## **Guidelines**

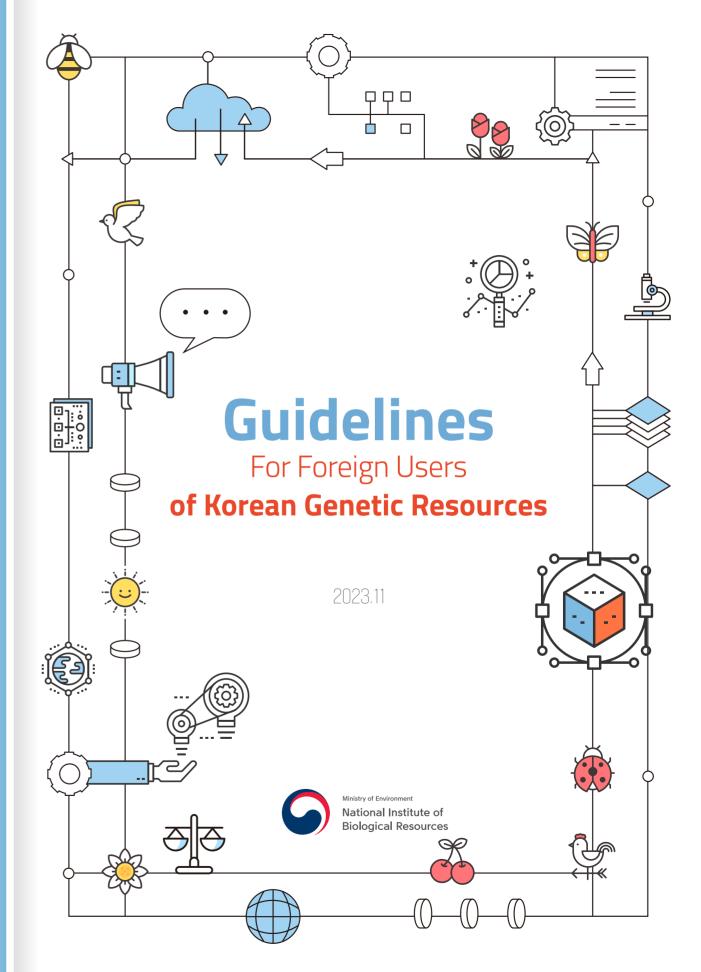
For Foreign Users

of Korean Genetic Resources



National Institute of Biological Resources







## **Guidelines**

For Foreign Users

of Korean Genetic Resources

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**Genetic Resources Act** 



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#### 01. Policy Background

#### A. CBD (Convention on Biological Diversity)

- The Convention on Biological Diversity (CBD) was adopted at the United Nations Conference on Environment and Development (UNCED) in 1992 to respond to ecological crises and unfair interests related to biological resources between developed and developing countries.
- CBD is the international legal instrument for "the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources" that has been ratified by 196 nations.

#### **B.** Nagoya Protocol

Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention on Biological Diversity.

- The Nagoya Protocol was adopted in 2010 as an international commitment to realize the third objective of the Convention on Biological Diversity, 'fair and equitable sharing of benefits arising from the utilization of genetic resources'.
- The concept of Access and Benefit-Sharing (ABS) for genetic resources consists of Access, Benefit-Sharing, and Compliance.
- \* Access Acquire Prior Informed Consent (PIC) according to the procedures set by the provider country as a preliminary activity for the utilization of biological genetic resources, such as research and development.
- \* Benefit-Sharing Share the benefits generated from the utilization of biological resources according to the Mutually Agreed Terms (MAT) concluded between the provider and the user.
- \* Compliance Submit PIC and MAT information according to the domestic system of the user country that confirms compliance with the provider country's access procedures.

