

ABS in India

Overview of legal requirements, procedures and relevant authorities



Prepared for the European Seed Association (ESA)

by the Union for Ethical BioTrade

July 2019

Disclaimer: This document is for information purposes only. The information provided is not legal advice. UEBT aims to ensure its accuracy, but provides no guarantees in this regard. Official information on laws and regulations on ABS is available through national focal points, competent authorities or the ABS Clearing House (<https://absch.cbd.int/countries>).

Table of contents

1. Legal framework.....	3
INTERNATIONAL AGREEMENTS	3
NATIONAL LAWS AND REGULATIONS	3
DRAFT RULES OR AMENDMENTS	3
2. Scope of ABS-related requirements	3
BIOLOGICAL RESOURCES.....	3
RESEARCH, COMMERCIAL UTILIZATION AND OTHER RELEVANT ACTIVITIES	4
3. National rules and the ITPGRFA	5
4. Access requirements.....	6
5. Benefit sharing requirements	7
6. Sanctions and compliance.....	8
7. Relevant authorities	8
8. List and links of relevant laws and regulations	8

1. Legal framework

International agreements

- Convention on Biological Diversity (CBD): Party since 19 May 1994
- Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits resulting from their Utilization (ABS): Party since 12 October 2014
- International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA): Party since 29 June 2004

National laws and regulations

- The [Biological Diversity Act](#) (2002), in force since 1 October 2003 and 1 July 2004 (depending on the specific provisions)
- The [Biological Diversity Rules](#) (2004), in force since 1 July 2004
- [Guidelines](#) on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations (2014), in force since 21 November 2014
- Notification on [Exemption of Crops](#) listed in the Annex I of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), in force since 17 December 2014
- Guidelines for Implementing the [International Treaty](#) of Plant Genetic Resources for Food and Agriculture for Facilitated Access under the Multilateral System, adopted by Department of Agriculture and Cooperation on 30 July 2014
- Notification on biological resources normally traded as [commodities](#) (2016), in force since 7 April 2016, with [amendments](#) in force since 7 November 2017
- Guidelines on [Upfront Payments](#) (not-dated)

Draft rules or amendments

In April 2019, the National Biodiversity Authority (NBA) called for public comments or suggestions on “Draft (revised) Guidelines on Access to Biological Resources and Associated Knowledge and Equitable Sharing of Benefits Regulations, 2019.”

2. Scope of ABS-related requirements

Indian rules on biodiversity regulate access to any biological resource occurring in India or associated traditional knowledge, for the purposes of research, characterization or commercial utilization. That is, ABS requirements in India have a broad scope, covering a wide range of both resources and activities.

Biological resources

Biological resources are defined as “plants, animals, and microorganisms or parts thereof,” as well as “their genetic material and by-products.” The reference to “by-products,” though the term is not defined, could cover biochemical compounds, even if such compounds have undergone physical or chemical processing – this would need to be assessed on a case-by-case basis. Moreover, Indian requirements cover not only species native to India, but also exotic plants or other biological resources that have been obtained from the country.

Human genetic resources are not included. Additionally, there are two important exceptions to biological resources subject to ABS requirements:

- Plants [normally traded as commodities](#) (commonly referred to as NTACs). The Ministry of Environment, Forest and Climate Change (MoEFCC) has notified a list of over 400 plant species, from crops to medicinal plants, that are widely traded and, therefore, excluded from ABS requirements. The NTACs exception only applies if the company is trading the

specific plant part and type of plant (e.g. cultivated or wild) in the list. To be excluded, trading of the specified plant part must also be for “common practice” – for the purposes the plant is generally traded and processed. Products made from NTACs are also excluded, as long as the company is able to show that such products are also traded as commodities. That is, the NTAC exception does not apply if plants or resulting products are used for other activities, including research or intellectual property applications.

- Value-added products (commonly referred to VAPs) are defined as products that have portions or extracts of biological resources “in unrecognizable and physically inseparable form.” That is, for this second exception, there is no list but rather a set of specific criteria. In trainings conducted by the NBA, the term “products” has been described as referring to consumer products – that is, products that have undergone all stages of production and are packaged in their final container. However, there is no official definition of the “value-added product” concept.

