

Administrative Regulations for Biological Genetic Resources in the NARO Genebank Project of the National Agriculture and Food Research Organization

GRC No. 0101018

April 1, 2016

Article 1

OBJECTIVE

Based on Article 9 of the National Agriculture and Food Research Organization (hereinafter referred to as “NARO”) Genebank Project Implementation Regulations GRC No. 0101017 (hereinafter referred to as the “Project Implementation Regulations”), the administration of biological genetic resources to be handled in the NARO Genebank project (hereinafter referred to as the “the Project”) shall comply with the provisions of the present Regulation.

Article 2

USE OF TERMS

1. The terms used in this Regulation are consistent with those used in the Project Implementation Regulations.
2. The Standard Material Transfer Agreement (hereinafter referred to as “SMTA”) is the agreement provided in Article 12.4 of the International Treaty on Plant Genetic Resources for Food and Agriculture (hereinafter referred to as “ITPGRFA”).

Article 3

COLLECTION AND ACCEPTANCE OF BIOLOGICAL GENETIC RESOURCES

Each of the biological genetic resources to be in accordance with and agreed by a donor shall comply with the purposes of the Project and shall satisfy the following requirements, except under special circumstances.

1. Plant genetic resources shall satisfy the following requirements:
 - (1) species, name, and origin of the plant shall be known;
 - (2) a sufficient amount of plant material shall be provided for conservation.
2. Microorganism genetic resources shall satisfy the following requirements:
 - (1) species, characteristics for classification/identification, name of the line (strain), origin, etc. of the microorganism shall be known;
 - (2) a sufficient amount of microorganism material shall be provided for conservation;
 - (3) the microorganism shall not be highly hazardous;
 - (4) the microorganism shall not be difficult to culture or conserve.

3. Animal genetic resources shall be known with respect to species, variety name, and name of line, origin, etc.
4. DNA and other biological genetic resources shall satisfy the following requirements:
 - (1) the name, donor species, and information regarding the origin, including the supplier, shall be known;
 - (2) the resource shall not be difficult to preserve or proliferate.

Article 4

PROPAGATION AND CONSERVATION OF BIOLOGICAL GENETIC RESOURCES

The biological genetic resources that have been collected and accepted by the Project shall be appropriately propagated, conserved, and maintained.

Article 5

ADMINISTRATION AND PROVISION OF INFORMATION ON BIOLOGICAL GENETIC RESOURCES

Each of the biological genetic resources to be conserved shall be given a registration number and, as a general rule, be made accessible to the public upon recording the type, product name, origin, characterized information, conserved quantity, etc.

Article 6

DISTRIBUTION OF BIOLOGICAL GENETIC RESOURCES

1. As a general rule, the purpose of the distribution of the biological genetic resources (excluding the specific distribution of biological genetic resources outlined in Article 9) shall be limited to research (including breeding) or educational use (hereinafter referred to as “research purposes”) and the distribution shall be charged. However, overseas distribution of biological genetic resources shall meet all of the conditions prescribed by the Director of the Genetic Resources Center, except for the transfer of plant genetic resources that meets the terms and conditions of the SMTA.
2. Plant genetic resources distributed under the SMTA are those that are collected under the terms and conditions of the SMTA or are designated to be included in the multilateral system of the ITPGRFA by the Ministry of Agriculture, Forestry, and Fisheries. The said distribution shall comply with Articles 12.3 and 12.4 of the ITPGRFA. After the said distribution, it shall be notified to the governing body of the ITPGRFA, pursuant to Article 6.4 of the SMTA.
3. Application for distribution of the biological genetic resources shall be made by submitting a form for the Application for Distribution of Biological Genetic Resources (attached Form

No. 1), the Material Transfer Agreement that specifies the terms and conditions for the use of the biological genetic resources (attached Form No. 2), and other documents necessary for distribution. However, in cases of plant genetic resources where the SMTA shall be applied, the SMTA shall be submitted instead of Form No. 2.

4. The distribution quantity and price shall be specified by the Director of the Genetic Resources Center and conform to the provisions outlined in the Appendix. However, in cases where any of the following conditions apply, biological genetic resources may be distributed free of charge:
 - (1) application for distribution from an organization commissioned under Paragraph 5, Article 3 of the Project Implementation Regulations to provide for relevant commissioned operations;
 - (2) application for distribution from an organization or a person conducting free-of-charge media coverage, exhibits, etc., which would benefit the public relations of the Project;
 - (3) application for distribution of plant genetic resources (excluding the NIAS Core Collections) from a foreign public organization or equivalent;
 - (4) application for distribution from an organization or a person who has provided the Project with biological genetic resources (excluding DNA, etc.), which can be distributed to third parties (limited to the provided quantity);
 - (5) application for distribution to provide biological genetic resources for educational purposes in senior high schools or lower (excluding the NIAS Core Collections);
 - (6) application for distribution from an organization or a person who has offered to contribute to the Project by implementing the characterization and evaluation of the genetic resources conserved by the Project, according to the conditions prescribed by the Director of the Genetic Resources Center;
 - (7) applications for distribution of plant genetic resources under the SMTA; or
 - (8) other cases specified by the Director of the Genetic Resources Center.
5. In cases where biological genetic resources are to be distributed for a fee, the NARO shall issue an invoice to the organization or a person who has applied for distribution (hereinafter referred to as the “Applicant”). The Applicant shall make payment of the fee to a specified bank account based on the invoice.
6. Biological genetic resources shall be distributed after confirmation of the payment, except for the cases provided in Article 6.4 of the Regulation where biological genetic resources are to be distributed free of charge. The Notice of Distribution of Biological Genetic Resources (attached Form No. 3) shall be sent with the biological genetic resources.

