

# The Nagoya Protocol and its impact on AnGR and gene banking

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**FAO/ERFP Workshop *In situ* and *Ex situ* gene conservation**

12-13-14 April 2016, Gödöllő

**NAGOYA PROTOCOL  
ON  
ACCESS TO GENETIC RESOURCES  
AND THE FAIR AND EQUITABLE  
SHARING OF BENEFITS ARISING  
FROM THEIR UTILIZATION  
TO THE  
CONVENTION ON  
BIOLOGICAL DIVERSITY**

**TEXT AND ANNEX**



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**A short reminder  
on main elements  
of the Nagoya Protocol...**

# Implementation of the Protocol

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- ❑ Most countries are both users and providers of genetic resources
- ❑ Many countries have developed legislation on access to domestic genetic resources based on Article 15 of the CBD and Bonn guidelines
- ❑ Only limited number of countries addressed users of genetic resources in their legislation
- ❑ National legislation is necessary to comply with Nagoya Protocol and be able to ratify this treaty

**National legislation should provide for transparency and clarity regarding access requirements**

# Obligations of Parties

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- Establishment of the „National Focal Point on ABS“
- Establishment of one or more „Competent National Authority/ies on ABS“ (NCA)
- Development of national legislation
- Provision of necessary information to the ABS CH
- Facilitation of access to GR and TK

# Obligations of users

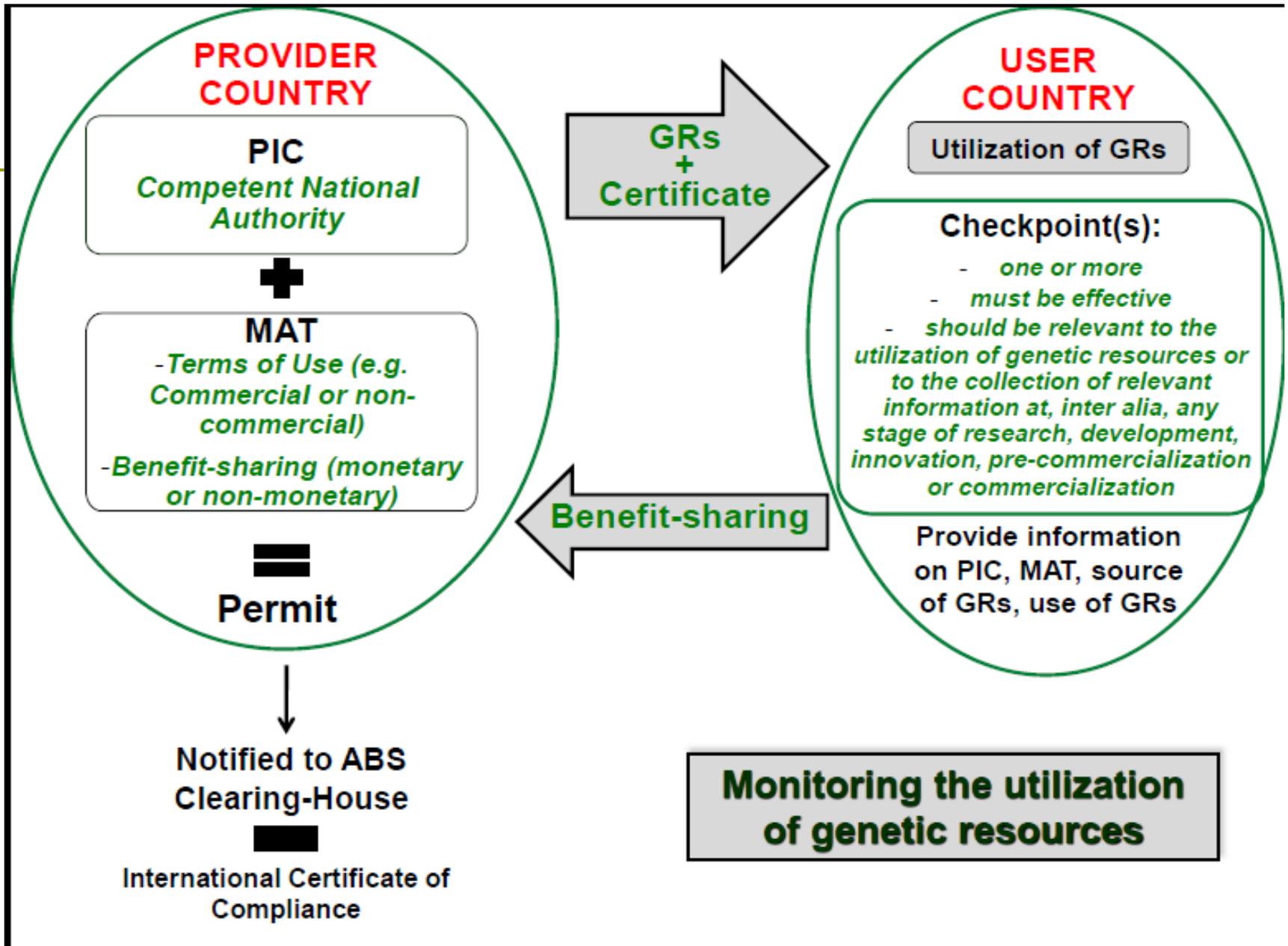
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- Access - users seeking access to genetic resources must

