Ministry of Environment, Forest and Climate Change

National Biodiversity Authority

Implementation of ABS Mechanism in India

International Symposium of National Implementation of ABS System under the Nagoya Protocol: Sharing Lessons & Discussing Future Challenges – 6th July 2017 at Seoul

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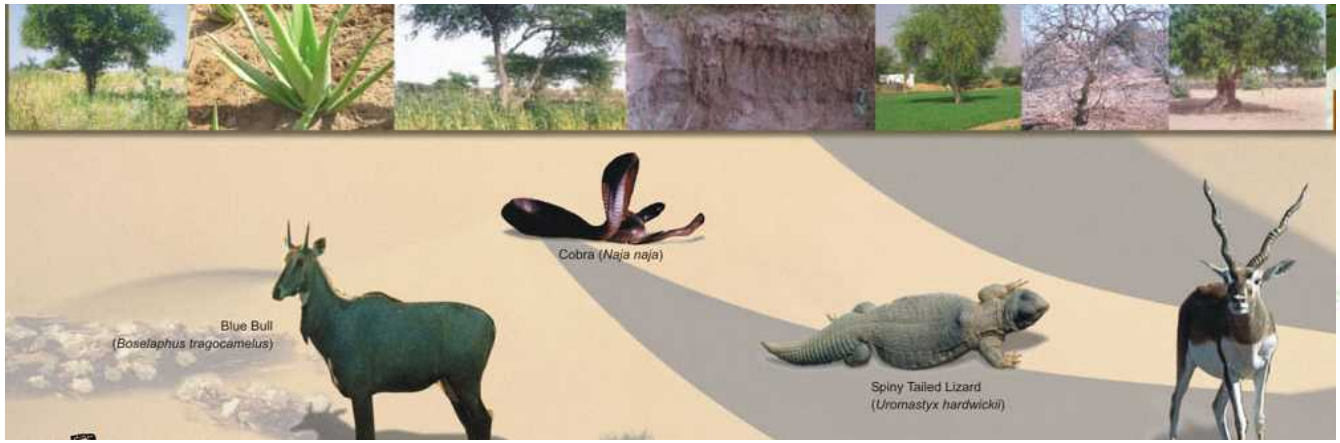
Biological Diversity Act, 2002

Biological Diversity Act was enacted **in 2002** on the lines of CBD;

To implement the provisions of the BD Act, the **National Biodiversity Authority** was established in October 2003 at Chennai.

Objectives are:-

1.Conservation of biodiversity,
2.Sustainable use of its components,
3.Fair and equitable sharing of benefits arising out of the use of bioresources

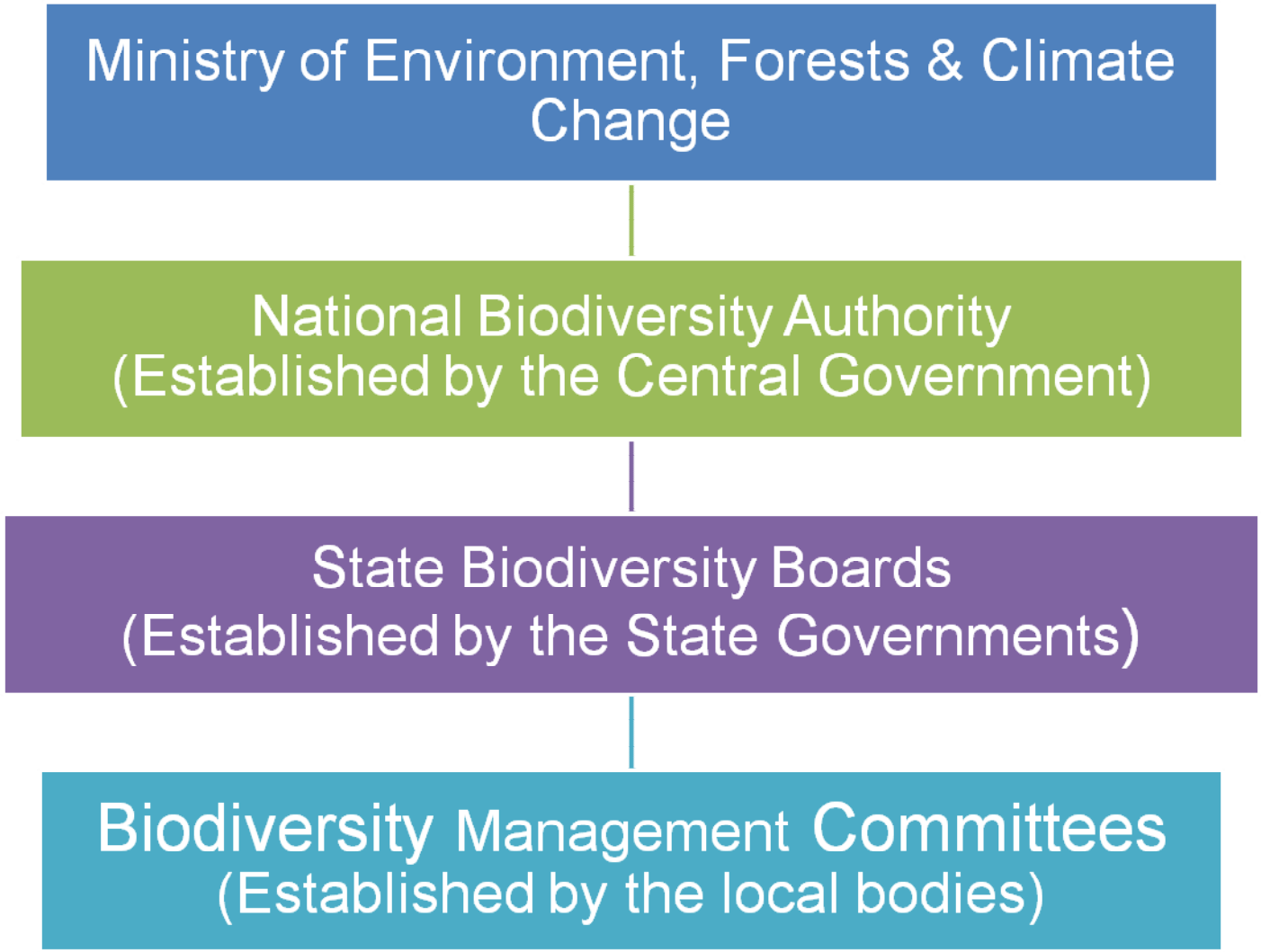


Biological Diversity Act, 2002

salient features

- To protect sovereign rights of India over her biological resources;
- To stop misappropriation of biological resources and associated knowledge (Bio-piracy);
- To regulate access & use of Biological resources and /associated knowledge ;
- To ensure sustainable utilisation and equitable benefit sharing;
- To provide legal recognition & support to the Biological resources and associated traditional knowledge.

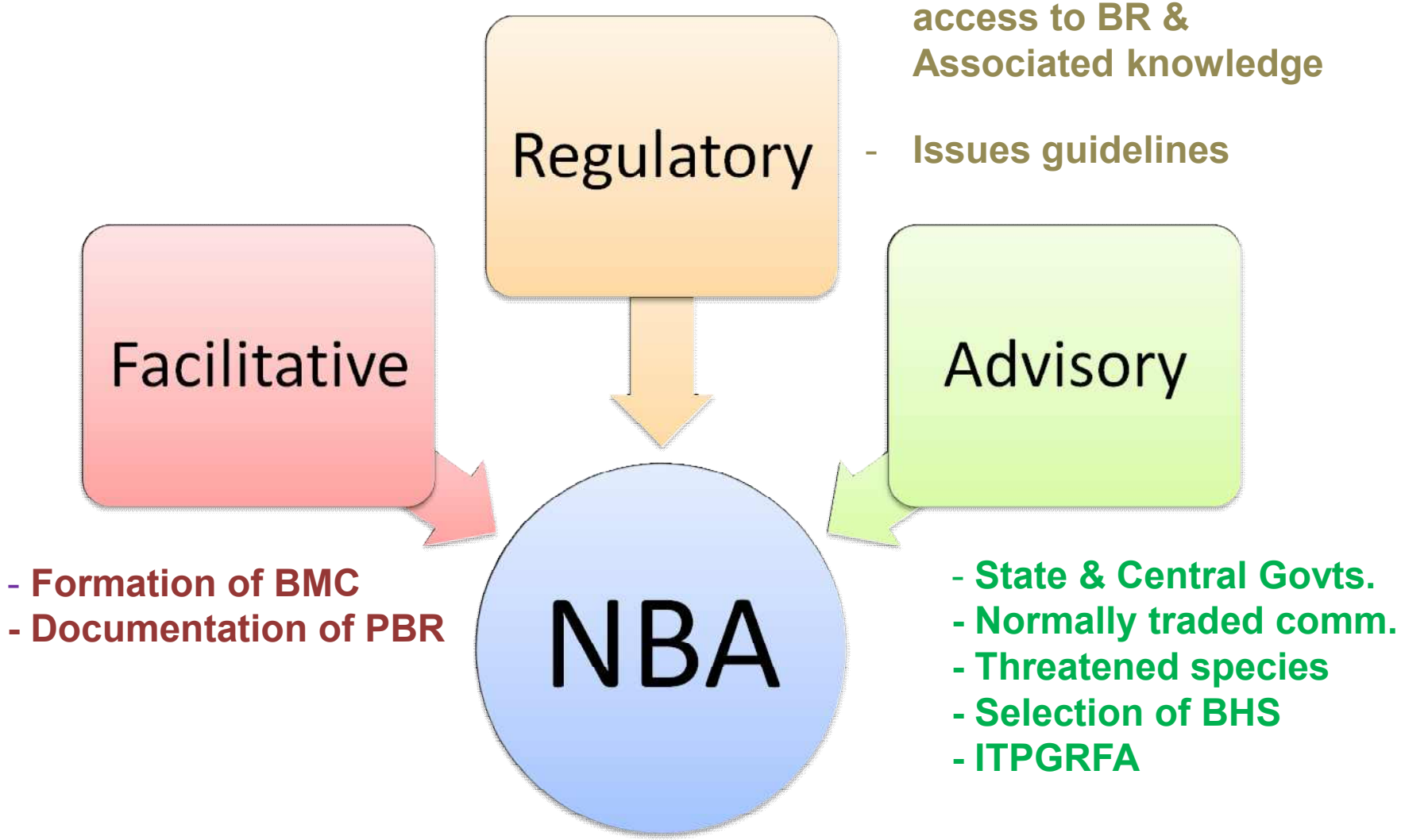
Institutional Structure for Implementing BD Act



Composition of NBA

- **Chairperson**
- **One representative from the Ministry of Tribal Affairs**
- **Two Representative of Ministry of Environment Of Environment , Forests and Climate Change**
- **One Representative** from the following Departments;
  - Department of Agricultural Research and Education,
  - Department of Agricultural Cooperation
  - Department of Biotechnology
  - Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy,
  - Department of Scientific and Industrial Research,
  - Department of Science and Technology
  - Department of Ocean Development
- **Five Expert Members** having experience in, matters relating to conservation of biological diversity, sustainable use of biological resources and equitable sharing of benefits arising out of the use of biological resources,

Functions of National Biodiversity Authority



Functions of National Biodiversity Authority

- Advise the Government on matters on conservation of biodiversity, sustainable use of its components and equitable sharing of benefits arising out of utilization of biological resources.

- Advise the State Governments -selection of areas of biodiversity importance as heritage sites and suggest measures for their management .

Functions of National Biodiversity Authority

- Take necessary measures to oppose the grant of IP rights in any country outside India on any biological resource or knowledge obtained from India, illegally.

- Provide guidance and technical support to Biodiversity Management Committees (BMC) for preparing People's Biodiversity Registers (PBR).

Scope of the Biological Diversity Act 2002

Resources	Activities
Biological resources and Associated knowledge	Access for - Research - Commercial utilization - Bio-survey and bio-utilization
	Intellectual Property Rights (IPRs)
	Transfer of research results
	Transfer of already accessed biological resources/associated knowledge

Application formats seeking approval

Form no.	Purpose of application	By whom
I	Access to biological resources and/or associated traditional Knowledge for research, commercial utilization, bio-survey or bio-utilization	Non- Indian, NRI, Foreign entity or Indian entity having non-Indian participation in share capital or management
II	Transfer the results of research	Any Indian/non-Indian or entity to any non-Indian, NRI, foreign entity or Indian entity having non-Indian participation in share capital
III	Applying for Intellectual Property Right	Any Indian/ Non-Indian or entity
IV	Transfer of biological resources/knowledge already accessed, to a third party	Any person who obtained approval of NBA in Forms I to Indians/ Non-Indians or entities

Functions of State Biodiversity Boards

- State Biodiversity Boards constituted by State (province) Governments,
- To regulate the access to biological resources and /or associated knowledge by Indians for commercial purposes,
- SBB has power to restrict any such activity which violates principle of conservation, sustainable use and equitable sharing of benefits,
- NBA and SBBs are required to consult concerned BMCs on use of biological resources and associated knowledge within their respective jurisdictions,
- SBBs will advise the State Government on biodiversity related matters.

Functions of Biodiversity Management Committee

- Promoting conservation, sustainable use and documentation of Biological Diversity.
- Levy charges by way of collection fees from person(s) accessing or collecting bioresource for commercial use from its territorial jurisdiction.
- To prepare People's Biodiversity Register (PBR) in consultation with local people.
- Maintain Register about details showing bioresource/TK accessed, fees imposed, benefits accrued and mode of sharing
- Provide support to NBA and SBB in their decisions.

Roles of the Governments

- Establish NBA, SBBs and BMCs.
- Develop national strategies, plans, programmes for biodiversity.
- Issue directives to the State Governments for amelioration of threatened habitats.
- Integration of the conservation, promotion and sustainable use of biodiversity into relevant sectoral or cross sectoral activities.
- Assess impact of projects on environment and biodiversity and address biosafety concerns.
- The Central Government may, in consultation with NBA notify –
  - threatened species and prohibit or regulate their collection and conservation,
  - designate repositories for different categories of biological resources and
  - exempt certain biological resources as normally traded commodities.
  - issue of guidelines for collaborative research
- State Govts. to notify BHS in consultation with the local bodies.

Expert Committees

➢NBA is carrying out its mandate through the consultative process with the assistance of Expert committee on various subjects.

➢The following committees are in place to assist the NBA to preform its duties;

- **Access and benefit sharing** for evaluating the ABS application
- **Agrobiodiversity** – To deal with the issues relating to Agrobiodiversity and other matters
- **Medical Plants** - To suggest the conserve and sustainable use biological resources having Medicinal value and issues related to.
- **Biodiversity Management Committee** – to deal with the issues related to the BMC and developing guidelines thereof.
- **Normally Traded Commodities** – to identify the normally traded commodities for providing exemption u/s 40 of the Act.

Conservation

- The State Government may declare areas of biodiversity importance as Biodiversity Heritage Sites. (Sec. 37). NBA has issued guidelines for the identification of BHS.

- 7 BHS notified in three States

- The Central Government, in consultation with the concerned State Government, to notify certain species of plants and animals, **as a threatened species (Sec. 38).** NBA drawn a methodology through an expert committee.

- notified in 16 States and 2 Union Territories

- As per Section 41 of the Act read with Rule 22 (6) of the Rules, 2004, the main function of the BMCs is to prepare **People's Biodiversity Registers (PBRs)** in consultation with local people.

- 2485 PBRs have been documented in 17 states

➢ The central Government designate institutions/ organizations from time to time as repositories for safe custody of representative samples as voucher specimens of the biological resources accessed in accordance with the provisions contained under Section 19 of the Act.

- 15 Institutions designated

Guidelines for the stakeholders

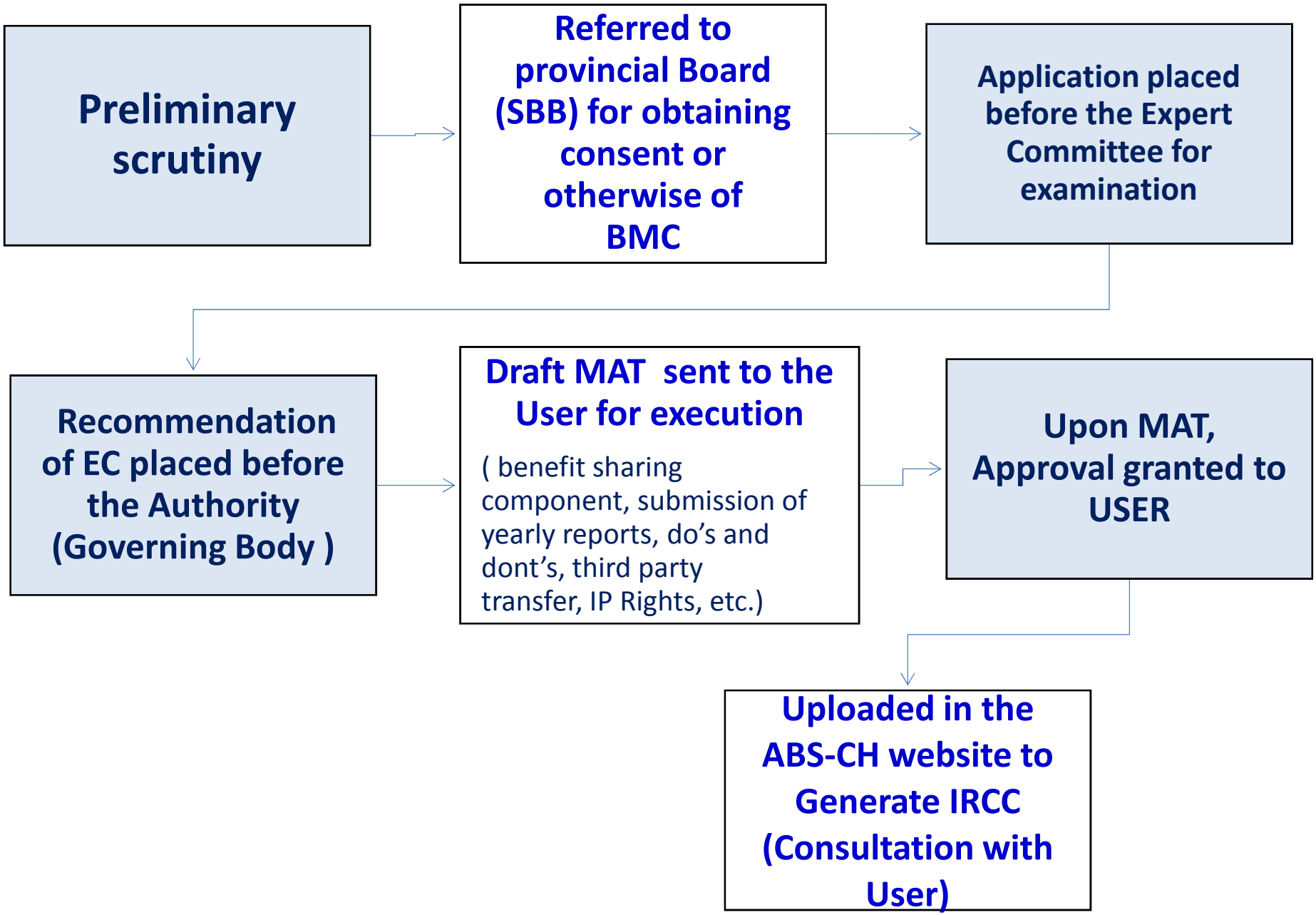
International Collaborative Research Projects	8th Nov 2006
People's Biodiversity Register	2009, *revised ver.* in 2013
List of normally traded commodities	26th Oct 2009
Officers authorized to file complaints under Section 61(a) of the Act	17th Nov 2008 7th Jan 2009 (amendt.)
Biodiversity Heritage Sites	2010
Form filling guidelines to user groups	Feb, 2013
Operationalization of Biodiversity Management Committees	March, 2013
Access and Benefit sharing	21st Nov 2014
Exempting Annex-I crops from Section 3 and 4	17th Dec 2014

