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Law on Transboundary Movement, etc., of Living Genetically Modified Organisms

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Report Highlights:

On March 28, 2001, the Ministry of Commerce, Industry & Energy (MOCIE) published in final the "Law on Transboundary Movement, etc., of Living Genetically Modified Organisms," an Act which reflects local interpretation of the Cartagena Protocol for Bio-Safety. The law conveys to MOCIE and other Ministries legal authority to regulate production and distribution of living modified organisms not elsewhere addressed. The law becomes effective with ratification of the Cartagena Protocol. Implementation guidance is being drafted.

Includes PSD changes: No
Includes Trade Matrix: No
Unscheduled Report
Seoul [KS1], KS

(Law Number 6448)
LAW ON TRANSBOUNDARY MOVEMENT, ETC., OF LIVING GENETICALLY MODIFIED ORGANISMS

(Government Gazette 14762, dated March 28, 2001)

Ministry of Commerce, Industry & Energy

Law Number 6448

LAW ON TRANSBOUNDARY MOVEMENT, ETC., OF LIVING GENETICALLY MODIFIED ORGANISMS

Chapter 1 General Provisions

Article 1 (Purpose) The purpose of this Act is to promote international cooperation and enhancement of people's livelihood by establishing details necessary for implementing the *Cartagena Protocol on Bio-safety* (hereon referred to as the "Protocol") and for pursuing the ensurement of safety in the field of development, production, import, export and marketing, etc. of living genetically modified organisms. This is to prevent in advance of any risk that may be imposed upon the conservation and sustainable use of biological diversity and human health that may come from living genetically modified organisms.

Article 2 (Definitions) The definitions of the terms used in this Act shall be as follows.

(1) "Living genetically modified organisms (hereon referred to as 'LMO')" means the following organisms that contain genetic materials that have been newly modified using modern bioengineering technology.

A. Technology that artificially modifies the gene or directly injects nucleic acid that composes the gene into a cell or into the minor organ of the cell.
B. Fussion of cells that go beyond the range of taxonomic family that is not a natural physiological proliferation or modification of the gene under a natural condition or a technology that is not used in traditional breeding or selection.

(2) "Environmental release" means intentionally exposing LMO into the natural environment without taking measures to seal the LMO, such as facility, equipment or other types of structure.

(3) "Relevant Central Government Agency" means the appropriate central government agency that deals with the standards set under the Presidential decree in accordance with the type of work, such as development, production, import, export, sale, transportation, storage, etc. of LMO (hereon referred to as "import/export, etc.").

Article 3 (Exemption of Application) This Act shall not apply to LMO that is used for microcosmic pharmaceutical purposes under other Acts.

Article 4 (Relationship with other Acts) Other than where there are special provisions in other Acts about the handling and safety management in import, export, etc. of LMO, the provisions in this Act shall prevail.

Article 5 (Responsibility of the Government, etc.) The government and the local autonomy body must take necessary measures to prevent any risk by LMO that may be imposed upon the conservation and sustainable use of biological diversity and public health.

Article 6 (Competent National Authority, etc.)

(1) The Ministry of Foreign Affairs & Trade (MOFAT) shall be the national focal point and the Ministry of Commerce, Industry and Energy (MOCIE) shall be the competent national authority as provided under the provisions in Article 19 of the Protocol.

(2) The head of the competent national authority shall carry out necessary work in implementing the Protocol as the competent national authority, in accordance with the Presidential Decree.

Article 7 (Establishment of Safety Management Plan of LMO)

(1) The head of the relevant central government agency shall establish and implement the safety management plan for LMO (hereon referred to as "Safety Management Plan") by the respective responsible agencies.

(2) The safety management plan must include the following factors:

A. Factors on basic principle relevant to safety management of import, export, etc. of LMO
B. Factors on the safety of workers and facilities handling LMO.
C. Factors related to the support and development of LMO technology.
D. Other major factors related to the safety management of LMOs.

