

# Legalizing the Acquisition of Genetic Resources in Chinese Taipei: A Proposal

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#### **Abstract**

Agricultural production in Taiwan is based on our active breeding programs. But these breeding programs are very much indebted to foreign genetic resources. On the other hand, Taiwan also hosts a great genetic diversity and has been one of the targets for bioprospecting. To date there is no legal instrument to manage the prior informed consent and accesses-benefit sharing of genetic resources in Taiwan, though some regulations dealt with the biological conservation at large are in place. This article will introduce a draft proposal that is aimed to legalize the acquisition of genetic resources in Taiwan. In the draft proposal, the application and approval procedures are differentiated based on the nature of access. The competent authority shall examine application for first-class bioprospecting that is of pure scientific interest after obtaining the landholder's consent. Should the genetic resources obtained through first-class bioprospecting be used for commercial purposes, the applicant must apply in advance as second-class bioprospecting. In an application for second-class bioprospecting for economic purposes, the representatives of the landholder, applicant and the competent authority are to reach an agreement concerning bioprospecting activities, material transfer, and benefit sharing. This proposal also provides some post-supervision and control clauses, such as regular prospecting reports, measures controlling export of the genetic materials acquired, notification of commercial value derived from genetic materials, and disclosure issue of the origin of the genetic materials in patent applications. Finally, the other draft proposal on the protection of the traditional knowledge of the indigenous peoples, which is related to issues of genetic resource, is briefly described.

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#### I. Introduction

Since the 1960s, more and more governmental institutions and biotech companies in developed countries have spent their effort to explore genetic resources. They have invested a large amount of capital to collect genetic resources for the screening of potentially useful chemicals. These activities are often known as bioprospecting. In fact, genetic resources may be utilized in all respects of human life, especially in the agricultural and pharmaceutical sectors. However, once the resource-poor but technology advanced countries of the north were able to make inventions from genetic materials they had acquired from the south; they would frequently patent the invention, or sometimes even the original genetic resources. As a result, the countries of the south, as well as various NGOs, have relabeled bioprospecting as "biopiracy." The North-South conflict on genetic resources has consequently become a hot issue in various international fora. (e.g. Dutfield, 2004)

Agricultural production in Taiwan is very much indebted to foreign genetic resources. More than 95% of the plant species now cultivated were introduced to the island during its long history of human inhabitation, but mostly the past four centuries. (Yen, 2005) Cultivated staple crops such as rice, millet, taro, and sweet potatoes; vegetables such as cabbage, peas, and sweet peppers; fruits such as bananas, mangoes, and pineapples; cash crops such as sugar cane, tea and tobacco; ornamental crops such as chrysanthemums, roses and *Phalaenopsis* orchids—all are of foreign origin or at least bred with foreign cultigens or wild species. For example, Taiwan boasts of a 50% share of the international market for *Phalaenopsis* orchids, but only two native species within this genus occur naturally in Taiwan, and both are also distributed across Southeast Asia. Meanwhile, many of the more than 60 species of the *Phalaenopsis* genus introduced from abroad have contributed to the successful orchid-breeding activities of this country.

On the other hand, although Taiwan occupies only 0.03% of the earth's land, it hosts a great variety of life. Taiwan and its outlying islands have more than 5,000 native plant species (2.1% of the world total), more than 25,000 native animal species (2.4%), and more than 10,000 native microbe species (8.6%). Within the above categories, the percentages of endemic or native species of fungi, birds, plants, reptiles, and insect species in Taiwan are 2%, 17%, 25%, 31% and 62.5% respectively. Some of these have been introduced to other countries for commercial production. For example, varieties of *Epinephelus awoara* (fish) and *Penaeus monodon* (shrimp) have been exported to and cultivated in Australia and Brazil respectively. Local varieties of millets, which were carried to Taiwan at least several thousand years ago by the indigenous peoples, have been collected in the National Seed Storage Laboratory, USA. In 1970s, an American acquired seedlings of *Rhododendron oldhamii* from Taipei. Several years later, a cultivar "Fourth of July" was selected from the offspring of the original seedlings. By crossing with "Fourth of July" one breeder was able to create 14 hybrids, and US plant patents

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Data calculated from a table in http://www.taibif.org.tw/



were granted. *Nothapodytes nimmoniana* (synonym *N. foetida*), a native plant of Orchid Island, was cultivated and raw materials exported to Kabushiki Kaisha Yakult Honsha, a Japanese pharmaceutical company, which extracted camptothecin from it and further processed into irinotecan hydrochloride, (CPT-11, Campto), which has been widely used around the world to treat colon cancer.