Access and Benefit Sharing Mechanism

Activities Regulated under the Act

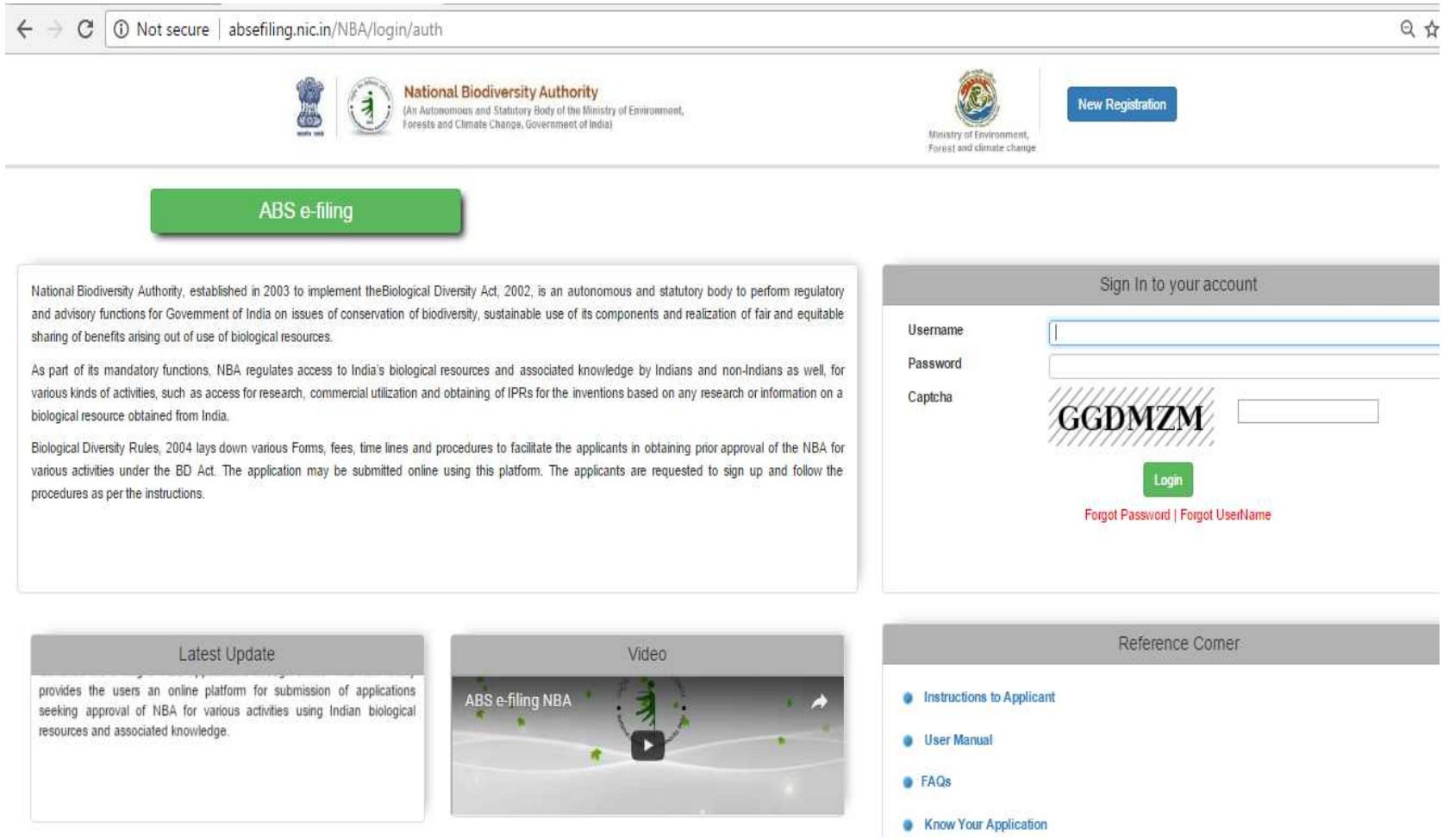
Activities	Persons u/s 3 (2)	Persons u/s 7
Research (S. 3)	NBA	NA
Bio-survey and Bio-utilization (S. 3)	NBA	SBB
Commercial utilization (S. 3)	NBA	SBB
Intellectual Property Rights (S. 6)	NBA	NBA
Transfer of research results (S. 4)	NBA	NBA
Third party transfer of already accessed bioresources/ knowledge (S.20)	NBA	NA

Process of Applications



ABS e-filing

- NBA has launched an online portal for e-filing of ABS application which can be accessed at www.nbainia.org .
- This online portal is user-friendly and will provide a step-by-step guidance for choosing and filing correct application form, providing tool tips, pop up messages for easy filing with mandatory columns.



Access and Benefit Sharing Regulations

Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014 have been notified on 21st November, 2014. The Regulation provides for

- ✓ legal certainty
- ✓ clarity and transparency
- ✓ simplified procedure to the Indian researchers / Govt. institutes to carry out basic research outside India
- ✓ options of benefit sharing for different users
- ✓ graded benefit sharing
- ✓ establishing supply chain from source to manufacturer
- ✓ upfront payment on high economic valued bioresources (Red sanders, Sandal etc.)
- ✓ apportioning accrued benefits to the community/BMC.

Facilitate non-commercial research by Indian researcher / Government Institutions

- Through this guideline, NBA introduced a special Form (Form B) for the Indian research/scientists or Govt . Institutes to carry/send the biological resources outside India for doing research.

- Govt. institutes may send the biological resources outside to carry out studies to avert emergencies like epidemics etc.

- NBA has to accord approval or otherwise within **45 days**.

Benefit sharing component

1. **Commercial Utilization:**

Annual Gross ex-factory sale of product	**Benefit sharing component**
Up to Rupees 1,00,00,000	**0.1 %**
Rupees 1,00,00,001 up to 3,00,00,000	**0.2 %**
Above Rupees 3,00,00,000	**0.5 %**

2. **Transfer of results of research** , the benefit sharing obligation is **3.0 to 5.0% of the monetary consideration.**

3. **Intellectual Property Rights :**

If applicant himself commercialize the process/product/innovation	**0.2 – 1.0%** of Annual Ex-factory gross sale (minus govt. taxes)
If applicant assigns / licenses the process / product / innovation to a third party for commercialization	**3.0 – 5.0 %** of the fee received in any form. And 2.0 – 5.0 % of Royalty

4. **Transfer of accessed bioresources and AK**, the benefit sharing obligation is 2.0 to 5.0%(following sectoral approach) of any amount and / or royalty received from the transferee.(Reg. 12)

- Where the trader sells the biological resource purchased by him to another trader or manufacturer, the buyer,

    a) **if he is a trader - pay 1.0 to 3.0% of the purchase price.**
    b) **If he is a manufacturer – pay 3.0 to 5.0% of the purchase price.**

- If the **buyer submits proof of benefit sharing by the immediate seller** in the supply chain -

    The buyer shall be only on that portion of the purchase price for which the benefit has not been shared in the supply chain. (Reg. 3)

- In cases of **biological resources having high economic value** such as sandalwood, red sanders, etc. -

    the **benefit sharing may include an upfront payment of not less than 5.0%, on the proceeds of the auction or sale amount**, as decided by the NBA or SBB, as the case may be. **(Reg. 3(3))**

- If the sale is through auction, the successful bidder or the purchaser shall pay the amount to the designated fund, before accessing the biological resource.

Status of Applications on ABS

Form	Category	Applications received	Agreements signed / approval granted
Form I	Access to Biological resources and associated traditional Knowledge.	**330**	**111**
Form II	Transferring the results of research to foreign nationals, companies, NRI's for commercial purposes.	**50**	**17**
Form III	Seeking Intellectual Property Right	**1261**	**305**
Form IV	Third Party transfer of the accessed biological resources and associated traditional knowledge.	**81**	**29**
	Total	**1722**	**462***
Form-B	Conducting of non-commercial research or research for emergency purposes outside India by Indian researchers/ Government institutions	**39**	**24**
	Total	**1761**	**486**

- Out of **951** applications cleared by NBA, so far **462** agreements have been executed.

Benefit Sharing Realized by the NBA

1. Benefit sharing received – **47.26 Crores**

a. Access of Red sanders – 45.38 Crores
b. Access of bovine cattle embryos – 1.09 Crore
C. Others – 0.79 Crore

Purpose	Benefit sharing amount received	Benefit claimer	Amount shared
Export of neem leaves to Japan.	44.53 Lakhs	Amarchinta BMC in Mahboob nagar district, Andhra Pradesh	**Rs.20,000/-**
Access of Red Sanders wood	45.38 Crores	AP Forest Dept. through AP SBB	**Rs 3.00 Crores**
Access of seaweeds	39.10 lakhs	Tamil Nadu SBB	**Rs 32.00 Lakhs**

Exemptions under the Act

- Act provides exemption of certain activities from its purview :
  - To local people and community for free access to use bioresources within India.
  - To growers and cultivators, vaids and hakims (practitioners of traditional medicinal systems) to use bioresources.
  - To biological resources, normally traded as commodities notified by the Central Government under section 40 of the Act.
  - To collaborative research through government-sponsored institutes subject to conformity with guidelines and approval of the Central / State Governments.
  - To access value added products.
  - For research by Indians in India.

ABS
CASE STUDY

No.1

Access to biological resource for research

1	Applicant	Dr.Alison Snow, Prof. Ohio University USA
2	Access to	Wild brinjal varieties – leaf squash and fruits from Tamil Nadu & Karnataka.
3	Purpose	To study the genetic variation within and among species and publish in a reviewed journal.
4	Partners	Pondicherry University – will collect specimens and do certain studies in India
5	NBA Secretariat	- Referred the matter to State Boards – Tamil Nadu and Karnataka to provide consent after consulting the BMCs.

No.1

6	Exp. Comm.	- Conservation aspects - Recommended for approval
7	Authority	Accepted the recommendation of the expert committee
8	NBA secretariat	- Draft MAT forwarded to the applicant - Approval granted in October 2014
9	Monitoring mechanism	- As per MAT the applicant needs to submit the six month report on the activities carried out on the accessed BR.

No.2

Seeking approval to obtain IP rights

1	Applicant	Dr.Geetha pandurang, Ayurvedic Doctor, pune
2	Invention	Invention on ayurvedic anti snake venom composition. Four medicinal herbs used (*Erythina indica, Eugenia jambolana, Mangifera indica, Jasminum sambac*)
3	Abstract of the invention	The tablet name PINAK, to be administered to the victim of snake bite, it act as a temporary relief instantly before victim taken to hospital.
4	Expert committee	- Examined and imposed benefit sharing - 2% of the gross sales or gross revenue.

5	Authority	Accepted the recommendation of the expert committee
6	NBA secretariat	- Draft MAT forwarded to the applicant - Approval granted in July 2009
7	Sharing of Benefits	- Since 2009-16 the applicant has paid to the tune of INR 9162.00
8	NBA secretariat	- Of the 5% of the benefits were equally shared between Maharashtra sbb and NBA for an administrative expenses.
9	Monitoring mechanism	- As per MAT the applicant needs to submit the six month report on the activities carried out on the patent granted.

No.3

Access to biological resource for research for commercial

1	Applicant	M/s. Brasif S.A. Brazil
2	Access to	4000 bovine cattle embryos (Ongole, Gir and Kankrej)
3	Purpose	Zoo-technological research (5-10 yrs) to upgrade the breeding cattle in Brazil
4	Exp. Comm. examined	- Large quantity - Economic value of the embryo - Technical opinion sought from NBAGR / DAHDF - Sub-committee developed a upfront ABS - Applicant appeared before the EC - Recommended the request for access subject to payment of upfront ABS

5	Authority	Cleared the case as recommended by the Exp. Committee
6	NBA Secretariat	Forwarded the draft MAT to applicant for execution, as required under the Rule.
		-Applicant raised some clarification / modification on the draft MAT -Clarification provided -Applicant paid upfront payment of INR 1.20 crores (12 Millions) -MAT entered and approval granted in April 2016

No.4

Access to biological resources for research for commercial

1	Applicant	M/s Reliance Industry Ltd.,
2	Access to	500 ml of seawater to collect blue green algae from the 3 coastal states
3	Purpose	Screen microbes for use in animal feed, human nutritional suppliments, treatment of effluents/sewage, fertilizers, bio-fuel.
4	Partners	The research will be done by University of Pune on behalf of the applicant
5	NBA Secretariat	- Referred the matter to State Boards – Goa, Maharashtra, Gujarat to provide consent after consulting the BMCs.

6	Exp. Comm.	- Conservation aspects - Economic value - Recommended for approval subject to payment of upfront INR 5.9 lakhs (0.5 mn)
7	Authority	Accepted the recommendation of the expert committee
8	NBA secretariat	- Draft MAT forwarded to applicant - Applicant paid upfront payment - Approval granted in august 2015
9	Monitoring mechanism	- As per MAT the applicant needs to submit the six month report on the activities carried out on the accessed BR.

No.5

Transfer of Research Results

1	Applicant	Tamil Nadu Agriculture University
2	Research result	Transfer of results of research on isolated *Bacillus thuringiensis* to M/s. Bioseed Research India, Hyderabad for generation of insect resistant crop plants. (only result not BR)
3	Expert committee	- Examined and imposed benefit sharing - 3% of the monetary consideration received from the M/s Bioseed India Ltd.
4	NBA secretariat	- Forwarded the draft MAT to the applicant. - Approval granted in December 2015.

Nagoya Protocol obligations

- Ministry of Environment, Forest and Climate Change is the Nodal Ministry /**National Focal Point**.
- NBA is the **Competent National Authority (CNA)**
- NBA is a **National Authorized User (NAU)** for ABS-CH website – *for updating national records (ABS Legislative measures), other publications etc.*
- The details of Records updated in the ABSCH is

IRCC – 47
ABS Measures – 31

Nagoya Protocol obligations

- In purusant to Art. 4 of the Nagoya Protocol, the Ministry of Environment, Forest and Climate issued a notification exempting crops covered under ITPGRFA from the approval of NBA under Section 3 & 4 of the Act.

- Ministry and NBA is in the process of identifying the Check-points and developing the user country measures.

Projects in NBA

➢**UNEP-GEF-MoEFCC ABS project** - “Strengthening the Implementation of the Biological Diversity Act”.

➢**Centre for Biodiversity Policy and Law (CEBPOL):**-

- ❖ To focus on biodiversity Policies and laws that cater to the needs of national and international rule-making and subsequent implementation on biodiversity related issues.

➢**BIOFIN Global Geographical Area –**

- ❖ To develop a methodology for quantifying the biodiversity finance gap at national level for improving cost-effectiveness through mainstreaming of biodiversity into national development

➢**Indo-German Access and Benefit Sharing (ABS) Partnership Project under the Indo-German Biodiversity Programme (GIZ) :**

- ❖ To strengthen the capacities of the NBA, SBBs and selected BMCs for the effective implementation of ABS mechanisms under the BD Act

➢**ACB-NBA Cooperation Project –**

- ❖ Capacity Building towards Implementing the Nagoya Protocol on Access and Benefit Sharing, the City Biodiversity Index and the Strategic Plan for Biodiversity

Challenges in implementation of ABS mechanism

a)Awareness level at different stakeholders.

b)Capacity building

c) Formation of Biodiversity Management Committee at the Local body level in the States.

d) Co-ordination among State (Provincial) Biodiversity Boards.

e) Functional limitations – data availability/ generation/ analysis

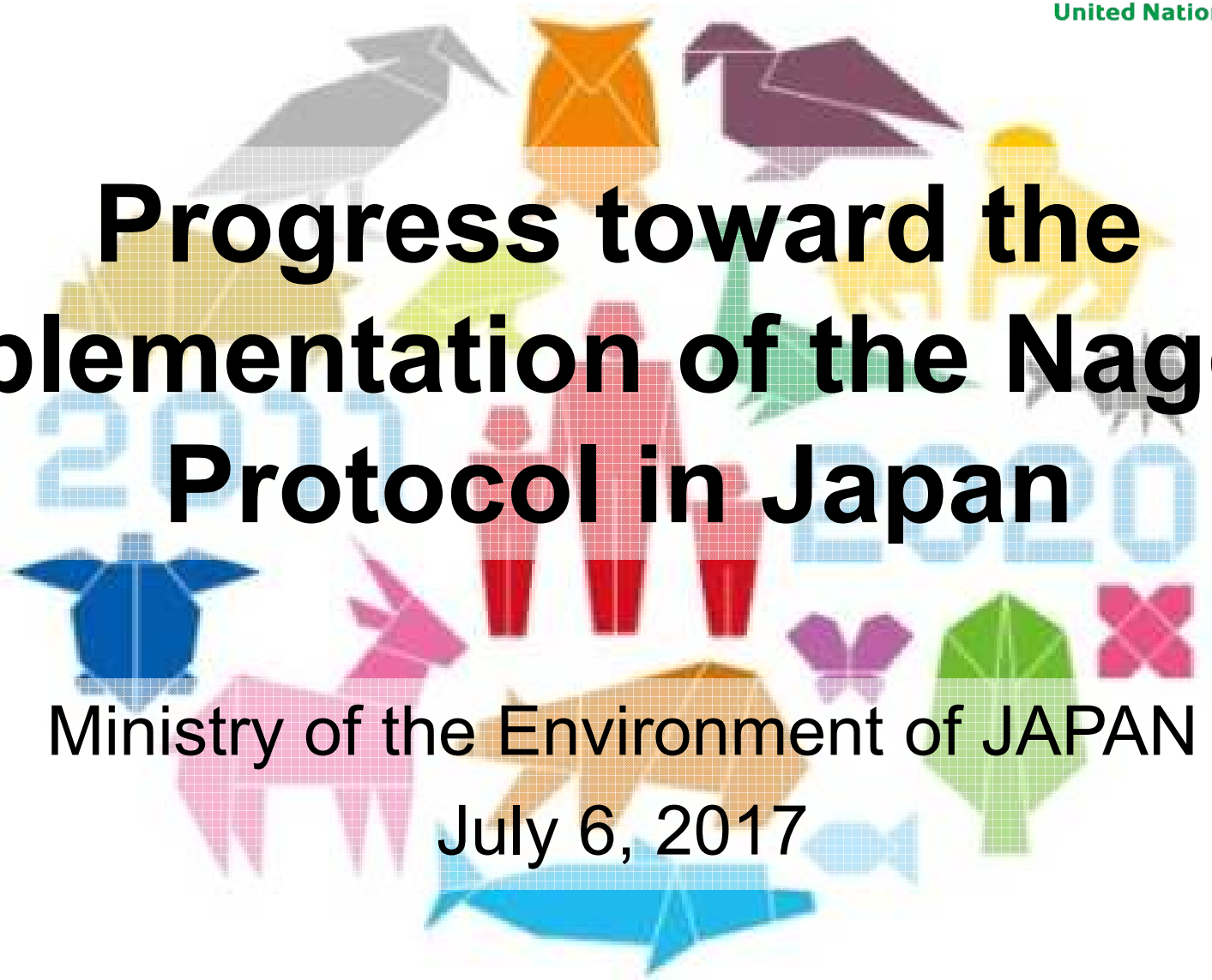
Thanks to…..

