

COUNTRY EXPERIENCES

Global workshop on monitoring utilization of genetic resources under the Nagoya Protocol

Bonn, Germany , September 30 to October 2 2019



Convention on
Biological Diversity



Federal Ministry
for the Environment, Nature Conservation
and Nuclear Safety

Country presentations

- Short interventions less than 3 minutes
- Be ready to explain your slides
- Take notes and ask questions

43/54 countries sent their presentations

Common challenges and concerns

- Lack of capacity
- Lack of awareness
- Legal framework not yet ready
- Lack of available/reliable information
- Lack of communication with NFPs
- Designating checkpoints
- Identifying users
- Illegal access/biopiracy
- Lack understanding on how monitoring utilization and compliance
- Negotiating MAT

Permits and Certificates

Permits and Certificates

1. If prior informed consent (PIC) is required to access genetic resources in your country, please describe the procedures (steps) a user would typically follow.

Regulating access

40/53 countries answered this question

Not all countries regulate access

Don't regulate access (8): Poland, Germany, UK, Switzerland, Serbia, The Netherlands, Austria, Belgium

Regulate access (31): Moldova, Cambodia, Ecuador, Brazil, Bhutan, Costa Rica, Lao PDR, Belarus, India, Seychelles, Cameroon, Antigua and Barbuda, Saint Kitts and Nevis, Venezuela, Uruguay, South Africa, Senegal, Rwanda, Pakistan, Nepal, Madagascar, Kuwait, Kenya, Jordan, Guyana, France, Côte d'Ivoire, Burkina Faso, Benin, Brazil, Australia

Regulate access in some cases (1): Finland

ABS Procedures

Countries with procedures (26):

Ecuador, Brazil, Bhutan, Costa Rica, Lao PDR, Belarus, India, Seychelles, Cameroon, Antigua and Barbuda, Australia, Saint Kitts and Nevis, Venezuela, Uruguay, South Africa, Rwanda, Madagascar, Kuwait, Kenya, Jordan, Guyana, France, Finland, Burkina Faso, Benin

Countries with procedures in development (6):

Cambodia, Moldova, Senegal, Pakistan, Nepal, Cote d'Ivoire



ABS Procedures on the ABS Clearing-House

- Belarus
- Cameroon
- Kenya
- India

Why should you publish your ABS Procedures
on the ABS Clearing-House?

Why haven't you?

Countries with procedures (26):

Ecuador, Brazil, Bhutan, Costa Rica, Lao PDR, Belarus, India, Seychelles, Cameroon, Antigua and Barbuda, Australia, Saint Kitts and Nevis, Venezuela, Uruguay, South Africa, Rwanda, Madagascar, Kuwait, Kenya, Jordan, Guyana, France, Finland, Burkina Faso, Benin

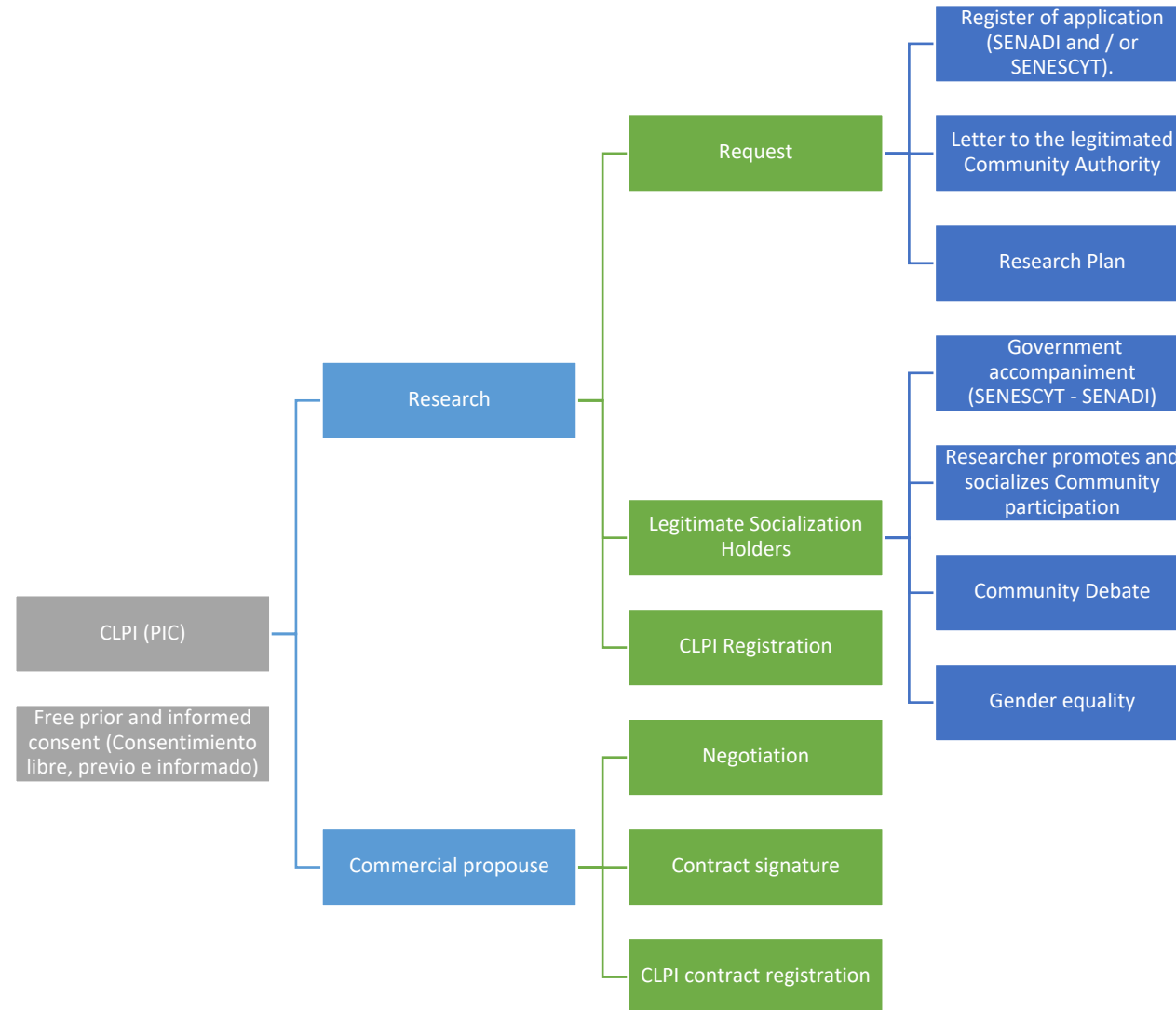
Bhutan, Ecuador, Belarus, Burkina Faso

3 mins or less to explain your procedure

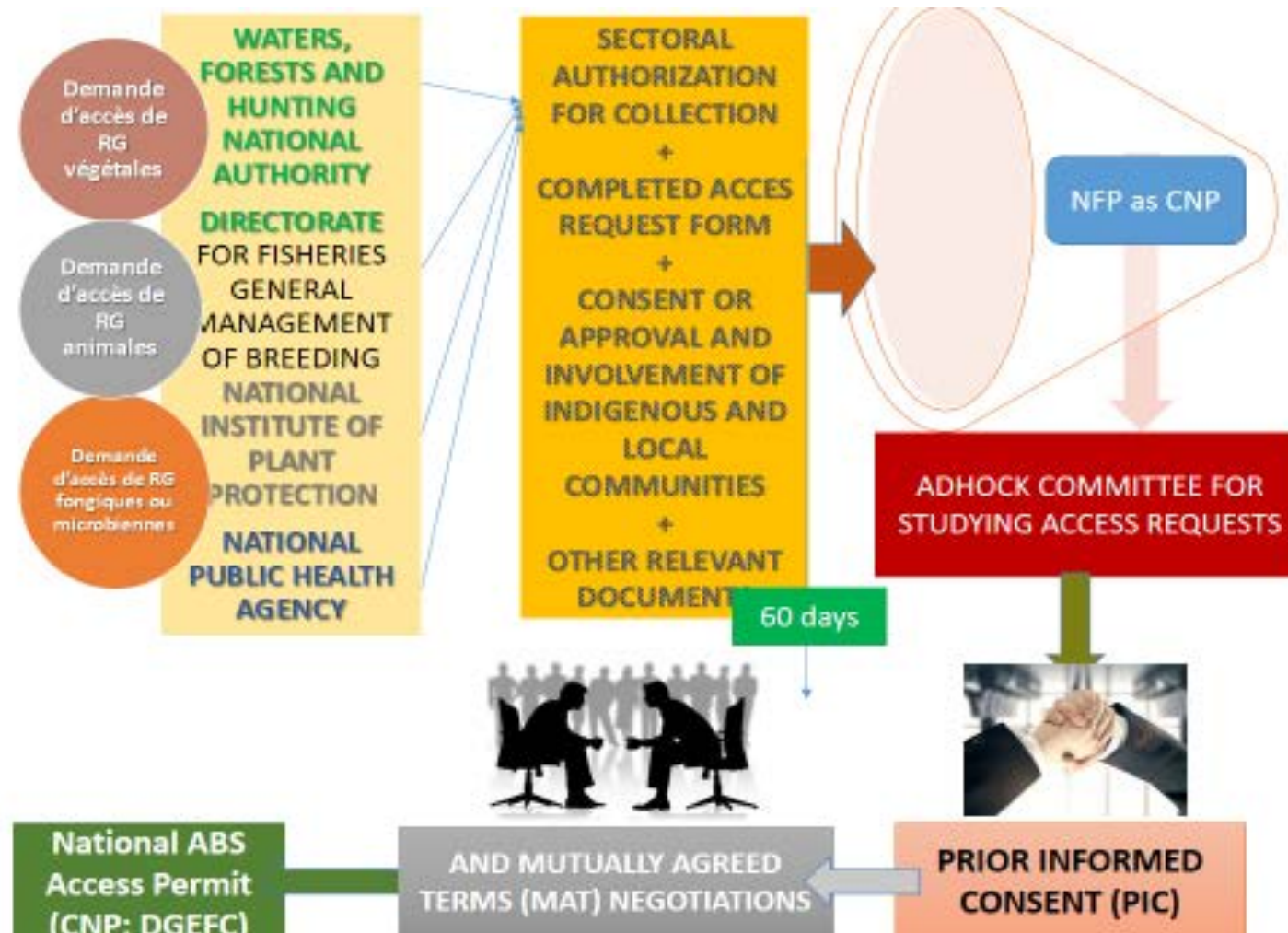
Be ready for some questions:

- Did it result in permits being granted?
- How has your procedures been working in practice?
- What are some of the challenges?
- What can be improved?
- Have you received feedback from users?
- What is the timeframe from beginning to the end?

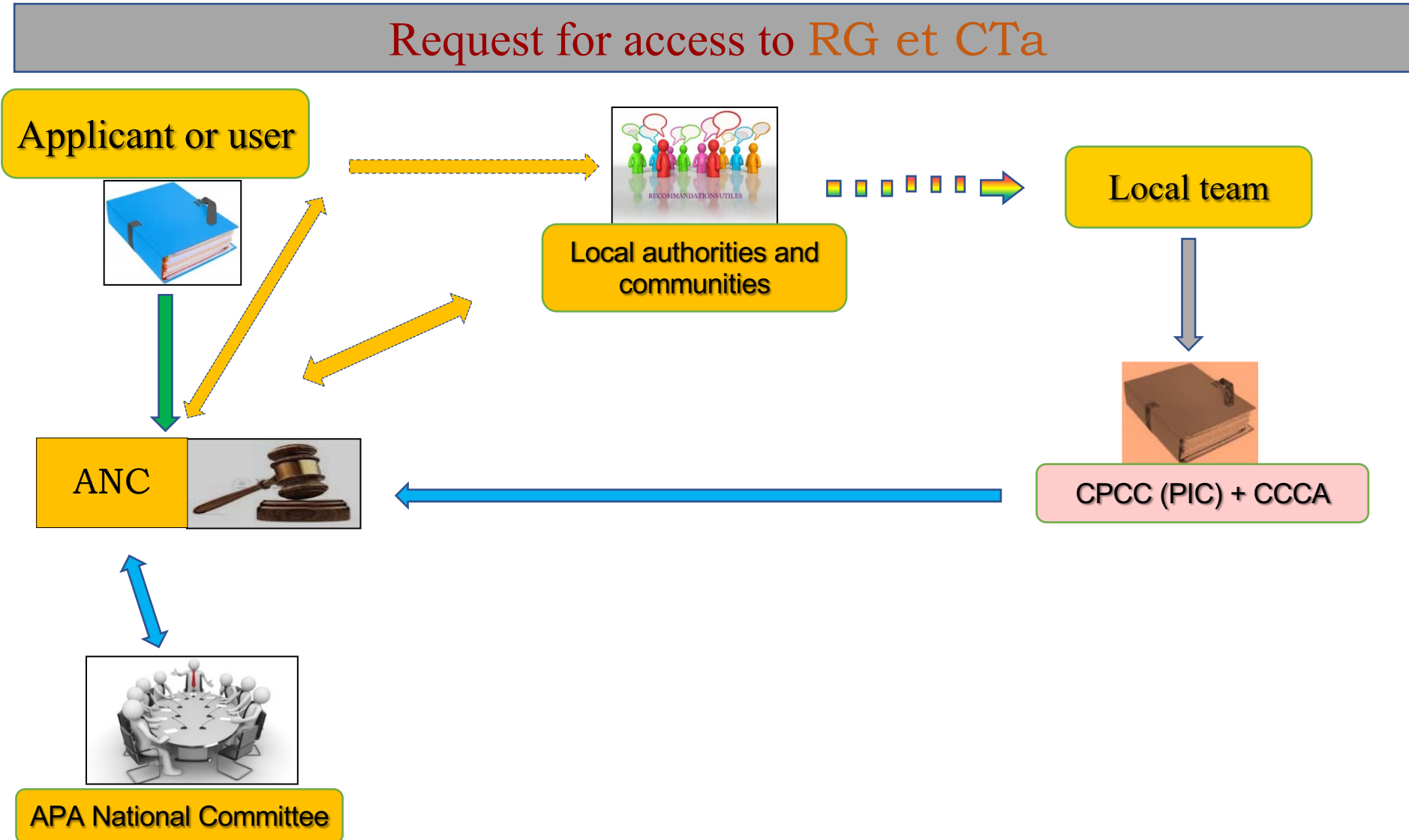
1. If prior informed consent (PIC) is required to access genetic resources in your country, please describe the procedures (steps) a user would typically follow.



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Country experiences – Lao PDR, Uruguay

Temporary systems

How did you set it up?

What type of measure?

How long did it take?

Is it working?

What could be improved?

1. If prior informed consent (PIC) is required to access genetic resources in your country, please describe the procedures (steps) a user would typically follow.



In the absence of a specific ABS regulation and a formal administrative system, NCA creates an administrative procedure that enables it to handle requests for access to genetic resources on a case-by-case basis. The potential user can contact the national focal point given in the CBD website and provide information in the application form with requested supported documents to NCA. The NCA with consultation with the NFP and relevant authorities shall analyze the submitted information and making decision whether to issue NRCC or IRCC or PIC or reject it.

During the analyze procedure, MAT between user and provider will be checked and reviewed for genetic resources utilization in the collaboration agreements to ensure the NP compliance. Then user can conduct R&D based on the agreed activities with the provider or NCA.

1. If prior informed consent (PIC) is required to access genetic resources in your country, please describe the procedures (steps) a user would typically follow.

According to Ministerial Resolution 1844/2017, which establishes a Provisional Regime of Access to Genetic Resources, the Prior Informed Consent (PIC) is granted by the National Environment Directorate (DINAMA) of the Ministry of Housing Land Management and Environment (MVOTMA) .

Therefore, the negotiation is carried out between DINAMA and the user.

[Link to the procedure:](#)

<http://www.mvotma.gub.uy/ambiente/conservacion-de-ecosistemas-y-biodiversidad/biodiversidad/recursos-geneticos/solicitud-de-acceso-a-recursos-geneticos>

The screenshot shows the website of the National Environment Directorate (DINAMA) of Uruguay. The top navigation bar includes 'Vivienda', 'Ambiente' (highlighted), 'Territorio', 'Aguas', and 'Cambio climático'. On the right of the bar are social media icons for Twitter, Facebook, YouTube, RSS, and Email. A left sidebar menu lists various environmental topics, with 'Conservación de ecosistemas y biodiversidad' highlighted. The main content area is titled 'Solicitud de Acceso a Recursos Genéticos' and contains text explaining the process for accessing genetic resources, including the requirement for a physical or legal entity and the prohibition of commercial purposes. It also lists exceptions for human genetic resources and agricultural fitogenetic resources. At the bottom, there is a section for 'Enlaces de interés' with links to 'Ir al trámite', 'Resolución Ministerial', and 'Preguntas frecuentes'.

Vivienda Ambiente Territorio Aguas Cambio climático

Cuidado del ambiente

Dinama

Plan Ambiental Nacional

Observatorio ambiental

Prevención y control para el cuidado del ambiente

Conservación de ecosistemas y biodiversidad

Biodiversidad

Áreas protegidas

Costa y mar

Solicitud de Acceso a Recursos Genéticos

Entre los usuarios de recursos genéticos y/o compuestos bioquímicos se encuentran institutos de investigación, universidades, investigadores de las industrias (farmacéutica, cosmética, alimentos y bebidas, semillas, insumos agropecuarios, biotecnológica), jardines botánicos, coleccionistas.

El trámite de solicitud de acceso debe ser realizado por personas físicas o jurídicas que quieran acceder a recursos genéticos y/o compuestos bioquímicos, para desarrollar investigación científica con fines no-comerciales o comerciales.

