BioResource Now !

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"Report on the Present Situation of the Nagoya Protocol — COP12/COP-MOP1 and Trends in the EU"

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Introduction

The Nagoya Protocol was adopted during the tenth meeting of the Conference of the Parties to the Convention on Biological Diversity (COP10) in 2010 in order to establish international legally binding enforcement for the fair and equitable sharing of the benefits arising out of the utilization of overseas genetic resources. Following this meeting, the number of ratifying parties exceeded 50 (the minimum requirement), and the Nagoya Protocol came into effect on October 12, 2014.
The Nagoya Protocol states that potential users of genetic resources must obtain the prior informed consent (PIC) of the country in which the genetic resource is located before accessing the resource. Negotiation and agreement on the terms and conditions of access and use of the resource would be conducted through the establishment of mutually agreed terms (MAT). The country intending to use the genetic resource is obligated to establish a checkpoint to ensure the above matters.

This article describes the twelfth meeting of the Conference of the Parties to the Convention on Biological Diversity (COP12) and the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol (COP-MOP1) held in Pyeongchang, Republic of Korea in October 2014. This article also describes information about regulations on biological diversity in the European Union (EU) and the current situation and future problems of the Nagoya Protocol.

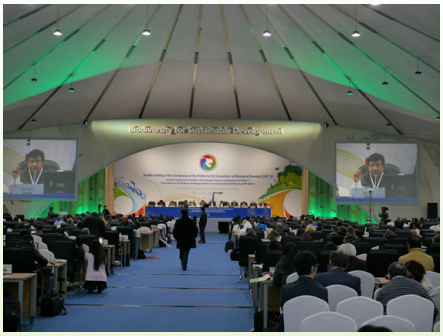

Photo 1 ：Conference hall of COP12/COP-MOP1
The person on the screen is Hem Pande (India), Chair of COP-MOP1

1. Report on COP12/COP-MOP1

During COP12, 35 decisions were made, and synthetic biology, a topic of interest to many researchers, was discussed. In the discussion, representatives from developing countries voiced concerns about their economic losses caused by products manufactured using synthetic biology and argued the necessity of establishing an international framework. A decision was made to insert text indicating the importance of international cooperation. In addition, a committee of experts would be founded to discuss various matters regarding genetic resources. We will be focusing on the activities of this committee.

Because many subjects had been discussed at three previous inter-governmental meetings, COP-MOP1 progressed smoothly. Opinions of non-signatory countries, including Japan, must be supported by signatory countries. Many of the arguments were related to actual systems to examine genetic resources after the implementation of the Nagoya Protocol. Discussions included the issues of how to promote compliance with the Nagoya Protocol, how to support potential ability development, and how to mobilize human resources in order to implement the Nagoya Protocol. Future methods of examining genetic resources were also determined. Model contract clauses, codes of conduct, and best practices were set to be examined in four years, and the examination items included protocols regarding resources in local communities. However, the mechanism of monetary support among multiple countries was not discussed.
Along with the implementation of the Nagoya Protocol, the Access and Benefit-Sharing Clearing-House (information exchange center) was officially launched (https://absch.cbd.int). This website lists the laws, regulations, and profiles of each country. In the future, information about an international compliance certificate will be managed by and exhibited from this website.

Photo 2: Welcome event of COP12 (Korean traditional dance in front of the ski jumping arena; Pyeongchang will be the host city of the Olympic Winter Games in 2018)

2. The Present Situation of Genetic Resources in the EU

The EU Committee, the EU Council, and the European Parliament discussed compliance measures for users of genetic resources, approved a genetic resources-related regulation in March 2013, and ratified the Nagoya Protocol in May 2013. At present, these organizations have been examining the Implementing Act. The penalty for noncompliance will be determined in the future based on the draft of each member state. The characteristics of the approved EU regulation (No 511/2014) are described below.

1) Due Diligence

Users of genetic resources are required to perform due diligence, i.e., the necessary procedures such as acquisition of PIC and MAT following the laws and regulation of the country in which the genetic resource is located. The recipient of a research fund must declare the implementation of due diligence.
At the final stage of manufacturing a genetic resource-related product in conformity with the rules, the manufacturer is obligated to report the implementation of due diligence to the EU Committee and to submit an international compliance certificate. At present, because an actual method to declare the implementation of due diligence is to be determined in the Implementing Act, the content of the method is unknown. However, researchers may be affected greatly depending on the content of the declaration method.

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2) Collection Register

A system of registering a collection was established in the EU. In the system, a person acquiring a genetic resource from a collection in the register is considered to have performed due diligence regarding the collection of necessary information. This system should offer convenience to collection users and contribute to the reduction of the amount of office work. Table 1 shows the conditions required for the collection register.
Each collection needs to a) apply standardized procedures, b) acquire PIC and MAT for the corresponding genetic resource, c) keep records of all samples of genetic resources, d) establish or use unique identifiers when supplying genetic resources to third persons, and e) use appropriate tracking and monitoring tools.

When a person in the EU uses a genetic resource, the person needs to obtain information about that genetic resource. This information includes whether the resource is listed in the EU collection register and whether its international compliance certificate exists. If these are not satisfied, the person needs to obtain information about PIC and MAT.

