

Status of Policies Relating Biosafety

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Abstract

Biotechnology is certainly one of the major landmarks in the 20th century history of science. It may produce enormous utility to human beings, but at the same time, it carries huge potential risks to the environment and public health. Thus, with a view to securing safety for the environment and public health in relation to the development and use of living modified organisms (LMOs), the Cartagena Protocol on Biosafety was adopted, in which a regulation Procedure as to the transboundary movements, transportation, handling, and use of LMOs were drawn up. In order to prepare for the entry into force of the Protocol, the Republic of Korea legislated the "Act on the Transboundary Movements of living modified organisms(hereinafter referred as the 'Act')" in Mar 2001, and has pre-announced the enactments of the enforcement ordinance and the enforcement regulation to the Act. Pursuant to the Act, the Ministry of Commerce, Industry and Energy, as a Competent National Authority, is making efforts to implement domestic biosafety schemes in cooperation with other bio-related government ministries. In order for these efforts to reap fruits, industry, academia, and research institutions should cooperate with one another, and civic groups and NGOs should narrow the differences in opinions and timely respond to the fast-changing situations. Focusing on the precautionary principle, the Protocol puts a great emphasis on the importance of information sharing amongst countries, and the Act also follows this principle. In order to guarantee biosafety, countries around the world, including the ROK, agreed to establish National Biosafety Clearing, designed to provide the information on the export/import of LMOs, R&Ds, risk assessment, safety control, etc. and register it on the CBD Central Biosafety Clearing House.

Key words: LMOs, Cartagena Protocol on Biosafety, The Act on Transboundary Movement of LMOs and Etc., KBCH

Introduction

Faced with the incredible increase of population as well as the accelerated industrialization, the entire world is urgently promoting efforts to resolve problems of energy depletion, environmental devastation and the agricultural environment. The rapidly developing contemporary biotechnology is emerging as a revolutionary tool for such problems.

By using genetic reproduction technology of modern biotechnology, useful genes are separated, and inserted into the other organisms to grant new characteristics or make existing characteristics stronger. The organisms created in this way are called as living modified organisms (hereinafter referred to as "LMOs"). For example, people make crops by manipulating genes to have increased production as well as having higher nutrition and better treatment effect and others. This is a way to obtain better quality of productions. This is applicable for not only the crops, but also in the field of organisms for environmental purification, animals used for pharmaceutical products, and others. Such developments are made in countries over the world. Furthermore, there is a vast investment made in these development projects as well as finding its place as national strategic projects on a nationwide movement (Saskatchewan Agricultural Biotechnology Information Centre 1999; Norman and Subray 2002).

The development and production of LMOs is rapidly increasing, and the LMOs products in turn have started to move over national territories for trading. But we are facing with potential adverse effects of LMOs to the environment and the human health. For the prevention of such potential risks the international society have exerted many efforts to prepare proper measures for potential adverse the effect of LMOs on environment. The most representative of it is the 'The Cartagena Protocol on Biosafety (hereinafter "Protocol")' that was adopted

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in January of 2000 (CBD 2000).

This article will take a look at the content and implementation system of the Protocol. And it will make mention of the Korean situation around the Protocol including its national biosafety system.

Main argument

1. The Cartagena Protocol on Biosafety

The protocol saw its completion through many meetings of special subworking groups under the Meeting of Parties of the Convention on Biodiversity though a not-so-easy course for narrowing down the differences in opinion among countries (KBCH 2000).

The Protocol consists of a total of 40 articles including the introduction with 3 supplements, and the contents include Protocol, procedure of transboundary movement of LMOs, matters on assessment and management of risks in order to ensure safety of LMOs under the transboundary movement, and the matters on structuring the information system for practical and applicable effects of the Protocol. It clarifies the application of a trading procedure governed by the Advance Informed Agreement (AIA) on the transboundary movement and handling, application on the fields of LMOs that are released to the environment. LMOs for food, feed and processing can also be managed by AIA procedure by national laws.

The adoption of the Protocol finds its implication in preparing the foundation to seek concrete procedure for ensuring safety device when importing and exporting of LMOs and applying the precautionary principle in spite of scientific uncertainty on potential risks of LMOs that may effect on human and the environment. And the protocol declares that it has an equivalent position with other international treaties and present the infra structure for its practical application.

This Protocol is effectuated after 90 days from the date of

entrustment of ratification documents from 50 countries, and has a probationary period of two years for preparing the implementation regulations and rules. As of October 2002, there are 35 countries that finished ratification of the Protocol. 26 of those 35 countries ratified it. In the Light of this trend of ratification of the Protocol, it will be likely to be put into effect around the middle of next year (Figure 1) (<http://www.biodiv.org/biosafety>; CBD 2002).