Specific questions on scope

- *Native and non-native plants.* No distinction is made in ABS-related rules between native or non-native plants. As long as biological resources are obtained in India, they are considered to fall within the scope of ABS requirements.
- *Microbes.* The definition of biological resources includes a specific reference to microorganisms, thus bringing them into the scope of ABS requirements.
- *DNA samples.* The definition of biological resources includes a specific reference to genetic material, thus bringing DNA samples into the scope of ABS requirements.
- *Ex-situ access.* The Biological Diversity Act and Rules have no specific provisions on *ex-situ* access. However, *ex-situ* access is implied through the use of terms such as “obtain” and “occurring in India” in Section 3(1). ABS requirements thus apply to cases of access of biological resources from collections, seed banks, gene banks, botanical gardens, etc.

Research, commercial utilization and other relevant activities

Prior approval is required to use biological resource or associated traditional knowledge for “research,” “bio-survey and bio-utilization,” and “commercial utilization.” Plant breeding using conventional breeding methods is excluded from the definition of “commercial utilization” (see below). Additionally, no application for an intellectual property right, in or outside India, should be made for inventions based on any research or information on a biological resource obtained from India, without obtaining the relevant permit. Transfers of biological resources and research results are also regulated.

The case of plant breeding

ABS-related rules in India include cultivated and domesticated plants. Indeed, access to any plant variety obtained from India requires prior authorization and mutually agreed terms under the Biodiversity Act and Rules. No exception is made for commercial varieties. That is, plant breeding involving exclusively plant varieties that have been developed and purchased from companies still requires authorization from the National Biodiversity Authority (NBA) or State Biodiversity Boards (SBBs), with corresponding benefit-sharing arrangements.

Even plant varieties protected under the 2001 Protection of Plant Variety and Farmers Right Act (PVP Act), which has its own benefit sharing provisions, are not generally excluded from ABS requirements under the Biodiversity Act and Rules. This is because the PVP Act benefit-sharing provisions respond to different objectives and involve different stakeholders. Research, bio-survey and bio-utilization and commercial utilization linked to plant breeding must, therefore, comply with ABS requirements under the Biodiversity Act and Rules.

There are, however, three situations in which plant breeding is exempted from ABS requirements in the Biodiversity Act and Rules:

- *Applications for plant variety protection.* The Biodiversity Act includes an exception for plant variety protection in regard to the prior approval required from NBA for any application for intellectual property protection involving biological resources.
- *Crops listed in Annex I of the ITPGRFA.* As explained below, these crops are subject to specific ABS procedures, managed by Department of Agriculture, Cooperation and Farmers' Welfare.
- *Conventional breeding.* The Biological Diversity Act includes an exception for "conventional breeding or traditional practices" used in agriculture and horticulture. These activities are not considered commercial utilization of biological resources. To date, NBA has not adopted a definition or criteria for "conventional breeding." However, the draft regulations on benefit sharing (see above) include an explanatory note that defines "conventional breeding and traditional practices" as activities aiming to develop more genetic variability or improvement of animal and plant species by facilitating meiotic combination of genes expressing themselves in the subsequent generations – as practiced in agriculture, animal husbandry, bee keeping and other activities – conducted by farmers themselves and based on traditional knowledge. The draft explains that, if these activities are conducted at a commercial level, they would not be considered as conventional breeding and traditional practices.

3. National rules and the ITPGRFA

Specific rules apply to crops listed in Annex I of the ITPGRFA. The Biological Diversity Act and Rules make no specific reference to this treaty. However, in 2014, the MoEFCC, in line with its competences under biodiversity provisions, empowered the Department of Agriculture and Cooperation (DAC – today the Department of Agriculture, Cooperation and Farmers' Welfare), to exempt crops listed in the Annex I of the ITPGRFA, as it may consider necessary, from ABS requirements. The aim is fulfilling India's obligation, as an ITPGRFA party, to facilitate access to plant genetic resources for food and agriculture.

On 16 February 2015, DAC declared all crops in Annex I of the ITPGRFA – when accessed for the purpose of utilization and conservation for research, breeding and training for food and agriculture – to be exempted from ABS requirements in the Biodiversity Act and Rules. This exemption extends to crops other than Annex I already held in the *ex-situ* collections of research centers in the Consultative Group on International Agricultural Research (CGIAR) in India.