(3) When the head of the relevant central government agency wants to establish and implement the safety management plan, he/she must have it reviewed in advance by the bio-safety committee in accordance with the provisions in Article 31.

(4) The head of the relevant central government agency must establish and implement a detailed implementation plan needed for implementing the safety management plan. He/she can establish and notify the Guideline for Safety Management, if it is necessary for the above.

Chapter 2. Safety Management and Import & Export, etc. of LMO

Article 8 (Import approval, etc.)

(1) A person who intends to import (including hand-carried imported products. Hereon ditto.) LMOs must receive the approval of the head of the relevant central government agency in accordance with the provisions in the presidential decree. Approval must also be obtained when changes are made. When changes are made to minor factors, as listed in the presidential decree, changes must be reported.

(2) The importer who wants to import LMO that will be used in environmental release must request for import approval to the head of the relevant central government agency through the head of competent national authority, regardless of the provision in clause (1). In this case, the head of the relevant central government agency and the head of competent national authority must follow the necessary procedures for transboundary movement of LMO, under the provisions of Articles 8 thru 10 of the Protocol, in accordance with the Presidential Decree.

(3) The person that submits the application under the provisions of clause (1) and (2) must submit a risk assessment document prepared by the producer or exporter of the LMO and the risk assessment document prepared by the government of the LMO exporter.

(4) Despite the provision in clause (3), there may be cases where there may not be a government agency that can issue a risk assessment document on LMO or there may be reasons as defined under the Presidential Decree. In such cases, the head of the relevant central government agency must submit a risk assessment document prepared by the Risk Assessment Agency designated in accordance with the Presidential Decree (hereon referred to as Risk Assessment Agency).
(5) When the head of the relevant central government agency receives a request for approval, under the provisions of clauses (1) and (2), he/she shall assess the risk of the subject LMO and will decide whether to give approval or not after taking into consideration of the social and economic impact of the LMO to the value of domestic biological diversity.
(6) The head of the relevant central government agency must notify the head of the competent national authority on whether approval or not is given under the provision in clause (5).
(7) Things necessary for the risk assessment document under the provisions in clause (3), such as things to be assessed, criteria for assessment, etc. shall be established and notified by the head of the relevant central government agency.

Article 9 (Import of LMO for Testing, Research, etc.)
(1) Notwithstanding the provisions in Article 8, when a person wants to import LMO to be used for testing, research etc. or when the import is made to be used at an exhibition or for display purposes, he/she must either receive approval from the head of the relevant central government agency or report it to the head of the relevant central government agency, in accordance with the Presidential Decree.
(2) The head of the relevant central government agency must notify the head of the competent national authority on whether he/she has given approval or not and the content of the approval under the provision in clause (1).

Article 10 (Import inspection of LMO that is imported via mail)
(1) When the head of the Customs office receives international mail that contains LMO or is suspected of containing LMO that has not received approval or reported under the provisions of Article 8 or 9, he/she must notify this to the head of the relevant central government agency without delay.
(2) When the head of the relevant central government agency receives the notification from the head of the Customs office under the provisions provided in clause (1), he/she must inspect the subject international mail and take necessary measures, such as destruction or ship back.
(3) When a person who receives an international mail package that contains LMO and it becomes known that it had not received approval or had been reported under the provisions of Article 8 or Article 9, he/she must report this to the head of the relevant central government agency without delay. He/she must take measures according to the order given out by the head of the relevant central government agency.

Article 11 (Designation of Import Port, etc.)

(1) When the head of the competent national authority recognizes it as necessary for the safe management of LMO, he/she can designate the seaport, airports, etc. where LMO can be imported, after consulting with the head of the relevant central government agency.
(2) When the head of the competent national authority designates the seaport, airports, etc. under the provisions in clause (1), he/she must immediately notify this publicly.

Article 12 (Approval for production, etc.)

