

## Recommendation of the Regulations on the Legal and Effective Access to Taiwan's Biological Resources



### Preface

Considering that, many countries and regional international organizations already set up ABS system, such as Andean Community, African Union, Association of Southeast Asia Nations (ASEAN), Australia, South Africa, and India, all are enthusiastic with the establishment of the regulations regarding the access management of biological resources and genetic resources. On the other hand, there are still many countries only use traditional and existing conservation-related regulations to manage the access of biological resources.

Can Taiwan's regulations comply with the purposes and objects of CBD? Is there a need for Taiwan to set up specific regulations for the management of these access activities? This article plans to present Taiwan's regulations and review the effectiveness of the existing regulations from the aspect of enabling the legal and effective access to biological resources. A recommendation will be made on whether Taiwan should reinforce the management of the bio-resources access activities.

Review and Recommendation of the Regulations on the Legal and Effective Access to Taiwan's Biological Research Resources

#### (1) Evaluate the Needs and Benefits before Establishing the Regulation of Access Rights

When taking a look at the current development of the regulations on the access of biological resources internationally, we discover that some countries aggressively develop designated law for access, while some countries still adopt existing regulations to explain the access rights. Whether to choose a designated law or to adopt the existing law should depend on the needs of establishing access and benefit sharing system. Can the access and benefit sharing system benefit the functioning of bio-technological research and development activities that link closely to the biological resources? Can the system protect the interests of Taiwan's bio-research results?

In Taiwan, in the bio-technology industry, Agri-biotech, Medical, or Chinese Herb Research & Development are the key fields of development. However, the biological resources they use for the researches are mainly supplied from abroad. Hence, the likelihood of violating international bio-piracy is higher. On the contrary, the incidence of international research houses searching for the biological resources from Taiwan is comparatively lower, so the possibility for them to violate Taiwan's bio-piracy is very low.

To look at this issue from a different angle, if Taiwan establishes a separate management system for the access of biological resources, it is likely to add more restrictions to Taiwan's bio-tech R&D activities and impact the development of bio-industry. Also, under the new management system, international R&D teams will also be confined, if they wish to explore the biological resources, or conduct R&D and seek for co-operation activities in Taiwan. Not to mention that it is not a usual practice for international R&D teams to look for Taiwan's biological resources. A new management system will further reduce their level of interest in doing so. In the end, the international teams will then shift their focus of obtaining resources from other countries where the regulation on access is relatively less strict.

Before Taiwan establishes the regulations on the legal and effective access to bio-research resources, the government should consider not only the practical elements of the principal on the fair and impartial sharing of the derived interests from bio-research resources, but also take account of its positive and negative impacts on the development of related bio-technological industries.

Even if a country's regulation on the access and benefit sharing is thorough and comprehensive enough to protect the interests of bio-resource provider, it will, on the contrary, reduce the industry's interest in accessing the bio-resources. As a result, the development of bio-tech industry will be impacted and the resource provider will then be unable to receive any benefits. By then, the goal of establishing the regulation to benefit both the industry and resource provider will not be realized.

To sum up, it is suggested to evaluate the suitability of establishing the management system for the access to biological resources through the cost-effect analysis first. And, further consider the necessity of setting up regulations by the access the economic benefits derived from the regulation for both resource provider and bio-tech industry.

## (2) The Feasibility of Managing the access to Bio-research Resources from existing Regulations

As analysed in the previous paragraphs, the original intention of setting up the Wildlife Conservation Act, National Park Law, Forestry Act, Cultural Heritage Preservation Act, and Aboriginal Basic Act is to protect the environment and to conserve the ecology. However, if we utilize these traditional regulations properly, it can also partially help to manage the access to biological resources.

When Taiwan's citizens wish to enter specific area, or to collect the biological resources within the area, they need to receive the permit from management authority, according to current regulations. Since these national parks, protection areas, preserved areas, or other controlled areas usually have the most comprehensive collections of valuable biological resources in a wide range of varieties, it is suggested to include the agreements of access and benefit sharing as the mandatory conditions when applying for the entrance permit.

Therefore, the principal of benefit sharing from the access to biological resources can be assured. Furthermore, the current regulations already favour activities of accessing biological resources for academic research purpose. This practice also ties in with the international trend of separating the access application into two categories - academic and business.

Australia's practice of access management can be a very good example of utilizing the existing regulations to control the access of resources. The management authority defines the guidelines of managing the entrance of control areas, research of resources, and the collection and access of resources. The authority also adds related agreements, such as PIC (Prior Informed Consent), MTA (Material Transfer Agreement), and benefit sharing into the existing guidelines of research permission.

In terms of scope of management, the existing regulation does not cover all of Taiwan's bio-research resources. Luckily, the current environmental protection law regulates areas with the most resourceful resources or with the most distinctive and rare species. These are often the areas where the access management system is required. Therefore, to add new regulation for access management on top of the existing regulation is efficient method that utilizes the least administrative resources. This could be a feasible way for Taiwan to manage the access to biological resources.