Las únicas excepciones a la aplicación de este régimen la constituyen el acceso a recursos genéticos humanos y a recursos fitogenéticos comprendidos en el Anexo I del Tratado Internacional sobre Recursos Fitogenéticos para la Alimentación y la Agricultura (TIRFAA), siempre que pretendan ser utilizados, precisamente, para la alimentación y agricultura.

Enlaces de interés

- > Ir al trámite
- > Resolución Ministerial
- > Preguntas frecuentes

Permits and Certificates

2. Please elaborate on how your country informs users on the national ABS Procedures? (for example, through an online system, guidance material, ABS Clearing-House... etc.)

Informing on procedures

- Many ABS Procedures rely on NFP to be responsive and answer questions
- ABS Clearing-house is not being used effectively to share ABS procedures
- Many countries use national website to share information on ABS procedures

2. Please elaborate on how your country informs users on the national ABS Procedures? (for example, through an online system, guidance material, ABS Clearing-House... etc.)



Many ABS Procedures rely on NFP to be responsive and answer questions

- ☐ For now, the only way is to contact the ABS Focal Point by email or phone for the whole procedure to follow.

2. Please elaborate on how your country informs users on the national ABS Procedures? (for example, through an online system, guidance material, ABS Clearing-House... etc.)

- Users will be informed through:
 - ABS Clearing-house
 - Publication materials
 - Legislation distribution to the public institutions
 - Capacity building events

Countries have
procedures are not
publishing them on the
ABS Clearing-house



2. Please elaborate on how your country informs users on the national ABS Procedures? (for example, through an online system, guidance material, ABS Clearing-House... etc.)

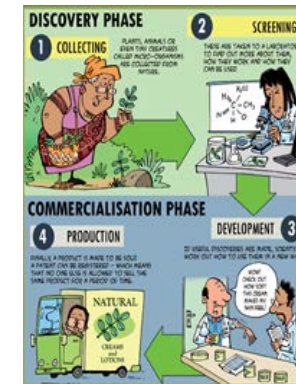
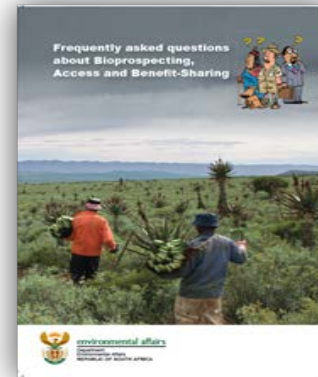
- Through the departmental website: www.environment.gov.za and ABS Clearing House.

- Capacity building and awareness raising workshops.

Many country have national website to share information on procedures

- South Africa have 11 official languages, and the ABS guidelines are translated in all the 11 languages to ensure that the user understands the procedures.

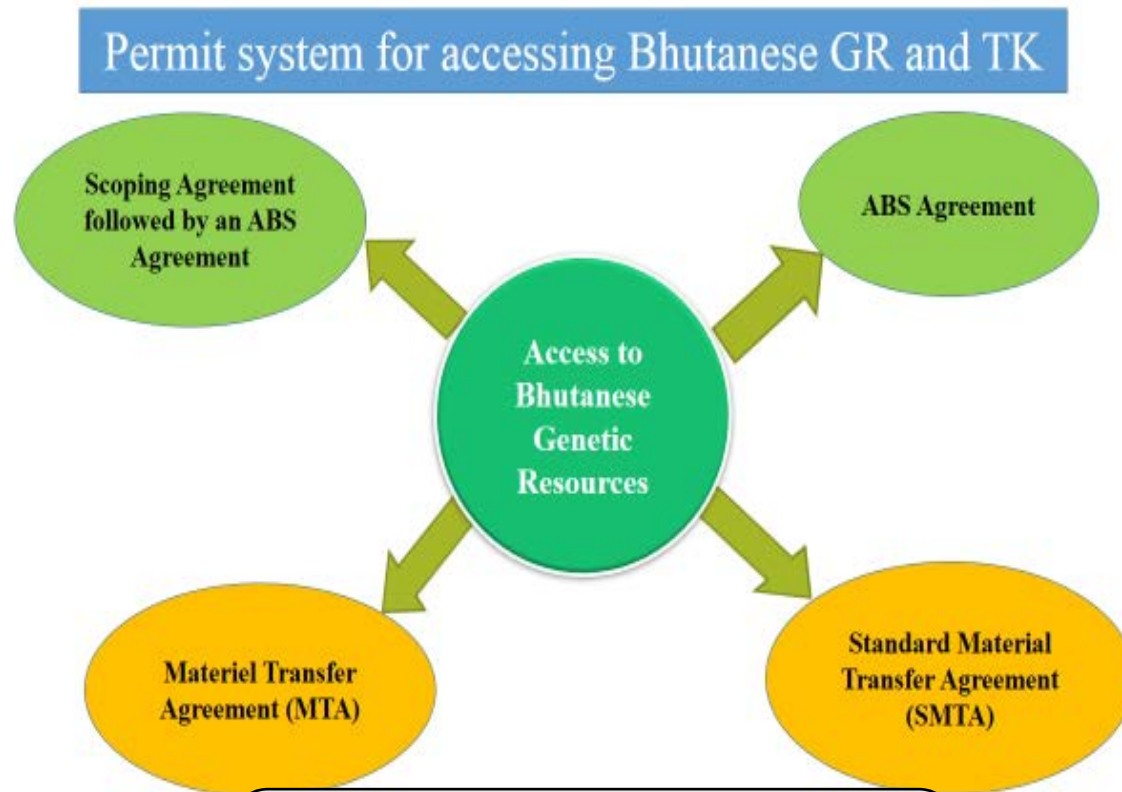
- Promotional materials such as posters, pamphlets and booklets.



Permits and Certificates

3. Describe the internal process and elements (additional permits, permissions, sign-offs) required for constituting an ABS permit or its equivalent in your country

5. Has your country developed (or has plans to develop) an electronic/online permitting system? Please describe the system.



Seems like 4 agreements there -
What would you publish as an
certificate?

- Manual Execution
- Developing a checklist for permit system and upload in the website
- Plans to make it online

3. Describe the internal process and elements (additional permits, permissions, sign-offs) required for constituting an ABS permit or its equivalent in your country?

We are currently studying all the scientific collection processes that have competence regulations of this Ministry and that are prior to the request for access to genetic resources, in order to avoid duplication of information from users:

- 1.- Scientific collection for terrestrial fauna.
- 2.- Import and export permits.
- 3.- Collection of samples in Protected Areas.
- 4.- Collection in jurisdictional waters.

All these procedures are prior required for constituting an ABS permit.

How does this work?
What is your plan to implement this?

3. Describe the internal process and elements (additional permits, permissions, sign-offs) required for constituting an ABS permit or its equivalent in your country?

- Permit for non commercial research is issued by Seychelles Bureau Of Standards (SBS)- NISTI to undertake this role
- Applicant needs to be granted access by CNA and agree on conditions of MTA prior to release
- In certain instances, additional permission may also be required on providers (e.g. private landowners)
- CITES Permit (if GR species is listed on the Annexes)
- Phytosanitary Certificate may be required depending on the countries of export

Are these permits meant to be ABS permit?
Would you post them on the ABSCH?

4. Please describe the process established in your country to share information on permits to constitute international certificates of compliance on the ABS Clearing-House?
-

In accordance with the Environment Agency's **Order no. 18 from 29.03.2019**, there was established a E-Permit system which contains the Passports for wild plants/animals export/import Permits.

Their documents are available on the official web page of the Environment Agency - subdivision of the Ministry:

<http://mediu.gov.md/sites/default/files/document/attachments/3%20Passport%20Acord%20Imp%20Plante%20Animale.pdf>

Are these permits meant to be ABS permit?
Would you post them on the ABSCH?

4. Please describe the process established in your country to share information on permits to constitute international certificates of compliance on the ABS Clearing-House?

- No international certificates have been reported through the ABSCH because all the authorizations issued refer to research permits.

Doubt: Can research permits be reported through ABSCH?

What you you think?

Do any other countries have questions about if their permit can be a certificate or not?



Please **STAND UP** if you have issued ABS permits but not published them as certificates.

How many?
Why not?

Permits and Certificates

4. Please describe the process established in your country to share information on permits to constitute international certificates of compliance on the ABS Clearing-House?

INDIA - PERMITS PUBLISHING CHAMPIONS

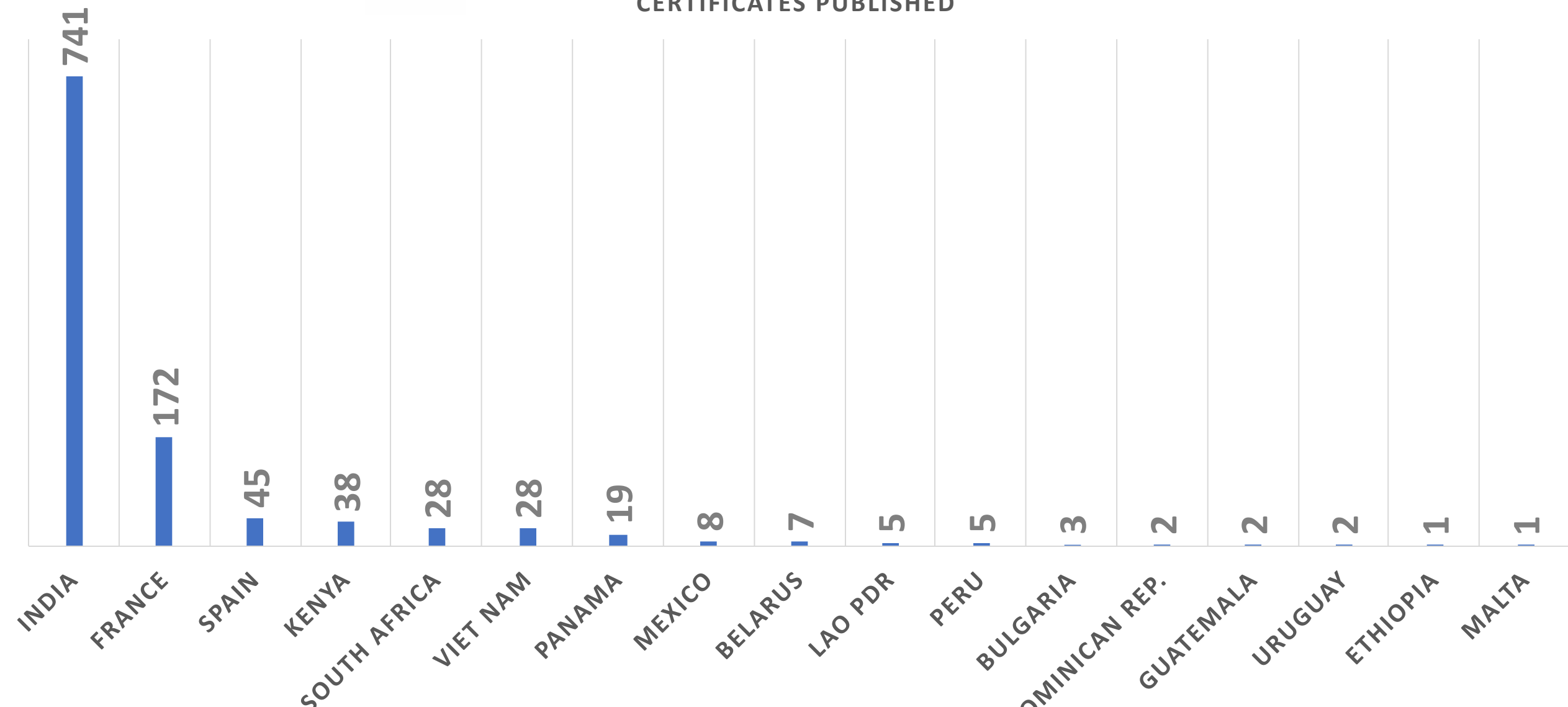


741 PERMITS PUBLISHED



1107 certificates published by 17 Parties

CERTIFICATES PUBLISHED





4. Please describe the process established in your country to share information on permits to constitute international certificates of compliance on the ABS Clearing-House?

- Once a permit is approved and signed, the permit applicant receives original permit document, signed it and send a scanned copy back to the Department.
- The National Authorised User, then work with the permit holder in the generation of the IRCC, to identify information that is considered confidential.
- Then the National Authorised User captures the permit information in the ABS Clearing House to generated IRCC.
- The Publishing Authority reviews the captured permit information for quality control and publish the IRCCC.

4. Please describe the process established in your country to share information on permits to constitute international certificates of compliance on the ABS Clearing-House?



- After approval, Applicant will be asked to fill in IRCC format and submit to CNA



- Secretariat of CNA will upload the information required as per IRCC format to ABSCH Portal



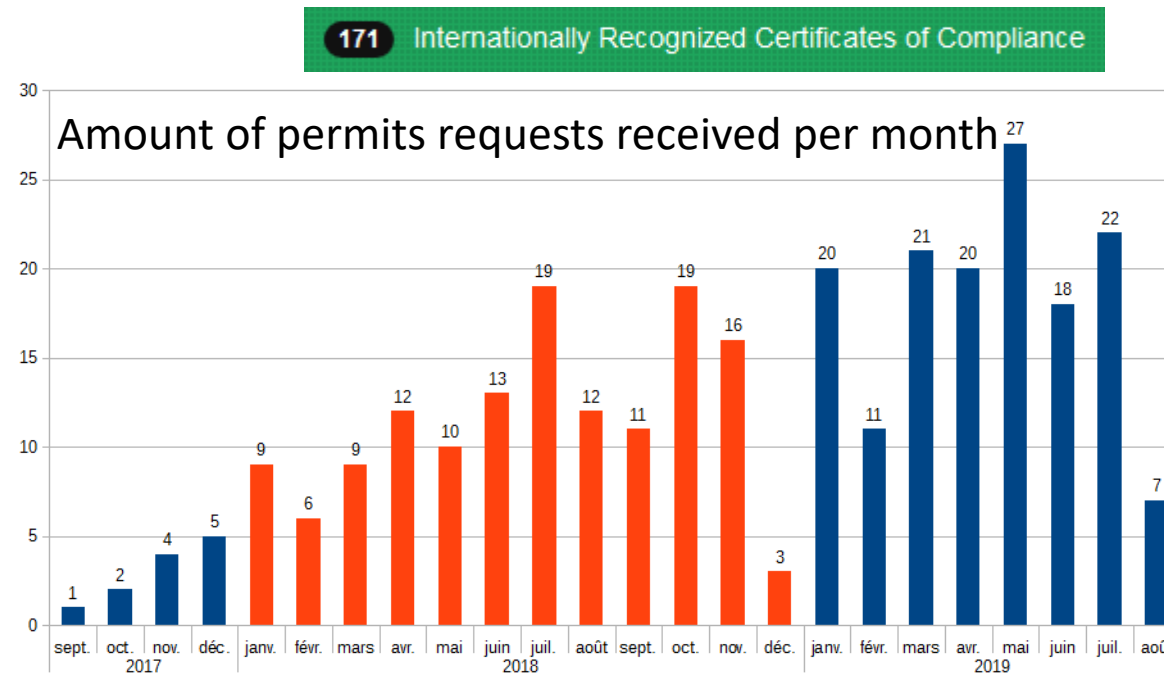
- Secretariat of CNA (NAU) will review the information and initiate the 'Request for publication'



- NFP being the Publishing Authority reviews the information and publishes it

6. Please reflect on your experience with granting permits. What are some of your biggest challenges, primary concerns, most important questions or greatest accomplishments?

- We are happy to see that more and more people are aware of this legislation and abide by it, hence more permits are granted
- Furthermore, it is very convenient that the ABSCH team can pre-fill the IRCC drafts based on the charts we send, before we publish them



3. Please reflect on your experiences with the ABS Clearing-House. What are some of your biggest challenges, primary concerns, important questions or greatest accomplishments?

- **Challenges:**

Inputting information for the IRCCs – the permits presently does not have all the information required for the IRCCs.

It is not possible to publish and IRCC without completing all fields.

What is the missing information from your permit?
What are you plans to address?
Has any other country faced this issue?

4. Please describe the process established in your country to share information on permits to constitute international certificates of compliance on the ABS Clearing-House?

- Declare in the local newspaper.
- The request before and after the permission.
- ABS clearing house (NO REQUESTS YET).
- Unfortunately, it one of issue need to have capacity building program.

4. Please describe the process established in your country to share information on permits to constitute international certificates of compliance on the ABS Clearing-House?



Brazil does not have an Internationally Recognized Certificate of Compliance - **IRCC** under the terms of the Nagoya Protocol

however



SisGen provides a **certificate of registration of access, shipment and notification** that can be used as International Certificate of Compliance

4. Please describe the process established in your country to share information on permits to constitute international certificates of compliance on the ABS Clearing-House?
-

As a Non-Party, we are not issuing the international certificates of compliance on the ABS-CH

What you think about Non-Parties publishing their permits as certificates in the ABSCH?

Permits and Certificates

5. Has your country developed (or has plans to develop) an electronic/online permitting system? Please describe the system.

