# The Governance Challenges of Biotechnology

## The Case of GMOs

This article uses Genetically Modified Organisms (GMOs) as an example to indicate three kinds of social implications of biotechnology, namely the rapidity of technological change, the proliferation of intractable issues, and the scarcity of consensus; and suggests that these social implications constitute significant challenges for governance of biotechnology. Some instances of Taiwan about GMOs are used when necessary.



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# Introduction

Governance is the way that governments deal with an increasing number of responsibilities and novel problems<sup>1</sup>. The governance of biotechnology is one of the most widely-debated issues of the late 20<sup>th</sup> and early 21<sup>st</sup> centuries. The major challenge for governance of technology is to strike an appropriate balance between benefits, opportunities and risks, and uncertainty; between promotion and regulation of innovation; between what is feasible technically and commercially, and what is publicly acceptable and desirable; and to deliver the claimed societal benefits without challenging accepted societal norms<sup>2</sup>.

GMO represents a good opportunity to observe the governance challenges and regulatory difficulties when a government is confronted with new science, technology and innovation, which triggers the hot debates over the uncertainty of both the benefit and risk of this technology<sup>3</sup>.

# The Rapidity of Technological Change

It is suggested that the speed of technological change is a crucial issue<sup>4</sup>. The competition involved in development of biotechnology among scientists, academics, industries, and countries speeds up both the research and development, and the diffusion phase of technological change. This fast, and somehow dynamic development of new technologies, differs from conventional sciences and technologies that build incrementally on existing paradigms. It is

very likely that the rapid rate of technological advances makes the effects and impacts of newly developed technologies difficult to predict and to manage5. This social implication of the rapidity of technological change, as a challenge to governance of biotechnology, can be found in the case of GMOs. Risks associated with modern biotechnology, especially with GMOs, can be divided into scientific risks and social risks. Scientific risks, which are also known as technology inherent-risks6, concern potential longterm effects on the natural environment and human health<sup>7</sup>. Social risks, which are also known as technology-transcending risks, refer to a variety of social, ethical, legal, industrial, managerial, economic and political problems. These include the increase in the prosperity gap between the rich and the poor both internationally and within individual societies that result in the use of biotechnology. In other words, this risk relates to the use of the technology, not the technology itself8. The rapid evolvement of new technology provides limited time and scientific knowledge or method for the society to define, to observe, to evaluate, to manage or to handle the risks that are introduced by unknown cause of this technology or other natural processes. In addition, profound technological advances and knowledge revolution challenge legal systems, including constitutions9. In contrast to the rapidity of technological advances and developments, and the associated unpredictable impacts on the society, the sophisticated and inflexible legal system and time-consuming law-making process are unlikely to cope with all kinds of risks and impacts; although some of these risks or social impacts are not brand-new. Even in cases where new rules are in place, risks and uncertainties caused by the rapid rate of technological changes leave controversies unresolved.

# The Proliferation of Intractable

Among the key governance challenges raised are the demands and pressure for

greater transparency and intelligibility of new technologies to wider public and social interest groups, and for greater accountability of the main commercial, governmental or professional users of the technology<sup>10</sup>. The intractability of GMO issues is reflected in the uncertainty of potential scientific risks as well as the diversity of social, ethical and legal concerns and impacts. As a matter of fact, the more intractable the GMO issues are, the more challenging the governance is.

Many of these impacts generated by GMOs involve highly technical and fast-developing knowledge. This feature is strongly related to the knowledge gaps that result from the rapid rate of technological advances, and relevant to the quality and quantity of information that is used in the governance of GMOs. The information, especially scientific evidences and knowledge in relation to the potential risks of GMOs on human health and nature environment is very likely to be insufficient. This increases the difficulties in handling a variety of controversies and concerns in

governance to meet the demands and pressure for greater transparency and intelligibility of GMO. In addition, the insufficiency of scientific information and knowledge creates a significant challenge for governance on whether, or under what circumstances the precautionary principle can be justifiably applied when addressing potential health or environment risks. This is an extremely complex controversy in global society regarding to the governance of GMOs.