#### C. Genetic Resources Act

- Korea ratified the Nagoya Protocol on May 19, 2017, and became a Party on August 17, 2017. Korea enacted the Act on Access to and Utilization of Genetic Resources and Benefit-Sharing (Genetic Resources Act).
- \* Act on Access to and Utilization of Genetic Resources and Benefit-Sharing (Act No. 14839, enforced on August 17, 2017)
- \* Enforcement Decree of the Act on Access to and Utilization of Genetic Resources and Benefit-Sharing (Presidential Decree No. 28246, enforced on August 17, 2017)
- \* Enforcement Rules of the Act on Access to and Utilization of Genetic Resources and Benefit-Sharing (Ministry of Environment Ordinance No. 720, enforced on August 18, 2018)

## 02. Major Details of the Genetic Resources Act

#### OVERVIEW OF THE GENETIC RESOURCES ACT

- ▶ When foreigners seek access to Korean genetic resource(s) for their utilization, they shall report such access to the Competent National Authority and agree to share the benefits of Korean genetic resources.
- Any person who intends to access foreign genetic resource(s) for their utilization in the Republic of Korea shall follow the procedures by providing country and report compliance to the National Checkpoint.

#### A. Scope of Application (Genetic Resources Act Articles 2, 3 and 12)

- **Genetic resources**: Plants, animals, microorganisms containing functional units of heredity, or other genetic materials of genetic origin that have actual or potential value.
- Traditional knowledge related to genetic resources: knowledge, innovation, practices of individuals or local communities embodying traditional lifestyles for the conservation and sustainable use of genetic resources.

#### Excluded from application:

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

**Prohibition of access and utilization:** The head of the Competent National Authority notify prohibition and restrictions for the following cases.

- Where it actually harms or is deemed to risk harming the conservation and sustainable use of biodiversity.
- Where it has a negative impact or is deemed to risk having a negative impact socio- economically on the value of biodiversity.

#### B. Reporting Access (Genetic Resources Act Articles 9, 10 and 12)

- Who should report: Foreigners, overseas Koreans, foreign institutions, international organizations, and those other persons designated by Ordinance of the Ministry of Environment seeking to access Korean genetic resources for the purpose of utilization.
- Where to report: Competent National Authority via the Integrated Reporting Service website. (www.abs.go.kr)

Exemptions from reporting access: Reporting procedures may be simplified or exemption notified in any of the following cases:

- Where it is deemed that expedited access to or utilization of the genetic resources is required for the development of therapeutic drugs and food security in the event there are threats to the life and health of animals and plants.

#### I . Genetic Resources Act

- Where genetic resources are accessed for non-commercial purposes such as pure research.
- \* As of November 2023, one public notice was issued to international organizations or organizations cooperating with international organizations for the purpose of urgent diagnosis and quarantine of livestock diseases.

#### C. Benefit-Sharing (Genetic Resources Act Article 11)

- The Genetic Resources Act specifies that providers and users of genetic resources shall agree to share the benefits of domestic genetic resources fairly and equitably.
- The benefit-sharing ratio is determined by Mutually Agreed Terms, which is a contract between the provider and user of genetic resources, and there is no form of Mutually Agreed Terms set by law.
- Mutually Agreed Terms can be submitted with access report if applicable. Even after the access certificate is issued, it is possible to submit the Mutually Agreed Terms and applying for confirmation of the conclusion of the Mutually Agreed Terms (Enforcement Decree of the Genetic Resources Act Article 4(4)).

#### D. Compliance (Genetic Resources Act Article 15)

- Who should report: A person who intends to access foreign genetic resources for their utilization in Republic of Korea.
- Where to report: Integrated Reporting Service website (www.abs.go.kr) to the National Checkpoints according to their field of jurisdiction.

#### E. Penalties (Genetic Resources Act Article 26)

- Any person who accesses or utilizes genetic resources prohibited or restricted from access or utilization, in violation of Article 12 (Prohibition of Access to and Utilization of Domestic Genetic Resources (1), shall be punished by imprisonment with labor for not more than 3 years or by a fine not exceeding 30 million(30,000,000₩), and the applicable genetic resource shall be confiscated and collected.
- Any person who fails to access reporting, or compliance reporting shall be subject to a fine of 2 million(2,000,000₩). A person who fails change reporting when a change occurs shall be subject to a fine of 1 million(1,000,000₩) (aggravated punishment depending on the number of violations).