Ministry of Environment, Government of Korea

National Institute of Biological Resources

United Nations Decade on Biodiversity

Progress toward the Implementation of the Nagoya Protocol in Japan



Ministry of the Environment of JAPAN

July 6, 2017

CONTENTS

I.The Road up to Ratification

–The Process of Developing Domestic Measures –

Background – The Nagoya Protocol

COP10, Nagoya

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** was adopted on 29 October 2010, during COP10 to the CBD, held in **Nagoya, Japan**.

- The Protocol entered into force on 12 October 2014. The first Meeting of the Parties to the Protocol was held in Pyeongchang, South Korea.
- **Japan ratified the Nagoya Protocol on 22 May 2017.**

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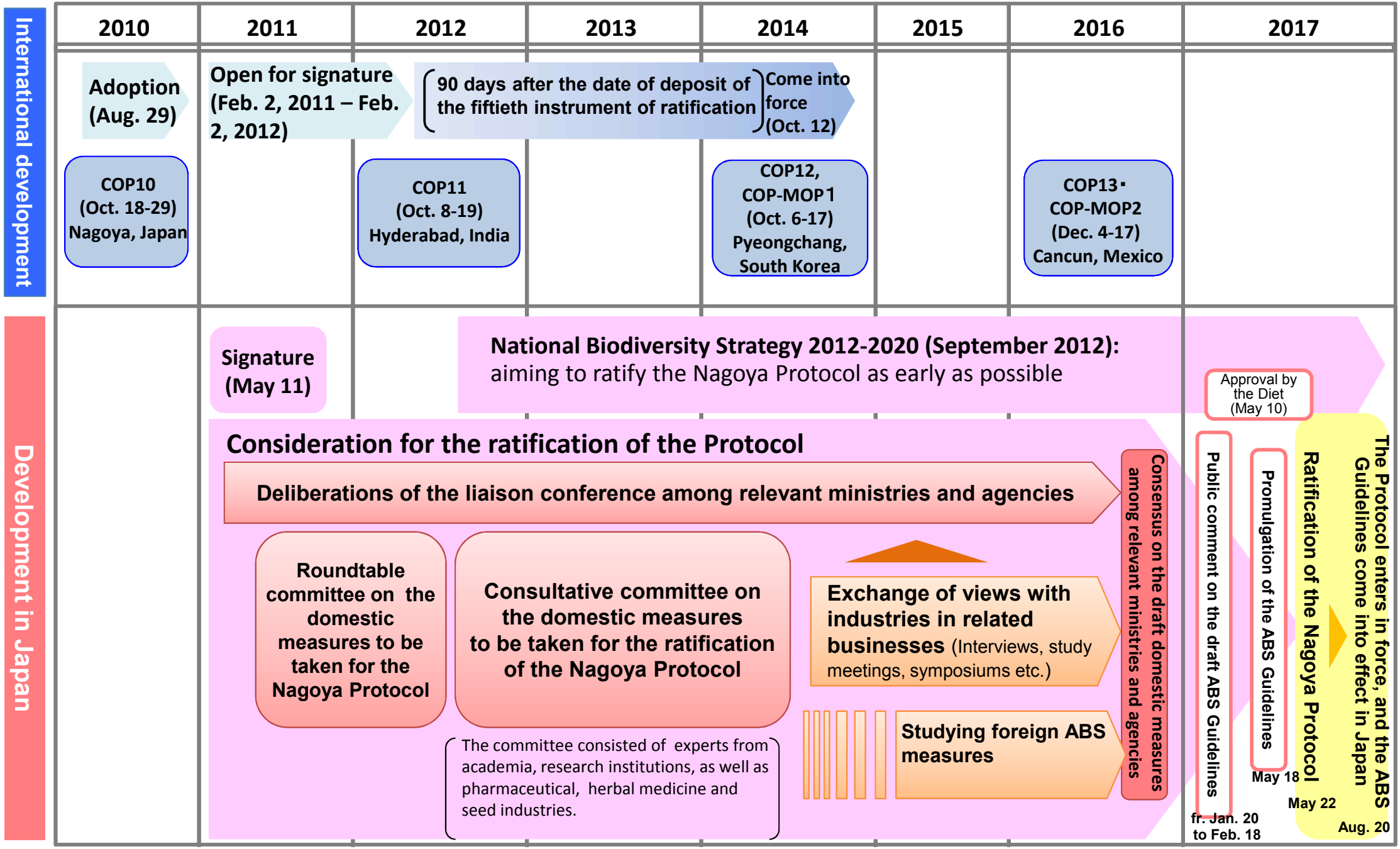
COP 10 / MOP 5


Japan's ratitication to the Protocol

The Path to Ratification



Development of Domestic Measures

- Ministry of the Environment established a consultative committee to consider the domestic measures for the Nagoya Protocol.
- The committee, consisted of 14 ABS experts including key persons from industries and academia*, held 16 meetings in total during 2012-2014.
- The committee published a recommendation report on modalities of feasible domestic measures for Japan in March 2014.

*e.g. RIKEN, National Institute of Genetics and the NITE Pharmaceutical, natural medicine, breeding, food and cosmetic industry

Key recommendations of the report

■ On compliance measures:

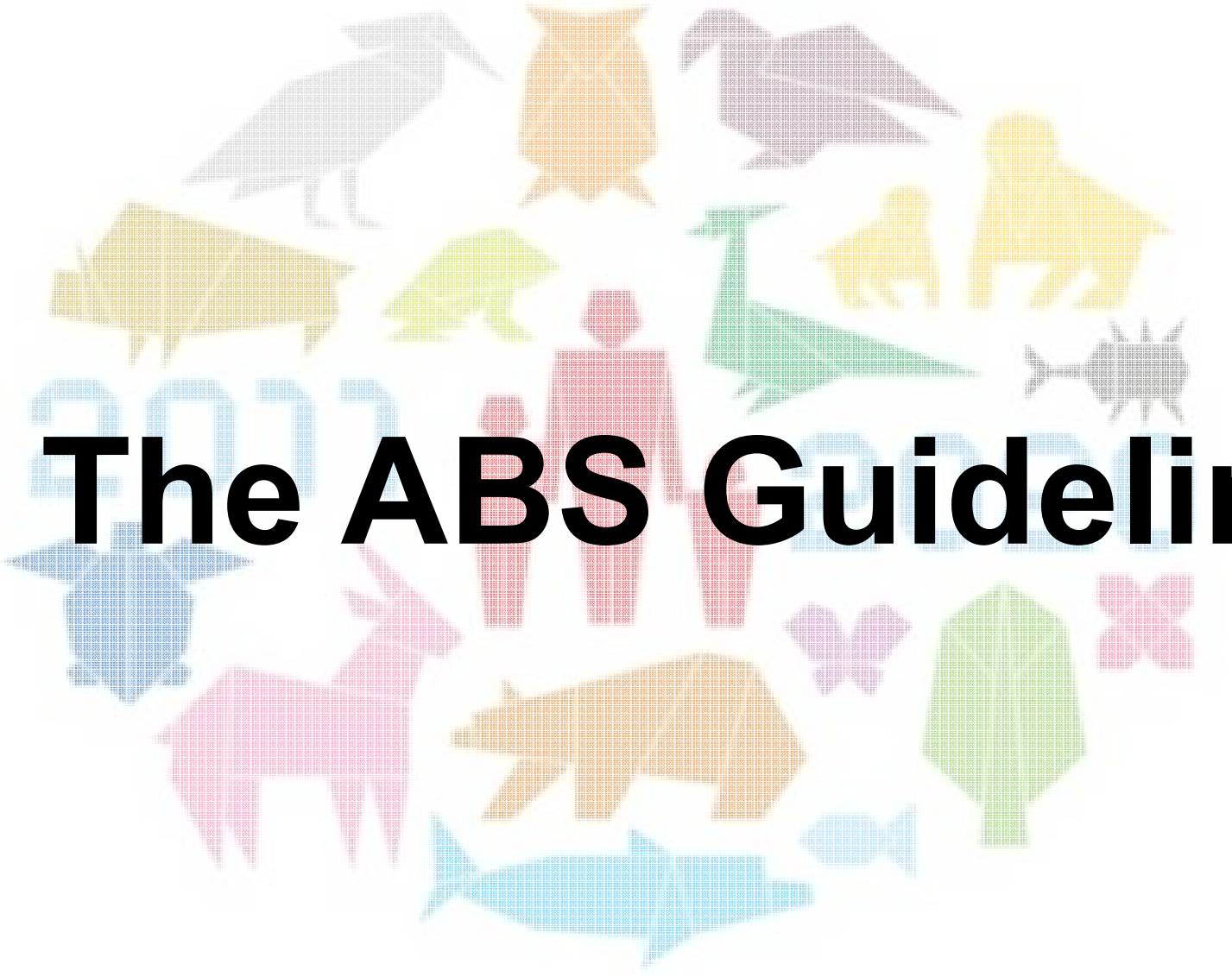
- Measures for compliance should be simple, clear, practicable, flexible, transparent, effective and feasible.
- Measures should promote , rather than discourage, proper access of genetic resources.
- Measures should promote use of genetic resources without hindering academic, research and industrial activities of domestic users.

■ On access measures:

- Requiring PIC for access to genetic resource in Japan will highly likely pose burden on international joint research.
- Provider measures should not be needed at this moment. Evaluation on future needs for PIC should be continued.

Relevant ministries and agencies considered the modality of domestic measures based on the report and developed ABS guidelines.

The establishment of the ABS guidelines.



II. The ABS Guidelines

Key Components of the Guidelines

Status and the Purpose

- The guidelines are a joint public notice from the:
  - Minister of Finance (MOF),
  - Minister of Education, Culture, Sports, Science and Technology (MEXT),
  - Minister of Health, Labor and Welfare (MHWL),
  - Minister of Agriculture, Forestry and Fisheries (MAFF),
  - Minister of Economy, Trade and Industry (METI), and the
  - Minister of the Environment (MOE).
- These guidelines are aimed at ensuring the effective implementation of the Protocol and thereby contributing to the conservation and sustainable use of biological diversity.

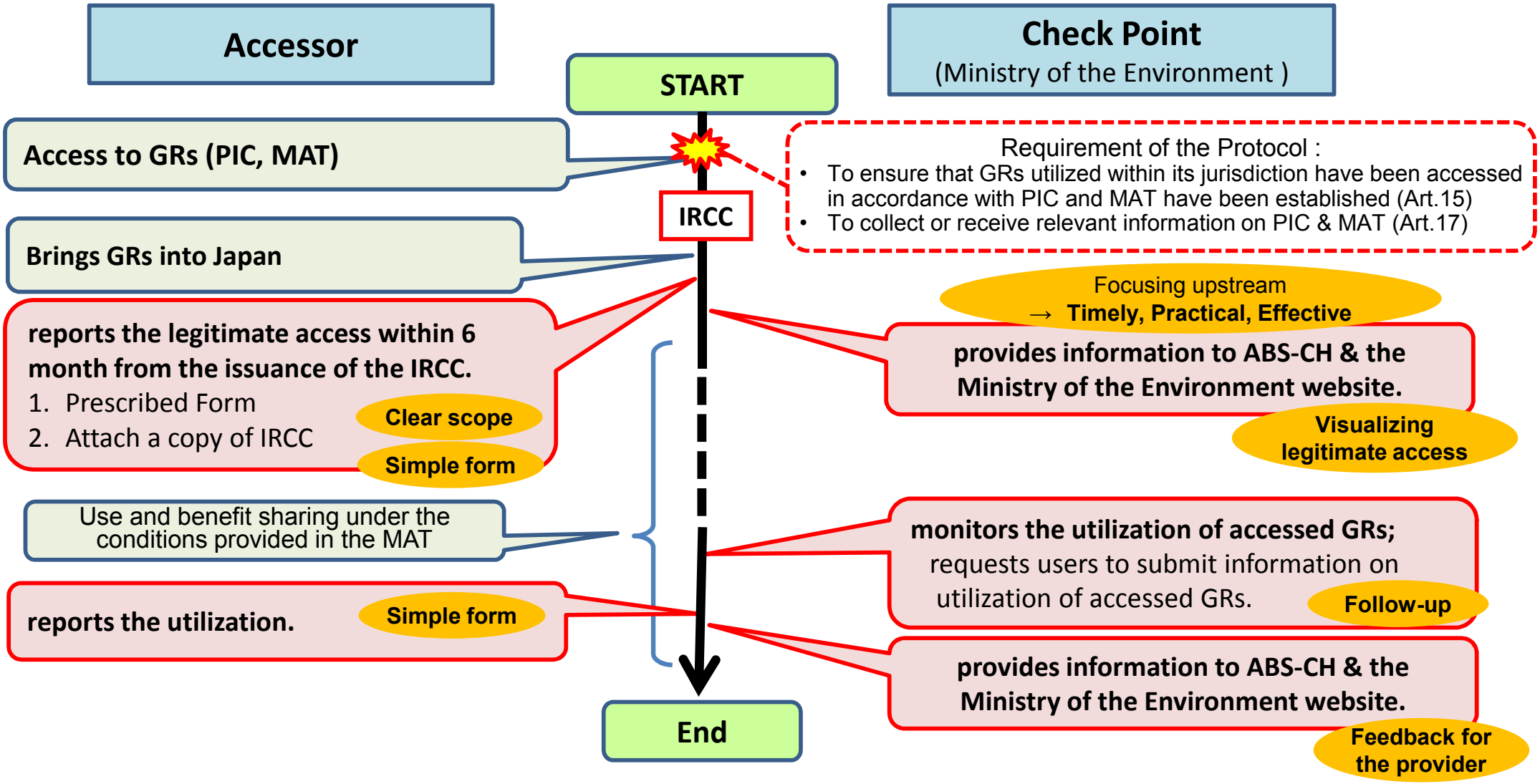
Key Components

1. **Compliance Measures** (NP Art. 15, 16, 17)
2. **Access Measures** (NP Art. 6)
3. **Recommendation of the Promotion of ABS Frameworks** (NP Art. 5, 9, 17, 20)

1. Compliance Measures

Basic Concept

- Measures should **facilitate appropriate utilization of GRs.**
- Measures should be **clear, simple, practical, and effective**.



When and how will compliance measures be exercised?

1. Report of the Legitimate Access (within 6 months from the issuance of the IRCC)

- Accessors shall submit reports on their legitimate access if …
  - they directly access to GRs within the jurisdiction of a Party to the Protocol and bring them back to Japan.
  - an IRCC is Issued for the GRs in question.
- Accessors or importers may submit voluntary reports when …
  - importers wish to visualize that IRCCs have been issued for the original access to the GRs in question.
  - accessors or importers who have access permits (e.g. PIC) under applicable ABS legislation in hand wish to report their legitimate access prior to the issuance of the IRCC.
- When Accessors to GRs also access to traditional knowledge associated the GRs in question; ...
  - they shall include those information in their access reports.

2. Monitoring the Utilization of GRs (5 years after reporting the legitimate access)

- Accessors will be asked to provide information related to the utilization of GRs after 5 years of initial reporting.

3. Providing Information to ABS-CH and the Ministry of the Environment Website

- All the information provided through reports submitted under the ABS guidelines will be provided to the ABS-CH and published on the website of the Ministry of the Environment without prejudice to the protection of confidential information.

4. Cooperation in Addressing Cases of Non-Compliance with Legal Requirements of Provider Countries

In case of alleged violation of domestic access and ABS requirements of the other Party, Ministry of the Environment shall, when needed, request persons handling GRs to provide information and transfer it to the said Party.

2. Access Measures

Recommendations by the Consultative Committee

- ◆Requiring PIC for access to genetic resources in Japan will highly likely pose burden on international joint research.
- ◆Access measures are not needed for the moment. But evaluation on the demand for it should be continued.

Based on the provision for the optional determination on access to domestic genetic resources in Article 6.1, Japan made a decision not to put access regulations in the guidelines.
In other words, users intending to access to genetic resources in Japan are not required to acquire the prior informed consent (PIC) defined in Article 1 of the Protocol.

No PIC requirement DOES NOT mean FREE ACCESS.
Accessors should note that collecting and/or importing plants, animals, microorganisms or other biological materials may be subject to existing regulations and agreement with land/specimen owners.

Regulations Related to Access to GRs

Although Japan does not require PIC under its ABS policy, there are regulations for other purposes, such as protection of endangered species.
Collecting samples in Japan should be conducted in compliance to those existing rules.

- Act on Conservation of Endangered Species of Wild Fauna and Flora
- Protection and Control of Wild Birds and Mammals and Hunting Management Law
- the Natural Parks Law
- Nature Conservation Act
- Act on Protection of Cultural Properties
- Plant Protection Act
- Fishery Act
- Act on Regulation of Fishing Operation by Foreign Nationals
- Act on the Exercise of the Sovereign Right for Fishery, etc. in the Exclusive Economic Zone
- Act on the Protection of Fishery Resources
- Guidelines for Scientific Investigation by Foreign Nationals in Maritime Belt, Exclusive Economic Zone or Continental Shelf
- Plant Variety Protection and Seed Act

3. Recommendation on the Promotion of ABS Frameworks

The guidelines recommend relevant stakeholders to:

- facilitate ABS frameworks.
- make use of ABS frameworks for conservation of biodiversity.

Providers and users of genetic resources of Japan or users of genetic resources from other Parties are invited to:

- establish agreements for the fair and equitable sharing of benefits.
- allocate benefits arising from the utilization of genetic resources to the conservation of biodiversity.
- include information-sharing terms in mutually agreed terms.

Industry groups and academic associations that use genetic resources are invited to:

- develop model contractual clauses, code of conduct, guidelines and best practices , and standards.
- make them available for public use.

III.Next Steps

Next Challenges and Direction

Our challenges in the next stage are…

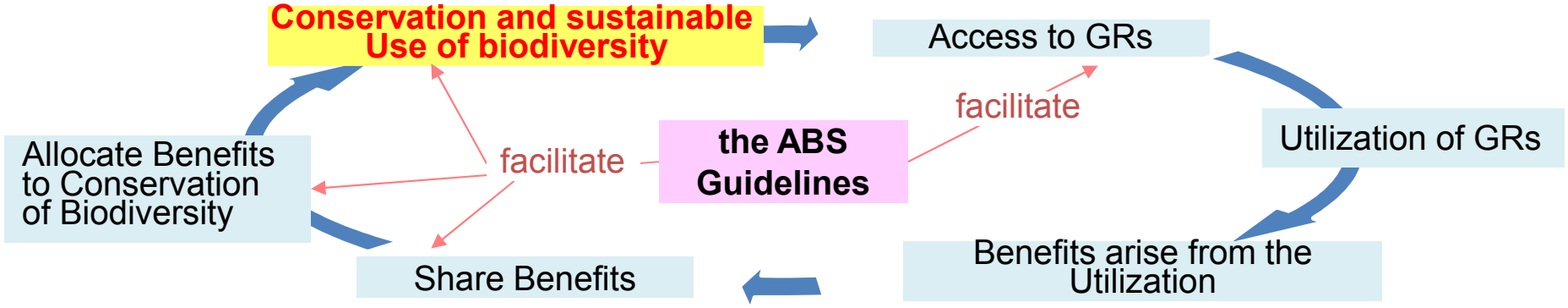
- how to ensure effectiveness of the national ABS Framework.
- how to make the most of it for conservation and sustainable use of biodiversity.
- how to contribute to the global implementation of the Nagoya Protocol via the Framework.