(1) A person who wishes to produce LMO must receive approval from the head of the relevant central government agency, in accordance with the provisions in the Presidential decree. This is the same when changes are made to factors that he/she received approval for. However, when changes are made to minor factors, as designated under the Presidential decree, such changes must be reported.
(2) A producer who wishes to receive approval under the provisions in clause (1) must submit the risk assessment documentation, as provided under the provision in Article 8-3.
(3) When a person wishes to produce LMO, provisions in Article 8-5 thru 8-7 shall be applied.

Article 13 (Procedures for examination of the risk assessment and vicarious execution, etc.)

(1) When the head of the relevant central government agency assesses the risk of LMO, under the provisions of Article 8-5 or Article 12-3, he/she shall hold prior consultations with the Minister of Health & Welfare for the impact of the LMO on human body. As for LMO that will be released to the environment or where there is concern for environmental release, he/she must hold prior consultations with the head of the following agency.

   A. The Minister of Environment for the impact that the subject LMO will have on nature's ecosystem.
   B. The Minister of Agriculture & Forestry for the impact on crop cultivation environment.
   C. The Minister of Marine Affairs and Fisheries for the impact on the marine ecosystem.

(2) The head of the relevant central government agency will designate and notify the detailed standard, method and other necessary factors regarding the examination of the risk assessment under the provisions of Article 8-5 or Article 12-3.
(3) The head of the relevant central government agency can designate an agency and have that agency execute the examination of the risk assessment of an LMO (hereon referred to as "examination agency"), under the provisions of Article 8-5 or Article 12-3, in accordance with the Presidential decree.
(4) When approving the import or production of LMO under the provisions of Article 8 or Article 12, the head of the relevant central government agency must provide information on the subject LMO to the general public and collect comments.

Article 14 (Prohibition, etc. of import or production)

(1) The head of the relevant central government agency can prohibit or limit the import or production of LMO (including the organism in clause 2) when it falls under one of the following categories:

A. When it is recognized that there are concerns for a risk that may be imposed upon the conservation and sustainable use of biological diversity and human health.
B. When the organism is produced through hybridization with the product in clause (1).
C. When it is recognized that there are concerns for a negative social/economical effect or when there is such negative social/economical effect in relation to the value of the domestic biological diversity.

(2) When the head of the relevant central government agency prohibits or limits the import or production of LMO, under the provisions provided in clause (1), he/she must notify this to the head of the competent national authority.
(3) The head of the competent national authority must make a public notification of the necessary facts, such as the name of LMOs, etc., whose import or production is prohibited or limited, under the provisions provided in clause (1).

Article 15 (Non-hazzard LMO)

(1) The head of the competent national authority must make a public notification of the LMO that is not of concern for risk that may be imposed upon the conservation and sustainable use of biological diversity and human health.
(2) The head of the competent national authority must undergo a review in advance by the bio-safety committee, in accordance with the provision in Article 31, when making a public notification of the LMO, etc. under the provisions in clause (1).
(3) When a person that plans to import or produce LMO that is notified under the provisions in clause (1), he/she must report this to the head of the competent national authority, notwithstanding the provisions in Article 8 or Article 12.

Article 16 (Legal fiction of import approval, etc., under the Foreign Trade Act)

(1) When the head of the competent national authority gives import approval or accepts import report for LMO under the provisions of Article 8 and Article 9, it shall be considered as having received the import approval of the Minister of Commerce, Industry & Energy, under the provisions of Article 14-2 of the Foreign Trade Act.
(2) When a person who wishes to import or export LMO under the provisions of Article 15-3 and Article 20 and that person reports or notifies it to the head of the competent national authority, it shall be considered as having received the import or export approval of the Minister of Commerce, Industry & Energy, under the provisions of Article 14-2 of the Foreign Trade Act.

Article 17 (Cancellation of the approval)

(1) The head of the relevant central government agency can cancel the import approval or production approval given under the provisions of Article 8, Article 9 or Article 12 if it falls under one of the following categories. However, he/she must cancel the approval if it falls under category A and B.

