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INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE

Sixteenth Session
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POLICIES, MEASURES AND EXPERIENCES REGARDING INTELLECTUAL
PROPERTY AND GENETIC RESOURCES: SUBMISSION BY THE RUSSIAN
FEDERATION

Document prepared by the Secretariat

1. At its fifteenth session, held from December 7 to 11, 2009, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee'):

“invited Member States and observers to make available to the Secretariat papers describing regional, national and community policies, measures and experiences regarding intellectual property and genetic resources before February 12, 2010, and requested the Secretariat to make these available as information documents for the next session of the Committee.” [...]

2. Further to the decision above, the WIPO Secretariat issued a circular to all Committee participants, dated January 15, 2010, recalling the decision and inviting participants to make their submissions before February 12, 2010.

3. Pursuant to the above decision, the Delegation of the Russian Federation submitted a document entitled “Regional, national and community policies, measures and experiences regarding intellectual property and genetic resources” and requested it be made available as an information document for the sixteenth session of the Committee.

4. The document is reproduced in the form received and contained in the Annex to this document.

[Annex follows]

ANNEX

Russian Federation

REGIONAL, NATIONAL AND COMMUNITY POLICIES,
MEASURES AND EXPERIENCE REGARDING INTELLECTUAL PROPERTY AND
GENETIC RESOURCES

This information report has been prepared on the following basis:

- the term “genetic resources” is understood as adopted in accordance with Article 2 of the Convention on Biological Diversity (Rio de Janeiro, June 5, 1992) and used as a basis for further work on the subject of “genetic resources” by the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore at its first session, i.e.
- “genetic resources” – are genetic material of actual or potential value and including any material of plant, animal, microbial or other origin, containing functional units of inheritance;
- in the broader sense, genetic resources are considered to be “biological resources”, which include genetic resources, organisms or parts thereof, population and any other biotechnical components of ecosystems of actual or potential use for the whole of humanity.

Pursuant to Article 15 of the Convention on Biological Diversity (CBD), access to genetic resources shall be determined by the national government of each State and regulated by national legislation based on the recognition of the sovereign rights of States over their natural resources.

For the purposes of preservation of the biodiversity of Russia, in accordance with the country’s obligations as part of the Convention on Biological Diversity (Article 6, CBD), a National Strategy and Plan of Action for the Preservation of Biodiversity were devised and adopted at the National Forum on the Preservation of Living Natural Resources in Russia (Moscow, June 2001).

In Russia there is currently a large number of programs being implemented in connection with the preservation of biodiversity. They are both State programs (federal, regional, sectoral and intersectoral), and also projects implemented by non-governmental organizations (Russian and international foundations and public organizations).

The National Strategy and National Plan envisage the use of legal, economic, special ecological and economic, and other mechanisms. In particular, legal mechanisms include the development of legislation on access to genetic resources and the production of benefits from their use, based on the fact that Russia may act as both an exporter and also an importer of genetic resources.

In some subjects of the Russian Federation, in accordance with the recommendations of the National Strategy regional strategies and programs have been created and are being created for the preservation of biodiversity (for example, in the Volgograd, Nizhegorod and other oblasts, North Ossetia, the Republic of Kalmykiya, the Taimyr Autonomous District

etc.).

The economic mechanisms for the implementation of the National Strategy include such measures as devising a system of economic evaluation of genetic resources, provision of targeted use of funds from taxation on natural resources for the purposes of protecting nature, and devising economic mechanisms for access to genetic resources.

The legal relations, relating to the preservation and use of genetic resources in the Russian Federation, are regulated by a number of legislative and other normative acts:

1. the Constitution of the Russian Federation
2. the Civil Code of the Russian Federation
3. Federal Law No. 52-FZ on the Animal World of April 24, 1995.
4. Federal Law No. 7-FZ on Environmental Protection of January 10, 2002.
5. Federal Law No. 33-FZ on Natural Territories for Special Protection of March 14, 1995.
6. Federal Law No. 174-FZ on Environmental Examination of November 23, 1995.
7. Law No. 2395-I of the Russian Federation on Mineral Resources of February 21, 1992.
8. The Water Code of the Russian Federation.
9. The Forestry Code of the Russian Federation.
10. The Criminal Code of the Russian Federation.
11. Federal Law No. 191-FZ on the Exclusive Economic Zone of the Russian Federation of December 17, 1998.
12. Federal Law No. 86-FZ on State Regulation of Genetic Engineering Activity of July 5, 1996.
13. Federal Law No.49-FZ on Territories for Traditional Use of Natural Resources of Indigenous and Minority Peoples of the North, Siberia and Far East of the Russian Federation of May 7, 2001.
14. Federal Law No. 82-FZ on Guarantees of the Rights of Indigenous and Minority Peoples of the Russian Federation of April 30, 1999.
15. Federal Law No. 104-FZ on General Principles of Organization of Communities of Indigenous and Minority Peoples of the North, Siberia and Far East of the Russian Federation of July 20, 2000.
16. Federal Law No. 74-FZ on National Cultural Autonomy of June 17, 1996; etc.

