2.2.3 Regulatory science

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Abstract

There is a gap between science and policy. The gap is especially large when there is a high degree of scientific uncertainty, as in the case of new technologies or emerging infectious diseases. In order to make use of new science and technology without causing social conflict—that is, in order to link these to innovation, policy responses—appropriate regulations, systems, procedures and guidelines are essential. The procedures and know-how for the formulation of such measures is known as “regulatory science.” This paper explains the background and process by which regulatory science became established as a scientific field in its own right.

Keywords

Trans-science, post-normal science, reference value

1 The discovery of trans-science

When they do not know something, scientists are supposed to answer, “I don’t know”; in contrast, policymakers are forced to make some decisions under uncertainty. This is because doing nothing is also a decision. Naturally, when this happens, a gap appears between science and policy. The faster the pace of scientific and technological development and the greater the uncertainty, the wider the gap between science and policy becomes. This gap should not be overcome using the intuition of policymakers or the adventures of scientists; rather, the existence of the gap should be made visible and then explicitly filled through regulatory science.

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In response to the naive notion that policy decisions are partially automatic, based on data generated by objective, neutral science, Weinberg (1972), a nuclear physicist, pointed out the existence of "a set of questions that can be asked by science but cannot be answered by science" and called this "trans-science." Weinberg cited the biological effects of low-dose radiation, low-frequency high-impact events, engineering decisions, social science issues, and values in science. While the biological effects of low-dose radiation and other problems are theoretically solvable given enough money and time, in practice, they are impossible to implement and solve. It has been pointed out that social scientific issues are extremely difficult to predict because they involve human psychology and behavior. Meanwhile, "values in science" refers to science policy, such as which sciences to budget for; this in itself is impossible to determine scientifically.

In the early 1990s, Funtowicz and Ravetz et al. proposed the concept of "post-normal science" (Funtowicz and Ravetz, 1993) as a concept related to trans-science. As both the magnitude of the stakes involved in decision-making and systemic uncertainty increase, a picture was presented of moving from normal science, through applied science and delegation to experts, to post-normal science.

2 The birth of regulatory science

The term "regulatory science" was independently proposed in Japan and the United States at about the same time. In Japan, the term was defined in 1987 by Uchiyama Mitsuru of the then National Institute of Hygienic Sciences (now the National Institute of Health Sciences) as "the science of prediction, evaluation, and judgment to regulate scientific and technological progress into its most desirable forms that are truly useful to people and society" (Mitsuru Uchiyama, 1987). Removed from the glamorous notion of science's search for the truth, it appears that the intention was to inspire those responsible for formulating reference values and developing methods of measurement, seemingly simple tasks which could be considered as subcontracting to the government by positioning that work as another science. In the US, Rashevsky, a political scientist, used it as a concept in contrast to "normal science" in 1986. Jasanoff (1990), a professor of the social theory of science and technology, independently proposed it as a concept in contrast to "research science" in terms of goals, organization, deliverables, motivation, timeframe, options, and accountability.

Trans-science, post-normal science, and regulatory science all deal with the gap between science and policy. However, the first two emphasize the aspects that "cannot be answered by science" and demonstrate the need for knowledge from the humanities and social sciences, while the third is characterized by trying to answer the questions posed by policy using new approaches from science as much as possible. This can be viewed as a difference in attitude between trying to bridge the gap between science and policy from the policy side and from the science side. In fact, what Weinberg classified as the biological effects of low-dose radiation and engineering decisions have become major fields of regulatory science through risk assessment. Moreover, "social science issues" have been institutionalized as socioeconomic analysis and, for regulations, as regulatory impact analysis, which form part of regulatory science. However, "values in science," that is, science policy, cannot be covered by regulatory science (see Section 2.1.2).

