Policy Trends and Regulatory Style for Genetically Modified Products in the United States

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Summary of Research Result

In this research, we analyzed the situation in the US, where the commercialization of genetically modified organisms (GMOs) is most advanced, to define features of related regulations and clarify the trend toward reviewing them. This paper also outlines US support to developing countries concerning GMO and presents a hypothetical opinion on where the difference between the US and EU comes from in their style of regulation.

1. Regulatory structure in the US and the future revisions

GMO regulations in the US are enforced under the supervision of three agencies: US Department of Agriculture (USDA), Environmental Protection Agency (EPA), and Food and Drug Administration (FDA) in accordance with "Coordinated Framework for Regulation of Biotechnology" announced in June 1986. The basic principle of GMO regulations administered by each agency under a coordinated framework can be summarized as below.

The USDA regulates GMOs from the viewpoint of preventing the spread of plant pests under the Federal Plant Pest Act (FPPA), while the EPA regulates pesticidal substances generated in plant bodies under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The EPA also regulates GM microorganisms under the Toxic Substance Control Act (TSCA). The FDA is responsible for regulations concerning the safety of food, food additives, livestock feed, medical products, etc. under the Federal Food, Drug, and Cosmetic Act (FFDCA).

As described above, the structure of GMO regulations in the US is very complicated, as they are implemented by extending interpretation of the existing acts without enacting new legislation. This structure in terms of pre-market and post-market authority is illustrated in Table 1, which shows that the scope of regulatory authority of each agency differs, depending on the law on which it is based. In the example of the USDA, by deregulations on GMOs it loses its regulatory authority over such GMOs, and therefore it is unable to track their actual planting.

Within the US government, review of GMO regulations is currently under way. Behind such movement is the recent development of new types of GMOs that had not been thought of before (e.g. GM crops generating pharmaceuticals, animals such as GM fish, etc.).

In USDA, in particularly, proposals for drastic review of the existing regulating system were presented last year (expanding the regulatory basis to include noxious weed in addition to plant pest, introducing a regulatory system based on risk categories and GMO testing methods for pharmaceuticals and industrial materials, etc) and an environmental impact statement assessing the impact of such regulatory reform on the environment is being prepared. Then eventually federal regulations are expected to be revised. Also, the FDA has just come up with draft guidelines for adventitious GMO mixing in the experimental stage of novel proteins (recently finalized).

As for GM animals, the FDA proposed draft regulations under the authority on new animal drugs. The USDA is also expected to propose new rules to make GM animals subject to regulations.

2. Active support to developing countries in GMO research and development

The US is active in providing GMO-related

Table 1. Authorities of Each Department and Agency over GM Crops

	Pre-market Authority	Post-market Authority
USDA [Federal Plant Pest Act]	Field Test General Cultivation Interstate Movement	None (Note 1)
EPA [Federal Insecticide, Fungicide, and Rodenticide Act]	Field Test (Note 2) General Cultivation	Insect resistance control (Note 3)
FDA [Federal Food, Drug, and Cosmetic Act]	None (Note 4)	Removal of adulterated food

Note: 1. When deregulated.
2. When the area is 4 ha or more.
3. The authority covers the developers only, not the producers.
4. When not considered food additive. Consultated on a voluntary basis.

support to developing countries in technical development as well as helping them plan policies on biosafety. Specifically, a series of projects such as the Agricultural Biotechnology Support Program II (ABSP II) and the Program for Biosafety Systems (PBS) are being implemented by Cornell University and the International Food Policy Research Institute (IFPRI) with funds provided by the United States Agency for International Development (USAID) (2002-06). ABSP II is a program to support research and development concerning GMO, and PBS provides support in biosafety policy planning by recipient countries. The predecessor program of ABSP II, which is called ABSP, was carried out mainly by Michigan State University (1991-03). On a global level, there are almost no other support programs for developing countries focusing on GMO, except for the relatively small scale BIOEARN program by Sweden, and therefore these programs are worthy of attention in order to grasp future trends of GMO commercialization in developing countries. The participating countries in each program mainly consist of specific countries in Asia and Africa, some of them receiving continuous support from the US. (Table 2).

The target countries and crops of ABSP II are listed below. As it shows, ABSP II concentrates on research into those crops that are likely to be grown for commercial purposes.