Get permission from the provider country (Prior Informed Consent: PIC), unless the provider country determines otherwise

- Benefit-sharing - provider and user must:

Negotiate an agreement to share benefits resulting from the use of a genetic resource (Mutually Agreed Terms: MAT)



# Obligations of users and providers

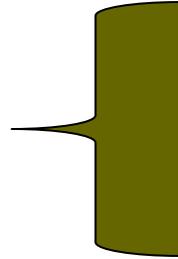
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- **Compliance** – Nagoya Protocol creates obligations to:
  - Comply with national ABS legislation and mutually agreed terms (**users**)
  - Monitor the utilization of genetic resources (**NCA**)
    - Internationally recognized certificate of compliance (IRCC)
    - Checkpoints

# Summary: ABC of the Protocol

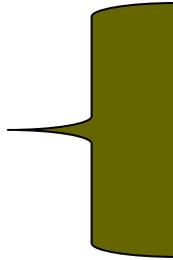
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## □ Access



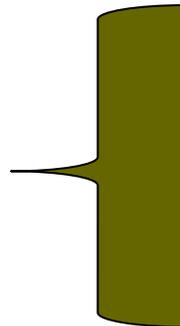
- to GR and TK (PIC)
- (or no access regulations)

## □ Benefit Sharing



- according to MAT
- the GMBSM?

## □ Compliance



- national legislation
- IRCC/checkpoints
- monitoring users
- sanctions

# Website: all important information

The screenshot shows a web browser window displaying the website for the Convention on Biological Diversity. The browser's address bar shows the URL <https://www.cbd.int/abs/>. The website header includes the logo of the Convention on Biological Diversity, navigation links for 'The Convention', 'Cartagena Protocol', 'Nagoya Protocol', 'Programmes', 'Information', and 'Secretariat', and a search bar. The main content area features a banner with images related to genetic resources and benefit-sharing, followed by a navigation menu on the left and a main article titled 'The Nagoya Protocol on Access and Benefit-sharing'. The article text describes the protocol's purpose and the role of the ABS Clearing-House. A sidebar on the right highlights 'The ABS Clearing-House' and 'ABSCH'. At the bottom, there is a reference to 'Business.2020, November 2015'.

The Nagoya Protocol on Access and Benefit-sharing

The *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity* is an international agreement which aims at sharing the benefits arising from the utilization of genetic resources in a fair and equitable way. It entered into force on 12 October 2014, 90 days after the date of deposit of the fiftieth instrument of ratification. [Learn more about the Nagoya Protocol.](#)

The *Access and Benefit-sharing Clearing-House* (ABS Clearing-House) is a platform for exchanging information on access and benefit-sharing established by Article 14 of the Protocol, as part of the Clearing-House of the Convention established under Article 18, paragraph 3 of the Convention. The ABS Clearing-House is a key tool for facilitating the implementation of the Nagoya Protocol, by enhancing legal certainty and transparency on procedures for access and benefit-sharing, and for monitoring the utilization of genetic resources along the value chain, including through the internationally recognized certificate of compliance. By hosting relevant information regarding ABS, the ABS Clearing-House will offer opportunities for connecting users and providers of genetic resources and associated traditional knowledge. [Learn more about the ABS Clearing-House.](#) [Visit the ABS Clearing-House.](#)

The ABS Clearing-House  
**ABSCH**

Business.2020, November 2015

**News & Communications**[Web Announcements](#)[Statements](#)[Notifications](#)[News Headlines on Biodiversity](#)[Press Releases](#)[RSS Feeds](#)[Twitter](#)[Facebook](#)[Discussion Forums](#)**National Information**[Country Profiles](#)[List of Parties](#)[Lists of National Focal Points](#)[National Biodiversity Strategies and Action Plans \(NBSAPs\)](#)[National Reports](#)[Status of Contributions](#)**Multimedia**[Video Gallery](#)[YouTube](#)**General References**[Information](#) > [Meetings](#) > Meeting Documents

## Meeting Documents

### First meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol on Access and Benefit-sharing

13 - 17 October 2014 - Pyeongchang, Republic of Korea

13 decisions

25 document(s)

5 notification(s)