During the last decade, a Welsh nurseryman visited Taiwan several times to hunt plants with ornamental potential in mountainous areas and collected more than 2,000 samples. Many plants have since been put on his sale list. Among them at least three varieties of *Clematis*, *Cardiandra*, and *Tricyrtis* have been selected from the samples brought back to Wales.<sup>2</sup>

Thus it seems that the status of Taiwan in terms of genetic resources is quite unusual, if not unique. It has had strong public- and private-sector breeding activities in agriculture. Vast numbers of foreign genetic materials have been and are being used in various breeding programs. On the other hand, Taiwan has a long history of bioprospecting by persons from other countries. Unfortunately, to date it still has no proper regulation to manage the acquisition of genetic resources.

#### II. Proposal of a draft

Although Taiwan is not one of the parties of the Convention on Biological Diversity (CBD), Taiwanese scholars and NGO members have attended various CBD meetings since 1992. However, because most of the persons attending these meetings are biologists, their reports back to the country have concentrated on the scientific issues of biological conservation. After 1996, when specialists of environmental law began to notice the social and legal issues surrounding the CBD, voices to draft regulations on genetic resources emerged. In 1998, the Council of Agriculture announced that it would propose a law on genetic resource management. However, progress has been slow.

In 2004, the first author recruited a research team comprising four biologists and four law professors. The biologists were asked to investigate the current status of bioprospecting activities in Taiwan by overseas natural persons or legal persons, or both, while the law experts were to make comparative studies on the regulations of selected countries and international arrangements.

Various publications concerning the legislation works were intensively collected and studied (e.g. Biodiversity Rights Legislation of the GRAIN<sup>3</sup>, ten Kate and Wells 2001). After intensive study, the law experts settled on a framework on the draft proposal of the "Act on the Acquisition of Genetic Resources" on July 1<sup>st</sup> 2005 at their 7<sup>th</sup> meeting. The preliminary draft proposal was finished 45 days later. Together with the preliminary proposal, a booklet entitled *Access and* 

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<sup>&</sup>lt;sup>2</sup> http://www.crug-farm.co.uk/

<sup>&</sup>lt;sup>3</sup> http://www.grain.org/brl/



Benefit-sharing of Genetic Resources was prepared and distributed to various stakeholders, such as taxonomists, pharmaceutical companies, biomaterial exporters, NGOs, government officials, professors, and lawmakers. The first edition of the proposal draft was finished on November 7<sup>th</sup> 2005, and had been subjected to public criticism through several round table discussions. The second edition of the proposal draft was finished on August 15<sup>th</sup> 2006.

#### III. Basic considerations and main points of the draft proposal

#### A. Basic considerations

When we began work on designing the framework of the draft proposal, we first identified a set of basic principles or considerations.

#### 1. The Act would be in accordance with relevant international instruments

Presently, the CBD and the Commission on Genetic Resources for Food and Agriculture under the Food and Agriculture Organization (FAO) are the main international bodies working on the issue of genetic resources. Even though Taiwan is party to neither organization, we kept in mind the conventions attached to these two organizations when drafting the proposal.

The CBD (CBD, 2002) was adopted at United Nations Conference on Environment and Development (UNCED) in June 1992 and entered into force on December 29<sup>th</sup>, 1993. The objectives of this Convention, as stated in its first Article, "are 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, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies."

In Article 15 (Access to Genetic Resources), the Convention recognizes "the sovereign rights of states over their natural resources," and states that the "authority to determine access to genetic resources rests with the national governments and is subject to national legislation." The same Article sets out the principle of prior informed consent of parties to the Convention in providing access to genetic resources and sharing the benefits. However, the method of implementing that principle remained unspecified until the adoption of the non-legally binding Bonn Guidelines.

To ensure the principle's implementation, the Secretariat of the Convention held three intergovernmental meetings to discuss the wording of the text and eventually prepared a draft version of "Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of Their Utilization" at a working group meeting in October 2001. The Guidelines were approved by the Conference of the Parties to the Convention at its sixth meeting in April 2002 (CBD, 2002). As a result of this decision, all parties to the CBD voluntarily (but not obligatorily) follow or execute the provisions of the Guidelines until the Guidelines may be upgraded to legally binding protocols. However, the detailed provisions of



the Guidelines were an important reference for our draft proposal.

