



# Nagoya Protocol of CBD, Mechanism to Facilitate International Collaborative Development of Plant-Based Products: India a Case Study

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#### **Abstract**

Man's search among natural resources for food and other material needed for living, including health, personal care, wellness, and livelihood support have been predominantly plant based. For a long time, biodiversity and genetic resources were considered part of the heritage of mankind and were available without restriction for scientific research and commercial use. Plant diversity predominantly occurred in old world countries with significant associated traditional knowledge about their potential value. However, they were predominantly exploited by the technologically rich countries, earning major commercial benefits under the auspices of intellectual property rights (IPR). This realization led to division of the world into biodiversity rich and technologically rich countries and global discontentment on unfair sharing of benefits accrued from their commercialization. It led to development of Convention on Biological Diversity (CBD), providing nations the sovereign ownership over biological resources found in their territory, controlling access, ensuring community rights, IPR and right for fair and equitable benefit sharing arising from commercialization. In pursuance, it led to development International Treaty on Plant Genetic Resources for Food and Agriculture under FAO in 2001, to regulate access and benefit sharing of genetic resources of major agricultural crops. It was followed by the Nagoya Protocol, another Access and Benefit System (ABS) system in 2010, covering all biological resources to ensure fair and equitable benefits arising from their commercialization. The present article discusses, how fair and transparent provisions Nagoya Protocol can facilitate greater international cooperation in development and use of plant-based phytonutraceutics, phytotherapeutics and phytocosmetics. Keywords: Access, Biological/Genetic resources, Fair and Equitable Benefit Sharing, Convention on Biological Diversity (CBD), Nagoya Protocol, Phytonutraceutics, Phytotherapeutics, **Phytocosmetics** 



#### Introduction

Ever since mankind started searching biological resources to ensure availability of food through practicing agriculture, it also looked for biological resources, particularly among plants to support health, personal care and wellness, referred as phytonutraceutics, phytotherapeutics, phytocosmetics, etc. These have often been part of traditional knowledge/heritage systems, particularly medicinal systems. They are mostly confined to developing tropical and subtropical regions/countries of the Old world, which are rich in biodiversity and have been the seat of various cultures and civilizations.

From the time of global recognition of the potential economic value of plants and plant-diversity, and their

role in overall development, these biological/genetic resources for a long time were considered part of the heritage of mankind. This led to development of global international mechanism to promote their availability without restriction for scientific research and commercial use, to ensure food and nutritional security and other related benefits to mankind.

This led to extensive exploitation of biological resources by the technologically rich countries, earning major commercial benefits from known plant resources, for which considerable associated indigenous knowledge predominantly came from biodiversity rich countries of the Old world. These commercial benefits were further ensured under the auspices of intellectual property



rights (IPR). However, realization of these facts led to discontentment, particularly in the Old world, about not getting fair and equitable benefits on the plants/biological resources of their country (origin), conserved by generations of local tribes/communities with discovery of significant associated traditional knowledge on their use. The issue of IPR on plant resources also falling within the scope of discussion in General Agreement on Trade and Tariffs (GATT) negotiations made this concern further deep, particularly for countries like India, which have been the seat of old civilizations with rich indigenous traditional knowledge (ITK)-base on plants properties and use under the established systems for research and use, such as *Ayurveda*.

### India, a Rich Center of Floristic Diversity and Endemism

India is among the 12 mega-biodiversity centers of the world. It contains 3 of the 34 global biodiversity hotspots, the Himalayas, the Eastern Indo-Myanmar region and the Western Ghats and Sri Lankan region. The Indian flora represents nearly 12% of the global floral diversity. India has 47513 plants species, including species of bacteria. Of these, about 20141 taxa are of angiosperms with 17926 species belonging to 2991 genera and 251 families, approximately 7% of the described world plant species, including around 6014 lower plants.

