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ACT ON ACCESS TO AND UTILIZATION OF GENETIC RESOURCES AND BENEFIT-SHARING

[Enforcement Date 25. Jun, 2019.] [Act No.16016, 24. Dec, 2018., Amendment by Other Act]

Ministry of Environment (Biodiversity) 044-201-7251

CHAPTER I GENERAL PROVISIONS

Article 1 (Purpose) The purpose of this Act is to provide for necessary matters for implementing the Nagoya Protocol on Access to and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity; and for those for promoting the fair and equitable sharing of the benefits arising from accessing and using genetic resources and traditional knowledge associated with genetic resources thereby contributing to the conservation and sustainable use of biological diversity, improving the lives of the people, and promoting international cooperation.

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

- 1. The term "genetic resources" shall have the meaning ascribed thereto in subparagraph 4 of Article 2 of the Act on the Conservation and Use of Biological Diversity;
- The term "traditional knowledge" means knowledge, innovations, practices of individuals or local communities embodying traditional lifestyles relevant for the conservation and sustainable use of genetic resources;
- The term "access" means acquiring specimen or substance of a genetic resource; or collecting genetic resources and information regarding traditional knowledge associated with genetic resources (hereinafter referred to as "genetic resource(s)");
- The term "utilization" means conducting research and development on the genetic and biochemical composition of genetic resource(s), including through the application of biotechnology;
- 5. The term "benefits" means monetary benefits, including, but not limited to, royalties and income, from utilizing genetic resource(s), and non-monetary benefits, including, but not limited to, sharing of research results and transfer of technology.

Article 3 (Applicability) This Act shall not apply to any of the following:

- 1. Human genetic resource(s).;
- 2. Genetic resource(s) existing in an area beyond national jurisdiction, such as Antarctica;
- 3. Genetic resource(s) accessed for any purpose other than utilization.
- 4. Genetic resource(s) subject to other international treaties related to access to genetic resource(s) and benefit-sharing;
- 5. Genetic resource(s) granted patent rights pursuant to Article 87 (1) of the Patent Act.

Article 4 (Responsibilities of State)(1) The State shall formulate and implement policies necessary for

systematically protecting and managing genetic resource(s).

(2) Providers and users of genetic resource(s) shall be cognizant of the importance of genetic resource(s) and actively support the State's policy of protecting and managing genetic resource(s).

Article 5 (Relationship to Other Acts) Except as otherwise provided for in any other Act, the access to and benefit-sharing of genetic resource(s) and benefit-sharing of shall be governed by the provisions of this Act.

Article 6 (Formulation of Support Measures) To support access to and utilization of genetic resource(s), the State shall formulate the following measures:

- 1. Providing current status on the research of access to and utilization of genetic resource(s);
- Providing domestic and foreign information regarding access to genetic resource(s) and benefit-sharing procedures;
- 3. Protecting the rights of those who access and utilize genetic resource(s);
- 4. Providing other support to those who access or utilize genetic resource(s).

CHAPTER II ACCESS TO AND UTILIZATION OF DOMESTIC GENETIC RESOURCE(S) AND BENEFIT-SHARING

Article 7 (National Focal Points)(1) In accordance with Article 13, paragraph 1 of the Nagoya Protocol on Access to Genetic Resource(s) and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (hereinafter referred to as the "Protocol"), the national focal points (hereinafter referred to as the "National Focal Point") and their duties are as follows:

1. Ministry of Foreign Affairs: Liaising with the secretariat of the Convention on Biological Diversity;

2. Ministry of Environment: Disseminating information on access to and benefit-sharing of genetic resource(s).

(2) The scope of the information provided pursuant to paragraph (1) and matters concerning the duties of the National Focal Point shall be prescribed by Presidential Decree.

Article 8 (Competent National Authorities)(1) In accordance with Article 13, paragraph 2 of the Protocol, the competent national authorities (hereinafter after referred to as the "Competent National Authority") and their fields of jurisdiction are as follows: <Amended by Act No. 14839, Jul. 26, 2017>

- 1. Ministry of Science and ICT: Bio-resources in accordance with the Act on the Acquisition, Management, and Utilization of Biological Research Resources;
- 2. Ministry of Agriculture, Food and Rural Affairs: Agricultural bio-resources in accordance with the Act on the Conservation, Management, and Use of Agricultural Bio-Resources;
- 3. Ministry of Health and Welfare: Pathogenic organism resources in accordance with the Act on the Promotion of Collection, Management, and Utilization of Pathogen Resources;
- Ministry of Environment: Biological resources in the field of wildlife in accordance with the Wildlife Protection and Management Act and biological resources in accordance with the Act on the Conservation and Use of Biological Diversity;
- 5. Ministry of Oceans and Fisheries: Marine and fisheries bio-resources in accordance with the Act on Securing, Management, Use, etc. of Marine and Fisheries Bio-Resources.