How should we approach the next stage?

In order to overcome these challenges, we should…

- refine operation manners of the ABS Framework.
- conduct awareness raising programs in collaboration with relevant ministries and organizations.
- establish a supportive setting which helps appropriate access to GRs and facilitates international traffic of GRs.

Our Goal: Accelerate the virtuous cycle of conservation and sustainable use of genetic resources



Contribution to the global implementation

Japan Biodiversity Fund (JBF)

JBF Overview

- Established by the announcement of Japan as the Presidency of the CBD COP 10 (with a contribution of 5 billion yen in 2010-2011)
- Aimed at helping developing countries build capacity to achieve the Aichi Targets (global biodiversity targets for 2011-2020)
- Operated by the CBD Secretariat until 2020

Main Purposes

- To support the formulation and review of National Biodiversity Strategies and Action Plans (NBSAP)
  →Organized regional workshops (22 regions; more than 170 countries) e.g.
- To support the achievement of the Aichi Biodiversity Targets, including Target 16 (Nagoya Protocol)

Contribution to the Nagoya Protocol

- Support for establishment and operation of the ABS-CH, including establishment of a trial system and development of training tools for its utilization.
- Development of awareness-raising tools (https://www.cbd.int/abs/awareness-raising/)
- Organizing workshops in 5 regions/sub-regions (to facilitate signing and implementation of the Protocol, development of national road maps etc.)
- Development of training tools and organized training courses for Parties or potential parties to learn how to establish domestic ABS frameworks
- Workshops for the mutual supportive implementation of ITPGR and NP (in Africa/Asia)

Contribution to the global implementation

Nagoya Protocol Implementation Fund (NPIF)

NPIF Overview

- Established by the announcement of Japan as the Presidency of the CBD COP 10 (with a contribution of 1 billion yen)
- Aimed at facilitating the early entry into force and effective implementation of the Protocol
  (At the beginning, support was focused on the 52 signatory countries that have committed to ratifying the Protocol)
- Managed by the GEF and operated by the NPIF Council until 2020
- Contributed by France, Norway, Switzerland and UK and participated by Japanese companies
- Financing individual projects in 10 Central African and Pacific countries

Main Purposes

(a) To help countries to establish domestic ABS frameworks
(b) To implement national and regional projects to facilitate technological transfer and participation by private sector in the conservation and sustainable use of genetic resources
(c) To develop the capacity to manage traditional knowledge associated with genetic resources held by indigenous peoples and local communities.
(d) To implement awareness-raising activities of the Nagoya Protocol
(e) To facilitate the knowledge and scientific basis for the implementation of the Nagoya Protocol

Example: The First Project in Panama

Overview: discovery of chemical compounds to cure cancer and other diseases; technology transfer for discovering effective compounds and the sustainable use of biodiversity; **sharing of benefits for the management of national parks etc.**; and establishment of domestic ABS frameworks
Co-financed by: NPIF, Panamanian Government, research institutions, international organizations, and private companies

Contribution to the global implementation

Global Environment Facility (GEF)

GEF-TF Overview

- Established as a financial mechanism for environmental treaties, including the CBD and its Nagoya Protocol
- Financing projects implemented by 18 international organizations and NGOs, including UNDP
- Aimed at financing global environmental projects in developing countries
- Operated by the World Bank / UNEP / UNDP and run by the CEO Naoko Ishii
- Providing a grant of over $ 14.6 billion around the world; co-financing 5 times more funds
- Designed to be replenished with contributions pledged by donor countries for each of the next 4 years

gef GLOBAL ENVIRONMENT FACILITY
INVESTING IN OUR PLANET

GEF-6 Overview: July 2014 - June 2018

- Replenished with the largest donation in GEF history of $ 4.43 billion (Cf. $4.34 billion pledged to GEF-5)
- Japan pledged approx. $ 600 million (approx. 60 billion yen) and overtook the US to become the largest contributor
- Biodiversity: allocated with the largest portion of the funding (30%); increased driven by the CBD resource mobilization strategies.
- **$ 50 million allocated to Program 8 "Implementing the Nagoya Protocol on ABS"** in the biodiversity sector.
  - Target countries: those that have ratified or committed to ratifying the Protocol within 4 years
  - Purposes: to support the establishment and enforcement of ABS-related rules, develop the capacity of stakeholders, prepare national reports etc.

GEF-4 & GEF-5 Projects: assisted more than 100 countries in implementing ABS
GEF-4 (2006-2010): provided $9 million for the implementation of CBD Article 15
GEF-5 (2010-2014): provided $37 million for ratification and implementation of the Nagoya Protocol

Summary

- Japan has reached a milestone with finalizing its domestic measures, “the ABS guidelines”, after its careful consideration process.
- The ABS guidelines are one solution for Japan to implement the Nagoya Protocol in a simple, practical and effective manner.
- Aiming at the effective implementation of the ABS guidelines, related ministries and relevant organizations continue to work together on possible awareness raising programs and strengthen ties among each other.
- Also, Japan keeps on supporting the global implementation of the Nagoya Protocol through JBF and other channels.


Thank you !

CHINA'S STATUS & ACTIONS

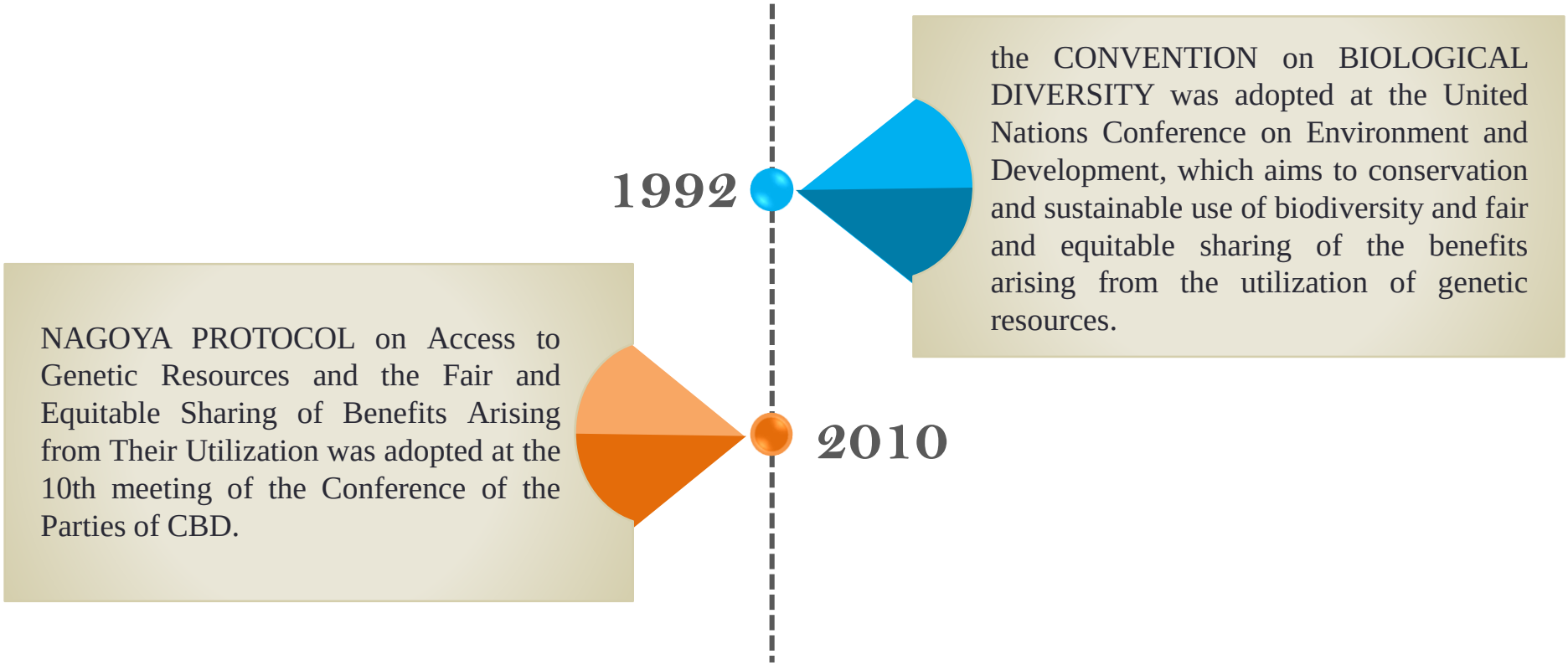
on Access to and Benefit Sharing of Bio-genetic Resource

Dr. Cai Lei
Division of Bio-resources Conservation,
Department of Nature & Ecology Conservation,
Ministry of Environmental Protection, the People's Republic of China
2017.7.6

Contents

I. Bio-genetic Resource & Nagoya Protocol

Bio-genetic resource is a strategic resource of the country, a base of social & economic sustainable development, and its richness is one of the important indicators to measure national comprehensive competitiveness.



General Principles of Nagoya Protocol

Sovereign Rights of States: States have the sovereign rights over their genetic resources, and whether the GRs are able to be accessed depends on its authority and is subject to national legislation.

Prior Informed Consent: Access to GRs shall be subject to the prior informed consent of the Party providing such GRs that is the country of origin of the GRs or has acquired the GRs in accordance with CBD. And as for traditional knowledge related to GRs, shall be subject to the PIC or approval and involvement of ILCs.

Benefit Sharing: Benefits arising from the use of GRs shall be shared in a fair and equitable way with the providing party, being based on mutually agreed terms.

At October 12 of 2014, Nagoya Protocol came into effect and held its first meeting of the Conference of the Parties at Pyeongchang, Korea.

100 countries have ratified it by this day; 96 countries become its Party members.

China becomes its Party member at September 6, 2016.

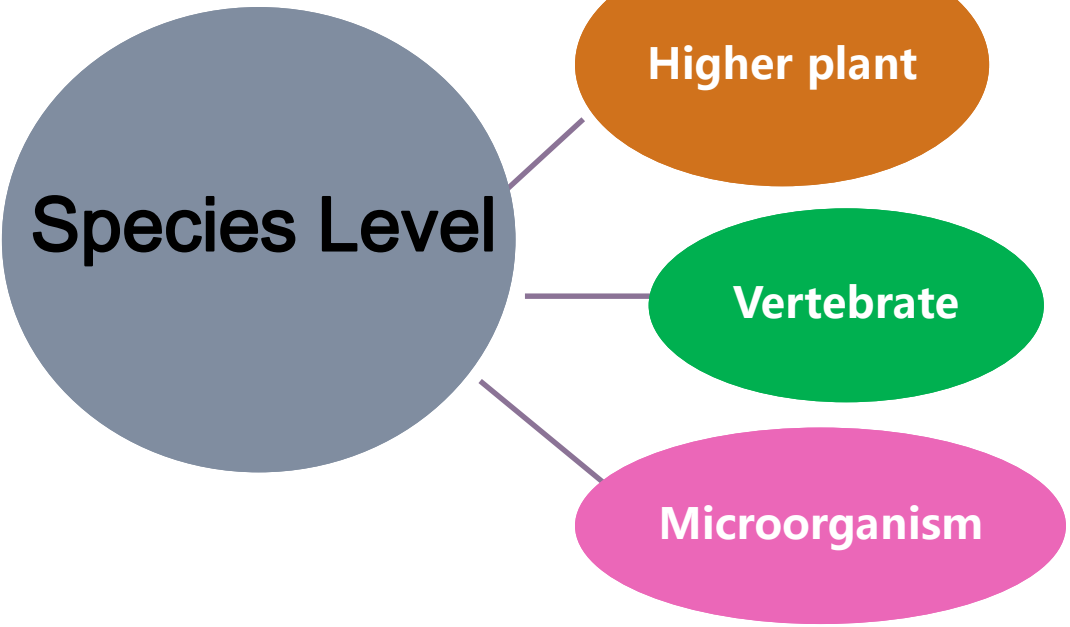




II. Actuality of China's Bio-genetic Resource

China is one of the mega-diversity countries and has the most diversified bio-genetic resource as well as traditional knowledge.

Species Diversity



- 34,984 species
- ranks 3rd in the world

- 6445 species
- 13.7% of the world resource

- Epiphyte species ＞10,000
- 14% of the world resource





Genetic Diversity

Sub-species Level

Key center of origin

- Crops like rice, soybean
- Wild and cultivated fruit trees

Cultivated plant

- 1339 species
- Fruit species ranking the first in the world

Domesticated animal

- 576 varieties
- One of the countries famous with the highest diversity of domesticated animals

Also 56 ethnic groups have been creating different categories of traditional knowledge relevant to conservation and sustainable use of bio-genetic resource and transmitting them by generations for thousands of years.

Five categories of TK are, as follows, knowledge on:

- Traditional utilization of agricultural genetic resource;
- Traditional utilization of medicinal biological resource;
- Traditional techniques, know-how & living ways associated with sustainable use of biological resource;
- Traditional culture & folklore associated with biodiversity;
- Traditionally biological & geographical indication products.

III. Threats to China's Bio-genetic Resource

- More than 11% wild higher plants are threatened species;
- More than 21.4% vertebrate species except for marine fishes are threatened species;

- The habitats of some wild crop relatives have been degenerating;
- Some rare and endemic germplasm resources of crops, trees, flowers, livestock, poultry and fish are continuing to loss;
- Misappropriation and misuse of genetic resource and traditional knowledge related to genetic resource frequently occur in a long time.

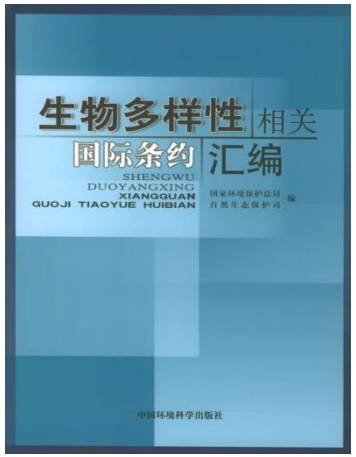
rice

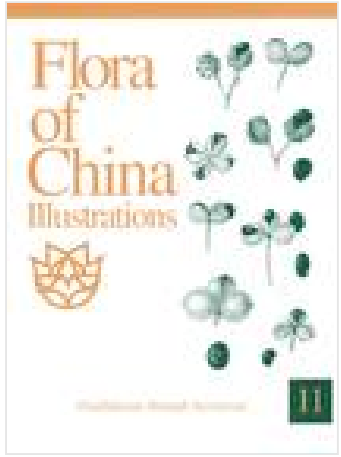
flowers

poultry

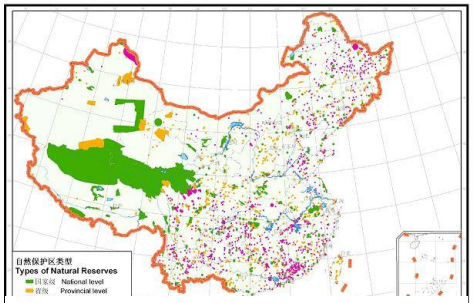
IV. Achievements on Bio-genetic Resource Conservation

- The Chinese government deeply concerns effective protection and management of bio-genetic resource. The State Council launched a coordination mechanism ***Inter-ministerial Joint Meeting for Biological Species Resource Protection*** in 2003, consisting of 17 competent agencies, in order to organize and coordinate national protection and management of biological species resource.





The Chinese government also set up the ***National Committee for Biodiversity Conservation*** in 2010, consisting of 25 competent authorities, in order to organize and coordinate protection and management of biodiversity at national level.



National Natural reserves distribution


Elk national park


Plant park

Since 2004, the State Council has issued several plans on bio-genetic resource conservation, such as:

- **National Planning Outline for Protection and Utilization of Bio-species Resource:** *By 2020, bio-species resource will be effectively protected and a set of regime on ABS will be established.*

- **National Biodiversity Conservation Strategies and Action Plan(2011–2030):** *To develop ABS regime is to be considered one of the* ***STRATEGIC MISSIONS***.

In 2014, the ***National Work Program for Strengthening Management of Bio-genetic Resource(2014-2020)*** was adopted by NCBC at its second meeting, which aims:

- *To draw an ABS specific regulation on BGR and traditional knowledge related to BGR;*
- *To set up national check points, focal point and clearing-house for ABS issue;*
- *To improve tracing and monitoring and inspection capacity for BGR & TK;*
- *To develop investigation, inventory and database integration of BGR & TK;*
- *To increase publicity and education for protection of BGR & TK.*

V. Existing Legal System on ABS

- **Law On Wildlife Protection**
- **Law Of Seed**
- **Animal Husbandry Law**
- **Regulation On Wild Plant Protection**
- **Patent Law**
- **Chinese Medicine Law**

Regulation on Access to and Benefit Sharing of Bio-genetic Resource

- China has initiated a legislation process on development of a special ABS regulation;
- A multi-ministerial working group is improving the draft;
- the draft has been disclosed for the views of public;
- We are researching the received suggestions now.

***Notice on Strengthening Utilization of Bio-genetic Resources and Management of Benefit Sharing Activity in Foreign Cooperation and* Exchange (jointly promulgated by MEP, MOE, MOST, MOA, SFA and CAS in 2014) :**

- Art.2. Strengthen management of project initiation in FCE;
- Art.3. Strengthen supervision of implementation of FCE project;
- Art.4. Strengthen tracking on research results of FCE project;
- Art.5. Regulate exportation of bio-genetic resources in FCE project.

Thanks for your attention !