The International Treaty on Plant Genetic Resources for Food and Agriculture (FAO, 2001) was signed at Food and Agriculture Organization of the United Nations in November 2001 and entered into force in June 2004. Fearing that the implementation of the CBD and Bonn Guidelines might hinder breeding efforts of agricultural crops and eventually affect global security of food and agriculture, the main goal of the Treaty is to create a multilateral system, within which access to more than 60 species of agricultural crops is to be facilitated. Parties of the Treaty are entitled to acquire germplasm for these species within the system without having to go through a process of application, review and contract signing with provider countries. The Treaty also specifies that the interests of the genetic resources arising out of their use should be fairly and equitably shared in accordance with the system. Intellectual property rights arising from the germplasm and those derived from the germplasm are also considered.

In our draft proposal, we are inclined not to treat separately the plant species that are within the multilateral system of the International Treaty on Plant Genetic Resources for Food and Agriculture, because none of the crops within the multilateral system originated from Taiwan, and virtually all their local varieties developed by farmers of past generations have been stored in the National Plant Genetic Resource Center (NPGRC). However, on its part the NPGRC may take additional measures to comply with the Treaty.

#### 2. Genetic resources are to be treated separately from traditional knowledge

Although we recognize that indigenous peoples have developed a tremendous amount of knowledge concerning the use of biota in their surroundings, and some countries in their legislation have integrated the issues of genetic access and traditional knowledge, it would be impractical for Taiwan to integrate the two issues in any single act. On February 5<sup>th</sup> 2005, the Basic Law of the Indigenous Peoples went into force. Among its clauses, Article 13 states clearly that the government should protect by acts the knowledge concerning conservation of biodiversity and intellectual creations of the indigenous peoples. Article 22 states that academic research, ecological conservation, land exploration, and resources utilization should be subjected to prior informed consent of and/or participation of the indigenous peoples, and that a mechanism for sharing profits arising from commercial utilization should be established. To avoid introducing a "bipolar" system, we propose that the competent authority on genetic resources to be the relevant office of the Council of Agriculture, and that the competent authority on traditional knowledge to be the Council of Indigenous Peoples, with the interface between this draft proposal and the existing Basic Law of the Indigenous Peoples to be considered carefully. Fortunately, because the same team was later commissioned to draft an act concerning the protection of the traditional knowledge of the indigenous peoples, the task was made much easier.

#### 3. The definition and scope of genetic resources are to be clearly set forth



According to CBD Article 2, "'Genetic resources' means genetic material of actual or potential value," and "'Genetic material' means any material of plant, animal, microbial or other origin containing functional units of heredity." It is clear that genetic resources include any material of plant, animal, microbial, or other origin that contain functional units of heredity of actual or potential value, excluding those belonging to humans.

We define genetic resources as biological materials that contain genetic units by which the biological materials can reproduce by themselves or with human assistance. By this definition we exclude dried herbarium specimens, which contain no viable seeds, from control under this act. Criticism concerning this point came through the round table discussions, for it is claimed that the DNA embodied in dead tissues can be extracted, the sequence determined, and potential applications explored. Another concern is whether the exportation of biomaterial intended for direct use (not for the purpose of reproduction), such as *materia medica* and living plants for flower or plant arrangement, should be under control by the act. We propose that these are subject to traditional uses of biological materials and are thus exempted from control, together with human genetic resources. It was also claimed during the round table discussions that these exemptions present a loophole. In both the dead tissue and direct use cases, we acknowledge the possibility of loopholes. However, closing these loopholes would create onerous procedures that would amount to a barrier to trade, and they would be virtually impossible to enforce, since scientists can extract DNA content from microscopic samples.

If we admit that the probability of making a profit from bioprospecting is actually very low, then one of the solutions to the dilemmas described above is to put more weight on the control of bioprospecting activities, rather than on genetic resource materials. In this context, the seeds or young plants of cultivated plants in international trade for the purpose of planting should be excluded from the scope of the act. The intellectual property right for new varieties of cultivated plants should be protected under Plant Variety and Plant Seed Act<sup>4</sup>, and the export of living wild organisms should be under control only if they are native to Taiwan. Live native plants for use in flower or plant arrangement should be checked before export to ensure that the samples have not been gained through bioprospecting activities. The exchange of herbarium specimens can be allowed only if the material transfer arrangements have been made.