Article 7

REFUSAL OF DISTRIBUTION AND ADJUSTMENT OF THE DISTRIBUTION QUANTITY OF BIOLOGICAL GENETIC RESOURCES

1. In cases where any of the following conditions apply, distribution of biological genetic resources may be refused.
 - (1) The purpose of usage submitted by the Applicant is deemed inappropriate.
 - (2) The inventory quantity is insufficient for the distribution (excluding cases where the quantity to be distributed may be adjusted).
 - (3) The Applicant has breached the provisions of this Regulation.
 - (4) The distribution is deemed inappropriate after examining various laws, treaties, regulations, etc.
 - (5) The distribution is deemed inappropriate for reasons such as potential adverse effects on the food and agriculture of Japan.
2. In cases where any of the following conditions apply, the distribution quantity of biological genetic resources may be adjusted.
 - (1) Adjustment of the distribution quantity is deemed necessary considering the purpose of usage submitted by the Applicant.
 - (2) The inventory quantity is insufficient.

Article 8

RESPONSIBILITIES OF RECIPIENTS

The recipient shall comply with the terms and conditions of the Material Transfer Agreement (attached Form No. 2).

However, in cases where plant genetic resources are distributed under the SMTA, the recipient shall comply with the terms and conditions of the SMTA.

Article 9

EXCHANGE OF BIOLOGICAL GENETIC RESOURCES BETWEEN GENE BANKS AND CULTURE COLLECTIONS

1. In cases where all of the following conditions are satisfied, the specific distribution (hereinafter referred to as “exchange”) to genebanks and culture collections—subject to acceptance of biological genetic resources from those genebanks and culture collections—may be free of charge.

Conditions of the use and treatment of the said exchanged biological genetic resources, including terms of benefit sharing, shall be in accordance with this rule as well as the regulations and provisions of the said genebanks and culture collections (hereinafter

referred to as the “Exchanging Organization”), respectively.

- (1) When an agreement has been reached for the exchange between the genetic resource center, NARO, and the Exchanging Organization prior to exchange of the biological genetic resources and on the type and quantity of biological genetic resources to be exchanged, the conditions of use and terms of benefit sharing in written form.
 - (2) When the biological genetic resources to be subjected to the exchange satisfy the requirements listed in Article 3 of this Regulation.
 - (3) When the biological genetic resources to be exchanged do not fall under any item of Article 7 of this Regulation (in this case, the term “Distribution” in Article 7 shall be read as “Exchange”).
 - (4) When the biological genetic resources to be subjected to the exchange are not protected under intellectual property rights such as a patent right or any other rights of third parties.
2. In the case of exchange of foreign biological genetic resources and biological genetic resources under regulation of laws and ordinances, all of the procedures and handling of the exchange shall comply with the related treaties, laws, and regulations listed in Article 10 of this Regulation.

Article 10

COLLECTION, ACCEPTANCE, AND DISTRIBUTION OF BIOLOGICAL GENETIC RESOURCES UNDER THE REGULATION OF LAWS AND ORDINANCES

In cases of collection, acceptance, and distribution of biological genetic resources as stated in Article 3 to Article 6 and Article 9 of this Regulation, the import/export of biological genetic resources subjected to all applicable treaties, laws, and regulations shall be appropriately carried out in cooperation with related organizations based on the following items.

1. In the case of importation of biological genetic resources, all related procedures shall comply with:
 - Plant Protection Act (Act No. 151 of May 4, 1950);
 - Act on Domestic Animal Infectious Diseases Control (Act No. 166 of May 31, 1951);
 - Invasive Alien Species Act (Act No. 78 of 2004);
 - Convention on International Trade in Endangered Species of Wild Fauna and Flora;
 - Convention on Biological Diversity; and
 - the ITPGRFA.
2. In the case of exportation of biological genetic resources, all related procedures shall comply with:
 - Foreign Exchange and Foreign Trade Act (Act No. 228 of December 1, 1949);

Export Trade Control Order (Cabinet Order No. 378 of December 1, 1949);
Foreign Exchange Order (Cabinet Order No. 260 of October 11, 1980);
Ministerial Ordinance on Trade Related Invisible Trade, etc. (Ordinance of the Ministry of International Trade and Industry No. 8 of March 4, 1998);
Convention on International Trade in Endangered Species of Wild Fauna and Flora;
Convention on Biological Diversity;
ITPGRFA; and
other treaties, laws, regulations, and quarantine regimes.

Article 11

MISCELLANEOUS PROVISIONS

Items necessary for the administration of biological genetic resources that are not specified by these Regulations shall be specified elsewhere.

Supplementary Provisions (GRC No. 0101008)

This procedure shall come into force as of April 1, 2016.

Supplementary Provisions (GRC No. 1227005)

This procedure shall come into force as of April 1, 2017.