About 5725 (recent estimate 6000) species endemic to India, belonging to about 148 genera and 47 families of higher plants, representing 33.5% of the Indian flora. India has three mega-centers of endemic plants, the Western and the Eastern Himalayas, the Northeastern Indo-Myanmar region and the Western Ghats and 25 microcenters centers.<sup>3</sup> Of the 5725-endemic species, 3,471 are found in Himalayas, 2051 in peninsular region, and 239 species in Andaman and Nicobar Islands. About 4045 taxa belonging to 975 genera in 155 families are strict endemic to the present Indian political boundaries. Central Himalaya and moist evergreen forests of the Western Ghats are the main centers of active speciation due to varied topography/microclimatic regimes.<sup>4</sup>

# India, a Center of Knowledge Associated with Medicinal and Aromatic Properties of Plants

Rigveda and Ayurveda (2000 BC), perhaps are the oldest documented repository of human knowledge, representing the first mention of diseases and medicinal herbs in Osadhi-Sukta (Rv. 10.47, 123). Sixty-seven species are mentioned in Rigveda, 81 in Yajurveda and 290 in Atharvaveda. However, the scientific foundation of Ayurveda was laid during the Samhita (compilation) period. The three legendary and authoritative classical texts with documentation of potential knowledge for many plant species are Charak Samhita (700 BC) for 1100 plant species, Sushruta Samhita (200 years BC) for 1270 plant species and Astang Hridayam (AD 700) for 1150 plant species.<sup>5</sup> Vrikshayurveda of Surapala (1000 AD)

describes the properties of 170 plants.<sup>6</sup> Kapoor<sup>7</sup> in 2001 brought out the descriptions of 250 plants, commonly used in constitution of herbal medicine of prevailing *Ayurveda* system.

Being is a reservoir of plant diversity, scientists from India are still describing plant species and indigenous knowledge associated with them from different regions of countries. For example, 70 and 266 medicinal plants have been listed from Ladakh (based on Tibetan *Amchi* system),<sup>8,9</sup> whereas, a total of 166 plants with medicinal properties have been listed from only Balod district of Chattisgarh,<sup>10</sup> one of the reservoirs of plant diversity. These can be the source and basis for further research and systematic exploitation for human welfare, meeting the today's IPR requirements.

# Biopiracy and Need for Establishment of a Transparent Mechanism on Agreed Terms

Biopiracy term was coined by Pat Mooney, to describe a practice in which knowledge discovered by indigenous peoples about nature, including properties of plants/ plant diversity is used by others for commercial profit, without obtaining authorization or compensation to the indigenous people of the country of origin. Instances of patenting plant-based products of Indian origin are, patenting of the fungicidal properties of Neem [USDA and an American MNC W.R. Grace in the early 90s sought a patent No. 0426257 B from the European Patent Office (EPO) on the "method for controlling fungi on plants by the aid of hydrophobic extracted neem oil], long-grained and aromatic variety of Rice [US Patent and Trademark Office (USPTO) granted a patent (No. 5663484) to a Texas based American company, Rice Tec Inc for "Basmati rice lines and grains] indigenous to the Indian subcontinent, and products of many more plant species, such as turmeric, ginger, bitter gourd, etc. are internationally known. Many of the patented products or applied for, are based on indigenous knowledge associated and documented in ancient literature, particularly Sanskrit or in the folk lore of local or tribal communities. Therefore, there are severe concern for protection of the rights of country of origin and the rights of indigenous tribes and communities, the custodians of associated knowledge regarding the properties and use of plant species and their wild relatives. Thereby, demanding development of transparent mechanisms for access and ensuring fair and equitable benefit share on commercial use of the bioresources and the associated knowledge. This would help accelerate the process of research and utilization of bioresources for greater welfare of mankind. In last few decades, several international conventions and mechanisms have been developed in this regard, to facilitate access to bioresources and to protect the rights of various stakeholders, promoting their use, particularly of plants for greater welfare of mankind and to meet the challenges of pollution, climate change that are creating the problems of health and wellness, including that of mother earth.

#### **Convention on Biological Diversity**

Convention on Biological Diversity (CBD) adopted during the Earth Summit in Rio de Janeiro in 1992, entered into force on 29 December 1993.11 It aims at -1. conservation of biological diversity, 2. the sustainable use of its components, and 3. fair and equitable benefit sharing arising out of the utilization of biological/ genetic resources by appropriate access and benefit sharing agreement. It recognizes sovereign rights of States on biological resources, provides mechanism for facilitated access to plant genetic resources (PGR) on mutually agreed terms with prior and informed consent, and protect and promote the rights of communities. It recognizes the IPR (including ingenious innovation of tribes and communities facilitating conservation and use) supportive of CBD and access to technologies, which makes use of these resources attractive, based on fair and equitable sharing of benefits arising from commercial use of the biological resources.