- [Official Web Site](#)
- [All PDF Documents \(ZIP\)](#)
- [ABSCH workshop](#)
- [In-Session Documents](#)

[Outcomes](#)[Official Documents \(14\)](#)[Information Documents \(10\)](#)[Notifications \(5\)](#)

### Final Report

**UNEP/CBD/NP/COP-MOP/1/10**

Report of the First Meeting of the Conference of the Parties to the Convention on Biological Diversity Serving As the Meeting of the Parties to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising from Their Utilization

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 [اللغة العربية](#) [中文](#) [English](#) [Français](#) [Русский](#) [Español](#)

### Decisions

**1. Decision NP-1/1**

Rules of procedure for meetings of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol

 [اللغة العربية](#) [中文](#) [English](#) [Français](#) [Русский](#) [Español](#)

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**2. Decision NP-1/2**

The Access and Benefit-sharing Clearing-House and information sharing (Article 14)

 [اللغة العربية](#) [中文](#) [English](#) [Français](#) [Русский](#) [Español](#)

 [اللغة العربية](#) [中文](#) [English](#) [Français](#) [Русский](#) [Español](#)

**3. Decision NP-1/3**

Monitoring and reporting (Article 29)

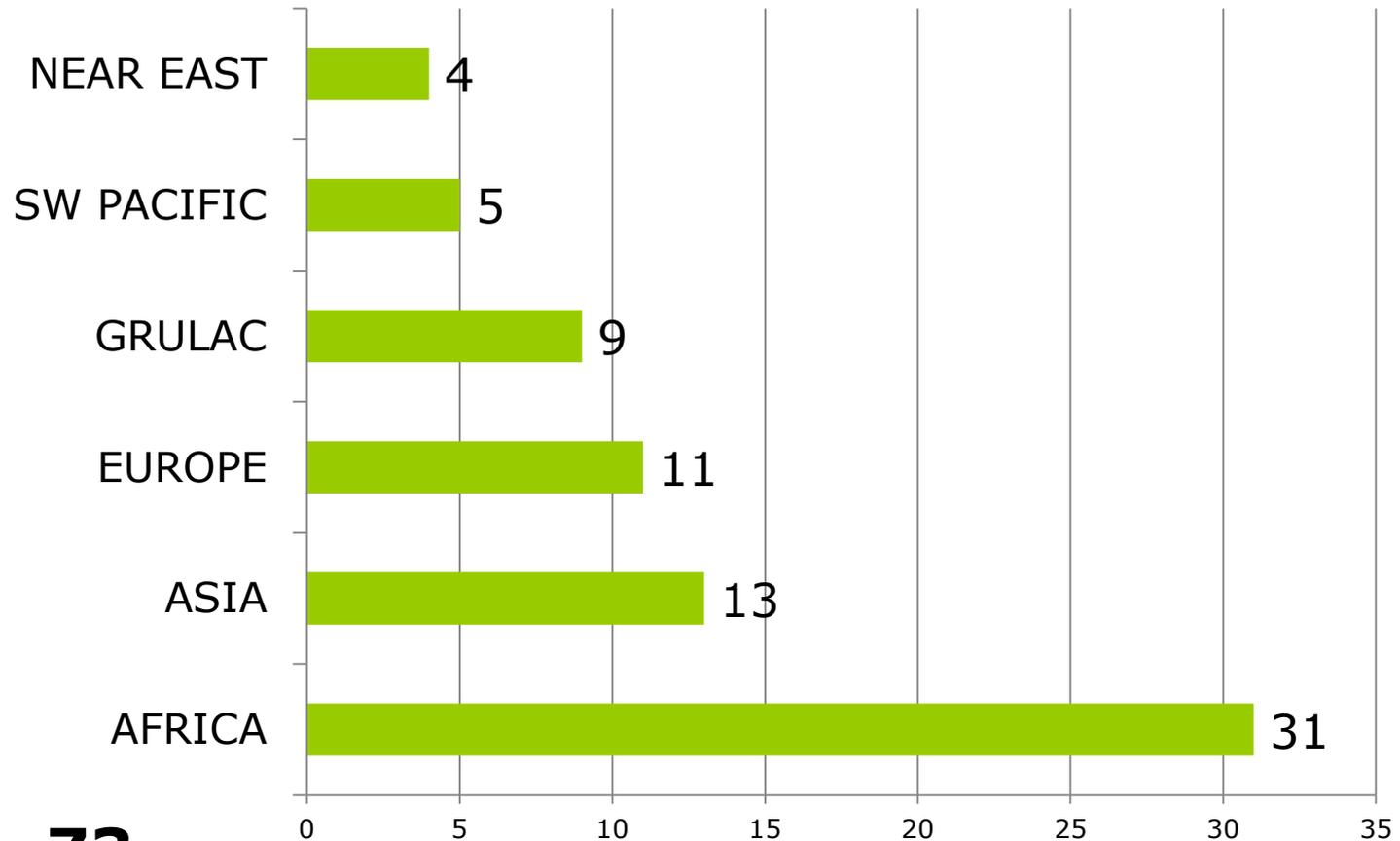
 [اللغة العربية](#) [中文](#) [English](#) [Français](#) [Русский](#) [Español](#)





