Vietnam Journal of Biotechnology **22**(1): 1-33, 2024. DOI: 10.15625/vjbt-20230

REVIEW

STATUS ON MANAGEMENT OF ACCESS TO GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND BENEFIT SHARING

Le Thi Thu Hien[1,2,✉], Nguyen Hai Ha[1,2], Nguyen Thuy Duong[1,2], Pham Le Bich Hang[1], Ta Thi Kieu Anh[3], Nguyen Chi Mai[4], Tran My Linh[4]

[1]*Institute of Genome Research, Vietnam Academy of Science and Technology, Hanoi, Vietnam*

[2]*Graduate University of Science and Technology, Vietnam Academy of Science and Technology, Hanoi, Vietnam*

[3]*Department of Nature Conservation and Biodiversity, Ministry of Natural Resources and Environment, Hanoi, Vietnam*

[4]*Institute of Marine Biochemistry, Vietnam Academy of Science and Technology, Hanoi, Vietnam*

✉To whom correspondence should be addressed. E-mail: hienlethu@igr.ac.vn

Received: 09.12.2023
Accepted: 20.03.2024

ABSTRACT

The management of access to genetic resources, traditional knowledge (TK), and benefit sharing among indigenous people and local communities worldwide is extensively addressed in international legal instruments, including the Convention on Biological Diversity (CBD) and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits (ABS) Arising from their Utilization. The CBD aims to promote the conservation of biological resources, the sustainable use of biodiversity components and the equitable, fair sharing of benefits arising from the use of genetic resources. The Nagoya Protocol sets out core obligations for its contracting Parties to take measures in relation to ABS and compliance. In 2021, the Secretariats of the CBD released the first draft of the Post-2020 Global Biodiversity Framework with the mission for the period up to 2030, aiming towards the 2050 vision: "To take urgent action across society to conserve and sustainably use biodiversity and ensure the fair and equitable sharing of benefits from the use of genetics resources, to put biodiversity on a path to recovery by 2030 for the benefit of planet and people." Therefore, capacity building and development are crucial for the implementation of the Nagoya Protocol, especially for developing countries. One of the most commonly identified new capacity building needs is digital sequence information on genetic resources and their roles in ABS.

As a member of the CBD and the Nagoya Protocol, Vietnam has obligations to develop the National Strategy Framework on Biodiversity to 2030, with a vision to 2050, consistent with the requirements of the Post-2020 Global Biodiversity Framework, Protocols, and relevant Agreements. This includes developing recommendations on the management of access to genetic resources and TK, as well as benefit sharing within the Draft of the National Biodiversity Strategy and Action Plan. This research aims to contribute to implement the

Post-2020 Global Biodiversity Framework and the Nagoya Protocol in Vietnam by assessing the status of management regarding access to genetic resources, TK, and benefit sharing.

Keywords: access to genetic resources and benefit sharing (ABS), biodiversity, digital sequence information, traditional knowledge.

INTRODUCTION

The first draft of the Post-2020 Global Biodiversity Framework was released on 6/7/2021, by the Secretariats of the Convention on Biological Diversity (CBD). The framework envisions living in harmony with nature, with the goal of achieving: "By 2050, biodiversity is valued, conserved, restored and wisely used, maintaining ecosystem services, sustaining a healthy planet, and delivering benefits essential for all people." The mission for the framework's period up to 2030, towards achieving the 2050 vision, is: "To take urgent action across society to conserve and sustainably use biodiversity and ensure the fair and equitable sharing of benefits from the use of genetic resources, to put biodiversity on a path to recovery by 2030 for the benefit of planet and people." (https://www.cbd.int/article/draft-1-global-biodiversity-framework).

The draft of the framework has four long-term Goals for 2050 related to the 2050 Vision for Biodiversity. One of the four Goals related to Access and Benefit Sharing (ABS) issues, Goal C, specified: "The benefits from the utilization of genetic resources are shared fairly and equitably, with a substantial increase in both monetary and non-monetary benefits shared, including for the conservation and sustainable use of biodiversity." For these Goals, the Framework has 21 action-oriented Targets for urgent action over the decade to 2030, of which Targets 13 and 20 are related to genetic resources and traditional knowledge (TK).

Target 13. Implement measures at the global level and in all countries to facilitate access to genetic resources and to ensure the fair and equitable sharing of benefits arising from the use of genetic resources, and as relevant, of associated TK, including through mutually agreed terms (MAT) and prior and informed consent (PIC).

Target 20. Ensure that relevant knowledge, including the TK, innovations and practices of indigenous peoples and local communities with their free, prior, and informed consent, guides decision-making for the effective management of biodiversity, enabling monitoring, and promoting awareness, education and research.

Vietnam has been a member of the CBD since 1994 and the Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising from their Utilization since 2014. Vietnam is obligated to develop a National Strategy Framework on Biodiversity to 2030, with a vision to 2050, consistent with the requirements of the Post-2020 Global Biodiversity Framework, Protocols and relevant Agreements. To formulate recommendations on management of access to genetic resources and TK, as well as benefit sharing, within the Draft of the National Biodiversity Strategy and Action Plan, and to contribute to implementation of the Post-2020 Global Biodiversity Framework, Nagoya Protocol in Vietnam, report entitled "Status on management of access to genetic resources, TK and benefit sharing and recommendations on

management of access to genetic resources, TK and benefit sharing in compliance with the Draft of the Post-2020 Global Biodiversity Framework (Targets 13 and 20)" was developed under the National Biodiversity Strategy and Action Plan to 2030, vision to 2050 (NBSAP) Program that conducted by The World Wide Fund for Nature (WWF). This paper is part of the report and was completed with the following main activities as follows:

- Collaborate with relevant stakeholders and conduct surveys to collect information and data for report development.
- Review, analyze the global and Vietnam status on issues related to Targets 13 and 20, including:

- Analyzing the global status of genetic resource management, TK and benefit sharing, focusing on international agreements such as the CBD and Nagoya Protocol.
- Analyzing the status of genetic resource management, TK and benefit sharing in Vietnam, considering achievements up to the period before 2021.
- Identify shortcomings and limitations in the development of policies, legal and institutional regulations, the implementation of management of access to genetic resources, TK and benefit sharing in Vietnam.

THE GLOBAL STATUS ON MANAGEMENT OF ACCESS TO GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND BENEFIT SHARING

The relevant international agreements

In the world, the management of access to genetic resources, TK, and benefit sharing of indigenous people and local communities are extensively focused in instruments by international organizations such as CBD and Nagoya Protocol, Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) under The World Intellectual Property Organization (WIPO), United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP), Agreements of World Trade Organization related to Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (Article 27.3 (b) on traditional knowledge and biodiversity). However, due to the unique characteristics and complexities of TK and genetic resources, several unresolved issues persist. These include the protection of TK and genetic resources, which are approached from perspectives such as human rights, inherent natural rights, the right of benefit economically, property rights establishment, identification of rights holders, benefits-sharing mechanisms, scope of protection, and prevention of unauthorized use by third parties.

Access to genetic resources, traditional knowledge and benefit sharing of Convention on Biological Diversity and Nagoya Protocol

The CBD focused on conservation of biological resources, sustainable use of biodiversity components, and the equitable, fair sharing of benefits arising out of the utilization of genetic resources. The fair and equitable sharing of the benefits arising out of the utilization of genetic resources is one of the three objectives of the CBD. CBD

requires PIC from genetic resources providers (Article 15.5). Subject to its national legislation, respect, preserve and maintain the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge (Article 8j).

Based on this foundation, the Nagoya Protocol, adopted in 2010, establishes a transparent legal framework to effectively implement these objectives. The Protocol covers genetic resources and associated traditional knowledge, as well as the benefits arising from their utilization, by setting out core obligations for its contracting Parties to take measures in relation to ABS and compliance. According to the Nagoya Protocol, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party (Article 6.1). Each Party has to implement measures, as appropriate, in order to obtain prior informed consent. Nagoya Protocol regulates to: (i) provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements on ABS (Article 6.3.a); (ii) provide information on how to apply for prior informed consent (Article 6.3.c); (iii) provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time (Article 6.3.d); (iv) provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms (Article 6.3.e); (v) set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources (Article 6.3.f); (vi) provide for fair and non-arbitrary rules and procedures on accessing genetic resources (Article 6.3.b); (vii) establish clear rules and procedures for requiring and establishing mutually agreed terms (Article 6.3.g); In the Nagoya Protocol, one of the important factors is TK associated with genetic resources, which contributes to increasing the added values of genetic resources. Each Party shall take measures, as appropriate, with the aim of ensuring that TK associated with genetic resources that are held by indigenous and local communities is accessed with the prior and informed consent, approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established (Article 7). Parties shall endeavor to support, as appropriate, the development by indigenous and local communities, including women within these communities, for the minimum requirements of MAT and clauses of model contracts (Article 12.3). On 25/3/2020, the Secretariats of CBD released the assessment report on the Strategic Framework for capacity building and development to support the effective implementation of the Nagoya Protocol. According to the report, through national, regional and global initiatives and projects on ABS, many countries have made significant achievements in capacity building and development to support the ratification and implementation of the Nagoya Protocol. The legal framework for ABS had been developed, in which National

Competent Authorities (NCAs) were nominated, checkpoints were set up, relevant measures on ABS were applied and published via ABS Clearing-House. The report also stated that many parties still lack the capacity and financial resources needed to implement the Nagoya Protocol. Therefore, capacity building and development are needed, especially for developing countries, small island nations and parties that have a transition economy.

