2.2.1 Decision-making approaches, tools, and evidence in STI governance

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Abstract

In this section, I discuss “what” and “how” to evaluate, examine, and make decisions in policy decision-making surrounding the social adoption of STI.

As policy considerations for the social adoption of STIs vary depending on the degree to which the STI in question is socially entrenched, this section provides a comprehensive overview of the state of the social adoption of STIs and policy process considerations, together with useful approaches and tools for assessing them: (1) horizon scanning, (2) foresight, (3) technology assessment (TA), (4) risk approach, and (5) regulatory gap study and regulatory impact assessment. This section then describes the characteristics of the “evidence” (i.e., the basis for decision-making and policy judgment) that is required regardless of the approach or tool used, noting how the content of the required “evidence” (e.g., items, specificity, quantitative/qualitative) varies depending on the stage of the policy process. This paper also underscores how important it is for governance to design institutions in which the outcomes of individual activities based on these approaches and tools are coordinated, transferred, and linked from a holistic perspective in step with the advance of the social adoption of STI and the policy process.

Keywords

Evidence, joint fact-finding (JFF), horizon scanning, foresight, technology assessment (TA), risk approach, regulatory gap study/regulatory impact assessment, adaptive governance, transition management

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1 Useful approaches and tools in the policy process

1.1 The state of social adoption of STI and policy processes

Although STI does not necessarily develop linearly, its social adoption can be categorized into germination, development, marketization, and socially established stages. In the policy process, the responses to be considered or taken will vary in emphasis depending on the degree of social adoption (in this section, the "policy process" is viewed as a process by which policy responses are implemented according to the social adoption of STI). In the germination/developmental stage, greater emphasis is placed on understanding the signs apparent at the basic research level, identifying options for the direction of emerging technologies, comparing them with existing technologies, relating them to alternative technologies, and forming a vision of the society in which the technology will be situated. Entering the developmental/social adoption stage, it is necessary to evaluate the safety and social impact of the emerging technology field as a whole (ELSI: ethical, legal, social issues), and formulate policies and plans at the government level. At the stage where a new technology is actually commercialized and introduced into society, it is necessary to establish a management system for each field, including laws and regulations for each field of application, and consider policy and standardization to promote the technology in question. Following the introduction and establishment of the technology in society, it is necessary to review the measures taken and issues that emerge, and provide feedback to policies.