# **Development of Multilateral System for Agricultural Plants**

Despite having fair and equitable benefit sharing arising out of the utilization of genetic resources as one of the main objectives, CBD did not prescribe any mechanism to ensure this objective. As the PGR of the crops were of primary concerns in this regard, a mechanism was evolved to regulate access/exchange of PGR for use in research and crop improvement and is called The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)12. It was adopted by the Thirty-First Session of the Conference of the Food and Agriculture Organization (FAO) of the United Nations on 3 November 2001 to ensure better use of PGR in efforts of genetic improvement of crop plants for achieving food and nutritional security globally. It recognizes the enormous contribution of farmers in generating the diversity in crops species that feed the world, and establishes a multilateral global system to provide farmers, plant breeders and scientists a facilitated access to plant genetic material and ensures that recipients share benefits they derive from the use of these genetic materials with the countries wherefrom these have originated or obtained and the communities associated with them. Thus, meeting the needs of farmers, plant breeders/researchers with guarantee of availability PGR for food and agriculture, on terms agreed for fair and equitable benefit sharing. It is in harmony with CBD and entered into force on June 29, 2004, 90 days after ratification by 40 states. It became operational in 2007 and presently has membership of 130 sovereign nations.<sup>12</sup>

#### Access and Benefit-Sharing Under ITPGRFA

Contracting parties (CPs) recognize the sovereign

rights of States over PGRFA and authority to determine access, subject to national legislation. ITPGRFA facilitate exercising of sovereign rights, with efficient, effective, and transparent mechanism both to facilitate access and to share fair and equitable benefits arising from the utilization of these resources, on a mutually agreed terms/basis, under a multilateral system. This Multilateral System covers the PGR of 64 food and agriculture crops listed in Supplementary file 1 of the document, selected based on importance for food security meeting 80% global demand and interdependence.

## Nagoya Protocol, another System of Access and Benefit Sharing on Use of Biodiversity

ITPGRFA covered only 64 food and agriculture crops but left the regulation for access and use of remaining biodiversity in a transparent manner, ensuring fair and equitable benefit sharing of commercial gains. Nagoya protocol, which is a supplementary agreement to the CBD was adopted on 29 October 2010 in Nagoya, Japan to take care of access to remaining bioresources/genetic resources and fair and equitable benefits sharing arising from their utilization.13 It provides a transparent legal framework for the effective implementation of one of the three objectives of the CBD, i.e. the fair and equitable sharing of benefits arising out of the commercial utilization of bioresources/ genetic resources. It entered into force on 12 October 2014, 90 days after the deposit of the fiftieth instrument of ratification. Its objective is to ensure the fair and equitable sharing of benefits arising from the utilization of genetic resources (GR), thereby encouraging conservation and sustainable use of biodiversity.<sup>13</sup> Figure 1 depicts diagrammatic of functioning of Nagoya Protocol.

### Objective

Facilitate creation of greater legal certainty and transparency for both providers and users of genetic resources by establishing more predictable conditions for access to genetic resources and helping to ensure benefit-sharing when genetic resources leave the boundaries of providing country. With facilitated access and ascertaining benefit-sharing, the Nagoya Protocol creates incentives for conservation and sustainable use of genetic resources, and therefore enhances the contribution of biodiversity in development and human well-being.

#### Scope

The Nagoya Protocol applies to genetic resources (biodiversity) that are covered by the CBD and ensure benefit sharing, arising from their utilization. The Nagoya Protocol also covers ITK associated with genetic resources that are covered by the CBD and the benefits arising from their utilization.

#### **Core Obligations**

The Nagoya Protocol set out core obligations for the

#### Nagoya Protocol on Access and Benefit Sharing

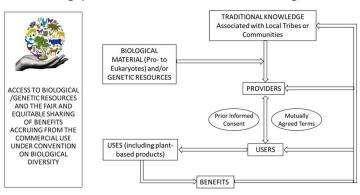


Figure 1. Nagoya Protocol on Access Benefit Sharing.

contracting parties (CP) to take measures in relation to access to genetic resources, benefit-sharing and compliance required thereof.

