimatur for codes that meet agreed procedural and substantive standards;

¹²²See, e.g., Responsible Care Global Charter, adopted by the International Council of Chemical Associations, <http://www.responsiblecare.org/page.asp?p=6341&l=1>, visited 10 Sept 2009.

¹²³See The Royal Society. The role of codes of conduct in preventing the misuse of scientific research, RS policy document 03/05, available at <http://royalsociety.org/document.asp?id=3215>, visited 10 Sept 2009; Developments in codes of conduct since 2005, available at [http://www.unog.ch/80256EDD006B8954/\(httpAssets\)/358F8EE5D00C281CC125747B004F57CF/\\$file/codes+background+paper+-+advanced+copy.pdf](http://www.unog.ch/80256EDD006B8954/(httpAssets)/358F8EE5D00C281CC125747B004F57CF/$file/codes+background+paper+-+advanced+copy.pdf) (biosecurity codes), visited 10 Sept 2009.

¹²⁴See Bowman, Diana M., and Graeme A. Hodge. 2009. Counting on codes: An examination of transnational codes as regulatory governance mechanism for nanotechnology. *Regulation & Governance* 3: 145–64. In addition to codes adopted by firms or industry associations, multi-stakeholder groups and public authorities, the Coalition of Non-Governmental Organizations adopted “Principles for the Oversight of Nanotechnologies and Nanomaterials” in 2007. More aggressive than most of the other codes, e.g., in prescribing precautionary measures and calling for mandatory regulation, the Principles seek to shape the regulatory dialogue as well as the behavior of firms. *Ibid.*

¹²⁵<http://www.foresight.org/guidelines/current.html>, visited 10 Sept 2009.

¹²⁶<http://www.responsiblenanocode.org>, visited 10 Sept 2009; Information on the responsible nano code initiative, May 2008, available at *id.*

¹²⁷See European Commission Adopts Code of Conduct for Responsible Nanosciences and Nanotechnologies Research, IP/08/193, Feb. 8, 2008, <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/193&format=HTML>, visited 10 Sept 2009.

and disseminate information regarding the design and implementation of high-quality codes. The goal would be to create a “race to the top,” in which industries, researchers and professions compete to be seen as appropriately regulating their activities.¹²⁸ The institutions of FASTIR, e.g., its secretariat and scientific advisory committee, could pursue this goal by working with existing groups. Those institutions could also participate in the process more directly, at least to some extent: for example, the convention’s scientific and business advisory committees could develop model codes or work to to harmonize existing codes.

Trans-governmental networks perform a variety of regulatory functions, including facilitating enforcement. Most important for present purposes, “networks of agencies negotiate, implement, and diffuse norms that are often precise and elaborate, and may be politically powerful though not binding as a matter of [international law]. . . .”¹²⁹

Many international financial regulatory regimes operate trans-governmentally. An important example is the Basel Committee on Banking Supervision, made up of central bank officials and banking regulators from major economies. The Basel Committee has formulated widely implemented guidelines for judging the adequacy of bank capital, as well as principles of effective bank supervision and norms allocating national jurisdiction to supervise international banks.¹³⁰ Trans-governmental norms such as the Basel guidelines are closer to “soft law” than to treaties or protocols, but they can be adopted more rapidly than treaties, are more flexible, and better reflect technical expertise. They can, moreover, be powerful mechanisms for learning, socialization and technical assistance.¹³¹ To be sure, trans-governmental networks have significant weaknesses, especially when the participating agencies have conflicting interests or face domestic legal and political constraints.¹³² Nonetheless, they would be a valuable element in an overall system of coordination, steering and facilitation. Under FASTIR, the same trans-governmental bodies that share information and formulate best practices in the use of scientific information and the design of regulatory processes could develop more specific substantive norms to steer and coordinate national regulations.

Finally, at the *international* level, this chapter has already discussed the framework convention-protocol approach to the incremental adoption of legally binding inter-state rules. Yet protocols need not be limited to the traditional inter-state

¹²⁸ Abbott & Snidal, Strengthening International Regulation, note 31 supra.

¹²⁹ Abbott, Kenneth W. 2008. Enriching rational choice institutionalism for the study of international law. *University of Illinois Law Review* 5: 27.

¹³⁰ *Ibid.*, at 27. The 2008 financial crisis revealed the Basel capital adequacy guidelines to be *substantively* deficient. However, there is no reason to conclude that the *trans-governmental structure* of the Basel Committee was responsible for the deficiencies; indeed, the widespread adoption of the guidelines, which may have contributed to the breadth of the crisis, demonstrates the power of the trans-governmental approach.

¹³¹ Slaughter, supra note 12, at 3–5, 36–55.

¹³² See Verdier, Pierre-Hugues. 2009. Transnational regulatory networks and their limits. *Yale International Law Journal* 34: 113–172.

approach of treaties, in which implementation is left almost wholly to individual states. Instead, FASTIR protocols could themselves incorporate elements of the transnational and trans-governmental approaches.

9.8 Conclusion

Keeping pace with rapid scientific and technological innovation is one of the most challenging problems facing modern society. It is a multi-faceted problem, involving environmental, health and safety issues, economic issues, even social, cultural and ethical issues. It is fraught with uncertainty. Its structure poses difficult political and institutional challenges: it requires preliminary action before any concrete problems have appeared, then very fast action once problems do appear. Exacerbating all of these difficulties, it is a transnational problem, not merely a national one, and its transnational character is expanding as more and more countries develop capacities for innovation.

No institutional innovation will meet these challenges perfectly. But the framework convention approach proposed here would engage a wide range of governance approaches to address the many facets of the problem; would reduce uncertainty by promoting the sharing of information, common assessments and normative deliberations; and would facilitate institutional action by easing both initial preliminary responses and more concrete, adaptive regulatory responses over time. While imperfect, it may be the best transnational response to the “wicked” problem of innovation.