In the era of information overload, the difficulty of dealing with a flood of information lies not only in the fact that may be too handy to ignore, but also in that it normally contains certain degrees of expert language and cannot be challenged easily by a layperson. Consequently, this limits the opportunity of public and social interest groups to participate in risk communication and to comment on the policy on the table; which also impedes successful governance<sup>11</sup>. Moreover, the multiform of the "regulatory" life cycle of GMOs also affects the intractability of governance issues; from lab-

oratories to the approval of this product, and from farming to the marketing. Governance issues in the process include the procedural matters such as risk assessment, standard setting12, risk management, paper work or licensing among different governmental bodies, as well as intellectual property rights, consumer and environmental protection, international trading relationships, and public communication<sup>13</sup>. A broad range of government agencies that belong to different departments are included; they coordinate with each other either vertically or horizontally. In Taiwan, at least ten competent authorities at different governmental departments and levels are involved depending on the different stages of "regulatory" life circle. The National Science Council looks after researches at laboratories; the Council of Agriculture takes over the fields studies and agricultural usages, such as farming and feeds; The Department of Health is in charge with GMOs for foods and pharmaceuticals; Ministry of Economic Affair handles GMOs in industrial sectors, technical



standards setting and intellectual property rights; environmental issues of course lay in the hand of the Environmental Protection Agent; consumer protection is the job of the Consumer Protection Commission, and trading of GMOs are relevant to all the mentioned governmental departments. The kind of bureaucratic issues indeed are relevant to the culture of the government, and its political background. Governance of GMOs therefore includes a wide spectrum of institutional, regulatory, or even cultural regimes. This phenomenon is likely to increase the intractability of GMOs issues and to decline the efficiency of governance, when no mechanism of coordination existing so as to integrate the policy and make regulations and laws consistent with each other at both vertical and horizontal levels.

# **The Scarcity of Consensus**

Reaching consensus on GMO policies and regulations is another tough challenge. Decisions on biotechnology demand not only expert knowledge on likely physical and economic harms and benefits, but also the consideration of fundamental questions about the kind of world in which people wish to live14. The scarcity of consensus among the public and/or policy-makers on various GMO issues results from several factors. In respect of health and environmental protection, the adequacy of conventional risk assessment is challenged by the high political salience of both ignorance (we don't know what we don't know) and indeterminacy (the validity of knowledge depends on unpredictable human behavior and environmental circumstances)15. When scientific evidence or knowledge concerning risks is uncertain, the uncertainty reflects the current limitations of scientific knowledge to provide, in every case, reliable, long-term information about harmgenerating process and/or their impact on receiving ecosystems and human health 16. Consensus on how to regulate or accept GMOs is unlikely to achieve easily. Governance challenge in this respect appears to be the difficulty for policy-makers when determining risk and making decisions on whether or not to take a promotional, permissive, precautionary, or preventive policy17.

Even when there is no debate over the credibility of scientific evidences, controversies continue to affect the adoption of consensus among the public and stakeholders. Diverse or contradicting views simultaneously

exist, when people take different positions, on issues such as what kind of benefit or risks that GMOs bring to society, what level of risk is acceptable, ethical concerns about the extent to which it is acceptable to interfere with nature, socio-economic and political questions about enhanced corporate control over the food sector, and distributional issues such as possible economic dislocation for small or organic farmers. In addition, laymen often show a remarkable sensitivity to issues when policy experts fail to address them. Challenges to governance become serious when the public loses confidence in the government's capacity to carry out risk assessments, to make appropriate decisions and policies, and to implement adequate legislation. Since 1999, four versions of draft GMO Laws had been proposed in Taiwan. They are either proposed by law makers, individual study, or Executive Yuan. Two Executive Yuan's draft GMO Laws was made in 2004 and 2005. These "GMO Constitutions" were expected to be the mother law of all the GMO related regulations adopted by various governmental departments. However, the approach of "GMO Constitution" was later reconsidered and no conclusion was researched till now. As a result, even now, GMOs are mainly regulated by administrative rules which are made by different competent authorities. Certain levels of inconsistence remain.

# Conclusion

Governance of biotechnology demands a series of policy-making processes and decisions through continuing scrutiny and debate at the national and international levels in a matter that is science-based, efficient, transparent, and enjoys the confidence of the public and business and farming communities. Challenges to governance can be observed in case of GMOs when the rapidity of technological changes leads to proliferation of the intractable issues, and results in the scarcity of consensus on various issues. The potential incompatibility between evidence-based decision-making and greater stakeholder engagement therefore enhances the complication of GMO controversies significantly, and constitutes challenges in achieving effective, integrated governance of biotechnology. Understanding the features of the social implications of GMOs better is thus an important task for understanding the dynamics of governance, for targeting the nature of governance challenges involved.

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