No plans / not sure: Antigua and Barbuda, Venezuela, Serbia, Pakistan, Nepal, Burkina Faso, Benin

Plan to develop electronic online system for permits: Cambodia, Tajikistan, Dominican Republic, Bhutan, Lao PDR, Saint Kitts and Nevis, Senegal, Rwanda, Madagascar, Kuwait, Cote d'Ivoire

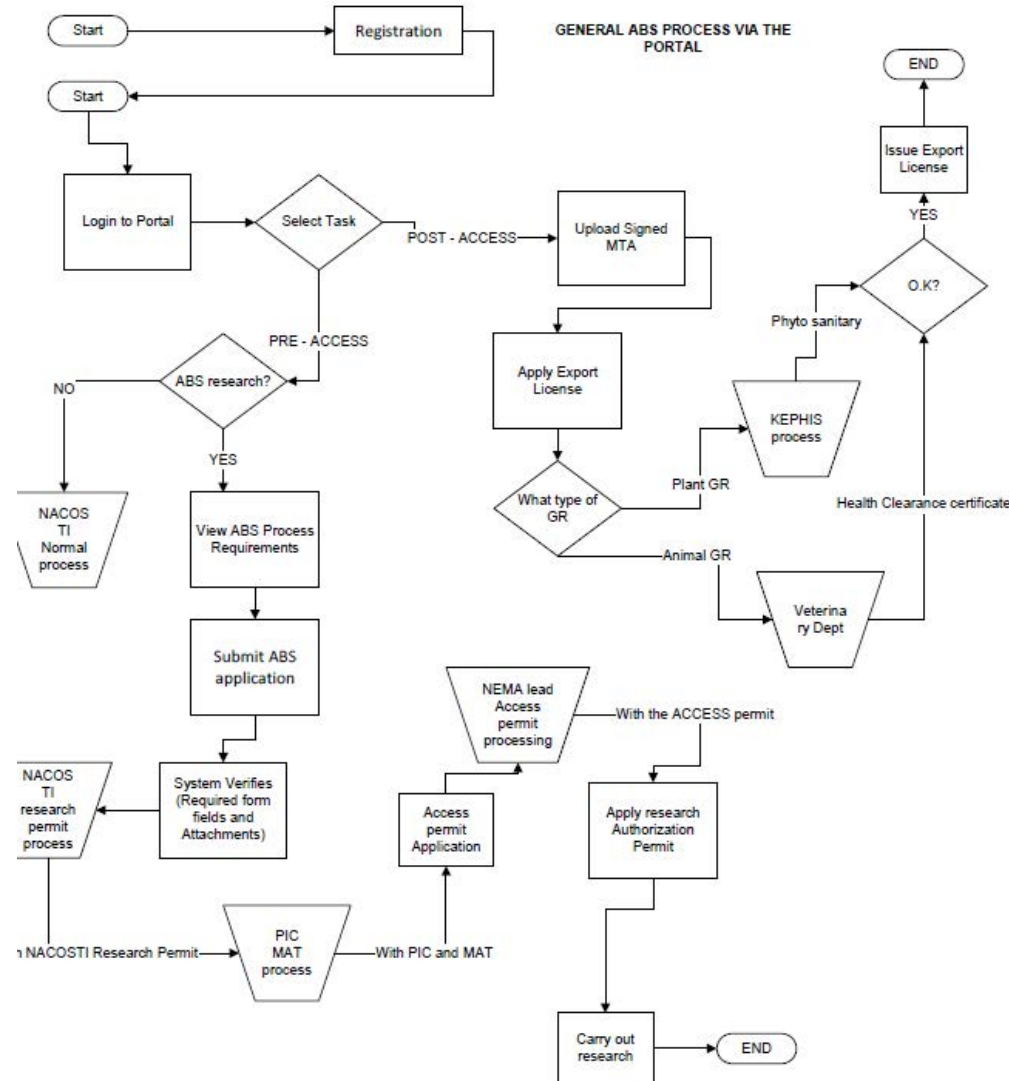
In progress: Peru, Belarus, Seychelles, Cameroon, Uruguay, South Africa,

System already in place: Moldova, Ecuador, Brazil, Costa Rica, India, Queensland, Kenya, Guyana, France

Elements of the online system:

- ABS Procedures external (step for the user to follow)
- ABS Procedures internal including elements that constitute and define an ABS permit
- Procedure to publish permits as certificates on the ABSCH
- Many countries have done the work to setup the electronic system but lack the last step to link them to the ABSCH through interoperability

5. Has your country developed (or has plans to develop) an electronic/online permitting system? Please describe the system.



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<http://absefiling.nic.in/>

The screenshot shows the homepage of the ABS e-filing portal. At the top, there is a green button labeled "ABS e-filing". Below this, the page is divided into several sections. On the left, there is a text block providing information about the National Biodiversity Authority (NBA) and its functions. In the center, there is a "Sign In to your account" section with fields for Username, Password, and a Captcha (displaying "LXWTVK"), along with a "Login" button and links for "Forgot Password" and "Forgot UserName". At the bottom, there are three columns: "Latest Update" (containing a notice about the launching of the e-filing portal), "Video" (containing a video player), and "Reference Corner" (containing links to "Instructions to Applicant", "User Manual", "FAQs", and "Know Your Application").

ABS e-filing

National Biodiversity Authority, established in 2003 to implement the Biological Diversity Act, 2002, is an autonomous and statutory body to perform regulatory and advisory functions for Government of India on issues of conservation of biodiversity, sustainable use of its components and realization of fair and equitable sharing of benefits arising out of use of biological resources.

As part of its mandatory functions, NBA regulates access to India's biological resources and associated knowledge by Indians and non-Indians as well, for various kinds of activities, such as access for research, commercial utilization and obtaining of IPRs for the inventions based on any research or information on a biological resource obtained from India.

Biological Diversity Rules, 2004 lays down various Forms, fees, time lines and procedures to facilitate the applicants in obtaining prior approval of the NBA for various activities under the BD Act. The application may be submitted online using this platform. The applicants are requested to sign up and follow the procedures as per the instructions.

Sign In to your account

Username

Password

Captcha

Login

[Forgot Password](#) | [Forgot UserName](#)

Latest Update

LAUNCHING OF E-FILING OF ABS APPLICATION PORTAL

Video

Reference Corner

- [Instructions to Applicant](#)
- [User Manual](#)
- [FAQs](#)
- [Know Your Application](#)

- ABS e-filing portal
- Login page is facilitated with
 - Know your application wizard
 - User manual
 - Instructions
 - Video tutorial and
 - helpdesk – Phone and Email

5. Has your country developed (or has plans to develop) an electronic/online permitting system? Please describe the system.

Costa Rica has developed a virtual platform to apply for ABS permits and monitor and control benefits sharing.

<https://www.conagebio.go.cr/Conagebio/login.xhtml>

The user can:

- apply for ABS permits
- watch animated tutorials
- include personal information only once
- upload the required documents
- receive notifications from CONAGEBIO
- know the permit request status
- download forms
- use digital signature (Costa Ricans)
- download permits
- keep track of the acquired commitments
- request modifications or extensions

CONAGEBIO has:

- A digital document management system
- An important tool for monitoring and control

5. Has your country developed (or has plans to develop) an electronic/online permitting system? Please describe the system.

- An online system is accessible since April 2018
- Users can fill online their declaration file, either as an individual (<https://www.demarches-simplifiees.fr/commencer/apa-declaration-pphysique>) or a legal person (<https://www.demarches-simplifiees.fr/commencer/apa-declaration-pmorale>)
- Types of information to provide :
 - A description of the activities for which the declaration is being made, as well as their objective
 - The designation of the taxa concerned, as precisely as possible, and reference of the place where the samples were collected, or, if the material is in a collection, of the entity holding the samples
 - A description of the technical means of access to the genetic resources and the modalities of sampling
 - The projected timetable for carrying out the activities
 - The applicant's preferred method of sharing the benefits of their activities, as well as the beneficiary or beneficiaries
 - Any confidential information that the declarant considers might breach industrial or business secrets, if disclosed

5. Has your country developed (or has plans to develop) an electronic/online permitting system? Please describe the system.



SisGen - Registration and notification of researches and products developed under the Brazilian Law on Biodiversity:



Access to GR or TK for purposes of research or technological development and economic exploitation of finished product or reproductive material arising from the access **can only be carried out following their registration, authorization or notification**



In order to obtain accreditation for accessing genetic heritage or associated traditional knowledge, the natural person or organization must **complete the electronic form - SisGen** (National System of Management of Genetic Heritage and Associated Traditional Knowledge)



The registry is a **mandatory self-declaratory** system which must be submitted to SisGen. It is important to note that the access to genetic heritage or associated traditional knowledge by **foreign-based institutions** can only be carried out when **associated with a Brazilian national institution** of technological and scientific research, whether public or private

6. Please reflect on your experience with granting permits. What are some of your biggest challenges, primary concerns, most important questions or greatest accomplishments?



Use of technology for granting certificates and simplifying Registry



Provisional Act 2.186-16/2001 1st legal framework to regulate access to GH and ATK in BR

- Creation of the Genetic Heritage Management Council (CGen)
- Negative impact on scientific research - bureaucratization and criminalization
- Discouragement for R&D of Brazilian biodiversity



Law 13.123/15

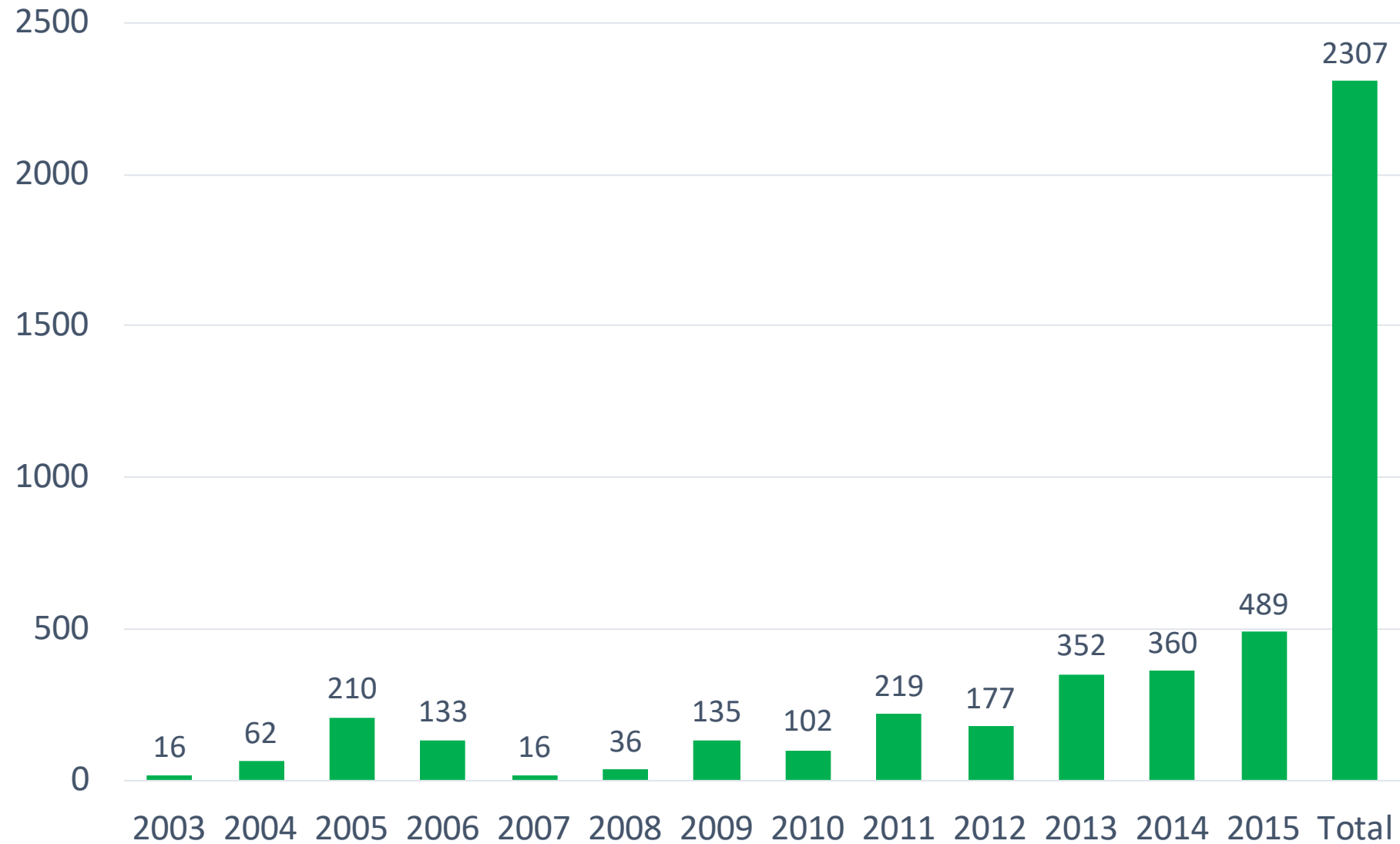
- Replacement of the previous authorization by the current registry
- Can be carried out during the R&D with GH and ATK in SisGen
- Significantly reduced bureaucratization of R&D in Brazil
- *Some cases require prior registration*



Upon completing the SisGen electronic forms:

- Registration receipt or notification will automatically be issued
 - Demonstrates that the user has provided the required information.
 - The user may request a Certificate of Access Regulatory from CGen

CGEN: Number of Granted Permits (2000 - 21015)



SISGEN (06/11/2017 to 13/09/2019)

49.213

Registers
Access

725

Registers
sample shipment

1750

Notifications
Finished Products

25K +

Users
Natural persons

837

Organizations



**Additional Information required for the registration of the activity of access
Genetic Heritage**



Electronic registration form (SisGen):

Provide information on research or technological development activities, including:

- i) Summary of the activity and its respective objectives
- ii) Application sector, in the case of technological development
- iii) Expected or obtained results, depending on the moment of the registration
- iv) Responsible staff, including student
- v) Indication of other institutions participating in the execution, where appropriate
- vi) Period of execution of activities
- vii) Identification of genetic heritage at the taxonomic level, as strict as possible
- viii) Origin of the GH, including georeferenced coordinate in degrees, mins and secs
- ix) Participation, when it's the case, of an institution with foreign headquarter
- x) Identification of national partner institutions, when appropriate
- xi) Registration number or previous authorization, in case of research or technological development carried out after 30 June 2000

Additional Information required for the registration of the activity of access
Genetic Heritage



Electronic registration form (SisGen):

Provide information on research or technological development activities, including:

- ✓ request, if appropriate, the confidentiality of certain informations,
- ✓ Declare, as appropriate:
 - i) classification in the event of legal exemption or no incidence of benefit sharing
 - (ii) If GH being accessed is traditional local, Creole variety or locally adapted
 - (iii) If the species being accessed is on the official list of endangered species
- ✓ If **changes** in info provided to SisGen, update the data at **least once a year**
- ✓ Update registration to **include info** of application of **IP rights** or patent licensing

Additional Information required for the registration of the activity of access

Associated Traditional Knowledge



Indication of ATK provider and sources of obtaining, even from secondary sources



Georeferenced coordinates of the respective community except when it comes to knowledge traditional associate of unidentifiable origin



Participation, if the case, of a foreign institution associated with a national institution



Verify that prior informed consent has been obtained from the associated traditional knowledge provider of identifiable origin, as appropriate

5. Has your country developed (or has plans to develop) an electronic/online permitting system? Please describe the system.

According to the Uruguayan policy, most governmental procedures are being done online, so it is possible to make the proceeding of access to genetic resources in an online manner.

Also, we have signed a Cooperation Agreement with Brazil to enhance our electronic system to a more thorough management system in order to include researchers, research centers, universities and private enterprises (industries).

2014 Uruguay approves the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization through Law N° 19.227.

2017 The ABS Global Project starts in Uruguay. A provisional regime for Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization is established by Ministerial Resolution N° 1844/2017. This regime is in force today..

2018 The article 216 of Law N° 19.670 modified the article 22 of the General Law for the Protection of the Environment, which declared the general interest of Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization.

The forms for Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization were uploaded at the Mvotma website.

2019 The procedure for the request of Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization was uploaded at the Mvtoma website.

An ABS website at the Mvtoma webpage was created.

First certificate of international compliance granted in Uruguay (2 permits have been granted so far).

Participatory consultations with researchers, governmental sector and civil society organizations about the regulation of decree N° 22 of the Law N° 17.283.

We are working on a south-south cooperation Project which will enable us to monitor our genetic resources from the scientific collection to the end of the project.

Permits and Certificates

6. Please reflect on your experience with granting permits. What are some of your biggest challenges, primary concerns, most important questions or greatest accomplishments?

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Access permissions granted 2004- August 2019

Biggest challenges:

- Development of the legislation on access to genetic and biochemical resources from indigenous people and associated traditional knowledge

Primary concerns:

- International monitor and control of GR and capacity building for checkpoints
- Give prominence to ABS and TK into the Post 2020 biodiversity framework

Accomplishments:

- Put in place ABS framework. Commercial use permits
- Launch of “ABS Costa Rica Biobenefits” Distinctive Mark
- Development of General Mechanism for Consultation of Indigenous Peoples. Executive Decree No. 40932-MP-MJP
- Link ABS and Bioeconomy National Strategy

[VIDEO](#)

Permissions	Total
Basic Research	551
Bioprospection	85
Commercial use	2
Total	638



6. Please reflect on your experience with granting permits. What are some of your biggest challenges, primary concerns, most important questions or greatest accomplishments?

Major Accomplishments	Challenges
• More than 1,000 ABS Agreements signed (MAT) • Realized Benefit Sharing to the tune USD 16 Million–(INR 115 crores)	• Facilitating access to genetic resources requires capacity building and co-ordination among multiple implementing agencies.
• Network of about 150,000 biodiversity management committees (village level) across the country.	• Raising of awareness among multiple stakeholders
• Documentation of people's biodiversity register to understand the local species available.	• Traceability of geo-location of GR
• Recognition through India Biodiversity Awards	• Taxonomic Identification
	• Monitoring movement of Genetic Resources



6. Please reflect on your experience with granting permits. What are some of your biggest challenges, primary concerns, most important questions or greatest accomplishments?

Challenges:

- One of the challenges the country face is that the user some sometimes complain about the time it takes for the ABS permit to be issued. According to our legislation, the prescribed time frame is 120 working days.
- To get the companies that were established before promulgation of our ABS Regulation to comply.
- To get the users understand the importance of benefit sharing with the traditional knowledge holders and the access provider.

Primary concern:

- There are very few permits involving users from foreign countries.

Most important questions:

- None

Accomplishments:

- Despite all the challenges, 94 ABS permits have been issued.
- Successfully facilitated the negotiations of an Industry-Wide Benefit Sharing Agreement on Rooibos-Traditional Knowledge for 9 years.