# Ratifications by region

1st April, 2016



**73**

**Africa 42%**

**Europe 15%**

## AFRICA

## EUROPE

Albania

Belarus

Denmark

European Union

Hungary

Norway

Spain

Switzerland

Croatia

Slovakia

United Kingdom of  
Great Britain and  
Northern Ireland

Benin

Botswana

Burkina Faso

Burundi

Comoros

Côte d'Ivoire

Ethiopia

Gabon

Gambia (the)

Guinea-Bissau

Kenya

Madagascar

Mauritius

Mozambique

Namibia

Niger

Rwanda

Seychelles

South Africa

Sudan

Uganda

Malawi

Guinea

Lesotho

Democratic Republic  
of the Congo

Congo

Liberia

Mauritania

Djibouti

Togo

Senegal

## ASIA

Bhutan

India

Indonesia

Lao People's  
Democratic Republic

Mongolia

Myanmar

Tajikistan

Viet Nam

Cambodia

Kyrgyzstan

Kazakhstan

Philippines

Pakistan

## GRULAC

Guatemala

Guyana

Honduras

Mexico

Panama

Peru

Uruguay

Dominican Republic

Cuba

## NORTH AMERICA

## SW PACIFIC

Fiji

Micronesia (Federated  
States of)

Samoa

Vanuatu

Marshall Islands

## NEAR EAST

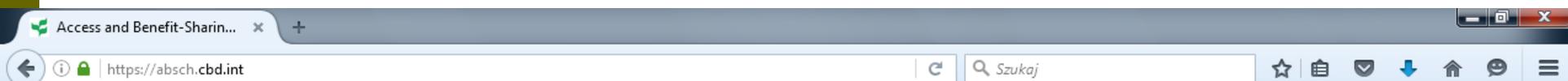
Egypt

Jordan

Syrian Arab Republic

United Arab Emirates

# ABS Clearing House



The Access and Benefit-sharing Clearing-house (ABSCH) is a platform for exchanging information on ABS and a key tool for facilitating the implementation of the Nagoya Protocol.

## ABSCH Record Overview

70 Parties to the Nagoya Protocol

National Records Reference Records

### ABS National Focal Points

170 Countries have submitted 181 ABS National Focal Points

### Competent National Authorities

23 Countries have submitted 33 Competent National Authorities

### Legislative, Administrative or Policy Measures

20 Countries have submitted 65 Legislative, Administrative or Policy Measures

### National Websites or Databases

9 Countries have submitted 11 National Websites or Databases

### Checkpoints

4 Countries have submitted 6 Checkpoints

### Internationally Recognized Certificates of Compliance

3 Countries have submitted 27 Internationally Recognized Certificates of Compliance

### Checkpoint Communiqués

0 Countries have submitted 0 Checkpoint Communiqués

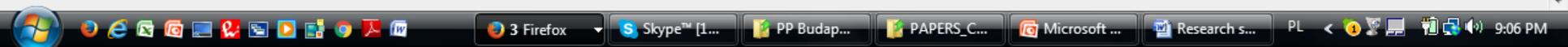
### 63 Virtual Library Resources

2 Model Contractual Clauses, Codes of Conduct, Guidelines, Best Practices and/or Standards

0 Capacity-building Resources

3 Capacity-building Initiatives

0 Community protocols and procedures and customary laws





## ABSCH-IRCC-IN-204353-1

### 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)

<http://absch.cbd.int/database/ABSCH-IRCC-IN-204353>

##### ABS-CH Unique Identifier (UID)

ABSCH-IRCC-IN-204353-1

#### Issuing Authority

##### Competent National Authority

##### National Biodiversity Authority (NBA)

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](mailto:secretary@nbaindia.org), [chairman@nba.nic.in](mailto:chairman@nba.nic.in), [secretary@nba.nic.in](mailto:secretary@nba.nic.in)

Website: <http://www.nbaindia.org>

#### Details of the permit or its equivalent

##### Reference number of the permit or its equivalent

India/NBA/App/9/684

##### Additional national references or identifiers

Application in Form-I for accessing ethno-medicinal knowledge of the Siddi community from Gujarat for research

##### Date of issuance of the permit or its equivalent

27 Mar 2015

##### Date of expiry of the permit or its equivalent

26 Mar 2018

#### 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

Ms Seema Solanki

##### Medical Anthropology and Ethno biology.

Research Scholar (-)

University of Kent

Canterbury

United Kingdom of Great Britain and Northern Ireland

Phone: +91 9717032453

Email: [seemasolanki.du@gmail.com](mailto:seemasolanki.du@gmail.com), [ss830@kent.ac.uk](mailto:ss830@kent.ac.uk)

#### 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 not obtain any form of IPR based on the biological resources and /or associated knowledge accessed under this agreement in any manner without obtaining the prior approval of NBA under provisions of the Biological Diversity Act, 2002.
2. The applicant shall submit a report to NBA on the outcome of the research work.