#### 4. The Act will focus on the access and benefit-sharing of genetic resources

We have seen that the objectives of CBD are 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." However, the scope of conservation of biological diversity and sustainable use is quite broad; conservation, access to genetic resources, and the role of indigenous peoples in conservation are only parts of it. Under the draft proposal, therefore, a legal framework is designed to deal with the access and benefit—sharing of genetic

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<sup>4</sup> http://seed.agron.ntu.edu.tw/IPR/PVPSA20041025.pdf



resources only, not the complete regime of biological diversity conservation, because Taiwan already has several acts to deal with different aspects of biological diversity, such as the Wildlife Conservation Act, the Forestry Act, National Park Law, Cultural Heritage Preservation Act, Basic Law of Indigenous Peoples, and so on. Drafting a single biodiversity act would encounter a lot of difficulty, for it would involve issues arising from changes of administrative organizations, regional planning for economic development, powers and responsibilities of local governments, concurrence of laws, to name just a few. This would make it impossible within the time constraint to devise a new general biodiversity act. Thus, this draft proposal focuses only on the issues of access and benefit sharing of genetic resources.

#### 5. Recognize the sovereign rights of states over their natural resources

Both the CBD and International Treaty on Plant Genetic Resources for Food and Agriculture recognized the sovereign right of states on genetic resources. Article 3 of CBD provides that states "have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not damage the environment of other States or of areas beyond the limits of national jurisdiction." Article 10 of the International Treaty on Plant Genetic Resources for Food and Agriculture has a similar provision. Based on these provisions, our draft proposal begins by stating the principle that the sovereign right of genetic resources belongs to the state, and that the state shall be entitled to consider whether it will authorize others to access genetic resources, judged by a comprehensive consideration of the state's interests. Specifically, the state will take into account the effects of access to genetic resources on local and marginal environments, society, traditional culture, livelihood of inhabitants, and national policies on defense, economy, and environmental protection. The State will also have the right to make the final decision on access and to coordinate benefit sharing.

The Bonn Guidelines also provides that each Party shall designate one national focal point for informing applicants on the procedures for applying for access to genetic resources, including where the competent national authority and stakeholders are, how to acquire prior informed consent, and mutually agreed terms. In our proposal we do not designate the nature and composition of the national focal point—we intend to leave these matters for the competent authority to decide, since this involves reorganization—but the competent authority will be required to bear responsibility for the execution and supervision of this act.

## 6. Application and approval procedures will be differentiated based on the nature of access

Under the draft proposal, the execution of all bioprospecting activities will be permitted only after approval. However, it would be improper to hinder academic research and biological conservation efforts *per se* through the creation of an onerous, lengthy application and approval



process. Hence the application and approval procedure for sampling for academic research should differ from that of commercial bioprospecting, with the one being much stricter than the other. However, to prevent leakage, unintended or intended, resulting from commercial utilization of academic research, the draft proposal provides a mechanism to ensure that genetic materials acquired through academic research may only be used for academic research. If the genetic materials or the derived materials or technologies are to be commercialized, the applicants will be required to go through the stricter application and approval procedure.

#### 7. Basic principles for the approval of bioprospecting are to be set forth

We decided that the wording of the draft proposal with respect to access to genetic materials should be closely based on the provisions of CBD Article 15 (sections 1, 5, and 7) and the more detailed proposals on the relevant procedure and approval processes that are contained in the Bonn Guidelines, specifically the ones that cover prior informed consent, mutually agreed terms, and benefit-sharing. The content of the source materials may be summed up as follows.

CBD Article 15 (Access to Genetic Resources), Section 1 recognizes the "sovereign rights of States over their natural resources," so it specifies that "the authority to determine access to genetic resources rests with the national governments and is subject to national legislation." Section 5 of the same article provides that "Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party." Moreover, Section 7 of the same Article states: "Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development, as well as the benefits arising from the commercial and other utilization of genetic resources with the contracting party providing such resources. Such sharing shall be upon mutually agreed terms."