6. Please reflect on your experience with granting permits. What are some of your biggest challenges, primary concerns, most important questions or greatest accomplishments?

- **Grands défis**

- Faible connaissance du processus et les étapes d'obtention du permis APA par les parties prenantes. Conséquence : Trop de sollicitation du PF/APA et lenteur
- Manque de compétence juridique nationale pour négocier et rédiger des contrats commerciaux jugés acceptables par les tribunaux. Conséquence : Peur/hésitation à délivrer des permis APA à but commercial.
- Faible pouvoirs des partenaires de négociations : Ils ne sont pas investis des mêmes pouvoirs pour négocier d'égal à égal. Conséquence : Lenteur dans la délivrance des permis et mauvaise perception de l'APA

- **Principales préoccupations**

- Elaborer un guide pratique d'accès aux RG et CTA y compris les autres documents sectoriels préalables et le poster sur le CHM/APA
- Visualiser le mécanismes d'accès aux RG et CTA ou d'obtention du permis APA ainsi que des autres documents sectoriels préalables et le poster sur le CHM/APA
- développer des compétences de négociation. Cette compétence est un besoin majeur de renforcement des capacités au Bénin.
- Envisager un système de délivrance de permis électronique / en ligne

- **Principales réalisations** : 13 permis établis. 26 nouvelles demandes étudiées et conclues. Permis en cours d'émission.

Permits and Certificates

7. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to granting permits?

Permits and certificates



in 3 minutes or less

7. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to granting permits?

Submission of the access proposal by Company X



Assessment of the access proposal by the National Focal Point and Consultation with the local community



Submission of the recommendation to the Competent National Authority for approval



Execution of Scoping Agreement for R&D (5years) Access is granted for research and development



Research on 25 plants, 5 promised, one in a final stage of R &D



Sharing of Monetary and Non-monetary benefits to the community



Launch of products by 2020 and signing of ABS Agreement

7. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to granting permits?



[VIDEO](#)

Lisanatura®

LANZA NUEVO JARABE PARA LA TOS

BRONTOX®
Jarabe contra la tos
con miel

Primer producto nacional
en obtener un permiso de
aprovechamiento económico
y el Distintivo ABS

Somos *esencial*®
COSTA RICA

ABS
COSTA RICA
BIOBENEFICIOS

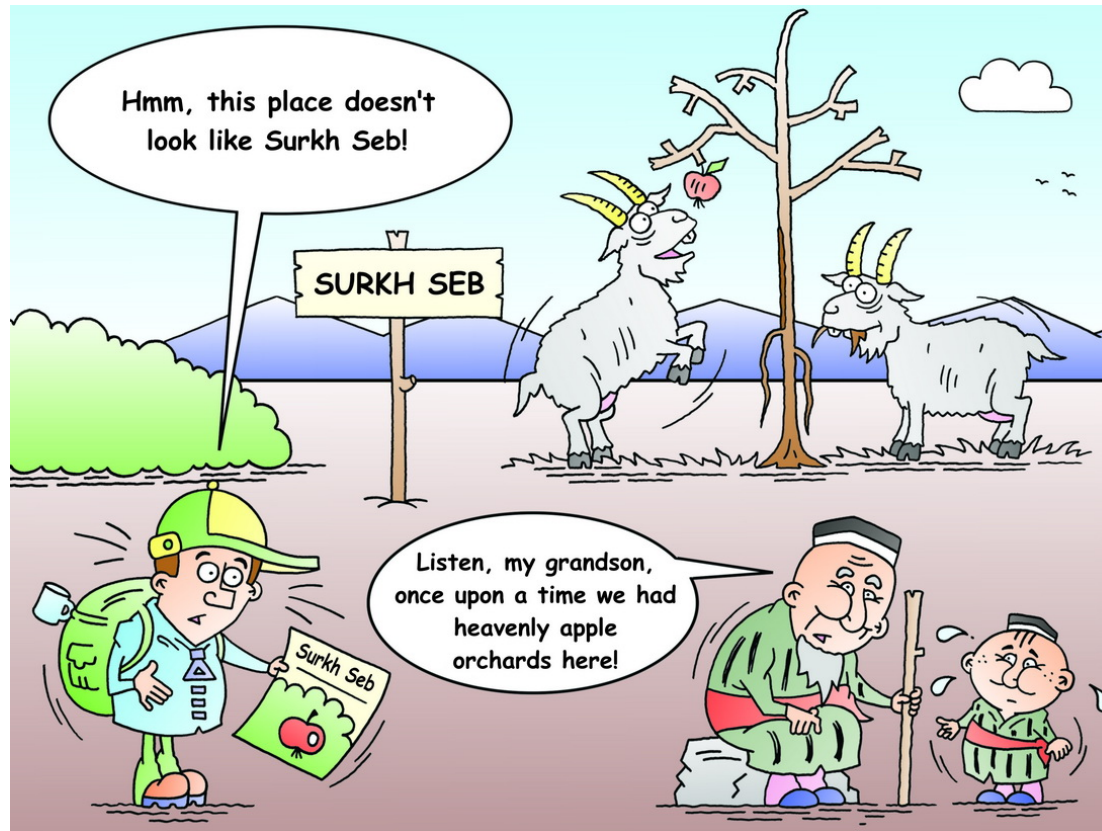
GOBIERNO DEL Bicentenario
2018 - 2022

minae

CONAGEBIO
Comisión Nacional para la Gestión de la Biodiversidad

Lisanatura®
excelencia en medicamentos

6. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to monitoring utilization of genetic resources?



One of interesting cases was monitoring of the Surkh Seb genetic resource (apple variety). The uniqueness lies in the fact that this apple variety is resistant to climatic conditions.

This variety then served as the basis for grafting of other apple varieties which grow in mountainous regions of the country.

7. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to granting permits?

- Good permit leading to good benefit Sharing



Royal Horticultural Society
Sharing the best in Gardening

Case Study: Seychelles Busy lizzie

Impatiens 'Ray of Hope'





Dr Alistair Griffiths
(RHS Director of Science & Collections)



@BotanyRocks



PlantNetwork
The Plant Collections Network



7. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to granting permits?

The story when we had to sign the first MAT with a French Firm called V. MANE fils, he had to take the challenge to go right to the local community of Magha inspite of the bad roads and poor relief nature of the Area. The interesting issue there is that he had to face the community and negotiate with them showing proof of his interest for the project .

7. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to granting permits?



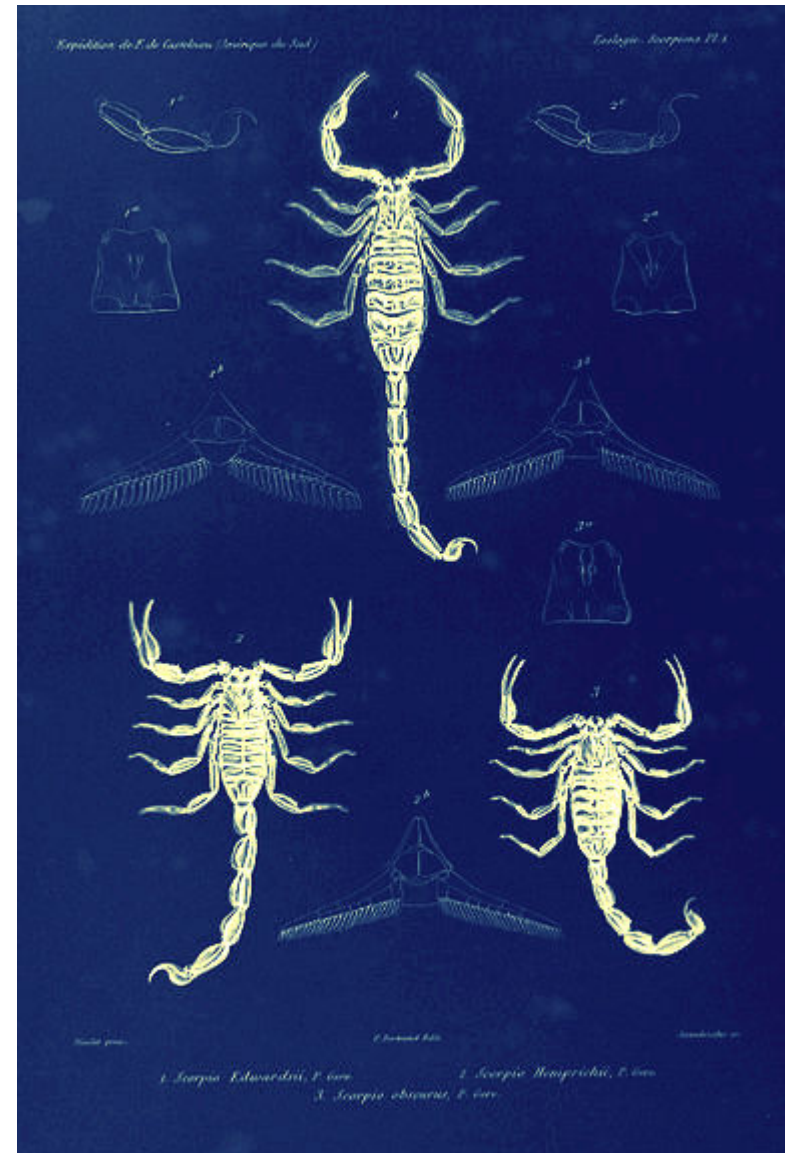
A Tale of two
Redonda's





5. Please share a **very interesting real-life story, funny anecdote, amazing case or marvelous example related to monitoring utilization of genetic resources?**

- ✓ The project with the **scorpion venom** to cure cancer that has constituted an important contribution to human well being.



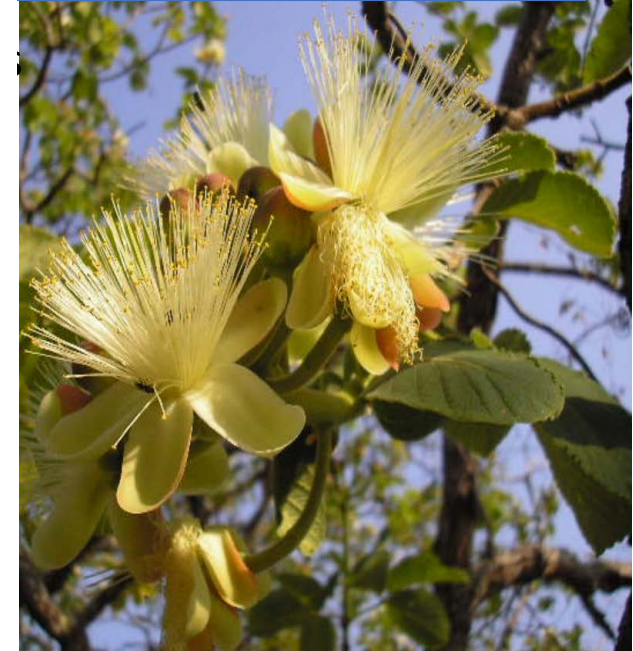
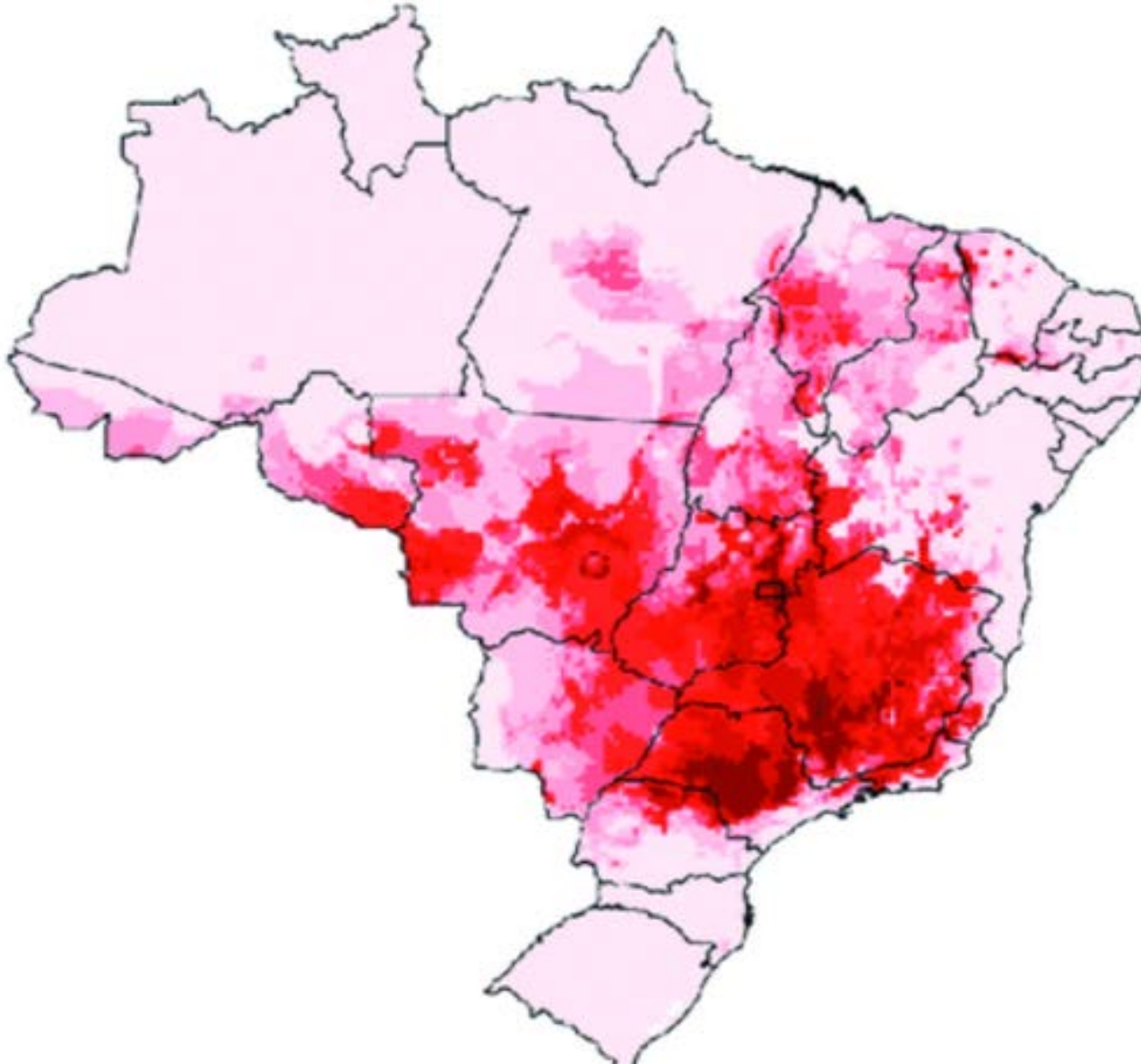
5. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to monitoring utilization of genetic resources?



Wildlife →
MAE

URBAN life →
GADs

7. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to granting permits?



7. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to granting permits?



And many interesting stories but we couldn't highlight them all...

Tajikistan, Dominican Republic, Ecuador,
Bhutan, Costa Rica, Lao PDR, India,
Seychelles, Cameroon, Antigua and Barbuda,
Uruguay, South Africa, Kuwait, Kenya, Benin

Monitoring
utilization

Monitoring utilization

1. Provide an overview of the designated (or envisioned) checkpoints for your country? How and why were they chosen?

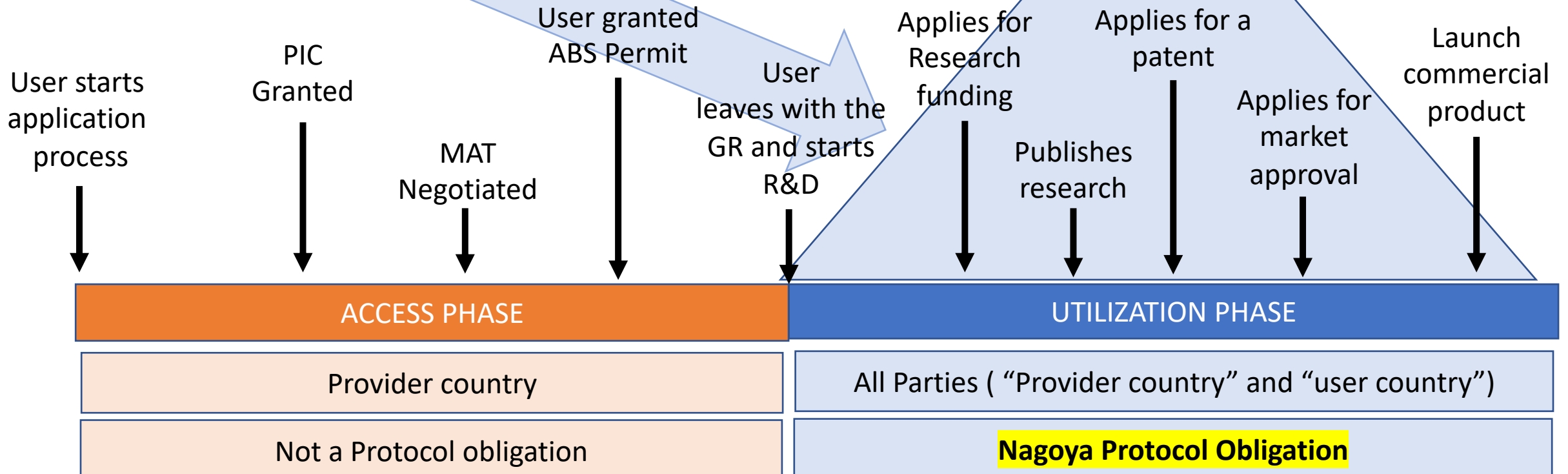
- **Has designated checkpoints:** Peru, Dominican Republic, Ecuador, Poland, Lao PDR, Belarus, UK, Switzerland, Kuwait, Kenya, France, Finland, EU, Austria, Germany
- **In progress/ Not yet ready:** Tajikistan, Cambodia, Bhutan, Costa Rica, India, Seychelles, Cameroon, Antigua and Barbuda, Saint Kitts and Nevis, Venezuela, Uruguay, Serbia, Senegal, Rwanda, Pakistan, Nepal, Madagascar, Jordan, Guyana, Cote d'Ivoire, Burkina Faso, Benin, Belgium
- **Not planned:** Moldova, Brazil

Mechanism to monitoring own GR “National Bio-pirate Police”

- Monitor utilization of own GR

Nagoya Protocol Checkpoint

- Monitor utilization of GR
Particularly of foreign GR



Activity: checkpoint checklist

Stand up if you have designated (or planned) +1 checkpoints

Are they collecting or receiving information from users on PIC, MAT, source, utilization?