#### Subject-matter

##### Subject-matter or genetic resources covered:

Accessing ethno-medicinal knowledge of the Siddi community from Gujarat for research

#### 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:

The user shall not transfer or part with the biological resources and /or associated knowledge accessed under this agreement in any manner without obtaining the prior approval of NBA under provisions of the Biological Diversity Act, 2002.

#### Certificate History

Date	Action	Author	Comment
01 OCT 2015 11:52 AM	PUBLISHED	Hem Pande ( <a href="mailto:hempande@nic.in">hempande@nic.in</a> )	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 (<http://absch.cbd.int/>).

##### 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](mailto:secretariat@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.

# First IRCC

# Research student receives first certificate of compliance under the Nagoya Protocol

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The first ICCR was issued to SAC PhD student Seema Solanki on 1 October 2015.

Seema received a permit from India's National Biodiversity Authority to conduct research on the ethnomedical knowledge of a Siddi community in Gir Forest, Gujarat. The Siddis are descended from African slaves. They have an extensive knowledge of local flora and fauna.

# 3 countries (India, Guatemala , South Africa): 27 IRCC as of 8 April, 2016

The screenshot shows a web browser window displaying the ABSCH website. The browser's address bar shows the URL <https://absch.cbd.int/search/national-records/IRCC>. The website header includes the ABSCH logo and the text "THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE" and "Convention on Biological Diversity". The navigation menu includes "HOME", "FIND INFORMATION", "SUBMIT INFORMATION", and "HELP". The breadcrumb trail is "CBD > ABSCH > Find Information > Search".

The main content area shows search results for "Internationally Recognized Certificates of Compliance". The search results are filtered by country, showing 3 countries and 27 records. The results are displayed in two sections: Guatemala and India.

**Guatemala** (Party) has 1 record:

- Contract of access to genetic resources for research purposes on Mahogany (*Swietenia macrophylla* King) and Cedar (*Cedrella odorata* L) (ABSCH-IRCC-GT-206790)

**India** (Party) has 25 records:

- India/NBA/App/9/684 (ABSCH-IRCC-IN-204353)
- India/NBA/App/9/719 (ABSCH-IRCC-IN-206802)
- India/NBA/App/9/582 (ABSCH-IRCC-IN-206803)
- India/NBA/App/9/608 (ABSCH-IRCC-IN-206811)
- India/NBA/App/9/790 (ABSCH-IRCC-IN-206810)
- India/NBA/App/9/631 (ABSCH-IRCC-IN-206807)

The left sidebar contains navigation options: "Country Profiles", "National Records", and "Group results by country". The "Group results by country" section includes filters for keyword, Party status, countries, regions, and record type. The "Group results by country" section also shows "ABS National Focal Points" (181) and "Competent National Authorities" (33).

The Windows taskbar at the bottom shows the system tray with the date and time: 8:47 PM. The taskbar also shows several open applications: Outlook, Mozilla Firefox, Access an..., Skype, PP Budap..., and Microsoft.

# EU implementation of the Nagoya Protocol

❑ EP Council Regulation  
511/2014, 16.04.14

❑ Commission Implementing  
Regulation  
2015/1866, 13.10.15

❑ Member States laws  
(esp. access regimes)

20.5.2014

EN

Official Journal of the European Union

L 150/59

## REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMT AND OF THE COUNCIL of 16 April 2014

on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union

(Text with EEA relevance)

THE EUROPEAN PARLIAMT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure <sup>(2)</sup>,

Whereas:

- (1) The main international instrument providing a general framework for the conservation and sustainable use of biological diversity and the fair and equitable sharing of the benefits arising from the utilisation of genetic resources is the Convention on Biological Diversity, approved on behalf of the Union in accordance with Council Decision 93/626/EEC <sup>(3)</sup> (the 'Convention').
- (2) The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity <sup>(4)</sup> (the 'Nagoya Protocol') is an international treaty adopted on 29 October 2010 by the Parties to the Convention. The Nagoya Protocol further elaborates upon the general rules of the Convention on access to genetic resources and sharing of monetary and non-monetary benefits arising from the utilisation of genetic resources and traditional knowledge associated with genetic resources (access and benefit-sharing). In accordance with Council Decision 2014/283/EU <sup>(5)</sup>, the Nagoya Protocol was approved on behalf of the Union.
- (3) A broad range of users and suppliers in the Union, including academic, university and non-commercial researchers and companies from different sectors of industry, use genetic resources for research, development and commercialisation purposes. Some also use traditional knowledge associated with genetic resources.
- (4) Genetic resources represent the gene pool in both natural and domesticated or cultivated species and play a significant and growing role in many economic sectors, including food production, forestry, and the development of medicines, cosmetics and bio-based sources of energy. Furthermore, genetic resources play a significant role in the implementation of strategies designed to restore damaged ecosystems and safeguard endangered species.
- (5) Traditional knowledge that is held by indigenous and local communities could provide important lead information for the scientific discovery of interesting genetic or biochemical properties of genetic resources. Such traditional knowledge includes knowledge, innovations and practices, of indigenous and local communities embodying traditional lifestyles, relevant for the conservation and sustainable use of biological diversity.

<sup>(1)</sup> OJ C 161, 6.6.2013, p. 73.

<sup>(2)</sup> Position of the European Parliament of 11 March 2014 (not yet published in the Official Journal) and decision of the Council of 14 April 2014.

<sup>(3)</sup> Council Decision 93/626/EEC of 25 October 1993 concerning the conclusion of the Convention on Biological Diversity (OJ L 309, 13.12.1993, p. 1).

<sup>(4)</sup> Annex 1 to Document UNEP/CBD/COP/DEC/XI of 29 October 2010.

<sup>(5)</sup> Council Decision 2014/283/EU of 14 April 2014 on the conclusion, on behalf of the Union, of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (see page 231 of this Official Journal).

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2014:150:TOC>

The screenshot shows the EUR-Lex website interface. At the top, there is a navigation bar with the EUR-Lex logo and the text "Access to European Union law". A search bar is located on the right side of the header. Below the header, there is a breadcrumb trail: "EUROPA > EU law and publications > EUR-Lex > EUR-Lex - JOL\_2014\_150\_R\_0002 - EN". A navigation menu contains links for "Home", "Official Journal", "EU law and related documents", "National law", "Legislative procedures", and "More". A cookie consent banner is displayed, asking if the user wants to keep cookies. Below this, there are options to "Save to My items", "Bookmark this item", and "Download notice". The main content area is titled "Document JOL\_2014\_150\_R\_0002" and includes tabs for "About this document", "Text", "Linked documents", and "All". The "Text" tab is active, showing the title and reference of the document: "Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (Text with EEA relevance)". Below the title, the document reference is given as "OJ L 150, 20/05/2014, p. 59-71 (BG, ES, CS, DA, DE, ET, EL, EN, FR, GA, HR, IT, LV, LT, HU, MT, NL, PL, PT, RO, SK, SL, FI, SV)". A section titled "Languages, formats and link to OJ" provides a grid of links for different languages (BG, ES, CS, DA, DE, ET, EL, EN, FR, GA, HR, IT, LV, LT, HU, MT, NL, PL, PT, RO, SK, SL, FI, SV) and formats (HTML, PDF, Official Journal). A note below the grid states: "To see if this document has been published in an e-OJ with legal value, click the icon above". On the right side, there is a "My EUR-Lex" sidebar with options for "Sign in", "Register", "My searches (0)", "My items (0)", "My RSS feeds (0)", "RSS feeds", "Webservice registration", "Guided Tour", "Statistics", and "We'd like to hear from you".

# Main features of the regulation

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1. General obligation on users to exercise due diligence
2. Establishing a system of EU registered collections
3. Formally recognizing best practices
4. Monitoring user compliance and checkpoints
5. Penalties
6. Enabling a collaborative approach to implementation

Access to GR and to TK in discretion of the MS

# Article 2      Scope

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1. This Regulation applies to genetic resources over which **States exercise sovereign rights** and to traditional knowledge associated with genetic resources  
that are **accessed after the entry into force** of the Nagoya Protocol for the Union.

It also applies to the benefits arising from the utilisation of such genetic resources and traditional knowledge associated with genetic resources

# Article 3    Definitions

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## 7. "traditional knowledge associated with genetic resources"

means traditional knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources and that is as such **described in the mutually agreed terms** applying to the utilisation of genetic resources;

# Article 3 Definitions

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## 8 "illegally accessed genetic resources"

means genetic resources and traditional knowledge associated with genetic resources which were **not accessed in accordance with the national access and benefit-sharing legislation** or regulatory requirements of the provider country that is a Party to the Nagoya Protocol requiring prior informed consent;

# Article 4      Obligations of users

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- All users would be obliged to exercise **due diligence** to ascertain that genetic resources and traditional knowledge associated with genetic resources used **were accessed in accordance with applicable legal requirements** and that, where relevant, benefits are fairly and equitably shared upon mutually agreed terms
- All users would need to seek, keep and transfer to subsequent users information relevant for access and benefit-sharing

# Due diligence concept (Timber Regulation)

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- ❑ **Information:** The operator must have access to information describing the timber and timber products, country of harvest, species, quantity, details of the supplier and information on compliance with national legislation.
- ❑ **Risk assessment:** The operator should assess the risk of illegal timber in his supply chain, based on the information identified above and taking into account criteria set out in the regulation.
- ❑ **Risk mitigation:** When the assessment shows that there is a risk of illegal timber in the supply chain that risk can be mitigated by requiring additional information and verification from the supplier.