There are many international treaties that may be evaluated as providing models for regulating LMOs. However, they are not equipped with the comprehensive system for controlling the transboundary movement of LMOs like the Protocol. International environmental treaties are divided into the others that focus on the matters related to LMOs and the ones that treat it as a subsidiary issue (KBCH 2000; Lim 2002). Among those treaties Codex Alimentarius and WTP/SPS are discussed here because they have potentially conflict with the Protocol.

Considering WTO principles described above, the precautionary principle introduced in the Protocol may conflict with them (Anne and Terje 2002). The U.S. that has yet to come up with the clear response to the Protocol, takes a principle of

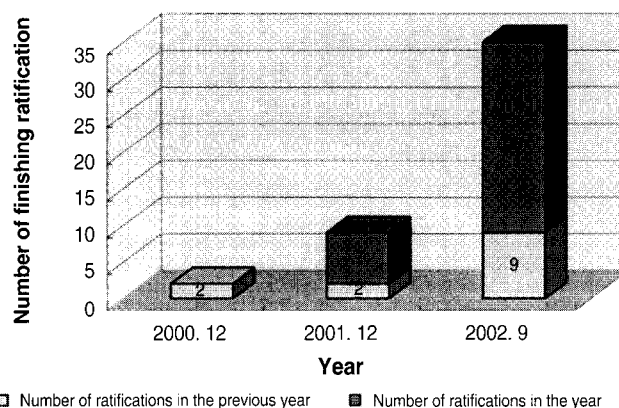


Figure 1. Status of ratifications of the Protocol

Table 1. Treaties including LMOs regulation

	Purpose and Contents	Regulations relating to LMOs
Codex Alimentarius	<ul style="list-style-type: none"> - Agreement of food standard developed internationally - Establishing the agreement on food standard, sanitation and technological method, and evaluation on food additives and others - Voluntary system 	<ul style="list-style-type: none"> - Principle for risk analysis of food made by biotechnology (2001) - Guideline on implementing the safety assessment of rDNA technique derived food(2001)
WTO/TBT (Agreement on Technical Barriers to Trade)	<ul style="list-style-type: none"> - Prevention of trade barrier due to biotechnology regulation and standard 	<ul style="list-style-type: none"> - Exclusion of unreasonable labelling
WTO/SPS (Agreement on Sanitary and Phytosanitary)	<ul style="list-style-type: none"> - Prevention of trade distortion effect in the name of the protection of human health and the environment - Launching an action based on scientific evidence principle 	<ul style="list-style-type: none"> - Effectuate when LMOs are scientifically recognized as threatening lives of human, animal and plants

substantial equivalence, and in terms of public awareness, it has a wideopen view on trusting the government's assessment system on the safety of LMOs and have the practical view on LM products. The farmers of the US are surveyed that they think that LMOs crops make a great contribution to the wealth of farmers. The US that has not been trying a separate law for implementing the Protocol recently shows changes. Recently, the US is proposing a new assessment criteria on genetically modified agricultural products of outdoor packing testing stage, and process certification program of genetically modified agricultural products.

On the contrary, EU enacted a law on LMOs and permitted some cases for the practical use of LMOs. The newly enacted and revised laws made more strict the risk assessment and approval procedure of LMOs. In 1990, there have been many developments on LMOs in EU, but, unlike the US, EU has not yet started to commercialize them. It only implements the labelling system on the imported LMOs and other products made of them.

In Japan, the Ministry of Education and Science is involved in the experiment stage for biosafety review, followed by the Ministry of Economy and Industry, the Ministry of Agriculture, Forestry and Fisheries, the Ministry of Welfare and Labor to review the 'substantial equivalence' to assess the safety. In relations with LMOs, it did not have yet any regulation on manufacturing, selling or importing. However, it has now notified its domestic guidelines and some approval cases of LMO-FFPs to CBD BCH. The following Table 2 indicates Japanese domestic measures to regulate LMOs.

2. The Act on Transboundary Movement of LMOs and Etc. (Korean Case)

A system to ensure safety of LMOs has been regarded very necessary in Korea, because Korea imports substantial volume of genetically modified agriculture products (bean, corn, etc.), while many people express fears to LMOs though vague (Yi 2002).