The Constitution of the Russian Federation envisages that land and other natural resources are used and protected in the Russian Federation as the basis of the life and activity of peoples living on the corresponding territory. The provisions of Article 9 of the Constitution of the Russian Federation, in accordance with which genetic resources may be owned by citizens (natural persons), legal entities, and also the Russian Federation, subjects of the Russian Federation and municipal associations, are also extended to such resources which in accordance with the definition are part of natural resources.

Further to the provisions referred to above, Article 209 of the Civil Code of the Russian Federation states that the possession, use and disposal of lands and other natural resources (and consequently genetic resources, within natural resources) shall be freely exercised by the owner, to the extent to which their circulation is permitted by the law, provided this does not damage the environment or infringe the rights and legal interests of other persons.

The Law on the Animal World outlines the powers of the federal State authorities, subjects of the Russian Federation and local government authorities in relation to the protection and use of the animal world, a management system in this sphere is defined, and requirements for the preservation of subjects of the animal world, their habitats, procedure for the grant of licenses for the use of such subjects, the rights and obligations of users of those subjects and responsibility for the infringement thereof are envisaged.

A special section is devoted to traditional methods of protection and use of subjects of the animal world. Pursuant to Article 48 of the Law on the Animal World, citizens of Russia, whose existence and income are fully or partially based on the traditional systems of livelihood of their ancestors, including hunting, fishing and harvesting, shall have the right to use traditional methods of exploiting subjects of the animal world, if such methods do not directly or indirectly lead to a reduction in biodiversity, do not reduce the numbers and stable reproduction of subjects of the animal world, do not harm their habitat and do not represent a danger for humanity.

The Federal Law on Environmental Protection strengthens the principle of payment for the use of natural (including genetic) resources.

Chapter 26 of the Criminal Code of the Russian Federation “Environmental crimes” contains a number of articles relating to the protection of natural (including biological) resources.

The Federal Law on the State Regulation of Genetic Engineering Activity governs relations in the sphere of use of natural resources, environmental protection and provision of ecological safety, arising as a result of the use of genetic engineering. The procedure for performing genetic engineering activity and application of its methods to man, tissues and cells as part of the human organism are not regulated by the above Law.

Article 2 of the Law defines the basic concepts of genetic engineering, genetic engineering activity, genetically modified organisms etc.

The Law defines the basic trends in State regulation of genetic-engineering activity (Article 5), the forms of genetic engineering activity subject to licensing (Article 6), in accordance with which the following shall be subject to licensing: the production of preparations obtained by using genetically modified organisms; purchase, sale, exchange, other transactions and activities related to genetic-engineering technologies, genetically modified organisms and/or their products, which do not have certified quality or a mark of authenticity, granted or recognized by a duly competent authority, including in the sphere of international activity.

The rules for the State registration and keeping of a combined State register of genetically modified organisms are established by Decree No. 120 of the Government of the Russian Federation of February 16, 2001 on the State Registration of Genetically Modified Organisms.

The procedure for implementing legal relations arising as a result of the use of the animal, plant and microbiological world is regulated also by other normative acts:

“on the Procedure for the State Accounting, Updating, Storage, Acquisition, Sale, Transfer, Export outside the Borders of the Russian Federation and Import onto its Territory of Zoological Collections” – Decree No. 823 of the Government of the Russian Federation of July 17, 1996;

“on Provisions for Groups of Experts on Zoological Collections” – Order of the State Ecology Commission of the Russian Federation No. 560 of October 5, 1998;

“on Provisions for Zoological Collections” – Order of the State Ecology Commission of the Russian Federation No. 411 of September 30, 1997.