Annex I crops, though exempted from the Biodiversity Act and rules, are governed by the "Guidelines for Implementing the International Treaty of Plant Genetic Resources for Food and Agriculture for Facilitated Access under the Multilateral System," adopted on 30 July 2014. These guidelines establish ABS-related requirements and procedures (see box), with the aim to provide facilitated access to plant genetic resources as per ITPGRFA obligations and in line with the CBD, the Nagoya Protocol, and relevant national laws and regulations. To date, several thousand accessions belonging to the following nine crops within Annex I have been approved: Barley, chickpea, finger millet, lentil, rice, pearl millet, pigeon pea, sorghum and wheat.

Procedure to access crops listed in Annex I of the ITPGRFA

The guidelines designate DAC, as the national focal point for the ITPGRFA, as the competent authority. It is mandated to consider requests for plant genetic resources for food and agriculture from designated accessions of Annex I crops, in line with the following procedure:

- Access requests for Annex I crops must be addressed to DAC.
- Only requests from ITPGRFA Contracting Parties are considered.
- The Germplasm Export Facilitation Committee (GEFC) is constituted to examine the request and submit recommendations to DAC.
- Access to Annex I crops is granted with the approval of DAC and under the conditions of a Standard Material Transfer Agreement (SMTA).
- The National Bureau of Plant Genetic Resources (NBPGR), as the agency managing plant genetic resources for research purposes in India, coordinates the supply of Annex I crops, in consultation with other relevant national research institutions.
- Annex I crops are only supplied in the quantities specified in the regulations.

4. Access requirements

In India, an authorization is required prior to the utilization of biological resources and associated traditional knowledge, as per the activities listed in the Biodiversity Act as triggering ABS requirements. The authorization is granted through mutually agreed terms – a contract that outlines permitted uses, establishes terms and conditions for research or other activities and defines the mechanism and amount for benefit sharing – agreed upon between the applicant and the competent authorities, which represents the providers.

The process is launched through an application to the competent authorities (see section 7). Requirements for selected applications are described in Table 1. The applicant is not responsible for negotiating prior informed consent with local actors. It is the competent authorities that, having received an application, are charged with consulting relevant stakeholders. For example, the NBA involves the relevant State Biodiversity Board (SBB), which in turn holds consultation with the Biodiversity Management Committee in the area where biological resources will be collected or harvested.

At the national level, once an application is completed and local consultations concluded, it is forwarded to the Expert Committee on Access and Benefit Sharing, which is comprised of over 25 experts and representatives from government entities and academic institutions. The expert committee reviews the application and advises on the terms and conditions, including on fair and equitable benefit sharing. Based on these recommendations, the NBA proposes and agrees upon mutually agreed terms with the applicant. The approval for access to biological resources is then granted and communicated to the ABS Clearing House Mechanism. In the past year, approvals have generally taken between 6 months to one year.

Table 1. Selected applications for access to biological resources

Proposed activities	Application	Information required includes: ¹	Fee
Research	Online application using form I	<ul style="list-style-type: none"> • Description and quantity of biological resources and any associated traditional knowledge • Area where collection or harvest will take place • Person accessing on behalf of applicant 	10'000 INR

¹ All forms are available at <http://nbaindia.org/content/26/59/1/forms.html>.

		<ul style="list-style-type: none"> • Purpose of access • Expected economic and other benefits for applicant • Proposed arrangements for benefit sharing 	
Commercial utilization	Online application using forms I and A	Additionally, form A requires information on supplier, price paid for biological resources and prospective buyers, if known.	10'000 INR
Intellectual property application	Online application using form III	<ul style="list-style-type: none"> • Description of invention • Biological resources or associated traditional knowledge used • Location of collection or harvest/ information of identified individual or community holding TK • Entity that conducted R&D • Expected economic and other benefits for applicant 	500 INR

5. Benefit sharing requirements

Mechanisms and arrangements for benefit sharing are established in the mutually agreed terms signed by applicants with the competent authorities. However, since 2014, parameters for benefit sharing arrangements in the case of commercial utilization of biological resources and intellectual property applications have been established through regulations entitled "Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing" (see Table 2). Additionally, the NBA has issued guidelines defining the amount of upfront payments required for access to biological resources for research activities, based on the type of biological resources, the quantity collected, the sector in which research is taking place and any access to associated traditional knowledge. For example, the wild collection of 5 kg of plants for research into cosmetic applications would be subject to a payment of 20'000 INR. The payment for accessing 500 ml of industrial effluent for research into environmental remediation would amount to 1'000 INR.