The report had identified needed issues for capacity building to implement the Nagoya Protocol for the post-2020 period: (i) Capacity for negotiating contracts, capacity of indigenous people, local communities and parties, including the business sector and research communities related to Nagoya Protocol implementation, and national capacity for the development of research to increase the value of genetic resources have been identified as priorities for continued support. The report also recommended that capacity building measures for indigenous and local communities should be separated from those of other sectors, such as business and research communities, based on their different characteristics and needs; (ii) The most commonly identified new capacity building needs are digital sequence information (DSI) on genetic resources and their roles in ABS, and how monetary and non-monetary benefits arising from the use of genetic resources are measured and reported; (iii) The report also pinpointed the regional and national approaches, trainers training, and the exchange of national experiences and lessons as the most effective methods for application and development in the post-2020 period. The added factors were identified to support ABS implementation, such as strategic communication on ABS, better linkage between CBD and other protocols and conventions related to biodiversity and mainstreaming gender issues into capacity building recommendations. Therefore, requirements to strengthen the Nagoya Protocol implementation for the post-2020 period were clearly identified based on national status and needs assessment. This is the main basis for Vietnam to develop and implement the National Strategy on Biodiversity to 2030 with contents related to ABS.

Beyond the Nagoya Protocol, progress has been made since 2010 under a number of international bodies and initiatives to extend access to genetic resources and the fair and equitable sharing of benefits from their utilization. These international instruments relevant to ABS are addressed in Table 1.

Table 1. Progress made in other relevant ABS international agreements and initiatives (https://www.cbd.int/gbo/gbo5/publication/gbo-5-en.pdf).

Relevant ABS International bodies and initiatives	Progress	References
The International Treaty on Plant Genetic Resources for Food and Agriculture	The Treaty facilitates access to plant genetic resources for farmers and plant breeders, helping to develop new crop varieties and adapt agricultural production to a changing environment. As of February 2020, more than 5.5 million samples have been transferred globally, through more than 76,000	Secretariat of the Convention on Biological Diversity (2020) CBD/ SBI/3/2/Add.1

	contracts known as Standard Material Transfer Agreements (SMTAs).	
The Commission on Genetic Resources for Food and Agriculture of the Food and Agriculture Organization (FAO)	In 2015, the Commission developed the 'Elements to Facilitate Domestic Implementation of Access and Benefit-sharing for Different Subsectors of Genetic Resources for Food and Agriculture (ABS Elements)'.	Secretariat of the Convention on Biological Diversity (2020) CBD/ SBI/3/2/Add.1
The Intergovernmental Conference on the Conservation and Sustainable Use of Marine Biodiversity of Areas Beyond National Jurisdiction (BBNJ)	In 2017, the Conference convened to develop the text of an international legally-binding instrument under the United Nations Convention of the Law on the Sea. The negotiating text addresses access and benefit-sharing for marine genetic resources, as well as traditional knowledge of indigenous peoples and local communities associated with marine genetic resources.	Secretariat of the Convention on Biological Diversity (2020) CBD/ SBI/3/2/Add.2
The Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (PIP Framework)	In 2011, the Framework was adopted by the World Health Organization (WHO). WHO coordinates the sharing of influenza viruses through an international network of public health laboratories called the 'Global Influenza Surveillance and Response System' (GISRS). The laboratories in GISRS exchange viruses using standard material transfer agreements, binding contracts that establish the conditions and obligations for benefit-sharing.	https://www.absfocalpoint.nl/en/absfocalpoint/internationalinstruments/PIP-Framework.htm
The Global Initiative on Sharing All Influenza Data (GISAID)	GISAID is a mechanism to promote and incentivize the rapid sharing of influenza virus data, permitting free and open access to anyone who provides positive identification, and agrees to respect the inherent rights of the contributor. GISAID requires users to acknowledge the origin and contributors in their publication, and to make the best efforts to collaborate with them, thus making data-sharing beneficial for the submitter. In 2020, GISAID entered the global research effort to understand the virus responsible for the COVID-19 pandemic. As of 26 May 2020, more than 32,000 such SARS-CoV-2 sequences had been added to the GISAID database, thereby helping to detect viral mutations and track the movement of the virus across the planet.	Clabot, Gilligan (2017)

The traditional knowledge, innovations and practices of indigenous and local communities

There is limited global level information on the extent to which TK and customary use are being integrated into the implementation of the CBD. Despite increasing recognition of the potential value of traditional knowledge for conservation and sustainable use, there is often a lack of communication between indigenous peoples, local communities and the scientific community (Abreu *et al*., 2017) and assessments of

biodiversity often do not take local and TK factors into account (Sutherland *et al*., 2014). Numerous examples have demonstrated the ways in which bringing TK together with science can lead to constructive solutions to various challenges (Tengö *et al*., 2014) and lead to the development of policies that are more tailored.

Despite an increasing number of positive examples of national progress (Table 2), the role of TK and of indigenous peoples and local communities in conserving and sustainably using biodiversity is generally poorly recognized in national processes. For example, only 40 Parties of the CBD reported that indigenous people and local communities were involved in the revision processes of their national biodiversity strategies and action plans (Secretariat of the CBD (2020) CBD/SBI/3/2/Add.1). Common actions reported by Parties include efforts to document TK more comprehensively, protect TK, ensure fair compensation for the use of indigenous knowledge, and implement capacity building programs focusing on TK. Some national reports also mention actions aimed at improving the legal recognition of the rights of indigenous peoples and local communities. A prevalent challenge noted in the reports is the lack of capacity and resources for incorporating and reflecting TK and customary sustainable use in issues related to conservation (Secretariat of the CBD (2020) CBD/SBI/3/2/Add.4).

In short, there has been an increase in the recognition of the value of TK and customary sustainable use, both in global policy fora and in the scientific community. However, despite progress in some countries, there is limited information indicating that TK and customary sustainable use have been widely respected and/or reflected in national legislation related to the implementation of the Convention or on the extent to which indigenous peoples and local communities are effectively participating in associated processes.

Table 2. Examples of country experiences and national progress (https://www.cbd.int/gbo/gbo5/publication/gbo-5-en.pdf).

Country	National experiences and progress	References
Australia	The Environment Protection and Biodiversity Conservation Act established the Indigenous Advisory Committee (IAC) to provide advice to the Minister for Environment and the Australian Government on policy and implementation matters relating to indigenous land and sea management, specifically in relation to the implementation of the Act. The IAC has contributed advice ensuring recognition of and support for the transfer and integration of indigenous traditional knowledge with national biodiversity policy, programmes and regulatory decision processes. The Threatened Species Scientific Committee has engaged member expertise to improve indigenous engagement and understanding relating to the on-the-ground implications of their decisions on indigenous Australians.	Australia's Sixth national report. https://www.cbd.int/doc/nr/nr-06/au-nr-06-en.pdf
Eswatini	Ethno-botanical surveys are conducted, in consultation with traditional healers, to identify plant species commonly used in traditional medicine and rituals. These surveys help inform decisions on sustainable use.	Eswatini's Sixth national report. https://www.cbd.int/doc/nr/nr-

		06/sz-nr-06-en.pdf
Canada	Some indigenous communities protect and manage land and marine resources through Indigenous Guardians programs. While these programs have existed for several decades, they have mostly worked in isolation. In 2017, Canada invested 25 million Canadian dollars over five years to support a pilot initiative to establish a national network of existing Indigenous Guardians programs. The objective of this initiative is to give indigenous peoples greater responsibility and resources to manage their traditional lands and waterways. It will facilitate partnerships with indigenous communities and provide additional funding to existing indigenous programs to support their activities related to monitoring ecological health, maintaining cultural sites, and protecting sensitive areas and species. In addition, Canada is supporting the implementation of a pilot Guardian program in Arctic Bay, Nunavut. The funding will support the Qikiqtani Inuit Association in investigatingways to involve Inuit in the management of the Tallurutiup Imanga National Marine Conservation Area, the newest and largest marine protected area in Canada.	Canada's Sixth national report. https://chm.cbd.int/database/record/C54338B1-F853-7542-B2AD-34985A78BE08
Costa Rica	In 2018, a mechanism for consultation with indigenous peoples was established. The objective of this mechanism is to ensure consultation with indigenous peoples through appropriate procedures and through their representative institutions, whenever administrative measures or bills are likely to affect them. To help operationalize this mechanism the Costa Rican government and 22 indigenous peoples' representatives developed a guide that indicates to government institutions how to comply with the obligation to consult these peoples when a measure or project is likely to affect their collective rights.	Costa Rica's Sixth national report. https://chm.cbd.int/database/record/158F6797-D2D0-91DF-E1D1-55EF84D295E0