Beyond these CBD provisions, the Bonn Guidelines provides detailed clauses suggesting how to design the procedures for managing the access of genetic resources and benefit sharing, as stipulated in the CBD:

#### (1) Prior informed consent:

The Guidelines propose that national procedures for prior informed consent should be of "legal certainty and clarity"; that they should facilitate accessing genetic resources at minimum cost; and that "restrictions on access to genetic resources should be transparent, based on legal grounds" (Article 26, paragraphs a, b, c). The competent authority or authorities shall grant the prior informed consent, and this consent "may be required from different levels of Government" (Articles 28, 29). The applicants shall provide various types of information, such as the "type



and quantity of genetic resources" to be collected, "The starting date and duration of the activity," "The geographical prospecting area," and an evaluation of the impacts that access activities might bring on biodiversity (Article 36, paragraphs c, d, e). The applicants also need to supply "Accurate information regarding intended use (e.g., taxonomy, collection, research, commercialization)," "Possible third party involvement," types of benefits coming from obtaining access to the resource, and benefit-sharing arrangements (Article 36, paragraphs f, j, l, m). "A national registration system could [also] be used to record the issuance of all permits or licenses" (Article 39).

#### (2) Mutually agreed terms:

The landholders shall consent to a prospecting application only when both the landholders and the explorers reach mutual agreement. Basic requirements for mutually agreed terms are legal certainty and clarity, minimization of transaction cost and negotiation time, obligations of resource providers and users (Article 42, paragraphs a, b, c). Different contractual arrangements shall be developed on the basis of different resources and uses (Article 42, paragraph d). Considering that many landholders may not have enough capability to negotiate with the explorers, it is essential that the competent authority should assist them in some way.

#### (3) Benefit-sharing:

Mutually agreed terms could "cover the conditions, obligations, procedures, types, timing, distribution and mechanisms of benefits to be shared" (Article 45). "Near-term, medium-term and long-term benefits should be considered, including up-front payments, milestone payments and royalties" (Article 47). "Benefits should be shared fairly and equitably with all those who have been identified as having contributed to the resource management, scientific and/or commercial process. The latter may include governmental, non-governmental or academic institutions and indigenous and local communities" (Article 48). Benefit sharing shall be divided into monetary and non-monetary benefits (Article 46). Monetary benefits may include fees per sample, up-front payments, milestone payments, salaries, research funding, special fees to trust funds supporting conservation and sustainable use of biodiversity, license fees and joint ownership of intellectual property rights (Appendix II, paragraph 1).

Non-monetary benefits may include sharing of the results of research and development, technology transfer, participation in product development, collaboration, cooperation and contribution in education and training, admittance to *ex situ* facilities of genetic resources and to databases, and contributions to the local economy (Appendix II, paragraph 2).

#### B. Main points of the draft proposal

The main points of the draft proposal of the act concerning the acquisition of genetic resource are as follows:



#### 1. Legislation purpose

The purpose of this act is to promote the conservation and the utilization of genetic resources that are embodied in diverse biota, and to ensure fair and equitable sharing of the benefits that arise from the development and utilization of these genetic resources. The draft proposal does not mention the goal of "conservation" *per se* but it uses "promote conservation" instead, because we already have several laws explicitly directed at conservation as stated above. Harmonization of the act concerning acquisition of genetic resources with other Acts would not be easy if this act was to cover all aspects of conservation. Consequently, the above laws will apply where this act does not.

#### 2. The scope of the Act

Since we adopted the idea that the state has the sovereign right over genetic resources, it is apparent that prospecting activities of foreign natural persons and/or legal persons should follow the requirements set in this act. That is not to say that native persons and/or legal persons of this country can be exempted, since it would be meaningless in a globalized economy to control the prospecting activities of foreigners alone. However, Article 19 of Taiwan's Basic Law of the Indigenous Peoples permits indigenous people to collect plants and fungi for non-commercial purposes. Moreover, CBD Article 10c specifies that each country should "protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements." Article 16(a)(iii) of Bonn Guidelines also emphasizes that the "commercialization and any other use of genetic resources should not prevent traditional use of genetic resources." Thus in our draft we exclude the traditional use of biological material from the regulation.

Besides the traditional use of biological materials, human genetic resources are also excluded, based on Article 9 of the Bonn Guidelines and Article 4 of Decision No. 391 of the Andean Community.

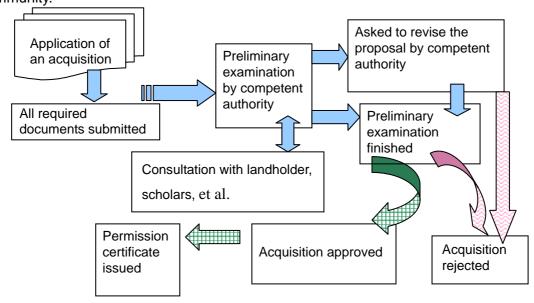


Fig. 1: Procedure of application and approval for first-class acquisition (e.g. taxonomic exploitation)



#### 3. Application and approval of bioprospecting

According to the draft proposal, the application and approval procedures for bioprospecting differ depending on the nature of access, i.e., academic research or commercial exploitation. Acquisition of genetic resources purely for the purpose of academic research, not for commercial exploitation, is named "first class bioprospecting" in the proposal, while prospecting activities from which the genetic resources thus acquired are intended for commercial utilization immediately or that may be exploited for commercial utilization in the future are named "second class bioprospecting".