- **Yes** - keep standing **No** - sit back down

Do you require users to provide the information to checkpoints?

- **Yes** - keep standing **No** - sit back down

Do you collect information from on the use of GR provided by other countries?

- **Yes** - keep standing **No** - sit back down

1) At what stage at the value chain do you gather information from users?

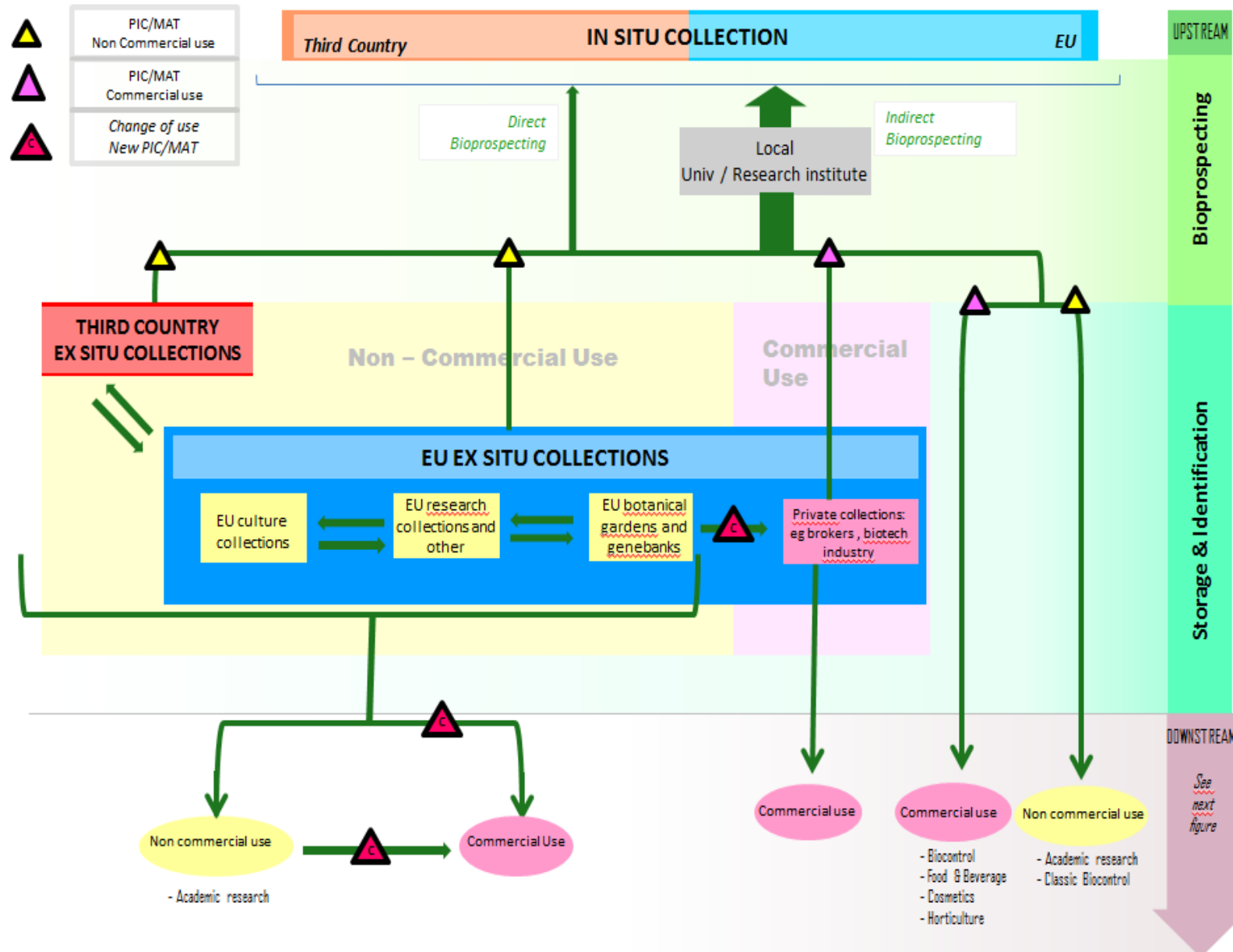
2) How do you plan to provide this information to the provider country?



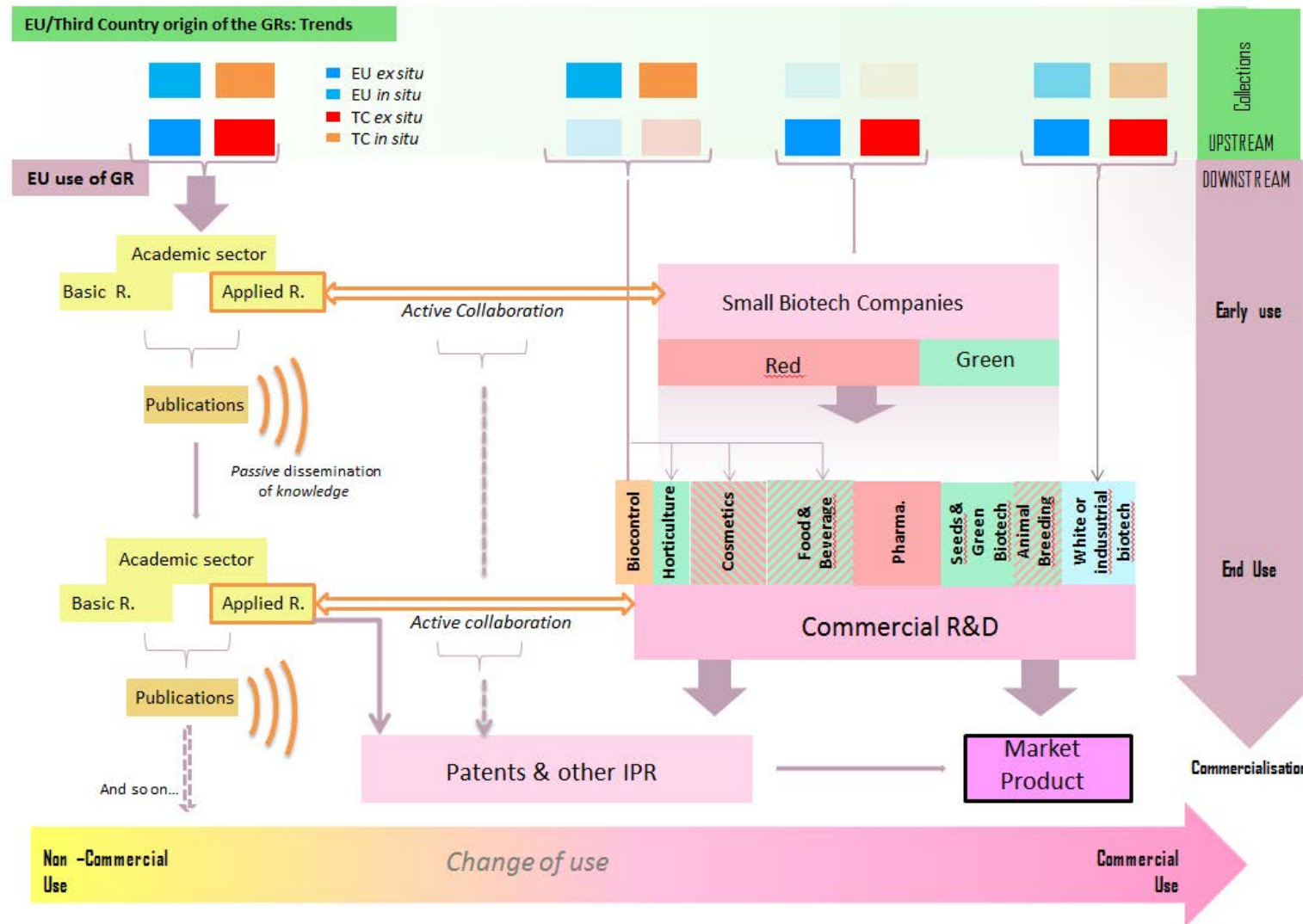
1. Provide an overview of the designated (or envisioned) checkpoints for your country? How and why were they chosen?

- Two checkpoints:
 - at the stage of **research funding** where research involves utilisation of GR and TKaGR → designated CNAs in MSs
 - at the stage of **pre-commercialisation** (final stage of development of the product) → designated CNAs in MSs
- Selected following impact assessment prepared by the EC in view of the adoption of the EU ABS Regulation
 - The EU system is based on due diligence
 - Important to cover various stages of value chain

EU upstream activities and actors involved



EU downstream activities and actors involved

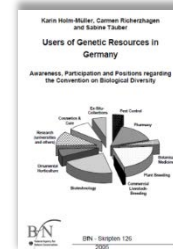


1. Provide an overview of the designated (or envisioned) checkpoints for your country? How and why were they chosen?

- BfN as single “institutional checkpoint”



- Collects & receives infos from different sources



**CNAs of
provider
states, NGOs,
competitors,
etc.**

- Due diligence declarations at stage of research funding & at last stage of product development

- Reports on country of origin disclosed in patent applications – 2 times p.y.

- User surveys, general research, compliance checks

- Internat. collaboration & substantiated concerns

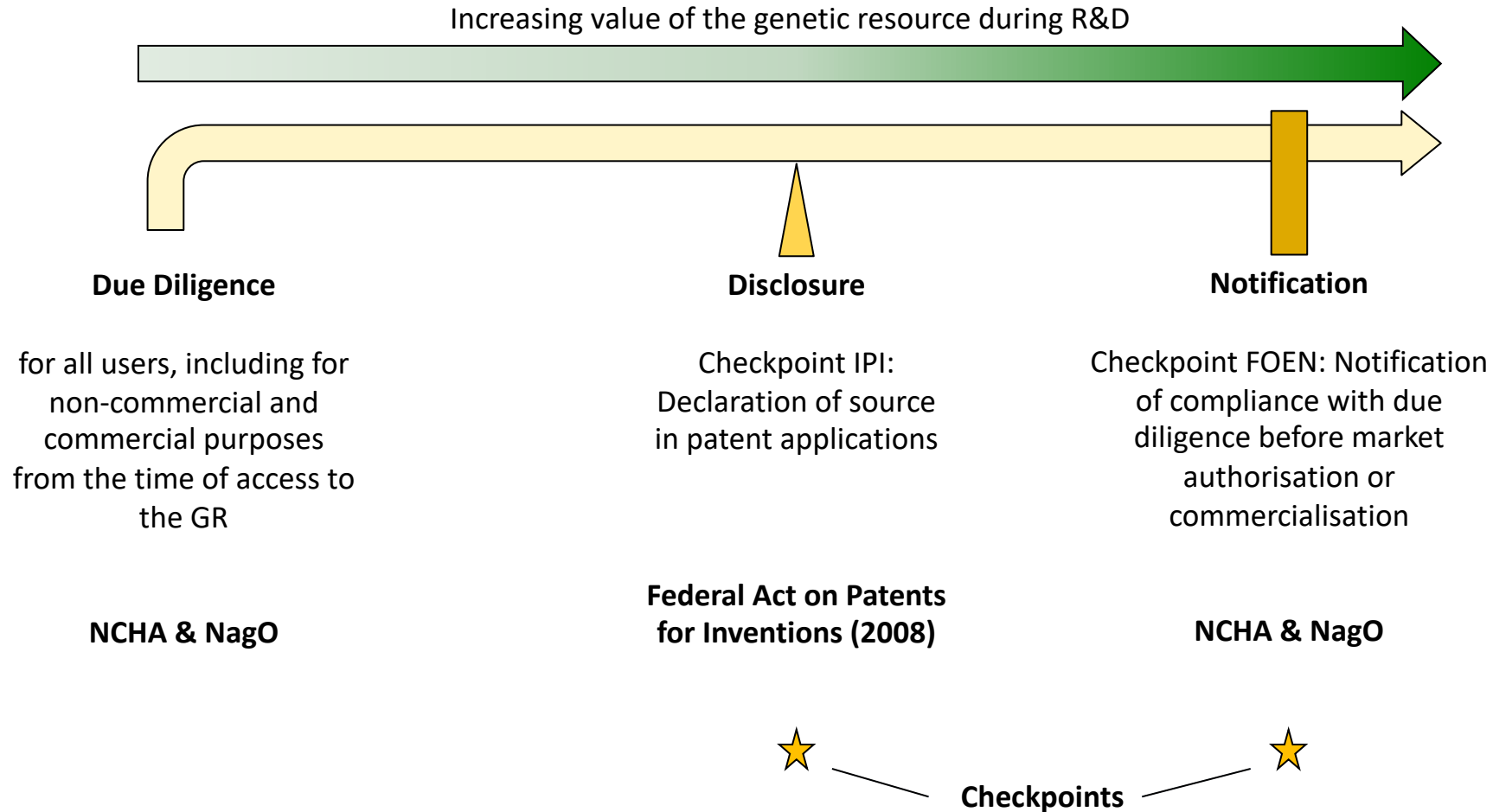
1. Provide an overview of the designated (or envisioned) checkpoints for your country? How and why were they chosen?
-

The Office for Product Safety and Standards (OPSS), part of the Department for Business, Energy and Industrial Strategy (BEIS) is the designated checkpoint.

OPSS was designated as checkpoint because of its experience implementing other scientific and technical areas of legislation, and its position in the Government Department that is best place to be engaging with businesses (“users”).



1. Provide an overview of the designated (or envisioned) checkpoints for your country? How and why were they chosen?



Questions and summary of discussion

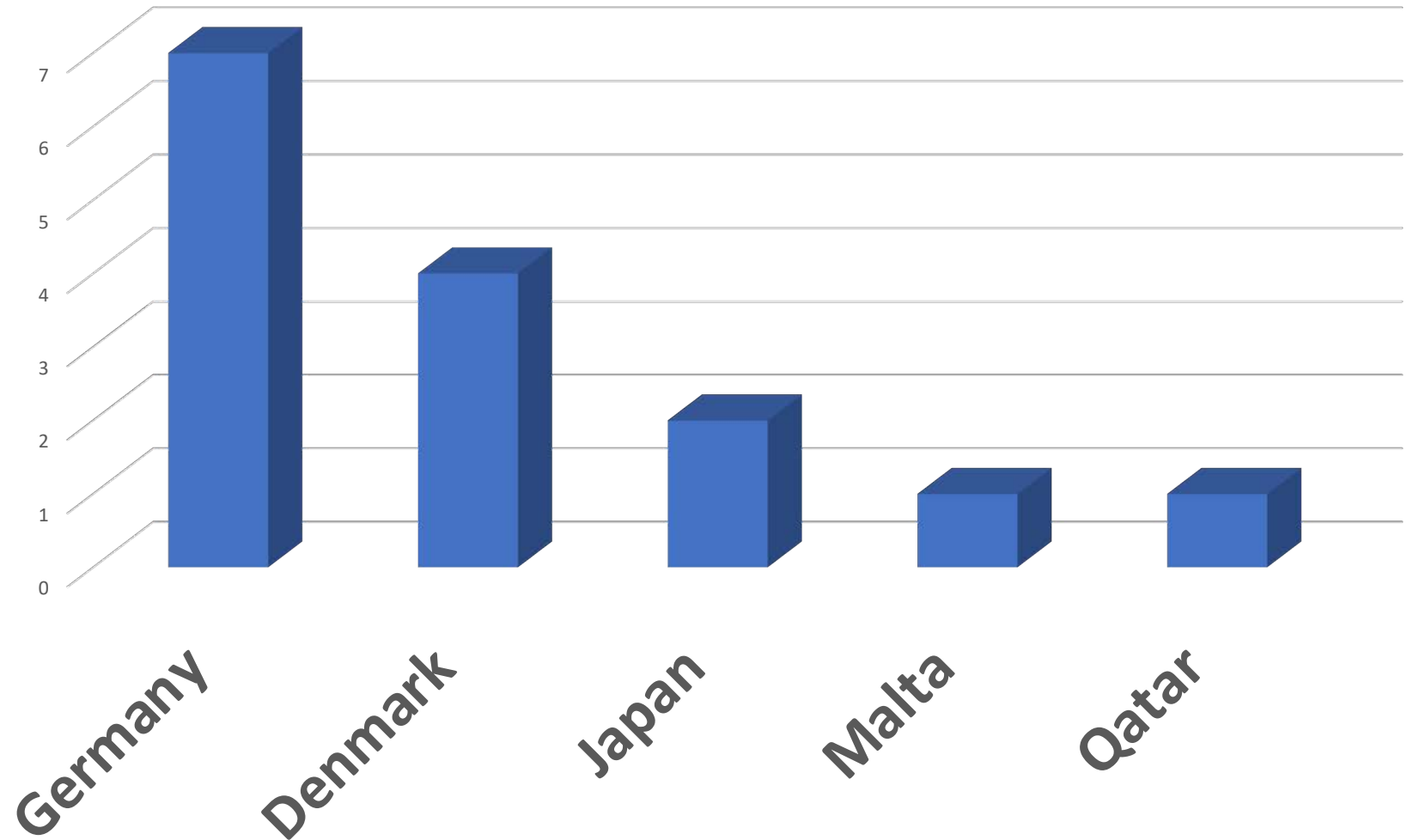
After the scenarios from yesterday, and the discussions today:

- How could you improve your system?
- Is there something you would do differently?