Digital sequence information database related to genetic resources

Research into constructing DSI databases and leveraging big data at the genetic and genomic level is applied in many fields and has a great impact on social life globally. DSI serves as a particularly valuable source of information to support genetic resource management, species identification, exploitation and use, commercial supervision, and identification of national ownership rights on genetic resources. In the world and Vietnam as well, the guidance on building and developing the open or limited access online DSI has been carried out and developed strongly in recent years. Many countries have focused on promoting and investing in terms of building, storing, managing and effectively exploiting these DSI. Many large projects on human, animal, plant and microbial genomes have been and are being conducted independently or cooperatively by a network of scientists in many specialized fields such as gene technology, bioinformatics, computational biology, automation, and artificial intelligence of national or multi-national scientific and technological organizations. For example, the Barcode of Life Data Systems (BOLD) (www.boldsystems.org/), and the GenBank/EMBL/DDBJ have been built and developed to collect, store, analyze and publish information on genes and

genomes, including DNA barcodes according to common international standards. In addition, many projects and programs have developed their own DSI database for various target groups from humans to animals, plants, and microorganisms. The complete sequence data of the human genome is stored on the database of the National Human Genome Research Institute (USA), which allows scientists worldwide to access for biomedical research (www.genome.gov). The large-scale genomic sequencing project of up to 1,000 human individuals has been conducted by the international scientific community, and the project's data has been freely shared with the global scientific community (https: //www.international genome.org/). Project on sequencing of the entire genomes of 100,000 patients with rare diseases or cancer from the National Health Service, UK (https://www.genomicsengland .co.uk/). Project on sequencing of the 10,000 vertebrate genomes (2009): a project had been carried out by a network of biologists and genomics researchers to identify and sequence the entire genome of 10,000 vertebrate species, to contribute to understanding the complexity of animal life through changes at the gene level (https://genome10k.soe.ucsc.edu/). The International Vertebral Genome Project aims at high-quality sequencing and annotation of the complete genome of 66,000 vertebrate species on Earth, whichsupports basic scientific research on biology, pathology and conservation. Genomic data is stored and shared with the scientific community through the open genomic data system, Genome Ark, a new digital library built by the G10K-VGP Network with the participation of more than 150 experts from 12 countries, over 50 research institutes, universities and companies, in supporting the identification and conservation of the genetic resources of endangered species (https://vertebrategenomesproject.org). Project of 1,000 plant transcriptomes and the phylogenomics of green plants (One Thousand Plant Transcriptomes Initiative, 2019). The 100k Pathogen Genome Project had developed the genome database to support public health (https://100kgenomes.org/). Additionally, the Global Biogenomics Project had sequenced, archived, and analyzed the genomes of all eukaryotes on Earth, involving an international network of experts from many countries and regions, such as the European Union, the United States, Australia, Japan, China, Brazil, Canada, and South Africa (https://www.earthbiogenome.org/org).

Protection of the genetic resources, traditional knowledge, initiatives and practical experiences of indigenous people and local communities

Traditional knowledge of indigenous and local communities represents valuable experiential knowledge derived from practical activities, holding significant intrinsic values for these communities. TK is considered an important resource that is planned to research, collect, preserve and develop its value by many countries, interested governmental and non-governmental organizations around the world. Institutions such as the World Bank (WB), the United Nations Educational, Scientific and Cultural Organization (UNESCO), the World Intellectual Property Organization (WIPO) and the Food and Agriculture Organization of the United Nations (FAO) acknowledged their role and contribution to sustainable development (Vu Truong Giang, 2010).

Traditional knowledge consists of information transmitted across generations or exchanged among communities, making it vulnerable to loss over time or illegal exploitation outside the control of the communities holding it. These activities can cause economic damage to communities by breaking the principles that keep benefit balance between the holding communities and the users of TK, destroying efforts to preserve and develop knowledge, and against the traditional cultures, customs of the community. Therefore, international communities are interested in the most appropriate measures and tools to effectively protect this type of special property, in reality to protect the intellectual property (IP) aspect of TK.

In 2009, WIPO-IGC agreed to develop an international legal instrument to effectively protect tangible products of TK, genetic resources, and traditional culture. The acknowledgement of traditional types of initiatives and innovations as protected IP would be a historical change in an international law, thereby allowing indigenous peoples and local communities as well as governments to play a decisive role in the use of their TK instead of others. Thus, for example, traditional remedies are protected against the appropriation and local communities have the opportunity to control and benefit from their commercial exploitation. Two types of intellectual property rights (IPRs) protection are considered by WIPO-IGC: (i) Defensive protection to prevent people outside the community from obtaining IPRs to TK. For example, India has developed an open database of traditional medicine that can be used as proof of past existence to help appraisers review and evaluate patent applications. There was actually a well-known case in which the US Patent and Trademark Office (USPTO) granted a patent for the use of turmeric to treat wounds, then revoked this patent because it was an asset known to traditional communities in India and was recorded in Sanskrit ancient documents. Defensive strategies can also be used to protect sacred cultural symbols and words of the community that are not registered as good trademarks; (ii) Active protection is the empowerment that allows communities to promote their TK, control its use and profit from commercial exploitation. Some usage of TK can be protected through existing law systems on IP that have been developed by some countries. However, many particular measures that are applied to a national law may not apply to other countries, so many indigenous and local communities as well as governments propose that a developed international legal instrument be valid for those countries. The WIPO's activities on TK have focused on three distinct related areas: TK in the limited sense (technical know-how, practices, skills and innovations related to biodiversity, education, agriculture or health); traditional cultural/folk expressions (music, art, design, symbol and performance) and genetic resources (genetic material having actual or potential value found in creatures). While TK, genetic resources, and traditional cultural expressions form an integrated heritage, for many communities, they present different challenges from an IP perspective and may require distinct solutions. To enable communities to utilize existing IP legal frameworks more effectively, governments should support the development and enhancement of national, regional, and international systems to protect TK through policies, laws, information systems, and practical tools.

Regarding genetic resources, initiatives based on or derived from them (whether associated with TK or not) may be protected in the form of patents, good trademarks, geographical indications, trade secrets or protection-rights for plant varieties. WIPO supports international legal and policy frameworks such as CBD and the Nagoya Protocol: (i) Defensive protection of genetic resources to prevent patenting of genetic resources (and related TK) that does not meet the requirements for novelty and creativity; (ii) Mandatory requirement for applicants is disclosure of origin for patent. Failure to meet this requirement may result in the patent being invalidated entirely. Similar discussions have also occurred within WTO-TRIPS.

For TK, community members can utilize the patent system to protect their initiatives developed within its framework. However, TK having an ancient origin, often informal and orally, is not protected by conventional IP systems. This has encouraged some countries to develop their own *sui generis* (specific, special) systems to preserve TK. In addition, many initiatives are underway to document TK. In most cases, the objective is only to preserve or disseminate knowledge, or to use TK, for example, in environmental management, but not for the purpose of protection based on the legal system of IPRs. However, there are concerns that if documents on TK are made more widely available to the public, especially if they can be accessed on the internet then it could lead to appropriation and be used in ways that TK holders are not intended or foreseen. At the same time, documentation can help protect TK, for example, by making confidential records of TK available only to the relevant community. Some registered documents and TK are supported by the *sui generis* protection system, while TK databases, for example, the database on Indian traditional medicine - play a defensive role in the existing legal system on IPRs. These examples demonstrated the importance of ensuring that TK documentation is aligned with IP strategy and not outside of policies or legislation. During the WIPO's discussions, it was suggested that the use of TK requires PIC, especially for confidential and sacred documents. However, there is concern that giving exclusive control to traditional cultures could constrain innovations, reduce access rights for communities, and be difficult to implement in practice (https://www.wipo.int/tk).

Thus, TK is an important cultural factor that contributes to creating national identity. It can be considered an asset of indigenous peoples and local communities, reflecting the relationship of each community with their natural and social environment. The protection of TK, particularly its IPRs, is seen as an urgent necessity at both national and international levels.

THE CURRENT STATUS OF MANAGEMENT OF ACCESS TO GENETIC RESOURCES, ASSOCIATED TRADITIONAL KNOWLEDGE AND BENEFIT SHARING IN VIETNAM

Genetic resources and traditional knowledge associated with genetic resources in Vietnam

Vietnam had been recorded as one of the countries with the highest biodiversity value, ranking 16th in the world (World Bank, 2005). Situated in the Indo-Burma region, Vietnam is one of 25 global biodiversity hotspots (Myers *et al*., 2000). The country's biodiversity is evidenced by its diverse natural ecosystems and rich, endemic