(2) In regard to the fields of jurisdiction as prescribed in paragraph (1), the head of the Competent National Authority shall perform the following duties:

- 1. Processing a report on access or a report on changes in accordance with Article 9;
- 2. Prohibiting or restricting access to and utilization of domestic genetic resource(s) in accordance with Article 12 (1);
- 3. Supporting the fair and equitable sharing of benefits arising from domestic genetic resource(s);
- 4. Other matters prescribed by Presidential Decree, which are related to access to and utilization of domestic genetic resource(s).

Article 9 (Reporting Access to Domestic Genetic Resource(s)) (1) Where foreigners, overseas Koreans, foreign institutions, international organizations, and those other persons designated by Ordinance of the Ministry of Environment seek access to domestic genetic resource(s), they shall report such access to the head of the Competent National Authority, as prescribed by Presidential Decree.

(2) Notwithstanding paragraph (1), where any of the following procedures including reporting is undergone, it shall be deemed that the reporting is made in accordance with paragraph (1): <Amended by Act No. 16016, Dec. 24, 2018>

- 1. Where approval is obtained in accordance with Article 11 (2) of the Act on the Conservation and Use of Biological Diversity or where reporting is completed in accordance with Article 13 (1) of the same Act;
- 2. Where approval is obtained in accordance with Article 18 (1) of the Act on the Conservation, Management, and Use of Agricultural Bio-Resources;
- 3. Where permission is granted under Article 11 (1) of the Act on Securing, Management, and Use, etc. of Marine and Fisheries Bio-Resources or where approval is obtained in accordance with Article 22 (1) of the same Act;
- 4. Where approval or permission is obtained under Article 16 (1) or 18 (1) of the Act on the Promotion of Collection, Management, and Utilization of Pathogen Resources or where reporting is completed in accordance with Article 16 (2) of the same Act;
- 5. Where approval is obtained in accordance with Article 9-3 (2) of the Act on the Acquisition, Management, and Utilization of Biological Research Resources.

(3) Where a person who has reported in accordance with paragraph (1) seeks to change any matters prescribed by Presidential Decree, such person shall report the change to the head of the Competent National Authority.
(4) In cases prescribed by Presidential Decree, such as where it is necessary to verify that a country providing the genetic resource(s) (referring to either a country that provides the genetic resource(s) as the country of origin, or a country that has legally acquired and provides the genetic resource(s) in accordance with the Convention on Biological Diversity) is the Republic of Korea , a local Korean resident may report an access to such domestic genetic resource(s) for their utilization to the head of the Competent National Authority pursuant to paragraphs (1) and (3).

- **Article 10** (Exemptions from Reporting Access to Domestic Genetic Resource(s)) Notwithstanding Article 9 (1), the head of the Competent National Authority may, as prescribed by Presidential Decree, seek to simplify procedures for reporting access to genetic resource(s) or waive such reporting following consultation with the head of the relevant central administrative agency, in any of the following cases:
 - 1. Where it is deemed that expedited access to or utilization of the genetic resource(s) is required for the development of therapeutic drugs and food security in the event there are threats to the life and health of humans, animals, and plants;
 - Where genetic resource(s) are accessed for non-commercial purposes such as pure research: Provided, That, if the intended purpose has changed, the access shall be reported without delay in accordance with Article 9 (1).
- **Article 11** (Benefit-Sharing of Domestic Genetic Resource(s)) Providers and users of genetic resource(s) shall agree to share the benefits of domestic genetic resource(s) fairly and equitably.
- **Article 12** (Prohibition of Access to and Utilization of Domestic Genetic Resource(s)) (1) The head of the Competent National Authority may seek to prohibit or restrict access to and utilization of domestic genetic resource(s), following consultation with the head of the relevant central administrative agency, in any of the following cases:

- Where it actually harms or is deemed to risk harming the preservation and continuous use of biodiversity (hereafter in this paragraph, referred to as "biodiversity") referred to in subparagraph 1 of Article 2 of the Act on the Conversation and Use of Biological Diversity;
- 2. Where it has a negative impact or is deemed to risk having a negative impact socio-economically on the value of biodiversity.

(2) If the head of the Competent National Authority seeks to prohibit or restrict access to and utilization of genetic resource(s) pursuant to paragraph (1), he/she shall publicly notify the target genetic resource(s) and the details of prohibition or restriction.