Korea made the Act on Transboundary Movements, Etc. of LMOs (hereinafter "Act"), promulgating on March 28, 2001 as Law No. 688 (Ministry of Commerce, Industry and Energy 2001). This Act has a characteristic of basic law for the purpose of ensuring safety of LMOs beyond the compliance of the Protocol. Furthermore, in order to prevent the potential risk from unintentional release of LMOs, it includes regulation on the LMOs in the laboratory level. The effectuation of Act is due to be simultaneous with the effectuation of the Protocol.

The main contents of the Act consist of a total of 6 chapters with 44 articles with supplements. It comprises general provision, approval procedure for export and import and safety management of LMOs, information protection, national bio-safety commission, supplements and penalty.

The Korean Act has similar characteristics with the Protocol in that precautionary principle underlies it. Therefore, the Korea Act may cause a conflict with regulations by WTO. The Protocol and the Korean Act fundamentally follow the precautionary principle while WTO SPS (Agreement on the Application of Sanitary and Phytosanitary Measure) has the principle of scientific basis.

Table 2. Status of domestic measures for LMOs in Japan

Ministries	Contents
Ministry of Agriculture, Forestry and Fisheries	<ul style="list-style-type: none"> - From 2001, requires labelling for LMOs and FFPs on the revised JAS law - On the imported LMOs, it requires the distinguished management - Based on the revised Feed Safety Act, it prohibits the manufacturing and importing of feeds that have not passed the safety assessment - It also allows administrative prosecution of imprisonment or fine penalty for being against the rules
Ministry of Welfare and Labor	<ul style="list-style-type: none"> - The standardization of Food and Sanitation Law was made in 2001 that prohibits the manufacturing and importing of food that have not passed the safety review
Ministry of Economy and Industry	<ul style="list-style-type: none"> - It enacted a Guideline on the industrial use of rDNA technology

Table 3. Labelling for LMOs food and agricultural products

	Ministry of Agriculture and Forestry	Korea Food and Drug Administration
Relevant Regulations	Article 16 of Agricultural Product Quality Management Act (Labelling guideline for genetically modified agricultural products)	Provision of Clause 1 of Article 10 of Food Sanitation Act (Labelling standard of rDNA derived food)
Implementation Date	March 1, 2001	July 13, 2001
Items to Indicate	Bean, corn, bean sprout	27 kinds of food produced from and processed with genetically modified bean, corn and bean sprout

As for LMOs labelling, it is required to be made on the container or package by the person who develops, produces, or imports. Now, the labelling guidelines are notified and put into effect by the Ministry of Agriculture and Forestry and the Korea Food and Drug Administration (Table 3) (Park 2002).

3. Enforcement Regulations and Enforcement Ordinance (proposed)

Planning to complete the subsidiary regulation of the Act by this year, Korea went through consultation with relevant departments, and confirmed the scope of matters to be delegated to each department and the necessary details for implementation and made a advance notice of legislation in June of 2002 (Ministry of Commerce, Industry and Energy 2000).

For main contents, it provides undertakings of pertinent central administrative agencies and the Competent National Authority related to LMOs (Table 4), procedure of import approval, production approval, export notification, route report and others (Figure 2, 3) and designation of risk assessment institution, regulation of management of LMOs research facilities, establishment of Korea Biosafety Clearing House as a national focal point in international information sharing especially under the Protocol.

Furthermore, it specifies details for safety management of research facilities, and people, when undertaking the development and experiment on LMOs, shall acquire permission or implement it in the reported facilities. Also there is a provision that the Minister of Science and Technology and the Minister of Health and Welfare may determine and notify all necessary

matters for ensuring safety under the mutual consultation but it's action shall be reviewed by the Commission. The specific cases requiring such a mutual consultation process shall possibly arise when the organisms are not clear about human pathogenic or the notified pathogenic organisms are used.