genetic resources. Incomplete statistics as of 2021 indicate that Vietnam has identified approximately 61,700 species of organisms in its natural environment, including 7,500 species of microorganisms, 2,200 species of fungi, 2,544 species of micro-algae, 14,433 species of plants, and 900 species of freshwater invertebrates, 7,000 species of marine invertebrates, 1,000 species of terrestrial invertebrates, 20,000 species of insects, 491 species of spiders, 1,000 species of freshwater fish, 2,500 species of marine fish, 240 species of amphibians, 470 terrestrial reptile species, 21 marine reptile species, 891 bird species, 331 terrestrial mammal species, 25 marine mammal species (Ministry of Natural Resources and Environment - MONRE, 2021). Besides diverse natural ecosystems, Vietnam is also one of the world's diverse centers of local plant and animal genetic resources, with over 800 plant and 887 animal species. With a remarkable biodiversity of 800 known species of medicinal and aromatic plants, including approximately 600 species associated with TK, Vietnam has become an exceptionally appealing destination for biodiversity research (MONRE, 2019). There are 12,307 varieties of 115 plant species conserved into the national plant gene bank, including many indigenous genetic resources with valuable characteristics only found in Vietnam (MONRE, 2021). A unique feature of the diverse natural resources in Vietnam is the endemism of the species, as well as the rare genetic resources. The statistics of the database of plant and animal groups show that Vietnam has at least 467 endemic animal species, much higher than neighboring countries such as Laos, Cambodia, and Thailand (Tran Van Bang, 2020). Particularly in Lao Cai province, the results of a general survey on genetic resources and related TK were recently announced: 617 plant genetic resources; forest plant genetic resources include 8 branches, 10 classes, 82 orders, 247 families, 1,270 genera, 3,962 species (with 947 endemic species) and 88 subspecies; 186 species of medicinal plants; there are 2 branches of wildlife, 5 classes, 25 orders, 119 families, 396 genera (varieties), and 667 species; 7 TK stores (recipes) have been recorded in the whole province and 29 TK in Ta Phin commune, Sa Pa district. TK associated with the genetic resources of medicinal plants of the local people is very rich, especially the Dao ethnic people. The TK is usually limited to the family, tribe or clan and are accumulated and transmitted through generations. The retention of the TK may or may not be documented. Access is often passed on to the dedicated and suitable people, with a responsibility to ensure the proper use of knowledge in public health care. TK, therefore, is usually the collective heritage of the community in the area, or of a group of tribes, ethnic minorities. Even if the TK belongs to a specific individual or family, it is still considered a collective heritage because it is preserved and used for a noble purpose for the community (https://www.thiennhien.net/). The survey results also discovered 18 genetic resources having economic value, 105 genetic sources of agricultural crops with potential for exploitation and development, which have been proposed for research, exploitation and development and will continue to be added in next time. The report also proposed 82 genetic resources with economic value in Ta Phin commune, which need to be properly exploited and developed to get the benefits (refer to reports of the ABS Project, MONRE, 2019-2021; http://abs.prc.org.vn/). Ecosystems and biological resources are parts of a country's economy and culture,

reflected in the important values of environmental protection (ecological functional values); use directly (economic value); and social and cultural values. Biodiversity makes a significant contribution to the national economy.

Belonging to the group of high biodiversity centers in the world with rich and endemic genetic resources, with 54 ethnic groups, including 50 ethnic groups living in the highlands with diverse cultural identities, over many generations, Vietnam's ethnic groups have accumulated a lot of knowledge, initiatives and practical experience in the conservation and use of genetic resources, thereby consolidating a rich and diverse treasures of TK. TK associated with indigenous peoples and local communities is the property of the whole community and is developed from generation to generation. TK has played an important role in solving many problems for indigenous peoples and local communities. Agricultural knowledge (intercropping techniques, animal husbandry, crop diversity, animal health care, plant variety selection), taking care of human health (by traditional remedies), using and managing natural resources (land protection, irrigation and other forms of water management); education (oral knowledge) have had certain effects on poverty alleviation and socio-economic development (Vu Truong Giang, 2010). Currently, the TK of indigenous people is considered an important resource and one of the comparative advantages of Vietnam. The use of TK, e.g., plants for healing, has particularly developed among some ethnic minority groups and research institutions, private pharmaceutical companies and NGOs in recent years have recognized the importance of preserving and developing this knowledge, and make a benefit.

Recognizing the importance of genetic resources, the Government has prioritized investment and implemented numerous activities related to their conservation and sustainable use over the years. On September 28, 2015, the Prime Minister signed Decision No. 1671/QD-TTg approving the Program for the conservation and sustainable use of genetic resources until 2025, with an orientation towards 2030. With governmental priority policies, at present, Vietnam has established a network of agencies with a number of focal points and 68 units under 6 ministries/sectors participating in the implementation of the tasks of the program on conservation and sustainable use of genetic resources of animals, plants, and microorganisms. The collection, storage, and conservation of indigenous plant varieties, domestic animals, and wild relatives of precious and rare plant varieties, livestock, and microorganisms have been conducted annually. A large number of genetic resources of agricultural, forestry, medicinal plants, livestock, aquatic products, and microorganism species are rapidly increasing; many new species have been discovered and announced (Tran Van Bang, 2020). Many genetic resources have been documented in genetic resource databases. Numerous websites, books, newspapers, and leaflets have been created and published to promote and share information about plants and animals. Specialized software for storing information has been developed. Typically, for example, the genetic resources of agricultural crops have been standardized and unified within the national system for conserving agricultural crop genetic resources. The database "Vietnam Plant Genetic Resources" (http://prc.org.vn) has been developed and operates stably. The Vietnamese Academy of Forest Sciences has published 7 Atlas of

Vietnamese forest trees with 800 species. Currently, 88,968 genetic resources/seed sample have been collected and stored, 111 genetic resources have been developed into commercial products, and 3,179 genetic resources have been shared for research and applied for production. The software for managing genetic resources within the preservation system of medicinal genetic resources and plant varieties has been developed by the National Institute of Medicinal Materials (NIMM), a focal point of the health industry. Information on medicinal genetic resources has been gradually updated on the NIMM's website. Collaborating with media outlets like People's Newspaper, the Documentary Film Center, People's Television, and VTC Video Channel, the NIMM has produced reports on the conservation and sustainable development of Vietnamese medicinal plant resources. Additionally, documentation of livestock genetic resources in Vietnam has advanced with the development of software like VIETBIODIVA and VIETGEN, aimed at managing profiles of each livestock breed. More information can be found on the website http://www.vcn.vnn.vn/. For managing the database of microbial genetic resources, although no specific unit has specialized software, Vietnam Type Culture Collection at Vietnam National University in Hanoi, along with several other units, has established websites and online catalogs (Ministry of Science and Technology - MOST, 2019; 2020).

For the DSI database, in line with the current international trend, Vietnam has prioritized investment and development towards building databases of human and endemic organism genes and genomes that have hold national values. A number of DSI databases have been established and developed such as the Vietnamese gene variants database (https://genomes.vn). The largest biomedical data management and analysis system in Vietnam has been invested by the VinBigData Institute of Vingroup in collaboration with 21 prestigious research organizations worldwide, with a focus on developing reference genomes for Vietnamese and sequencing the genomes of over 1,000 Vietnamese people (https://genome.vinbigdata.org). Within the framework of scientific and technological projects, a number of DSI databases for separated species (human, black tiger shrimp, pangasius, marine algae, ginseng, bacteria, etc.) have been developed and/or integrated into international DSI databases such as GenBank/EMBL/DDBJ, but organisms are still limited and genetic and genome databases have not been identified much because the research direction is quite new, human resources, research funding, infrastructure and equipment are lacking and inconsistent (Le Thi Thu Hien *et al*., 2021).

The results of the evaluation of the implementation of the framework project on genetic resources funds at ministerial and provincial levels (2012-2019 period) and genetic resource sharing showed that: (i) Vietnam's precious genetic resources have been conserved and properly exploited and have created high-quality product lines that are popular with consumers; (ii) The work of preservation, conservation, exploitation and development has gradually formed an information system on genetic resources, however, there is no consensus in the whole country, and many localities have not yet established websites on the protection, preservation and conservation of genetic resources. MOST is currently focusing on developing a science and technology task framework project on ministerial and

provincial genetic resources funds for 2021-2025 (Dispatch No. 161/BKHCN-CNN dated 21/01/2020 on the development of the science and technology task framework project on genetic resources funds at ministerial and provincial levels). TK is increasingly interested in research, collection and use to support the process of industrialization and modernization of the country in general, and sustainable development in mountainous areas and local communities in particular.

Legal documents and policy system on access to genetic resources, traditional knowledge and benefit sharing

The Law on Biodiversity No. 20/2008/QH12 promulgated on the date of 13/11/2008 ,which is the highest and most important legal document, affirmed national sovereignty over genetic resources and national responsibility for the conservation and sustainable use of genetic resources in the territory of Vietnam. The Law on Biodiversity has provided a legal basis for the conservation and sustainable development of biodiversity; established the rights and obligations of organizations, households and individuals in the conservation and sustainable development of biodiversity and developed regulations on ABS. The law also affirms national sovereignty over genetic resources and the need to promote the conservation and sustainable use of biodiversity resources as well as fair and equitable sharing of the benefits arising from biodiversity use, the need to protect TK and the biodiversity-related interests of people. Besides, this is also a legal document regulating the conditions for ABS, providing a separate system to protect plant varieties and conditions to protect TK associated with genetic resources. The Law on Biodiversity also establishes the mechanism for ABS, regulates PIC requirements from different stakeholders, and provides registration and licensing for access to genetic resources. The law requires that the registration of a license to access genetic resources must be certified by the local People's Committee. In order to ensure PIC, fulfill national obligations of CBD and international agreements to which Vietnam is a member, the Law on Biodiversity also requires the establishment of MAT between suppliers and users of genetic resources and related TK as well as the negotiation and signing of MAT (Article 57). The order and procedures are regulated: 1. Access registration; 2. Sign contracts in writing on access to and benefit sharing with organizations, households and individuals who are assigned to manage genetic resources; and 3. Apply for an access permit.