#### (1) First-class bioprospecting

For first-class bioprospecting, the application and approval procedure is quite simple (Fig. 1). Upon receiving application the competent authority is required to inform the landholder and ask for their consent. With the consent of the landholder, understanding that no benefit-sharing agreement is to be discussed or made, it is up to the competent authority to examine the case and decide whether or not to permit the acquisition request. The competent authority is required to make its decision on the basis of criteria such as the public interest and environmental impact, based on the content of the documents delivered by the applicants. The documents must include: (1) the purpose, area, duration, and the method of prospecting; (2) the species and quantities to be collected; (3) the anticipated results of the research; and (4) the anticipated intention of transferring the germplasm thus acquired and/or the research result, as well as the material transfer agreement.

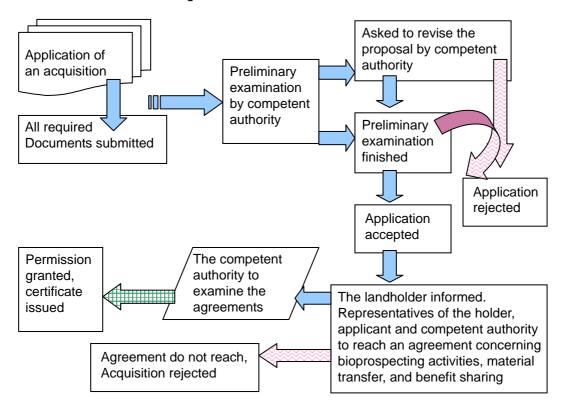


Fig. 2: Procedure of application and approval for second-class acquisition (e.g. commercial exploitation)



#### (2) Second-class bioprospecting

The application and approval procedure for "second class bioprospecting" (Fig. 2) is much stricter than that of the first class in terms of prior informed consent and benefit sharing.

In addition to the documents used in a first class application, the second-class bioprospecting applicants will be required to provide a commercial use plan illustrating the possibility of commercial use and expected economic outcomes. The competent authority would be then required to examine them and make its decision based on criteria such as the public interest and environmental impact, based on the content of the documents delivered by the applicants. In this phase, the competent authority will decide whether or not to permit the acquisition request, without informing the landholder, although experts may be consulted during the examination process.

After passing the initial examination phase, the competent authority will then be required to inform the landholder of the area to be prospected. The competent authority will then invite the representatives of the landholder and the applicant to join in a three-party meeting to discuss the agreement on bioprospecting activities, material transfer, and benefit sharing.

The competent authority may also invite scholars and experts in relevant fields to make presentations at the negotiation table. The landholder will designate representatives to attend the negotiation before the negotiation begins. During the negotiation, the applicants will elaborate on the prospecting proposal. Afterwards, the interested parties together will reach an agreement on the terms of fair and equitable benefit sharing. The details of the possible arrangements for benefit sharing are not laid in the draft proposal. However, possible content of these details will be announced on other occasions, in the form of, for example, regulations or executing orders published by the competent authority and extension booklets. The arrangement will follow that of Appendix II of the Bonn Guidelines. Benefit sharing may pay in monetary or non-monetary ways. The monetary payments may adopt the form of up-front payments or milestone payments.

#### (3) Reaching an agreement:

After receiving a first-class prospecting application, the competent authority may, providing that the informed landholders agree to such prospecting for academic purposes, refuse or approve the application. After approval, the applicant will receive a certificate and be allowed to start the exploration in accordance with the proposal that has passed the competent authority's examination.

For second-class prospecting, negotiation should begin only after the competent authority has accepted the application. Upon the negotiation's completion, the competent authority will



examine the agreement in detail. The competent authority will be required to consider the following factors when refusing or approving the application: (a) the impacts of bio-prospecting activities on environments, society, traditional culture, and the livelihood of inhabitants around the prospecting area; (b) the impacts of bioprospecting activities on national policies, such as national defense, economy, intellectual property rights, and environmental protections around the area of prospecting; (c) the opinions of stakeholders on the prospecting activities as well as the benefit-sharing arrangement; (d) whether or not the application case would violate other acts. If the case is approved, the applicant will receive a certificate and start exploration.

