Compliance rules under the Nagoya Protocol: Implications for countries of origin

BIOTRADE III FACILITATION PROGRAMME

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Getting started: what is what

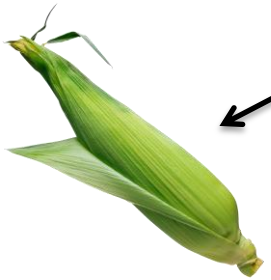
- Most **countries** are **both users and providers** of genetic resources and associated TK

- The Nagoya Protocol is **mandatory** for ratifying countries BUT it is **not self-executing**
  - It requires national and/or regional regulations to be implemented.

- The applicable law will be that of the **country and/or region were** the GR and/or TK is **sourced**, as well as that where it is **used**.

Example 1: Straightforward situation

Company A: based in Spain



Crop Z from Viet Nam

R&D on the GR of Crop Z

Example 2: Complex situation

What happens when we don't get the GR from its country of origin BUT from another company or third party?

Has the 3rd party lawfully accessed the GR or associated TK?

YES

Can the 3rd party **TRANSFER** that access right?

YES

- Same conditions of access of the entity that obtained legal access for the first time apply (e.g. same uses)
- There might be a need to require legal access again

NO

No legal transfer is possible for R&D or commercial use.

NO

We **CAN'T USE** the GR or associated TK without getting an **ABS contract or permit from the country of origin**

We neet to go to the country of origin and negotiate an ABS contract with the to access and use the GR and the associated TK

User country regulation's implications on compliance and monitoring: The EU Regulation

1. All EU users of GR and associated TK have to **exercise "due diligence"**:
    - Accessed in accordance with applicable legal requirements; and
    - Benefits have been shared as relevant.
2. All EU users are obliged to **declare at specific check points** that the correct procedure has been followed
3. **Non-compliance** with "due diligence" and other user obligations **will be penalized** by measures and provisions within EU member states national regulations:
    - Measures must be effective, proportionate and dissuasive.

Due diligence obligation: how can it be obtained?

Internationally recognized Certificate of Compliance (IRCC)

OR

Gather, keep and transfer all information required by law to comply with the "due diligence" obligation.

Internationally Recognized Certificate of Compliance

UNEP | Convention on Biological Diversity

ABSCH-IRCC-IN-206827-1
Internationally recognized certificate of compliance constituted from information on the permit or its equivalent made available to the Access and Benefit-sharing Clearing-House

In accordance with Article 17, paragraph 2, of the Nagoya Protocol on Access and Benefit-sharing, 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.

General Information

Issuing country

INDIA

Verification link (view latest version)

https://absch.cbd.int/database/ABSCH-IRCC-IN-206827

ABS-CH Unique Identifier (UID)

ABSCH-IRCC-IN-206827-1

Issuing Authority

Competent National Authority

National Biodiversity Authority

5th Floor, TICEL Biopark, CSIR Road, Taramani
Chennai, Tamilnadu
600 113, **India**

Phone: +91 44 2254 2777
Fax: +91 44 2254 1200
Email: secretary@nbaindia.org, chairman@nba.nic.in, secretary@nba.nic.in
Website: www.nbaindia.org

Details of the permit or its equivalent

Reference number of the permit or its equivalent

India/NBA/Appl/9/664

Additional national references or identifiers

Application in Form-III for seeking approval for the invention " Garlic formulation and a process for preparing the same for treatment of diabetes" for obtaining IP Rights in India and United States of America.

Date of issuance of the permit or its equivalent

11 Mar 2015

Reference to other internationally recognized certificate(s) of compliance that relate(s) to this permit

Application in Form-III for seeking approval for the invention " Garlic formulation and a process for preparing the same for treatment of diabetes" for obtaining IP Rights in India and United States of America.

Prior Informed Consent (PIC) Information

Confirmation that prior informed consent (PIC) obtained or granted

YES

Provider The person or entity that holds the right to grant access to the genetic resources in accordance with domestic legislation.