International Symposium of National Implementation of the Nagoya Protocol on ABS: Sharing Lessons & Discussing Challenges

Current Status of Legislation and Implementation of the ABS System in Myanmar

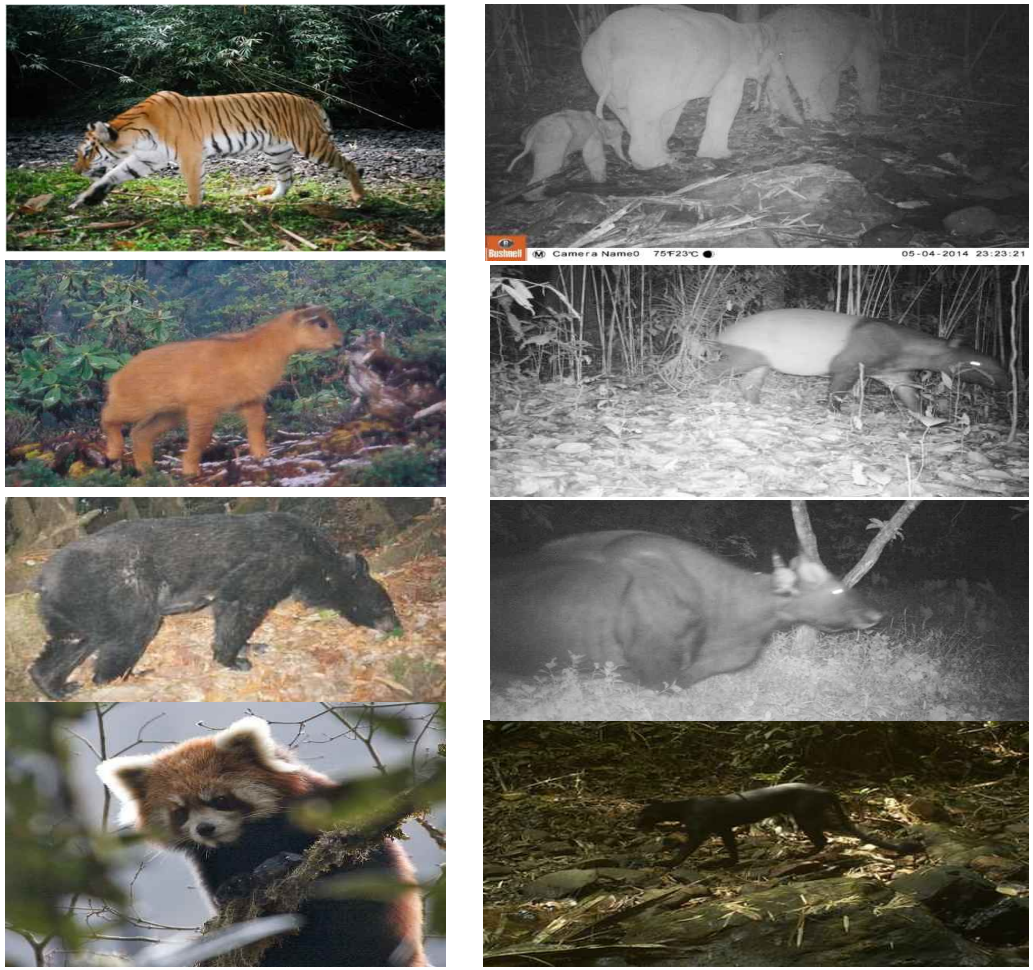
Dr. San Oo
Director
Environmental Conservation Department
Ministry of Natural Resources and Environmental Conservation
MYANMAR

Contents

- Introduction
- International Convention and Protocols on Biodiversity
- ABS relevant legislations in Myanmar
- Previous ABS related Projects in Myanmar
- Myanmar ABS Institutional and policy Framework (draft)
- Upcoming ABS Project in Myanmar
- Conclusion

Introduction

Status of Biodiversity:



Category	No. of Species
Plants	11,824
Mammals	252
Birds	1,056
Reptiles	295
Amphibian	139
Fresh & Mirine Water Fish	775
Marine Turtle	5
Coral	52

Source: Myanmar's Fifth National Report to UNCBD, 2014

Myanmar counts:

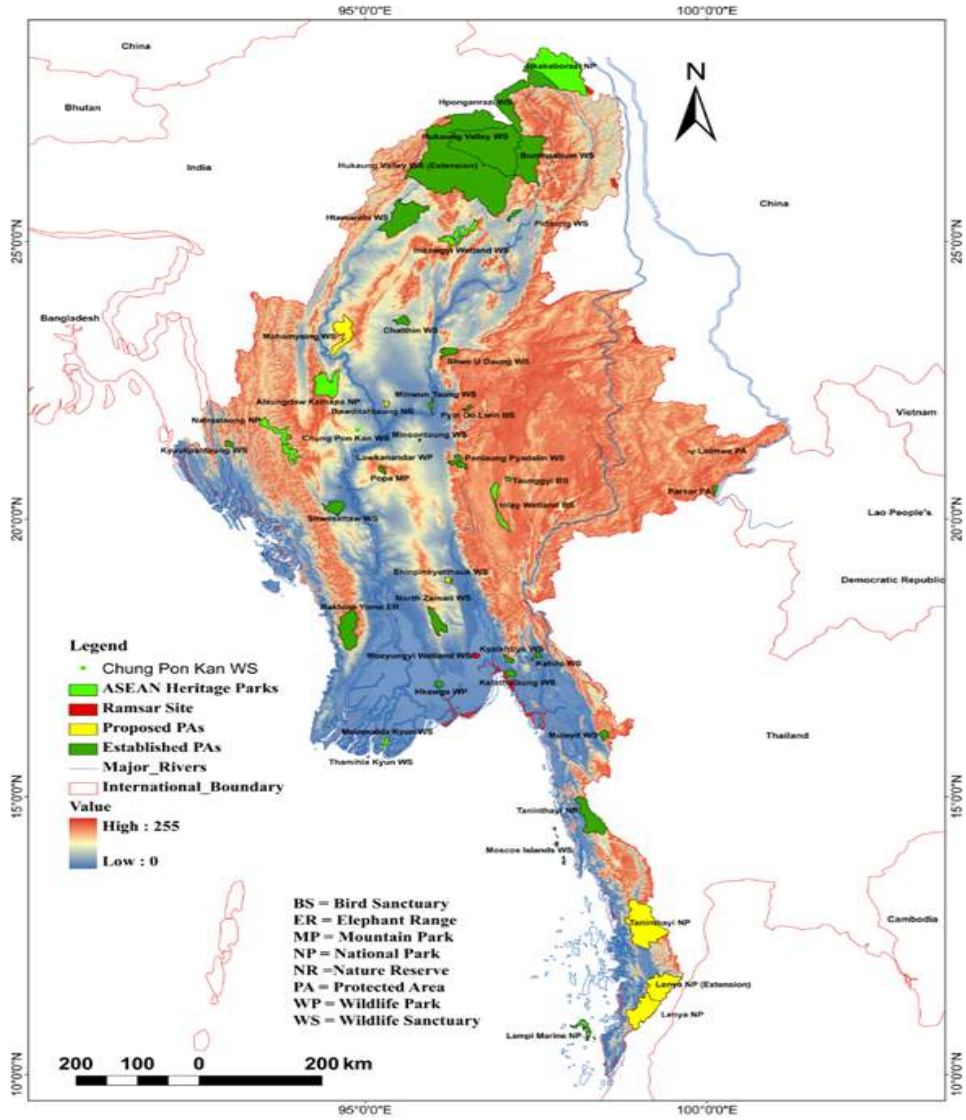
- ✓ **144 globally threatened species**
- ✓ **39 endangered species**

Introduction (Contd:)

Protected areas in Myanmar

Policy targets: to establish 5 % of total land as **Protected Areas** in short term and 10% in long term.

- Gazette (39)- 38025.01 Km^2 (5.75%)
- Proposed (7)- 8065.09 Km^2 (1.09%)



Introduction (Contd:)

- Major threats to biodiversity in Myanmar include:
  - hunting
  - overfishing
  - forest depletion and degradation
  - encroachment
  - forest fire
  - habitat destruction (which is expected to grow due to increasing urbanization)
  - climate change
  - introduction of alien invasive species
  - increasing markets for wildlife and their derivatives in neighboring countries
  - Lack of proper EIA in the past

International Conventions and Protocols on Biodiversity

- Myanmar ratified CBD on 25th Nov 1994
  - 5th national report to CBD submitted in March 2014
- Myanmar ratified Cartagena Protocol on Biosafety in 2008
  - National Biosafety Framework (draft)
  - Law on Biosafety (draft)
- Party to the Nagoya Protocol on Access and Benefit-sharing
  - Signed: 30 Dec 2013
  - Entered into force on: 12 Oct 2014
  - Accession (become member): 08 Jan 2014
  - ABS National Focal Point: Director General, Environmental Conservation Department

ABS relevant legislations in Myanmar

Environment & Forestry

- ✓ National Environment Policy (1994)
- ✓ Myanmar Agenda 21 (1997)
- ✓ National Sustainable Development Strategy-NSDS (2009)
- ✓ Environmental Conservation Law (2012)
- ✓ Environmental Conservation Rules (2014)
- ✓ Environmental Impact Assessment Procedure (2015)
- ✓ Revised National Environment Policy (draft)
- ✓ National Environmental Strategy and Action Plan (draft)

ABS relevant legislations in Myanmar (Contd:)

Environment & Forestry (contd:)

- ✓ Forest Policy (1995)
- ✓ Forest Law (1992)
- ✓ Community Forestry Instructions-CFI (1995)
- ✓ Protection of Wildlife, Wild Plants and Conservation of Natural Areas Law (1994)
- ✓ Revised CFI (2016)

Agriculture and Irrigation Sector

- ✓ The Pesticide Law (1990)
- ✓ The Plant Pest Quarantine Law (1993)
- ✓ The Fertilizer Law (2002)

ABS relevant legislations in Myanmar (Contd:)

Cultural Sector

- ✓ The Protection and Preservation of Cultural Heritage Region Law (1998)

Industrial Sector

- ✓ The Private Industrial Enterprise Law (1990)

Livestock and Fisheries Sector

- ✓ The Law Relating to the Fishing Rights of Foreign fishing vessels (1989)
- ✓ The Law Relating to Aquaculture (1989)
- ✓ The Myanmar Marine Fisheries Law (1990)
- ✓ The Freshwater Fisheries Law (1992)
- ✓ The Animal Health and Development Law (1993)

ABS relevant legislations in Myanmar(Contd:)

Science and Technology Sector

- ✓The Science and Technology Development Law (1994)
- ✓The Atomic Energy Law (1998)

National Planning and Economic Development Sector

- ✓The Myanmar Special Economic Zone Law (2011)

Previous ABS related Projects in Myanmar

- **Project Title:** **Building Capacity for Regionally Harmonized National process for Implementation of CBD provisions on Access to Genetic Resources and Sharing of Benefits in Myanmar**
- **Executing Agency:** **ECD**
- **Coordinating Agency:** **UNEP (Funding Agency: GEF)**
- **Project Period:** **26 Feb 2013 to 30 March 2014**
- **Outputs:**
  - ✓ Reports of the NP on ABS to be references to Myanmar Government/National Road Map
  - ✓ National ABS Framework (draft)
  - ✓ Publication of national consultation workshop reports
  - ✓ Publication of CBD and NP provisions on ABS in Myanmar
  - ✓ National ABS policy assessment report (draft)
  - ✓ Legislative and institutional capacity assessment report (draft)

Previous ABS related Projects in Myanmar (Contd:)

Project title : Building Capacity of Countries in support of the development and implementation of National ABS Framework in Myanmar

Project Period: **31 January 2016 to 31 August 2016**

Executing Agency: ECD

Coordinating Agencies: UNEP, ACB, China-ASEAN (Funding Agency: UNEP, China ASEAN)

Objective:

- ✓ to fulfill the country's commitments under CBD , Nagoya Protocol and support of the development and implementation of National ABS Framework

Output:

- ✓ ABS Institutional and policy Framework for Myanmar

Previous ABS related Projects in Myanmar (Contd:)

Piloting of ABS Measures: Implementation of Nagoya Protocol – ABS in Biotechnology Research Department (BRD) as Piloting of ABS Measures in MoU

Period: 13 June 2016 to 20 July 2016

Outputs:

- ✓ Effective awareness raising to research departments and students who are studying life science and people who are dealing with private sectors and market places
- ✓ Solutions to some biomaterial exchange issues faced by young researchers and staffs who had conducted international collaboration projects and joint researches
- ✓ Organize a new and specific format of MoU for biotechnological research collaborations by applying annexes of NP-ABS
- ✓ Active participation of faculty members to conserve and prevent the biodiversity of microorganisms, commercially important crops and traditional knowledge of our people (by planning different researches in biodiversity and TK conservation)
- ✓ Planning to reach out the farmers and local people in different regions where the valuable TK and biological resources needed to maintain and repair by biotechnological means

Myanmar ABS Institutional and policy Framework (draft)

- **Scope:** The collection, research, utilization and commercialization of Myanmar's genetic resources and traditional knowledge associated with genetic resources.
- **Objective:** The Policy Framework shall ensure the fair and equitable sharing of benefits from the utilization of Myanmar's genetic resources and traditional knowledge associated with genetic resources

Myanmar ABS Institutional and policy Framework (draft)

National Focal Point	• Environmental Conservation Department-ECD • Responsible for liaison with the Secretariat of the Convention on Biological Diversity
Competent National Authorities	• Ministry of Natural Resources and Environmental Conservation through the Environmental Conservation Department and the Forest Department • Ministry of Agriculture, Livestock and Irrigation through the Department of Agricultural Research • Ministry of Health, through the Department of Traditional Medicine, and Food and Drug Authority • Ministry of Agriculture, Livestock and Irrigation through the Fisheries Department • Ministry of Education through the Department of Science and Technology • Ministry of Commerce for export / import licenses • Ministry of Ethnic Affairs to comment on the rights of ethnic peoples
Role of Region and State Governments	• Shall likewise exercise their power over genetic resources concurrently or in a shared manner with the Ministries hereby designated as competent national authorities, in accord with the relevant laws enacted by the Union
Appeals Committee	• Will deal with the appeals that may be made by the applicant for access from any decision that may be made by the relevant competent national authorities
Other Agencies and Entities	• Research and Development – the Ministry of Education, through the Biotechnology Department • Checkpoints: Research Committee ,Intellectual Property Office ,Food and Drugs Authority

Myanmar ABS Institutional and policy Framework (draft)

INSTITUTIONAL MECHANISMS FOR COORDINATION

Union Government Committee on ABS	• Composed of the National Focal Point, the various designated Competent National Authorities and the suitable citizens
Parliamentary (Hluttaw) Liaison	• Union Government Committee on ABS should establish a liaison unit that will work with the Parliament on ABS issues and to respond to Parliament's concerns on ABS
Involvement with the Communities and Other Stakeholders	• Union Government Committee on ABS shall establish coordination mechanisms to ensure the involvement of the ethnic peoples, communities and other stakeholders

Myanmar ABS Institutional and policy Framework (draft)

IMPLEMENTING ACTIONS

- Established a technical working group led by the Environmental Conservation Department of MONREC that will review the initial roadmap developed for identifying the actions and resources, including international support; necessary to establish and enhance Myanmar's institutional and policy framework for ABS

Upcoming ABS Project in Myanmar

Project title : Strengthening the legal , policy and Institutional Capacity to implement Nagoya Protocol

Executing Agency: ECD

Coordinating Agency: UNDP (Funding Agency: GEF)

Project Period: 2016 – 2018

Expected Outputs:

- ✓ National ABS law / regulation / policy proposal drafted and submitted for approval to competent authorities
- ✓ Existing and emerging partnerships for Biodiversity between users and providers of genetic resources to generate "success stories " and practical lessons, as well as reinforce trust
- ✓ Campaign increases ILCs awareness on the importance of genetic resources and TK associated with genetic resources and related access and benefit-sharing issues , including the need to participate in the national ABS policy-making process

Conclusion

- Need to improve the drafted ABS institutional and policy framework
- Necessary legislative, administrative and policy measures at the regional, national and/or local level need to be developed for the implementation of ABS on the ground
- Awareness on ABS needs to be strengthened at the national and local level
- Capacity building programs at various levels are needed
- Law Enforcement plays a great role

Thank You!

Federal Ministry for the
Environment, Nature Conservation,
Building and Nuclear Safety

The implementation of the Nagoya Protocol in the EU and in Germany - Legal framework and steps towards enforcement

Dr. Stefan Lütkes
Head of Unit „Nature Conservation and Landscape Management Legislation“
6 July 2017, National Implementation of the Nagoya Protocol on ABS, Seoul, South Korea

Federal Ministry for the
Environment, Nature Conservation,
Building and Nuclear Safety

1. Implementation in the EU
2. Legislative process in Germany
3. Competent authorities in Germany
4. Checks on user compliance
5. Sanctions
6. Patent legislation
7. Access measures in Germany?
8. Implementing the EU Regulation

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Environment, Nature Conservation,
Building and Nuclear Safety

1. EU Regulation

- The „Compliance Pillar“ of the Nagoya Protocol is implemented comprehensively at the EU level in Regulation 511/2014.
- Access to genetic resources is not dealt with at EU-level; some MS have their own rules.
- EU Regulations are applicable directly in all MS.
- They are enforced by MS authorities.

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1. EU Regulation

- 12.10.2014: Nagoya Protocol & EU Regulation enter into force
- August 2016: Scope Guidance published
- Ongoing: Sectoral Guidance documents under consideration
  - Animal breeding
  - Plant breeding
  - Pharmaceutical
  - Food & Feed
  - Biocontrol
  - Cosmetics
  - Basic research
  - Collections of genetic resources
  - Biotechnology

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1. EU Regulation

- Art. 4: Due diligence obligation
  - Users of genetic resources need to seek, keep and transfer information relevant to ABS within the chain of utilization
  - This supports PIC & MAT requirements in provider states
- Article 4.5: If doubts regarding the legality of access persist, users need to discontinue utilization
- Article 7: Users need to submit Due Diligence declarations at two stages: when they receive research funding and at the stage of final development of a product
- Article 9: Member states need to check on user compliance
- Article 11: Member states need to foresee penalties for non-compliance

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1. EU Regulation

- Artikel 2: Scope
  - Temporal:
    GR accessed after 12/10/2014…
  - Geographical:
    …in a party to the NP…
  - Factual:
    …which has access legislation applying to the specific GR in question.

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1. EU Regulation

- MS need to :
  - Carry out checks on user compliance (Article 9)
  - Accept DD-declarations (Article 7)
  - Carry out checks on Registered Collections (Article 5)
  - Cooperate with other agencies and the ABS-CHM (Article 12)
  - Awareness raising & information sharing (Article 13)
  - Provide guidance to users (Article 13)
  - et.al.

