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THE INTERFACE BETWEEN ACCESS AND BENEFIT-SHARING RULES AND BIOTRADE

IN VIET NAM



UNITED NATIONS

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Acronyms and Abbreviations

| | |
|--------------|--|
| ABS | Access and benefit sharing |
| ASEAN | Association of Southeast Asian Nations |
| BCA | Biodiversity Conservation Agency |
| BIG Viet Nam | BioTrade Implementation Group Viet Nam |
| BL 2008 | Biodiversity Law of Viet Nam of 2008 |
| BTFP | BioTrade Facilitation Programme |
| CBD | Convention on Biological Diversity |
| CITES | Convention on International Trade of Endangered Species of Wild Fauna and Flora |
| CRED | Centre for Rural Economic Development |
| FAO | United Nations Food and Agriculture Organization |
| GIZ | (Deutsche Gesellschaft für Internationale Zusammenarbeit) German Agency for International Cooperation |
| GR/GRs | Genetic Resource/s |
| IP | Intellectual property |
| IPRs | Intellectual property rights |
| ITPGRFA | International Treaty on Plant Genetic Resources for Food and Agriculture |
| IUCN | International Union for Conservation of Nature |
| MAT | Mutually agreed terms |
| MARD | Ministry of Agriculture and Rural Development of Viet Nam |
| MOH | Ministry of Health of Viet Nam |
| MOIT | Ministry of Industry and Trade of Viet Nam |
| MONRE | Ministry of Natural Resources and Environment of Viet Nam |
| MOST | Ministry of Science and Technology of Viet Nam |
| NIMM | National Institute of Medicinal Materials |
| PIC | Prior informed consent |
| PPC | Provincial People Committee |
| SECO | State Secretariat for Economic Affairs (Switzerland) |
| SIPPO | Swiss Import Promotion Programme |
| TK | Traditional knowledge |
| UEBT | Union for Ethical BioTrade |
| UNCTAD | United Nations Conference on Trade and Development |
| VACNE | Viet Nam Association for Conservation of Nature and Environment |
| VEA | Viet Nam Environment Administration |
| VIETRADE | Viet Nam Trade Promotion Agency |
| VIMAMES | Viet Nam Material Medical Society |
| VND | Vietnamese Dong |
| WHO | World Health Organization |
| WIPO | World Intellectual Property Organization |
| UNCTAD | United Nations Conference on Trade and Development |
| US\$ | United States Dollar |

EXECUTIVE SUMMARY

Viet Nam has enjoyed strong economic growth in the last 25 years. In fact, its GDP per capita growth has been among the fastest in the world averaging between 6.4 and 6.7 per cent annually since the 2000s. By the same token, the World Bank reports that about 30 million Vietnamese live close to the poverty line – that is about a third of the population being classified under the “poor” or “near poor” groups. A majority of the members of these groups are farmers, indigenous communities and those whose livelihoods depend on biodiversity. Obvious impediments of poverty aside, the same groups of people are also the most vulnerable to shocks from climate change, natural disasters as well as economic and health shocks.

In 1994, Viet Nam became a member of the Convention on Biodiversity (CBD). By being a Party to the CBD, Viet Nam had pledged to mainstream biodiversity considerations and sustainable use of biological resources (including equitable sharing of benefits from their use) in its policy-making agendas. Recognizing that biodiversity conservation and sustainable development cannot be successful without the participation of the poor, the Biodiversity Law of 2008 (BL 2008) was envisaged as a legal instrument which could integrate pro-poor principles and involve biodiversity holders at the grass roots level. Coupled with the Decree No. 65/2010/ND-CP (jointly, “the Regulations”), which details implementation procedures for the BL 2008, the Government attempted to put in place legislative and administrative measures which, from the findings of this report (see III.B Snapshot: Viet Nam’s national ABS regulatory framework from p. 7), are still unclear with respect to certain definitions and legal aspects-related access and benefit-sharing (ABS) and the demarcation of ministerial assignments relating to the State management of genetic resources’ (GRs) giving rise to impractical implementation of the Regulations. In addition, the Regulations put in place so far do not provide tools for compliance and enforcement (e.g. a national database for GRs and TK) which creates an arbitrary mechanism for sharing benefits and ambiguous roles of stakeholders in the ABS process. Overall and in consideration of the Regulations being legal instruments pre-Nagoya Protocol (Protocol), the provisions intended to satisfy the CBD requirements are too general to be functional and provide inadequate interpretation of the ABS rules while being compounded by the lack of supporting mechanisms to be applicable in practice. The subsequent entry into force of the Nagoya Protocol in 2014, Viet Nam’s consequent ratification of it and the growing impact of the Protocol domestically and internationally entail that the country is faced with a greater challenge to comply with the ABS rules and make them workable if it were to achieve its own sustainable development objectives.

On the back of these policy and administrative integration challenges, UNCTAD BioTrade, in collaboration with the Biodiversity Conservation Agency of Vietnam, Helvetas - Viet Nam and the recently created BioTrade Implementation Group (BIG Vietnam) and with the support of SECO Switzerland, has demonstrated a slow but steady rise as a bolster for sustainable development through trade and investment in biological resources in keeping with the objectives of the CBD and the Protocol. Although in legal terms, ABS and BioTrade are subtly different (see V Access and Benefit-Sharing rules and the BioTrade approach from p.25), these two concepts converge in a manner that BioTrade fortifies implementation of the ABS Regulations, and the Regulations become the enabler and promoter of BioTrade as a viable livelihood option for various actors in the value chain, especially the local and indigenous communities. The BioTrade Principles and Criteria particularly: Principle 3 (on fair and equitable sharing of benefits, Principle 5 (on compliance with national and international regulations and Principle 7 (on clarity of access rights and prior informed consent) give the means to its practitioners, albeit indirectly, to comply with the ABS Regulations.

Through the promotion of sustainable sourcing and use of biological resources e.g. medicinal and aromatic plants for trade, and distributing benefits fairly (monetary and non-monetary) and equitably sharing the benefits with the communities and the actors involved in the value chain, BioTrade practitioners are also able to comply with the benefit sharing principle of the Protocol (See V.C Synergies, Implementation and Lessons Learned on p. 25). Also, through its capacity development programmes coupled with the sensitization of ABS rights, local communities (stakeholders) are able to take part in the value addition, commercial and trade activities. Through this process, the communities play an active role in the negotiation of the mutually agreed terms (MATs) and are able to give Protocol compliant Prior Informed Consent (PIC). Essentially, since its inception in Viet Nam and despite the existing challenges noted in this report, BioTrade has proven itself as a working model on ABS compliance. Its preliminary projects results have created the basis for its long term development in the country.

The current revision and improvement of ABS Regulations in Viet Nam so that they are not only aligned with the definitions and obligations under the Nagoya Protocol but are also bespoke, clear and detailed legal instruments to incentivise both biological and genetic resource users and providers could close the gaps on the interaction of ABS and BioTrade. In the spirit of the principle of sovereignty of the State, such adaptation could prove to be an opportunity for Viet Nam to resolve how best it could regulate BioTrade activities vis-à-vis overseeing ABS through its legislative and administrative approaches. Subject to the extent of modification of the Regulations' clarity, scope and flexibility, BioTrade may fall under the Protocol and ABS rules which are of mandatory nature. However, it must be noted that the BioTrade achievements, in terms of the coverage of its Principles and Criteria, only provide, on voluntary basis, the minimum standard required by the ABS rules under the CBD and the Protocol. BioTrade projects and activities in the country will therefore still be largely dependent on the national programmes as guided by the revised ABS Regulatory framework, supportive administrative practice and technical assistance.

Finally, in order to promote a BioTrade-friendly implementation of the Nagoya Protocol and potentially introducing some BioTrade-related provisions in future and revised ABS regulations, this study provides a series of recommendations and proposals for the consideration by policy makers and regulators in Viet Nam. These recommendations do not only apply to Vietnam alone but they could also serve as a blueprint for other biodiversity-rich countries in the Mekong region as they share common challenges and opportunities, biological and genetic resources, traditional practices and communities.



I. INTRODUCTION

Located in the Indo-Burma Biodiversity Hotspot (IBBH), Viet Nam is ranked as the 16th most biodiversity-rich country in the world. It is home to more than 42,900 identified species, nearly 14,000 of which are recognized species of flora, 11,000 marine species and a remarkable number of rare endemic species. The Mekong River which boasts the world's largest inland fishery - accounting for up to 25 per cent of the global freshwater catch and providing livelihoods for at least 60 million people flows south through Viet Nam to the Mekong Delta, nicknamed the "rice bowl" of Viet Nam. With its abundant indigenous plant varieties, livestock breed, medicinal plants, herbs and associated traditional knowledge, it is unsurprising that Viet Nam's biodiversity has a crucial role in contributing to sustainable livelihoods over many generations through the provision of food security and health care, especially for local people living in remote areas who are directly dependent on resources exploitation.

With the growing concern about threats to its biodiversity, the Government of Viet Nam has introduced measures for its protection, conservation and development through the creation of national policies and implementation of international conventions and protocols it has signed up for post-Convention on Biological Diversity ("CBD"), one of which is the Nagoya Protocol ("Protocol"). Two years after it became a Party to the Protocol in April 2014, the Prime Minister issued Decision No. 1141/QĐ-TTg on 27 June 2016 approving a national scheme spanning from 2016 to 2025 to strengthen the government's management capacity of access to genetic resources and fair and equitable sharing of benefits arising from their utilization. To this effect, the Ministry of Natural Resources and Environment ("MONRE") was designated to coordinate with other related ministries and agencies in the drafting of a new decree to implement the Protocol, particularly on access and benefit sharing ("ABS") that will enhance the existing national legal framework. Such legal instrument aims to establish ABS systems that will define the way in which genetic resources can be accessed and how the benefits resulting from their utilization can be shared among users, providers and other related stake-holders as well as yield (maximum) benefits to users and providers, contribute to ecosystem conservation and support the livelihoods

of communities located where the genetic resources are found or accessed.

Historically, Viet Nam's commitment to sustainable use and conservation of its biodiversity dates back to 1995 when it ratified the CBD and launched its first National Biodiversity Action Plan (NBAP 1995) in the same year. Among its Prioritized Activities (within the framework of NBAP 1995) was to "promote international cooperation for biodiversity conservation by way of appealing to international organizations, foreign governments and individuals to provide technical and financial support and staff training to realise biodiversity action plans."¹ By 2003, the BioTrade concept was introduced in Viet Nam via UNCTAD's BioTrade Initiative ("BioTrade"). The intervention aimed to provide technical assistance to support partners to develop specific sectors of biodiversity products and services through a broad range of trade promotion tools. Such tools operate on BioTrade's concept of fostering activities of collection, production, transformation, and commercialization of goods and services derived from native biodiversity (genetic resources, species and ecosystems) under the criteria of environmental, social and economic sustainability. Between 2012 and 2014, BioTrade worked in close partnership with Helvetas Viet Nam to implement the project "The development of value chains for natural ingredient products." This project's key objective was for Viet Nam to be acknowledged internationally as a recognized supplier of natural ingredient products that were CBD compliant and as guided by the BioTrade Principles.

Nevertheless, in the face of the manifest linkages between Biotrade and ABS principles, there is a practical challenge for stakeholders to determine how BioTrade can adopt the mandatory ABS principles under the Protocol and how the implementation of certain aspects of the Protocol will impact BioTrade businesses and activities. On this account, UNCTAD through the BioTrade Facilitation Programme III (BTFP III) is working to develop policy options for the implementation of the Protocol on Biotrade, pitching towards ABS systems that are supportive of BioTrade activities. In line with this undertaking, UNCTAD offered technical support to countries, of which Viet Nam was a beneficiary. During the course of technical support, Viet Nam was provided a review of their national regulation on BioTrade-related issues, an in-depth analysis of the status of BioTrade and ABS in the country, and face-to-face training for interested stakeholders.

This report (i) identifies and explores main regulatory challenges in Viet Nam, (ii) addresses issues of concern and policy options to develop in response to (i), (iii) assesses the country's national competent

authorities' ABS frameworks supportive of BioTrade, and finally (iv) considers the outlook for businesses and other relevant stakeholders in line with the new obligations under the Nagoya Protocol in Viet Nam.



II. OVERVIEW

A. Viet Nam's biological resources

Aside from Viet Nam's global importance for its natural biodiversity, the country is also well known for its seemingly inexhaustible agro-biodiversity. Its rich repository of genetic resources (GRs) has played a critical role in the country's economic development in recent years, notably in the agriculture, forestry and fishery sectors. Moreover, the unprecedented development of biotechnology, pharmaceuticals and cosmetics industries and trade has generated additional benefits for the country and its people. Indisputably, the GRs (and their associated traditional knowledge if any) are one renewable resource which can be considered as a key driver to attain Viet Nam's sustainable development objectives and a replacement for the current exploitation of non-renewable resources such as coal, oil, gas and minerals in Viet Nam.

B. Genetic resources

Vietnam has an abundant and diverse, but relatively unknown, flora. According to the "Flore Générale de L'Indochine", the country has more than 7,000 plant species, 1,850 genera and 290 families. Of these, 64 genera and 2,084 species are endemic. The NBAP 1995, estimates that there are about 12,000 plant species in Vietnam (7,000 of which have been named).

One excellent example of GRs diversity in Viet Nam is rice (*Oryza sativa*), one of the most widely consumed staple food in Asia (and the rest of the world) and the most important and most abundant GRs in Viet Nam. The Mekong Delta, home to 17 million Vietnamese, yields more than half of Vietnam's rice production and a third of its GDP - this is owing to the quality of soil and abundance of water supply in the region. The National Plant Gene Bank (belonging to the Plant Resources Center, Vietnam Academy of Agricultural Sciences) currently preserves 6,000² varieties of local rice. One example, of a versatile rice GR is the aromatic Jasmine rice, which can be grown in other countries in temperate zones. The Cuu Long Delta Rice Research Institute maintains 1,800 samples of traditional rice and 160 samples of wild rice from Southern Viet Nam.

Other sources of abundant GRs is the forest which in total contributed US\$ 2.4 billion to the economy in 2011

(approximately 17 per cent of the GDP),³ are 20,000 terrestrial and aquatic flora species which includes 150 protein tree species, 130 fruit tree species, 100 oil tree species, 90 fiber tree species, more than 1,000 wood tree species, 3,850 plant species used for medicine, and several hundred cosmetic tree species. There are more than 12,000 plant species in the forests, among which, there are 7,000 species belonging to 1850 lines of 267 angiosperm families. About 2,300 forest tree species are used for food, medicine, animal feed, or materials for national timber requirements purposes.

The GRs of domestic fauna also have significant economic value in Viet Nam⁴. As an example, endemic Mong chickens brought, on average, breeding benefits of 3 billion VND (about US\$ 134,336) to each village and 4 million VND (about US\$ 179,115) for each village's household. Viet Nam is also a center of primate genetic diversity. Primates in the country comprise 25 species and sub-species belonging to three families, of which several are endemic, facing extinction, vulnerable or are of high-value.⁷ These include: Tonkin snub-nosed monkey, golden-headed langur (Cat Ba langur), black langur, stripe-headed black langur (Hatinh langur), Delacour's langur, and the white-rumped black langur. All these are listed in the Red Data Book of Viet Nam as threatened with extinction. By 2007, the total number of endangered wildlife species is 882, including 418 animal species and 464 plant species, which is 161 species more than that in the period 1992-1996⁸. Currently, 28 per cent of total animal species, 10 per cent of birds, and 21 per cent of reptiles and amphibians are at risk of extinction.

C. Traditional Knowledge associated with GRs

To date, the use of traditional knowledge (TK) with medicinal plants by way of traditional medicine or oriental medicine contributes significantly to the available treatment options for many people in Viet Nam, both in rural and urban settings. It is an integral part of the national health care system in that a majority of the population uses the traditional knowledge for treating common health problems as it is widely believed that medicinal plants produce no or few side effects than that of the medicines available commercially. Viet Nam is home to an estimated 12,000 species of high-value plants, of which 10,500 have been identified, and approximately 3,780, or 36 per cent of which, have medicinal properties. Vietnamese medicinal plant species account for

approximately 11 per cent of the 35,000 species of medicinal plants known worldwide. This figure is artificially low as there are many medicinal plants species (ethno-medicine plants) whose properties are not yet generally known and are used only by ethnic minority groups in the country who make up 14 per cent of the total population.