CHAPTER III ACCESS TO AND UTILIZATION OF FOREIGN GENETIC RESOURCE(S) AND BENEFIT-SHARING

- Article 13 (National Checkpoints)(1) Subject to Article 17 of the Protocol, the national checkpoints (hereinafter referred to as the "National Checkpoint") and their fields of jurisdiction are as follows: <Amended by Act No. 14839, Jul. 26, 2017>
 - 1. Ministry of Science and ICT: Bio-resources in accordance with the Act on the Acquisition, Management, and Utilization of Biological Research Resources;
 - 2. Ministry of Agriculture, Food and Rural Affairs: Agricultural bio-resources in accordance with the Act on the Conservation, Management, and Use of Agricultural Bio-Resources;
 - 3. Ministry of Trade, Industry and Energy: Agricultural bio-resources in accordance with the Act on the Acquisition, Management, and Utilization of Biological Research Resources;
 - 4. Ministry of Health and Welfare: Pathogenic resources in accordance with the Act on the Promotion of Collection, Management, and Utilization of Pathogen Resources;
 - Ministry of Environment: Biological resources in the field of wildlife in accordance with the Wildlife Protection and Management Act and biological resources in accordance with the Act on the Conservation and Use of Biological Diversity;
 - 6. Ministry of Oceans and Fisheries: Marine and fisheries bio-resources in accordance with the Act on Securing, Management, Use, etc. of Marine and Fisheries Bio-Resources.

(2) In regard to the fields of jurisdiction as prescribed in paragraph (1), the head of the National Checkpoint shall perform the following duties:

- 1. Processing procedural compliance reporting in accordance with Article 15;
- 2. Monitoring and recommending procedural compliance Article 16;
- 3. Supporting persons who utilize foreign genetic resource(s) domestically;
- 4. Other matters prescribed by Presidential Decree, which are related to access to and utilization of foreign genetic resource(s).

Article 14 (Procedural Compliance regarding Access to and Utilization of Foreign Genetic Resource(s)) (1) Any person who intends to access foreign genetic resource(s) for their utilization in the Republic of Korea shall follow the procedures established by the country providing such resources.

(2) Any person who wishes to access foreign genetic resource(s) for their utilization in the Republic of Korea shall endeavor to fairly and equitably share the benefits of foreign genetic resource(s) with the providers of the relevant genetic resource(s).

Article 15 (Procedural Compliance Reporting)(1) A person who intends to access foreign genetic resource(s) for their utilization in the Republic of Korea shall report to the head of the National Checkpoint, as prescribed by Presidential Decree, that the person has complied with the procedures prescribed in Article 14 (1).

(2) Reporting referred to in paragraph (1) shall be limited to the cases where the genetic resource(s) is provided from a country that is party to the Protocol and has established access and benefit-sharing procedures of

genetic resources, and such resource(s) is used in the Republic of Korea.

Article 16 (Monitoring of Procedural Compliance)(1) The head of the National Checkpoint may monitor

whether a domestic user of foreign genetic resource(s) has complied with the procedures prescribed in Article 14

- (1), in any of the following cases:
- 1. Where a country providing the genetic resource(s) raise an objection to a violation of the procedures referred to in Article 14 (1);
- 2. Where a third party has provided information regarding violation of the procedures referred to in Article 14 (1);
- 3. Where substantial grounds exist to believe that the procedures referred to in Article 14 (1) were not complied with.

(2) Where necessary as a result of the monitoring conducted under paragraph (1), the head of the National Checkpoint may recommend a person utilizing foreign genetic resource(s) domestically to comply with the procedures prescribed in Article 14 (1).

(3) A person utilizing foreign genetic resource(s) domestically shall cooperate in monitoring conducted under paragraph (1).

(4) The details of and methods for monitoring prescribed in paragraph (1) shall be determined by Presidential Decree.

CHAPTER IV SUPPLEMENTARY PROVISIONS

Article 17 (Genetic Resources Information Center)(1) To expertly perform duties related to access to and utilization of genetic resource(s) and benefit-sharing, the Minister of Environment shall establish and operate an information center (hereinafter referred to as the "Genetic Resources Information Center").

(2) The Genetic Resources Information Center shall perform the following duties:

- 1. Collecting, managing, monitoring, and providing information related to access to and utilization of domestic and foreign genetic resource(s) and benefit-sharing;
- 2. Providing information on domestic genetic resource(s) in regard to the Access and Benefit-Sharing Clearing-House in accordance with Article 14 of the Protocol;
- 3. Other matters prescribed by Presidential Decree, which are related to the duties of the National Focal Point, Competent National Authority, and National Checkpoint.