“on the import into the territory of the Russian Federation and export from the territory of the Russian Federation of seeds of plant varieties and breeding material for animal breeds” – Instructions approved by the Ministry of Agriculture and Food of the Russian Federation, State Customs Committee Nos. 12-04/5 and 01-23/8667 of May 8, 1997).

The legal norms concerning liability for infringement of licensing requirements and conditions of use of living resources are enshrined in the Federal Law on the Exclusive Economic Zone of the Russian Federation, in accordance with which licensees are obliged to make the prescribed payments in accordance with deadlines.

Several types of fees for calculating the level of compensation for damage have been approved for the unlawful exploitation of subjects of the animal world.

The Federal Laws on Territories for Traditional Use of Natural Resources of Indigenous and Minority Peoples of the North, Siberia and Far East of the Russian Federation, on Guarantees of the Rights of Indigenous and Minority Peoples of the Russian Federation and on the General Principles of Organization of Communities of Indigenous and Minority Peoples of the North, Siberia and Far East of the Russian Federation contain definitions of the concepts of “indigenous and minority peoples of the Russian Federation”, “indigenous and minority peoples of the North, Siberia and Far East of the Russian Federation”, “communities of minority peoples”, “indigenous habitat”, “authorized representatives of minority peoples”, “traditional way of life of minority peoples” and “territories of traditional use of natural resources”.

In accordance with the Constitution of the Russian Federation and rules of international law, the above Laws establish the legal foundations for guarantees of distinctive social, economic and cultural development of indigenous and minority peoples of the Russian Federation, protection of their indigenous habitat, traditional forms of life, economy and industries. The Laws state in particular that “for the purposes of protecting the indigenous habitat, preservation and development of traditional ways of life and economy of minority peoples, the members of a community of minority peoples shall enjoy the privileges established by Federal legislation and legislative systems of subjects of the Russian Federation”.

Genetic resources and intellectual property

In accordance with the Civil Code of the Russian Federation (Article 1225), a number of subjects are included among the outcomes of intellectual activity, to which legal protection is granted, i.e. intellectual property. Some of them are based or may be based on the use of genetic resources.

1. Selection achievements (Chapter 73 of the Civil Code of the Russian Federation)

A selection achievement, for example in relation to plants, shall refer to a clone, line, first generation hybrid, population, and also plant seeds or part thereof, used to reproduce a variety, or plant material – a plant or parts thereof used for purposes other than the aims of reproducing a variety. Issues relating to the grant of a patent to an applicant and of an author's certificate to an author shall fall within the remit of the State Commission of the Russian Federation on the Testing and Protection of Selection Achievements. The term of validity of a patent for a selection achievement is 30 years from the day on which it is entered in the State Register of Protectable Selection Achievements. In this regard, for varieties of such cultures as grapes, arboreal, decorative, fruit and forest breeds, including their tree stocks, the term of validity of a patent is 35 years. Since January 1995, the State Commission has issued the Official Gazette in which it publishes all the information on the applications accepted, names of selection achievements, withdrawn applications, decisions on applications, changes to names of legal entities and natural persons, and also other information relating to new varieties of plants and breeds of animals.

The patent owner shall have the exclusive right to use a selection achievement (Article 1421).

The application of seeds and breeding material of a selection achievement for the following purposes shall be considered use of a selection achievement:

- (1) production and reproduction;
- (2) bringing up to seeding conditions for subsequent propagation;
- (3) offer for sale;
- (4) sale and other means of entry into civil circulation;
- (5) export from the territory of the Russian Federation;
- (6) import into the territory of the Russian Federation;
- (7) storage for the above purposes.

The exclusive right in a selection achievement shall extend also to plant material, i.e. to a plant or part thereof used for purposes other than the aims of reproduction of a variety, on marketable animals, i.e. on animals used for purposes other than the aims of reproducing a breed, which were obtained accordingly from seeds or from bred animals, if such seeds or bred animals were introduced into civil circulation without the patent owner's consent. In this regard, seeds shall include a plant or part thereof, used to reproduce a variety.

The exclusive right in a selection achievement shall extend also to seeds and breeding material which:

- essentially inherit the features of other protectable (indigenous) varieties of plants or breeds of animals, if these protectable varieties or breeds are not themselves selection achievements essentially inheriting the features of other selection achievements;
- do not differ clearly from protectable varieties of plants or breeds of animals;
- require repeated use of a protectable variety of plants for the purposes of seed production.