A. When the LMO that received import or production approval is recognized as having or concerns for having adverse risk that may be imposed upon the conservation and sustainable use of biological diversity and human health.
B. When the approval was received illegally, such as beguilement, etc.
C. When the LMO products are used for purposes other than the purposes for which the products were approved for.
D. When there has been a violation of this Act or a violation to the order or instructions given under this Act.
E. Other cases which have been designated under the Presidential decree take place. When there has been a cancellation under the provisions provided in clause (1), the head of the relevant central government agency must immediately notify to the head of the competent national authority.

Article 18 (Reexamination)

(1) A person that objects to the measure imposed on him/her, under the provisions of Article 8, Article 12 and Article 17-1-A, can request for a reexamination of the measure to the head of the relevant central government agency under the Presidential decree.
(2) When the head of the relevant central government agency receives a request for the reexamination under the provisions in clause (1), he/she must consult with the head of the competent national authority and undergo a review by the bio-safety committee under the provisions of Article 31. After doing this, he/she has to make a decision on the reexamination.

Article 19 (Destroy, etc.)

(1) The head of the relevant central government agency can order the owner of the LMO that fall under one of the following category to destroy or ship back, etc., the LMO after designating a certain amount of time in accordance with the Presidential decree.

A. LMO that has not received approval or approval of changes from the head of the relevant central government agency or LMO that has not been reported to the head of the relevant central government agency, under the provisions of Article 8, 9 or 12.
B. LMO whose import or production is prohibited or limited, under provisions of Article 14.
C. LMO whose import approval or production approval has been cancelled, under the provisions of Article 17.

(2) If the owner of the LMO that has been ordered to destroy or ship back, etc. the LMO, under the provision of clause (1), fails to take action, the head of the relevant central government agency can have the relevant public official directly destroy or ship back the subject LMO at the cost of the LMO owner, under the Presidential decree.

(3) The head of the central government agency must inform the head of the Korea Customs Service when he/she orders the destruction or ship-back of the imported LMO, under provisions of clause (1).

Article 20 (Notification of export) A person that wishes to export LMO must notify the Minister of Commerce, Industry & Energy on things designated under the Presidential decree in advance, such as the commodity, the amount, country exported to, etc.

Article 21 (Reporting of transit) A person that wishes to export LMO to another country through Korea must report the facts that have been designated under the Presidential decree to the head of competent national authority, such as commodity, amount, country exported to, etc.

Article 22 (Approval for establishment, operation, etc. of research facility)

(1) A person who wishes to establish and/or operate a research facility for development or usage of LMO (hereon referred to as "research facility") must receive the approval or report to the head of the relevant central government agency. Approvals will be different depending on the level of safety control needed for the research facility, in accordance with the Presidential decree. This will be the same when making changes to factors on which the initial approval were given. If a person wants to make a minor change, as designated in the Presidential decree, the person must report this change in accordance with the Presidential decree.

(2) The head of the relevant central government agency must notify the approval for establishment and/or operation of the research facility and the details of the reported facts in clause (1) to the head of the competent national authority.

(3) A person who has reported or has received permission to establish and/or operate the research facility under the provision of clause (1) can develop LMOs or conduct experiments using such LMOs, in accordance with the level of the research facility, in accordance with the Presidential decree. However, in cases where the development or testing is conducted on LMO that has high risk of hazardousness as designated by the Presidential decree, such test and development can only be conducted after receiving approval from the head of the relevant central government agency.

(4) The level of safety of a research facility, criteria for approval of the establishment/operation of a research facility, etc. will be designated by the Presidential decree.

Article 23 (Cancellation of approval, etc.)

(1) The head of the relevant central government agency can cancel the approval or suspend the operation of the facility within a one year period if the person that has reported or received approval for the establishment/operation of a research facility fall under one of the following category. However, if it falls under the category (A), the approval must be canceled.