(3) The heads of the Competent National Authority and National Checkpoint shall provide the following information regarding access to genetic resource(s) and benefit-sharing to the Genetic Resources Information Center:

1. Matters concerning reporting or reporting on changes under Article 9;

2. Matters concerning reporting prescribed in Article 15 and monitoring and recommending under Article 16;

3. Other matters prescribed by Presidential Decree.

(4) Matters necessary for establishing and operating the Genetic Resources Information Center shall be determined by Presidential Decree.

Article 18 (Composition and Operation of the Council)(1) The Minister of Environment may establish and operate the Council to consult with the head of the relevant central administrative agency regarding matters necessary for access to and utilization of genetic resource(s) and benefit-sharing.

(2) The composition and operation of the Council prescribed in paragraph (1) and other necessary matters shall be determined by Presidential Decree.

Article 19 (Protection of Information)(1) The heads of the National Focal Point, Competent National Authority, National Checkpoint, and Genetic Resources Information Center shall take necessary measures to protect information on genetic resource(s) to protect the rights for the providers and users of genetic resource(s).

(2) No head of any agency or of the Center prescribed in paragraph (1) shall use any information related to genetic resource(s) for any commercial purpose or provide them to any third person, except for cases prescribed by Presidential Decree.

Article 20 (National Subsidy)The State may grant subsidies to an agency, corporation, or organization performing projects that promote access to and utilization of genetic resource(s) and benefit-sharing, to help cover all or part of the expenses incurred in such projects.

Article 21 (Securing Financing) The State shall formulate measures to secure funding to promote access to and utilization of genetic resource(s) and benefit-sharing.

Article 22 (Fees)(1) Any person intending to report or report on changes under Article 9 (1), (3), and (4) shall pay a fee.

(2) The amount of a fee referred to in paragraph (1), payment method, and payment period, shall be determined by Ordinance of the Ministry of Environment.

Article 23 (Delegation and Entrustment of Authority)(1) Part of the authority of the Competent National Authority and National Checkpoint vested under this Act may be delegated to the heads of their respective agencies or entrusted to other administrative agency heads, as prescribed by Presidential Decree.
(2) The duties of the Competent National Authority and National Checkpoint specified in this Act may be entrusted to the heads of related specialized institutions, corporations, or organization, as prescribed by

Presidential Decree.

Article 24 (Deemed Public Officials for Purposes of Penalty Provisions) Any executive officer or employee of related specialized agencies, corporations, or organizations performing duties entrusted pursuant to Article 23 (2) shall be deemed a public official in applying Articles 129 through 132 of the Criminal Act.

Article 25 (Review of Regulation)The Minister of Environment shall review the appropriateness of the following matters every two years, counting from the following relevant base date (referring to the period that ends on the day before the base date of every second year) and shall take measures, such as making improvements:

- 1. Reporting access to domestic genetic resource(s) under Article 9 (1): One year after the date the Protocol becomes effective in the Republic of Korea;
- 2. Prohibiting or restricting access to and utilization of domestic genetic resource(s) under Article 12: The date the Protocol becomes effective in the Republic of Korea;
- 3. Reporting on procedural compliance under Article 15 and monitoring and recommending procedural compliance under Article 16: One year after the date the Protocol becomes effective in the Republic of Korea;
- 4. Administrative fines prescribed in Article 28: One year after the date the Protocol becomes effective in the Republic of Korea.

CHAPTER V PENALTY PROVISIONS

- **Article 26 (Penalty Provisions)** Any person who accesses or utilizes genetic resource(s) prohibited or restricted from access or utilization, in violation of Article 12 (1), shall be punished by imprisonment with labor for not more than 3 years or by a fine not exceeding 30 million won.
- Article 27 (Confiscation and Collection) In cases falling under Article 26, the applicable genetic resource shall be confiscated: Provided, that, if confiscation is not possible, an amount equivalent to the price thereof shall be collected.
- Article 28 (Administrative Fines)(1) Any of the following persons shall be subject to administrative fines not exceeding 10 million won:
 - 1. Any person who fails to file a report under Article 9 (1);

2. Any person who fails to file a report under Article 15 (1).

(2) A fine not exceeding 5 million won shall be imposed on any person who fails to file a report on changes under Article 9 (3).

(3) The administrative fines referred to in paragraphs (1) and (2) shall be imposed and collected by the head of the Competent National Authority or the National Checkpoint, as prescribed by Presidential Decree.

H ADDENDA <Act No. 14839, Jul. 26, 2017>

Article 1 (Enforcement Date)

■ ADDENDA <Act No. 16016, Dec. 24, 2018>

Article 1 (Enforcement Date)

This Act shall enter into force six months after the date of its promulgation. Articles 2 and 3 Omitted.