In Viet Nam, the wealth of TK in traditional medicines is used not only to cure common ailments, but is also in combination with modern medicines to treat other more serious diseases. The Ministry of Health confirms that about 30 per cent of patients receive medical treatment alongside traditional medicine. Indeed, the last 50 years has shown that there has been a growing resurgence of traditional medicine use in Viet Nam. At first sight, this may seem favourable to patients, practitioners and users of TK in traditional medicine. However, as the demand for medicinal plants rapidly increases and they are accessed and appropriated indiscriminately, hundreds of thousands of tons of raw medicinal materials are exploited from wild plants. Consequently, the great commercial benefit such demands create could pose a threat to biodiversity through poor agricultural practices coupled with over-harvesting of the genetic resources for herbal medicines and other natural health care products. These practices, if not regulated, may lead to the extinction of endangered species and the destruction of natural habitats and resources. Recently, Viet Nam has started importing (mainly from China) more than 80 per cent of the raw materials it uses.

Traditional knowledge (particularly medicinal) associated with GRs is not well protected (if at all) by Viet Nam's intellectual property (IP) system. In effect, the rights and interests of the indigenous and local communities who are the holders of relevant TK are not taken into consideration when for example a new drug is invented out of the exploitation of the TK associated with GRs.

Despite being a party to the CBD since 1994, establishing stand-alone laws on ABS and incorporating administrative structures in the process,

the Nagoya Protocol on ABS remains a novel concept in Viet Nam. Legal obligations, if any, are based on the parties' bargaining power during the negotiations and not on operationalizing ABS in practice. Consequently, parties (especially the GR providers) to the agreements relating to the access and use of genetic resources and their associated TK are not able to fully benefit from the provisions of the Protocol. More often, the providers' participation during the course of and within the development of value chain(s) is limited to the stage where ownership of the materials is transferred to the user (access stage). Users take no account of the provider's rights and their obligations to share benefits under the Protocol. Another issue is the lack of awareness of the ABS provisions. Most notably, the indigenous and local communities who provide their TK have remained unaware of its value and their legal rights over them; hence – the inability to provide informed consent, negotiate fair and agreeable terms and require equitable compensation relating to such rights. The collection of GRs for research and development (R&D), and commercialization attracts foreign as well as national organizations and individual users. The extent of the loss of GRs to unauthorized collections is unknown, as is the scale of the benefits the country could have enjoyed, had it been aware and able to claim them.

Making the Vietnamese ABS issues more complex is the fact that the country is not a party to FAO's International Treaty on Plant Genetic Resources for Food and Agriculture (IT PGRFA). The Protocol takes into consideration that there are other existing 'specialized instruments' relating to plant GRs and to steer clear of overlapping legislation on them, Article 4 of the Protocol purports that materials covered by 'specialized instruments' like the ITPGRFA would not be within the scope of its ABS rules. Consequently and in light of national ABS regulations in Viet Nam, plant GRs for food and agriculture (including those consumed as food) will be in principle covered by the Nagoya Protocol as the country is not yet part to IT PGRFA as a specialised instrument. This does not preclude, however, that Viet Nam developed special rules for these resources due to their particular nature.

III. NAGOYA PROTOCOL ON ACCESS AND BENEFIT SHARING: STATUS IN VIET NAM

Viet Nam's rapid population growth, the compelling requirements for socio-economic expansion, and other direct or proximate processes with immediate impacts on biodiversity, such as deforestation, GRs degradation and alarming increase of protected species in the country's Red Data Book, regulation of use of biodiversity has never been more crucial. The ABS concept was introduced in Viet Nam in the 2000's but the government have yet to establish an effective management tool. The Biodiversity Law 2008 ("BL 2008") incorporates provisions on ABS (see Access and Benefit Sharing rules and the BioTrade approach: An overview, from p.42) and a masterplan for capacity building on ABS is underway since 2015.

A. Implementation Strategies

In addition to its national implementation strategies, the Vietnamese government also have access to global funds set up by developed countries to support their emerging counterparts to improve the implementation of the Protocol, update their existing national ABS regulatory regimes, contribute to biodiversity conservation, alleviate poverty and improve the livelihoods of local communities. Resources from such funds can also be used to raise awareness on the

Protocol and its national implementation, the values and potential benefits of GRs, TK and the importance of biodiversity conservation.

In this regard, Viet Nam has been working with international organizations and projects to raise awareness on the importance of biodiversity and to improve the existing regulatory systems that governed it for some time. The list below includes some of the projects that have contributed to Viet Nam's current systems and level of awareness on the importance of its biodiversity and their sustainable use:

- Building legislation on access to plant GRs (2000-2001) implemented by the Viet Nam Association for Conservation of Nature and Environment (VACNE) with the Ministry of Science, Technology and Environment (MOST) as supported by the International Development Research Centre of Canada;
- Capacity building for the development of a legislation on ABS (2002-2004) implemented by Viet Nam Environment Administration (VEA), MONRE, MOST, VACNE, International Union for Conservation of Nature (IUCN) and German Agency for International Cooperation (GIZ);
- Projects under the framework for the implementation of the National Action Plan for Biodiversity (1996-2005) implemented with various international partners with a budget of US\$ 13 billion.
- Several projects implemented by MONRE seeking to put in practice the BL 2008 including a project of



VACNE, IUCN, a project implemented by Institute of Strategy and Policy on Natural Resources and Environment and a background paper on theory, practice and recommendation for the ABS management regime from 2009-2010

- Collaboration of international organizations, several communities, companies, research institutions to develop and improve the stakeholders' working knowledge on ABS when they consider accessing GR for research projects on plant varieties, breeding, cosmetic and pharmaceutical products.

However, despite the above endeavours, social survey results identifying national priorities for ABS capacity building in 2013 showed that:

1. Access to GR had been taking place for a long time but the government authorities were unable to put in place a management system that could regulate it;
2. There was no official GRs and TK database that could enable systematized monitoring;
3. Many GR users were not aware of their responsibilities to obtain licenses to access GR, and negotiate and implement the MATS;
4. The complicated situation of the State's management of GRs resulted in the Protected Areas Management Boards' lack of understanding of their authorities and responsibilities;
5. ABS-related activities of the communities were unprompted, weak and seasonal, and were concentrated to some GRs that are known to have a high market value;
6. The Government's management authorities' knowledge about ABS concepts/issues was limited; and
7. The awareness of the communities on ABS issues was inadequate if not minimal.

Since becoming a Party to the Protocol, the Biodiversity Conservation Agency (BCA) has carried out a number of projects⁹ for (i) capacity building, (ii) enhancing of the national legal system and (iii) raising awareness related to ABS in Viet Nam:

1. The ASEAN Centre for Biodiversity ("ACB") project on "Building capacities of countries in support of the development and implementation of National ABS Frameworks". Viet Nam, Lao PDR, and Myanmar have been selected to participate in the project. The implementation will be carried out through collaboration between the UNEP Regional Office for Asia and the Pacific and ACB. The project aims at providing technical support to

countries for developing national ABS regulatory and institutional frameworks and piloting initiatives to implement the Nagoya Protocol on ABS for selected ASEAN Member States. The project has a strong focus on promoting regional cooperation, knowledge sharing and learning on ABS within ASEAN Member States and China.

2. UNDP-GEF project on "Capacity Building for the Ratification and Implementation of the Nagoya Protocol on Access and Benefit Sharing in Viet Nam". The project uses a non-refundable aid of over US\$ 2 million from the United Nations Development Programme (UNDP) via the Global Environmental Fund (GEF). This four-year project was implemented in Hanoi and the province of Lao Cai. The project supported the establishment of a comprehensive legal, regulatory and administrative framework in full compliance with the Nagoya Protocol in Viet Nam. Capacity at different levels of the government was strengthened to improve understanding and implementation of the national ABS regime. Specific experiences and demonstrations at the local level was also conducted to guide the application of ABS principles in Viet Nam and support sustainable use of genetic resources.
3. Collaboration with Bio Trade project of Helvetas' to develop a training material for ABS.
4. Activities under the BTFP III with UNCTAD. This study together with the revision of the Decree and draft Circular, as well as training workshops and national consultations that took place in June 2016.

A survey by questionnaire was also undertaken showing that:

- Domestic GR users are mainly institutes, research centers, and universities in agriculture, forestry, breeding, aquaculture and medicine;
- Foreign GR users on the other hand, tend to be institutes, research centers, universities, international organizations under the cooperation projects of countries such as Korea, China, Japan, Russia, France and Sweden, among others;
- Accessed genetic resources are mainly plants for food, industrial and medicinal (for example: *Oryza Sativa* L. (Asian rice), *Solanum tuberosum* (potato), *Ipomoea batatas* (sweet potato), *Canna edulis* (edible Canna), *Colocasia esculenta* (L.) (taro), *Manihot esculenta* Crantz (cassava), *Glycine max* (L) (soybean), *Vigna radiata* Wilczek. L. (Mung bean), *Arachis hypogaea* L. (peanut), *Gossypium hirsutum* L. (upland cotton), *Croton tonkinensis* GAGNEP

('Kho sam Bac Bo'), *Salacia cochinchinensis*¹⁰, and *Salvia miltiorrhiza* (red sage). Accessed GRs also included those from animals and microorganisms;

- The objectives of access to GRs mainly are for research and development finding new compounds, collection and exchange, technology transfer, databases, and trainings;
- The authorities that allowed the access to the GRs were: MARD, MOIT, MOST, the Vietnam Academy of Science and Technology, and the Viet Nam Rubber Group;
- Benefits from corporations for accessing GRs were mainly capacity building, exchange of knowledge, trainings, finding new compounds for development of medicines, financial support for research, as well as sharing of information.

The numbers of applications for access to GRs that have been submitted to the Biodiversity Competent State Agencies are increasing gradually. This is an indication that there has been enhanced awareness of the ABS concepts and implementation of the Nagoya Protocol and ABS regulatory in Vietnam. A summary of these ABS cases are provided in an Annex to this report.

B. Snapshot: Viet Nam's National ABS Regulatory Framework

This section introduces the existing ABS regulations and laws applicable in Viet Nam, notably: the 2008 Biodiversity Law No. 20/2008/QH12 (BL 2008) and the Decree No. 65/2010/ND-CP on Detailed Regulations and Guidelines for Implementation of some Articles of Biological Diversity Law pursuant to the Nagoya Protocol and the CBD.

The BL 2008 includes provisions on biodiversity conservation and sustainable development, as well as rights and obligations of organizations, households and individuals dealing with biodiversity. Decree No. 65/2010/ND-CP details and guides the implementation of a number of articles of the Biodiversity Law, including those on access and use of GRs. Together, they are referred to as the "Regulations" in this report.

i. Genetic resources and their legal status

The CBD and the Nagoya Protocol confirm the principle of sovereign rights over GRs but do not expressly specify who owns them. The default position therefore is that the States enjoy such sovereign rights and have the jurisdiction to regulate the licenses and the contracts relating to access and conditions of use of GRs.

Exercising this sovereign right, the Biodiversity Law of Viet Nam provides that *"The State uniformly manages all GRs in Vietnamese territory"* (Article 55.1). This confirms the State's representation and management of all GRs in the national territory on behalf of the Vietnamese people, essentially, assuming a guardian position to the management of the Vietnamese people's resources per Article 53 of the 2013 Constitution of the Socialist Republic of Viet Nam:

"Land, water resources, mineral resources, resources in the sea and airspace, other natural resources, and property managed or invested in by the State are public property, owned by all the people, and represented and uniformly managed by the State."

To exercise this overall representation and management role fully, the State assigns organizations and individuals to manage GRs with specific rights and responsibilities under Article 56 of the Biodiversity Law and Article 18 of Decree No. 65/2010/ND-CP. The GR "managers" are as follows:

1. Management boards of protected areas or organizations: management of GRs in protected areas;
2. Heads of biodiversity conservation facilities, scientific research and technological development institutions, GR storage and preservation establishments to manage their own GRs;
3. Organizations, households and individuals assigned to manage or use land, forests or water surface to manage GRs assigned to them;
4. Commune-level People's Committees: to manage GRs in their localities¹¹

By legal doctrine on property ownership, rights may be classified as tangible, corporal or intangible. In the case of GRs, there may be a basis for distinction between the rights over the physical entity (physical property of the resource) and over the genetic information that the resources contain (intangible property).¹² This intangible property aspect of the property represents the real value of the resources, and is where legal implications are particularly complex.

"The material and geographic aspects of a GR pose an extraordinary challenge because most living organisms reproduce and disperse naturally, irrespective of restrictive measures that policy makers wish to lay on them, carrying out into the world the very qualities that bioprospectors and users are seeking rights and provider countries are seeking to control. This biological fact is compounded by the elusive nature of information as valued added: information, even

when derived from biological resources, is intangible and therefore requires a special property regime.”¹³

However, the concept of ownership per usual does not tend to distinguish between ownership of the tangible and intangible elements of the GR.

A further complication may arise when dealing with cases of access and/or use of TK associated with GRs. While GRs are, by law and general practice, managed by the State, there is no specific provision stating the same for TK in Viet Nam. In other words, while a GR involves tangible and intangible property rights that belong to the people of Viet Nam, TK is purely an intangible property that may belong to an individual person, communities or an undetermined owner such as folk knowledge or be publicly owned TK. State may define rights over TK, however it must be borne in mind that holders of that knowledge already have possession and customary law rights over such knowledge.

ii. Access to Genetic Resources in Viet Nam

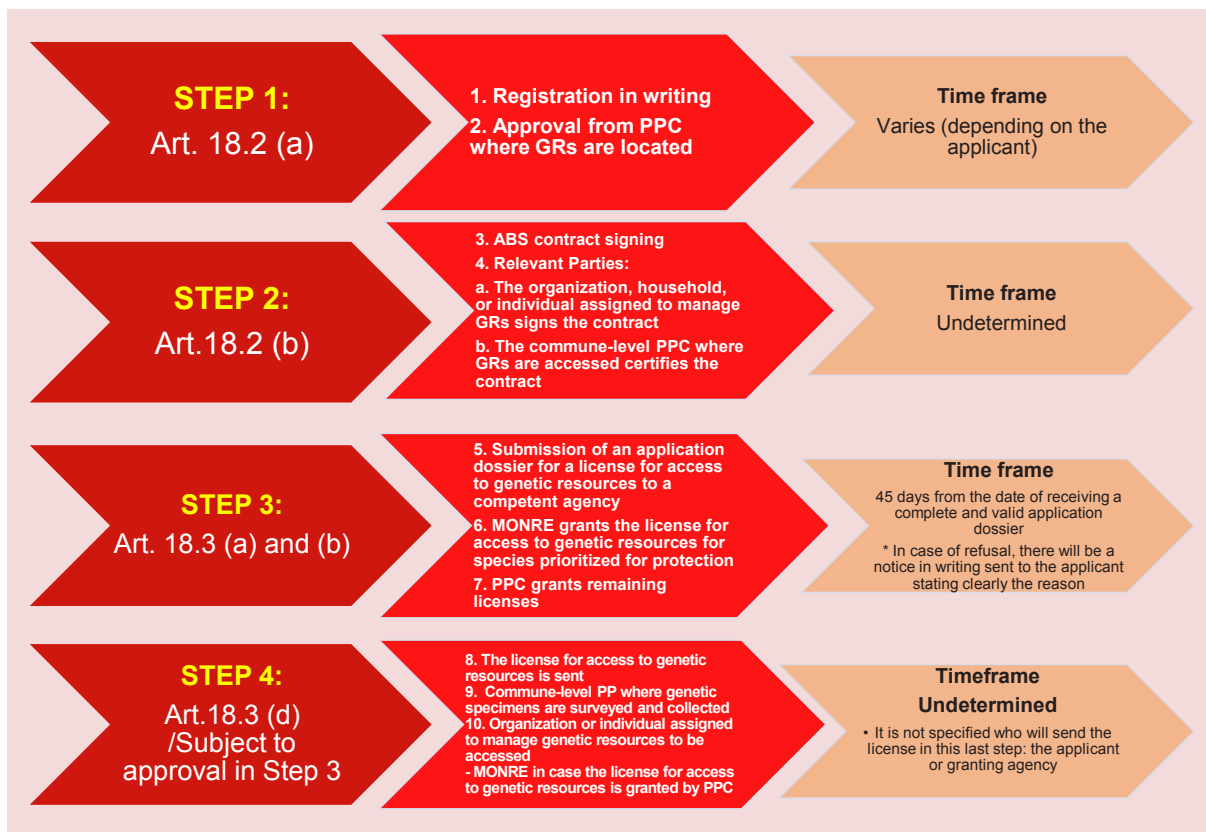
Procedures to access GRs are set out in Article 57 of the BL 2008, which stipulates three key requirements:

(i) to register the access; (ii) to negotiate and sign written contracts for the access and for benefit-sharing with organizations or individuals assigned to manage the GR; and (iii) to apply for licenses for access as provided by Article 59.

The Decree No. 65/2010/ND-CP provides more details on the procedural steps required for access. These include a written registration, signing an agreement on access and benefit-sharing for the use of the GR, submitting an application dossier to the competent national authority, and obtaining the permit. However, these provisions do not provide deadline guidelines or the relevant documents and forms required. The provisions of Decree No. 65/2010/ND-CP are too general to be applied in practice and therefore do not meet the Protocol requirements for legal certainty, clarity and transparency of domestic access and benefit-sharing legislation and for fair and non-arbitrary rules and procedures for accessing GR in a cost-effective manner and within a reasonable period of time.