A. If the person has received the approval illegally, such as through deception.
B. When a person has changed a major factor designated by the Presidential decree without receiving the approval, as provided in the provisions of Article 22-1.
C. When development or testing is conducted without receiving approval under the provisions of Article 22-3.
D. When it fails to meet the criteria for approval as provided in provisions of Article 22-4.

(2) The head of the relevant central government agency can cancel the approval for the LMO that has received approval for development or testing under the provisions of Article 22-3, if there are concerns for a major adverse risk that may be imposed upon the conservation and sustainable use of biological diversity and human health arising from such development or testing.

Article 24 (Labeling)
(1) A person who develops, produces or imports LMO must label things that are designated by the Presidential decree, such as the type of the LMO, etc. on the subject LMO or the container or package of the LMO.
(2) Nobody shall put false labels, or change or delete the label made under the provision in clause (1).
(3) Details for meeting the provisions in clause (1), such as labeling method and other necessary details shall be decided and notified by the head of the relevant central government agency.

Article 25 (Management and handling)
(1) A person who imports, exports, etc. LMOs must obey the standards for management and handling of LMOs such as contained transportation, etc., as designated by the Presidential decree.
(2) The handling method and other necessary factors for the provisions in clause (1) shall be decided and notified by the head of the relevant central government agency.

Article 26 (Preservation of the management and operation records) The person that imports, exports, etc. or establish or operates research facilities for LMO must maintain a record on the importing, exporting, etc. of LMO as well as the management and operation of the research facility for LMOs, in accordance with the Ministerial Ordinance of the Ministry of Commerce, Industry and Energy.

Article 27 (Emergency measures for preventing hazardousness)
(1) The head of the competent national authority must take the necessary measures without delay, as designated by the Presidential decree when there is a major adverse risk or when it is recognized that there are concerns for a major adverse risk that may be imposed upon the conservation and sustainable use of biological diversity and human health.
(2) When a person who imports, exports, etc. LMO finds out about the adverse effect of the LMO, he/she must inform the head of the relevant central government agency or the head of the competent national authority, without delay.

Chapter 3. Protection of Information on LMO

Article 28 (Protection of information) The heads of the relevant central government agency, competent national authority, risk assessment agency, the agent of risk assessment agency and biosafety clearing house under the provisions of Article 32 (hereon referred to as “biosafety clearing house”) shall take measures to protect the information on the LMO so that it will not be stolen, leaked or damaged.

Article 29 (Limitations to using and providing information)
(1) Except for those designated under the Presidential decree, the head of the biosafety clearing house shall not use the LMO information for commercial purposes or release it to anyone.
(2) When the head of the biosafety clearing house provides information on LMO to somebody else, he/she can put limitation on necessary facts, such as the purpose of the usage or usage method or request for other measures needed for protecting the information.

Article 30 (Obligation of Executive and Employee Handling Information) An executive or employee or a former executive or employee of a biosafety clearing house cannot use the information that he or she has obtained while working, for unjust purposes, such as revealing or providing the information to another person to use the information.

Chapter 4. Biosafety committee, etc.

Article 31 (Biosafety Committee)
(1) A Biosafety Committee (hereinafter referred to as "committee") shall be established under the Prime Minister to review the following factors relevant to the import & export of LMO.

A. Factors relevant to implementation of the Protocol
B. Establishment and implementation of the safety management plan of LMO
C. Notification of a commodity list of LMOs that is no harm in accordance with the provision of Article 15.
D. Reexamination in accordance with the provision of Article 18.
E. Factors relevant to legislation and notification pertinent to the safety management and import, export, etc. of LMO.
F. Factors relevant to prevention and measures taken for damage caused by LMO.
G. Factors requested for review by chairman of the committee or the head of competent national authority.

(2) Committee members including the chairman shall be 15 or more but not exceed 20.
(3) The Prime Minister shall be the chairman and committee members are as follows.