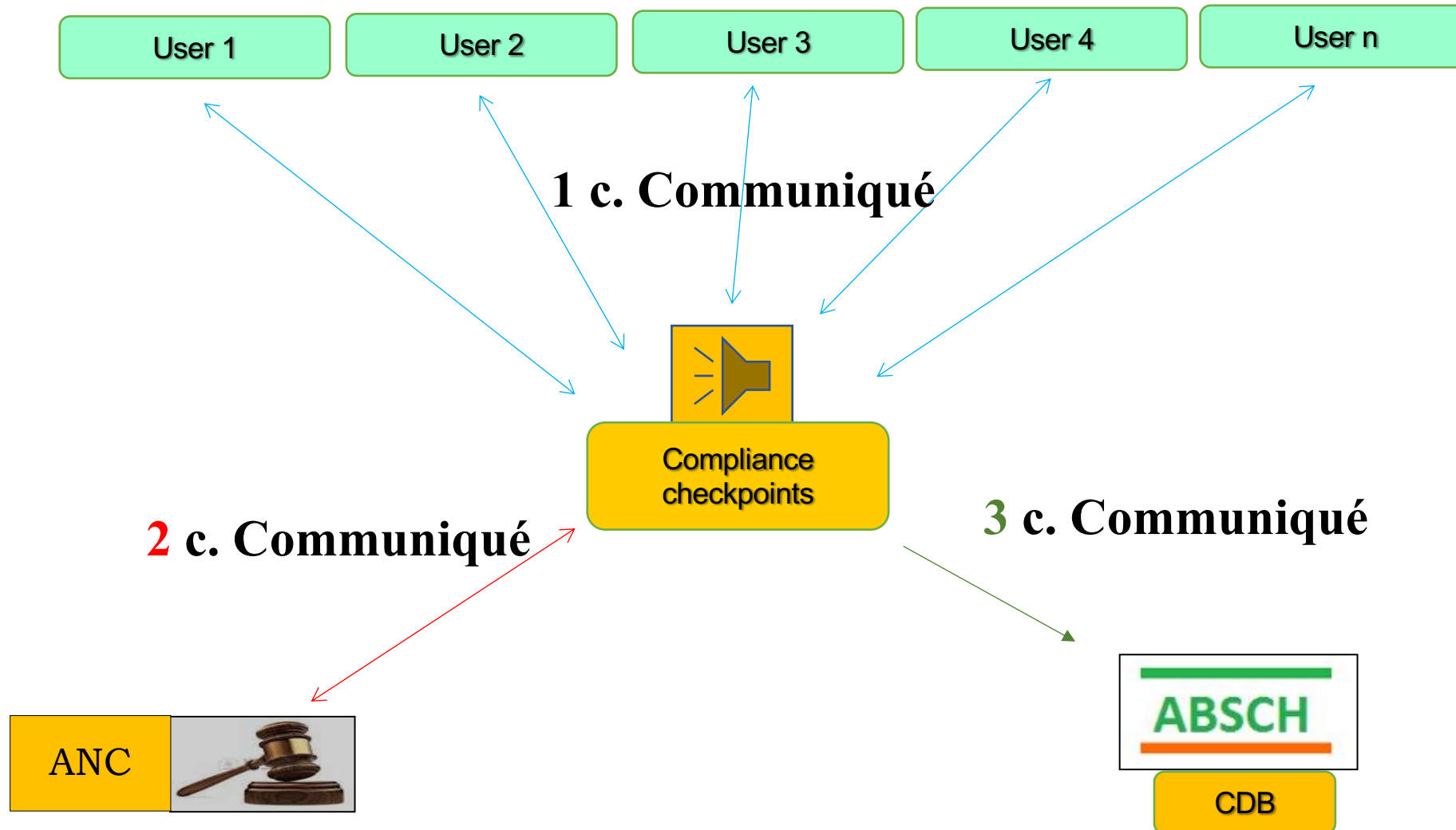
Monitoring utilization

2. Describe the (or envisioned) process of how information gathered from the user at the checkpoint is (or will be) shared on the ABS Clearing-House (checkpoint communiqué) ?

Checkpoint communiqué champions



2. Describe the (or envisioned) process of how information gathered from the user at the checkpoint is (or will be) shared on the ABS Clearing-House (checkpoint communiqué) ?





2. Describe the (or envisioned) process of how information gathered from the user at the checkpoint is (or will be) shared on the ABS Clearing-House (checkpoint communiqué) ?

- The designated Checkpoints should have user account that enables them to capture information in the Checkpoint Communiqué to be transmitted to the relevant Competent National Authority, in this case, it would be the Department of Environment, Forestry and Fisheries.

Who is the PA?
Who has the NAU account?

2. Describe the (or envisioned) process of how information gathered from the user at the checkpoint is (or will be) shared on the ABS Clearing-House (checkpoint communiqué) ?
-

The idea is that the checkpoints will have sufficient information on the intended use of the GR (through the permits issued). Once the checkpoints gather information from the user they should communicate to the Provider through the ABS CHM to inform whether there is compliance or not to the terms and conditions of the permits.

BUT MATs will not be posted on ABS CHM

What happens if the information is confidential?

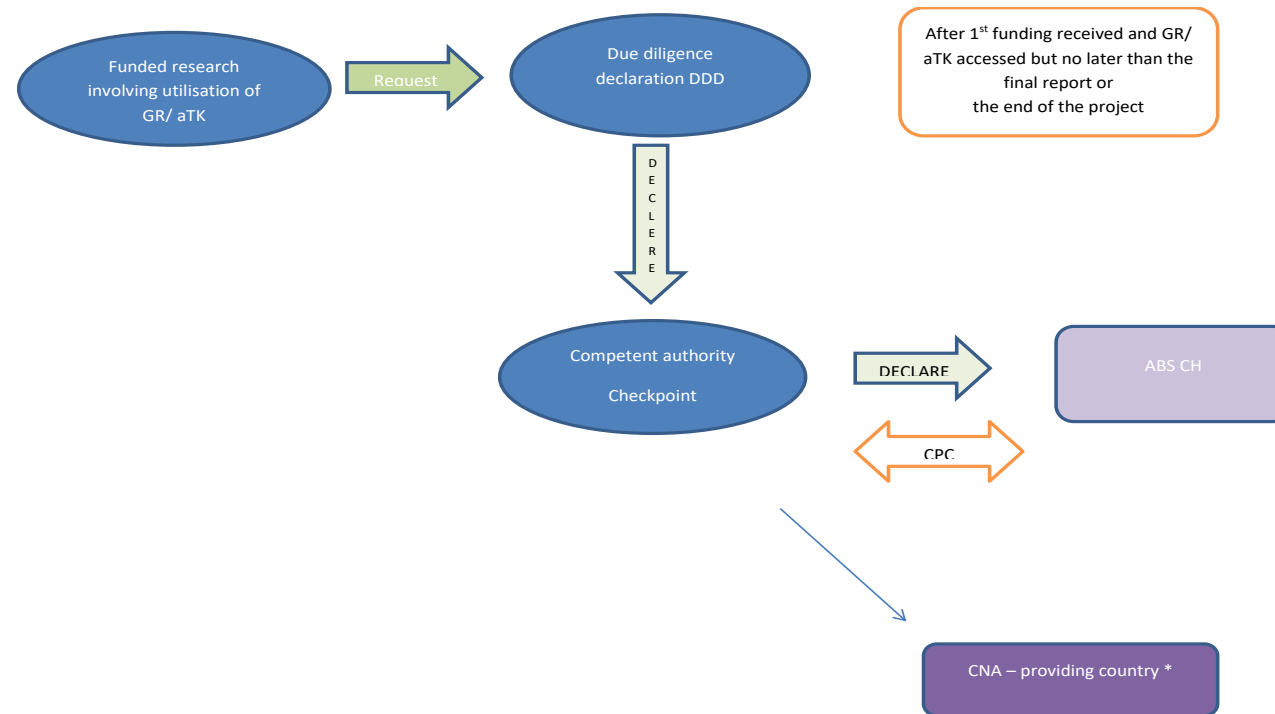
2. Describe the (or envisioned) process of how information gathered from the user at the checkpoint is (or will be) shared on the ABS Clearing-House (checkpoint communiqué) ?

- The process is still in formulation stage, but the information should be gathered from users by specialized electronic forms that are linked to the ABS clearing-house managing authority and the accumulated data is processed for display.

Please explain how would it work?

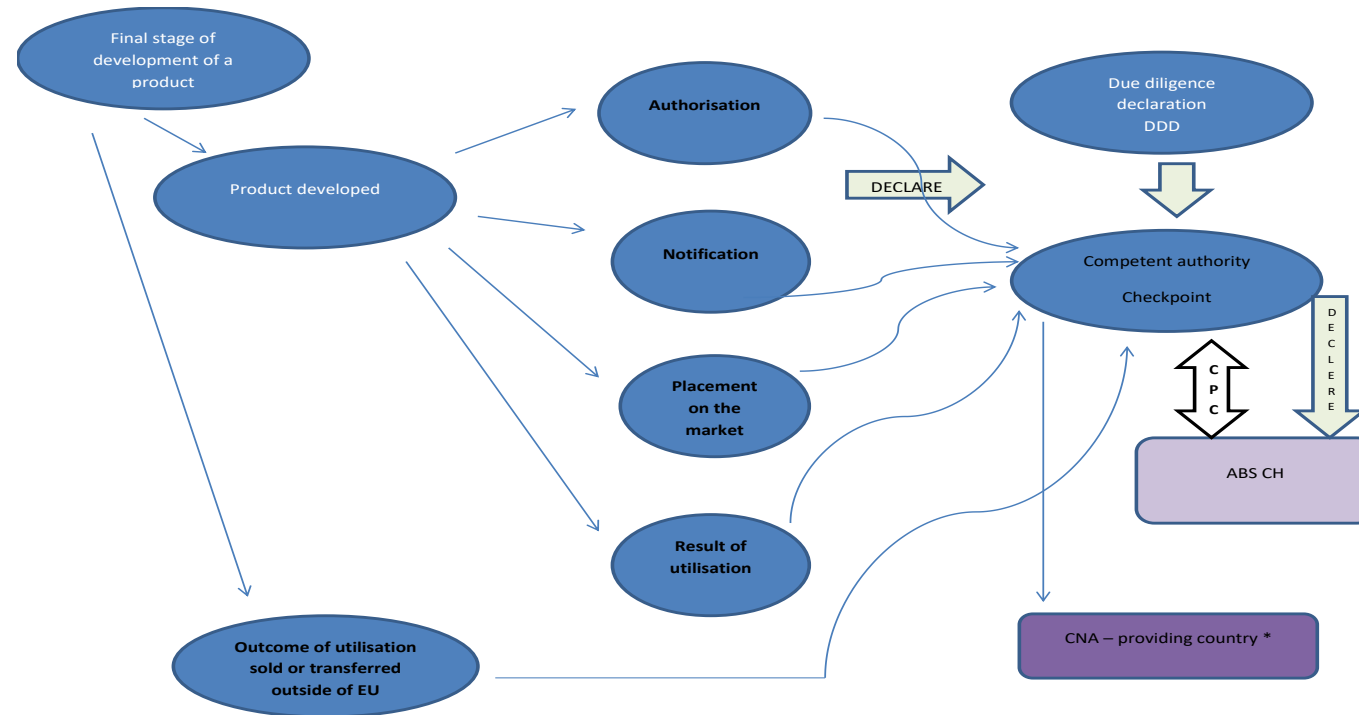
2. Describe the (or envisioned) process of how information gathered from the user at the checkpoint is (or will be) shared on the ABS Clearing-House (checkpoint communiqué) ?

- 1st checkpoint



2. Describe the (or envisioned) process of how information gathered from the user at the checkpoint is (or will be) shared on the ABS Clearing-House (checkpoint communiqué) ?

- 2nd checkpoint

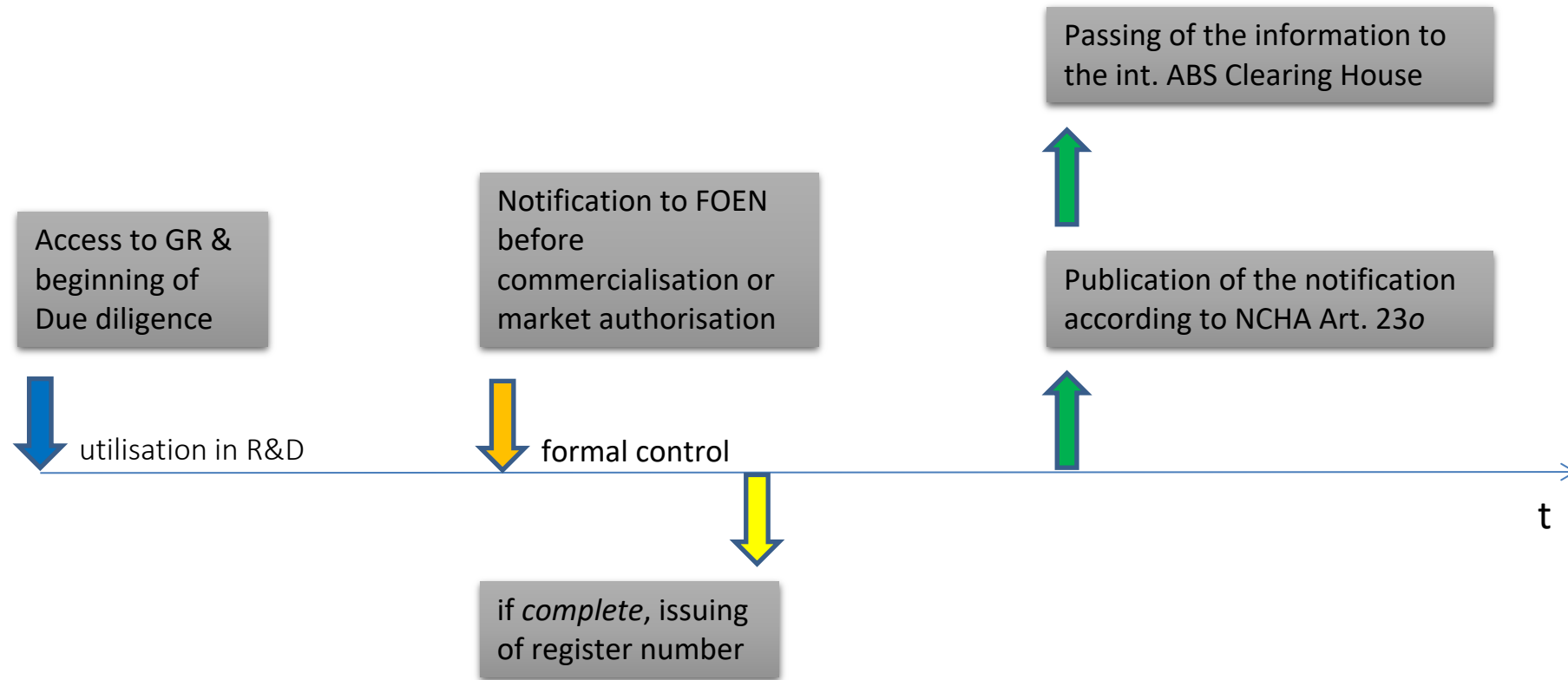


2. Describe the (or envisioned) process of how information gathered from the user at the checkpoint is (or will be) shared on the ABS Clearing-House (checkpoint communiqué) ?

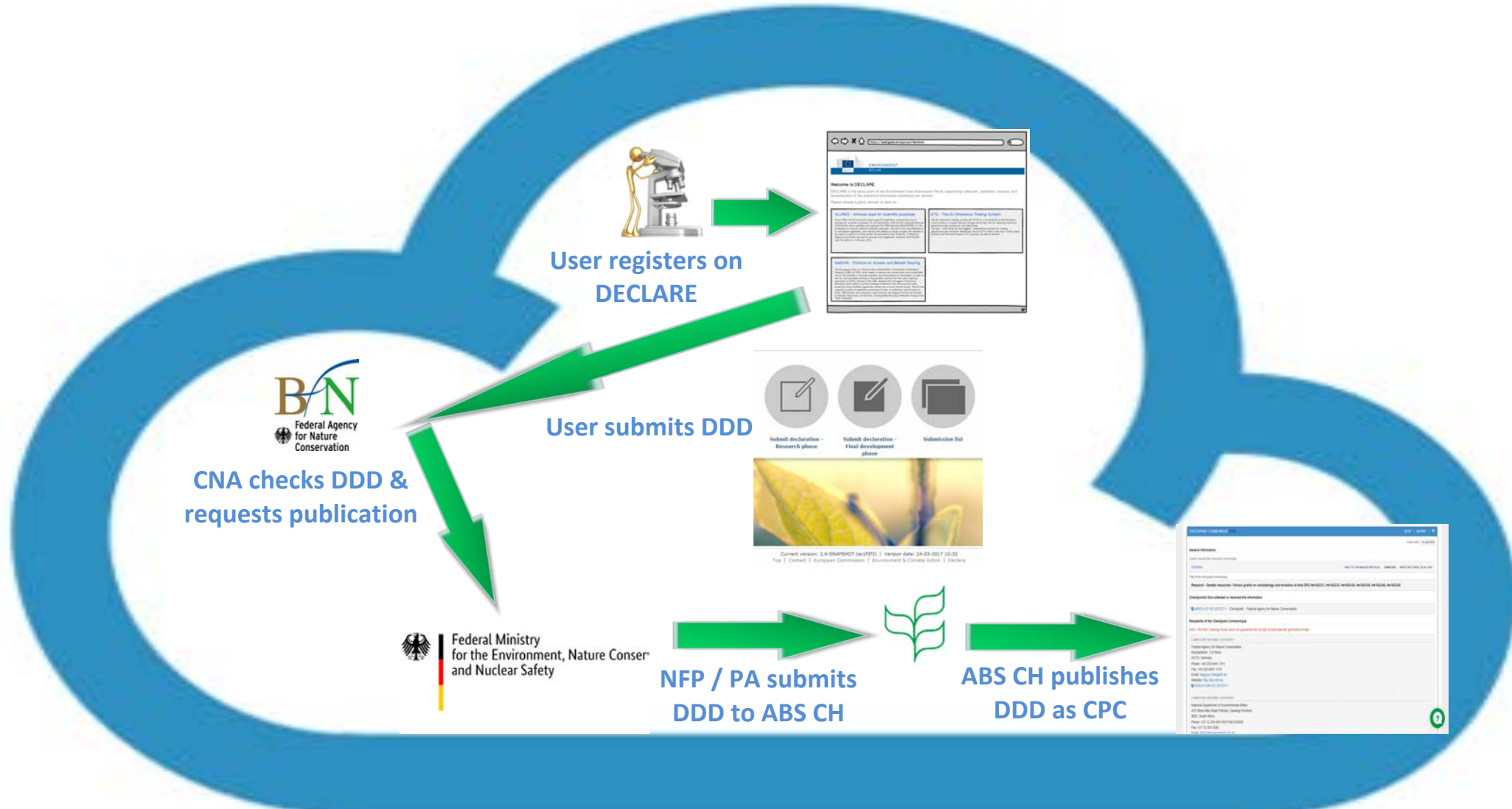
- Via DECLARE (EU-tool) the non-confidential information of the due diligence declaration is forwarded to the ABS-CH. However, there have not been final due diligence declarations in the Netherlands yet.
- The CNA can contact provider countries directly with more detailed information.