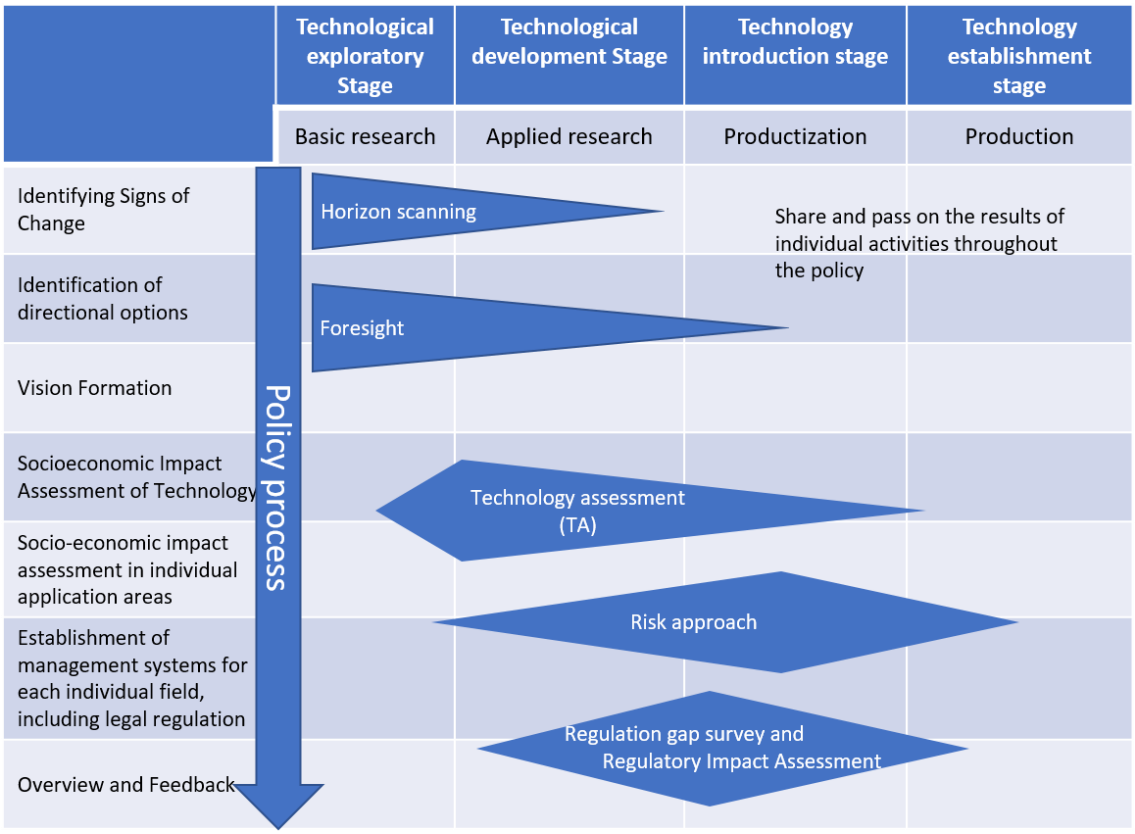

Figure 1: Initiatives for the governance of emerging technologies.
Source: (Matsuo Makiko and Kishimoto Atsuo, 2017)

1.2 Useful approaches and tools

Different approaches and tools may be useful depending on the state of social adoption of STI and the policy process considerations described above. This section introduces the following approaches and tools, which are particularly useful for STI governance: (1) horizon scanning, (2) foresight, (3) technology assessment (TA), (4) risk approach, and (5) regulatory gap study/regulatory impact assessment. The usefulness of these approaches and tools depends on the state of social adoption of a technology and the response required by the policy process (see Table 1 for individual overviews).

Table 1: An overview of useful methods and approaches for the governance of emerging technologies[2]

①Horizon scanning	Activities to capture a wide range of future signs and buds. It may be considered as a limited method or technique, or it may be considered as a series of foresight processes. STEEPLD (Society, Technology, Environment, Economic, Politics, Legal, Ethical and Demographic) analysis is conducted by collecting a variety of information.
②Foresight	Activities to formulate a vision of the future from a long-term, bird's-eye viewpoint, and to formulate policies based on that vision, including Horizon scanning, the Delphi method, scenario planning, road mapping, and various other methods.
③Technology assessment (TA)	Activities to anticipate potential positive and negative social impacts of specific science and technology, and to support issue setting and social decision-making on technology development and its use. There are (i) traditional methods by experts, (ii) participatory methods (consensus meetings, scenario workshops, citizen juries, etc.), and (iii) methods such as constructive TA (CTA) and real-time TA (RTA), which are developed from the upstream of science and technology through interaction between R&D and TA.
④Risk-based approach	Activities to estimate the likelihood (probability/frequency) of the occurrence of negative impacts on the target to be protected, such as human life, ecosystems, or the survival of a country, and the magnitude of such impacts, and to consider measures to keep them below the level acceptable to society. Scientific analysis methods have been developed in fields such as chemicals, machinery, disaster prevention, security, and finance.
⑤Regulation gap survey and Regulatory impact assessment	Regulatory Gap Survey is an activity to examine whether there is a "regulatory gap" where the impact of the development of emerging technologies is not covered by current laws and regulations. Regulatory Impact Assessment is an activity to quantitatively examine the regulatory compliance costs, expected effects, and secondary effects of multiple alternatives that can achieve the objectives of new or revised laws or regulations.

Source: (Organized with reference to Matsuo Makiko and Kishimoto Atsuo, 2017)

2 However, it is worth noting that there are various definitions of these methods and approaches.

Horizon scanning and foresight are well-suited to the broad identification of signs of change in emerging technologies and strategically shaping a long-term vision over decades. In contrast, TA involves evaluating and analyzing the positive and negative social impacts (risks and benefits) of emerging technologies that are expected to be introduced into society with a high degree of certainty in the near future, and supports social decision-making by presenting alternatives (Yoshizawa Tsuyoshi, 2009; Shiroyama Hideaki et al., 2010; Shiroyama Hideaki et al., 2011). The risk approach aims to manage the risks posed by technologies that are more realistically expected to be introduced into society at a level below that considered socially acceptable. Regulatory gap studies examine whether the risks to be managed can be addressed within the current legal framework. This is also done in the TA and risk approaches. When the results are used to introduce or review regulations, regulatory impact assessments are conducted.