Table 2. Benefit sharing options and parameters

Proposed activities	Options for benefit sharing	Parameters for benefit sharing	Considerations
Commercial utilization	Percentage of purchase price of biological resources	Trader.....1-3% Manufacturer....3-5%	Specific amount is proposed by NBA, considering activities, potential markets, investments and technologies involved, in line with recommendations from expert committee.
	Percentage of net ex-factory price of resulting product	Depending on total amount, 0.1-0.5%	
Intellectual property	For own exploitation, percentage of net ex-factory price of resulting product	Depending on sector, 0.2-1.0%	
	For licensing, percentage of fees and royalties received	<ul style="list-style-type: none"> • 3-5% for fees • 2-5% for royalties 	

Benefit sharing promotes local livelihoods and conservation and sustainable use of biodiversity. Payments are made to the competent authorities, which nevertheless only retain 5% of total benefits shared, to cover administrative fees. The remaining 95% is transferred to the providers of biological resources or associated traditional knowledge. If it was not possible to identify these providers, then benefits would be invested in projects in the relevant areas. It is important to note that it is also possible to share non-monetary benefits. However, this is an option that in practice has not yet been explored.

6. Sanctions and compliance

The Biological Diversity Act and Rules include provisions on enforcement and penalties. At the state level, notices and fines have been issued, based these provisions. NBA has not, to date, itself issued any notices or fines for non-compliance. However, NBA has filed a complaint in a judicial court against a company for violation of ABS provisions in the Biodiversity Act.

Section 10(4)(d)(ii), Section 25(1)(j) and Section 25(2)(j), and Section 64(1)(p) of the Patents Act (as amended in 2005) establish disclosure of origin requirements for inventions involving biological material and the possibility of opposition and revocation of the patent for lack of compliance. The Indian Patent Office has, additionally, issued guidelines that outline the processing of such patent applications to ensure compliance with ABS requirements. NBA is in the process of filing opposition on the grant of several patents in the Indian Patent Office. NBA also has filed third party observations in foreign patent offices on applications using Indian biological resources in the inventions.

7. Relevant authorities

The Biodiversity Act and Rules establish both state and national-level ABS procedures and authorities, depending on the type of applicant.

- *State Biodiversity Boards.* Indian citizens and companies incorporated in India with no foreign participation in their shares or management apply for ABS permits before SBBs, which have now been established in all of India's 29 states.
- *National Biodiversity Authority* Other persons or companies apply for ABS permits before NBA, which is based in Chennai and involves state and local level authorities in its consultations. NBA is the only competent authority at the national level under the Biodiversity Act and Rules.

For crops listed in Annex I of the ITPGRFA, which are exempted from the provisions of the Biodiversity Act and Rules, the competent authority in relation to ABS is the Department of Agriculture, Cooperation and Farmers' Welfare, as described in section III.

8. List and links of relevant laws and regulations

Name	Number	Date	Link
Biological Diversity Act	N/A	2002	http://nbaindia.org/content/25/19/1/act.html
Biological Diversity Rules	N/A	2004	http://nbaindia.org/content/17/20/1/rules.html
Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations	N/A	2014	http://nbaindia.org/uploaded/pdf/Gazette_Notification_of_ABS_Guidelines_1.pdf

Notification on Exemption of Crops listed in the Annex I of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)	N/A	2014	http://nbaindia.org/uploaded/pdf/Gazette_Notification_on_exemption_of_crops_listed_in_the_Annex-I_of_the_ITPGRFA_1.pdf
Guidelines for Implementing the International Treaty of Plant Genetic Resources for Food and Agriculture for Facilitated Access under the Multilateral System	N/A	2014	https://seednet.gov.in/PDFFILES/final_Guidelines_of_ITPGRFA_Treaty_26_06_2014.pdf
Notification on biological resources normally traded as commodities	N/A	2016	http://nbaindia.org/uploaded/pdf/Notification_of_Normally_Traded_Commodities_dt_7_April_2016.pdf
Notification on biological resources normally traded as commodities amendments	N/A	2017	http://nbaindia.org/uploaded/pdf/NTC_amendments_S.O.1352.pdf
Guidelines on Upfront Payments	N/A	N/A	http://nbaindia.org/uploaded/pdf/Guidelines_for_Upfront_Payment.pdf