2. Describe the (or envisioned) process of how information gathered from the user at the checkpoint is (or will be) shared on the ABS Clearing-House (checkpoint communiqué) ?



2. Describe the (or envisioned) process of how information gathered from the user at the checkpoint is (or will be) shared on the ABS Clearing-House (checkpoint communiqué) ?



3. Why your country has not reported any (or so few cases of) utilization of genetic resources in your country on the ABS Clearing-House (checkpoint communiqué) ?

- 7 out of 15 CPCs on ABS CH are from Germany (as of 10 September 2019)
- Number of due diligence declarations (at stage of research funding) steadily increasing

Germany

PARTY TO THE NAGOYA PROTOCOL

SIGNATORY

ENTRY INTO FORCE: 20 JUL 2016

7

CHECKPOINT COMMUNIQUÉ (CPC)

Research - Genetic resources: German Research Foundation grant number: KN 1097/7-1 (Treponemes in wild lagomorphs: Genetic diversity and relatedness to human pathogenic *T. pallidum*)

Research - Genetic resources: German Research Foundation grant number: KN 1097/7-1 (Treponemes in wild lagomorphs: Genetic diversity and relatedness to human pathogenic *T. pallidum*)

CHECKPOINT COMMUNIQUÉ | GERMANY | ABSCH-CPC-DE-247424-1 | CHECKPOINT: FEDERAL AGENCY FOR NATURE CONSERVATION | SOURCE: SPAIN | IRCC NOT AVAILABLE | 04 SEP 2019

Research - Genetic resources: Genetic species identification of hosts of terrestrial leeches using metabarcoding. Funded by the German Federal Ministry of Education and Research - BMBF FKZ: 01LN1301A

Research - Genetic resources: Genetic species identification of hosts of terrestrial leeches using metabarcoding. Funded by the German Federal Ministry of Education and Research - BMBF FKZ...

CHECKPOINT COMMUNIQUÉ | GERMANY | ABSCH-CPC-DE-247422-1 | CHECKPOINT: FEDERAL AGENCY FOR NATURE CONSERVATION | SOURCE: LAO PEOPLE'S DEMOCRATIC REPUBLIC | IRCC NOT AVAILABLE | 04 SEP 2019

Research - Genetic resources: Genetic species identification of hosts of terrestrial leeches using metabarcoding. Funded by the German Federal Ministry of Education and Research - BMBF FKZ: 01LN1301A

Research - Genetic resources: Genetic species identification of hosts of terrestrial leeches using metabarcoding. Funded by the German Federal Ministry of Education and Research - BMBF FKZ...

CHECKPOINT COMMUNIQUÉ | GERMANY | ABSCH-CPC-DE-247421-1 | CHECKPOINT: FEDERAL AGENCY FOR NATURE CONSERVATION | SOURCE: VIET NAM | IRCC NOT AVAILABLE | 04 SEP 2019

Research - Genetic resources: Genetic species identification of hosts of terrestrial leeches using metabarcoding. Funded by the German Federal Ministry of Education and Research - BMBF FKZ: 01LN1301A

Research - Genetic resources: Genetic species identification of hosts of terrestrial leeches using metabarcoding. Funded by the German Federal Ministry of Education and Research - BMBF FKZ...

CHECKPOINT COMMUNIQUÉ | GERMANY | ABSCH-CPC-DE-247420-1 | CHECKPOINT: FEDERAL AGENCY FOR NATURE CONSERVATION | SOURCE: VIET NAM | IRCC NOT AVAILABLE | 04 SEP 2019

Research - Genetic resources: Isolation of *Pristionchus* nematodes from insects, i.e. scarab beetles. This work has institutional funding through the Max-Planck Society until 2031.

Research - Genetic resources: Isolation of *Pristionchus* nematodes from insects, i.e. scarab beetles. This work has institutional funding through the Max-Planck Society until 2031.

CHECKPOINT COMMUNIQUÉ | GERMANY | ABSCH-CPC-DE-240858-1 | CHECKPOINT: FEDERAL AGENCY FOR NATURE CONSERVATION | SOURCE: FRANCE | IRCC NOT AVAILABLE | 28 SEP 2018

Research - Genetic resources: Evolution, genetic basis, and behavioural consequences of cuticular hydrocarbon profiles in parabiotic ants

Research - Genetic resources: Evolution, genetic basis, and behavioural consequences of cuticular hydrocarbon profiles in parabiotic ants

CHECKPOINT COMMUNIQUÉ | GERMANY | ABSCH-CPC-DE-240857-1 | CHECKPOINT: FEDERAL AGENCY FOR NATURE CONSERVATION | SOURCE: FRANCE | IRCC NOT AVAILABLE | 28 SEP 2018

Research - Genetic resources: Various grants on sociobiology and evolution of ants DFG He1623/31, He1623/33, He1623/34, He1623/39, He1623/40, He1623/42

Research - Genetic resources: Various grants on sociobiology and evolution of ants DFG He1623/31, He1623/33, He1623/34, He1623/39, He1623/40, He1623/42

CHECKPOINT COMMUNIQUÉ | GERMANY | ABSCH-CPC-DE-240383-1 | CHECKPOINT: FEDERAL AGENCY FOR NATURE CONSERVATION | SOURCE: SOUTH AFRICA | IRCC NOT AVAILABLE | 14 JUN 2018

Japan

PARTY TO THE NAGOYA PROTOCOL

SIGNATORY

ENTRY INTO FORCE: 20 AUG 2017

?

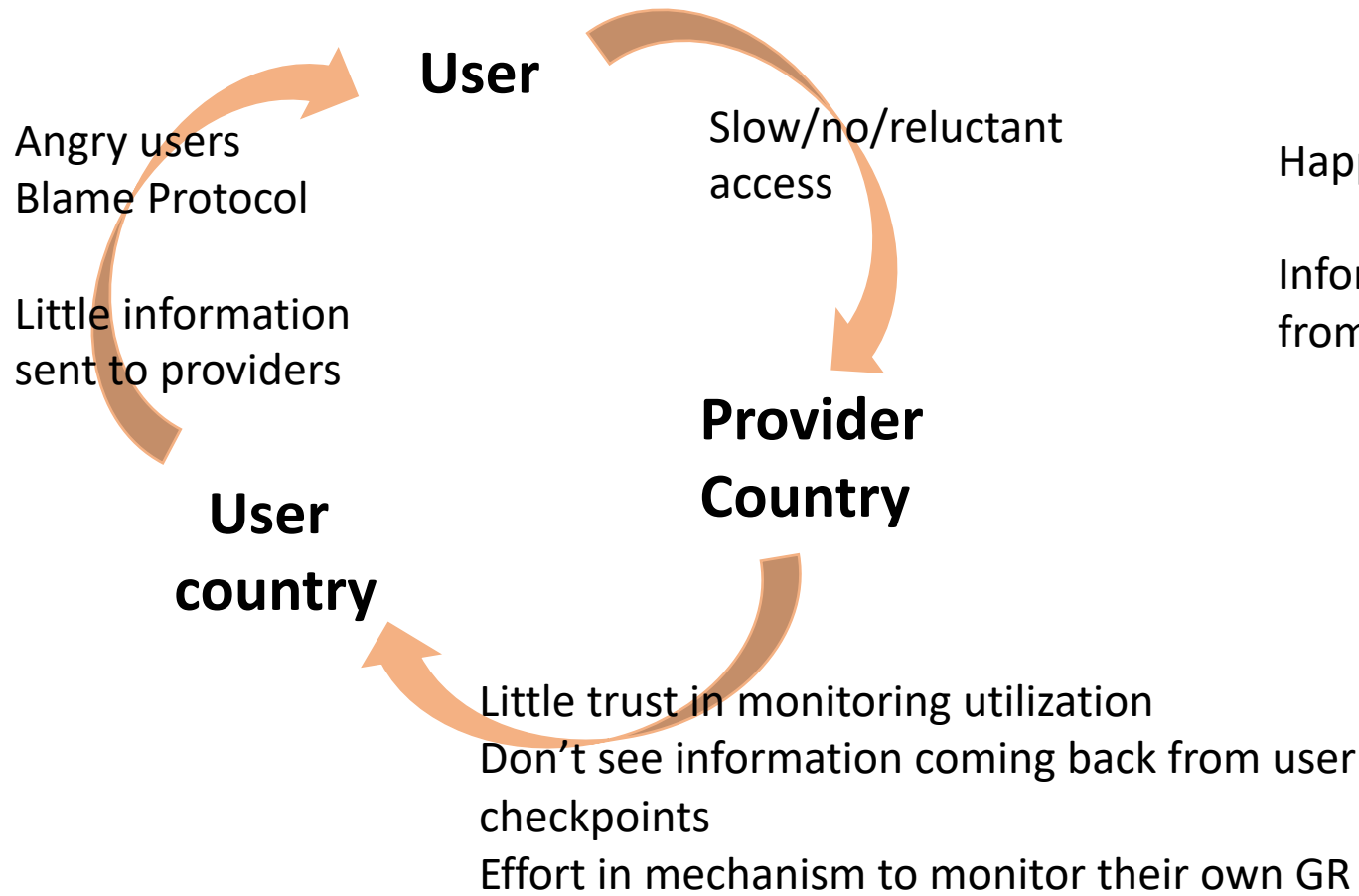
CHECKPOINT COMMUNIQUÉ (CPC)

24

Monitoring utilization

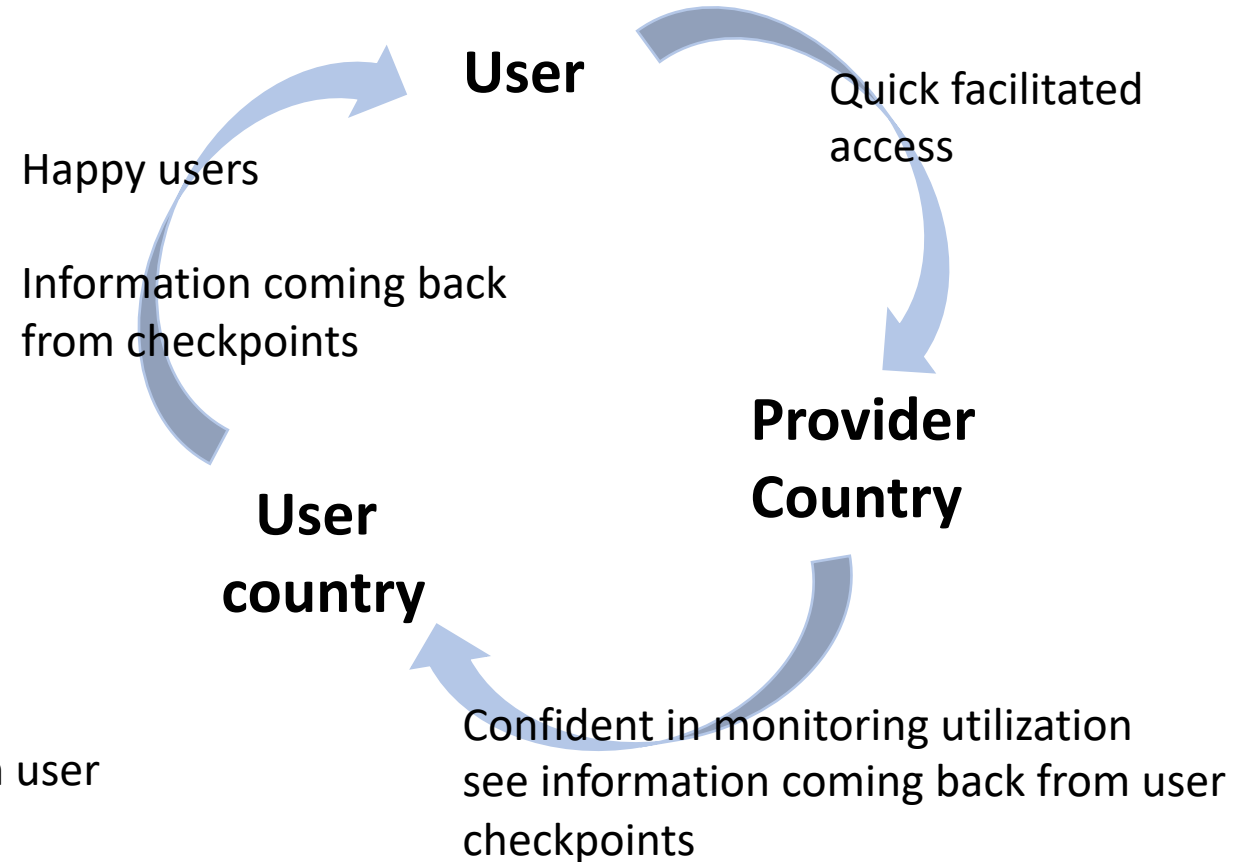
3. Why your country has not reported any (or so few cases of) utilization of genetic resources in your country on the ABS Clearing-House (checkpoint communiqué) ?

Vicious cycle



ABS Suffering

Virtuous cycle



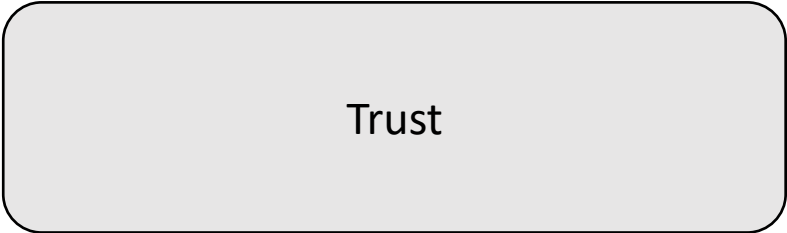
ABS Flourishing

4. What methods does your country take to monitor utilization of your national genetic resources? (electronic monitoring system, standard MAT terms for periodic user reporting, automated patent database or published research searches...). Please describe the methods (or those that you may be interested in).

In the Republic of Belarus, under the International Technical Assistance Project “Strengthening of human resources, legal frameworks and institutional capacities to implement the Nagoya Protocol in the Republic of Belarus”, a database to monitor the GRs use has been developed.

If the terms of transfer or use of the transferred genetic resources change, the provider and user must notify the Checkpoint and this information will be entered into the database and the Clearing-House.

At present, we do not consider it necessary to trace the transferred GRs use, as other countries do (e.g. Peru). We believe that providers and users fully trust each other and the Checkpoint function is to ensure the legality of their relationship.



Trust

3. Why your country has not reported any (or so few cases of) utilization of genetic resources in your country on the ABS Clearing-House (checkpoint communiqué) ?

- First CPC submitted to the ABS Clearing House by the EU Member States;
- Reasons for relatively small amount of CPCs:
 - Time needed to make system operational
 - Designation of competent authorities in Member States;
 - Development of an support IT tool (DECLARE)
 - Possibility to submit a due diligence declaration at the end of research project (projects spin 5-6 years)
 - Time needed to develop a product based on a genetic resource (min.3-4 years)

3. Why your country has not reported any (or so few cases of) utilization of genetic resources in your country on the ABS Clearing-House (checkpoint communiqué) ?

- In one case, the declaration comprised entirely confidential information, so could not be uploaded to the ABSCH.
- **Checkpoint 1: Stage of research funding** - The timeframe for submitting declarations at this checkpoint is broad. The time between receiving the first instalment of grant funding and the “project end” could be years. So it may take some time before we start receiving them.
- **Checkpoint 2: Placing product on the market** - The timeframe from access to product development/commercialisation could again take years and in many cases, utilisation will not result in product development at all.
- Lack of awareness of the requirement to submit declarations.
- There are many reasons to be out of scope (e.g. country and date of access, nature of work). We expect this to change as more countries become party, implement access measures and the further we get from Oct 2014.
- Shifts towards using DSI rather than physical genetic resources.

3. Why your country has not reported any (or so few cases of) utilization of genetic resources in your country on the ABS Clearing-House (checkpoint communiqué) ?