3 Development of regulatory science

In Japan, a research project entitled the “Comprehensive Study on Regulatory Science for Drugs and Medical Devices” was launched in 2004, as part of the Ministry of Health, Labor and Welfare's Science and Technology Research Program. Moreover, in 2010, the Ministry of Agriculture, Forestry and Fisheries launched the Regulatory Science New Technology Development Project. The Society for Regulatory Science of Medical Products, a general incorporated association for pharmaceuticals, was established in the same year. In 2011, the Science Council of Japan published “Proposal: Regulatory Science for Japanese Food Safety.” In the Fourth Science and Technology Basic Plan, which was approved by the Cabinet in August 2011, the phrase “the government will enhance and strengthen regulatory science...” was included in the measures for “promoting life innovation,” and cited Uchiyama’s definition. However, the term “regulatory science” itself is not cited in the Fifth Science and Technology Basic Plan, which was approved by the Cabinet in January 2016. Instead, in “Chapter 6: Deepening the Relationship Between Science, Technology and Innovation and Society,” “research into the science of making accurate predictions, evaluations, and judgments based on scientific evidence in the formulation and implementation of regulations” is listed together with technology assessment as social technologies necessary to promote the use of science and technology in society. This indicates that the concept of regulatory science, which was limited to the field of public health in the fourth plan, is considered as necessary in all fields of science and technology.

The US Food and Drug Administration (FDA) is actively using the regulatory science concept. They have defined regulatory science as “the science for developing new tools, standards, and approaches for assessing the safety, efficacy, quality, and performance of all FDA-regulated products” and developed a strategic plan in 2011. In Europe, the European Chemicals Agency (ECHA) published its Regulatory Science Strategy in 2015. While the European Medicines Agency adopted a similar definition to that of the US FDA, it differs insofar as it specifies that social sciences are also included. Australia’s Pesticides and Veterinary Medicines Authority (APVMA) also developed a “Regulatory Science Strategy,” which it defines as being “concerned with the practical application of the scientific method for the purpose of making decisions about whether to allow something (e.g., a chemical substance) to be used within a limited legal or time framework.” Unlike science as the search for truth, where there are virtually no time constraints, regulatory science is characterized by responding to the policy side’s need to reach tentative conclusions within a certain amount of time based only on the scientific knowledge at hand. In Australia, nine federal regulatory authorities have established Regulatory Science Networks (RSNs).

4 Diversity in regulatory science

In Japan, although the term “regulatory science” is currently used in a variety of ways, they all share the same goal of bridging the gap between science and policy. One type of regulatory science involves the research being conducted, led by the science side, to link uncertain facts to policy. A second type involves

the policy side taking the lead in creating the logic for regulatory measures to be implemented with the help of scientists. This is the case when deliberative committees formulate regulatory measures and reference values. A third type involves research commissioned by the policy side to the scientific side in order to obtain information required to create policy. Such situations appear to be no different from traditional science, but are "regulatory" insofar as they have been commissioned by the policy side. There may be other types of regulatory science that are considered internally by regulatory agencies that are not externally visible. Table 1 shows various examples of regulatory science practices.

Table 1

	Leading actors	Contents	Specific examples
Type 1	Scientists	Scientist-led research to turn uncertain facts into evidence for policy decisions.	Development of risk assessment methods for chemical substances and new technologies.
Type 2	Administration	Create logic for regulatory measures to be implemented by the administrative policy side	Creation of regulatory logic at deliberative committees (study groups, etc.).
Type 3	Administration	Research commissioned by the government from scientists in order to obtain scientific knowledge necessary for policy.	Research for risk management measures and the development of measurement and evaluation methods.
Type 4	Administration	Practices for creating policy logic within the government.	Proposed reference values prepared internally by the ministry.

Regulatory science research is also interdisciplinary. In addition to the so-called science-side approach, policy-side approaches (e.g., economics and public administration) and third-party observations (e.g., political science, sociology, and social theory of science and technology) are also important. The gap between science and policy is often eventually bridged in the form of decisions on reference values. In such cases, the process of determining reference values themselves is regulatory science (Murakami Michio et al., 2014). In Japan, the deliberative committee (including study groups and working groups) process plays an important role in bridging science and policy. In this respect, the selection of committee members, the scope of the committee's functions, and the way in which stakeholders are involved are all possible research topics in themselves (Morita Akira 2006, 2014, 2016).

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