2 Characteristics of evidence required in decision making

2.1 Materials for decision-making: What is evidence?

"Evidence" is the body of evidence to which decision-makers refer and which they consider when making decisions based on specific objectives and needs. As discussed in Section 2.1.1, "STI governance structure" (Shiroyama Hideaki et al., 2021a), as both the subjects of STI and its effects have become increasingly expansive and multidimensional, the facts upon which decisions are based must also become more comprehensive. Evidence[3] includes both qualitative and quantitative evidence, and is not limited to the natural sciences. It also covers a wide range of domains including the humanities and social sciences, as well as tacit knowledge rooted in the community, field, and so on (Matsuo Makiko et al., 2015). Evidence only becomes usable when it is visualized (quantified, converted into data,[4] statements, and so on). Moreover, the scope of what constitutes evidence relates to the framing of the problem. It is for this reason that it is particularly important to set issues upstream of the policy process (see 1.1 above). Moreover, making balanced decisions presents the challenge of assessing both the risks and benefits during evaluation.

The evidence required varies depending on the stage of the policy process. Nonetheless, in the following, I focus on evidence in the risk approach stage (monitoring and risk management). Evidence can be broadly categorized into "scientific facts" and "other facts." The term "scientific fact" refers to facts derived from scientific data and scientific reasoning and methods, and the methods for evaluating these have evolved in individual disciplines. Some scientific facts are global to some extent, such as hazard assessment in food risk assessment, while others are influenced by local factors (e.g., geographical, climatic, cultural, and institutional factors), such as disclosure risk assessment. Meanwhile, "other facts" is a general term for

3 This section understands "evidence" in this way, but there are various definitions (see, for example, Center for Research and Development Strategy, Japan Science and Technology Agency, 2010). Although documents such as the Science and Technology Basic Plan refer to "evidence (objective basis)," as discussed in this section and in Section 2.1.2, "STI policy process" (Shiroyama Hideaki et al., 2021b), evidence for STI, which has far-reaching social impacts, should not be limited to "objective" evidence in a narrow sense, but be broadly viewed as any basis that is referenced and considered in decision-making. Depending on the subject of the assessment, decision-makers must make appropriate judgments during the upstream design of the assessment as to whether it is appropriate to take a more limited or broader view of evidence.

4 For example, WHO (2015) data on illnesses and deaths caused by contaminated food revealed previously unknown foodborne illnesses and deaths (estimated to cause 600 million cases and 420,000 deaths per year), and more proactive measures are being taken to ensure food safety.

facts about social implications besides "scientific facts," and specifically includes elements such as feasibility, costs and benefits, domestic and international standards and regulations, fairness and ethical considerations, and other so-called ELSI (ethical, legal, and social implications). Some of these can be implemented quantitatively, while others are qualitative.

Evidence is an element that is commonly required regardless of which tool mentioned above is used (1.). In the upstream of the policy process, more qualitative and wide-ranging "evidence" must be collected, while in the downstream of the process, more specific and quantitative "evidence" tends to be utilized.

2.2 Institutional design for judging scientific uncertainty

In the following, I focus on "scientific facts" involving the potential risks of emerging technologies and examine the lines of scientific judgment. Risk assessment involves the assessment of the aforementioned "scientific facts," while risk management is the function that provides comprehensive examination, including "other facts," and takes countermeasures based on that risk assessment. However, the boundary between the two is not so obvious in practice. The treatment of uncertainty in respect to "scientific facts" may differ depending on the discipline's scientific reasoning (assumptions and defaults such as safety factors, extrapolation, and so on) (Figure 2) and the nature of the subject under evaluation. Moreover, differences in interpretation between individual experts may yield different results. The scope of scientific facts and the extent to which either risk assessment or risk management plays a role in determining uncertainty vary depending on the risk area (e.g., environment, food, hygiene) and the ministry or agency in charge. In fact, there are many variations. For instance, risk assessment may include scientific reasoning in addition to scientifically certain parts, and may be limited to scientifically certain parts. Meanwhile, the examination of scientific reasoning may be carried out by the risk management side or by neither party (Figure 3) (on this point, also see "Regulatory science" in 2.2.3). Moreover, the "appropriate level of protection" in society is a comprehensive judgment involving subjective judgments that consider "other factors," including social implications, in addition to the various "scientific facts" mentioned above.