## Access Obligations

It requires development of a domestic-level access system with measures that help create legal certainty, clarity and transparency with-

- Provision of fair and non-arbitrary rules and procedures
- Establish clear rules and procedures for prior informed consent and mutually agreed terms (MAT)
- Provide mechanism for issuance of a permit or equivalent when access is granted
- Create conditions to promote and encourage research contributing to biodiversity conservation and sustainable use
- Pay due regard to cases of present or imminent emergencies that threaten human, animal or plant health, and
- Consider the importance of genetic resources for food and agriculture to food security and otherwise for human welfare.

### **Benefit-Sharing Obligations**

It requires development domestic-level benefit-sharing mechanism (legislations) to-

- Provide for the fair and equitable sharing of benefits arising from the utilization of bio- or genetic resources with the contracting party providing these resources.
- Utilization includes research and development on the genetics and on biochemical composition of bio- or genetic resources, as well as subsequent applications and commercialization.
- Sharing is with prior informed consent and based on mutually agreed terms. Benefits may be monetary or non-monetary-

## Possible Monetary Benefits

(a) Access fees/fee per sample collected or otherwise

acquired;

- (b) Up-front payments;
- (c) Milestone payments (Staggered or stepwise);
- (d) Payment of royalties;
- (e) License fees in case of commercialization;
- (f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
- (g) Salaries and preferential terms where mutually agreed;
- (h) Research funding;
- (i) Joint research and commercial ventures;
- (j) Joint ownership of relevant intellectual property rights.

#### Possible Non-monetary Benefits

- (a) Sharing of research and development results;
- (b) Collaboration and contribution in scientific research and development programs, particularly biotechnological research activities, where possible to the party providing genetic resources; Participation in product development;
- (d) Collaboration, cooperation and contribution in education and training;
- (e) Admittance to *ex situ* facilities of genetic resources and to databases;
- (f) Transfer to the provider, knowledge and technology under most favorable terms, to facilitate use of genetic resources, including biotechnology, or the conservation and sustainable utilization of biological diversity;
- (g) Strengthening capacities for technology transfer;
- (h) Institutional capacity-building;
- Human and material resources development to strengthen capacities for the administration and enforcement of access regulations;
- (j) Training related to genetic resources, with participation of countries providing genetic resources;
- (k) Access to scientific information for conservation and sustainable use, including inventories and

- taxonomic studies;
- (l) Contributions to the local economy;
- (m) Research directed towards priority needs, such as health and food security, for the party providing genetic resources;
- (n) Institutional and professional relationships for subsequent collaborative activities;
- (o) Food and livelihood security benefits;
- (p) Social recognition;
- (q) Joint ownership of relevant intellectual property rights.

#### Compliance Obligations

Specific obligations to support compliance with the domestic legislation or regulatory requirements of the CP providing bioresources or genetic resources, and contractual obligations reflected in mutually agreed terms, are significant innovation of the Nagoya Protocol. CPs are supposed to:

- Take measures providing that bioresources or genetic resources utilized within their jurisdiction have been accessed in accordance with prior informed consent, and that mutually agreed terms have been established, as required by another contracting party
- Cooperate in cases of alleged violation of another contracting party's requirements
- Encourage contractual provisions on dispute resolution in mutually agreed terms
- Ensure an opportunity is available to seek recourse under their legal systems when disputes arise from mutually agreed terms
- Take measures regarding access to justice
- Take measures to monitor the utilization of biological or genetic resources after they leave a country including by designating effective checkpoints at any stage of the value-chain, i.e. research, development, innovation, pre-commercialization or commercialization

# Addressing Associated Traditional Knowledge Held by Indigenous/Local Communities

The Nagoya Protocol addresses ITK associated with biological (species)/genetic resources with provisions on access, benefit-sharing and compliance. It further goes making consent of the indigenous and local communities to be part of the established right of state to grant access to biological/genetic resources. CPs are to take measures to ensure prior informed consent of these communities' and fair and equitable benefit-sharing, keeping in mind the community laws and procedures as well as customary practices on use and exchange. More information on the Nagoya Protocol and traditional knowledge can be found on the Traditional Knowledge program of work webpage.