Vietnam has joined the Nagoya Protocol of CBD since 2014. In order to implement the Law on Biodiversity and enforce the obligations of the Nagoya Protocol, Vietnam has developed and strengthened the policy system and legal documents on ABS; and strengthened the capacity of national focal points (NFPs) and NCAs on ABS. On 12/5/2017, Decree No. 59/2017/ND-CP was promulgated, which governs the management of access to genetic resources and benefit sharing from the use. This Decree outlines the scope, subjects for access and benefit sharing, order and procedures, information, and reports. On 11/9/2019, Circular No. 15/2019/TT-BTNMT regulated the organization and operation of the Appraisal Committee's Regulations, which govern the granting of license to access genetic resources for commercial research and product. Circular No. 10/2020/TT-BTNMT on 29/9/2020

regulated the reporting forms on ABS; Circular No. 07/2020/TT-BNNPTNT on 22/5/2020 regulated the organization and operation of the Appraisal Committee's Regulations on granting license to access on genetic resources for research for commercial purposes and to develop commercial products under the licensing authority of the Ministry of Agriculture and Rural Development (MARD). Besides, access to genetic resources and benefit sharing are still a new and complex issues that requires comprehensive understanding in many fields. Therefore, in order to support stakeholders in implementing ABS regulations, a number of management documents and related documents have been developed such as: a scheme on fee collection for appraisal of dossiers for granting licenses to access genetic resources; Handbook of typical models of access to genetic resources and benefit sharing in the world and Vietnam; Leaflets briefing information on access to genetic resources and benefit sharing for different user groups (management agencies, national and international research agencies, enterprises). In addition, in order to promote the controlling role of the IP management agencies in the management and use of genetic resources, and to integrate ABS issues in the development of legal documents on IP, the Intellectual Property Office (NOIP) is taking the lead in developing the draft amendment to the IP Law, consulting with stakeholders to propose an additional mandatory requirement for disclosure of the origin of genetic resources/TK in the patent registration policy.

It should be emphasized that ABS regulations apply to genetic resources in Vietnam, including wild or farmed species, through access direct to genetic resources or indirectly to genetic material from genetic resources. Clause 2, Article 3 of the Law on Biodiversity clearly states: "Genetic resources include all species and genetic specimens found in nature, protected areas, biodiversity conservation units, scientific and technological research units and in nature". For cultured species, exotic species must undergo management if they are introduced into Vietnam. The ABS rules focus on research and development activities that include access not only to genetic resources but also to derivatives of genetic resources. To clarify this scope, Decree 59 provides a definition for "utilization" as interpreted from the Nagoya Protocol. The legal framework regulating the access to related TK and benefit sharing from its use is still in the early stages of development. Based on the legal framework of ABS, Vietnam has prioritized capacity building for stakeholders, especially the National Focal Points (NFPs) on ABS and National Competent Authorities (NCAs) to effectively enforce the Biodiversity Law and the Nagoya Protocol.

The system of organization of state management agencies on access to genetic resources, traditional knowledge and benefit sharing

The responsibility of state management for biodiversity is currently assigned to MONRE by the Government. Ministries and ministerial-level agencies, within their duties and powers, implement the state management of biodiversity as assigned by the Government. According to the decentralized mechanism, People's Committees at all levels implement the biodiversity conservation in their localities (Article 6, Clause 2-4, Law on Biodiversity). Each ministry often organizes into

functional departments and divisions at the provincial and district levels, carrying out its tasks and executing state management functions through an administrative and functional framework.

Currently, MONRE is NFP for implementing multilateral environmental conventions and treaties, including CBD and the Nagoya Protocol. The Nature and Biodiversity Conservation Agency (BCA) under MONRE is assigned to the state management of biodiversity. The BCA is the Government's representative agency in developing the national mechanisms and programs for ABS implementation in Vietnam, including promoting the implementation of ABS agreements in accordance with the Law on Biodiversity and Decree No. 65/2010/ND-CP, which regulates details and guides a number of articles of the Law on Biodiversity (Decree 65). In the field of ABS, the BCA is responsible for license granting access to priority species for protection, managing the national database on biodiversity, developing and implementing ABS regulations as required by the Nagoya Protocol and coordinating ABS activities among relevant stakeholders.

MARD is assigned responsibility for forest management (in addition to responsibilities for other sectors) through the activities of the Forest Protection Department, including the national protected areas management of special-use forests on land and marine areas with administrative areas located in two or more provinces, central cities (Article 9, Clause 2, Decree 65). The Center for Plant Resources under MARD is the NFP of the national network on the conservation of plant genetic resources. This center is responsible for researching, collecting, preserving, documenting, and utilizing plant genetic resources, including wild plant species.

MOST is responsible for the state management of science and technology activities, development of scientific and technological potential, IP, standards, measurement and quality control. MOST is the implementing agency of the national program on *ex-situ* conservation of genetic resources and coordinates activities on conservation of genetic resources in the country. MOST is also responsible for guiding the registration of TK copyrights and issues related to national genetic resources.

The Ministry of Health (MOH) has been assigned by the Government to be the NFP for the implementation of the National Program on the development of medicinal plants up to 2020 and a Vision to 2030. The purpose of this program is to ensure the production of goods to meet market demand for medicinal herbs, the production of raw materials, and the diversification of production from medicinal plants to ensure safety and quality, to meet domestic and export demand; encourage investment in the development of medicinal plants. MOH implements this Program through the Institute of Medicinal Materials.

At the local level, People's Committees at all levels play an important role and are responsible for biodiversity conservation management. Vietnam currently has 63 provinces and cities with about 698 districts and more than 11,000 communes. Provincial People's Committee is the state administrative authority that has responsibility for guiding and implementing the regulations, guidelines and policies of the Government with the District People's Committee and the Commune People's

Committee, including the development and implementation of programs for local socio-economic development and nature conservation. Regarding the responsibility of local authorities for biodiversity, the Provincial People's Committee is responsible for "investigation, statistics, inventory, assessment of the current status of biodiversity, establishment of the mechanism for sustainable development of the natural ecosystem and determining the location and area of wetlands on the map of land use status or coordinates on the sea surface" (Article 35, Clause 3, Law on Biodiversity). Related to ABS, People's Committees at all levels play an important role in institutionalizing ABS frameworks, negotiating and monitoring ABS agreements, and granting licenses to access genetic resources for species not on the priority list for conservation.

Regarding to ABS, in order to support the implementation of national regulations, a system of NFPs, ABS licensing authorities and check-points has been established. MONRE is the NFP to implement the Nagoya Protocol, which is responsible for: (i) Implement unified management of activities of granting, renewing and withdrawing licenses to access genetic resources; (ii) Being as a focal point to provide and exchange information with the CBD Secretariat through the ABS Clearing-House in compliance with Nagoya Protocol; take a lead to develop the national report on the implementation of the Nagoya Protocol in Vietnam; recommend and propose the implementation and organize the implementation of the decisions of the Conference of the Parties to the Nagoya Protocol according to the Government's assignment; coordinate and organize the implementation of the country's obligations under the Nagoya Protocol; (iii) Coordinate with other countries in implementing measures to comply with the Nagoya Protocol applicable to Vietnam's genetic resources abroad; organize the implementation of bilateral and multilateral international cooperation activities on access to genetic resources and benefit sharing (Article 5, Decree 59). Regarding NCAs, Decree 59 assigned the MONRE, MARD as NCAs to grant, extend and revoke permits. access to genetic resources. In particular, MARD is responsible for granting, renewing and revoking licenses to access genetic resources of plant varieties, livestock breeds, aquatic breeds and forestry plant varieties. MONRE is responsible for granting, renewing and revoking licenses to access genetic resources for the remaining cases (Article 6, Decree 59). The check-points help to check and monitor the enforcement of ABS regulations, Article 22 of Decree 59 has introduced reporting requirements, whereby the MONRE and MARD have the authority to request parties to report on the implementation of access to genetic resources and benefit sharing. MONRE, MARD and Commune People's Committees are assigned tasks related to genetic resources management during the access licensing process as well as after its issuance. The Commune People's Committee bears the responsibility of certifying the ABS contract (Article 11, Decree 59), thereby aiding the competent authorities in the licensing process for managing access to genetic resources. Besides, the Commune People's Committee is also assigned to supervise the implementation of access to genetic resources and related activities by organizations and individuals that have been licensed to access genetic resources in the commune (Article 26, Clause 6b, Decree 59). In addition, it is also important to establish check-points that are agencies with relevant

roles and functions such as customs offices and patent offices in Vietnam, which will help NCAs continue to monitor the use of genetic resources by accessors after a permit has been issued. The functions of NCAs would be difficult to do without the establishment, operation and support of checkpoints. This will contribute to strengthening the ABS management system comprehensively and effectively at national and international levels.

After four years of implementing Decree 59, ministries and sectors have issued 10 licenses to access genetic resources. MONRE has granted two licenses for commercial purposes and product development, and six licenses for non-commercial purposes. Additionally, MARD has issued more than 70 decisions to permit the transfer of genetic resources abroad for non-commercial study and research (https://vietnamabs.gov.vn/danh-muc-da-cap-phep/).

Activities to strengthen capacity, monitoring, raising awareness, education and research

In order to implement effectively ABS management regulations, stakeholders need to focus on capacity building, including: (i) NCAs (MONRE and MARD) and relevant agencies at central level (MOST, MOH, etc.), provincial, district and commune levels (Provincial People's Committees, districts, communes, Departments of Natural Resources and Environment, Department of Science and Technology, Department of Agriculture and Rural Development, Division of Forestry, etc.); (ii) Accessors/user (research institutes, enterprises, etc.); (iii) Suppliers (people, communities, some facilities, centers for conservation of genetic resources, management boards of protected areas, etc.). In the past, Vietnam has engaged in various activities:

- Needs assessment and capacity building program development: Conduct surveys, assess the current status, identify needs for capacity building, and raise awareness of various target groups at the central and local levels. On that basis, complete the training program, strengthen the capacity of relevant target groups, training content/materials, funding, and implementation time.