Some basic steps following Decree No. 65/2010/ND-CP include:

Figure 1: The Decree No. 65/2010/ND-CP Access to GRs procedures



License granting procedures for access to GRs have proven to be complex, burdensome and difficult to fulfil in practice. This is mainly because: a) there is no distinction between accessing GRs in-situ (in nature) or ex-situ (in collections); b) there is no distinction between accessing GR for scientific research or for commercialization purposes; c) some of the management of ABS issues have been assigned to authorities that do not have sufficient capacities to carry out their obligations as provided by the Regulations (e.g. Provincial Peoples Committees). In parallel, the provisions on who has the competence for granting access licenses are not fully consistent and feasible. In this respect, below is a summary of the overlaps and/or inconsistencies in the authority and competencies between the following ministries and agencies:

A) Between the MONRE and the MARD:

- Article 18.3 of Decree No. 65/2010/ND-CP stipulates that MONRE has authority to grant permit to access genetic resources of species prioritized for protection and that the Provincial Peoples Committees (PPCs) have authority to grant permits to access genetic resources for the remaining species. However, there are conflicts with the MARD's authority and competence that make this Article challenging for implementation purposes, namely:

- Species prioritized for protection under the Decree No. 160/2013/ND-CP dated Nov 12, 2013 include plant varieties and animal breeds, microorganisms and fungi under the management of MARD as provided by Article 18.2 of the Decree and in line with the Ordinances on plant varieties and livestock breeds. However, according to Decree No. 65/2010/ND-CP, the PPC is responsible for granting access to these GRs.

- Decree No. 82/2006/ND-CP dated August 10, 2006 on management of export, import, re-export, introduction from the sea, transit, breeding, rearing, artificial propagation of endangered, precious and rare wild fauna and flora species, provides that MARD is responsible to grant license for import, export, re-export of these species. While according to Decree No. 65/2010/ND-CP, MONRE is responsible for granting access to GR of these species and it is not clear whether the license for access to GRs under ABS regime can be replaced by the export license under the Decree No. 82/2006/

ND-CP or not.

- For wildlife, the competence for granting licenses is more clearly defined, with species prioritized for protection (excluding plant varieties and livestock breeds and for commercial purposes) falling under the responsibility of MONRE following the Decree No. 160/2013/ND-CP. However, the Ministry has difficulties in implementing the licensing as stipulated above because most of the protected areas are currently under the management of MARD and PPCs.

B) Among MONRE, The Departments of Natural Resources and Environment (DONRE) and the PPCs: the decentralization of licensing responsibilities to the PPC seems to be impractical and unrealistic.

The competency for granting access licenses to the remaining GRs is assigned to the PPCs but, according to the State's vertical management hierarchy, the MONRE is assigned to license access to GRs. The DONRE is assigned by the PPC to exercise the power of licensing to access to remaining GRs. However, the capacity of the DONRE is extremely limited to management of biodiversity in general and GRs in particular. In addition, the DONRE have no full time staff specialized in biodiversity who possess comprehensive understanding and knowledge of the Biodiversity Law.

C). Unclear demarcation of management between the MONRE and the MOST:

In many cases of ABS, access to GRs cannot be separated with TK associated with GR.¹⁴ The BL 2008 says that TK copyrights are protected by the State. The State encourages and supports organizations and individuals to register their TK copyrights.¹⁵ However, the authority for the management of TK copyrights is assigned to the MOST¹⁶. There is currently no cooperation between the MOST and MONRE with regards to this matter making it onerous to register TK IPRs as there is no facility to manage licensing access to GRs and TK.

This difficulty may be addressed if copyrights (or similar IP tool) applications are dealt with at the MONRE. This may be done at the same time with granting permit for access to GRs. There is no specific provision that responsibilities should be done by MOST only, hence considering MONRE to play a crucial role in this process would not be against the legal and administrative processes of the country.

Article 58 of the BL 2008 states the mandatory requirement that ABS contracts must include: i) Purpose of accessing the GR; ii) details of GRs to be accessed and volume of genetic resources to be collected; iii) Place of access; iv) Plan for access; v) Potential transfer of the results to a third party; vi) Planned activities of R&D or production of commercial products using GRs; vii) Participants in R&D or production of commercial products using the GRs; viii) Place for conducting R&D or production of commercial products using the GRs; ix) Sharing of benefits with the State and related parties, including benefits from the intellectual property rights over inventions resulting from the accessed GRs and any related TK. Without further guidance than what has been provided in Article 58, it will be difficult to prepare and implement an ABS contract in practice since communities and local people, who are the GRs suppliers, usually have a limited capacity and knowledge about ABS issues and have minimal or no experience in negotiating and signing a contract protecting their own interests. It is then necessary to have a sample contract and practical guidance for dealing with ABS-related agreements that follow the national legal requirements and ensure that there is a fair and equal distribution of benefits from the access and use of GRs.

The BL 2008 does not contain provisions on trade intermediaries supplying GRs for overseas users. The Regulations do not distinguish between domestic and overseas users either. In any event, a distinction between these two users is quite complex in practice. In a globalized setting, companies and business entities tend to have more complex and elaborate ownership. As an example, a national company in Viet Nam may act as a supplier of raw materials for companies abroad that may be undertaking R&D and foreign-owned companies may also have branch offices or have been incorporated in Viet Nam. In all these cases and in many other potential ones, the differentiation between local and foreign companies is at best perplexing.

It should be noted that as of yet, there have been no licenses nor any application of the above procedures under the Regulations from their coming into force until now. Clearly, an amendment or complementary regulations are needed to overcome the abovementioned constraints and shortcomings in order to ensure the Protocol requirements of legal certainty, clarity and transparency, as well as effective and fair procedures are satisfied.

iii. Benefit-sharing

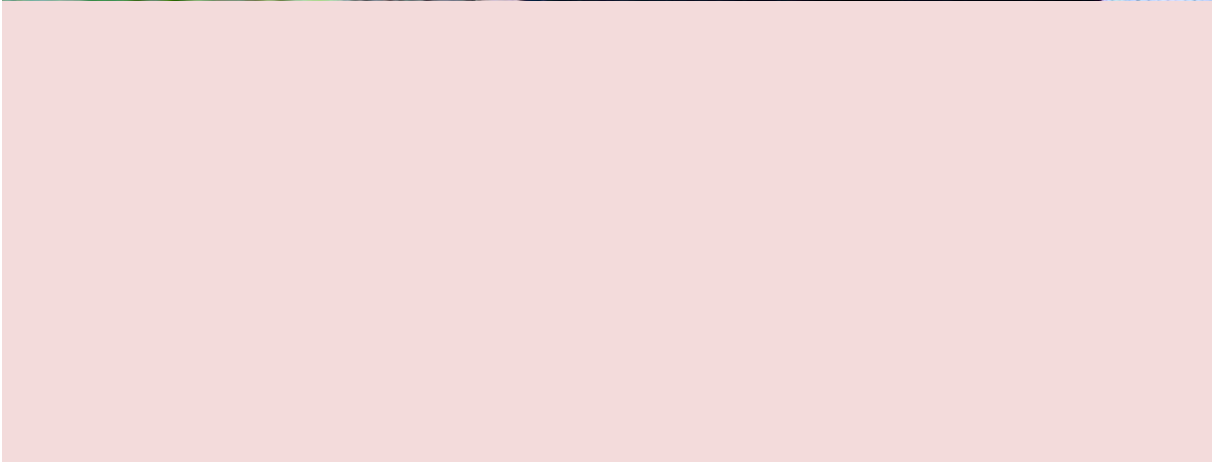
The Regulations have created a basic legal framework with minimum requirements for benefit-sharing under mutually agreed terms (MAT) that must be set out in an ABS contract. Regarding MAT, Viet Nam's regulatory regime conforms to the Nagoya Protocol, which merely stipulates that "*Each Party shall take legislative, administrative or policy measures, as appropriate...*" (Article 5.2) and requires that Parties "establish clear rules and procedures for requiring and establishing mutually agreed terms" (Article 6.3.g) without setting out any concrete requirements. In spite of its apparent conformity with the Protocol, however, it is difficult to ensure fair and equitable benefit-sharing under Viet Nam's current ABS regulatory regime. There are many serious loopholes for fair and equitable benefit-sharing that warrant a re-consideration of the Regulations and or a creation of supplementary regimes that could address the below incompatibilities with the Nagoya Protocol and other international instruments:

First of the numerous omissions regarding the Regulations is the right to benefit-sharing as provided by Articles 58 and 61 of the BL 2008, and as elaborated by Article 19 of Decree No. 65/2010/ND-CP.

Under Article 61 BL 2008, benefits arising from access to GRs must be shared with three parties: 1) the State, 2) the organizations, households and individuals who are assigned to manage the accessed GRs and; 3) the organizations and individuals that have access licenses to GRs (GRs users) and related parties as determined in the licenses.

This provision does not include the indigenous and local communities who provide TK associated with the accessed GR. The indigenous and local communities are not "related parties" as established in Article 59.3 BL 2008. Article 60.2.c, however, does recognize TK provider's rights by requiring users: "*to share benefits with related parties, including the distribution of intellectual property rights over invention results based on their access to GR and copyrights of TK associated with GR*".

The same problem arises regarding the sharing of benefits with local communities, residents in buffer zones of protected areas with whom the benefits should be shared primarily in order to encourage participation in conservation and sustainable development activities and practices. The BL 2008 does not include provisions to require their inclusion in benefit-sharing contracts. In fact, Article 55.2 only



mentions the management board of the protected areas and organization assigned to manage GRs in such areas as the recipients of benefits derived from the use of GRs accessed in the area. Even though local communities may reside within or near these protected areas, they are not assigned to manage the GRs in the area and are therefore, excluded in the related benefit sharing provisions under the law. Moreover, buffer zones under the Vietnamese law are not perceived as “protected areas”¹⁷ making it more difficult to find a legal basis for their inclusion in the ABS regimes for GRs in protected areas.

Decree No. 65/2010/ND-CP provides a list of benefits that may be shared, including both monetary and non-monetary types (Article 19.1). These include: sharing the results of R&D, transferring of technology, training, strengthening of capacities, contributions to local economic development and sharing of the profits earned from the commercialization of goods produced from the use of accessed GRs, and related TK (if any).¹⁸

The Decree No. 65/2010/ND-CP also tries to quantify the percentage of total benefit to be shared by users with provider parties. Although it leaves the specific amount free for negotiation among the parties, it does establish that it must not be below 30 per cent of the total benefits that are received in cash.¹⁹ On the face of it, this provision does not seem to be feasible and is difficult to apply in practice, especially since it does not specify how to determine the total benefits in the first place, when (i.e. at which stage in the value chain) such benefits can be quantified, whether benefits arising from use from third parties also need to be shared, as well as the time of termination for the sharing of benefit shall occur.

In Latin America and Africa for example, the mandated (or contract-specified) amount of monetary benefits to be shared ranges, depending of the case, from 1 to 4 per cent of the commercial sales or the revenue from those sales. When compared to these, the figure asked for by the Vietnamese law is unrealistically high which may discourage inflow of potential businesses and investments into the country.

Although the Decree No. 65/2010/ND-CP establishes a cooperation scheme between MONRE, MARD and the Ministry of Finance to issue a joint-circular to guide the management and use of shared benefits from access to GRs, the Regulations fail to address the issue regarding what happens with the benefits that

arise from the use of GRs accessed before the entry into force of the Protocol (i.e. on 12 October 2014) and/or without access license or agreement that meets PIC and MAT requirements. Just like in many other provider countries, many Vietnamese GRs had been accessed and taken out of Viet Nam before the CBD or the Regulations entered into force. In this case, the right to benefit sharing should still apply from the continuous use of those GRs till present to ensure that such benefits are received by the State, which consequently could contribute to the national biodiversity conservation. Although, the CBD and the Protocol rules are inexplicit regarding accessed GRs prior to their entry into force, there are some country experiences and related legislation that deal with such case.

An example is the benefit-sharing rules of Japanese government stipulating that: “*Where the laws and administrative measures of the providing country regarding pre-CBD matters provide otherwise, it is necessary to comply with them.*”²⁰

iv. Treatment of traditional knowledge under the Regulations

The BL 2008 defines TK associated with GR as “*means of knowledge, experience and initiatives of indigenous and local people on the conservation and use of GRs*” (Article 3.28). It also encourages organizations and individuals to “*invest in and apply scientific and technological advances and TK to the biodiversity conservation and sustainable development, and guaranteeing their lawful rights and interests*” (Article 5.3).

However, as discussed above, provisions on ABS agreements and actors with whom benefits need to be shared with do not include the TK providers. While Article 60.2.c of the BL 2008 stipulates that benefits need to be shared with related parties, including the distribution of intellectual property rights (IPRs) over resulting inventions based on accessed TK, it only covers copyrighted TK, i.e. *benefits are only shared when the TK has recognized copyrights, otherwise, no benefit sharing may be required.* Further to this, the current regime does not provide IPRs for TK. There is only a general provision in Article 64 stating that “the State protects TK copyrights on GR and encourages and supports organizations and individuals to register TK copyrights on GR”. It also specifies that 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 GR.” Until now, the MOST has not issued any guiding procedures for registration of TK copyrights on GR yet nor is there any provision to clarify the rights and benefits of indigenous and local communities.

The registration for the copyright of TK will be difficult if not impossible to be implemented because the TK that could be protected through copyrights, related rights or industrial property rights has not yet been defined in the first place. For copyrights, and in terms of general practice, the licensing competence is assigned to the Copyright Office, an agency under the Ministry of Culture – Information (now the Ministry of Culture, Sports and Tourism). The BL 2008 establishing the MOST as the competent agency, creates an overlap of state management procedures for the registration of TK copyrights making compliance onerous and simply unrealistic.

Viet Nam is a member state of both WIPO and the WTO as well as a member of the 1995 ASEAN Framework Agreement on Intellectual Property Cooperation. In the country, IPRs are regulated in a chapter of the Civil Code of 2005 - the Law on Intellectual Property of the same year, and the Decree No. 104/2006/ND-CP of the Government on detailed regulations to implement some articles in the Intellectual Property Law, Chapter on Plant Variety Rights dated 22 September 2006. Under these regimes, some types of TK have been protected under certain intellectual property rights such as Geographical Indications, Indications of Origin such as “PhuQuoc” for fish sauce, “MocChau” for green tea, traditional medicines for Vietnamese Ginseng Ngoc Linh, and patents granted for snake bite medicines and medical oils.

Last but not the least, the question regarding who owns and eventually who should benefit from the use of TK associated with GRs in the public domain also remains unanswered. As PIC and MAT requirements are expected to apply to such GRs, another mechanism for registration is by way of applying for IP protection through copyright. Potentially, this could provide national benefits to Viet Nam as brought up by India and China during the negotiations of the Nagoya Protocol- under the presumption that the State will be the de facto representative for TK in the public domain. However, whether this direction would be taken by the State or not, the fundamental issue as to ministerial competency relating to TK (associated with GRs) becomes an intermittent hurdle for parties that intend to be compliant.

v. Compliance and enforcement

Compliance and enforcement in the implementation of ABS Regulations and practices is important to ensure that provisions on access and fair and equitable benefit sharing according to the PIC and MAT are met. In addition to providing the option of acquiring an ‘international certificate of compliance’ based on the permits issued by a competent agency at the national level, the Nagoya Protocol requires member countries to have effective and appropriate legal, administrative, policy measures to ensure compliance.

Article 59 of the BL 2008 establishes the conditions required for the competent authority to grant an access license to GRs. Such conditions are: (i) registering with a government competent agency; signing a contract for access to GRs and benefit sharing with organizations, (the management of genetic resources shall be granted to an individual and a signing a household); and not seeking for a permission to access GRs which are included in the List of endangered, precious and rare species prioritized for protection²¹, (these species are not in any case allowed by the State’s competent agency to be accessed, as well as the use of GRs potentially harmful to humans, environment, and any such use which would threaten national security and defense and is against the public interest).

A license for access to GRs must include, at least, the following information: a) purpose for using the GR; b) which GR to be accessed and the collection volume; c) location of access; d) activities to be undertaken related to the GR; e) period reports on R&D results, as well as details on any production of commercial products related to the accessed GR.

The Protocol establishes that “a permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.”²² However, minimum information must be included in an internationally recognized certificate of compliance. The information required for such a certificate²³ is different from one stipulated by the BL 2008 of Viet Nam though. An internationally recognized certificate of compliance is required to include the following:

- issuing authority;
- issuing date;
- unique identification of certificate;
- The provider (the person or entity that holds the

right to grant access to the genetic resources in accordance with domestic legislation);

- individuals and entities that have granted PIC and confirmation that the PIC was obtained or granted;
- genetic resources and their specified use (commercial or non-commercial use) that is within the scope of the contract signed;
- conditions for third party transfer; and
- confirmed negotiation and relevant signatures in MATs.