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#### Guidelines for Foreign Users of Korean Genetic Resources

#### $^{\dagger}$ full korean and english text of the genetic resources act $^{\dagger}$

Korean	Name of Act	English
	Act on Access to and Utilization of Genetic Resources and Benefit-Sharing (Act No. 14839, Enforced Aug. 17, 2017)	
https://lrl.kr/M6pF	Enforcement Decree of the Act on Access to and Utilization of Genetic Resources and Benefit-Sharing (Presidential Decree No. 28246, Enforced Aug. 17, 2017)	回場合 東京 東京 東京 東京 https://lrl.kr/M6nV
	Enforcement Rule of the Act on Access to and Utilization of Genetic Resources and Benefit-Sharing (Ministry of Environment Ordinance No. 720, Enforced Nov. 27, 2018)	

#### | STRUCTURE OF THE GENETICS RESOURCES ACT |

Chapters	Articles
<b>CHAPTER 1</b> General Provisions	Article 1 (Purpose) Article 2 (Definitions) Article 3 (Applicability) Article 4 (Responsibilities of State) Article 5 (Relationship to Other Acts) Article 6 (Formulation of Support Measures)
CHAPTER 2 Access to and Utilization of Domestic Genetic Resource(s) and Benefit-Sharing	Article 7 (National Focal Points)  Article 8 (Competent National Authorities)  Article 9 (Reporting Access to Domestic Genetic Resource(s))  Article 10 (Exemptions from Reporting Access to Domestic Genetic Resource(s))  Article 11 (Benefit-Sharing of Domestic Genetic Resource(s))  Article 12 (Prohibition of Access to and Utilization of Domestic Genetic Resource(s))

#### I . Genetic Resources Act

Chapters	Articles
CHAPTER 3  Access to and Utilization of Foreign Genetic Resource(s) and Benefit-Sharing	Article 13 (National Checkpoints)  Article 14 (Procedural Compliance regarding Access to and Utilization of Foreign Genetic Resource(s))  Article 15 (Procedural Compliance Reporting)  Article 16 (Monitoring of Procedural Compliance)
<b>CHAPTER 4</b> Supplementary Provisions	Article 17 (Genetic Resources Information Center) Article 18 (Composition and Operation of the Council) Article 19 (Protection of Information) Article 20 (National Subsidy) Article 21 (Securing Financing) Article 22 (Fees) Article 23 (Delegation and Entrustment of Authority) Article 24 (Deemed Public Officials for Purposes of Penalty Provisions) Article 25 (Review of Regulation)
CHAPTER 5 Penalty Provisions	Article 26 (Penalty Provisions) Article 27 (Confiscation and Collection) Article 28 (Administrative Fines)

## **03. Genetic Resources Act Implementing Agencies**

## | GOVERNMENT AGENCIES RESPONSIBLE FOR IMPLEMENTING THE GENETIC RESOURCES ACT |

(Genetic Resources Act Articles 7, 8 and 13)

National Foca	Ministr	y of Foreign Affairs	Liasing with the CBD Secretariat			
Points	Minist	ry of Environment		ting information sources and ben	on access to genetic efit-sharing	
		自由自				
Genetic resources type	Biological resources	Agricultural bio-resources	Pathogenic organism resources	Marine and fisheries bio-resources	Bio-resources	
Competent National Authorities	Ministry of Environment	Ministry of Agriculture, Food and Rural Affairs	Ministry of Health and Welfare	Ministry of Oceans and Fisheries	Ministry of Science and ICT	
National Checkpoints	Ministry of Environment	Ministry of Agriculture, Food and Rural Affairs	Ministry of Health and Welfare	Ministry of Oceans and Fisheries	Ministry of Science and ICT/ Ministry of Trade, Industry and Energy	

	Field of Ju	risdiction		
Ministry of Environment	Wildlife area biological resources under the Wildlife Protection and Management Act and responsible biological resources under the Act on the Conservation and Use of Biological Diversity.	Wildlife Protection and Management and responsible biological resources Health and der the Act on the Conservation and Welfare		
Ministry of Science and ICT	Responsible bio-resources under the Act on the Acquisition, Management, and Utilization of Biological Research Resources.  Ministry of Oceans and Fisheries		Marine and fisheries bio-resources under the Act on Securing, Management, and Use of Marine and Fisheries Bio- resources.	
Ministry of Agriculture, Food and Rural Affairs	Agricultural bio-resources under the Act on the Conservation, Management and Use of Agricultural Bio-resources.	Ministry of Trade, Industry and Energy	Bio-resources under the Act on the Acquisition, Management, and Utilization of Biological Research Resources.	