#### 4. Post supervision and control

To ensure that the applicants execute the exploration strictly according to the proposal and the agreement that have been approved, the draft proposes that the applicants submit reports on exploring activities to the competent authority from time to time. The reports should contain: (a) the progress of the bioprospecting; (b) biological materials collected and the conditions of their transportation; (c) any information that is associated with the collected materials.

Moreover, the draft proposal states that the applicants must notify the competent authority and the landholder should any commercial products be derived from the acquired genetic materials. If, after study, the genetic resources acquired from first-class bioprospecting activities are believed to be of commercial value, the applicants should proceed with the entire second-class application procedure; any commercial activities concerning those genetic materials will be considered in violation of the act if they have not been approved by the competent authority.

Although tracing the outcome of the acquired genetic materials may be extremely difficult, especially after they are carried abroad, we propose in our draft that the applicants should take the responsibility to ensure that information concerning any constraint by the act on the acquired materials should be sent to the third party, if the materials are to be transferred to that party. We acknowledge that it is only a passive method at best; any deliberate takeover of the material without the consent of the applicants will contravene the control of the act.

#### 5. Export of genetic resources

Export of genetic resources acquired through either first- or second-class bioprospecting may be allowed, with the exception of resources that the competent authority or other regulations has already restricted. To acquire export permits, the applicants will be required to deposit a copy of each live sample to the due germplasm bank, along with the Material Transfer Agreement.

The export of any genetic material that is not acquired through legal activity, which means bioprospecting approved by this act, will be deemed to be in violation of the act. To prevent the deterrence of academic research, export of dead specimens will be allowed to be freely



exported, according to the draft proposal. As mentioned above, this clause was challenged during the round table meeting. It was claimed that this clause would allow free access of the domestic genetic resources by foreign institutions through DNA extraction techniques. However, it seems to us that providing a proper Material Transfer Agreement in the exchange or loaning process of dead specimens would be a suitable compromise.

#### 6. Disclosure of origin in patent applications

The origins of the genetic resources in a patent application should be or should not be disclosed has been a hot issue in many international fora, including TRIPS council meetings. According to a position paper presented by the Intellectual Property Office (Ministry of Economic Affairs), we are trying to find a balance among the right of the right holder of genetic resources, the incentive to innovate of the inventors, and the legal certainty as well as burdens of the patent system.

However, the authors believe that the requirement of disclosure commitment should be one of the criteria approving the application case of bioprospecting, regardless the final results of TRIPs' negotiations that will or will not change the patent laws. Thus, the draft proposal states that the applicants shall submit the permits for exploring genetic resources in Taiwan to the competent authority of IP, and to describe the origins of genetic resources they used for the invention when applying for IP protection if the genetic resources were acquired in accordance with the act. Any one who fails to disclose the facts that their invention is related to the use of the said genetic resources deem to infringe the act of acquisition of genetic resources, but not yet the Patent Act of Taiwan.

#### 7. The biodiversity fund

According to the draft proposal, both the monetary and non-monetary benefits should be shared with the state and the landholder in a fair and equitable manner. The landholder's percentage of benefits to be collected in a given case is not yet decided.

Monetary benefits will be collected by the competent authority, which will also establish a biodiversity fund the function of which would be to allocate all possible capitals in favor of biodiversity; for example, to establish conservation institutions, maintain and promote the research and exploitation of related genetic resources, and train human resources related to the preservation and utilization of genetic resources.

#### IV. Traditional eco-kowledge of indigenous peoples

#### 1. Indigenous peoples and their traditional eco-knowledge

Indigenous peoples of Taiwan are Austronesian, with population of about 448,000 today. There are 12 ethnical groups, from north to south: Kavalan, Atayal, Truku, Saysiyat, Bunun,



Thao, Tsou, Ami, Rukai, Puyuma, Tao (Yami), and Paiwan. Most of the tribes, such as the Atayal, Truku, Saysiyat, Bunun, Thao, Tsou, Rukai, and Paiwan, live on either side of the central mountain range. The Kavalan, Ami, Puyuma, and Tao live on the coast or plains.