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2. Legislative process

- October 2015: German legislation passed by the Federal Parliament
- July 2016: German legislation enters into force
- 20 July 2016: Germany becomes Party to the NP
- 2016: New enforcement unit within the Federal Agency for Nature Conservation (BfN) created

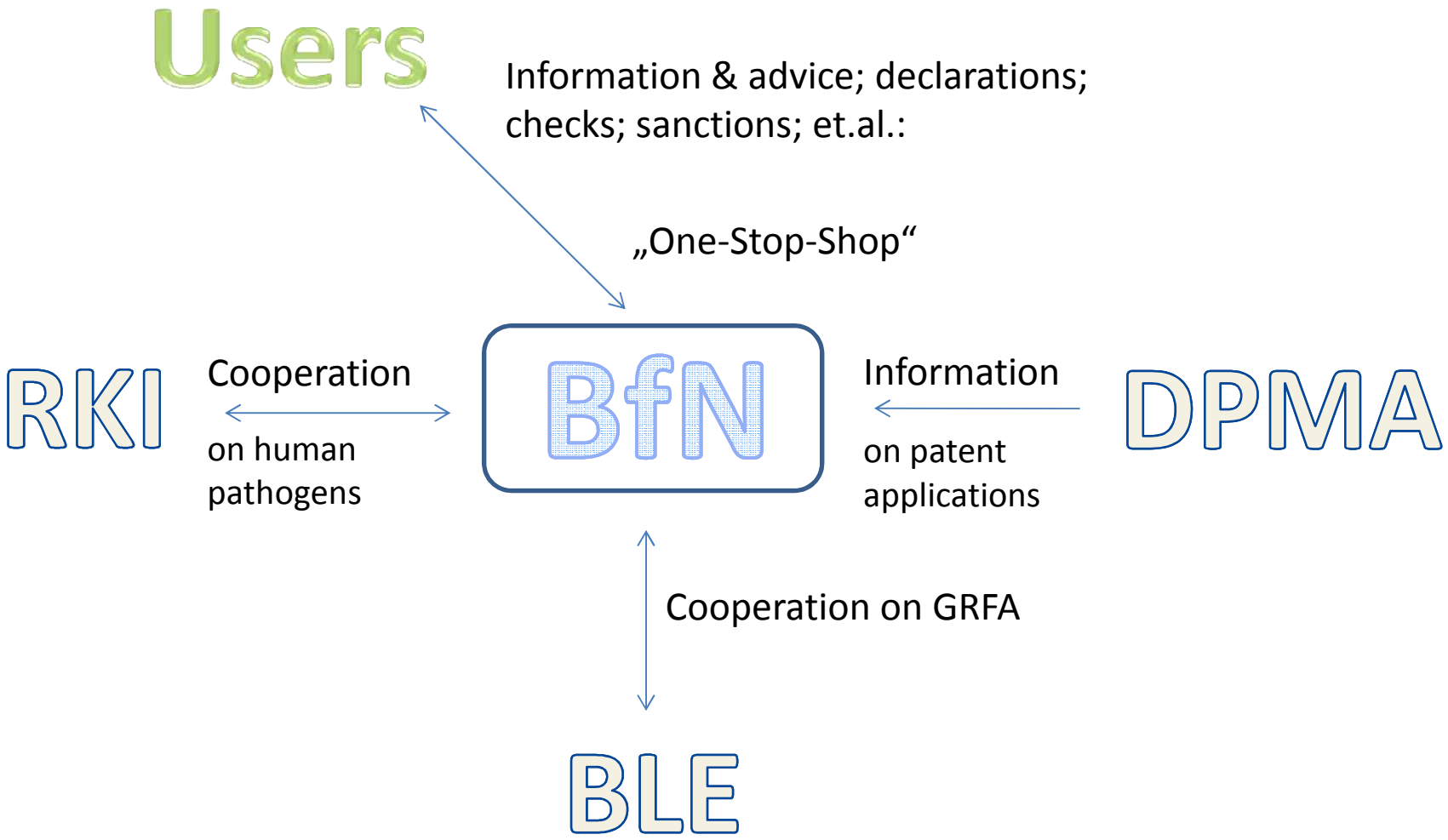
Federal Ministry for the
Environment, Nature Conservation,
Building and Nuclear Safety

3. Competent authorities

- Implementation exclusively at the Federal Level
- Four government agencies with experience in ABS issues:
  - Federal Agency for Nature Conservation (BfN)
  - Federal Agency for Agriculture and Food (BLE)
    - Informations- und Koordinationszentrum für biologische Vielfalt (IBV)
    - Informationssystem Genetische Ressourcen (GENRES)
  - Robert-Koch-Institut (RKI) for public health
  - German Patent and Trade Mark Office (DPMA)

Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety

3. Competent authorities



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4. Checks

➢ Authorizations for interventions:

- Right to require information from **potential** users (§ 1.2)
- Right to check documentation (§ 1.3)
- Right to enter premises (§ 1.3)
- Right to draw samples of genetic material (§ 1.3)
- Remedial orders (§ 2.1)
- Seizure and confiscation of genetic material (§ 2.2-3)
- Prohibition of specific utilisation activities (§ 2.3)

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5. Sanctions

- Art. 15 (2) of the Nagoya Protocol:

„Parties shall take appropriate, effective and proportionate measures to address situations of non-compliance…“

- Need to find a reasonable balance between „proportionate“ and „effective“.
- Sanctions: administrative sanctions (as opposed to criminal sanctions which are not foreseen)
- Two-step-approach:
- Up to 50.000 € as an upper limit;
- Principle of proportionality requires the Agency to consider:
    - type of utilization
    - commercial / non-commercial
    - Repeated non-compliance
    - Intentional or negligent non-compliance
    - et.al.

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5. Sanctions

- § 17.4 of the German Act on Regulatory Offences:

"The regulatory fine shall exceed the financial benefit that the perpetrator has obtained from commission of the regulatory offence. If the statutory maximum does not suffice for that purpose, it may be exceeded."

- In other words: 50.000 € may be exceeded, in principle ad infinitum.
- We want to ensure that nobody has an economic advantage from breaching relevant ABS obligations.
- However the CNA needs to demonstrate (and must ultimately be able to prove) that the specific user has obtained a financial benefit.
- The BfN has in the past on a similar legal basis succesfully enforced penalties amounting to several hundred thousand EUROs.
- Thereby it is ensured that sanctions/measures are „effective"; an absolute maximum (cap) might be ineffective in very specific cases.

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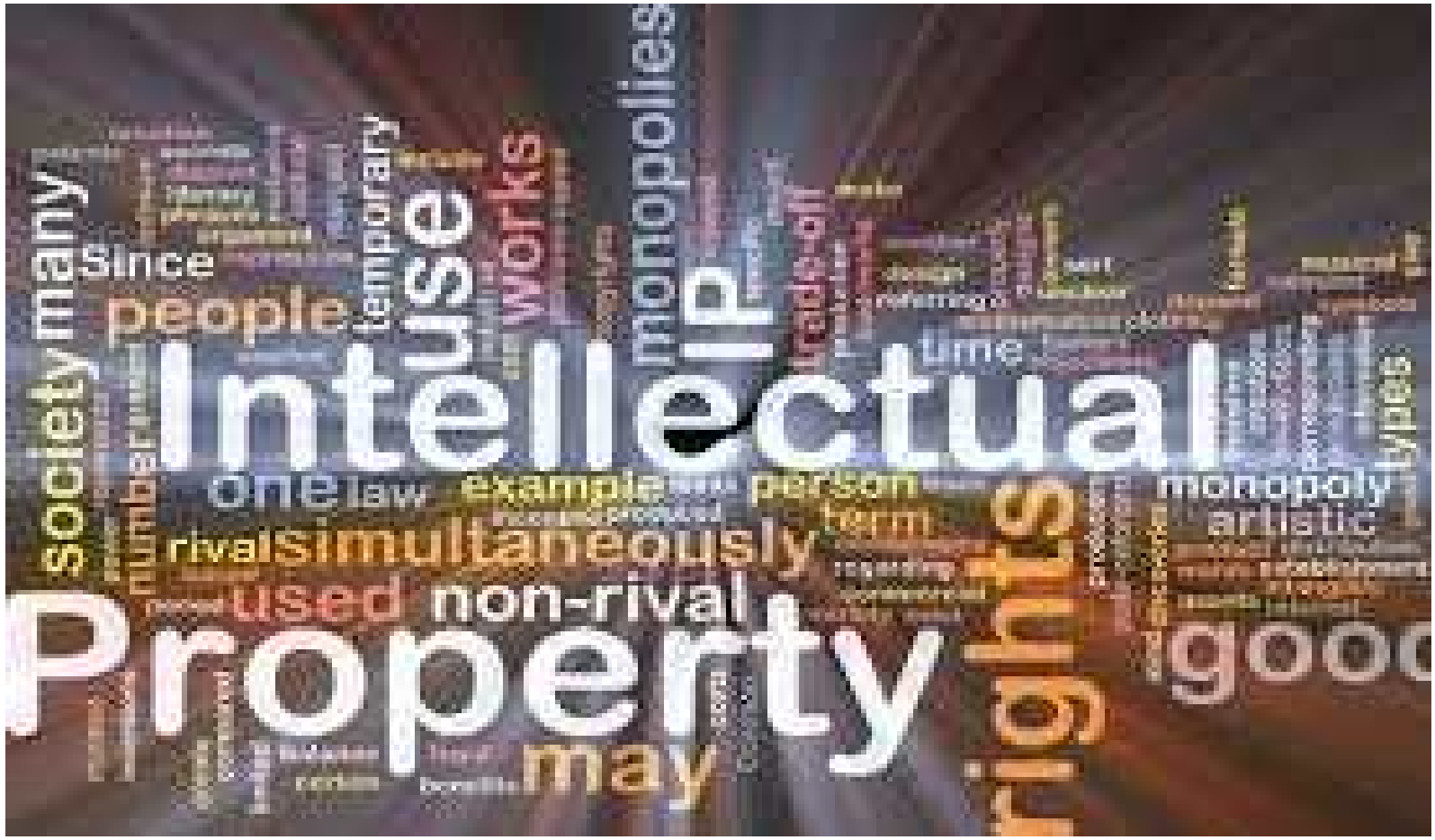
Building and Nuclear Safety

6. Patent legislation



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6. Patent legislation

- § 34a of the German Patent Act reads:

"Where an invention is based on biological material of plant or animal origin or if it uses such material, the application should include information on the geographical origin of such material, if known. This shall be without prejudice to the examination of applications or the validity of rights arising from granted patents."

- Amendment (inofficial translation):

"If the application contains information on the geographical origin (…), the Patent Agency forwards this application to the Federal Agency for Nature Conservation (…) after the publication of the summary (…)."

- Validity of the patent is not affected and the Patent Agency does not act as an enforcement agency.

- However the BfN receives relevant information at an early stage of the application process and could react accordingly, if necessary.

Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety

7. Access measures in Germany?

- Germany does not have any specific legislation on access to genetic resources.
- There are no plans to introduce any.
- Specific legislation on nature conservation, species conservation, private property et.al. may apply.
- We neither believe that an access regime would be beneficial for nature conservation nor that it would create any relevant revenues – at least under the conditions that we have in Germany.

Federal Ministry for the
Environment, Nature Conservation,
Building and Nuclear Safety

8. Implementing

- Start with internal conceptual work:
  - Agreements between authorities;
  - enforcement plans;
  - User identification study et.al.
- Then focus on awareness raising and distribution of information among users: Speeches, brochures et.al.
- Ask potential users to submit relevant information about their implementation.

Federal Ministry for the
Environment, Nature Conservation,
Building and Nuclear Safety

8. Implementing

- Gather information from various sources and bring them together within the BfN:
  - User declarations
  - Market observations
  - Patent applications
  - Communication with users
  - Communication with other countries
- Focus intelligence on ABS in one place
- Checks could start in a written manner
- Where these lead to more questions, they could be extended to more detailed checks „on-the-spot“ and - as a last resort - to enforcement measures and sanctions.

Federal Ministry for the
Environment, Nature Conservation,
Building and Nuclear Safety

For more information:

http://abs.bfn.de

and

nagoya-cna@bfn.de

AN OVERVIEW OF THE SOUTH AFRICAN LEGISLATIVE FRAMEWORK ON BIOPROSPECTING, ACCESS AND BENEFIT SHARING

Ms Natalie Feltman

Date: 06 July 2017

International Symposium: National Implementation of Nagoya Protocol on ABS

The K Hotel Seoul

Biodiversity and Conservation

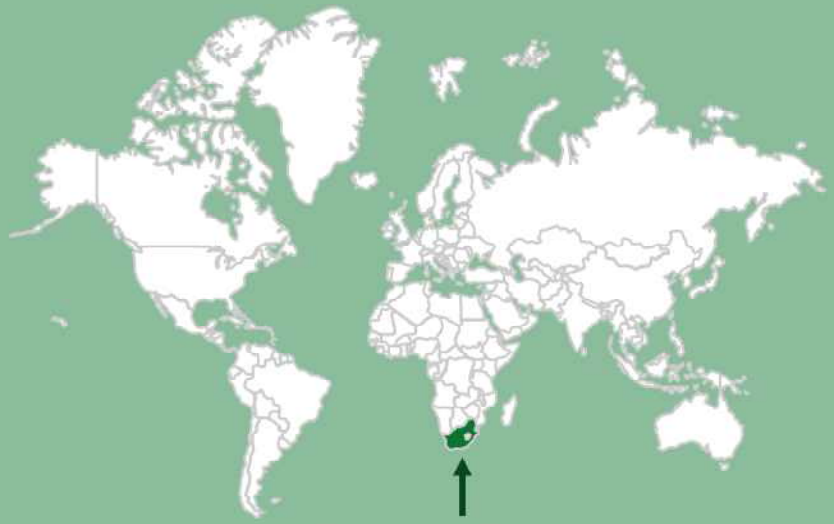
environmental affairs
Department:
Environmental Affairs
REPUBLIC OF SOUTH AFRICA

PRESENTATION OUTLINE

- Overview of South Africa's Biodiversity
- Overview of Bioprospecting in South Africa
- Overview: Overall Policy Objectives
- Legislative Framework in South Africa
- NEMBA provisions and key terms
- BABS Amendment Regulatory Provisions
- Challenges and Lessons Learnt
- NEMBA review
- Biodiversity Economy

OVERVIEW: SOUTH AFRICAN BIODIVERSITY

3rd most biodiverse country in the world



2% of the world's land area

7% of the world's reptiles, birds and mammals

10% of the world's plants

15% of the world's coastal marine species

OVERVIEW SOUTH AFRICAN BIODIVERSITY

OVERVIEW: SOUTH AFRICAN BIODIVERSITY

- One of South Africa's greatest assets.
- Rich in indigenous biological resources (IBRs) and cultural diversity.
- Rich with traditional knowledge (TK) on properties of plants, seeds, algae & other IBRs.
- Our IBRs & TK is desired by academics & commercial scientists to develop new information / commercial products.

IMPORTANCE OF INDIGENOUS BIOLOGICAL RESOURCES AND ASSOCIATED TRADITIONAL/ INDIGENOUS KNOWLEDGE

OVERVIEW: BIOPROSPECTING IN SOUTH AFRICA

- Historically, bioprospecting was free for all
- This unregulated bioprospecting led to biopiracy with –
  - Unfair, inequitable sharing of benefits arising from the use of IBRs; (**or no benefit sharing**)
  - Unsustainable use of indigenous biological resources (IBRs);
- These concerns led to the development of International and National legislation and frameworks.

OVERVIEW: OVERALL POLICY OBJECTIVES

1) To redress the injustice of the past in order to achieve socio-economic development goals ~ fair & equitable benefits sharing.

2)To provide regulatory framework for bioprospecting / biotrade activities ~ attain conservation and sustainable utilization of indigenous biological/genetic resources ~ Permitting System.

3)To provide obligatory requirements to the regulated sectors to recognize existing traditional knowledge on the usefulness of indigenous biological/genetic resources ~ Benefit Sharing Agreements.

4)To provide obligatory requirements to the regulated sectors to seek permission from the land owners to access/collect indigenous biological/ genetic resources ~ Material Transfer Agreements and Benefit Sharing Agreements.

5) **To implement international regulatory obligations adopted by South Africa**

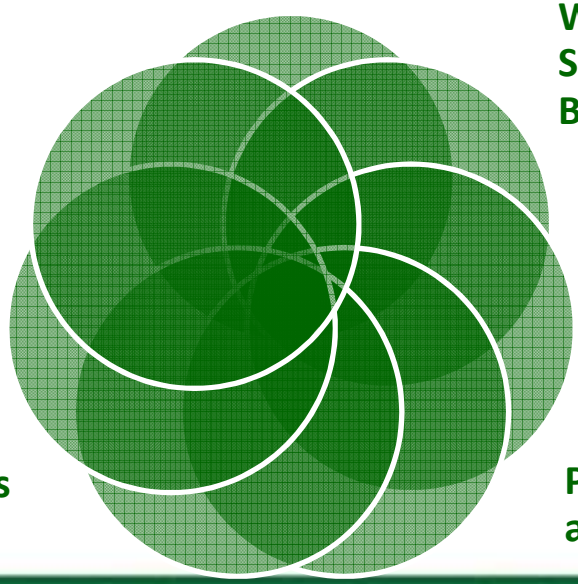
RELEVANT LEGISLATIVE FRAMEWORKS IN SOUTH AFRICA

CBD & Nagoya Protocol on Access to Genetic Resources & the Fair and Equitable Sharing of Benefits Arising from their Utilisation

Ratification
31 January 1996
10 January 2013

Constitutional mandate & NEMA

White Paper on Conservation & Sustainable Use of South Africa's Biodiversity of 1997 - 2007



Constitutional Concurrent Mandate, Provincial Ordinance

NEMBA (2004), BABS Regulations (2008 – amendments 2015)

Indigenous Knowledge Systems Policy-administered by DST

Patent Amendment Act-administered by DTI

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NATIONAL ENVIRONMENTAL MANAGEMENT BIODIVERSITY ACT

- Provides for, amongst other:
- Management and conservation of biological diversity within South Africa;
- Use of indigenous biological resources in a sustainable manner;
- Fair and equitable sharing of benefits arising from the use of indigenous biological resources and associated traditional/indigenous knowledge;

NEMBA CHAPTER 6: KEY PROVISIONS

- Chapter 6 of NEMBA provides a framework for:
- The regulation of bioprospecting involving indigenous biological resources
- The regulation of export from the Republic of indigenous biological resources for purposes of bioprospecting
- The fair and equitable sharing of benefits arising from bioprospecting involving commercial utilization of indigenous and biological resources and associated traditional knowledge
- South Africa's indigenous biological resources to be developed and utilized in an ecologically sustainable manner while promoting social and economic development, in particular in the areas where the indigenous biological resources and associated traditional knowledge are accessed

NEMBA CHAPTER 6: KEY PROVISIONS

- Permit requirements (Section 81)
- Notification requirements (Section 81A)
- Protection of interests of Access Providers and/or Traditional/Indigenous Knowledge Holders (Section 82)
- Bioprospecting Trust Fund (Section 85)
- Exemptions (Section 86)
- Offences & Penalties (Section 98(2), 101 &102)

KEY PROVISIONS: PERMIT REQUIREMENTS

NEMBA requires the permit applicants to fulfil the following requirements to ensure protection of the rights of the indigenous communities:

- Must disclose all material/important information about the bioprospecting/ biotrade project to the identified access provider/ TK holders.
- Must obtain prior consent for access to IBR & / or use of TK.
- Must enter into material transfer agreements (MTA).
- Must enter into benefit sharing agreements (BSA).
- BSA & MTA must be approved by the Minister before a permit is issued.

➢ **Benefits may be Monetary or Non-monetary, e.g:**

Community development projects, Equipment and infrastructures, Royalties, Milestones payments, Upfront payments, Bursaries etc.

KEY PROVISIONS: PROTECTION OF INTERESTS

Chapter 6 of NEMBA calls for the protection of certain interests of the following stakeholders before a permit is issued:

- A person, including organ of states, or community providing or giving access to the indigenous biological resources to which the permit application relates

- An indigenous community whose traditional use or discoveries of the indigenous biological resources to which the permit application relates have initiated or will contribute to the proposed bioprospecting/ biotrade

KEY PROVISIONS: OFFENCES

A person is guilty of an offence if that person

- Without a permit –
  - Undertakes bioprospecting/ biotrade involving IGBRs &TK
- Contravenes any provision of these Regulations
- Does not adhere to the permit conditions
- Permits, or allow any other person to do anything which is an offence in terms of these regulations

KEY PROVISIONS: PENALTIES

A person convicted of an offence is liable to –

- Fine not exceeding R5-million or imprisonment for a period not exceeding 5 years.

- Fine not exceeding R 10-million or imprisonment for a period not exceeding 10 years, in the case of second offence or subsequent conviction.