#### I . Genetic Resources Act

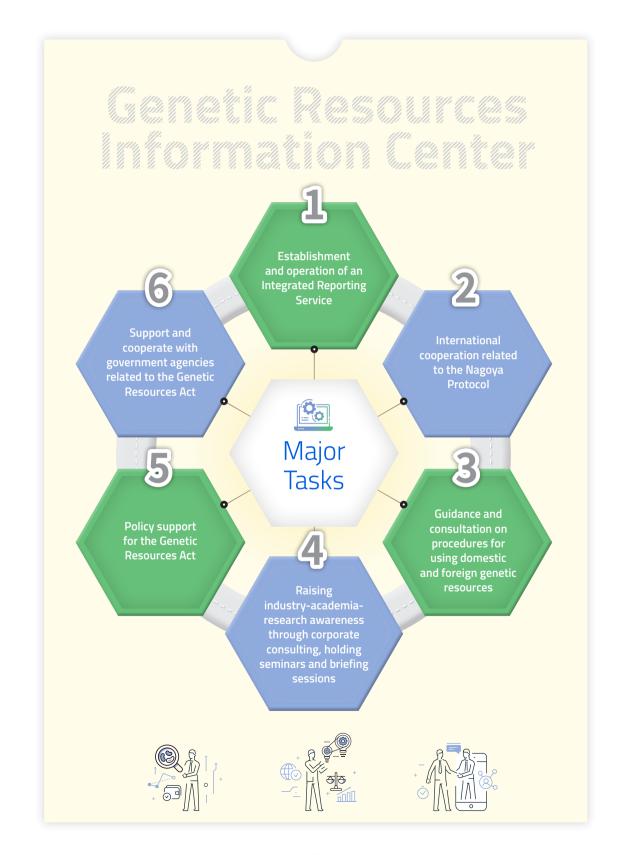
#### | GENETIC RESOURCES INFORMATION CENTER |

(Genetic Resources Act Article 17)

- Forea has established and operated the Genetic Resources Information Center, which specializes in accessing genetic resources and benefit sharing in the National Institute of Biological Resources, an organization under the Ministry of Environment.
  - Operating an Integrated Reporting Service (www.abs.go.kr) to process reports and resolve related inquiries on the genetic resource reporting system.
  - Publishing ABS guidebooks to support industry and research sectors, and sharing the latest global ABS trend by biweekly newsletters.
  - Providing consultations and seminars on ABS procedures with biotech companies.



Scenery of the National Institute of Biological Resources where the Genetic Resources Information Center is located



# CHAPTER I

Procedures for utilizing
Genetic Resources



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#### **01. Access Reporting Process Overview**









#### **Preparation stage**

- Systemize genetic resources utilization plan.
- Access the Integrated Reporting Service website (abs.go.kr) and identify required documents and detailed procedures.
- Inquire relevant procedures to the Genetic Resources Information Center if necessary.

#### **Conclude Mutually Agreed Terms**

**Access reporting** 

- Report before access and utilization.
- Competent authority selection, reporter, provider information, etc.
- Submit access report, copy of MAT agreement.
- URL: www.abs.go.kr (Submit documents online via the Integrated Reporting Service website)



If MATs are established after the access certificate is issued



#### Access and use of genetic resources

- Transfer genetic resources.
- Research and development.



#### Report processing and issue certificate

(By responsible Competent National Authority)

- Receive report, request
- supplementation, accept, etc. • Issue certificate within 30 days
- of receiving the report.
- Send original copy by postal mail. (Competent National Authority to Reporter)



(By responsible Competent National

confirmation certificate

• Receive application, accept and issue certificate of establishment of Mutually Agreed Terms.