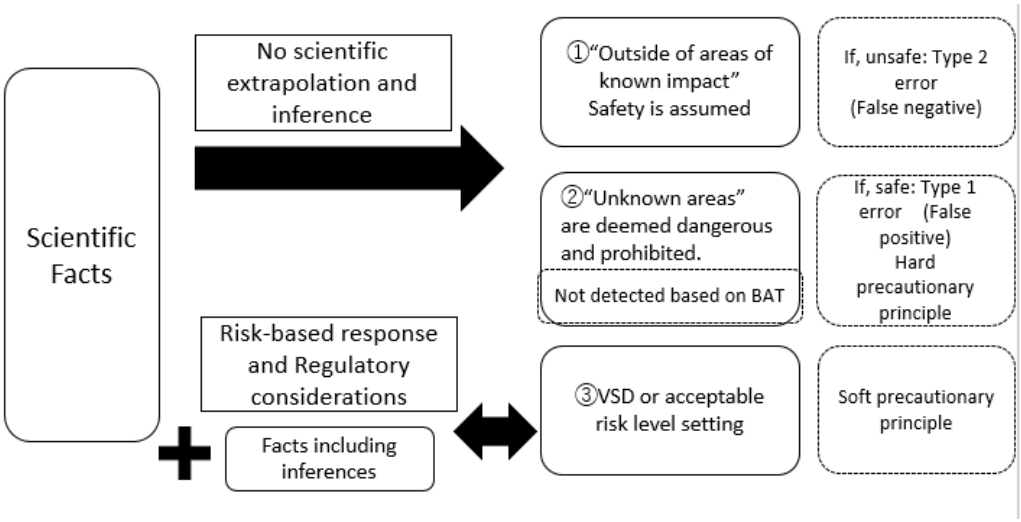

Figure 2: Patterns of dealing with uncertainty involving scientific facts in risk management
Source: Modified from Matsuo Makiko et al. (2015)[5]

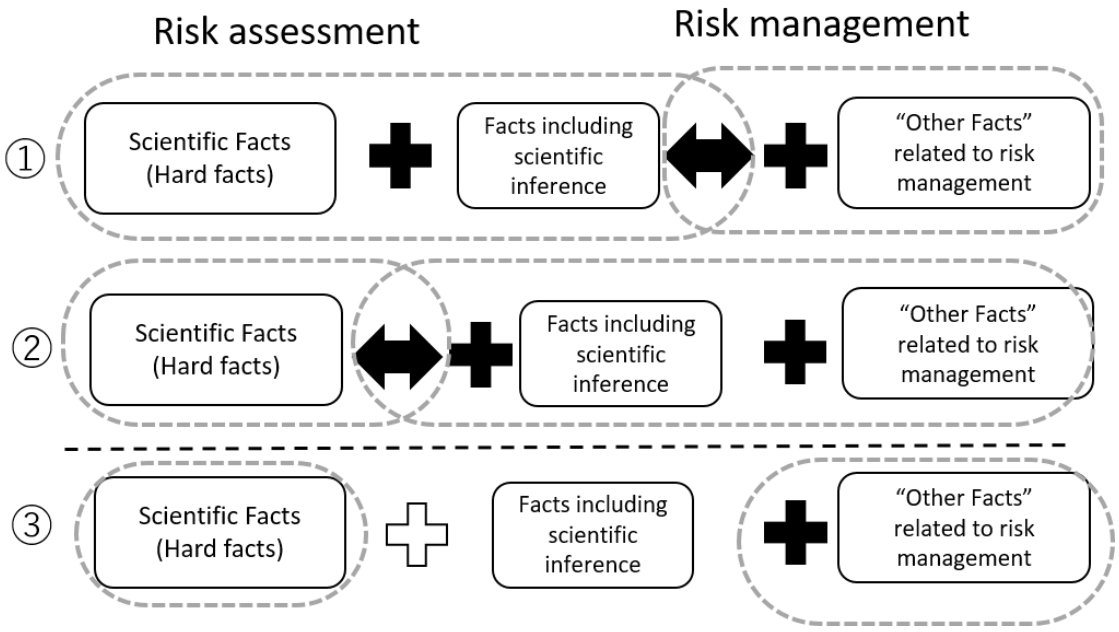

Figure 3: The risk assessment and management interface.
Source: Matsuo Makiko et al. (2015)[6]

5 Where there is uncertainty associated with scientific facts, there are three possible patterns for dealing with safety: (1) judging that areas other than those where the effects are clear from scientific facts are safe, (2) evaluating areas where the effects are not known to be dangerous, and (3) using scientific reasoning to determine the virtually safety dose (VSD) or acceptable level on the assumption that there are risks present in unknown parts. Choosing (1) will result in a type 2 error if it turns out to be unsafe, while choosing (2) will result in a type 1 error it is turns out to be safe. Pattern (2) can be characterized as the hard precautionary principle and (3) as the soft precautionary principle.