- Conduct surveys on conservation, and research agencies with activities related to ABS such as the Nha Trang Oceanography Institute, Mekong Delta Rice Research Institute, Ngoc Linh Ginseng Research and Development Center, Can Tho University, the Ninh Thuan Oriental Medicine Association and the management boards of national parks and protected areas in some provinces such as Lao Cai, Kon Tum, etc., on accessing and collecting genetic resources; disseminate and guide facilities to apply the relevant current legal documents to ABS management.

- Organize and implement capacity building activities on ABS: (i) Organize training courses on ABS in the North, Central and South regions with hundreds of participants who are officials of NCAs, national parks, nature reserves, experts, researchers, and university lecturers who have activities related to ABS. The training courses focused on providing trainers with an overview of ABS, enhancing their skills in negotiating ABS contracts and implementing the rights and obligations associated with ABS participation. About 200 participants from research institutes, universities and more than 100 officials from central and local

authorities, national parks and protected areas have been trained; (ii) Organize a workshop entitled "Legal framework on access to genetic resources and benefit sharing and implementation practices", to help strengthen capacity through updating the international legal framework related to sustainable use of genetic resources and implementation of national ABS regulations; exchange and share experiences in the application of ABS in the world and Vietnam; introduce the best practices of ABS Contract negotiation and keep informed on new ABS-related issues being discussed internationally; (iii) Organize a technical workshop to promote the ABS implementation at research institutes and universities. Participants are researchers and lecturers working for research institutes and universities related to ABS activities; (iv) Exchange and share experiences on biodiversity conservation and management of access to genetic resources and benefit sharing; set up an electronic information exchange portal system on management of access to genetic resources; inspect and supervise access to genetic resources; and enhance education on biodiversity conservation and environmental protection for the target groups of pupils and students and consider them mandatory requirements in the study program.

Regarding the sharing mechanism of the NFPs on ABS information, in recent years, Vietnam has focused on implementing a number of activities to promote the establishment and operation of the ABS website, and at the same time, launch coordination with the consulting units to develop information and data dossiers on the genetic resources of Vietnam. Specifically, a number of activities have been implemented: (i) Building and operating the ABS information website of Vietnam at http://www.vietnamabs.org.vn/ which provides and updates information on relevant regulations in this field, guiding the registration process and procedures for granting permits to access genetic resources and transfer genetic resources abroad for non-commercial study and research purposes, supporting online the guidance of licensing registration; (ii) Establishing a network of managers, researchers and experts on access to genetic resources and benefit sharing with nearly 200 members. The establishment of the network is in order to strengthen the capacity of relevant staff at the NFPs, NCAs and other relevant organizations to be updated regularly on ABS in Vietnam and internationally and to exchange and share experiences on ABS implementation. Participating in the network, experts have received publications on ABS and participated in workshops and trainings in related fields.

To carry out activities to raise awareness of ABS among related target groups, Vietnam has collaborated with relevant stakeholders to: (i) Develop a communication program to raise awareness of ABS among specific target groups; (ii) A series of activities to respond to the International Day of Biodiversity on 22/5, in which the Partnership Forum on Biodiversity was successfully organized on 22/5/2019 in Quang Ninh province with the participation of delegates from ministries, sectors, international organizations (UNDP, JICA, USAID, GIZ) and relevant research agencies and experts. The forum has recognized many positive comments as well as initiatives to coordinate management to increase efficiency in biodiversity conservation; (iii) Make reporting on conservation management of genetic resources; (iv)

Introduce the database of genetic resources and TK of Lao Cai province and guide the use and update of information and data on the database; (v) Support Ta Phin Commune People's Committee to organize a program to raise awareness of the local community and implement a pilot model on natural resource conservation by means of propaganda and visual communication through the system of banners, panels, posters, through the system of radio and educational propaganda in schools; (vi) Organize a photo contest on biodiversity, contributing to raising awareness and responsibility of the community on nature and biodiversity conservation (Reports of the ABS Project, MONRE, 2019-2021). Activities such as capacity building, monitoring, awareness raising, education and research need to be further implemented and scaled up.

PIC, MAT measures on access to genetic resources, benefit sharing and traditional knowledge protection

Within the framework of the ABS Project, Lao Cai province was selected to develop and implement a pilot model on ABS: Producing new products from indigenous natural materials and conserving genetic resources; PIC/MAT processes and community protocols; protecting TK.

- Establishing ABS agreements (MAT), in which the company (SapaNapro Company) had researched, developed and produced new product, Dao'Spa Red Dao Massage oil, from knowledge of using medicinal plants/remedies for pain relief among the Dao and H'mong people in Ta Phin commune, Sa Pa district, Lao Cai province (Figure 1). Benefits obtained from the commercialization of products are shared with local people in two forms: (i) A 7-year benefit-sharing contract was signed between SapaNapro Company and nine local healers of Mong and Dao people - are the ones who provide knowledge about medicinal plants/ remedies for pain relief as the initial basis for product research and development: The group of healers received 1.5% of the total annual gross sales of the Product. In case the that company transfers the technology producing the product to a third party, the group of healers will receive 2% of the total transfer value that the Company receives annually ; (ii) Contract for access to genetic resources and benefit sharing between SapaNapro Company and groups/households that grow and collect raw medicinal plants: After the product is researched, completed and commercialized, the Company (Accessor) shares benefits in cash equivalent to 1% of revenue earned from production and trading activities as of December 31 of each year to related parties (0.5% for households (Suppliers) and 0.5% is remitted to the state budget at the People's Committee of Ta Phin commune for conservation and sustainable use of biodiversity in the locality). In case the Company transfers the results of research, franchising or production technology of Products arising from the accessed genetic resources to a third party, the Company will share the benefits in cash equivalent to 2% of the total annual transfer value. These contracts were developed according to the sample forms specified in Decree 59, negotiated, agreed upon and signed between the parties, with the confirmation of the People's Committee of Ta Phin Commune. Currently, SapaNapro Company has submitted an application to MONRE for a license to access genetic resources (PIC) for commercial research and commercial

product development (Reports of ABS Project, MONRE, 2019-2021).

Currently, the management of access to genetic resources, related technology, and benefit sharing is relatively new both globally and in Vietnam. The ABS experience is still limited in globally and by country. Under the first officially approved ABS agreement in our country, Ta Phin implemented the pilot model of public-private partnership on access to genetic resources with related TK and benefit sharing. It is highly valuable for agencies, policymakers, and relevant stakeholders to adopt and replicate this model, implementing similar activities in various localities across the country. This effort contributes significantly to the management, sustainable exploitation, equitable sharing, and sustainable use of genetic resources in our country.

Figure 1. Dao'Spa Product (massage oil for pain refief).

- Conduct the documentation of TK in Lao Cai, building community protocol: (i) Develop a database of genetic resources and related TK in Lao Cai province: Develop the software to manage information, data on genetic resources and related TK in Lao Cai province (compatible with the National Biodiversity Database System in Vietnam); Analyze, review and evaluate the current status of existing information, data on genetic resources and related TK of Lao Cai province from the carried studies, the tasks implemented by the relevant units/authorities from central to local; Develop and standardize survey forms to collect general information by subject on genetic resources (Plant genetic resources include agricultural plants, forestry plants, medicinal plants,animal genetic resources include livestock and wild species, and

aquatic genetic resources); Genetic resources with high economic value or use value; Genetic resources with potential for exploitation and development related TK; Collect and synthesize information and data on genetic resources and related TK of Lao Cai province, including surveys, additional investigations, and updating information and data on genetic resources and TK related to genetic resources in conservation and sustainable use of valuable genetic resources in Lao Cai province, especially in the area of Sa Pa district, Hoang Lien National Park; (ii) Documenting the TK of herbal remedies in Ta Phin commune: Organize meetings to learn, exploit and record remedies from artisans in the community; Synthesize and group the collected remedies; take portraits, make certifications of medicine providers; Conduct a field survey of medicinal plants in the community; Create a link to compare medicinal plants with the recipes shared by the artisans and the community; Edit roughly of collected medicinal plants (Image, Name: scientific, popular, local; description; distribution; effects; usage of medicinal plants...). Up to now, the expert group has collected and recorded over 100 herbal remedies from artisans and communities in Ta Phin commune. These herbal remedies focus on the treatment of a number of diseases: bones and joints; skin diseases; digestion; respiratory; fever, high fever, cold. The editing and publication of the handbook will contribute to conserving and preserving TK knowledge and serve as reference material for utilizing available natural genetic resources in the daily healthcare practices of the indigenous community of Ta Phin commune. Additionally, it will support and collaborate with the People's Committee of Ta Phin commune and consulting units to develop and issue a protocol on the conservation and sustainable use of genetic resources in the pilot forest area of Ta Chai village, Ta Phin commune: This protocol is a community-developed document, which aims to establish general rules within the community. Its main purposes include ensuring the rights and benefits of people in using and managing land/forest resources based on respect for community protocol and state laws. Moreover, it aims to protect and develop genetic resources, conserve natural forest ecosystems, native plant varieties, and water sources, ensuring the livelihoods' safety of local people. It also aims to preserve and develop the resources of rare indigenous medicinal plants, maintain traditional values and indigenous knowledge, contribute to community healthcare and forest protection, and increase income from forests.