Thus, as a Party to the Protocol, Viet Nam needs to also require that its access licenses include the different elements mentioned above as provided for in Article 17.4 of the Protocol. The content required by the Protocol for the access license is appropriate and ensures the compliance with PIC and MAT.

According to Articles 59 and 60 of the BL 2008, organizations and individuals licensed to access GRs should: a) investigate and collect GRs and carry out other activities as indicated in their access licenses; b) refrain from taking out of the Vietnamese territory GRs which are on the list of those banned from export under the national law; c) trade with products made from GRs they have access licenses for; and d) other relevant rights as specified in their licenses and contracts for access and benefit sharing.

The list of GRs banned from export is under the regulation of the Decree No. 187/2013/ND-CP dated November 20, 2013 providing in detail the implementation of the Vietnamese Commercial Law regarding international sale and purchase of goods, processing and transit agency activities with foreign countries. The goods banned from export which are relevant to GRs are as follows:

- Precious and rare wild animals and plants as well as domestic animals and plants of IA-IB groups as specified in the Government's Decree No. 32/2006/ND-CP of March 30, 2006, on management of endangered, precious and rare forest plants and animals and precious and rare wild animals and plants in the "Red Book" per Viet Nam's commitment to the international organizations;
- Precious and rare aquatic species;
- Livestock breeds and plant varieties on the list of precious and rare livestock breeds and plant varieties banned from export promulgated by the MARD in conformity with the 2004 Ordinance on Livestock Breeds and the 2004 Ordinance on Plant Varieties.²⁴

At the same time, organizations and individuals

licensed to access GRs have the following obligations:

- a) to adhere to the provisions of their licenses for access;
- b) to submit reports to competent licensing agencies on R&D results or on commercial production according to the schedule prescribed in the licenses;
- c) to share benefits with related parties, including the distribution of intellectual property rights over invention results based on their access to GR and related TK copyrights; and
- d) other obligations specified in their licenses and contracts on ABS to and from the use of GRs.

The BL 2008 leaves space for parties to negotiate further rights and obligations in their ABS licenses and contracts. Therefore, the contents of licenses and ABS contracts should be carefully considered in all cases.

Where contravention to the obligations relating to GR licenses holders above occur, the Government of Viet Nam will apply an incremental approach to imposing sanctions. This has been done through the administrative enforcement Decree No. 179/2013/ND-CP dated 14 November 2013 which provides specific provisions applicable to ABS violations. Its Article 46 establishes monetary penalties ranging from VND 5 million to VND 50 million. In this regard, offending parties may be penalized depending on the circumstances of the breach (See Fig.2 below):

Additional sanctions to the ones specified in Figure 2 below:

- Taking away the right of use of a GR (for which the user had an access permit) from 6 to 12 months for violations specified in Item 2 of this Article 46;
- Confiscating exhibits and means of administrative violations for cases specified in Item 3 and 4 of this Article 46.

Remedial measures are to withdraw results arising from illegal activities of access to GR within the time set by the competent national authorities included in decisions on applied administrative sanctions for violations.

As of yet, the above provisions of Decree No. 179/2013/ND-CP have not been applied in practice due to the absence of specific regulations to identify the violations. For example, the Decree does not specify how to determine the level of a violation. These are some of the issues that should be addressed by the new Decree on ABS currently under development.

Although the Vietnamese Civil Code includes enforcement procedures for cases of non-compliance

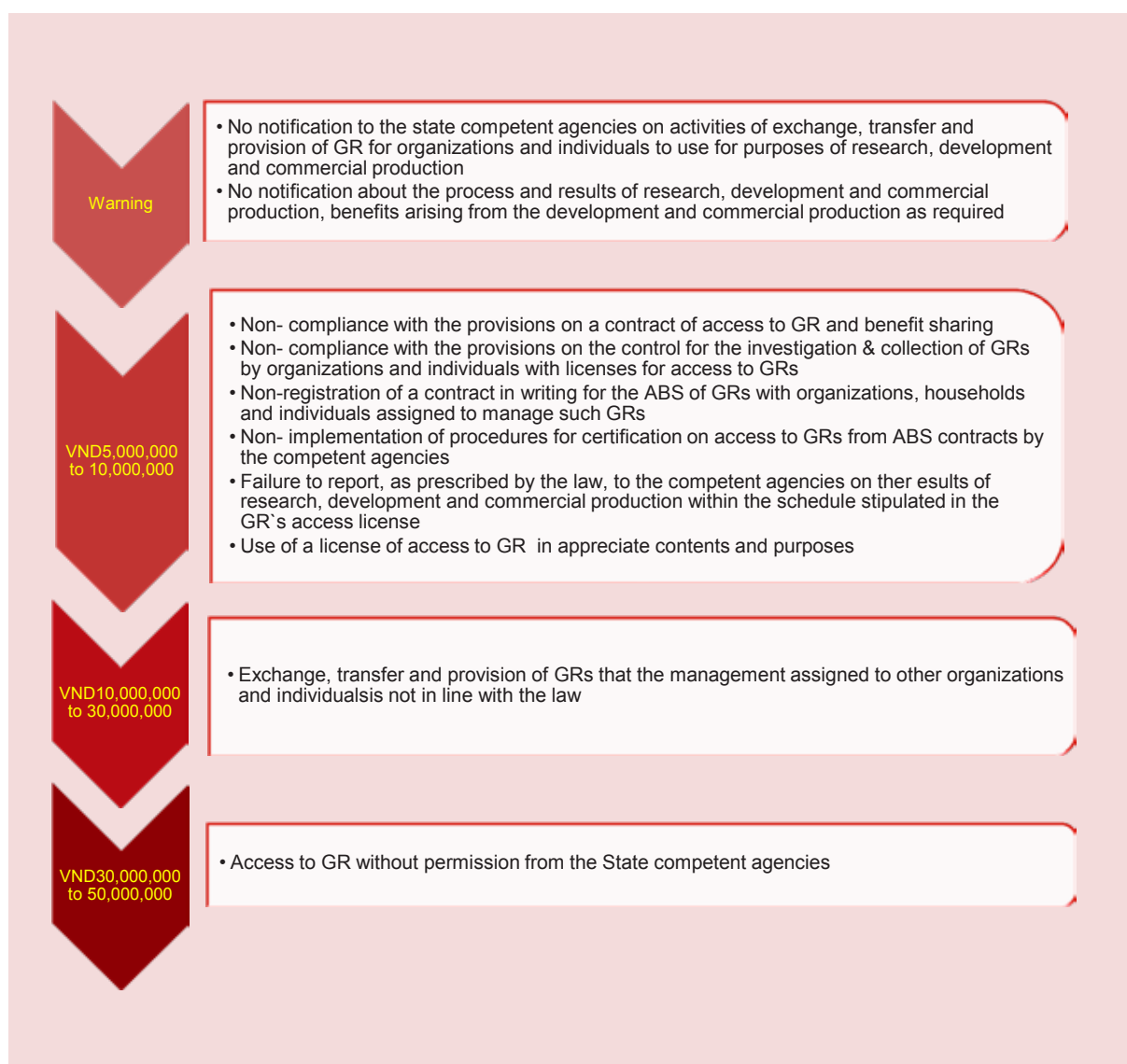
with national laws, such provisions would not be effective for ABS issues. This is partly because cases of violations regarding GRs may involve extraterritoriality issues that render the Vietnamese Civil Code not enforceable (in other jurisdictions) in addition to the possibility that the use of accessed GRs in Viet Nam might not actually happen within Vietnamese territory.

Since the Protocol has no specific and strict regulations on compliance, the national or regional laws that implement it need to include more specific and clear regulations to enforce the maximum level of compliance possible. These implementing regulations could include, provisions relating to foreign laws or mechanisms of bilateral judicial support and

cooperation and measures of reciprocity. To this end, the value of regional cooperation such as that of ASEAN needs to be reassessed.

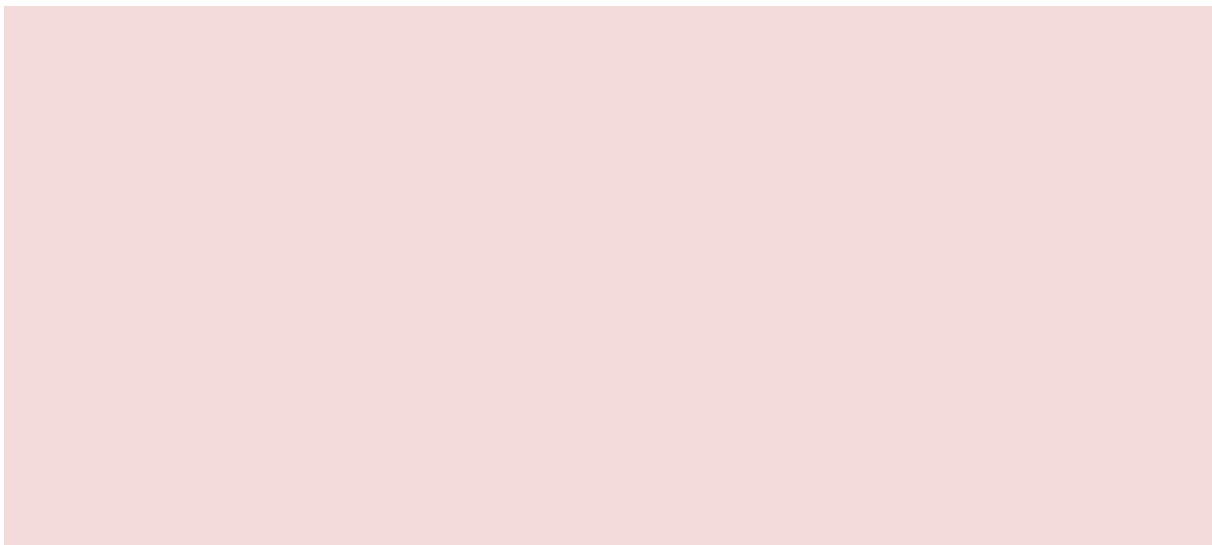
The Protocol further requires a series of national institutions for monitoring the use of GRs, enforcement, setting up check points, monitoring the use of GRs, establishing national focal points on ABS and establishing one or more national competent agencies on ABS. Article 13.3 of the Protocol, however, stipulates that a national focal point on ABS can perform all the functions of a national competent agency on ABS. Regrettably, the Vietnamese regime that is supposed to ensure the implementation, compliance and enforcement on ABS fails to do so.

Figure 2. Viet Nam ABS regulations offences and sanctions



In addition, enforcement of the ABS rules is not taken into consideration by the Regulations. Article 58.5 of the BL 2008 only states that “*Disputes over or complaints about access to GRs and benefit sharing shall be settled under Vietnamese law and international treaties to which the Socialist Republic of Viet Nam is a party*”. The Protocol, however, encourages providers and users of GRs and TK to take the specific dispute settlement provisions into account while negotiating MAT provisions. Such provisions should include the applicable settlement competence and resolution

process, the applicable law as well as alternative resolution options such as a mediation and arbitration. As discussed in this report, this provision is very practical and needs to be specified in the contract. The rights of the GRs suppliers in the country cannot be guaranteed merely by the reference to other general regulations such as Article 58.5 of the BL 2008. Adhering to the example of the Protocol, it would be beneficial if national competent agencies, while enacting legal texts, made specific mention to dispute settlement arrangements, applicable law, as well as alternative measures in dispute resolution.



UNCTAD/BCA/BIG/SECO Viet Nam Stakeholders Consultations on the Nagoya Protocol, National ABS regime and BioTrade, June 2016: Source UNCTAD/BIG Viet Nam (2016)



IV. BIOTRADE AND ITS DEVELOPMENTS IN VIET NAM

UNCTAD's BioTrade Initiative supports sustainable development through trade and investment in biological resources in line with the three objectives of the Convention on Biological Diversity. Through the establishment of partnerships with national, regional and international programmes, it seeks to strengthen the capacity of developing countries to enhance the production of value-added products and services derived from biodiversity for both domestic and international markets. Since its launching in 1996 as part of UNCTAD's "BioTrade Initiative", BioTrade has demonstrated the importance of multiple forms of conservation and sustainable use of biodiversity and ecosystems-oriented businesses.

A. The BioTrade concepts and principles

Defined as "activities of collection, production, transformation, and commercialization of goods and services derived from native biodiversity, BioTrade implements seven Principles, with their respective Criteria of environmental, social and economic sustainability that translate sustainable development goals into practical actions. The BioTrade Principles are the following:

Table 1. The BioTrade Principles and Criteria (Source: UNCTAD, 2016)

| Principle | Criterion |
|-------------|--|
| Principle 1 | Conservation of biodiversity |
| Principle 2 | Sustainable use of biodiversity |
| Principle 3 | Fair and equitable sharing of benefits derived from the use of biodiversity |
| Principle 4 | Socio-economic sustainability (productive, financial and market management) |
| Principle 5 | Compliance with national and international regulations |
| Principle 6 | Respect for the rights of actors involved in BioTrade activities |
| Principle 7 | Clarity about land tenure, use and access to natural resources and knowledge |

These BioTrade Principles and their respective Criteria were adopted by the Initiative and the national

programmes after extensive consultations in 2004. However, the Principles and Criteria have guided the activities of the BioTrade Initiative, the BioTrade national programmes and other related activities since 1999. In addition, BioTrade programmes and partners are implementing activities following the certain approaches:

- **Value chain approach** –refers to the coordinated relationship established among all actors in the value chain. The aim of these alliances is to strengthen the value chain by sharing the associated risks and benefits.
- **Adaptive management approach** – allows for the implementation of corrective measures in systems on an ongoing basis, based on a process of continued monitoring.
- **Ecosystem approach** – based on a holistic vision that integrates ecological and social issues, as well as the interactions and processes that are involved in a productive system.
- **Sustainable livelihoods approach** - strengthens the human, social, physical, financial and natural capital of people and communities to which BioTrade contributes.

It is important to note that the set of BioTrade Principles and Criteria adopted by UNCTAD and national programmes in 2004²⁵ merely provides the basis for the minimum criteria to be met. National programmes may make the adaptations required by their national contexts. In addition, the Union for Ethical BioTrade (UEBT) developed, through a global consultation process, a specific verification framework to measure the compliance of its members in the natural ingredients industry with the UNCTAD BioTrade Principles and Criteria. Therefore, the BioTrade Principles and Criteria should be applied at both the institutional (i.e. national programmes) and supply-chain actors' level (i.e. business or producer association).

Since its launching in 1996, the BioTrade Initiative has benefited over 20 developing countries in Africa, Asia (including Viet Nam) and Latin America. BioTrade covers sectors such as personal care, food, natural medicine, fashion, ornamental flora and fauna, handicrafts, textiles and natural fibers, and sustainable tourism (see Table 2). Sales revenues of BioTrade beneficiary organizations, working with small and medium-sized enterprises and multinational companies, amounted to US\$5.2 billion in 2012 – compared with US\$2.3 billion in 2010.

Table 2. BioTrade sectors prioritized by countries and partners in Africa, Asia and Latin America (Source: UNCTAD, 2016)

| Sector | Type of product |
|-------------------------------|--|
| Personal care | Essential oils, natural dyes, soaps, cream and butters, cosmetics, etc. |
| Pharmaceutical (Phyto-pharma) | Extracts, capsules and infusions from medicinal plants, etc. |
| Food | fruits pulps, juices, jams, cookies and sauces, spices, nuts, tuberous snacks food supplements, meat from caiman and fish, etc. |
| Fashion | Skin and belts, purses from Caiman yacare, etc. |
| Ornamental flora and fauna | Heliconias, orchids, butterflies, etc. |
| Handicrafts | Jewelry, decoration objects based on native species, garments, etc. |
| Textiles and natural fibers | Furniture and decoration objects based on natural fibers, purses, shoes, etc. |
| Sustainable tourism | Ecotourism, nature-based tourism, community-based tourism, etc. |

B. BioTrade in Viet Nam

Since 2003, stakeholders in Viet Nam have been collaborating with BioTrade with a view to advance the objectives and the policies created under the CBD. Between 2003 and 2010, the BioTrade Initiative provided technical assistance focusing on supporting partners to develop specific sectors of biodiversity products and services through a broad range of trade promotion tools. In collaboration with the Swiss Import Promotion Programme (SIPPO), the Programme

supported the value chains for food and pharmaceutical ingredients. During the project period, the Programme selected companies with export potential as well as guided them on the development of specific work plans to promote the exportation of their BioTrade products. It also provided specific technical assistance to selected companies including: 1) facilitation of market access (e.g. trade fair participation, market studies, direct contacts with importers); 2) advice on trade-related legal issues (e.g. intellectual property rights and geographical indications); 3) advice on sustainable use

Overview of the BioTrade Initiative

The BioTrade Initiative has been implemented in three phases:

1. The first phase's implementation started in July 2003. It facilitated the sustainable trade in biodiversity products and services through innovative collaborative arrangements and supported developing countries in accessing new markets, thereby diversifying their production base in a sustainable manner.
2. The second phase of implementation commenced in 2009 and was focused on creating a policy environment that promoted trade and investment through sustainable use. The Initiative helped create opportunities leading to jobs, incomes, export diversification and rural development for populations, small and medium enterprises and multinational organizations engaged in the sector. Consequently, it enhanced the livelihoods of rural and local communities in developing countries by generating not only economic but also environmental and social benefits.
3. The third and current phase implementation started in July 2015. The overall objective focuses on mainstreaming BioTrade in relevant multilateral, regional and national processes, as well as on strengthening the policy and regulatory environment of BioTrade sectors. In this regard, the Initiative, in parallel to mainstreaming and to its global implementation activities, is focusing on tailor-made technical advice on issues such as:
 - Compiling and analyzing existing Non-Tariff Measures (NTMs) for BioTrade sectors and products in key import and export markets;
 - Assessing the applicability and potential implementation of a "track and trace" or traceability systems for targeted CITES species; and
 - Mapping and providing recommendations for a BioTrade-friendly implementation of the Nagoya Protocol

practices (e.g. sustainable use protocols, management plans, certification schemes); and 4) providing advice on product development and quality improvement (e.g. R&D partnerships, quality systems, among others).