# Article 4 Obligations of users

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- ❑ **The internationally-recognised certificate** of compliance, as well as information on the content of the MTA relevant for subsequent users – a proof
- ❑ Users would be obliged to draw consequences from such information
- ❑ Breaches of the due diligence obligation would be sanctioned
- ❑ In the future EU users will not accept input to their R&D activities unless it comes with relevant information on ABS

# Article 5 Register of collections

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- Lowering the risk that illegally acquired genetic resources are used in the Union
- Collections wishing to be included in the register of Union collection would commit to supply fully documented samples of genetic resources to third persons for their use

# Article 5 Register of collections

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- ❑ Users acquiring a genetic resource from a Union registered collection **would be considered to have exercised due diligence** as regards the seeking of all necessary information
- ❑ System of EU registered collections would be particularly beneficial for academic researchers and small or medium sized enterprises
- ❑ Strengthening networks with EU collections could build mutual trust and create mutual opportunities

# Article 7

## Monitoring user compliance

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- Users would be obliged to declare at identified points that they complied with their due diligence obligation
  - All **recipients of research funding** involving the utilisation of genetic resources and traditional knowledge
  - At the **stage of final development of a product** developed via the utilisation of genetic resources or traditional knowledge

# Article 8 Best practices

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- ❑ Associations of users may request the Commission to recognise a specific combination of procedures, tools or mechanisms overseen by an association as best practice.
- ❑ Competent authorities of the Member States would be obliged to consider that the implementation of a recognised best practice by a user reduces that user's risk of non-compliance and justifies a reduction in compliance checks.

# Article 8 Best practices

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- Formal recognition of best practices would raise **legal certainty and lower costs** for users and public administration
- Implementation of ABS best practices will become **important reference point** in provider and in user countries

First two applications for recognition of best practices were submitted to the EC

# Article 9

## Checks on user compliance

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- Competent authorities of Member States would check on a risk-based approach whether users comply with their obligations under this Regulation
  - in accordance with a periodically reviewed **plan developed using a risk-based approach**;
  - when a competent authority is in possession of relevant information including on the basis of substantiated **concerns provided by third parties**, regarding a user's noncompliance

# Article 11

# Penalties

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- Infringements of the Regulation by users would be sanctioned by **effective, proportionate and dissuasive** penalties.
- Penalties in discretion of the MS.

# Article 15 Consultation forum

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- The Commission shall ensure a balanced participation of representatives of the Member States and other interested parties in issues related to the implementation of this Regulation.
- They shall meet in a consultation forum.
- The rules of procedure of that consultation forum shall be established by the Commission.

First meeting of the Consultation Forum took place in February 2016

# Commission Implementing Regulation 2015/1866, 13.10.15

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Sets details on implementation of three articles of the basic regulation

- Art. 5 (Register of collections)
- Art. 7 (Monitoring user compliance)
- Art. 8 (Best practices)

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### Title and reference

Règlement d'exécution (UE) 2015/1866 de la Commission du 13 octobre 2015 portant modalités d'application du règlement (UE) n° 511/2014 du Parlement européen et du Conseil en ce qui concerne le registre des collections, la surveillance du respect des règles par l'utilisateur et les bonnes pratiques

*OJ L 275, 20.10.2015, p. 4-19 (BG, ES, CS, DA, DE, ET, EL, EN, FR, HR, IT, LV, LT, HU, MT, NL, PL, PT, RO, SK, SL, FI, SV)*

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# Agriculture in CBD: still PGR only!