The Civil Code of the Russian Federation contains provisions relating to the disposal of an exclusive right in a selection achievement:

- licensing agreement (Article 1428);
- an agreement on the alienation of an exclusive right in a selection achievement (Article 1426);
- open license (Article 1429);
- compulsory license (Article 1423).

Article 1422 defines the acts which do not constitute an infringement of an exclusive right in a selection achievement.

Such acts include:

(1) those performed to satisfy personal, family, domestic or other needs unrelated to entrepreneurial activity, where the aim of such acts is not to obtain profit or income;

(2) those performed for scientific research or experimental purposes;

(3) the use of a protectable selection achievement as source material for creating other varieties of plants and breeds of animals, and also acts in relation to the varieties and breeds created, as stated in Article 1421(3) of the Civil Code of the Russian Federation, excluding cases provided for by Article 1421(4) of the Civil Code of the Russian Federation; etc.

2. Inventions

(Chapter 72 of the Civil Code of the Russian Federation, Patent Law)

The following shall, for example, be recognized as inventions patentable in the Russian Federation: medicinal preparations (species, extracts, decoctions, infusions, homeopathic remedies) based on grasses, products produced by bees and different animals, seaweeds etc., and also items relating to food products (formulation).

The subject matter of inventions may also be constituted by strains of microorganisms (in particular, strains of bacteria, viruses, bacteriophages, micro seaweed, microscopic fungi, groups of microorganisms), cultures (lines) of cells of plants or animals (lines of cell tissues, plant or animal organs, and groups of corresponding cells), genetic construction (in particular, plasmids, vectors, stably transformed cells of microorganisms, plants and animals, transgenic plants and animals, (Rule 10.4.1 of the Administrative Regulations on performance by the Federal Service for Intellectual Property, Patents and Trademarks of the State function as the organization for receiving and examining invention applications, and granting in accordance with established procedure patents of the Russian Federation for an invention, as approved by

Order No. 327 of the Ministry of Education and Science of the Russian Federation of October 29, 2008 (hereinafter – Administrative Regulations).

In accordance with Article 1375 of the Civil Code of the Russian Federation and Rules 10.7.1 and 10.7.2 of the Administrative Regulations, a description shall disclose an invention sufficiently fully for it to be carried out.

The essential features of an invention as a technical solution are expressed as a series of essential features sufficient to achieve the technical result provided by the invention (Rule 10.4.7.3 of the Administrative Regulations).

In order to characterize strains of microorganisms the following features in particular are used: generic and specific name of a strain (in Latin), origin (source of production, genealogy), biotechnological characteristic (conditions of cultivation); name and properties of useful substance produced by the strain; level of activity (productivity), principle of hybridization (for strains of hybrid microorganisms) etc.

In order to characterize lines of cells of plants or animals also used in particular are the following features: number of passages, growth (kinetic) characteristics, characteristics of cultivation in an animal organism (for hybrids) etc.

In order to characterize groups of microorganisms or plant or animal cells, the following features in particular are used in addition to those listed above: factor and conditions of adaptation and selection, taxonomical composition, number and dominant components, replaceability, type and physiological features of the group as a whole.

In order to characterize a transformed cell, the following features in particular are used: transformational element, the features (properties) acquired by a cell, an indication of the source of a cell (for a procaryotic cell – genus, family and/or type), conditions of cultivation of a cell and other characteristics sufficient to distinguish the cell in question from another cell.

For a transgenic plant, the following features in particular are used: the presence of a modified element in the genome, the features (properties) acquired by a plant, origin of a plant, taxonomical attribute and other characteristics sufficient to distinguish the plant in question from another plant.

For a transgenic animal, the following features in particular are used: gene and/or DNA, transformed in the gene of an animal and coding or expressing the whole product, the features (properties) acquired by the animal, the taxonomical attribute and other characteristics sufficient to distinguish the animal in question from another animal etc.

In accordance with Rule 10.7.4.5(3) of the Administrative Regulations, for an invention relating to a strain of a microorganism, line of plant or animal cells, or to groups of strains, a description of the means of obtaining the strain, cell lines or group is provided. If the description of the method of obtaining those items is not sufficient for carrying out the invention, information on the deposit of a strain, cell lines, group or strains forming part of a group (name or abbreviation of collection-depositary, its address, registration number allocated by the collection to the deposited item) shall be provided, the date of which shall not be later than the date of filing of an application or date of priority, if so requested.