The BioTrade Programme likewise established partnerships with national organisations and institutions in Viet Nam with the aim of enhancing the capacity of companies to produce value-added products and services derived from biodiversity as well as enable them to sustainably manage the natural resources these products are derived from.

Finally, in collaboration with national counterparts (such as government ministries, non-governmental organizations, trade promotion organizations, national service providers), the Programme carried out a sector assessment for food and pharmaceutical ingredients. This included a thorough identification of opportunities, barriers, and existing institutional capacities. Based on the sector assessment, national partners designed a sector strategy for the development of the trade potential of food and pharmaceutical ingredients.

From 2012 to 2014, The Swiss government, through the State Secretariats of Economic Affairs (SECO) supported Viet Nam through “*The development of*

value chains for natural ingredient products” project that was implemented by Helvetas with a budget of US\$ 1,000,000. Together with the implementing partner, the National Institution of Medicinal Materials (NIMM), a research institute from Ministry of Health, the project objective was to help establish the international recognition of Viet Nam as a supplier of choice for biodiversity derived natural ingredient products – sourced, processed and traded in compliance with the CBD objectives and BioTrade Principles and Criteria. Towards this end, this project:

1. Initiated a partnership with a group of interested and innovative phyto-pharmaceutical companies committed to high quality products to support them to take up the BioTrade approach. The project intervention implemented through companies along five natural ingredient value chains to the farmers and collectors in the communities.
2. Encouraged the value chain actors (e.g. from farmers, collectors to company staff) to achieve confidence in applying sustainable standards (e.g.: Ethical BioTrade, GACP) to their sourcing practices.
3. Established the verification system for Ethical BioTrade standard in Viet Nam. QUACERT, a government certification body which is

Photo 5: BioTrade Trade Fair. Source: Son Ta Minh / BIG Viet Nam (2016)



Table 3: Partnerships and actors involved in BioTrade activities

| Natural Ingredient | Type of Source | Product | Effect | Location | Processing Company |
|-------------------------|-----------------|-----------------------|--|-----------------------------------|---|
| Ampelopsis | Wild Collection | Ampelop | Treatment of Gastric Ulcer | Muong Hum, Bat Xat, Lao Cai | Traphaco Co. Jsc traphaco.com.vn |
| Polysias Fructicosa | Cultivation | Cebration | Treatment of insufficient cerebral circulation | Hai Hau and Nghia Hung, Namh Dinh | Traphaco Co. Jsc traphaco.com.vn |
| Gemnema Sylvestre | Cultivation | Diabetna | Treatment of Diabetes | Hai Loc, Hai Hau, Nam Dinh | Nam Duoc Co. Jsc. namduoc.vn |
| Phyllantus amarus | Cultivation | Phyllantus herbal tea | Improve symptoms of hepatitis and liver function | Tuy Hoa, Phu Yen | Vietroselle Co. Ltd. vietroselle.com |
| Plectranthus amboinicus | Cultivation | Eugica Lozenge | Improve cough and upper respiratory disorders | Tri Ton, An Giang | DHG Nature Co. Ltd. dhgpharma.com.vn |

Source: Ta Minh Son (2016)

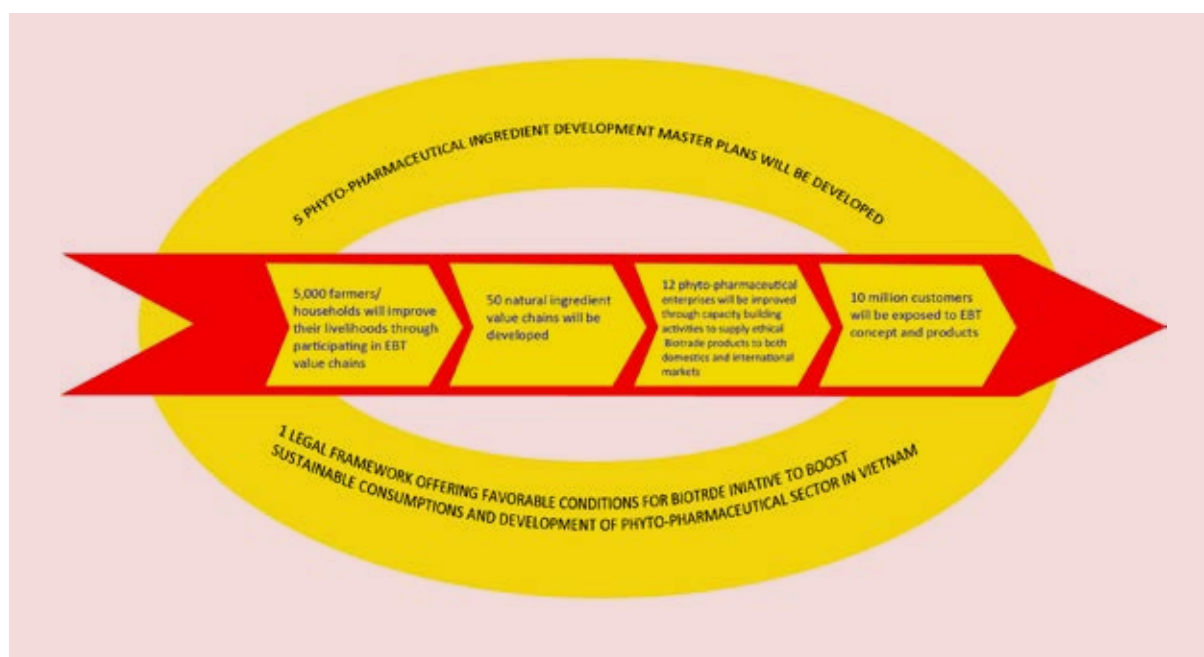
internationally accredited under MOST, was accepted and appointed as Ethical BioTrade standard auditor. From the date of its accreditation, three organizations became UEBT members, including two trading members and one affiliated member.

- Audited and certified compliance of BioTrade value chains with GACP standard by MOH. The BioTrade project collaborated with MOH's institutions to facilitate and support the GACP standard implementation. The value chain service

providers were also identified and their capacities were boosted by encouraging active participation in project activities. During this period, there were four over five BioTrade value chains audited and certified GACP by MOH and fifteen other BioTrade value chains plus other companies which were also audited and certified. After a long delay (from 2009), the Circular 14/2009/TT-BYT relating to GACP implementation in phyto-pharmaceutical sectors was finally disseminated.

- Raised awareness of ABS for natural ingredient

Figure 3. Results chain for “Scaling up of Ethical BioTrade activities within phyto-pharmaceutical sector in Viet Nam” Project / Source: BIG Viet Nam (2016)



value chains stakeholders and partners in Viet Nam via the project partnership between BioTrade and BCA – MONRE. A set of an ABS training document and ABS training manual was developed in 2014 back to back with an ABS training workshop organized by the BioTrade project with ABS experts from UEFT. At the workshop, it emerged that the natural ingredient value chain stakeholders have had indirect knowledge about BioTrade through existing GACP and ABS approaches in Viet Nam.

6. Organized workshops to provide fundamental understanding of the BioTrade Concept and Principles and Criteria and its practical implications for actors in the different value chains. The workshop topics included: Good Agricultural and Wild Collection Practice of Medicinal and Aromatic (Culinary) plants of World Health Organization (GACP- WHO standard) ABS for the value chain stakeholders and partners.
7. Participated in various project activities of relevant government institutions like the Ministry of Health (MOH); the Ministry of Industry and Trade (MOIT); the Ministry of Natural Resources and Environment (MONRE), and the Ministry of Agriculture and Rural Development (MARD); and

8. Created the BioTrade Interest Group of Viet Nam (BIG Viet Nam). BIG Viet Nam was established based on the close collaboration between HELVETAS Viet Nam and Viet Nam Material Medical Society (VIMAMES) for a long term vision of developing BioTrade activities in Viet Nam. BIG Viet Nam acts as the private and technical BioTrade focal point, to attract and support companies to take up BioTrade activities in Viet Nam.²⁶

9. Five BioTrade value chains under the project of “*The development of value chains for natural ingredient products*” under the support of SECO and implemented by Helvetas in Viet Nam.

Since mid-2015 and throughout the BTFP III project duration, UNCTAD has continued to support BioTrade activities in Viet Nam. It has done so by providing targeted technical assistance in key areas of interest to Viet Nam, mainly: (i) Identification and mapping of relevant NTMs that hinder the export of BioTrade products as well as biodiversity-based ones; (ii) development of a traceability system in the Mekong region for CITES-listed non-timber plant species (to be implemented in Viet Nam); and (iii) identification and enhancement of the understanding on the

Photo 6. Hai Toan farmer group meeting / Source: BIG Viet Nam (2016)



intersection between ABS under the Nagoya Protocol and BioTrade and how this affects Viet Nam's ABS and BioTrade practices.

The Initiative also works together with the Vietnamese Government and key BioTrade partners to provide solutions to the identified challenges above, as well as to determine the next steps and action plan to be followed, including an assessment of the current situation of ABS and BioTrade in Viet Nam, raising awareness on the interlinkages between the Nagoya Protocol, ABS and BioTrade in the country and provision of clear recommendations for a BioTrade-friendly implementation of the Nagoya Protocol and ABS systems in Viet Nam.

C. Steps ahead

From 2016 to 2020, the European Commission has set up a EUR 2,063,000 fund for the project, "Scaling up of Ethical BioTrade activities within phyto-pharmaceutical sector in Viet Nam". The project is currently being implemented by HELVETAS Viet Nam and the Center for Rural Economic Development (CRED). Its objective is to establish Viet Nam as an internationally recognized supplier of natural ingredients for phyto-pharmaceutical and cosmetic industries that are sourced and processed according to the BioTrade Principles and Criteria vis-a-vis the Ethical BioTrade standards. In addition, this project will include training activities on ABS mechanisms for all actors in the value chain.

Through the project (which was launched on 8 June 2016), around twelve Vietnamese phyto-pharmaceutical enterprises are expected to supply national and international markets with ethical BioTrade products, expand their BioTrade business, reduce their ecological footprint and improve the conditions of the workplace. More than 5,000 small holder farmers are also expected to increase their livelihoods through ethical BioTrade value chains and start to steadily supply their produce to ethical BioTrade enterprises. Also, around tens of millions of domestic consumers are also expected to be familiar with the BioTrade concept and benefits, therefore, increasing the demand for BioTrade products in Viet Nam. These activities, in essence, will build a conducive environment to create an enabling policy and regulatory framework for BioTrade initiatives that will stimulate the growth of the phyto-pharmaceutical sector in Viet Nam sustainably.

Further to the above, SECO is also supporting the project, "*Development of BioTrade activities within the Natural ingredient sector in Viet Nam*". This is a regional project which includes Viet Nam, Laos and Myanmar. The initial results of the previous project phase in Viet Nam is proposed to be disseminated and replicated in other ASEAN countries for the purpose of ascertaining the impacts of BioTrade in the natural ingredient sector regionally. HELVETAS Viet Nam has cooperated with BIG Viet Nam to develop and submit a proposal to SECO for the project's implementation and launching in the second half of 2016.

D. The Perception of BioTrade in Viet Nam

In a recent review of BioTrade practices in Viet Nam, it has been found that the government agencies, particularly the public authorities (who have direct mandate to BioTrade value-chain activities), were found to have insufficient awareness of BioTrade despite its ongoing activities in the country. The results of this institutional assessment for BioTrade Viet Nam showed the complexity of the management of natural ingredients in the country. There has been no government institution officially appointed as a focal point for BioTrade activities in Viet Nam so far, hence the inter-ministries' coordination is considered relatively weak in supporting BioTrade activities. As a result, the BioTrade Initiative had to collaborate with individual ministries for particular BioTrade-related issues. Representatives from other ministries are invited to participate in relevant project activities to facilitate the policy dialogues - however, preliminary interest to create a national programme in the government remains uncertain.

Regarding the actors of five selected value chains, it was found that there were not many opportunities for BioTrade actors to communicate directly to consumers. Ideally, the national project's objective was to raise awareness of the target group within the project intervention firstly, because, the concepts of BioTrade and relevant biodiversity definition are quite new and complicated for stakeholders in Vietnam. Once the project stakeholders and partners have a working knowledge about and interest in the BioTrade concepts as well as the related benefits, synergies with other stakeholders, especially with BioTrade companies whose key role is to communicate BioTrade concepts to consumers - direct links to the consumer could be achieved.

E. BioTrade in numbers

BioTrade in Viet Nam focuses on value chains for the collection, cultivation, processing and commercialization of medicinal and aromatic plants. Even though it started with only four pioneer phyto-pharmaceutical companies, their sales contribution in the domestic herbal medicines market is 80 per cent. The sales of BioTrade in Viet Nam have been estimated at US\$ 100 million for both herbal medicines and dietary supplements. The majority of products are related to medicinal and aromatic plant formulations, functional foods and derived products. Most of the sales take place in the domestic market but exports are slowly increasing. Currently, the domestic market shows promising growth rates of 30 per cent annually in medicinal plants which could be a boost for BioTrade. Nevertheless, and considering such a great potential for expansion, there are still many phyto-pharmaceutical companies that are only willing to focus on the domestic competition rather than set their eyes on the international markets.

BioTrade companies see benefits arising from BioTrade not only in terms of sales but also in terms of better preparation for the international competition within domestic market, while foreign companies can easily access domestic market as free trade agreements come into force. Their goodwill also increases while they invest more into conservation and engagement with the local communities. For example, there is a 10:1 positive price ratio when producing medicinal plants vis-a-vis rice in the countryside in Viet Nam. This is an interesting incentive for farmers to engage in BioTrade activities. In addition, cooperative groups of farmers (whose incomes increased around 10 per cent when they participated in the project) were set up. The scientific development of medicinal plants is attracting the interest of farmers, collectors and local authorities because not only they are increasingly becoming more profitable, they are also useful to improve the livelihoods of the communities and aid in climate change adaptation.