Due to the asymmetry of power of invaders and cross-cultural contacts over the past 400 years, Taiwan has witnessed, to different extents, severe destruction of the traditional eco-knowledge of indigenous peoples and of their social structures that had endured for thousands of years.

Although Western naturalists visited Taiwan before 1900, the Japanese were the first to take intensive ethnological and ethnobiological studies in the beginning of the 1900s. During the fifty years of the Japanese rule of Taiwan, these researchers published a large quantity of research and monographs. Since 1945, there have been few intensive ethnological and ethnobiological studies. In recent years, however, research into these fields has started to revive.

Many anthropologists and botanists conducted ethnological research during the Japanese Occupation. Anthropologists Torii Ryuzo (鳥居龍藏) and Ino Kanori (伊能嘉矩) were among the most prominent. Anthropology periodicals published most of their researches, but related botanical studies did not begin until 1911. Ethnobotanists such as Yaichi Shimada (島田彌市), Sasaki Syuniti (佐佐木舜一), and Yamada Kinji (山田金治) were among the most famous. Periodicals such as *Taiwan's Mountains and Forests* (台灣の山林), *Tropical Horticulture* (熱帶園藝), and compilations of the Taiwan Forestry Research Institute published some of these botanical studies.

The first author of the present article has conducted a complete survey of the Table of Contents sections of each journal published in Taiwan during the era of Japanese rule (1895 to 1945) and held in the archives of National Taiwan University, the Taiwan Forestry Research Institute, and the Taiwan Agricultural Research Institute, and he found twenty-one articles concerning ethnobotanical research. We also took a look at post-WWII studies (1945 to 2000), and found 24 articles concerning plant uses of the indigenous peoples.

According to our survey (Kuo *et al.*, 2005b), Taiwanese indigenous peoples have used about 700 plant species, for which we created a database using Microsoft Access. The database has several fields (i.e., commonly-accepted names, synonyms, common names, plant family, indigenous tribes, use, and description). Under the "use" category we have used the following subcategories: as food, as spice, as salt replacement, as medicine (Kuo *et al.*, 2005a), for chewing, for teeth-dyeing, for dyeing generally, for cleaning, for wine-making, for decoration, for fish-poisoning, for construction, for boat-making, for use as a container, for use as fabric, etc. The database contains several categories concerning plant species (i.e., accepted names, synonyms, common names, plant family, indigenous tribes associated with this plant, use, and description).

#### 2. Main points of the draft concerning the protection of TEK

The "Basic Indigenous Peoples Act" went into force on February 5, 2005. Article 13 of the Basic Act states that the government should protect by law within two years the biodiversity-related traditional knowledge as well as the intellectual creation. Accordingly the Council of Indigenous Affairs commissioned our team to draft a law concerning the protection of the biodiversity-related traditional knowledge of indigenous peoples.

The draft proposal depicts the tribal council as the authority that may exercise the right of the biodiversity-related traditional knowledge that belongs exclusively to the tribe; in case the knowledge belongs to more than one tribe, the ethnic group council does.

Traditional knowledge that already lies in the public domain should be used freely except when the use of the traditional knowledge has been coupled with the designation of the tribe or the ethnic group. In that case, the indigenous people are entitled to premium compensation.

Whoever wishes to inquire, record or use traditional knowledge that still remains in the private domain should make application to the tribal council/ ethnical group council. If the council agrees to carry on with the negotiation, then the representatives of the council and the applicant may proceed to talk and reach an agreement, which is to be passed by the council itself. The content of the agreement should include details of the benefit-sharing arrangement to be followed in case the application of the traditional knowledge begins to be profitable. The traditional knowledge recorded under the agreement should be put into the Database. There are two sets of database. The national database of traditional knowledge includes only the keywords or a simple description of each entry, and is open to public. The detailed content of each entry should be kept in secret in the tribal database, the access and use of which is to follow the process described above. The tribe reserves the right to demand the user to disclose of the origin of the traditional knowledge.

#### V. Final remark

Gene technology has brought the world into a new bio-industrial era. The power and speed of this technology in discovering new chemicals with a high degree of commercial potential from tiny pieces of bio-tissue is unprecedented. No matter how the new technology generates new changes, however, it can never diminish the importance and value of ordinary life. An ideal act concerning the acquisition of genetic resources will ensure effective control over the genetic resources within the territory of our country while presenting the least amount of inconvenience to ordinary life and common practices such as academic research, education, and trade. We anticipate that our draft proposal is still in need of improvement, so we would deeply appreciate any criticism or suggestion.



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