- Cassava (cassava mosaic disease resistant): Uganda
- Banana (quality improvement): Uganda
- Sweet Potato (virus disease resistant): Kenya, Philippines
- Tomato (virus disease resistant): Mali, Ghana, Indonesia, Philippines
- Eggplant (insect resistant): India, Bangladesh, Philippines
- Rice (drought resistant, salt resistant): India, Bangladesh
- Potato (late blight resistant): India, Bangladesh, Indonesia
- Beans (Pod borer resistant chickpea): Bangladesh
- Nuts and sunflower (virus disease resistant): India
- Papaya (virus disease resistant): Philippines

3. Background of the formation of GMO-related regulation style

Considering the background factor behind the formation of different styles of regulation in the US and EU, the regulating methods differ a great deal depending on which government agency took the lead in the process of developing the policy concerning practical application of GM crops in the 1980s. At that time, the US government defined the division of roles among agencies by establishing a coordinated framework based on the existing laws without enacting new legislation from the standpoint of maintaining its competitiveness. In Europe, on the other hand, several departments of the European Commission proceeded with the GMO policy from each standpoint. As a result, European Commission Directives were prepared for 2 different types of use: contained use and release into environment. The latter directive covering GMOs as agricultural crops was drawn up by Directorate General (DG) Environment as the competent authority.

These policy-making processes in US and Europe are in a sense quite opposite to each

Table 2. Support to Developing Countries Concerning Research and Development of GM Crops

	Country	U.S.			Sweden	Cartagena Protocol Ratifiers(June 2005)
		ABSP I (91-03)	ABSP II (02-06)	PBS (02-06)	BIO-EARN	
East Africa	Ethiopia				○	○
	Kenya	○	○	○	○	○
	Malawi			○		
	Tanzania			○	○	○
	Uganda		○	○	○	○
North Africa	Egypt	○				○
	Morocco	○				
Southern Africa	South Africa	○	○	○		○
West Africa	Ghana		○	○		○
	Mali		○	○		○
	Nigeria			○		○
Asia	Philippines		○	○		
	Indonesia	○	○	○		○
	Bangladesh		○			○
	India	○	○			○

Note: Prepared by the author.

other in that the US handled the GMO issue in the expanded framework of existing industrial policy (based on the assumption that GMO would not pose new risks) without introducing new regulations specific to GMOs, whereas Europe considered GMOs as new organisms requiring environmental impact assessment prior to commercial use and established new regulations to control GMOs from the environmental viewpoint. As more emphasis is placed on the prevention of adverse environmental effects in environmental regulations, there is a general tendency to establish a regulatory system from a precautionary perspective, which resulted in the introduction of cautious attitude towards the use of GMOs. As compared with the agricultural field, more input is provided by civil society groups in policy making in the environmental field and there are many opportunities for people to have their opinions reflected in the policy. In this context, the fact that the foundation for GMO regulations in Europe was built by DG Environment created a decisive difference between the US and Europe and subsequently brought about different development.

This difference between the EU, which considers practical application of GMOs as "release into environment" and adopted a Directive concerning release into environment from a precautionary perspective, and the US, which considers the same as the industrial use and applied expanded interpretation of regulations by government agencies supervising each industrial sector, is a difference in regulatory style among agencies or departments in charge (environmental protection department and industry promotion department).

Interestingly, the ministry or agency that takes the initiative in regulating GM crops (in particular, environmental safety assessment) differs by country (ministry of agriculture: US, Canada, Argentina, China, etc.; ministry of environment: EU; ministry of science and technology: Brazil, new independent agency: Australia). It would be important to examine the basic stance and methods of regulation of each country from this viewpoint in order to understand GMO regulations in such countries.

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Research on FTA Negotiation Strategy: Learning from the Case of Australia-United States Free Trade Negotiation

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1. Introduction

More Free Trade Agreements are coming into effectnowadays. In the negotiation process, weak or declining domestic industry is a frequent matter of concern. Interest groups of such industries sometimes strongly oppose FTA and apply strong pressure on the negotiation process. Agriculture is an industry that has shown strong opposition to FTAs. The FTA between Australia and the United States (AUSFTA), which came into force in January 2005, is one FTA in which agriculture became controversial, after the WTO ministerial meeting at Seattle.

AUSFTA answered one interesting question about how agricultural products should be treated in an FTA between advanced countries and major agricultural exporters. The answer is that completely free trade in agricultural products is very inconvenient, even for the major exporters. The aim of this research is to analyze the negotiation process and potential economic effect of AUSFTA and provides useful information and knowledge for planning FTA strategy.

2.Theoretical Analysis of Tariff Negotiation

Tariff negotiation is meaningful when each country can abolish their trade barriers and enjoy the benefits of free trade. In a tariff war between two countries, even if one country abolishes all tariffs unilaterally, it is beneficial for the other country to maintain its own tariffs. Therefore, both countries have no incentive to reduce tariffs, and maintain their own tariffs. They can improve their welfare through a free trade pact which can make both countries eliminate their tariffs. However, tariff negotiation does not necessarily lead to perfect tariff elimination.

Figure 1 shows how profit from tariff negotiation would be obtained. A necessary condition for the success of tariff negotiation is that both countries must improve their welfare respectively by the change of tariffs. This condition is called the individual rationality condition. On the other hand, the expected profit in case of failure is called the reference point of the negotiation. Then, we can identify the set of profits which a country can obtain from the