6 The interface between risk assessment (science) and risk management (decision making involving policy and political judgment) involves dealing with scientific uncertainty and scientific reasoning to address that uncertainty. In this respect, there are three

The treatment and weighting of evidence can sometimes lead to the "politicization of science," as it ultimately influences the allocation of resources. Accordingly, guaranteeing the independence and neutrality of science is necessary to ensure that politics does not influence the evaluation of individual pieces of evidence, especially scientific facts. This is why risk assessment and management should be functionally separated in the field of food safety field, for instance.[7] In the case of Codex Alimentarius, which sets international food safety standards and where national interests intersect, the makeup of the experts in the risk assessment body ensures the credibility of assessment results by requiring the participation of individual experts rather than national representatives. However, it has also been pointed out that while facts—the material of evidence—and the functions of risk assessment and management can be conceptually divided into two categories, too much independence can lead to side effects such as communication failures between the two. Indeed, for scientific advice to have policy relevance, it is essential to share the requirements of the risk management side and the social context through interaction. For example, institutional design in the food safety field takes different forms, such as the US FDA, in which risk assessment and management are functionally separated but performed within the same organization,[8] and organizationally independent risk assessment bodies like the Codex Alimentarius in Europe and Japan[9].

As there are advantages and disadvantages to any system design, there is no right solution to system design, and it is necessary to have a system that reduces the negative side effects that occur. To achieve this, it is essential to collect diverse evidence in a multifaceted manner[10] in order to ensure a mechanism to guarantee the quality of individual evidence, and conduct both qualitative and quantitative overhead mapping of evidence.

The most important point is to clarify and explain how a decision was made under uncertainty and based on what evidence.

3 Ensuring an overall view, coordination, and adaptation

Some of the methods and approaches to STI governance discussed above—including such as technology foresight, technology roadmaps, and risk approach—have become embedded in Japanese domestic policy processes and institutions depending on the field, while others, such as TA, have been developed on an ad hoc basis.

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possible patterns: (1) the risk assessment side makes scientific inferences to deal with uncertainty, (2) the risk management side makes scientific inferences, and (3) neither side makes scientific inferences.

7 Codex Alimentarius, "Working principles for the application of internal risk analysis," para. 9.

8 Organizational separation is not always required in the US because of the belief that complete separation is counterproductive (NRC, 1983, p. 6).

9 The extent of functional separation varies from field to field. Similarly, it has been pointed out that the World Organization for Animal Health (OIE), an international organization related to food, does not require such strict functional separation.

10 Joint fact-finding (JFF) is useful for collecting evidence from multiple perspectives. JFF is an approach/concept for collaboration by diverse actors and for "understanding diverse evidence." See, for example: Ozawa and Susskind, 1985; Ehrmann and Stinson, 1999; McCreary et al. 2001; Andrews, 2002; Adler et al. 2011; Karl et al. 2007; Rofougaran and Karl, 2005.

It is important to take a holistic view of the chain of activities involved in STI—that is, to understand the relationships among individual systems and sectors—and, from a meta-governance perspective, to develop a whole-of-government approach to consider measures that should be taken according to the state of social adoption of STI. In this case, it is essential that the activities of different entities are seamlessly linked; for example, that the results of foresight are used for TA, and these are further used for activities under the risk approach.

It is also important to strike a balance between ensuring "decentralization and diversity" and "aggregation and centralization" (Biermann et al., 2009) according to the state of social adoption. In other words, while decentralized activities that allow for a wide range of ideas and goal options are effective in promoting STI in its nascent stages, a certain degree of centralization[11] is required to address the various social implications that arise when STI is actually introduced into society. For this reason, flexible adaptive governance, anticipatory governance (Quay, 2010), transition management,[12] and reflexive governance (VoB and Bornemann, 2011) approaches based on their learning are more useful than rigid systems of governance.

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11 One thing to keep in mind during the centralization phase is that supervision should be commensurate with the STI. A discrepancy between the speed STI and the speed of regulation will result in over-regulation or under-regulation. Given the dynamic nature of STI and their accelerating speed, the oversight, regulation, and proper pacing of STI is required (Kuzma, 2014).

12 An approach to rearranging and managing existing frameworks by focusing on networks and learning processes, with multiple paths in mind, without deciding on the direction of STI and society at the outset (Kemp and Loorbach, 2006; Loorbach, 2007; Rotmans et al., 2001).

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