- Implement measures to conserve genetic resources, create long-term livelihoods for local people as well as supply raw materials for ABS agreements: Conduct the survey and investigation of the land fund; Assess the distribution and stock of medicinal plants on the land area of households (if any) and in the community forest area; Organize meetings with the Mong and Red Dao communities in Ta Phin to establish units/groups to plant, collect and supply raw materials for product production; Meetings of established units/groups to plant, collect and supply raw materials so they can register the type of trees and the planting area for each tree; Develop the seed supply and material area development plan; Develop a nursery to propagate medicinal plants at the Sa Pa Indigenous Products Trading Joint Stock Company.

- The registrative activity of product protection related to TK was piloted, in which the Ta Phin community built a dossier of registration of a trademark certificated for

herbal bath products of the Red Dao people in Ta Phin commune. On 30/3/2021, the National Office of Intellectual Property issued Decision No. 25410/QD-SHTT on approval the valid registration applications of the People's Committee of Ta Phin Commune; Develop a community protocol on conservation and sustainable use of genetic resources in the protection forest area of Ta Chai village, Ta Phin commune, Sa Pa town, Lao Cai province. The registered trademark "Herbal bath of the Red Dao community in Ta Phin" will contribute to protect the medicinal plant resources and TK of the Red Dao people in Ta Phin commune, Sa Pa, and to promoting the Herbal bath products as local characteristics and traditions in order to increase people's incomes, create jobs and be the basis for the development of tourism in the locality.

On the basis of these pilot activities, lessons learned in accessing and sharing benefits from the use of TK, usage practices and protection of TK in the community have been concluded; A financial mechanism has been established to re-invest revenue from ABS agreements for the conservation and sustainable use of biodiversity (Reports of the ABS Project, MONRE, 2019-2021).

Thus, in order to comply with and implement the Nagoya Protocol as well as strengthen the country's capacity for access to genetic resources and sharing benefits, Vietnam has developed a legal, policy and institutional framework on access to genetic resources and benefit sharing, nominated national focal points and national competent authorities, and conducted the license granting on access to genetic resources. Besides the achievements, the management of access to genetic resources and benefit sharing, and the protection of TK related to genetic resources in Vietnam still have limitations. The assessment of challenges and consideration of causes and impacts are the basis for identifying tasks, solutions and priority actions by 2030 for effective management of the country's genetic resources.

The shortcomings and limitations of management on access to genetic resources, benefit and related traditional knowledge sharing in Vietnam

Although Vietnam has made achievements in the development of a legal, policies and institutional system on ABS. The ABS legal framework also has many shortcomings and limitations such as the lack of specific regulations on TK associated with genetic resources and the lack of mechanisms for receiving and distributing benefits after sharing. Some provisions of the Law on Biodiversity were out of date at the time of promulgation of Decree 59 which caused conflicts and difficulties in enforcement. For example, in compliance with the Law on Biodiversity, the procedure for applying for an access permit has to require certification from the Commune People's Committee, so Decree 59 stipulates this step, making it more complicated. The handling of violations resulting from non-compliance remains unclear, and the capacity of competent agencies is still limited. Objects using domestic genetic resources for commercial purposes do not comply with ABS legislation. These limitations prevent relevant parties from implementing ABS regulations, implementing sustainable and responsible trade, and implementing social and environmental protection measures that Vietnam has recognized and committed to adopting in free trade agreements. The goal of conservation and sustainable use of

biodiversity has not been achieved (Reports of the ABS Project, MONRE, 2019-2021).

Shortcomings on legal documents as well on practical implementation of access to genetic resource and benefit sharing

Scope of application: According to the Law on Biodiversity, the definitions of "genetic resources", "access to genetic resources" are very broad, indefinite and unclear, so it is difficult to determine which activities fall under the scope of regulation of ABS and to distinguish ABS activities from other activities related to genetic resources. Decree 59 has more clearly defined the scope of regulation to be compatible with the Nagoya Protocol through the definitions of "derivation" and "use of genetic resources". However, Decree 59 does not clearly stipulate the registration of access and licensing, ABS contracts for derivatives of genetic resources and without access directly to genetic resources. In the absence of an access permit or an ABS contract, the Decree also does not provide for a benefit sharing agreement. Thus, for the case where access to derivatives only or access to genetic resources had been completed before the Law on Biodiversity was invalid but the usage is still continued, Decree 59 does not have provisions for adjustment.

To ensure the nation's interests, as well as create favourable conditions for users, Decree 59 needs to be amended and supplemented to address these issues. If the scope of regulation includes derivatives, or extends to Vietnamese genetic resources in overseas collections, it should not be mandatory for all cases to sign a contract with one of the four authorized entities who are assigned on the management of genetic resources, to have registration and licensing of access before benefit sharing is required. Suppliers can be identified as national competent authorities who are representative of the supplier in case the supplier is not identified or can accept benefit sharing without having to restart all procedures. Decree 59 does not specify a list of activities to use genetic resources within the ABS regulation scope of the Decree that must be registered and applied for a license, but is specified in the guidance document on the implementation of Decree 59.

Both the Law on Biodiversity and Decree 59 have not regulated the DSI on genetic resources. This content has different views on whether it is within the scope of the Nagoya Protocol or the DSI management mechanism to protect the rights and interests of suppliers, but it still facilitates and promotes research and information exchange among scientists. However, according to the assessment report of the Strategic Framework for Capacity Building and Development to Support the Effective Implementation of the Nagoya Protocol in the Post-2020 Period published by the CBD Secretariat on 25/3/2020, the DSI on genetic resources has been identified to play an important role in ABS and is one of the most common new capacity building needs that need to be prioritized.

For TK, the new Biodiversity Law provides a general definition and regulation of copyright protection for genetic resources. Decree 59 also does not contain regulation scopes for TK. Thus, the content of TK can be supplemented/ adjusted in legal documents or revised or newly issued guidelines.

Suppliers of genetic resources: The genetic resource supplier participates in ABS by negotiating and signing an ABS contract

with the accessor/ user. For the "suppliers" which are organizations, households or individuals, an important basis for determination is the right to use land, forest and water surfaces where genetic resources are located. The supplier of genetic resources is regulated by the four groups of subjects mentioned above. This limitation made it difficult to identify the supplier. For example, the genetic resource is in the oversea collection or the accessor cannot keep the supplier's information, they have not been contacted by the supplier, and have not identified the genetic resources.

License granting of access to genetic resources: A license to access genetic resources is identified for non-commercial research purposes, commercial research purposes; and commercial product development. The granting of a license to access genetic resources for commercial purposes must be approved by the Appraisal Committees to review the dossiers for an access license as regulated in Circular 15/2019/TT-BTNMT and Circular 07/2020/TT- BNNPTNT. However, the organization and operation of these committees are formal and administrative, which can prevent effective management of access to genetic resources, especially when the number of applications is increasing.

Decree 59 has separate regulations for Vietnamese students, graduate students and Vietnamese science and technology organizations that want to transfer genetic resources abroad (Article 20). Currently, this dossier accounts for the majority of dossiers at national competent agencies. If the number of these dossiers continues to increase, it may cause an "overload" of administrative management, so the option of authorizing the review and licensing of relevant state institutions in science and technology should be considered.

The validity of the access license can be decided by the national competent authority based on the proposed target and access plan to genetic resources in the dossier, but it should not exceed 3 years. The license to access genetic resources can be extended for an unlimited number of times (Article 17, Decree 59). The 3-year period is considered too short period of time, while the procedure for granting a license to access genetic resources is lengthy.

Conditions for license granting: To obtain a license to access genetic resources, organizations and individuals must fulfill the requirements outlined in Article 8 of Decree 59. These include registration with the national competent authorities, signing ABS contracts with suppliers, obtaining certification from the Commune People's Committee, and submitting a complete dossier as required by the national competent authority. Genetic resources that pose risks to people, the environment, national security, or national interests are prohibited from access under Article 59, Clause 4 of the Law on Biodiversity. Regarding the requirement for foreign individuals and organizations to collaborate with Vietnamese science and technology organizations to access genetic resources, shortcomings have been identified that necessitate adjustment and modification.

According to Article 3, Clause 3 of Decree 59, the NCA may issue a license to identify an organization, household, or individual managing genetic resources as a supplier for the benefit of the country and the community. However, the phrase 'benefit of the nation and the community' is not explicitly defined in the Law on Biodiversity or Decree 59.

Regarding IPRs, the registration of innovative results derived from the use of genetic resources must clearly indicate the source or origin of the accessed genetic resources and comply with the obligation of benefit sharing (Article 22, Clause 2, Decree 59). However, there is currently no mandatory control mechanism for registering IPRs related to innovations derived from the use of genetic resources and their derivatives.

The issue of benefit sharing from the use of genetic resources: Vietnam's ABS regulations identify two types of benefits from the use of genetic resources: Monetary and non-monetary (Article 21, Decree 59). Regarding monetary benefits, Decree 59 specifies that the monetary benefit from a product derived from genetic resources shall not be less than 1% of the total annual revenue of that product. The share of monetary benefit to the supplier, when obtained through the transfer of genetic resources or their derivatives, or the use of IPRs based on genetic resources, shall not be less than 2% of the total transfer value or total revenue from the use of IPRs (Article 22). However, currently, there is no guidance on implementing the financial aspects of Decree 59, which includes challenges such as paying the license application fee or receiving monetary benefits. It is also difficult to directly channel shared monetary benefits into the state budget or through state financial institutions due to the lack of specific regulations. Therefore, it is necessary, appropriate, and feasible to develop guidelines and utilize the Environmental Protection Fund to receive revenues from ABS activities for biodiversity conservation and community development. Furthermore, the issue of sharing benefits for local communities, especially non-monetary benefits, has not been adequately addressed for communities in the buffer zones of protected areas. These communities, while not assigned as managers of genetic resources, play a crucial role in biodiversity conservation. For non-monetary benefits, consideration should be given to converting them into a percentage of the total revenues that users can retain from utilizing the accessed genetic resources.