F. BioTrade challenges and additional actions in Viet Nam

Illegal trade of wild collected medicinal plants to China is still popular in Viet Nam and is the main reason for species over-exploitation. Together with raising awareness, providing local communities alternatives for livelihood plays an important role. Support for local

collectors to develop ex-situ cultivation of medicinal plants by transferring relevant research results in accordance to Ethical BioTrade standards, provision of technical support as well as facilitation of business linkage with private sector have been considered as effective and sustainable interventions to relieve the pressure of overexploitation for the species in the wild.²⁷

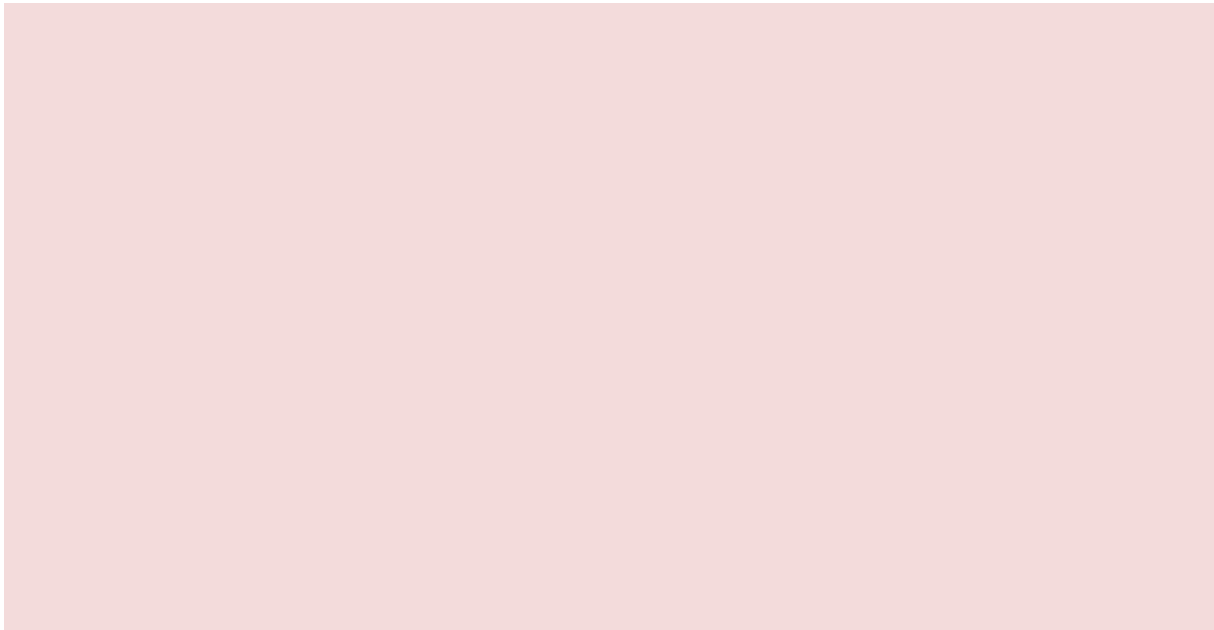
Raising BioTrade awareness of consumers and government authorities still is the most challenging task in Viet Nam. Working with government authorities for a BioTrade-friendly policy and regulatory environment, especially in the context of no clear ministerial mandate for overall natural ingredient development with weak inter-ministry coordination requires a long-term intervention. Nonetheless, the approach based on cooperation with relevant local authorities for particular value chain development still is an effective and efficient intervention, besides facilitating and supporting inter-ministerial cooperation in central level.

While the business context is changing very quickly, most BioTrade companies can expect more on the synergy between companies, government authorities and BioTrade projects to raise the awareness of consumers about BioTrade and its benefits - eventually, increasing the demand for BioTrade products. This response from consumers will help to motivate BioTrade companies to commit to adopting their activities within the concepts and principles of BioTrade.

There is a lack of market information for value chain actors in both domestic and international markets. The scope of government trade promotion agency (VIETRADE) is broad and they still do not have any particular strategy for exporting BioTrade products. There is an emerging need for a competent BioTrade focal point to closely collaborate with VIETRADE to include BioTrade products become a commodity in the National Export Strategy. One such possibility is the private and technical BioTrade focal point in Viet Nam (BIG Viet Nam) which is a “newborn” institution with potential capacity and ambitious objectives. However, it needs more time for its capacity building to provide effective and efficient services to BioTrade value chains actors. Meanwhile, a governmental BioTrade focal point is yet to be discussed and appointed, so far, Biodiversity Conservation Agency (VEA, MONRE) has played role as a contact point and connecting BioTrade issues into ABS regime revision process.

Research centres, ex-situ collections and universities point out that BioTrade should not only look at plants but also animals, insects and microorganisms because there is a huge potential in these areas. The MOIT

also indicated that BioTrade should not only look at “native” species but also “domesticated” varieties that have developed particular features. Viet Nam is also developing a national database for GRs.²⁸



V. ACCESS AND BENEFIT SHARING RULES AND THE BIOTRADE APPROACH: AN OVERVIEW

A. BioTrade and Viet Nam's laws on biodiversity

The BL 2008 does not specifically refer to BioTrade but rather is a set of general principles on access and benefit-sharing regimes. It serves as a framework for further regulations to determine its applicability to particular sectors and circumstances. As specific ABS provisions under the Regulations have not yet been enacted, it provides opportunities for amendment and/or considerations for supplementary laws and regulations. Currently, the Government of Viet Nam, together with UNCTAD and key BioTrade actors in the country are discussing the development of a new ABS implementing decree that would take into account the unique role of BioTrade in the application of the BL 2008 and the ABS rules under it as enshrined in the CBD. In addition, a circular is under development which would provide further details on the implementation of ABS provisions for BioTrade practitioners in the country.

When comparing national ABS provisions and BioTrade Principles and Criteria related to ABS, this report ascertains that:

Scope

Vietnamese ABS laws include provisions on benefit sharing but are narrower in scope than those in BioTrade's Criteria. Under Criterion 3.1, BioTrade requires benefit sharing that involves, where possible, actors along the whole value chain. In contrast, under the national ABS laws, the sharing of benefits obtained from access to GRs takes place as provided for in the contract negotiated, mutually agreed and signed between the parties.²⁹

Access

The legal provisions on access to GRs of Viet Nam correspond to the provisions in BioTrade's Principle 7, particularly Criteria 7.2 and 7.3 on access. Both criteria require PIC based on CBD provisions. The BL 2008 was also developed taking this principle of the CBD into account. Vietnamese BioTrade companies will thus be at an advantage for implementing such provisions in the law. For Criterion 7.3 on PIC for TK,

there is a lack of clear provisions on TK in the national laws. The regulation of ABS provision on TK in this respect, will be a big challenge for Viet Nam.

Benefit-sharing

The requirements of sharing benefits under explicit conditions of BioTrade's Criterion 3.2 are not mentioned in Vietnamese ABS laws. It is the same situation with Criterion 3.3 of BioTrade, which requires that "information and knowledge of target markets are made available and shared among actors". Although article 19 of the Decree No. 65/2010/ND-CP includes a list of benefits that should be shared, it does not include the key point of "information and knowledge of target markets" as foreseen in BioTrade's Criterion 3.2.

In this regard, and although it is a voluntary regime, BioTrade has been, the only vehicle for effective benefit sharing from sustainable use of biodiversity in Viet Nam so far. This state of affairs should be positively considered by national authorities and be reflected in the ABS regulations and practices. At the moment, this benefit is only evident when looking at sales and impacts of BioTrade in the creation of value chains.

B. Synergies, implementation and lessons learned

There have always been potential links or overlaps in scope between the Nagoya ABS requirements and BioTrade Principles and Criteria, particularly: Principle 3 on benefit sharing, Principle 5 on compliance and Principle 7 on clarity about the rights of the parties. In essence, compliant BioTrade companies, are already partly abiding by the key Nagoya Protocol principles and provisions. Additionally, if organizations/companies comply with ABS on a regular basis, they are able to satisfy at least two basic BioTrade Principles, mainly Principles 3 and 7. The intersection possibilities between ABS and BioTrade can be described through following figure:

BioTrade activities will almost certainly fall under the scope of the Nagoya Protocol and under national ABS frameworks when involving access and/or use of GRs, their biochemical and any associated TK.

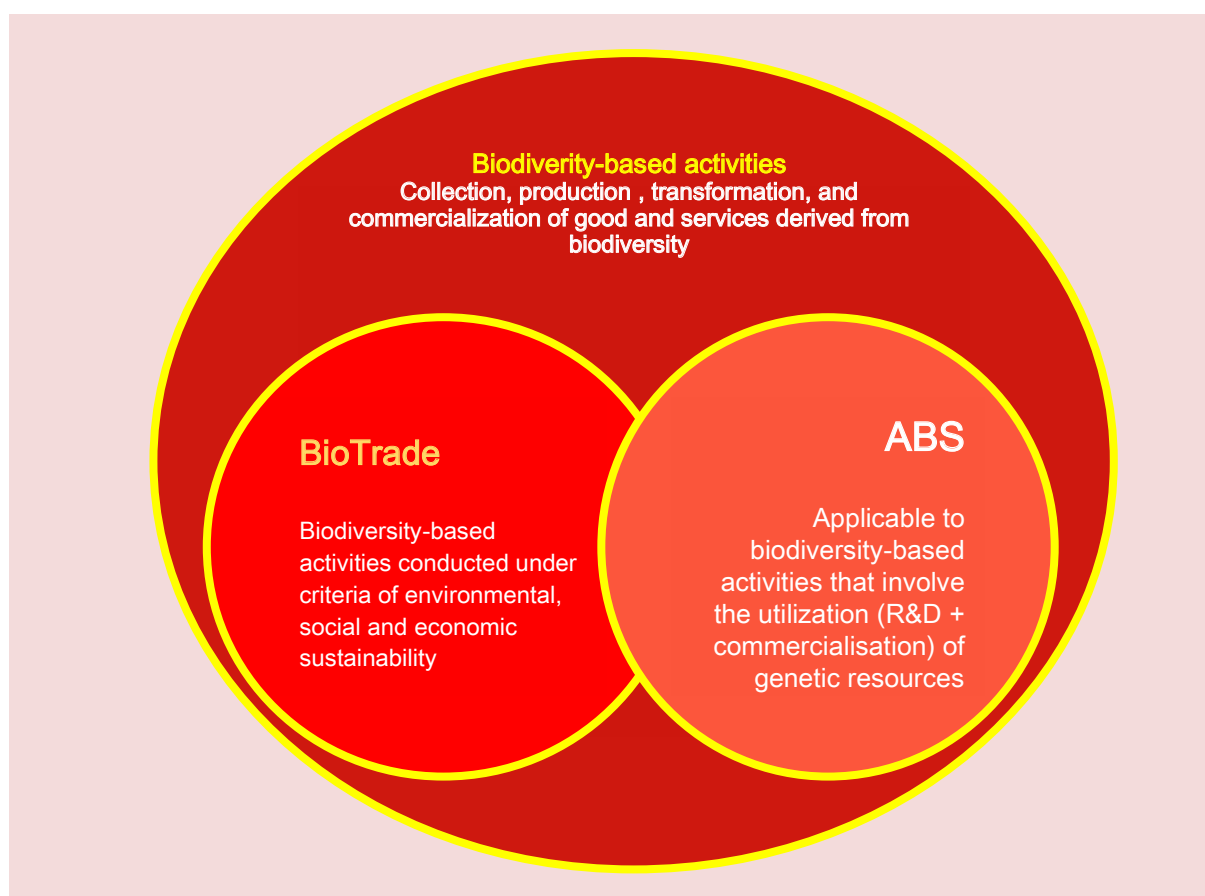
Some examples of BioTrade activities could potentially fall under the scope of the Nagoya Protocol include.

1. Accessing and undertaking R&D on extracts of medicinal plants, or identifying an active compound from a plant or microorganism;

Table 4. ABS provisions vis-a-vis BioTrade Principles and Criteria (Source: UNCTAD, 2016)

| Principles | Criterion |
|--|--|
| <p>3. BioTrade activities which involve the commercialization of genetic resources are linked to the benefit sharing objective of the CBD. Equitable benefit sharing also arises in the context of sustainable use of biodiversity. Benefit-sharing is therefore also important in activities dealing with biological resources, which form the vast majority of BioTrade activities.</p> | <p>3.1 The organization should interact and involve actors along the whole value chain, where possible. This reduces asymmetries and ensures negotiation of fair and equitable monetary and non-monetary benefits, especially by weakest links along the value chain.</p> <p>3.2 Income should be generated along the value chain, by contributing to the position of value-added products in the market, under transparent conditions, as a condition for benefit sharing.</p> <p>3.3 Information and knowledge of target markets should be made available and shared among actors, to enable access to market opportunities.</p> |
| <p>5. Compliance with national and international regulations Compliance with relevant legislation and regulations is fundamental for the legal legitimacy of an organization and its efforts to obtain market access for its products. There are two levels of implementation for this principle:</p> <p>(i) At the international level, where conventions and agreements are, for the most part, guides to principles and good practices. These should be observed and applied wherever possible; and</p> <p>(ii) At the regional and national levels, where there are existing regulations to be complied with</p> | <p>5.1 The organization should be aware of and comply with national and local legislation related to the sustainable use and trade of products and services derived from biodiversity (wildlife management, labour regulations, etc.) Every national regulation, including labour regulations, applicable to BioTrade projects must be strictly complied with.</p> <p>5.2 The organization should be aware of and comply with international and regional legislation related to sustainable use and the trade of products and services derived from biodiversity This includes, but is not limited to, the Convention on Biological Diversity, the Convention on International Trade in Endangered Species of Wild Fauna and Flora, the conventions of the International Labour Organization, the rules of the World Trade Organization and the Andean Community, and other regulations.</p> |
| <p>7. Clarity about rights of access is very important. Only then can long-term investments be made or corresponding management measures be implemented to ensure sustainability. At the same time, clarity on this issue means that the responsibilities of each actor can be clearly established.</p> | <p>7.2 Access to biological and genetic resources for sustainable use should be subject to prior informed consent. The Convention on Biological Diversity requires access and distribution of benefits in relation to genetic resources. In such cases, the consent of all relevant national authorities in the provider country should be obtained. These cases are normally regulated by national legislation, in line with the Convention on Biological Diversity.</p> <p>7.3 Access to traditional knowledge should be granted only where prior informed consent has been verified. Where traditional knowledge is used, the organization should follow all regulations and their established procedures to ensure that the rights of the actors providing this knowledge are recognized, including the right to prior informed consent of all relevant stakeholders, such as indigenous and local communities, as appropriate and subject to domestic law. Traditional knowledge should be valued and rewarded in the appropriate manner.</p> |

Figure 4. The BioTrade Principles and Criteria and the ABS Standards³⁰



Source: Oliva MJ (2012). Equitable Sharing of Benefits in Ethical BioTrade

2. Obtaining TK from an indigenous community and using it to orient and guide initial phases of R&D processes (e.g. regarding use, characteristics, and dosages of medicinal plants). For example, the case of Traphaco Sapa;³¹
3. Undertaking R&D on specific, isolated compounds and natural extracts of plants;
4. Undertaking research on different extraction processes regarding a plant extract, leading to potential compositional variations;
5. Plant or animal breeding using biotechnology;
6. Any biotechnology process which uses enzymes to lyse the plant cells and allow separating hydrophilic and lipophilic fractions from kernels, leaves, seeds;
7. The action of specific enzymes (e.g. elongase, desaturase) that will transform the naturally occurring composition of a vegetable oil to give a different fatty acid profile;
8. Insect reproduction or genetic modification for pest control;
9. Extraction processes and analysis of compositions;
10. Derivative: Triglycerides (vegetable oils such as Argan oil, Marula oil, etc.); Phospholipids of cell membranes (fractions of vegetable oils); Saps (Aloe Vera juice for example); Secondary metabolites (e.g. Polyphenols).³²

C. Differentiating between ABS and BioTrade

The scope of BioTrade is larger than that of the Nagoya Protocol. The Nagoya Protocol contains references to R&D on GRs, as well as on the 'biochemical' composition of GRs. Some national and regional implementing regulations also include in their scope 'derivatives'. BioTrade, however, covers "*production of value-added goods and services derived from biodiversity*". That means that the scope of BioTrade includes not only genetic resources and its derivatives but also species and ecosystem services.

The scope of ABS under the BL 2008 of Viet Nam also has a broader scope than the Nagoya Protocol, since its definition of GR includes “*all species and genetic specimens in nature, conservation areas, biodiversity conservation facilities and scientific research and technological development institutions and in nature*”.³³This is quite broad in scope and includes biological resources and genetic resources. The Vietnamese Law, however, does not contain a definition of “utilization” of GR or any reference to “derivatives”.

Regarding its nature, BioTrade is a voluntary system, while ABS is a mandatory one. Companies have the right to choose to become a BioTrade member and/or apply its principles. There are still many companies, projects that have “activities of collection/production, transformation, and commercialization of goods and services derived from native biodiversity” that do not satisfy the “criteria of environmental, social and economic sustainability” or do not register to be recognized or certified by Bio Trade programmes. However, when the company has activities that fall into ABS rules (access to GR and its utilization and biochemical through R&D or commercialization products and TK), they have responsibilities/liabilities to comply with ABS regulations or international and national laws obliging them to comply with ABS regimes.

Regarding subjects involved, Bio Trade includes various actors of value chain, including indigenous people, local communities, farmers, raw material providers, intermediaries, transporter, researchers, professors, and traders, among others. However, ABS provisions under the Nagoya Protocol mentions basically: providers, users, indigenous and local communities and national competent authorities.

D. Implementing the BioTrade Principles and the Vietnamese ABS law

In practice, there are some lessons to be learned from the implementation of the BioTrade project in Viet Nam.

The implementation of BioTrade’s ABS-related principles and criteria is voluntary. However, Principle 3 of BioTrade on benefit sharing has been continuously applied in Viet Nam. The benefits are shared along the whole value chain, in consideration of the Criteria set up under Principle 3, which is arguably much wider in scope than provisions on benefit sharing under the BL

2008 that only covers access to GRs and TK under ABS agreements.