A. Minister of Finance & Economy, Minister of Education & Human Resources, Minister of Foreign Affairs & Trade, Minister of Science & Technology, Minister of Agriculture & Forestry, Minister of Commerce, Industry & Energy, Minister of Health & Welfare, Minister of Environment and Minister of Maritime Affairs & Fishery.
B. Persons designated under the Presidential Decree who are recommended by the head of competent national authority and selected by the chairman shall be committee members.

(4) The head of competent national authority shall consult with the head of the relevant central government agency in advance if he/she wish to recommend private sector specialists according to the provisions in clause (3) B.
(5) The committee may have subcommittee and technical committee for effective operation of the committee.
(6) The committee shall have one chief secretary and he/she shall be appointed by the

chairman among government officials working at the Ministry of Commerce, Industry and Energy.

(7) Necessary factors relevant to formation, function, operation, etc. of the committees, subcommittees, and technical committees shall be designated by the Presidential Decree.

Article 32 (Biosafety Clearing House)

(1) The head of competent national authority may designate a biosafety clearing house that will specialize in carrying out work relevant to management and exchange of information on LMO.

(2) Biosafety clearing house shall publicize information pertinent to the safety of LMOs.

Chapter 5. Supplementary

Article 33 (Support of Fund, etc.)

(1) The government may support promotional and educational programs, etc., initiated by relevant agencies and groups to improve public understanding and consumer perception on safety of LMO.

(2) The government may support fund necessary to establish/operate facilities required to ensure the safety of research facility.

Article 34 (Securing Budget) The head of competent national authority shall seek a plan to secure budget so as to ensure the safety in case of any damages imposed upon the conservation and sustainable use of biological diversity and human health that may arise from import, export, etc. of LMO.

Article 35 (Fee)

(1) Anyone who falls under the followings shall be charged.

A. Who wishes to get import approval according to the provision of Article 8-1 & 2.
B. Who wishes to get import approval according to the provision of Article 9-1.
C. Who wishes to get production approval according to the provision of Article 12-1.
D. Who wishes to get research facility permit according to the provision of Article 22-1.

(2) Necessary factors relevant to fees, payment method, payment period, etc. in clause (1) shall be designated by the Presidential Decree.

Article 36 (Reporting and Inspection)

(1) For safety management of LMO, the head of the relevant central government agency or the head of the competent national authority can request the following people to either report or submit information or samples. They can also have the relevant government official go into the subject office, research facility, business area, storage place, etc. and have them inspect the relevant documents, facility, equipments, storage condition, etc.
   A A person who received import or production approval or applied for import inspection under the provisions of Articles 8-1 & 2, Article 9-1, or Article 12-1.
   B. A person who has submitted a report under the provision of Article 15-3.
   C. Risk assessment agencies
   D. Risk examination agencies
   E. A person who has received approval for the establishment or operation of a research facility or submitted a report under the provision of Article 22.
   F. A person who handles or manages under the provision of Article 25.

(2) The head of the relevant central government agency or the head of the competent national authority can give orders to the relevant government official to go into the subject office, research facility, business area, storage place, etc. and have them inspect the relevant documents, facility, equipments, storage condition, etc. against a person who imports & exports products that are suspected as an LMO that has not received approval or been reported and a person who is suspected as operating a research facility that is not approved.

(3) In accordance with the above (1) and (2), the government official who goes into facilities and conducts inspection needs to show ID proving authority to the relevant person.

Article 37 (Public Hearing) The head of a relevant central government agency shall hold a public hearing when he/she perform the followings.

   A. When import or production approval is canceled according to the provisions in Article 17.
   B. When permit for establishment or operation of research facilities is canceled according to the provisions in Article 23.

Article 38 (Fictitious Government Official Position When Imposing Penalties) An executive or an employee of a safety assessment agency, safety examination agency, and biosafety clearing house is regarded as a government official when he or she is subject to Article 129 through 132 of the Criminal Law.

Chapter 6 Penalties

Articles 39 through 44 are penalties and fines. AgSeoul has not included the translation for this chapter.

Addendum

This act shall be implemented from the date when the Protocol is ratified in Korea.