# **Tools and Mechanisms to Assist Implementation**

The Nagoya Protocol's success will require development tools and mechanism for effective implementation

of provisions at the domestic level. The range of tools and mechanisms developed under the Nagoya Protocol, which will assist CPs would include establishment of a National Focal Points (NFPs) and Competent National Authorities (CNAs) to serve as contact points for information, and grant access or cooperate on issues of compliance. In India these powers have been vested with National Biodiversity Authority (NBA).

It will need establishing, an access and benefit-sharing clearinghouse mechanism to share information, such as domestic regulatory ABS requirements or information on NFPs and CNAs, etc.

It may need capacity-building to support key aspects of implementation based on a country's self-assessment of national needs and priorities. It may vary from-

- Development of domestic ABS legislation to implement the Nagoya Protocol
- Negotiate mutually agreed terms (MAT)
- Develop in-country research capability and institutions for-
- Awareness development
- Technology transfer
- Targeted financial support for capacity-building and development initiatives through the Nagoya Protocol's financial mechanism, the Global Environment Facility (GEF)

### Opportunities, with Special Reference to India

- For example, global herbal medicine market was valued at \$71.19 B in 2016, It was expected to grow \$107 billion by 2017 and to increase \$ 140 billion by 2024
- China is largest suppliers of herbal products (US and Europe) based on 5000 plants
- India's share in the global herbal medicinal market is very limited 0.5% (\$358.60 million), while it has the traditional knowledge of about ~7000 plants
- The market for Ayurvedic medicines has been expanding at the rate of 20% in India, annually.
- Climatic diversity, floristic richness, particularly of those plants with medicinal properties and available associated knowledge puts India in a supreme position for further research and development of plant-based products
- Specifically, India needs to focus on research and development in biochemical profiling, identification of active principles in the sources, followed by molecular characterization, and developing agrotechnology and processing technology meeting the requirements of global and national IPR standards and for quality control.

### Some Examples Needing Immediate Attention/Cooperation

• Revisit to pharmaceutical properties of Cressa cretica, Selaginella bryopteris, Desmotrichum fimbriatum, Malaxis acuminata (M. wallichii, Microstylis wallichii) Trichopus zeylanicus and Terminalia chebula, considered to be source of Sanjeevani in search of real Sanjeevani.

- Reinvestigate the properties of yellowish-white cosmetic paste made from ground bark of *Hesperethusa* crenulata and obtained from *Murraya* spp. and *Limonia* acidissima (wood apple) and commonly applied to the face, called Thanaka in Myanmar and countries of Southeast Asia.
- Search for herbs Sarcostemma acidum and other proposed plant species, such as Amanita muscaria, Psilocybe cubensis, Peganum harmala and Ephedra sinica referred to be the part Soma yoga and Ayurveda.

#### Potential for Plant-Based Products

There has been growing concern about health and diet. In general people believe that meat and meat products are unhealthy because of increased risk of cardiovascular diseases, obesity and cancer and added synthetic antioxidants and antimicrobials. Many crops, particularly grain legumes, such soybean, pea and cereals like wheat and rice, besides being staple food, has significant potential as sources of protein to be ingredient(s) for fortification of food. Plant derivatives rich in protein and/or having antioxidant components including vitamins A, C and E, minerals, polyphenols, flavonoids and terpenoids that may decrease the risk of several degenerative diseases in meat products. Whereas, vegetable oil and plant fiber may work as fat replacers and spices and condiments may work as natural antimicrobials. In addition, there are several plant species that can be source of active botanicals and herbs that can be used to maintain or improve health in general, and function as source of sweeteners, seasonings, coloring and flavoring of foodstuffs. Plants can also be source of dairy alternatives, such as milk, beverages (Almond, Soy, Coconut, and Rice) and other drinks, and cultured products such as yogurt, frozen desserts, ice cream, etc.

There are ancient medicinal practices/systems, like *Ayurveda* that have stood the test of time for centuries. In fact, many of the life-saving pharmaceuticals or drugs we rely even today are derived from plants and were discovered by indigenous communities. *Aswagandha*, *Nidrajanana* Vati, morphine, aspirin, ephedrine, etc. are few to mention, and there are still many with untapped potential. Therefore, traditional knowledge from Indian Subcontinent can find prominent role in innovative drug discovery and production platforms.