In a stark contrast, Principle 7 of BioTrade on clarity about rights of access could not be applied. All the procedures for obtaining permit of access to GR following the Regulations were omitted. This proved to be a disabling circumstance for the BioTrade project in Vietnam (implemented by Helvetas) the reasons were as follows:

- Before 2014, Vietnamese ABS laws on access did not meet the first requirement of “clarity” under the Principle 7. There was uncertainty among BioTrade practitioners relating to BL 2008 itself and found it challenging if not impossible to comply with BioTrade’s Principle 7 relating to ABS;
- There were no legal requirements as there was no regulation on TK protection;
- BioTrade’s Criteria 7.2, which requires PIC for access to TK, could not be verified either. One example is the case of Traphaco SaPa, a medicinal herb whose associated TK was the basis of an R&D of a new natural ingredient for gastric ulcer and stomach ache. It could have been a good opportunity for the knowledge holders to benefit from the use of their TK, however, it was considered that the relevant TK already exists in the public domain of Viet Nam, and so identification of specific rights owners and potential beneficiaries proved difficult. The issue was made even more complicated by the fact that there was no management database for GRs and TK that made it easier or even possible to identify the right holders (individuals, communities, national or public) existed. There was no legal basis for pursuing PIC for access to TK associated with GRs and the Regulations did not have any provision on procedures for PIC for access to TK associated with GRs.

Moreover, the Regulations were all promulgated before the entry into force of the Nagoya Protocol, as well as before Viet Nam became a party to it. As of yet, no revision to adapt to the provisions of the Nagoya Protocol has taken place, let alone proposed.

Consequently, there is an urgent need to improve legal provisions on access to GRS with explicit procedures for PIC and to supplement these to obtain PIC for access to TK associated with GRs to ensure “clarity” (as foreseen, for example, under BioTrade’s Principle 7), as well as the ‘transparency’ and ‘certainty’ provisions foreseen both in BioTrade’s Principle 7 and in the Nagoya Protocol.

The companies under the BioTrade Project should also pay attention to comply with the PIC requirements of Principle 7 for access to GRs or TK if they proceed with BioTrade activities and such fall into the scope of ABS rules. Such requirements should be implemented particularly if the companies or entities are or have become involved in activities of conducting R&D on the genetic and/or biochemical composition of GRs, including through the application of biotechnology and commercialization of their products and TK. However, ABS regulations do not apply PIC for activities of trade in commodities or the direct sale of biological resources (e.g. dried fruits or seeds for human consumption) or even certain processed foods, (e.g. bottled juices, food preparations), hence, PIC is not required in these cases.

For selected companies under the BioTrade project implemented by Helvetas between 2012 and 2014, (these companies have already passed through the stages of R&D activities and are carrying out commercialization of their products), there should have adaptive and facilitated procedures for them to comply with PIC to obtain ABS license to access. Examples under this Helvetas experience are, the case of *Gymnemasylvestre* by NamDuoc company, wherein the stages of R&D were undertaken and the product (Diabetna) was introduced and commercialized;³⁴ or the TK case of *Ampelopsis* by Traphaco company,³⁵

and the case of *Polysias* (product of Traphaco's Gebraton).³⁶

A particularly remarkable product from the activities of the BioTrade project of Helvetas in collaboration with the Biodiversity Conservation Agency of MONRE is the manual for guiding ABS implementation in recognition of the importance of ABS in BioTrade projects in Viet Nam published at the end of 2014. The document provides basic knowledge of ABS for trainers and trainees involved in BioTrade activities. It is also addressed to officials of competent authorities, GR suppliers, communities, and GRs users, among others. The guide is comprised of three main chapters that provide information on the biodiversity of Viet Nam, the interpretation of ABS-related concepts, an analysis and description of the ABS regime of Viet Nam, as well as the role of different parties regarding ABS-related laws and provisions. The guide also includes a section of 'Questions and Answers' that covers frequent questions that arise from the ABS practice in Viet Nam in addition to its summary and analysis of some typical ABS cases in the country in recent years. These cases were investigated through many different channels and sources, including through surveys from field trips and are reflective of the ABS practice in Viet Nam, the development trends, lessons to be learned, as well as models that could be considered for mainstreaming purposes.

VI. POLICY AND REGULATORY OPTIONS AND RECOMMENDATIONS

Despite the apparent challenges relating to implementing ABS regimes complemented by BioTrade activities in the current administrative and legislative climate of Viet Nam, it is also self-evident that the country has a bursting potential for promoting ABS-BioTrade linked undertakings. Surely, issues such as lack of resources and capacities, as well as struggles from institutional mechanisms and policies seem to be obvious deterrents for the advancement of the CBD objectives. Notwithstanding, the robust synergies and mutual supportiveness between BioTrade and ABS rules on the back of a mega-diverse biodiversity make Viet Nam a rising key player in the promotion of ABS in Asia and beyond.

To achieve that, this report presents several options and recommendations for the consideration of policymakers, regulators as well as the various stakeholders in Viet Nam:

Improving the regulatory framework

(i) Integrating BioTrade provisions into ABS Regulations:

The Vietnamese Government is planning to revise its BL 2008. This will be a good opportunity to amend the provisions on ABS to meet the legal certainty, transparency and clarity requirements of the Nagoya Protocol and the demands from the actual practice of ABS activities in Viet Nam, particularly regarding BioTrade activities. This legislative amendment would, in BioTrade perspective, ensure clarity and certainty of scope and implementation and enhance compliance and enforcement through checkpoints. The regime for benefit sharing should be clearer and easier to comply with as well as provide clarity on the object and scope and define the type of use (e.g. definition of R&D through biotechnology and type of R&D) that triggers ABS consideration. This amendment should not be merely a general declaration of complying with the Protocol rules but should instead be concretized into practical implementation guidelines or provisions.

ABS focal points and competent authorities should be ready to adapt to the changes brought forth by the Protocol and to understand and recognize the contribution of BioTrade to the implementation of ABS provisions through its Principles and Criteria.

In addition, the assignments demarcation between ministries should be clarified to ensure an effective coordination amongst them and between other key players of BioTrade.

The amendment on provisions for MAT should be based on the guidance of the Nagoya Protocol and drafted to ensure its practical feasibility. The necessary tools and methods for compliance and enforcement should be set up, including on the internationally recognized certificate of compliance, check points and sanctions. The CBD's Clearing House Mechanism should be notified of all the relevant information on the ABS systems, regulations and permits.

Eventually, the creation of a sound and effective ABS legal framework will also facilitate the implementation of BioTrade Principles and Criteria.

(ii) Integrating BioTrade provisions into a new Decree on ABS

In parallel with the development of this report, the BCA and UNCTAD are working together to draft the BioTrade-related provisions under the new Decree on ABS that the Government of Viet Nam is currently developing. BioTrade has so far been included in the draft of the new Decree and the salient provisions are as follows:

1. Definition of BioTrade under the Article 3 - Interpretation of terms: *"BioTrade means activities of collection, production, transformation, and commercialization of goods and services derived from native biodiversity under the criteria of environmental, social and economic sustainability."*
2. A simplified procedure for access to genetic resources and traditional knowledge in BioTrade cases:
 - "Access to genetic resources, biochemical and derivatives undertaken by the companies under the Biotrade Programmes, which satisfy its principles and criteria, as well as the conditions of sustainable BioTrade"*.
 - "The time limit to assess the dossiers of application under the above Clause1 of this Article, is forty-five (45) working days from the day of receiving the sufficient dossier."*

It should be noted that the period of assessment foreseen for other dossiers of application is much longer. In this regard, this time frame (45 working days) is half of the time required for dossiers filed for commercial applications of non-BioTrade companies or institutions (which is 90 working days). In addition,

relevant ministries have been mandated to mitigate procedural and administrative issues when dealing with BioTrade applications in the following manner:

“The Ministry of Natural Resources and Environment takes prime responsibility with coordination of Ministry of Industry and Trade, Ministry of Health to provide in detail the principles, criteria and conditions for sustainable BioTrade and other related provisions.”

Requiring users to share 30 per cent of benefits, as stipulated in the current ABS national regulation, is not feasible. To this end, the new Decree should provide for a minimum and mandatory share of 1 per cent of the benefits to be shared, but leave the actual exact percentage to be negotiated between the actors during the MAT. Therefore, the Decree would demand a minimum of benefits to be shared, but not cap the maximum and leave it to the parties to negotiate.

Furthermore, the benefit shared through the application of the BioTrade principles should be recognized within the ABS system and the competent authorities. This should include the non-monetary benefits shared under BioTrade, especially in those cases where there is no commercialization involved or the stage of the production process is not yet final.

(iii) **Circular or detailed guidance on the implementation of ABS in BioTrade projects and activities.**

The provisions of the draft Decree mentioned above open an opportunity to develop a Circular to provide more in-detail guidance for the implementation of ABS in BioTrade projects and activities. The following issues should be considered during the development and promulgation of the Circular:

- Clarification of the scope of the regulation for BioTrade projects, for example, more detailed definitions of key terms such as utilization of GRs, R&D and derivatives;
- Incentives to facilitate the compliance with ABS rules and regulations for BioTrade projects and businesses;
- Detailed and simplified administrative procedures for BioTrade projects as mentioned by the Decree on ABS, including checklists of activities and documents.
- Clarification of rights and obligations of the respective actors involved in ABS in BioTrade projects and activities;
- Recognition of the type of PIC and benefit sharing

obtained under BioTrade as part of or as a substitute for PIC and benefit sharing under ABS rules and regulations;

- Institutional organization to implement ABS in BioTrade projects and businesses and assignment of a national focal point for BioTrade within the Government, for example, BCA under VEA of MONRE or through a public-private partnership model;
- Introduction of a “regularization or legal restoration” clause that would allow BioTrade companies that already had accessed GRs, biochemical and/or derivatives to subscribe to benefit sharing agreements and regulations and obtain ABS contracts and permits.

These recommendations are justified by the fact that BioTrade companies are regularly audited to verify their compliance with BioTrade principles and standards that already include certain ABS provisions. Therefore, a fast track provision for getting access permits or licenses would boost interest, activities and investment in the BioTrade sector in Viet Nam, internationally known for its sustainable practices for sourcing and using products from biodiversity. This fast track procedure would also lighten the administrative burden for the governmental agency in charge of the ABS processes. In addition, the benefits shared along the value chain of BioTrade businesses that may not be mandatory due to the nature of BioTrade itself may be a de facto sharing of benefits as those foreseen under the ABS regulations³⁷

Raising awareness and capacity building

Both BioTrade and ABS are relatively new concepts in Viet Nam which creates a great opportunity for awareness raising and capacity building among stakeholders all over the country. There are several ways to do so more effectively: (i) a joint effort of BioTrade and Biodiversity Conservation Agency’s through their various activities/projects (ii) as private and technical BioTrade focal point in Viet Nam, BIG Viet Nam could include ABS as one of its main communication content to private sectors and consumers (iii) also, BCA (VEA, MONRE) should also mention BioTrade as a sustainable sourcing practice, in which ABS is one of the key aspects. Likewise, the BCA should also continue to work towards raising awareness at the national and governmental level particularly among all relevant agencies and institutions, and (iv) for a more targeted and substantial impact, partnerships of the above actors should be consolidated with

Photo 8: Participants at UNCTAD's workshop on "Addressing the intersection between the Nagoya Protocol, ABS and BioTrade" (June 2016). Source: UNCTAD and BIG Viet Nam (2016).



other "like-minded" entities such as Helvetas, to raise awareness and build capacities among all value chains stakeholders and partners with a view to encourage all the actors to include ABS provisions in their contracts.

The CBD, UNCTAD, UEBT, Helvetas, GIZ and other relevant organizations' publications related to ABS and BioTrade should be updated and revised to promote awareness of both BioTrade and ABS. Training workshops (such as UNCTAD's workshop on "*Addressing the intersection between the Nagoya Protocol, ABS and BioTrade*" that was organized jointly with the BCA, Helvetas Viet Nam and BIG Viet Nam on 27-29 June 2016) should continue to be organized. Other relevant events could also be used to raise awareness on BioTrade and ABS issues. In addition, international cooperation and public-private partnership on ABS should be strengthened for capacity building for ABS implementation and BioTrade promotion.

Helvetas, the BCA and other relevant Ministries should cooperate to develop a 'National Programme on BioTrade Development'. This programme could be a public-private partnership initiative to duplicate the proven effective models and mainstream awareness raising at all levels.

Crucially, the Biodiversity Conservation Agency (BCA) of MONRE should be officially appointed as Governmental Focal point for BioTrade in Viet Nam. BCA could promote BioTrade through the development of policy and legislation for BioTrade, facilitate related administrative procedures related to BioTrade and ABS, coordinate with other BioTrade-involved Ministries, agencies, PPCs and private BioTrade focal points and other BioTrade actors to implement the "National Program on BioTrade Development".

The capacity building for BCA's ABS implementation should be a nexus to the new context of the BL 2008 revision, the Decree on ABS development, the potential national programme on BioTrade development, and the new Circular for guiding the implementation of ABS in BioTrade projects and activities. The BCA, BIG and UNCTAD should continue collaborating and in the interim, to prepare the guidelines for the implementation of the new ABS Decree in relation to BioTrade. This report should be prepared in parallel to the new draft Decree in order to be ready for the time when its implementation starts.

Equally, value chain actors like BIG Viet Nam should investigate cooperation opportunities between communities, domestic and international R&D

institutions and companies to further develop native medicinal plants. As these actors focus on working with natural ingredients mutual interrelationships could benefit each actor's BioTrade experience as well as such positive dealings among themselves could bring more practical ABS cases that could be valuable sources of learning by cooperative practicing of the ABS rules and BioTrade principles and Criteria.

Finally, the implementation of Principle 7 and its Criteria for access to biological and GRs for sustainable use should be subject to PIC from the government. Therefore, the companies under the Helvetas BioTrade Project phase 1 should start the procedures to obtain PIC and the license to access relevant GRs following the procedure of the Regulations if engaged in R&D, including through biotechnology.

National database

To facilitate ABS implementation, promote BioTrade development, put in practice the Nagoya Protocol requirements on legal certainty, clarity and transparency of access to GRs and their associated TK, a national database and a corresponding access policy and management for listing endemic species, GRs and TK should be developed. This could also be an effective mechanism to make information on GRs, TK and ABS in Viet Nam easily accessible and in a format that could be readily disseminated to relevant parties that practice BioTrade standards and/or required to comply with the ABS regime of Viet Nam.

Changes in purpose and confidentiality

Under the new draft Decree on ABS, access permits are not required for domestic companies for the purposes of scientific research. However, should there be a change in use (for example by engaging in commercialization of research outputs) of those GRs or an intention to do so, the user, be it a BioTrade entity or not, will be required to get a permit or license from the competent authority to access the GR for that particular purpose. For the avoidance of doubt, such access rule is only imposed on domestic users. Foreign users are required to procure access permits at *all* times and for whichever purpose (i.e. commercial or scientific). Given the complexity of the current structures of many companies or business entities, a working and effective system of classification of domestic and foreign users would lighten up the heavier load of ABS compliance for good faith users.

Last but not the least, enhancing financial and technical resources is very important to realize all common ABS and BioTrade targets. These resources do not only come from the State's budget but also from the BioTrade actors during the process of ABS implementation. In this respect, the new Decree will include provisions for the payment of application fees for access requests. Such fees should be minimal, fair and non-arbitrary as well as take into consideration the size of the entity accessing the GRs and the extent of access to GRs being required.

GLOSSARY

Access to genetic resources and benefit sharing (ABS) defines the way in which genetic resources can be accessed and how the benefits resulting from their utilization can be shared among users, providers and other related stake-holders.

BioTrade as defined by UNCTAD, means “activities of collection, production, transformation, and commercialization of goods and services derived from native biodiversity (genetic resources, species and ecosystems) under the criteria of environmental, social and economic sustainability”.

Biotechnology, pursuant to Article 2 of the CBD, means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

Biodiversity Law 2008 provides for the biodiversity conservation and sustainable development; rights and obligations of organizations, households and individuals in the biodiversity conservation and sustainable development.

Research and experimental development (R&D) tend to comprise creative and systematic work undertaken in order to increase the stock of knowledge – including knowledge of humankind, culture and society – and to devise new applications of available knowledge³⁸ In principle, this is any information or knowledge that could help to establish better resources assessment and management i.e.: any activity that generates new information to better understand the GR and /or its biochemical composition.

Traditional Knowledge associated with Genetic Resources is defined by the BL 2008 as “means of knowledge, experience and initiatives of indigenous and local people on the conservation and use of GRs”.

Utilization of genetic resources means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention.

Value chain approach refers to the coordinated relationship established among all actors in the value chain. The aim of these alliances is to strengthen the value chain by sharing the associated risks and benefits.