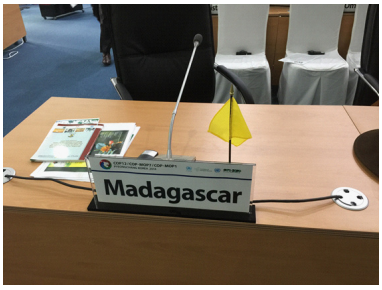


Photo 3: A yellow flag indicates a signatory country of the Nagoya Protocol

3) Best Practice

Each community of researchers can register a best practice with the EU Committee. Although a researcher in the EU may use a genetic resource in conformity with this best practice, the researcher may still need to declare the implementation of due diligence in the future.

Because the United States is not a signatory country of the Convention on Biological Diversity, the trends of the EU greatly affect other countries using genetic resources, including Japan. In the future, we should pay close attention to the content of the Implementing Act.

In order for a collection or a part of a collection to be included in the register, a collection shall demonstrate its capacity to:
(Article 5-3, Regulation (EU) No. 511/2014)

(a) apply standardized procedures for exchanging samples of genetic resources and related information with other collections, and for supplying samples of genetic resources and related information to third persons for their utilization in line with the Convention and the Nagoya Protocol;

(b) supply genetic resources and related information to third persons for their utilization only with documentation providing evidence that the genetic resources and the related information were accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements and, where relevant, with mutually agreed terms;

(c) keep records of all samples of genetic resources and related information supplied to third persons for their utilization;

(d) establish or use unique identifiers, where possible, for samples of genetic resources supplied to third persons; and

(e) use appropriate tracking and monitoring tools for exchanging samples of genetic resources and related information with other collections.

Table 1: EU collection register

3 Effects of the Nagoya Protocol on Scientific Research and Bioresource-related Organizations

It is not yet known when domestic measures related to the Nagoya Protocol will be determined and when the Nagoya protocol will be ratified in Japan. However, there is a possibility that these issues could be rapidly settled. The Nagoya Protocol is a system to monitor the appropriate use of genetic resources. It is a matter of course that a researcher appropriately acquires a genetic resource in conformity with the laws and regulations of the country in which the genetic resource is located. The user of a genetic resource must obey the laws and regulations regardless of the existence of the monitoring system.

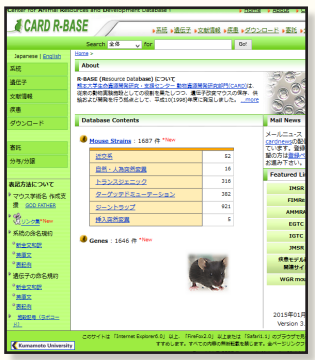
The Convention on Biological Diversity came into effect in 1993, and Japan ratified the Convention. In the future, laws and regulations concerning genetic resources will be established, and a sense of entitlement may be strengthened in countries that provide genetic resources. Because of the above-mentioned background, genetic resource-related organizations must construct their own systems to appropriately handle genetic resources from overseas, regardless of whether Japan ratifies the Nagoya Protocol.

The trend of the EU collection register suggests that the role of bioresource-related organizations in overseas genetic resources will be more important than ever, and an international certificate for legally acquiring overseas genetic resources will become increasingly necessary. We must monitor the international movement of genetic resources.

Database of this Month

CARD R-BASE

(Resource Database, Center for Animal Resources and Development, Kumamoto University)



Number ofstrains:1,687
Number of genes: 1,646
(As of January 2015)

DB name : CARD R-BASE
URL : http://cardb.cc.kumamoto-u.ac.jp/transgenic/
Langages : Japanese English
Original contents :
- Information about deposition, distribution, genes, references, diseases, and application fields of the following mouse strains preserved in the Center for Animal Resources and Development, Kumamoto University (CARD):
  - Inbred
  - Spontaneous/Chemical induced mutant
  - Transgenic
  - Targeted mutant
  - Gene trap
  - Insertion mutant
- Information about tools to support nomenclature of the scientific names of mouse and rat strains

Features: Information about mice can be inspected and searched from the perspectives of strains, genes, references, and diseases.
Because it is linked to a management database, this database can provide the latest information.
Cooperative DBs: IMSR(International Mouse Strain Resource), JSMR(Japan Mouse/Rat Strain Resources Database), MGI(Mouse Genome Informatics), AmiGO OMIM (Online Mendelian Inheritance in Man)
DB construction group:Kumamoto University, NIG
Management organization: Genetic Resource Center, NIG
Year of first DB publication: 2001 Year of last DB update: 2015

Comment from a developer : In addition to information provided by depositors, information about strains preserved in the CARD is linked with information stored in external databases such as Gene Ontology and OMIM, which improves the quality of information. The information we have been providing on IMSR and JMSR helps in the use of these databases for identifying strains preserved in the CARD. Since information is occasionally added from the management database to CARD R-BASE, please visit our database regularly.

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Editor's Note

Dr. Suzuki kindly reported on the twelfth meeting of the Conference of the Parties to the Convention on Biological Diversity (COP12) and the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol (COP-MOP1) held in 2014. Although this article may be heavy with technical information, I hope that our readers can follow it easily because Dr. Suzuki has written articles in this newsletter several times (v6.3, v6.12, and v7.1-2). I hope that the domestic measures related to the Nagoya Protocol are determined as soon as possible, as it is necessary for us to make the use of genetic resources easier. Anyway, all of us are responsible for conserving genetic resources (Y. Y.).

BioResource Information

(NBRP) www.nbrp.jp/
(SHIGEN) www.shigen.nig.ac.jp/
(WGR) www.shigen.nig.ac.jp/wgr/
(JGR) www.shigen.nig.ac.jp/wgr/jgr/jgrUrlList.jsp

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