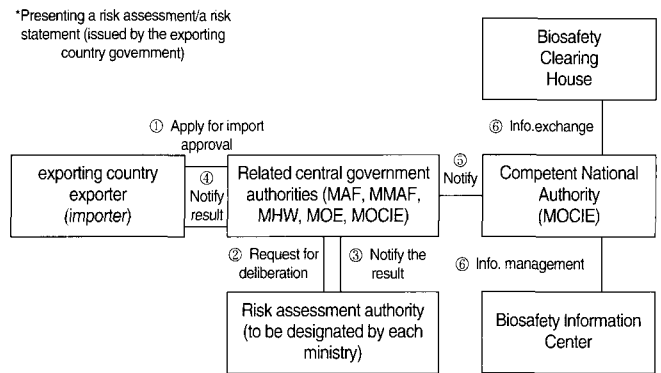


Figure 2. Import approval procedure of LMOs

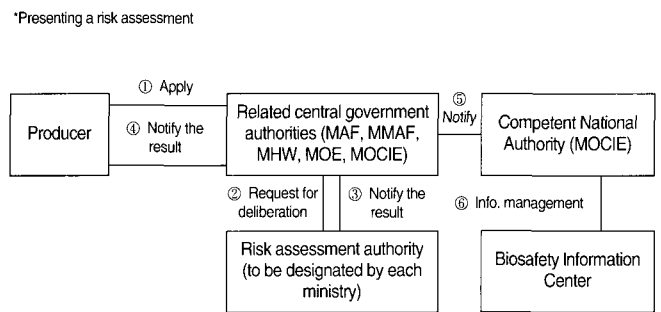


Figure 3. Production approval procedure of LMOs

Table 4. Work of ministries working scope on LMOs regulation

Classification	Department	Works	LMOs
Competent National Authority	Ministry of Commerce, Industry and Energy	Responsibilities as the Competent National Authority under the protocol including information delivery to the CBD BCH	
	Ministry of Health and Welfare	Safety management of LMOs for food, health and medicine	Crops such as bean, corn and others with genetic modification for food
	Ministry of Agriculture and Forestry	Safety management of LMOs in the open environment for agriculture, forestry and livestock	Crops such as bean, corn and others with genetic modification and LM animals
Relevant Central Administrative Agencies	Ministry of Maritime Affairs and Fisheries	Safety management of LMOs for fisheries in the environment	Super mud-fish, rainbow trout and others developed with genes insertion
	Ministry of Commerce, Industry and Energy	Safety management of LMOs for industry	LMOs used in the industrial processing
	Ministry of Environment	Safety management of LMOs for releasing into the environment or environment purification	Seeds, microorganisms for agricultural chemicals and environment purification and others with genetic modification
	Ministry of Science and Technology	Safety management of LMOs for experiment and research (However, the pathogenic organism is managed by the Ministry of Health and Welfare)	LMOs used for research at the laboratory which genetic modification

4. Korea Biosafety Clearing House

Under the auspice of the Competent National Authority, the Ministry of Commerce, Industry and Energy, Korea Biosafety Clearing House was established in July 2001. It undertakes the national fundamental obligation on providing information about movements of LMOs in the real procedure of AIA agreement of the Protocol including information on assessment of risks that LMOs may effect on the environment and human health. Furthermore, it collects and distributes the information related to LMOs at home and abroad, contributing ultimately to the sound development of bio-industry.

Also, it is required to provide and register to the CBD BCH information on domestic laws and regulation, instructions, bilateral and multi-lateral and regional treaties and agreements, risk assessment and management, final determination on import/release and others that are related to the Advance Informed Agreement (AIA) procedure. (Clause 1 of Article 20 of Protocol) And the procedure is as shown in the following Figure 4.

Conclusion

The entry into force of the Protocol is not so far away. Korea shall take steps to ratify it. At the same time, when considering the increasing importance of LMOs development and their potential risks to the environment, there has to be given interest and support continuously by the government as well as the support and cooperation of industry, academy, research institutions and public. To earn these, there has to be a national campaign especially in order to get high level of techniques for risk assessment of LMOs. These undertakings will have to come from many scientists. When these are established, the

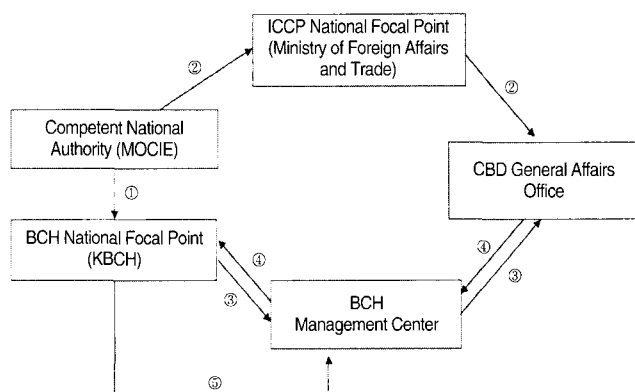


Figure 4. Procedure for registering information to CBD BCH ① Designation of BCH national focal point/②Written notice/③Applying for account (ID, PW)/④Account issuance/⑤Data registration

policies will gain the strength.

The Protocol directly will affect the development, export/import of LMOs, possibly determining what the future of biotechnology will be. This is one big reason why are in need of requiring national level of interests about the assessment of LMOs.

For the accomplishment of a robust national biosafety system, we have to not only make concerted efforts to monitor the events occurring, collect and analyze the information worldwide, but also maintain a close cooperation with the rest of the world.

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