CONFIDENTIAL INFORMATION

Entity to whom PIC was granted

CONFIDENTIAL INFORMATION

Mutually Agreed Terms (MAT) Information

Confirmation that mutually agreed terms (MAT) have been established

YES

Additional information about the mutually agreed terms

1. The user shall notify the NBA on the grant of IPR within 30 days from the grant.
2. If the user himself commercializes the process/product/innovation, the monetary sharing shall be 0.2% on the annual gross ex-factory sale minus government taxes.
3. The user needs to inform the NBA about any commercialization made on the IP Rights granted.
4. The user shall submit the half-yearly report to NBA as per the terms and conditions agreed upon.

Subject-matter

Subject-matter or genetic resources covered:

CONFIDENTIAL INFORMATION

Information on the utilization of the genetic resource(s)

Type of use allowed by the permit or its equivalent

CONFIDENTIAL INFORMATION

Conditions for third party transfer:

1. If the user assigns/licenses the process/product/innovation to a third party for commercialization, the user shall pay to NBA 3.0% of the fee received (in any form including the license / assignee fee) and 2.0% of the royalty amount received annually from the assignee/licensee.
2. In case the user assigns or transfer the IPR in whole or in part to any person, whether voluntarily or involuntarily, the user undertakes to attach this agreement as an appendix to the assignment instrument.

Certificate History

Date	Action	Author	Comment
06 APR 2016 10:15 AM	**PUBLISHED**	Hem Pande (hempande@nic.in)	Permit information published to the ABS clearing-house and certificate generated.

Further Information

Questions about the permit or its equivalent constituting an internationally recognized certificate of compliance should be addressed to the competent national authority issuing the permit or its equivalent. Additional information about the permit or its equivalent may be available in the Access and Benefit-Sharing Clearing House (https://absch.cbd.int/).

Questions about the Nagoya Protocol on Access and Benefit-sharing or the operation of the Access and Benefit-sharing Clearing-House may be directed to the Secretariat of the Convention on Biological Diversity.

Secretariat of the Convention on Biological Diversity
413 rue Saint-Jacques, suite 800
Montreal, Québec, H2Y 1N9
Canada
Fax: +1 514 288-6588
Email: secretariat@cbd.int

Due diligence obligation: what does it mean?

A. ABS is **available throughout the value chain**

B. Users need to **seek, keep and transfer to subsequent users information** on:

- Date and place of access;
- Description of the GR or associated TK used;
- Source from where they obtained them, as well as any subsequent users;
- Presence or absence of rights and obligations relating to ABS, including those regarding subsequent applications and commercialization;
- Any existing access permits; and
- MAT, including any benefit-sharing arrangements.

C. Users must **analyze if the information in their possession is sufficient and be certain that they comply with the applicable legal requirements in the provider country.**

→ If NOT sufficient, users must either:

- Obtain the missing information OR
- Discontinue the use of the GR or the associated TK

D. Users must **keep all** the relevant **ABS information for** a period **of 20 years** after the end of the period of use.

Monitoring compliance with user measures: the role of checkpoints

Parties to the Nagoya Protocol have to establish at least 1 national checkpoint for compliance

WHY?

To collect and receive relevant information related to PIC, MAT, the source of GR, including the associated TK, and its utilization

WHERE?

At any stage of the value chain

WHERE CAN I FIND ONE?

Checkpoints should be published at the ABS Clearing House Mechanism so that users and providers know of them.

Issues for policymakers to take into account

User country measures require users to comply with provider country regulations	If a country has no ABS rules, then users can directly access the GR or associated TK
Making a difference for ABS for R&D and commercialization purposes, might make implementation more difficult	It might be easier to cover both purposes in the scope of the national regulations, while having a simiplified and shortened process for ABS for R&D purposes only.
For users to be able to comply with them properly, ABS national and regional rules must be	Transparent
	Clear
	Efficient and effective
	Not overly burdensome or costly
	Enforceable
ABS regulations implementing the Nagoya Protocol should have provisions for both providers and users	Most national regulations from biodiversity-rich countries tend to focus only on their own resources. Countries should also establish measures for their own national users going abroad to source GRs and related TK.
Users can be either national or foreign. Both need to comply with user obligations.	Foreign users will apply user measures from the country or region they come from or from that where the “use” will take place.

Thank you

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