Apply for confirmation

of MAT conclusion

(Submit document online via the

Integrated Reporting Service website.) • 1 copy of MAT agreement.

- Issue certificate within 15 days of application.
- Send original copy by postal mail. (Competent National Authority ► Applicant)



#### **Benefit-sharing**

· Benefit-sharing with the provider according to the Mutually Agreed Terms.



## **02. Integrated Reporting Service**

#### Procedure for using Integrated Reporting Service

Access to the Website (www.abs.go.kr)

#### Create an account

Confirm the account (Check your verification Email address)



Sign in

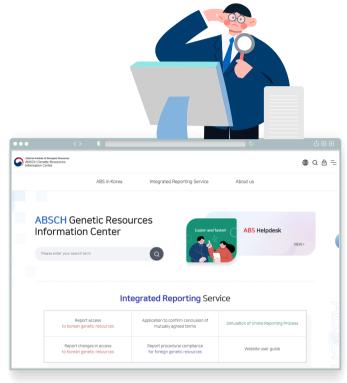
.....

Submit the form

Form reviewed



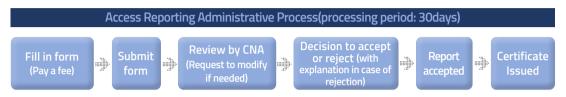
Report accepted



Classification	Reporting access for utilization of Korean genetic resources	Reporting Compliance for the utilization of Foreign genetic resources
Target	Foreigners, overseas Koreans, foreign institutions, and international organizations (Korean nationals if needed)	Any person in Republic of Korea who obtained Prior Informed Consent from the country that is a party to the Nagoya Protocol
Report to	Competent National Authority	National Checkpoints (within 90 days after obtaining Prior Informed Consent)
Procedure	Submit report before access ▶  process report ▶  Issue report certificate	Submit report to National Checkpoint ▶  Check documents ▶  Complete processing
Processing period	30 days	5 days

#### 03. How to report

#### REPORTING ACCESS TO KOREAN GENETIC RESOURCES



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#### Who should report

 Foreigners, overseas Koreans, foreign institutions, international organizations and other persons seeking access for the purpose of utilizing Korean genetic resources.
 (Genetic Resources Act Article 9 (1))

#### To report, you need

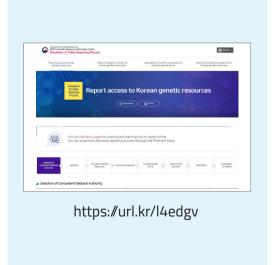
- Documents that can confirm your identity or affiliation, such as a passport
- For corporations, document equivalent to corporate registration certificate.
- Identity of a person with an alien registration

- card or a foreign corporation established under Korean law can be confirmed through sharing administrative information.
- A copy of the Mutually Agreed Terms (if concluded)
- Fee KRW 10,000 (attach electronic revenue stamp)
- ※ Purchase stamps from the Ministry of Strategy and Finance website at www.edoc-revenuestamp.or.kr. It is recommended that the applicants from overseas get help from partner organization in Korea to buy electronic revenue stamp.

#### **Access reporting guide video**

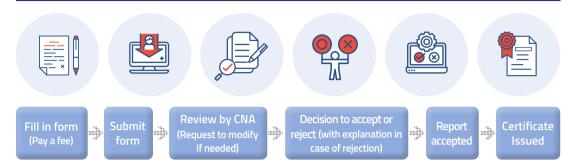


#### **Access reporting simulation page**



#### CHANGE REPORTING IN ACCESS TO KOREAN GENETIC RESOURCES

Change reporting administrative process (Processing period: 30 days)



#### Who should report

- Those who wish to change the following items among those who have reported access to genetic resources.
- (Genetic Resources Act Article 9 (3), Enforcement Decree of the same Act Article 4 (6))
- To change purpose for accessing the declared genetic resource(s);
- To increase at least 10/100 of the declared genetic resource(s) content or concentration (excluding microorganisms);
- To change the details of Mutually Agreed Terms concerning the relevant genetic resource(s) (only applicable where Mutually Agreed Terms are established).