**CBD brochure**

**Agrobiodiversity =  
PGR**

**The only reference  
to AnGR  
is the front  
picture!**



## Bioscience at a Crossroads

Access and Benefit Sharing in a Time of  
Scientific, Technological and Industry Change:

*The Agricultural Sector*



# Agro-biodiversity: sectoral differences

	<b>PGR</b>	<b>AnGR</b>
<b>Inbreeding</b>	<b>used extensively</b>	<b>not desirable</b>
<b>Value of individual</b>	<b>low</b>	<b>high to very high</b>
<b>Testing costs</b>	<b>inexpensive</b>	<b>expensive</b>
<b>GM</b>	<b>possible/efficient</b>	<b>difficult/not accepted</b>
<b>Exchange</b>	<b>S→N</b>	<b>N→N and N→S</b>
<b>Ownership</b>	<b>public genebanks</b>	<b>private</b>
<b>Patentability (TRIPS)</b>	<b>varieties</b>	<b>breeds not patentable</b>
<b>Centres of origin</b>	<b>well defined</b>	<b>multiple domestication</b>
<b>Trading</b>	<b>farmers'/breeders' rights</b>	<b>bilateral agreements</b>

# Gene flow in AnGR

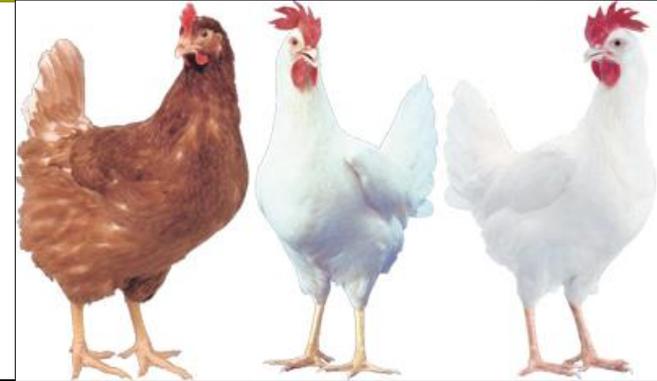


- ❑ Rare examples of introgression of exotic genotypes to mainstream breeds (e.g. Meishan pig)

- ❑ Use of wild species almost negligible

- ❑ Major gene flow:  
**N → N and N → S**

**N → S** Continuously increasing due to **the Livestock revolution**



# Exchange of AnGR

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- ❑ Farm Animal Genetic resources are privately owned
- ❑ Exchange of AnGR is very beneficial and smoothly running
  - Active international exchange by private-private transactions
  - Contracts from very simple to very sophisticated
  - Farmer owns AnGR after purchasing semen or animal
  - Price according to the genetic value
  - Models for best practices could further facilitate exchange
- ❑ Standards for transfer set by:
  - EU zootechnical legislation (pedigree, genetic value)
  - WTO: Sanitary and Phytosanitary measures (SPS)

# Impact on AnGR and gene banking

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Provider country decision to:

regulate access to GR

provide free access

does it cover farm animals?

YES  
PIC & MAT  
required

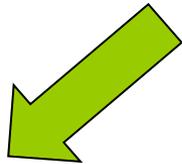
NO  
free access

- no user obligations
- genebanks operate according to own protocols/procedures

# Key questions for Europe

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Provider country regulating access?



Developed country



- Difficult to predict
- Depends on the scope (all/native)
- Impact proportional to importance of breeding sector in provider country



Developing country



- So far meaningless uptake of AnGR from South to the North
- but
- May create obstacles in future
- May create obstacles in South-South exchange of livestock

# Impact on gene banking

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## Article **19**

### **MODEL CONTRACTUAL CLAUSES**

1. Each Party shall encourage, as appropriate, the development, update and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms.
2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of sectoral and cross-sectoral model contractual clauses.

## Article **20**

### **CODES OF CONDUCT, GUIDELINES AND BEST PRACTICES AND/OR STANDARDS**

1. Each Party shall encourage, as appropriate, the development, update and use of voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit-sharing.
2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of voluntary codes of conduct, guidelines and best practices and/or standards and consider the adoption of specific codes of conduct, guidelines and best practices and/or standards.

# Decision NP-1/5

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on model contractual clauses, voluntary codes of conduct, guidelines and best practices and/or standards (Articles 19 and 20)

1. *Encourages* Parties, other Governments, international organizations, indigenous and local communities and relevant stakeholders to submit tools developed under Articles 19 and 20 of the Nagoya Protocol to the Access and Benefit-sharing Clearing-House;

2. *Also encourages* Parties, other Parties to the Convention, other Governments, international organizations, indigenous and local communities and relevant stakeholders to update tools relevant to Articles 19 and 20 of the Nagoya Protocol that were developed prior to the Nagoya Protocol;

3. *Decides* to take stock of the use of sectoral and cross-sectoral model contractual clauses, voluntary codes of conduct, guidelines and best practices and/or standards, indigenous and local communities' customary laws, community protocols and procedures, in accordance with Articles 12, 19 and 20, in relation to access and benefit-sharing four years following the entry into force of the Protocol and in conjunction with the first assessment and review of the Nagoya Protocol.

# Impact on gene banking

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Need for:

- Development of voluntary best practices
- They may include protocols and procedures for exchange of biological material
  - between genebanks
  - between genebanks and users
  
- Standard MAA
- Standard MTA

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Thank you very much