Vegetal extracts and herbs have been used for personal care and cosmetic purposes since time immemorial, and for centuries, they were the only source to obtain colorants, fragrances and products for soothing and protecting skin. They were replaced by synthetic materials with low price. However, because of their negative effects in the last few decades cosmetic ingredients based on plants or plants derivatives have made a powerful comeback. Products of

plant origin used in cosmetics include vegetable oils and other lipids, essential oils used as fragrances or for their antimicrobial activities, ingredients for skincare and hair care, and antioxidants, to name just a few. Plant material used to produce cosmetic ingredients comes from a variety of sources, which include not only conventional products coming from horticultural production (in field or greenhouse), but also from wild harvest in developing countries like India and biotechnological methods (e.g., tissue cultures, fermentation of genetically modified organisms, microalgae cultures, hydroponic systems, etc.). However, there is a need for greater attention for conservation and sustainable use of biodiversity and genetic diversity in general in search of unknown sources and of known source in particular for improved isolation and extraction techniques, the evaluation of safety of raw materials, and finally, the development of innovative formulations. As per one estimate in relation to food, there is +49 percent potential for plant protein based or supplemented products, + 14 percent for meat substitute, +20 percent dairy alternatives for totally around 16.3 billion.

#### Geographic Spread of Market, Estimates and Forecast

Based on region, the global plant-based biologics market is segmented into Canada, United States of America, Latin America (including Brazil), Europe (France, Germany, United Kingdom, Spain, Italy, Russia and rest of Europe), Japan, Asia Pacific (China, India and rest of Asia), Middle East, and Africa.

Global Market Study on the Plant-based Meat Market revealed that in terms of value, the global plant-based meat market is expected to register a healthy Compound Annual Growth Rate (CAGR) of 5.8% during the period 2018-2026, due to various factors, regarding which Persistence Market Research (PMR) offers vital insights in detail. Whereas, the global market for dairy alternative drinks has reached around US\$16.0 billion in 2018.

The global market for botanical and plant-derived drugs is growing from \$29.4 billion in 2017 and expected to grow around \$39.6 billion by 2022 with an expected CAGR of almost 8%, during the 2017-2021. It will be primarily due to the low cost of herbal medicines compared to allopathic and offers new opportunities.

As most of the consumers find cruelty towards animals unethical and are spreading awareness against this, cosmetic trends are changing towards plant-based cosmetics, affecting global marketplace rapidly. Further, trends towards embracing natural substitutes such as plant-based personal care products are working in favor of the market. For example, the global vegan (vegetarians) cosmetics market size is projected to reach US\$ 20.8 billion by 2025, progressing at a CAGR of 6.3% during the forecast period of 2018-2025. These estimations on various plant-based products reveal that the market of these products is going to increase in near future offering

various opportunities and there is a need for greater international collaboration in research and development to meet the global and national market demands.

#### **Emerging Markets**

Manufacturing of herbal based medicines by multinational and domestic pharmaceutical companies and the increased public interest in herbal based products had been significantly contributing to the economic growth of the plant-based medicine. For example, the global market potential of Aloe vera, used as medicine, to treat burns, added to skin creams and cosmetics, only was estimated in the billions of dollars of which India a major producer. Whereas, Devils claw used in the treatment of arthritis and other inflammatory diseases has been growing from Namibia, Africa as a major export. India is the hub of the regional trade. At the national level the 40% of the state forest-based revenues and 70% of the forest export resources come from medicinal and aromatic plants (MAPs) and non-timber products (NTFPs), mostly exported as unprocessed raw material. A small country like Nepal trades an estimated 20,000 tons of MAPs, worth US\$ 18-20 million every year of which about 90% of are forest collection, mainly exported to India in raw forms. Therefore, in developing countries, including India, there is a need for capacity building in manufacturing of final products. This can be achieved either through strengthening research and development program using indigenous knowledge and skills of technologically rich countries having expertise in biotechnological and biochemical research through international cooperation, which would facilitate strengthening government's make in India program.

# Conclusion

Development of awareness about the transparent access and benefit sharing mechanism of Nagoya Protocol that came into force in 2014, as a supplementary mechanism of CBD to facilitate creation of greater legal certainty and transparency for both providers and users of biological/genetic resources through PIC and MAT. It shall help promote greater international cooperation among nations in research and development of plant-based products for safer human health, care and wellness.

# **Competing Interests**

None

### **Supplementary Materials**

Online Supplementary file 1 contains structural details of Nagoya Protocol.

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