#### To report, you need

- Original Declaration Certificate for Access to Korean Genetic Resources (mail submission)
- A copy of the changed Mutually Agreed Terms (if applicable)
- Fee KRW 5,000 (attach electronic revenue stamp)

#### Change reporting guide video



#### Change reporting simulation page



#### | APPLICATION FOR CONFIRMATION OF MUTUALLY AGREED TERMS |



#### Who should report

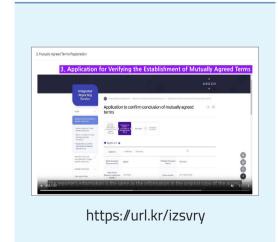
 A person who has entered into Mutually Agreed Terms after obtaining an access report certificate.

(Enforcement Decree of the Act on Access, Utilization and Profit Sharing of Genetic Resources Article 4 (4) and Enforcement Rules of the same Act Article 3 (3))

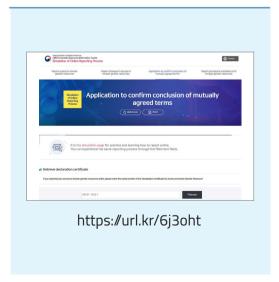
#### To report, you need

- A copy of the Mutually Agreed Terms
- No fees

#### MAT confirmation guide video



#### **MAT confirmation simulation page**



#### | COMPLIANCE REPORTING |



#### Who should report

 Any person in Republic of Korea who obtained Prior Informed Consent from the country that is a party to the Nagoya Protocol.

#### To report, you need

- A document demonstrating that the reporting person has been approved by the provider country for access to genetic resources
- A copy of Mutually Agreed Terms (if concluded)
- Certified copies of the reporting person's resident or alien registration (only if unverifiable through sharing administrative information)
- No fees

#### **Compliance reporting guide video**



#### **Compliance reporting simulation page**



#### Guidelines for Foreign Users of Korean Genetic Resources

#### 04. Q&A



1.I am a foreigner conducting joint research with a Korean researcher. Do I have to report access to Korean genetic resources?



Foreigners, overseas Koreans, foreign institutions, and international organizations (hereafter foreigners, etc.) who intend to access Korea's genetic resources must report access to the Competent National Authority from August 18, 2018, according to Korea's Genetic Resources Act Article 9.



I would like to acquire and research Korean genetic resources for academic purposes. Are there any exceptions to the Genetic Resources Act for academic purposes?



As of November 2023, it is mandatory to make a genetic resources access reporting regardless of the purpose of access (commercial or non-commercial). Article 10 of the Genetic Resources Act stipulates that the reporting process should be simplified or exempted and notified after deliberation by the council where genetic resource(s) are accessed for non-commercial purposes such as pure research. However, a public notice concerning exceptions to reporting access for non-commercial purposes such as pure research has not yet been notified.



I want to use Korean genetic resources acquired before the enactment of the Genetic Resources Act (2017). Is it necessary to report access?



For subsequent use of genetic resources, such as for research and development, it is mandatory to make an access reporting to the Korean Competent National Authority. If the acquirement and R&D on genetic resources were completed before the enforcement of the Genetic Resources Act, simply just adding genetic resource according to the established manufacture process is not subject to regulation under Genetic Resources Act in most cases.





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#### Who do I conclude the Mutual Agreement Terms (MAT) with?



- Article 11 of the Genetic Resources Act stipulates that 'Providers and users of genetic resources shall agree to share the benefits of domestic genetic resources fairly and equitably.' Therefore, the MAT must be concluded with the provider.
- There is no model template for Mutually Agreed Terms (MAT) in Genetic Resources Act. The contracting parties are free to decide the elements of MAT such as benefit sharing options.
- The provider is a person (Korean corporation or individual) who provides Korean genetic resources. When genetic resources are provided through an intermediary, you need to contact the person providing the Korean genetic resources.



In Genetic Resources Act, is there a distinction between wild and cultivated genetic resources?



The Act does not distinguish between wild species and cultivated species in relation to access to genetic resources and benefit-sharing, and thus there is no difference in the access reporting process.