## (3) Establish Specific Regulations to Cover the Details of the Scope of Derived Interests and the Items and Percentage of Funding Allocation

In addition to the utilization of current regulations to control the access to biological resources, many countries establish specific regulations to manage the biological resources. If, after the robust economic analysis had been done, the country has come to an conclusion that it is only by establishing new regulations of access management the resources and derived interests of biological resources can be impartially shared, the CBD (Convention of Bio Diversity), the Bonn Guidelines, or the real implementation experiences of many countries can be an important guidance when establishing regulations.

Taiwan has come up with the preliminary draft of Genetic Resources Act that covers the important aspects of international access guidelines. The draft indicates the definition and the scope of access activities, the process of access applications (for both business and academic purpose), the establishment of standardized or model MTA, the obligation of disclosing the sources of property rights (patents), and the establishment of bio-diversity fund.

However, if we observe the regulation or drafts to the access management of the international agreements or each specific country, we can find that the degree of strictness varies and depends on the needs and situations. Generally speaking, these regulations usually do not cover some detailed but important aspects such as the scope of derived interests from biological resources, or the items and percentage of the allocation of bio-diversity fund.

Under the regulation to the access to biological resources, in addition to the access fee charge, the impartial sharing of the derived interests is also an important issue. Therefore, to define the scope of interests is extremely important. Any interest that is out of the defined scope cannot be shared. The interest stated in the existing regulation generally refers to the biological resources or the derived business interests from genetic resources. Apart from describing the forms of interest such as money, non-money, or intellectual property rights, the description of actual contents or scope of the interests is minimal in the regulations.

However, after realizing the importance of bio-diversity and the huge business potential, many countries have started to investigate the national and international bio-resources and develop a database system to systematically collect related bio-research information. The database comprised of bio-resources is extremely useful to the activities related to bio-tech developments. If the international bio-tech companies can access Taiwan's bio-resource database, it will save their travelling time to Taiwan. Also, the database might as well become a product that generates revenues. The only issue that needs further clarification is whether the revenue generated from the access of database should be classified as business interests, as defined in the regulations.

As far as the bio-diversity fund is concerned, many countries only describe the need of setting up bio-diversity funds in a general manner in the regulations. But the definition of which kind of interests should be put into funds, the percentage of the funds, and the related details are not described. As a result, the applicants to the access of bio-resources or the owner of bio-resources cannot predict the amount of interests to be put into bio-diversity fund before they actually use the resources. This issue will definitely affect the development of access activities.

To sum up, if Taiwan's government wishes to develop the specific regulations for the access of biological resources, it is advised to take the above mentioned issues into considerations for a more thoroughly described, and more effective regulations and related framework.

## Conclusion

In recent years, it has been a global trend to establish the regulations of the access to and benefit sharing of bio-resources. The concept of benefit sharing is especially treated as a useful weapon for the developing countries to protect the interests of their abundant bio-research resources.

However, as we are in the transition period of changing from free access to biological resources to controlled access, we are facing different regulations within one country as well as internationally. It will be a little bit disappointing for the academic research institution and the industry who relies on the biological resources to conduct bio-tech development if they do not see a clear principal direction to follow. The worse case is the violation of the regulation of the country who owns the bio-resources when the research institutions try to access, exchange, or prospect

the biological resources without thorough understanding of related regulations.

For some of Taiwan's leading fields in the bio-tech industry, such as Chinese and herbal medicine related products, agricultural products, horticultural products, and bio-tech products, since many resources are obtained from abroad, the incidence of violation of international regulation will increase, and the costs from complying the regulations will also increase. Therefore, not only the researcher but also the government have the responsibility to understand and educate the related people in Taiwan's bio-tech fields the status of international access management regulations and the methods of legally access the international bio-research resources.

Currently in Taiwan, we did not establish specific law to manage the access to and benefit sharing of bio-resources. Comparing with the international standard, there is still room of improvement for Taiwan's regulatory protection to the provider of biological resources. However, we have to consider the necessity of doing so, and how to do the improvement. And Taiwan's government should resolve this issue. When we consider whether we should follow international trend to establish a specific law for access management, we should always go back to check the potential state interests we will receive and take this point into consideration. To define the interests, we should always cover the protection of biological resources, the development of bio-tech industry, and the administrative costs of government. Also the conservation of biological resources and the encouragement of bio-tech development should be also taken into consideration when the government is making decisions.

In terms of establishing regulations for the access to biological resources and the benefit sharing, there are two possible solutions. The first solution is to utilize the existing regulations and add the key elements of access management into the scope of administrative management. The work is planned through the revision of related current procedures such as entrance control of controlled areas and the access of specific resources. The second solution is to establish new regulations for the access to biological resources. The first solution is relatively easier and quicker; while the second solution is considered to have a more comprehensive control of the issue. The government has the final judgement on which solution to take to generate a more effective management of Taiwan's biological resources.

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