Shortcomings of policy and institutional and organizational system of state management agencies

At the national level, biodiversity in general and ABS in particular are being managed by MONRE and MARD. The management is conducted under the forestry, fishery and agriculture sectors under MARD rather than under MONRE according to the Law on Biodiversity. Decree 59 has regulated MARD and MONRE to be two NCAs to grant, renew and revoke licenses to access genetic resources. In particular, MARD is responsible for granting, renewing and revoking licenses to access genetic resources of plant varieties, livestock breeds, aquatic breeds and forestry plant varieties. This management system leads to scattered resources, inconsistent policies, a lack of centralization and difficulties and inefficiencies in implementation. At the national level, the BCA under MONRE has the task of developing ABS implementation mechanisms and programs in Vietnam, including promoting the implementation of PICs and MATs in accordance with the Law on Biodiversity and related Decrees. However, the system of specialized authorities, roles and responsibilities for management, organization and implementation of corresponding activities at

provincial and local levels have not been clearly established and demonstrated.

Shortcomings on legal documents and practical implementation of traditional knowledge

Regarding TK associated with genetic resources, Vietnam's policy is clearly stated in the Law on Biodiversity: "Encouraging and guaranteeing the lawful rights and interests of organizations and individuals to invest in, apply scientific, technological advances and TK to biodiversity conservation and sustainable development (Article 5, Clause 3). The State protects the TK copyright on genetic resources, encourages and supports organizations and individuals to register TK copyrights on genetic resources. MOST shall assume the prime responsibility for, and coordinate with concerned ministries and ministerial-level agencies in, guiding procedures for registration of TK copyrights on genetic resources (Article 64). The benefits obtained include the distribution of intellectual property rights for innovation results on the basis of access to genetic resources and TK copyright on genetic resources shared with the State and related parties (Article 58, Clause 3i and Article 60, Clause 2c). However, as analyzed in the global status section, the protection of TK is an issue that is being debated. TK is historical, is the living knowledge that is developed, maintained and transmitted from generation to generation in a community, and form a part of the cultural or spiritual identity of the community. Therefore, it is not easily protected by the current legal system of IPRs (which usually grant patent protection limited to the inventions and original products of specific individuals or organisations). In addition, "traditional" knowledge is not easy to define. Therefore, the provisions of the Law on Biodiversity on TK in Vietnam are difficult to implement in practice. The regulation only "protects copyright" and shares benefits only on the basis of the "copyright" approach and has no provision to define the rights and interests of local communities.

Decree 59 also limits "management of access to use and benefit sharing from the use of genetic resources" and does not include TK. However, the Decree requires that MONRE provide detailed instructions on accessing TK associated with genetic resources and sharing benefits from the use of TK (Article 26). This is the basis for developing feasibility regulations on TK in compliance with the Biodiversity Law as well as revising the provisions of the IP Law related to genetic resources and TK.

Recommendations for management of access to genetic resources, traditional knowledge, and benefit sharing in Vietnam

Based on the analysis of the current situation and the inadequacies of policies, laws, and institutions as well as experiences and implementation in practice on access to genetic resources, TK, and benefit sharing, some of the following activities are recommended to be implemented or continue to be implemented in the period to 2030 in order to strengthen the management of access to genetic resources, TK, and sharing of benefits:

The legal system: Continue to consolidate and complete the legal documents on ABS, specifically: (i) Define clearly and appropriately "genetic resources", "access to genetic resources", "use of genetic resources"; (ii) Regulate reasonably the

procedures for licenses granting access to genetic resources (PIC), cancel the steps, requirements for dossiers that are inefficient and impossible and licensing regulations for special cases; (iii) Supplement with the mechanisms of TK management and benefit sharing for local communities; (iv) Regulate and implement the benefit sharing from genetic resources accessed before the effective date of the Decree; Especially consider issuing specific guidance on financial mechanisms to receive benefit sharing; Financial mechanism for the protection of TK associated with genetic resources; (v) IP protection for TK aims to protect the economic rights (preventing others from commercializing their knowledge) and the spirit rights of holders of TK. The commercial exploitation of genetic resources and TK will bring economic benefits to those assigned to manage and hold them, as well as generate income for the community for the development and conservation of genetic resources and TK.

The institutional and organizational system of state management agencies: (i) Decentralization, clearly identified details and responsibilities for state management of biodiversity in general and ABS in particular; (ii) At the national level, the identification of responsibilities is clear and easy to implement among NCAs; Strengthen cooperation between NCAs and NFPs, contributing to the effective implementation of the legal framework on ABS; (iii) At the local level, strengthen the roles and responsibilities of biodiversity management, genetic resources and TK, as well as strengthen the organization and implementation of biodiversity and ABS management at the provincial level; (iv) Assign and authorize some stages of ABS administrative management to competent research institutions; (v) Strengthen the enforcement capacity of ABS competent authorities; (vi) Establish checkpoints/controls that are state management agencies with relevant roles and functions, such as customs offices, patent offices, to effectively supervise the use of genetic resources and TK related to genetic resources.

Policies: (i) Continue to consolidate and complete the policy system on biodiversity and ABS, including policies on awareness raising, education and training; policies that contribute to mainstreaming the use of TK into the protection, development and rational use of resources. For example, many local communities are associated to the forest, living mainly depend on the forest, so there is a very diverse system of TK related to forests, the implementation of the policy of land and forest allocation to the community will help contribute to bring the perceptions and activities of indigenous people in the traditional way into the protection, development and rational use of forest resources; (ii) Encourage, reward and recognize the titles of folk doctors and community doctors for those who have made great contributions to disease treatment; The title of folk artisan, etc. for those who keep many TK values of the indigenous people; (iii) Implement initiatives on policies and mechanisms to encourage the changing behavior (for managers and the community).

Implementation and enforcement: (i) Develop and replicate the implementation of ABS pilots, which include TK related to genetic resources in localities and countries. The ABS pilots include activities such as: Screening genetic resources and accessed TK to research and develop into commercial products and gain benefits; Documenting TK; Access to genetic resources and related TK; Production of new products from

indigenous natural materials; implementing PIC and MAT procedures; Conservation of genetic resources; Registration to protect the related products; (ii) Implement sanctions to handle violations of laws related to ABS; (iii) Strengthen law enforcement, including community supervision.

Research and development: (i) Continue to carry out systematic research investigations, collections, store and preservation of the updated, highly reliable information on genetic resources and related TK in Vietnam; (ii) Screen and increase the amount of genetic resources and access TK for research and development into commercial products and get benefits; (iii) Build and develop databases on genetic resources, including the digital sequence database (DSI), and TK treasures, with fields of information that are compatible/appropriate to the international database to support the management, use and protection of genetic resources and TK associated with genetic resources; (iv) Provide and share the available synthesized information and data on open databases on genetic resources and TK for managers, scientists, the community, etc. to support effective management of national biodiversity; (v) Share of information, national databases, and integration into international databases, e.g. species records in the Living Planet Index database, and records of the presence of marine species on the OBIS.

Making decisions for effective management of biodiversity: (i) Implement measures to exploit information on TK, initiatives and best practices in decision making for conservation, development and rational use of resources; (ii) Identify the appropriate, effective and sustainable genetic resources and TK; To combine the rational use of genetic resources, TK and scientific knowledge in local socio-economy-cultural - environment development projects, with a focus on female.

Regarding education and training: (i) Complete the policies on education, training and raise awareness on biodiversity; (ii) Develop and implement the education, training, dissemination and awareness-raising programs for sustainable development, including gender equality and human rights, as well as issues related to biodiversity, genetic resources and TK; Teaching and training programs for relevant groups of subjects (with emphasis on teacher training and student assessment) are applied at all levels, suitable to the specific conditions of each locality and the traditional culture of indigenous peoples and local communities (with emphasis on spoken languages and the number of indigenous peoples); (iii) Through various forms of communication and dissemination for people to understand the value of biodiversity, genetic resources and TK; Investigate the biodiversity understanding of visitors at the zoo and aquarium.

ACKNOWLEDGEMENT

The study is carried out with support from the World Wide Fund for Nature (WWF) and the Department of Nature Conservation and Biodiversity (BCA) - Ministry of Natural Resources and Environment. The report is made in the form of a legal document review, a secondary document study, and stakeholder consultation. The results of the report serve to review relevant issues in the context of Vietnam in association with global goals and Vietnam's ability to perform tasks.

We thank the experts invited to consult and the expert groups of WWF as well as BCA,

especially Vuong Quoc Chien and Hoang Thi Thanh Nhan, for providing information, sharing documents and providing comments on the manuscript. We also thank the American people through the United States Agency for International Development (USAID) for financial contribution to this work.

DISCLAIMER

This report is made possible by the generous support of the American people through USAID. The contents are the responsibility of author and do not necessarily reflect the views of USAID or the United States Government. The views expressed in this report do not necessarily reflect the policies or positions of WWF Vietnam.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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