- Both fine and imprisonment

KEY TERMS

Bioprospecting means any research on, development or application of indigenous genetic/biological resources (IGBRs) for commercial exploitation & includes-

a) *the systematic search, collection or gathering of IGBRs or making extractions from IGBRs; or*

b) *the utilisation of any information regarding any traditional uses of IGBRs by indigenous communities; or*

c) *research on, or the application, development or modification of traditional uses of IGBRs for commercial exploitation; or*

d) *trading in & exporting of IGBRs in order to develop and produce products such as industrial enzymes, fragrances, cosmetics, extracts, essential oil, drugs; medicines, food flavours & colours.*

KEY TERMS CONT…

NEMBA categorized bioprospecting into 2 phases:

1. Discovery phase

means any research on IGBRs where the nature & extent of any actual or potential commercial exploitation in relation to the project is not sufficiently clear or known to begin the process of commercialisation.

2. Commercialisation phase

means any research on, or development or application of IGBRs where the nature & extent of any actual or potential commercial exploitation in relation to the project is sufficiently established to begin the process of commercialisation.

KEY TERMS CONT….

IGBRs -animals, plants or microorganisms of indigenous species

Includes

- Living or dead
- Genetic material gathered from the wild , cultivated, bred or kept in captivity

- **Exotic** species altered with genetic materials or bio-chemical compounds from indigenous species





Excludes

- Genetic material of human origin
- All other exotic species

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KEY TERMS CONT….

Commercialisation includes the following activities-

- *Filing of complete intellectual property (IP) / patent application in SA or elsewhere;*
- *Obtaining or transfer of IP rights;*
- *Commencement of product development, including conducting market research & seeking pre-market approval for the sale of resulting products;*
- *Multiplication of IGBRs through cultivation, propagation, or cloning to develop & produce products such as: drugs, medicines, industrial enzymes, food flavours, fragrances, cosmetics, essential oils, emulsifiers, oleoresins, colours & extracts.*

KEY TERMS CONT….

- **Biotrade** means the buying & selling of milled, powdered, dried, sliced or extract of IGBRs for further commercial exploitation.

- **Commercial exploitation** means engaging in any bioprospecting activity with the intention of making a profit.

- **Traditional use or knowledge** refers to the customary utilisation or knowledge of IGBRs by indigenous community or specific individual, in accordance with written or unwritten rules, usages, customs or practices traditionally observed, accepted & recognised by them, & include discoveries about the relevant IGBR by that community or individual.

KEY TERMS CONT….

- **Material Transfer Agreement** refers to an agreement between the applicant & any person or organ of state or community providing access to IGBRs to which the application relates.

- **Benefit Sharing Agreement** refers to an agreement that provides for sharing of any future benefits that may be derived from bioprospecting between:
  - *the applicant & any person or organ of state or community providing access to IGBRs to which the application relates; and/or*
  - *the applicant & an indigenous community or specific individual whose traditional uses/knowledge/discoveries on IGBRs to which the application relates have initiated or are to be used in the proposed bioprospecting.*

KEY TERMS CONT….

- **Confidential Information** refers to information which, if disclosed, may be detrimental to the commercial, associated traditional knowledge or financial interests of the a party involved, and includes:

➢ *Information about research being or to be carried out including details of species to be collected and areas in which specified species are to be collected;*

➢ *Financial, commercial, scientific or technical information including trade secrets;*

➢ *Traditional knowledge if the disclosure of that knowledge may be detrimental to the relevant indigenous community or specific individual*

But excludes:

➢ *Information that has already been disclosed through publication in a scientific journal;*

➢ *Information that parties consent to its disclosure.*

BABS AMENDMENT REGULATORY PROVISIONS

The Regs applies to:

- Commercial or industrial sectors that uses IGBRs for biotrade, or for research, application or development of drugs, complementary medicines, neutraceuticals, industry enzymes, food flavours, fragrances, cosmetics, colours, extracts & essential oils.
- …that utilises TK associated with any IGBRs.
- Non-commercial sectors that export IGBRs from the Republic for research to generate scientific data.

BABS AMENDMENT REGULATORY PROVISIONS

PERMITTING PROCESS:

1. Discovery phase

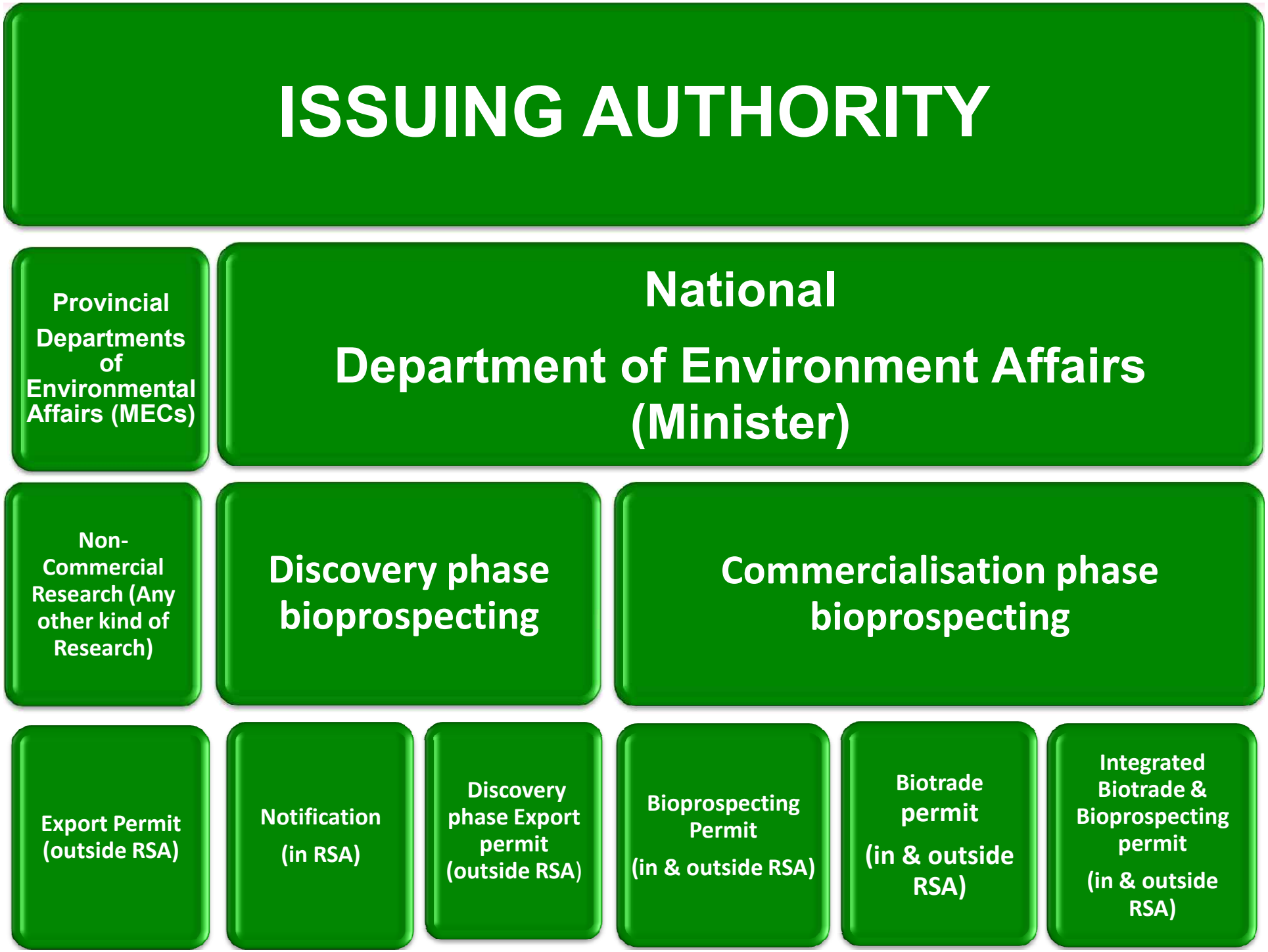
- Notification of the Minister (nationally)
- Discovery Phase Export permit (internationally)

2. Commercialisation phase

- Biotrade permit (nationally & internationally)
- Bioprospecting permit (nationally & internationally)
- Integrated biotrade & bioprospecting permit (nationally & internationally)

3. Any other kind of Research

- Export permit for research other than bioprospecting (internationally)


ISSUING AUTHORITY
Provincial Departments of Environmental Affairs (MECs)
National
Department of Environment Affairs (Minister)
Non-Commercial Research (Any other kind of Research)
Discovery phase bioprospecting
Commercialisation phase bioprospecting
Export Permit (outside RSA)
Notification (in RSA)
Discovery phase Export permit (outside RSA)
Bioprospecting Permit (in & outside RSA)
Biotrade permit (in & outside RSA)
Integrated Biotrade & Bioprospecting permit (in & outside RSA)

WHO MAY APPLY

A permit may only be applied by–

- A juristic person registered in terms of SA law.
- A natural person, who is a SA citizen or a permanent resident of SA.
- A non-juristic or natural person jointly with a juristic or natural person in terms of SA law.

PERMIT APPLICATION FEE STRUCTURE

Fees applicable to any natural person or juristic body in South Africa:

- Category I- **taxable turnover R 0-R300 000**
- Category II- **taxable turnover R300 001- R 750 000**
- Category III**-taxable turnover R 750 000 & above**
- Category IV–Bona fide research institutions

TIMEFRAMES

- The Issuing Authority:

➢ must consider & decide on any permit application within **120 working days** after the receipt of such an application, if satisfied that all the prescribed & requested information has been submitted.

➢ must within **10 working days** after the date of receipt of such an application & in writing, request the applicant to submit such information with 20 working days after date of receipt of such a request.

- If the additional information requested is not submitted to the issuing authority within **30 working days** after such a request, such an application must be deemed withdrawn.

RENEWAL & AMENDMENTS TIMEFRAMES

- Permit holder may, before the expiry, apply for renewal of such permit.

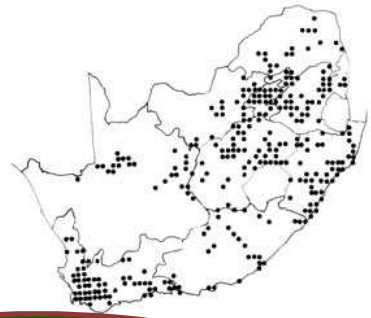
- Permit holder may, after annual project status reporting, apply for amendment of such permit.

OTHER KEY REGULATORY PROVISIONS

- How & where to submit notifications or permit applications (Chapter 3)
- Application forms (Annexes)
- Assistance by issuing authority to applicant or stakeholder (Chapter 2)
- Consultation between issuing authority & relevant stakeholders (Chapter 2)
- Issuing authority's right to access to information (Chapter 2)
- Criteria for evaluating notifications or permit applications or renewal or amendment by the issuing authority (Chapter 2 & 3)
- Circumstances for refusal of permits (Chapter 3)
- Communication of decision on notifications or permit applications by the issuing authority (Chapter 2)
- How to fulfil the BSA requirements, where relevant stakeholders cannot be identified (Chapter 4)
- How to fulfil the BSA requirements, as a Subsequent biotrader (Chapter 3)

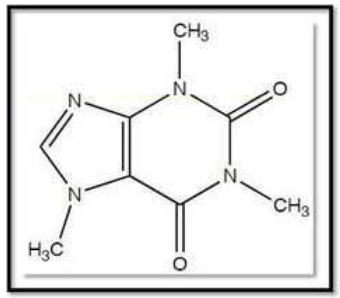
PRACTICAL ILLUSTRATION OF REGULATIONS

Use of traditional/indigenous knowledge



Use of indigenous biological resources

Commercial and/or Non-Commercial intent



Research on biochemical composition of resource

Extraction of biochemical compound from resource

environmental

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Environmental Affairs
REPUBLIC OF SOUTH A

CHALLENGES & LESSON LEANT

- National legislation (inclusive of inputs and participation in from relevant key stakeholders) is instrumental in facilitating access, ensuring that prior informed consent is obtained, leading to negotiations and entering into Mutually Agreed Terms.
- Clearly defined holders of traditional knowledge coupled with legal representation is key to any successful benefit sharing agreement or ABS project.
- Capacity building and training is critical.
- Foreign bioprospecting companies that access materials from the middleman/biotrader

Alignment to NP: Review of NEMBA and BABS

- Consistent use of terms
- Identification and Designation of checkpoints
- Designation of NFP and CNA
- Provisions for user measures (import of genetic resources for commercial or non commercial purposes
- Alignment of the provisions of the permitting requirements with those stipulated for the internationally recognized certificate of compliance under the NP
- Documentation of TK

Vision

South Africa is globally recognised for the sustainable and inclusive commercial use of its biodiversity

Key challenges inhibiting growth in the Bioprospecting Economy

How do we increase the supply?

1. 
Limited supply due to the dominance of wild harvesting and low levels of cultivation

How do we increase demand and local value addition?

2. 
Low levels of local value addition and product development

3. 
Limited local and international awareness other than the big five (rooibos, buchu, honeybush, *Aloe ferox* and *Pelargonium sidoides*)

4. 
Difficult access to markets for products with IBRs

Regulatory

5. 
Complex, costly and cumbersome national and international regulatory environment for a sector that straddles multiple industries

Transformation

6. 
Lack of participation of communities and traditional knowledge holders in the sector

Key initiatives to drive growth in the Bioprospecting Economy

How do we increase the supply?

1. **Promote a mass cultivation drive of 25 plant species of strategic importance and increase cultivation by 500 hectares per annum**

2. **Define management plans to ensure sustainable wild harvesting of 7 high value plant species to safeguard long term supply**

How do we increase demand and local value addition?

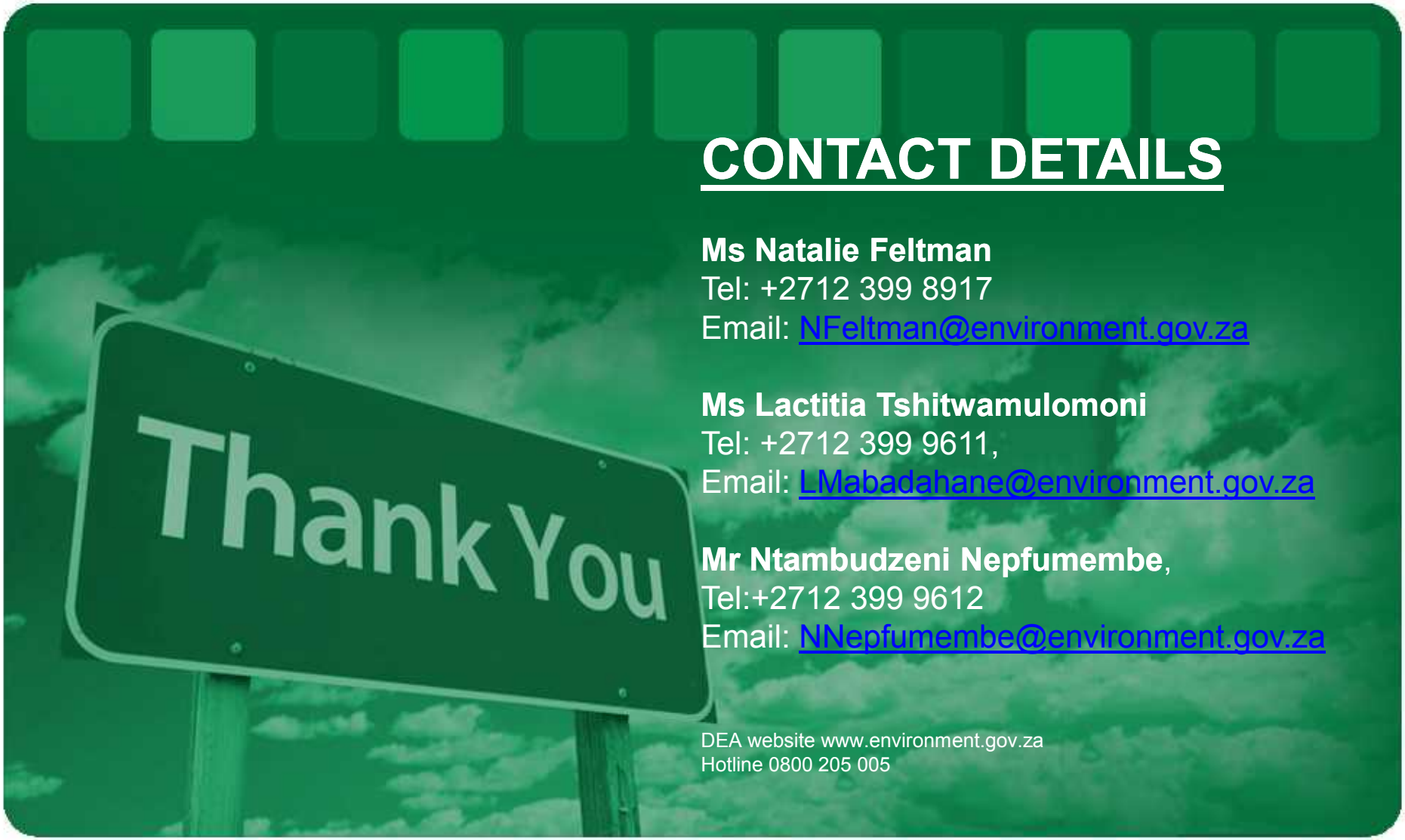
3. **Establish a coordinating and facilitating BioPANZA (Bio Products Advancement Network South Africa) to harness existing initiatives and to address the innovation chasm**
   - Promote applied research, local processing, innovation and product development; and to promote the use and awareness of products with IBRs

Regulatory

4. **Fast tracking amendments of Chapter 6 of National Environmental Management Biodiversity Act (NEM:BA) to ease compliance while ensuring protection of the rights and benefits of traditional knowledge (TK) holders and alignment with Nagoya Protocol on Access and Benefit Sharing**

5. **Improve efficiencies in the Bioprospecting Access and Benefit Sharing (BABS) permitting system**

Transformation is a cross cutting essential



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environmental affairs
Department:
Environmental Affairs
REPUBLIC OF SOUTH AFRICA

Ministry of Environment

Procedures for Access and Utilization of Domestic and Foreign Genetic Resources

『The Act on Access and Utilization of Genetic Resources and Sharing of Benefits ("Act on Genetic Resources")』

Thursday, 6 Jul 2017

National Implementation of The Nagoya Protocol on ABS:
Sharing Lessons &
Discussing Challenges

목 차

Ⅰ. Status of Biodiversity in Republic of Korea

Find the **FUTURE**
In Genetic Resources

Species in Korea	Species discovered	Endemic Species	Endangered Species
About 100,000	47,003	2,316	246

II. Legislative Process of the Act on Genetic Resources

January 17, 2017

Establishment of "The Act on Access and Utilization of Genetic Resources and Sharing of Benefits"

Draft, Resolution by State Council and Submission to the National Assembly (June, 2016)

Introduction to the Environment and Labor Committee and referring to subcommittee (21 November 2016)

Resolution by the subcommittee and Passing by the Environment and Labor Committee (23 December 2016)

Passing by the Legislation and Judiciary Committee and Plenary session (29 December 2016)

Promulgation of "The Act on Access and Utilization of Genetic Resources and Sharing of Benefits" (17 January 2017)

Ⅲ. Overview of the Act on Genetic Resources

Composition: 5 Chapters, 28 Articles, Addenda (2 articles)