I am foreign resident in Korea using genetic resources from a third country (other than Korea). Do I must report compliance?



Foreigners (foreign corporations) must also report compliance in accordance with Article 14 of the Genetic Resources Act when using foreign genetic resources in Korea.



I am using genetic resources after receiving an access report certificate issued by a Competent National Authority in Korea and would like to import additional genetic resources and extend the period of use. What steps should I take?



- According to the Enforcement Decree of the Genetic Resources Act Article 4(6), you must
  make a change report for the existing report if you intend to (1) change the purpose and
  use (2) change the quantity or use within 10% (3) change the Mutually Agreed Terms.
  Therefore, it is possible to make a change report if the additional import amount is less
  than 10%.
- However, you must make a new access report for extending the period of use.

# CHAPTER III

Progress review of Korea's Genetic Resources Act



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01

# Enactment of the Genetic Resources Act and Establishment of the ABSCH Genetic Resources Information Center

- The Republic of Korea ratified the Nagoya Protocol on May 19, 2017, and acquired the status of the 98th party of the protocol on August 17.
- The government enacted the Genetic Resources Act on January 17, 2017 and enforced the Act on August 17, 2017. (reporting obligation was postponed until August 18, 2018)
- The Genetic Resources Information Center was established in March 2018 to perform the following tasks to ensure smooth implementation of the Genetic Resources Act.
- Collection, management, investigation, and provision of information on access, utilization, and benefit-sharing of Korean and foreign genetic resources.
- Provision of information on domestic genetic resources for the access and benefit-sharing information system pursuant to Article 14 of the Protocol.
- Administrative and technical support for the work of National Focal Points, Competent National Authorities, National Checkpoints.
- International cooperation, such as information exchange with foreign genetic resources information organizations, to investigate the status of overseas use of Korean genetic resources.
- Promotion to raise awareness of access, utilization and benefit-sharing among providers and users of genetic resources.

02

## Operation of Integrated Reporting Service and Publication of national records on CBD ABSCH\*

- Supports for reporting related to access to and utilization of genetic resources online through Integrated Reporting Service.
- Provide on-line troubleshooting service through the ABS Help Desk.
- Provides ABS information of major provider countries through Integrated Reporting Service website.
- Published 45 internationally recognized compliance certificates (IRCC)\*\* with CBD ABSCH as of November 2023
- \* Access and Benfit-Shring Clearing-House (ABSCH): An access and benefit-sharing information system, an online platform to facilitate access to and exchange of ABS information and information disclosed by each Party related to the implementation of the Nagoya Protocol (cbd.absch.int)
- \*\* Internationally Recognized Certificate of Compliance (IRCC): A permit or its equivalent issued at the time of access as evidence that the genetic resource it covers has been accessed in accordance with the decision to grant Prior Informed Consent, and that Mutually Agreed Terms have been established for the user and the utilization specified therein by a competent authority in accordance with Article 6(3)(e) and Article 13(2) of the Nagoya Protocol, that is made available to the Access and Benefit-sharing Clearing House established under Article 14(1) of that Protocol.

03

### **Support for Private Sector and Research**

- Introducing the Nagoya Protocol, the Convention on Biological Diversity, and the Genetic Resources Act.
- Consulting on procedures for utilizing genetic resources, organizing seminars and briefing sessions and operating of the ABS Helpdesk via the website.
- Sharing the latest global ABS trend by biweekly newsletters.



## Contact and Visit us

E-mail

• gric@korea.kr

#### Websites

National Records

 CBD ABSCH Korea Country Profile (https://absch.cbd.int/en/countries/KR)

Institutions

- ABSCH Genetic Resources Information Center
   Abstraction and General Center
   Assured to the Control of the Control o
  - (https://www.abs.go.kr)
- National Institute of Biological Resources (http://www.nibr.go.kr)
- Ministry of Environment (http://www.me.go.kr)

Genetic Resources DB, etc.

- CBD CHM KOREA (http://www.kbr.go.kr)
- Biodiversity on the Korean Peninsula (http://species.nibr.go.kr)