

Administrative Regulations for Biological Genetic Resources
in the NIAS Genebank Project of the National Institute of Agrobiological Sciences

13 NIAS No. 69
April 1, 2001
Final revision 20 NIAS No. 022305
March 3, 2009

(Purpose)

Article 1 Based on Article 6 of the NIAS Genebank Project Implementation Regulations (hereinafter referred to as the “Project Implementation Regulations”) of the National Institute of Agrobiological Sciences, the administration of biological genetic resources to be handled in the project (hereinafter referred to as the “Genebank Project”) shall comply with the provisions of these Regulations.

(Terms)

Article 2 Terms used in these Regulations are consistent with those used in the Project Implementation Regulations.

(Collection and Acceptance of Biological Genetic Resources)

Article 3 As a general rule, each of the biological genetic resources to be collected and accepted shall comply with the purposes of the Genebank Project, and except in special circumstances, shall satisfy the following requirements.

- (1) Plant genetic resources shall satisfy the following requirements.
 - (i) The plant shall belong to a cultivated variety or line, an experimental line, a native variety, a wild relative or a wild variety, and its plant type, origin, etc. shall be known.
 - (ii) The plant shall be provided in a certain amount necessary for preservation.
- (2) Microorganism genetic resources shall satisfy the following requirements.
 - (i) The type, characteristics for classification/identification, line (strain) name, origin, etc. of the microorganism shall be known.
 - (ii) The microorganism shall be provided in a certain amount necessary for preservation.
 - (iii) The microorganism shall not be highly hazardous.
 - (iv) The microorganism shall not be difficult to culture or preserve.
- (3) Animal genetic resources shall satisfy the following requirements.
 - (i) The animal shall belong to a cultivated variety, native variety or wild relative, and its animal type, variety name, line name, origin, etc. shall be known.
 - (ii) So-called first-order characteristics such as morphological characteristics shall be known.
- (4) DNA and other genetic resources shall satisfy the following requirements.
 - (i) The name, related animal and plant species and information regarding the origin including the supplier shall be known.
 - (ii) The DNA, etc. shall not be difficult to preserve or proliferate.

(Proliferation and Preservation of Biological Genetic Resources)

Article 4 The biological genetic resources that have been collected and accepted shall be appropriately proliferated, preserved and maintained.

(Administration and Provision of Information on Biological Genetic Resources)

Article 5 Biological genetic resources to be preserved shall be given a registration number and as a general rule be accessible to the public upon recording the type, product name, origin, characteristic information, preserved quantity, etc.

(Distribution of Biological Genetic Resources)

Article 6 Biological genetic resources shall be distributed for research (including breeding) or educational purposes (hereinafter referred to as “Research Purposes”) and as a general rule be subject to fees.

2. Application for distribution shall be made by submitting the Application for Distribution of Biological Genetic Resources (attached Form No. 1), the Material Transfer Agreement that specifies the conditions for the use of the biological genetic resources (attached Form No. 2) and other documentation necessary for distribution.
3. The distribution quantity and price shall conform to the provisions 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 received from staff of an organization commissioned under paragraph 6, Article 3 of the Project Implementation Regulations to provide for relevant commissioned operations (excluding operations to proliferate biological genetic resources).
 - (2) Application for distribution received from an organization or a person conducting free-of-charge media coverage, exhibits, etc. which would benefit the public relations of the Genebank Project.

- (3) For the purposes of international cooperation and practice, application for distribution received from foreign public organization or equivalent.
 - (4) Application for distribution received from an organization or a person who has provided the Genebank Project with biological genetic resources (excluding DNA, etc.) which can be distributed to third parties (limited to the provided quantity).
 - (5) Application for distribution received from an organization or a person who has offered to contribute to the Genebank Project by implementing genetic exchange of farm animals and farm birds through using the relevant animal genetic resources to conduct preferred proliferation or preservation.
 - (6) Application for distribution to provide for educational purposes in senior high schools or lower.
 - (7) Other cases specified by the Director of the Genebank.
4. In cases where biological genetic resources are to be distributed for a fee, the Institute shall issue an invoice to the organization or 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.
 5. Except for the cases provided for in paragraph 3 where biological genetic resources are to be distributed free of charge, biological genetic resources shall be distributed after confirmation of the payment. Moreover, the Notice of Distribution of Biological Genetic Resources (attached Form No. 3) shall be sent with the distribution.

(Limitations, etc. on Distribution of Biological Genetic Resources)

Article 7 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 (excluding cases where the quantity to be distributed may be adjusted).
 - (3) The Applicant has breached the provisions of these Regulations.
 - (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 food and agriculture in Japan.
2. In cases where any of the following conditions apply, 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.

(Responsibilities of Recipients)

Article 8 The recipient shall use the received biological genetic resources only for the purposes of the research, etc. described in the Application for Distribution of Biological Genetic Resources without transferring, reselling or lending the biological genetic resources to a third party.

2. The properties, etc. of the distributed biological genetic resources shall be maintained by the recipient, and the Institute and other organizations will not be held responsible for any properties, etc. of the biological genetic resources after distribution.
3. The recipient may export the received biological genetic resources only after obtaining authorization from the Institute.
4. The recipient of animal genetic resources shall not produce progeny of the animal genetic resources for purposes other than those described in the Application for Distribution of Biological Genetic Resources.
5. When a change is to be made to items described in the Application for Distribution of Biological Genetic Resources, the recipient shall submit the Notice of Changes (attached Form No. 4) to the Institute in advance. Moreover, when a change is to be made to the purposes/general outline of the research, etc., the recipient may use the received biological genetic resources only after obtaining authorization from the Institute.
6. The recipient shall submit the Report on Research Results (attached Form No. 5) to the Institute without delay after completion of the research, etc. on the received biological genetic resources.
7. When the recipient wishes to publish the results of the research, etc. on the received biological genetic resources (including cases where new varieties were bred), the recipient shall indicate that the biological genetic resources were distributed from the Genebank Project and submit published articles and other documents to the Institute.
8. When the recipient is to obtain an intellectual property right including a breeder's right and patent right or other right as a result of the research, etc. on the received biological genetic resources, the recipient shall notify the Institute of this in advance.
9. Regarding profits obtained from the received biological genetic resources which were introduced from outside Japan, the recipient shall conform to the Convention on Biological Diversity by respecting the sovereign right held by the country of origin and conform to the conditions stated in the material transfer agreement, etc. concluded at the time of the distribution.
10. The recipient shall handle the received biological genetic resources within the range permitted by laws, treaties, regulations, etc.
11. When the recipient has breached any of these Regulations, the recipient shall immediately terminate the use and return or discard the received biological genetic resources according to instructions given by the Institute.

(Particulars)

Article 9 Items necessary for the administration of biological genetic resources which are not specified by these Regulations shall be specified elsewhere.