Deposit for the purposes of patent procedure shall be considered effected, if a strain, cell line or group have been placed with the international depositing authority, provided for by the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, or with the Russian collection authorized for their deposit, guaranteeing support for the viability of an object, at least for the term of validity of the patent and satisfying the other requirements established for collections carrying out deposits for the purposes of patent procedure. An example of the use of a strain, line or group for a claimed purpose is described (with information given on the conditions of cultivation, production and purification of a whole product, yield of a product, level of activity (productivity) of a product or producer and means of its definition (testing) etc.).

During the process of examining an application for an invention, legislation also establishes (provides for) the possibility of requesting additional materials from an applicant.

In accordance with Article 1386(5) of the Civil Code of the Russian Federation, during the process of a substantive examination of an invention application an applicant may be requested to provide additional materials (including amended claims), without which the examination may not be conducted. If, within the prescribed period, the applicant does not provide the requested materials or does not submit a request for an extension of this deadline, the application shall be recognized as withdrawn.

The accuracy of the information is verified when an examination is conducted of compliance with the criterion of “industrial applicability”. Pursuant to Article 1350(4) of the Civil Code of the Russian Federation and Rule 24.5.1 of the Administrative Regulations, an invention shall be industrially applicable, if it may be used in industry, agriculture, healthcare, other sectors of the economy or in the social sphere. When establishing the possibility of use of an invention in industry, agriculture, healthcare and other sectors of activity, it is verified whether the purpose of an invention is stated in the description contained in an application at the filing date (if at this date the application contained claims – then in the description or claims).

In addition, it is verified whether the means and methods by which the invention may be carried out in the form in which it is characterized in each of the claims are referred to in the above documents contained in the application at the filing date. Where such information is not provided, it is permissible for the means and methods in question to be described in the source which has been made available to the public before the priority date of the invention.

If only experimental data can attest to the possibility of carrying out an invention and achieving the aim indicated thereby, it is verified whether the description contains examples of it being carried out with a reference to the corresponding data (Rule 10.7.4.5 of the Administrative Regulations), and it is also established whether the examples cited are sufficient for the conclusion regarding observance of a requirement indicated to be extended to the different particular embodiments of a feature, covered by a concept cited by the applicant in the claims.

Where at least one of the indicated requirements is not observed, it is concluded that the invention does not meet the requirement of industrial applicability. In this case, a request may be sent to the applicant to detail the corresponding grounds and with a proposal to express his opinion regarding these grounds and to correct the claims (if, in the examiner’s opinion, the

application documents allow such correction, as a result of which the conclusion in question may be amended).

In relation to an invention for which non-compliance with the requirement of industrial applicability is established, the novelty and inventive step are not verified. The examiner shall decide to refuse to grant a patent for the application.

As already stated, the economic mechanisms for the implementation of the Russian National Strategy include, *inter alia*, measures such as devising a system for the economic evaluation of genetic resources, providing targeted use of funds from taxes on natural resources for the purposes of protecting nature, and devising economic mechanisms for access to genetic resources.

One of the most important of the measures above for resolving the issue of access to genetic resources is the development of contractual relations and devising guidelines for producing non-discriminatory agreements on access to and transfer of genetic resources, taking into account intellectual property aspects.

Contractual relations on access to GRs and the fair sharing of benefits from their use shall be based on conditions taking into account the interests of all parties and also, in addition to the above, giving consideration to the following points:

- different forms of access and benefit sharing;
- specific requirements of the different parties concerned;
- different types of genetic material;
- different forms of the transfer of genetic resources and their use.

There is no widespread practice for concluding agreements and tacit agreements on the joint use of benefits and predictable results. Experience of “contractual agreements” does exist (basically in the field of industrial microbiology, pharmaceuticals and selection), regulating access to genetic resources and sharing in the benefits of their use.

This is in the form of agreements on scientific and technical or creative cooperation between collections – stores of genetic resources of the Russian Federation, scientific centers for plant or animal husbandry, scientific research institutes for genetics and breeding of agricultural animals, collections of microorganisms and so on.

These agreements, in the section “obligations of parties”, contain conditions for the exchange of genetic resources, and also aspects relating to issues of intellectual activity: exchange of the results of research, preparation of joint publications or publications with appropriate references, the possibility of co-authorship in relation to future varieties, etc.

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