ANNEX

SUMMARY OF ABS APPLICATIONS, UNDER THE BIODIVERSITY CONSERVATION AGENCY GUIDANCE (BCA-MONRE)

1

| GRs Access Applicant | HANOI NATIONAL UNIVERSITY OF EDUCATION AND A JAPANESE INSTITUTE |
|---------------------------|--|
| Description of GR | <ol style="list-style-type: none"> 1. Specimen: Surbioidei Gobioidae, non-gobioid fish species 2. Purpose of access: Study sympatric fish communities, scientific research on taxonomy, life history and population genetics of gobies in Vietnam 3. Place of access: <ul style="list-style-type: none"> - Hoa Vang and Lien Chieu district, Da Nang and Tien Yen river, Quang Ninh. 4. Period of access: 23 February – 5 March, 2016 5. Terms of agreement: <ul style="list-style-type: none"> - All collected samples are identified to make an inventory, and deposited at both institutions for further research and museum display - Some species are to be subjected to further molecular work (at the Japan institute) 6. Benefit sharing agreement: <ul style="list-style-type: none"> - Funds to undertake the research - Provision of necessary equipment for the research, relevant training inside (Viet Nam) and outside the country (Japan) - Coordinate with other relevant universities and staff in Japan |
| Notes (Guidance from BCA) | <p>Request for provision of more details in the MOU between the two institutions on the following issues:</p> <ul style="list-style-type: none"> - Publication of research result; - Application of the collected genetic resources; - Intellectual property rights over the research results; - Provisions in case of transfer research result to a third party; - Storage and conservation of specimen, research product and related information. <p>In case of potential commercialization, request to contact MONRE for further guidance to satisfy national legislation and principles of the Nagoya Protocol requirements</p> <ul style="list-style-type: none"> - Request for further follow up activities during implementation of the access plan: <ul style="list-style-type: none"> + Inform competent authorities in writing at sites of collection and obtain confirmation of local government. + Follow requirements for information sharing, report on the result of collecting specimens and periodically report on the use of the collected GRs to MONRE. + In case of transporting specimens outside Viet Nam - should follow other requirements by the Government of Vietnam. |

2

| GRs Access Applicant | VIET NAM AGRICULTURAL UNIVERSITY AND PLANT VARIETIES CORPORATION OF THE NETHERLANDS |
|------------------------------|---|
| Description of GR | <ol style="list-style-type: none"> 1. Type of GRs: cultivated local varieties and wild relatives of crops¹. 2. Number of collection: 500 accessions per collection trip 3. Purpose of collection: cooperation to collect and research kinds of wild plants and native plant varieties in Viet Nam, to share knowledge and experiences, to research epidemics and antibodies related to vegetable varieties and seed of Viet Nam. 4. Site of collection: across Northeast, Northwest, Southeast and Southwest of Viet Nam (including Son La, Dien Bien, Lai Chau, Lao Cai) 5. Duration of collection: 14th November – 5th December, 2015 (the collection date has now been postponed till the end of 2016) 6. Terms of agreement: <ul style="list-style-type: none"> - No agreement has been set out under the MOU between Vietnamese Institute and the Company, “In case of further wish to collaborate, the Parties may enter into a separate agreement in which field of collaboration shall be specified and in which the terms and conditions that apply to such cooperation shall be agreed upon”; - No benefit sharing terms mentioned. |
| Notes (Guidance from BCA) | <ol style="list-style-type: none"> 1. Request for provision of more detailed information in the access plan: <ul style="list-style-type: none"> - List of provinces to conduct the collection, the access plan does not mention site of collection in Southeast and Southwest of Vietnam; - Follow regulations in the Decree 117/2010/ND-CP of 24/12/2010 on organization and management of special-use forest when collecting genetic resources in National park and nature reserve; - Detailed list of GRs for collections, quantities and numbers of samples to be transferred out of the country and form of transportation. 2. Request for addition of terms and conditions in the MOU and/or the agreement between the two Parties on: <ul style="list-style-type: none"> - Provisions on publication of research results and applications of collected GRs; - Storage and conservation of specimens, research product and attached information; - Benefit sharing agreements: monetary or non-monetary in forms of training, workshops, technology transfers. . .); (in line with the Nagoya Protocol principles) - Intellectual property rights over the research results; and - Mechanism for information sharing, and reporting on the result of collecting specimens and periodically reporting on the use of the collected GRs. 3. Other remarks: <ul style="list-style-type: none"> - Inform in writing to competent authorities at sites of collection and obtain confirmation of local government. - Refer to the Law on Biodiversity and Decree 65/2010/ND-CP for further implementation. |

3

| GRs Access Applicant | COOPERATION BETWEEN VIETNAMESE UNIVERSITIES AND JAPANESE UNIVERSITIES ON VIETNAMESE LOCAL HORSE GENES |
|---------------------------|---|
| Description of GR | <ol style="list-style-type: none"> 1. Samples: Collect blood samples of local horses in Viet Nam 2. Purposes: Research on diversity of genetics and phylogentic of horse orginated from Asia 3. Site of collection: Mountainous and remote villages in the north Dien Bien, Lao Cai, Ha Giang, Cao Bang, Bac Can, Lang Son. 4. Period of collection: from Jun – Dec 2016. 5. Terms of agreement: <ul style="list-style-type: none"> Research results are to be shared by both parties, publication of scientific papers with co-authorship of both Japanese and Vietnamese institutes; Monetary support needed for the research to be provided by Japanese research team; Samples collected are used for academic research purposes only, not for commercial purpose. No IP rights applied, no transfer to a third parties without agreement of both institutions. |
| Notes (Guidance from BCA) | <ul style="list-style-type: none"> - Reaffirm the information provided by the Vietnamese University: purpose of collection (scientific research only), number of samples to be collected, sites of collection. - Request for submitting collection report within 6 months from completion of collection process. - Some other remarks: <ul style="list-style-type: none"> + In writing, inform competent authorities at sites of collection and obtain confirmation of local government; + In case of transfer research result to a third party, request to contact MONRE for further guidance to satisfy requirements of national legislations and principles of the Nagoya Protocol. |

4

| GRs Access Applicant | A PRIVATE COMPANY IN VIET NAM AND A FRENCH PHARMACEUTICAL COMPANY |
|---------------------------|--|
| Description of GR | <ol style="list-style-type: none"> 1. GRs to be accessed: Some herbal plants of Viet Nam 2. Purpose: Conduct experiments on compounds and to separate biochemical components existing in some kinds of plants of Viet Nam for development of antineoplastic, anti-phlogistic drug, biological pesticide and active principle components used in the cosmetic industry. 3. Terms of agreement: In the contract signed by both parties: <ul style="list-style-type: none"> - Vietnamese company to prepare living specimen to be sent every 6 months within a 2-year period and send specimen to the other party for further processing in France. - Each specimen dispatch has at least 100g and maximum of 10kg with species from seed, body, root, leaves, branches or other parts of the plant. - Duration of agreement is 5 years, in case of successful research on the kinds of plants, provisions of benefits sharing may be extended up to 20 years. - The contract includes terms on sharing of benefits with native local communities and ensuring conditions on fair and equitable sharing of benefits sharing arising from the use of GRs; includes monetary and non-monetary benefits, intellectual property and technology transfer. - Provisions on dispute settlement also apply as specified in the Convention on Biological Diversity and Nagoya Protocol. |
| Notes (Guidance from BCA) | <p>Contract has been signed at the beginning of 2016 by two parties, but has not been submitted to BCA yet. Some initial remarks are:</p> <ul style="list-style-type: none"> - First agreement between the two companies for accession of GRs for commercial purpose that applies standard regulations on ABS under Nagoya Protocol, and regulations of Viet Nam. - Both parties are building genetic resources access plan and requiring more guidance from BCA to implement next steps. |

5

| GRs Access Applicant | AGREEMENT BETWEEN INSTITUTE OF MICROBIOLOGY AND BIOTECHNOLOGY, VIET NAM NATIONAL UNIVERSITY, HANOI (IMBT) AND BIOLOGICAL RESOURCE CENTER, NATIONAL INSTITUTE OF TECHNOLOGY AND EVALUATION OF JAPAN (NITE) ON TRANSFER AND BENEFIT-SHARING OF MICROBIAL RESOURCES |
|------------------------------|--|
| Description of GR | 1. GRs to be accessed: microbial resources (bacteria, archaea, microalgae, phages, fungi) that have been collected in the past 12 years (since 2004) of collaboration between the two institutions ² . 2. Purpose: To promote transfer and utilization of microbial resources of Japan and Viet Nam 3. Collection: A collection of over 13,000 microbial strains 4. Terms of agreement: <ul style="list-style-type: none"> - Material Transfer Agreements template to be agreed for two cases: distribution of the material not for commercial use, distribution of the material to a third party. - Benefit sharing terms: <ul style="list-style-type: none"> + For academic activities: non-monetary benefits + For commercial activities: shall be above 0 per cent and not be more than 1 per cent of the net sales. + Each party shall pay to the other Party 50 per cent of amount of money paid by the third party. + No payment applied in the case of the user of material has the nationality of the country of origin of the Material. |
| Notes (Guidance from BCA) | BCA's remarks are: <ul style="list-style-type: none"> - Agreement on utilization of microbial strains applied ABS principles should be prioritized; - MOU between NITE and IMBT on Transfer and Benefit-Sharing of Microbial Resources in compliance with the Convention on Biological Diversity, the Nagoya protocol on ABS and relevant laws and regulations of Vietnam; - Intellectual property and Benefit arising from utilization of microbial resources are clearly defined in MOU. |

Notes

1 Confidential information

2 Benefit sharing agreements for period 2004- 2016 between two institutions include the followings:

- Non-monetary benefits: Technology transfer , Enrichment of Viet Nam Type Cultures Collection (VTCC), - Providing qualified data for VTCC, Building up E-catalogue of VTCC, Finding new taxa of microbe in Vietnam, Manpower development, Publication in domestic & International Journals.
- Monetary benefits: 16 visits (Scientists and researchers) from VTCC to NITE (1-2 months), 10 visits of VTCC scientists to attended annual ACM meeting (I,II, III,IV,V,VI,VII.VIII,IX), >5000 sequence (18s, 23s, 16s ITS), Conducting 18 Technical training workshops at IMBT for a number of 150 Vietnam participants, Chemicals glassware for research activities at VTCC.

Notes

- 1 See: <https://www.cbd.int/doc/world/vn/vn-nr-04-en.doc>, page 29, (accessed 5 November 2016).
- 2 Plant resources Centre. National Plant Gene Bank of Viet Nam. Source is only available in Vietnamese. Available from: <http://www.prc.org.vn/Content.aspx?tab=news&lang=vi&pid=8&cid=18&id=85>, (accessed 5 November 2016).
- 3 <http://www.globalforestwatch.org/country/VNM>, (accessed 5 November 2016).
- 4 These animals include various endemic chickens (e.g. Dong Tao or Mong), ducks (e.g. Bau Quy or Muong Khuong or Meo or Soc or Quy Chau), pigs (e.g. Van Pa or Ba Xuyen), H'mong bulls, Phan Rang sheep, and black and grey rabbits.
- 5 Quotes based on Oanda published rates on 1 November 2016, available at <http://oanda.com> (accessed 1 November 2016).
- 6 Ibid.
- 7 For further information visit Wildlife Conservation Society (WCS) at: <https://programs.wcs.org/vietnam/Species/Primates.aspx>.
- 8 See Viet Nam Academy of Science and Technology and IUCN (2007): Viet Nam Red Data Book. This is the most recent version of the Viet Nam Red Book 2007. In order to obtain more recent data, there is a need to update such publication and contrast it with more recent releases of the IUCN Red list. The IUCN Red List can be accessed at: <http://www.iucnredlist.org/>.
- 9 In addition, BCA and MONRE also co-operated with other stakeholders to review and assess the ABS activities with foreign GR users between 2000 and 2013. The BCA organized meetings with the following: National Institute of Animal Sciences, the Department of Aquaculture, the Center of Plant Resources, the Office of Plant Varieties Protection, the Southern Institute of Fruit Research, the Cuu Long Delta Rice Research Institute, the Academy of Agriculture of Viet Nam, the Viet Nam Institute of Forestry, the Department of Science and Technology for economic-technical branches of MOST, National Institute of Medicinal Materials (NIMM), the Hanoi University of Pharmacies, the University of Can Than, as well as with localities of Lao Cai, Binh Dinh, Quang Nam, Kon Tum, Ninh Binh, Can Tho.
- 10 No synonyms are recorded for this name. See: <http://www.theplantlist.org/tpl1.1/record/tro-50290960> (accessed 6 November 2016).
- 11 Clause 2, Article 55 of Biodiversity Law 2008.
- 12 VOGEL.J.H et al. (2011). *'The Economics of Information, Studiously Ignored in the Nagoya Protocol on Access to Genetic Resources and Benefit-sharing'*, 7/1 Law, Environment and Development Journal (2011), p. 55, states that "Biological resources exhibit both tangible and intangible aspects the latter conceptualized as a set of natural information where value currently added in a patent is access to a subset not previously accessed."
- 13 See: Medaglia CJ, and Silva LC (2007), *Addressing the Problem of Access: Protecting Sources, while giving users Certainty*, IUCN Environmental Policy and Law Paper No. 67/1, p. 40.
- 14 "Traditional knowledge of genetic resources" means knowledge, experience and initiatives of native people on the conservation and use of genetic resources. (Article 3.38 of Biodiversity Law 2008 of Viet Nam).
- 15 Article 64.1 of the Biodiversity Law 2008 of Viet Nam.
- 16 Article 64.2 of the Biodiversity Law 2008 of Viet Nam.
- 17 Clause 4, Article 24, Regulation on forest management issued by Decision 186/2006/QĐ-TTg dated 14/8/2006.
- 18 In addition to the types of benefits that may be shared included in the Regulations, parties may also refer to Appendix 1 of the Nagoya Protocol on the kind of monetary or non-monetary benefits or to the Bonn Guidelines on access to GRs and benefit-sharing for alternative ways to share benefits.
- 19 Article 19.2 of the Decree No. 65/2010/ND-CP.
- 20 Ministry of Economy, Trade and Industry of Japan and Japan Bio-industry Association (2006) *Guidelines on Access to Genetic Resources for users in Japan*, p.13.
- 21 Promulgated together with the Government's Decree No. 160/2013/ND-CP dated November 12, 2013.
- 22 See article 17.2 of the Nagoya Protocol.
- 23 See article 17.4 of the Nagoya Protocol.
- 24 Appendix I of Decree No. 187/2013/ND-CP of November 20, 2013.

- 25 For further information, please see: http://unctad.org/en/Docs/ditcted20074_en.pdf.
- 26 Starting with primary members are 4 BioTrade companies, BIG Viet Nam mission is to attract and support other companies to take up BioTrade activities in Viet Nam. BIG Viet Nam is expected to (1) Provide technical support to Natural ingredient value chains actors to comply with sustainable sourcing practices (e.g.: Ethical BioTrade, GACP, organic.. standards); (2) Facilitate business linkage among value chains actors and partners in domestic and international markets; (3) Facilitate the policy dialogue between private and public sector for an enabling environment for BioTrade activities. BioTrade communication to all related stakeholders and partners will play a crucial tools contribute to the overall BIG mission. BIG should develop interesting and feasible BioTrade communication strategy and plan as well as effective coordinating the BioTrade communication in the country.
- 27 Interviews carried out by David Vivas Eugui, UNCTAD/DITC/TED (2016).
- 28 Feedback from interviews carried out by UNCTAD in 2016.
- 29 Article 61.2 of the Biodiversity Law 2008 of Viet Nam.
- 30 Ibid.
- 31 <http://biotradevietnam.org/en/du-an/ampelopsis-cantoniensis.html>.
- 32 It should be noted that it will depend on the national or regional implementation laws to decide whether derivatives fall within the scope of the ABS systems or not. The Nagoya Protocol does not make it mandatory to include them in the scope of application of the implementing regulations.
- 33 Article 3.22 of the Biodiversity Law 2008 of Viet Nam.
- 34 <http://biotradevietnam.org/en/du-an/gymnema-sylvestre.html>.
- 35 <http://biotradevietnam.org/en/du-an/ampelopsis-cantoniensis.html>.
- 36 <http://biotradevietnam.org/en/du-an/polysias-fruticosa.html>.
- 37 Notes from the minutes of the workshop on “Access and benefit sharing and BioTrade” 27-29 June 2016, Hanoi, Vietnam, UNCTAD/BCA/BIG/SECO.
- 38 OECD (2015), Frascati Manual 2015: *Guidelines for Collecting and Reporting Data on Research and Experimental Development, The Measurement of Scientific, Technological and Innovation Activities*, OECD publishing, Paris, quoted by Véronique, Rossow, in her presentation of “*Research priorities, types of use and changes in intention along the value chain*” Hanoi, 27-28 June 2016, UNCTAD.
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