「The Act on Access and Utilization of Genetic Resources and Sharing of Benefits」

Chapter 1. General Provisions	Chapter 2. ABS on Domestic GRs	Chapter 3. ABS on Foreign GRs
• Purpose • Definitions • **Scope of Application** • Responsibilities of State • **Relationship with other Acts** • Establishment of Support Measures	• National Focal Points • Competent National Authorities • **Access Declaration** • Exceptions to Access Declaration • **Sharing of Benefits** • Prohibition Against Certain Access and Utilization	• National Checkpoints • Compliance with Procedures regarding ABS of Foreign GRs • **Declaration for Compliance** • **Compliance Investigation**

Ⅲ. Overview of the Act on Genetic Resources

Composition: 5 Chapters, 28 Articles, Addenda (2 articles)

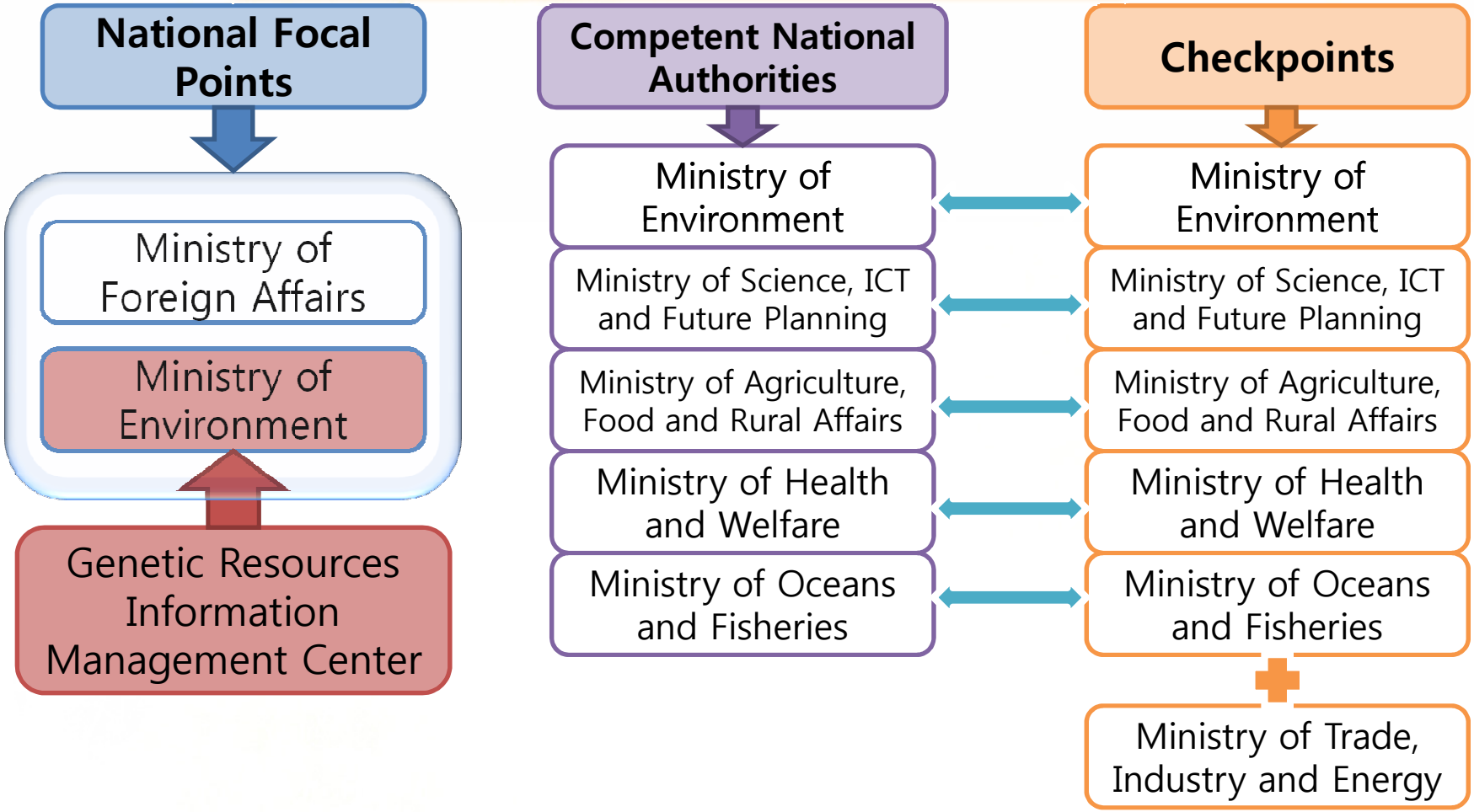
「The Act on Access and Utilization of Genetic Resources and Sharing of Benefits」

Chapter 4. Supplementary Rules	Chapter 5. Penal Provisions	Addenda
• **Genetic Resources Information Management Center** • Composition and Operation of **the Council** • Information Protection • State Subsidy • Securing Finances • **Fees** • **Delegation and Entrustment of Authority** • Legal Fiction as Public Official • Review of Regulation	• **Penalty** • Confiscation and Additional Collection • Administrative Fines (Fine for negligence)	• Enforcement date • Applicability

III. Overview of the Act on Genetic Resources

Authorities under the Act on Genetic Resources

Competent Authorities and their Functions



Ⅲ. Overview of the Act on Genetic Resources

Overview of the Act on Genetic Resources

Competent Authorities and their Functions

National Focal Points	**(MOFA)** Liaising with the Secretariat of the CBD **(MOE)** Dissemination of information on ABS
Competent National Authorities	Acceptance of an **Access Declaration** Management of the utilization of **Domestic GRs**
Checkpoints	Monitoring the utilization of **Foreign GRs in KOR** Acceptance of Procedural **Compliance Declaration**
Genetic Resources Information Management Center	Collecting, Managing, and **Sharing ABS information** Establishing and Operating **the Korea ABS-CH** **Awareness Raising**

Ⅲ. Overview of the Act on Genetic Resources

Essential Components of the Act on Genetic Resources

Access Declaration (Art. 9)

Foreigners wishes to access the domestic GRs for utilization,
SHALL DECLARE to the head of the CNA.

However, if approval or permission is obtained pursuant to the existing law, it shall be deemed to have been declared.

Procedural Compliance Declaration (Art. 15)

ANY USERS SHOULD DECLARE to the Checkpoint at a certain point in time to prove compliance with the procedure.

Only provided that the utilization of the GRs of the providing country in which the access procedure is established.

The **Checkpoints may**, if necessary, conduct an **investigation or advise** compliance with the procedure.

III. Overview of the Act on Genetic Resources

Essential Components of the Act on Genetic Resources

Definitions (Art. 2)

Genetic Resources

material of actual or potential value among any material plant, animal, microbial or other origin containing functional units of heredity.

Traditional Knowledge

knowledge, technology and practices, etc. of individual or local communities which have maintained a traditional life style appropriate for the conservation and sustainable use of genetic resources.

Access

obtaining samples or real objects of genetic resources, or **collecting information** on genetic resources and related traditional knowledge.

Ⅲ. Overview of the Act on Genetic Resources

Essential Components of the Act on Genetic Resources

Definitions (Art. 2)

Utilization

to conduct **research and development** on the genetic and biochemical components of genetic resources through the application of biotechnology, etc., using genetic resources.

Benefits

monetary benefits, including but not limited to royalties and income, etc. from the use of genetic resources and **non-monetary benefits**, including but not limited to sharing of research results and transfer of technology.

Ⅲ. Overview of the Act on Genetic Resources

Essential Components of the Act on Genetic Resources

Scope of Application (Art. 3) : Exception Clause

1. Human Genetic Resources etc.
2. GRs existing in area beyond national jurisdiction
3. GRs that are accessed for any other purpose than “Utilization”
4. GRs that are subject to other International Treaties relating to ABS
5. GRs that have been granted patents rights pursuant to Art. 87(1) of the Patent Act

IV. Details of the Act on Genetic Resources

1. Access to Domestic Genetic Resources (Art. 8 ~ 12)

Foreign Users

Foreigners, Overseas Koreans, Foreign Institutions and International Organizations

Others who are equivalent thereto, as prescribed by the Enforcement Rule of the Ministry of Environment

[Art. 2] 1. A juristic person established pursuant to foreign law.
2. A juristic person established in accordance with the laws of the ROK which has its H.Q. or principal office in a foreign country.

Processing Period

Within 30 Days from the date of receipt of declaration
※ Unless there is no requirement of supplementation by CNA, it shall be deemed that there is an acceptance of declaration on the day following the end of the period.

IV. Details of the Act on Genetic Resources

1. Access to Domestic Genetic Resources (Art. 8 ~ 12)

Deemed Provision → **If it has been granted permission or approval or declaration under the relevant laws, it shall be deemed to have been declared.**

1. Approval under Art. 11(2) of "**the Act on the Conservation and Utilization of Biological Diversity**" or declaration under Art. 13(1) of same act
2. Approval under Art. 18(1) of "**the Act on the Preservation, Management, and Use of Agricultural Bio-resources**"
3. Permission under Art. 11(1) of "**the Act on the Acquisition, Management, and Utilization of Marine Bio-resources**" or approval under Art. 22(1) of the same act
4. Approval or permission under Art. 16(1) or Art. 18(1) of "**the Act on the Collection, Management, and Utilization of Pathogen Resources**" or declaration under Art. 16(2) of the same act

IV. Details of the Act on Genetic Resources

1. Access to Domestic Genetic Resources (Art. 8 ~ 12)

Declaration Contents → Decree Art. 4(1)

1. **User Information**(Name, Affiliation, Address, Date of Birth, Contact)
2. **Common Name and scientific Name of the GR to be accessed**
3. **Access method**(Purchase, Gene bank etc.)**, Period of utilization**
4. **Provider Information**(Name, Affiliation, Address, Date of Birth, Contact)
5. **Access purpose**(Commercial or not)
6. **Purpose of Utilization**(Medical, Cosmetics etc.)
7. **Country seeking to utilize the applicable GR**
8. **Whether or not the Mutually Agreed Terms is concluded**

IV. Details of the Act on Genetic Resources

1. Access to Domestic Genetic Resources (Art. 8 ~ 12)

Notification of Change

- Access Purpose
- Purpose of Utilization
- Increase of not less than 10% of quantity or concentration
- Content of MAT

CHANGE

Apply *mutatis mutandis* Procedures on Access Declaration

Access Declaration of National

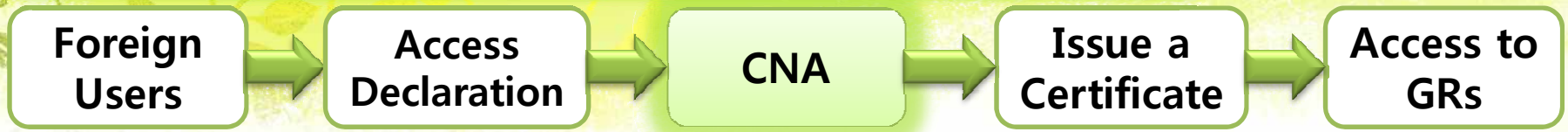
- Rights Protection
- GRs Access Legitimacy Check
- Confirm that Korea is a Provider Country

NATIONAL

Apply *mutatis mutandis* Procedures on Access Declaration or Notification of Change

IV. Details of the Act on Genetic Resources

1. Access to Domestic Genetic Resources (Art. 8 ~ 12)



5 Competent National Authorities have been designated

Ministry of Science, ICT and Future Planning	**Bio-Resources for Research** in accordance with the Act on the Acquisition, Management, and Utilization of Bio-Resources for Research
Ministry of Agriculture, Food and Rural Affairs	**Agricultural Bio-Resources** in accordance with the Act on the Preservation, Management, and Use of Agricultural Bio-Resources
Ministry of Health and Welfare	**Pathogenic Organism Resources** in accordance with the Act on the Collection, Management, and Utilization of Pathogenic Organsim Resources
Ministry of Environment	**Biological Resources** in accordance with the Act on the Wildlife Conservation and Management and the Act on Biodiversity Conservation and Utilization
Ministry of Oceans and Fisheries	**Marine Bio-Resources** in accordance with the Act on the Acquisition, Management, and Utilization of Marine Bio-Resources

IV. Details of the Act on Genetic Resources

1. Access to Domestic Genetic Resources (Art. 8 ~ 12)

Exceptions to Access Declaration (Art. 10)

If it is recognized that **expedited access or utilization of the GRs is required** for the development of therapeutic drugs and food security

In the case where **access to GRs for Non-Commercial purpose** such as pure research (however it the purpose changed, SHOULD BE DECLARED without delay

Benefits Sharing(Declarative Clause) (Art. 11)

(Act Art. 11) Providers and Users of GRs **SHOULD AGREE to share the benefits** of domestic genetic resources fairly and equitably.

Prohibition against Certain Access (Art. 12)

A risk of harm to the preservation and sustainable use of biodiversity
Negative impact socio-economically on the value of Biodiversity

IV. Details of the Act on Genetic Resources

1. Access to Domestic Genetic Resources (Art. 8 ~ 12)

Prohibition against Certain Access (Art. 12)

A risk of harm to the preservation and sustainable use of biodiversity
Negative impact socio-economically on the value of Biodiversity

Violation of Art. 12

Penalty (Art. 26, 27)

Art. 26(Penalty) Any person who access or uses genetic resources that are prohibited or restricted from access or use in violation of Article 12(1) SHALL BE PUNISHED by **IMPRISONMENT for not more than 3 years or a FINE not to exceed 30 Million Won (approx. 26,000 USD / 23,000 EUR).**

Art. 27(Confiscation and Additional Collection) In case of Article 26, the applicable genetic resources will be confiscated; however, if confiscation is not possible, then equivalent price thereof shall be collected.

IV. Details of the Act on Genetic Resources

2. Compliance with Procedures on Foreign GRs (Art. 13 ~ 16)

Any Person → Utilize In KOREA → Compliance Declaration → Checkpoint → Issue a Certificate

WHO ?	**Any person** who intends to **access foreign GRs for use in KOREA**
WHOM ?	**Checkpoints**
WHAT ?	**The GRs of the Provider Country which has established procedures on ABS as a country that is Party to the Protocol**
Processing Period	**Within 15 Days** from the date of receipt of declaration ※ Unless there is no requirement of supplementation by CPs, it shall be deemed that there is an acceptance of declaration on the day following the end of the period.

IV. Details of the Act on Genetic Resources

2. Compliance with Procedures on Foreign GRs (Art. 13 ~ 16)

Any Person → Utilize In KOREA → Compliance Declaration → Checkpoint → Issue a Certificate

Declaration Contents → Decree Art. 8(1) → **ONLY GRs**

1. **User Information** (Name, Affiliation, Address, Date of Birth, Contact)
2. Name of **Provider Country**
3. Name and address of **Provider**
4. **Issuer of PIC** (Issue date, issuance number)
5. **Name of the GR** for which PIC has been approved (Quantity, concentration)
6. **Purpose and usage** of GR
7. **Whether or not MAT is concluded**

IV. Details of the Act on Genetic Resources

2. Compliance with Procedures on Foreign GRs (Art. 13 ~ 16)

Any Person → Utilize In KOREA → Compliance Declaration → Checkpoint → Issue a Certificate

6 Checkpoints have been designated (5 CNAs + MOTIE)

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Ministry of Environment	**Biological Resources** in accordance with the Act on the Wildlife Conservation and Management and the Act on Biodiversity Conservation and Utilization
Ministry of Oceans and Fisheries	**Marine Bio-Resources** in accordance with the Act on the Acquisition, Management, and Utilization of Marine Bio-Resources
Ministry of Trade, Industry and Energy	**Bio-Resources for Research** in accordance with the Act on the Acquisition, Management, and Utilization of Bio-Resources for Research

IV. Details of the Act on Genetic Resources

2. Compliance with Procedures on Foreign GRs (Art. 13 ~ 16)

Any Person → Utilize In KOREA → Compliance Declaration → Checkpoint → Issue a Certificate

Investigation and recommendation of Procedural Compliance

TRIGGER

- Provider Country → Objection to the violation of procedure
- The Third Party → Providing Info about violation of procedure
- CPs → Considerable reasons to be suspicious

CP's Measure

- Investigation
- Request to Report or Submit docs
- Enter and Inspect facilities
- Recommendation of Compliance

IV. Details of the Act on Genetic Resources

3. Other matters related to Declarations

Confidential

It is possible to request that the contents of declaration be made confidential

- When applicants write a declaration form, they can choose the contents to be confidential

Legal Nature of Declaration

Declaration requiring acceptance (by authorities)

- If the acceptance is not notified within the period, it shall considered as accepted

Fine for negligence

1. Any person that has not filed an access declaration or an procedural compliance declaration SHALL BE SUBJECT TO FINE FOR NEGLIGENCE not to exceed 10 Million Won (approx. 8700 USD / 7700 EUR).
2. Any person that has not filed a notification of change SHALL BE SUBJECT TO FINE FOR NEGLIGENCE not to exceed 5 Million Won (approx. 4400 USD / 3800 EUR).

IV. Details of the Act on Genetic Resources

3. Other matters related to Declarations

It is necessary to conclude the Mutually Agreed Terms, but the Act on Genetic Resources only has a declarative clause about MAT.

If you receive a Prior Informed Consent for a foreign genetic resources, you need to declare the Checkpoints within 90 days.

What to do if you cannot conclude the MAT before the Access declaration period for domestic genetic resources has elapsed?

- Even if you cannot conclude the MAT, you should declare within the time limit and get the declaration certificate.
- If you conclude the MAT after declaration, apply for confirmation and get a certificate.
- **Access Declaration Certificate + MAT Conclusion Certificate = IRCC**

IV. Details of the Act on Genetic Resources

4. Support for Access and Utilization

Genetic Resources Information Management Center (Art. 17)

The Minister of Environment SHALL establish and operate a "Genetic Resources Information Management Center".

<Tasks>

1. **Collecting, managing, investing, and providing information** related to foreign and domestic access and utilization of genetic resources and benefit sharing.
2. **Providing information to access and benefit sharing clearing house** in accordance with Article 14 of the Nagoya Protocol for domestic genetic resources.
3. **Other necessary matters** relating to the tasks of National Focal Point, Competent National Authorities, and National Checkpoints **as prescribed by Presidential Decree.**

IV. Details of the Act on Genetic Resources

4. Support for Access and Utilization

Competent National Authorities (Art. 8(2))

Supporting the fair and equitable sharing of benefits from domestic GRs

National Checkpoints (Art. 13(2)

Support to persons who utilize foreign GRs domestically

Establishment of Support Measures (Art. 6)

The State shall establish a measure that providing current status on the research, domestic and foreign information regarding ABS procedures, and protecting the rights to those who utilize and access genetic resources.

National subsidy (Art. 20)

The State may subsidize all or part of the costs to an agency, corporation, or organization carrying out projects that promote ABS

V. Future Plans

Completion of Enforcement Decree and Enforcement Rule

Examination of the Ministry of Government Legislation (June 2017)

Deliberation of the State Council (expected July 2017)

Enforcement of the Act on Genetic Resources

Take effect on the date which the Nagoya Protocol enters into force in the ROK

17 August 2017

Enforcement of various Declaration Procedures

Declaration Procedures will be implemented 1 year after the enforcement date of the Act

Ministry of Environment