- Users have not made any due diligence declarations yet in the Netherlands. Potential users have registered in the system DECLARE, so we expect the declarations will follow.
- Users are avoiding genetic resources where access rules apply. They use pre-Nagoya material and free material. Process of getting PIC and MAT / IRCC is long.
- Researchers only have to submit a DD-declaration at the latest at the end of the project.
- Product developers have to submit a DD-declaration before entering the market, not during the development period.

3. Why your country has not reported any (or so few cases of) utilization of genetic resources in your country on the ABS Clearing-House (checkpoint communiqué) ?

- We have not operationalized the inspection plans (nor teams) yet
- Awareness raising still needed on the requirements and process for declaring
- Users tend to avoid using GR in the scope of the regulation (complexity of legislations)

3. Why your country has not reported any (or so few cases of) utilization of genetic resources in your country on the ABS Clearing-House (checkpoint communiqué) ?

- National implementing legislation came into force in 2016 -> users may still be unaware of their obligations

Thus no declarations (and few import notifications) have been received yet

More awareness raising is needed

3. Why your country has not reported any (or so few cases of) utilization of genetic resources in your country on the ABS Clearing-House (checkpoint communiqué) ?

- So far, we received only one notification concerning utilization of GR from abroad.

- Since the access dates back before entry into force of the protocol, we did not report it on the ABS clearing house. We consider it a voluntary notification.

Monitoring utilization

4. What methods does your country take to monitor utilization of your national genetic resources? (electronic monitoring system, standard MAT terms for periodic user reporting, automated patent database or published research searches...). Please describe the methods (or those that you may be interested in).

Checkpoint checklist

Obligation for Parties: ✓ Parties have an obligation to designate of one or more checkpoints relevant to the utilization of genetic resources

Function:

✓ Checkpoints collect or receive information on PIC, MAT, source, and utilization.

Where they are placed:

✓ The information is collected at any stage of research, development, innovation, pre commercialization or commercialization.

✓ Users are required to provide information to checkpoints

Obligation for Users: ✓ The information gathered is provided to the provider country and ABSCH (checkpoint communique)

Purpose:

Additional ways

Mechanism to monitoring own GR

“National Bio-pirate Police”

User periodic reporting

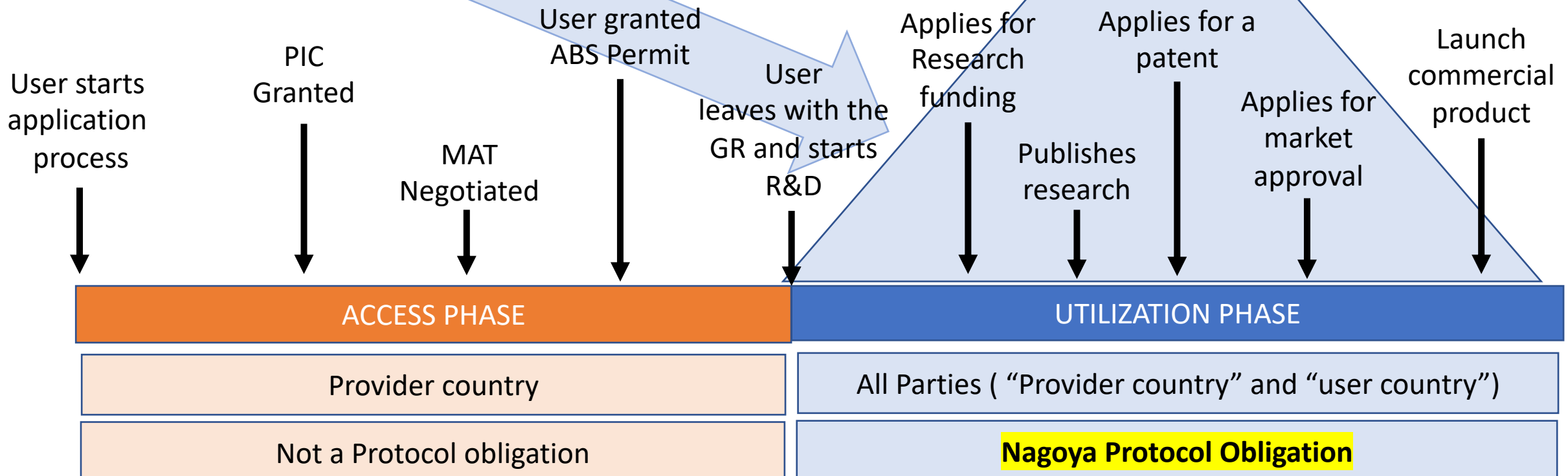
Published research searches

Patent searches



Nagoya Protocol Checkpoint

- Monitor utilization of GR
Particularly of foreign GR



4. What methods does your country take to monitor utilization of your national genetic resources? (electronic monitoring system, standard MAT terms for periodic user reporting, automated patent database or published research searches...). Please describe the methods (or those that you may be interested in).

Virtual Platform:

Automatized system to monitor benefits sharing commitments established in PIC and MAT.

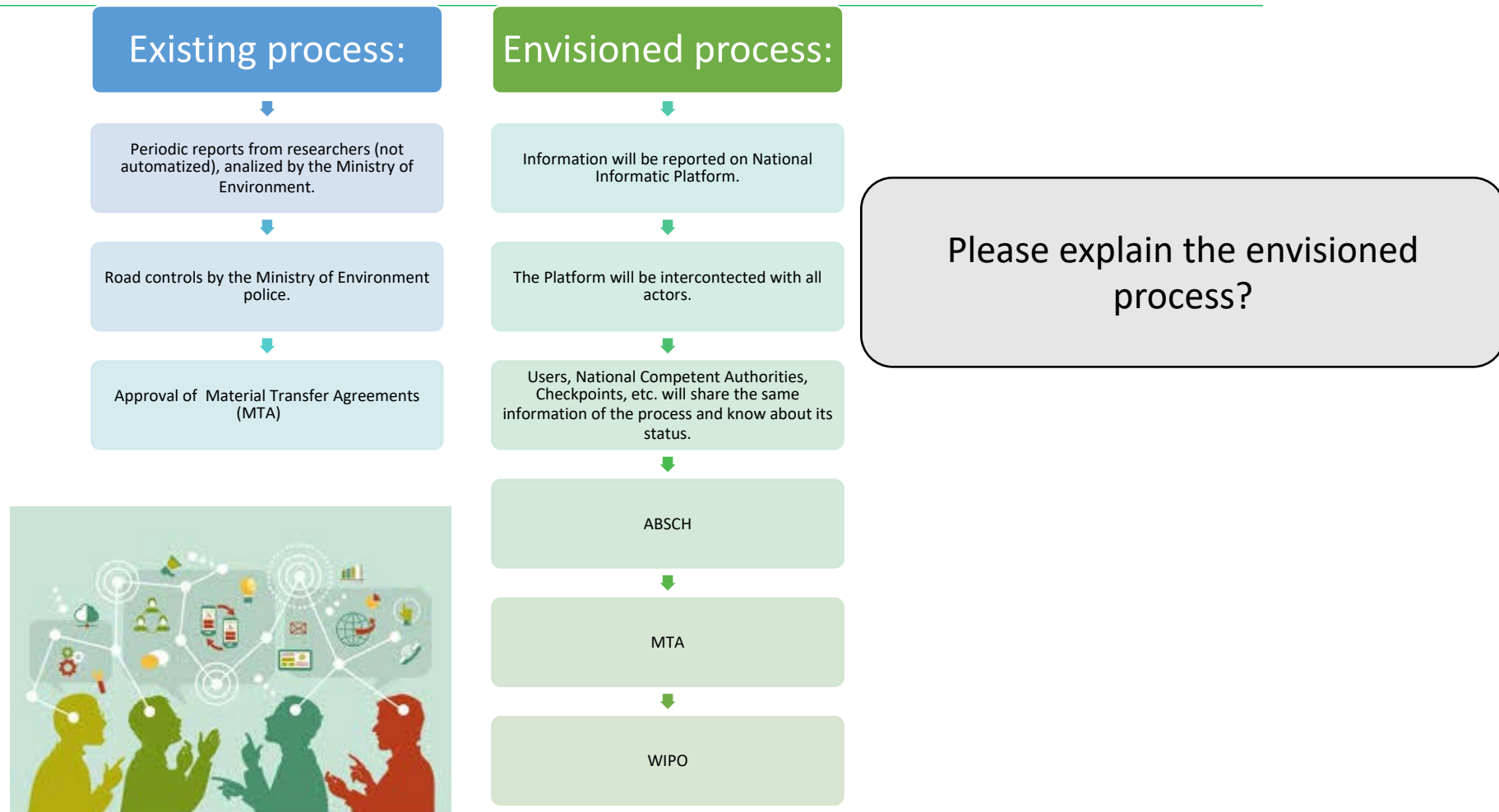
- CONAGEBIO program deadlines for those commitments.
- Users can upload documents to report fulfilment.
- If not, platform send automatic emails to user, provider and National Competent Authority

Executive Decree No. 39341-MINAE for the application of administrative sanctions

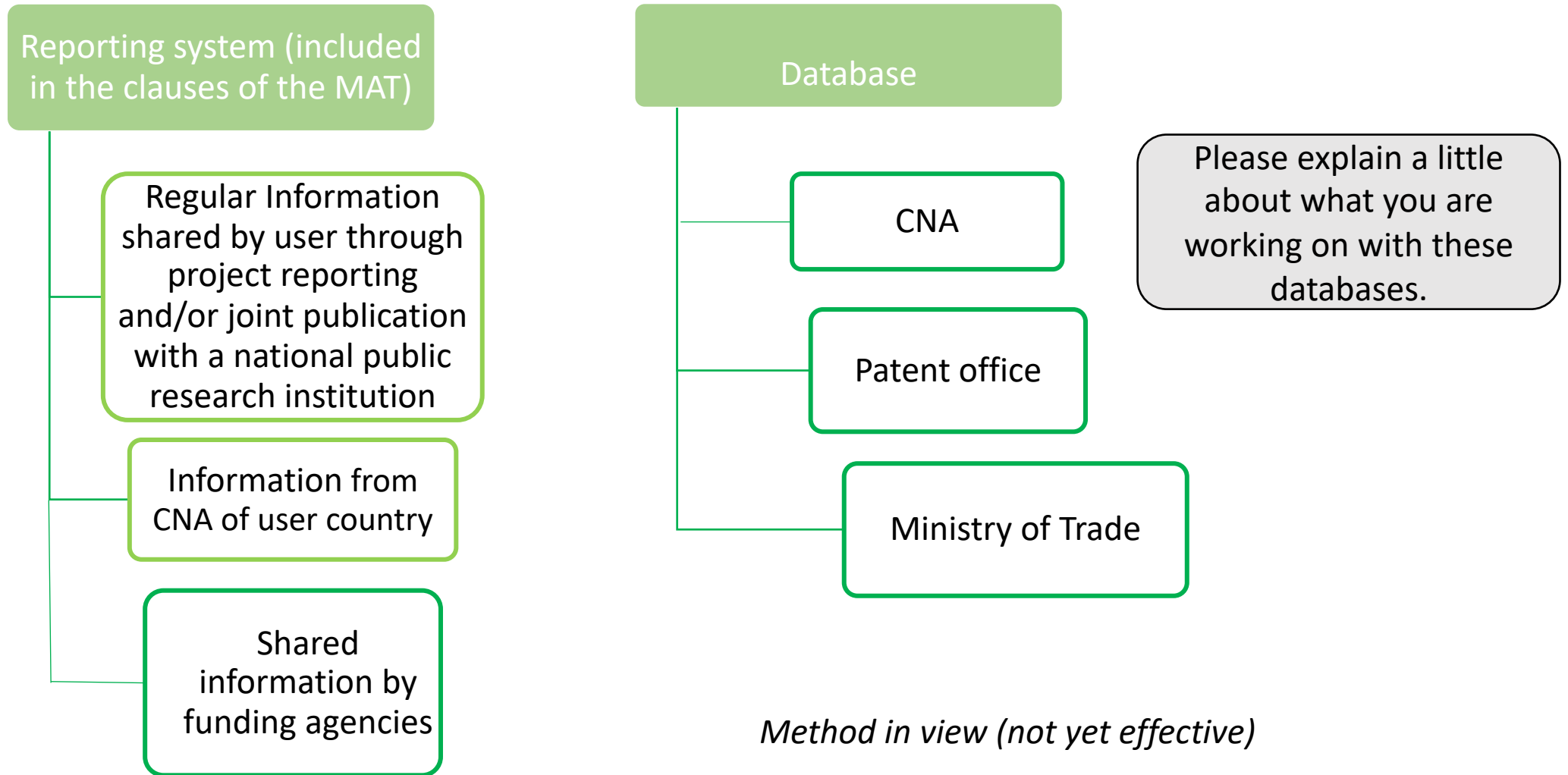
Published on March 16, 2016 and became effective in September 2016.

Its purpose is to establish a [clear procedure](#) to apply administrative sanctions [in the case of unauthorized access](#) to the genetic and biochemical resources of biodiversity, as established by the Biodiversity Law and [provide legal certainty](#) to permit applicants and competent authorities, to apply this sanctioning regime.

4. What methods does your country take to monitor utilization of your national genetic resources? (electronic monitoring system, standard MAT terms for periodic user reporting, automated patent database or published research searches...). Please describe the methods (or those that you may be interested in).



4. What methods does your country take to monitor utilization of your national genetic resources? (electronic monitoring system, standard MAT terms for periodic user reporting, automated patent database or published research searches...). Please describe the methods (or those that you may be interested in).



Check Point - National Commission against Biopiracy

- Presided by INDECOPI and Composed by 13 Institutions.
- Monitoring of patents (novelty, inventive level and industrial application) at international level that use genetic resources of Peruvian origin.
- Identify patents that use traditional knowledge linked to the genetic resources of Peruvian origin
- Prepare documentation with an analysis that the patent should not be granted, mainly due to the absence of novelty or inventive level.
- Peru Ministry of Foreign Affairs communicates with the patent offices and the applicant.
- In case patent had been granted, is necessary to make arrangements with lawyers for the cancellation of the patent, more expensive.



Check Point - National Commission against Biopiracy

2017

1600 patents reviewed
35 cases of biopiracy



2018

3200 patents reviewed

67 cases of biopiracy
45 cases in favor
18 cases in process

Species

- sangre de grado
- maca
- sachá Inchi
- tara
- camu camu
- pasuchaca
- yacón, otros

Countries

- United States of America, China, Japan, South Korea, Uruguay, Australia, Argentina, Europe, France, Canada, Philippines, others

2019

47 cases in favor

Sangre de grado, Maca, Sacha inchi, Tara, Yacon,
Camu camu, Pasuchaca, Ambrosia



Access and Benefit Sharing (ABS) Partnership Project

**Indo-German Biodiversity Programme
GIZ India**

**Dr. Aeshita Mukherjee-Wilske
Mr. Mithilesh Kandalkar**

PAUL

4. What methods does your country take to monitor utilization of your national genetic resources? (electronic monitoring system, standard MAT terms for periodic user reporting, automated patent database or published research searches...). Please describe the methods (or those that you may be interested in).

- Published research searches
- Media

In 1992, a researcher from a British University harvested some micro-organisms from the lake, and in 1995 sold them to companies in the Netherlands and the United States. Those companies were later sued by the Kenyan government for not sharing the financial benefits of their subsequent innovations with Kenya.

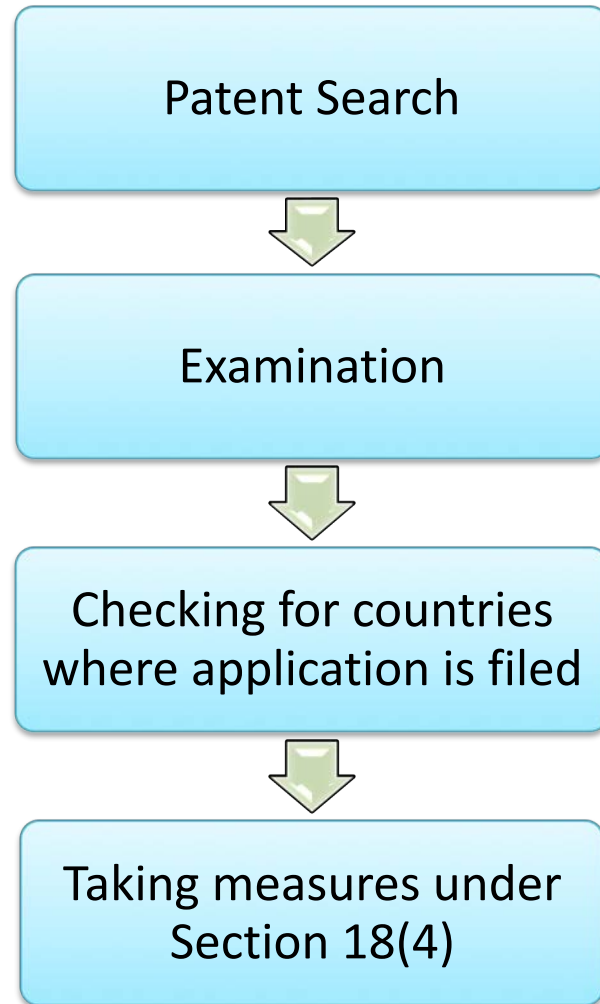
Wilson Kipkazi, chairman of the Endorois Welfare Council, says companies that conducted research at the lake never involved the community.

"We learned through media that multinational companies have made millions of dollars through genetic resources extracted from Lake Borogio. This really made the community furious...

"Fortunately, later on, some companies... decided to talk to the communities and pay back some royalties... It was not much money but it changed lives."

4. What methods does your country take to monitor utilization of your national genetic resources? (electronic monitoring system, standard MAT terms for periodic user reporting, automated patent database or published research searches...). Please describe the methods (or those that you may be interested in).

- Status reports from the USER – Required under MAT
- Monitoring of Foreign Patents
- Monitoring of Indian Patents
- IT enabled ABS Monitoring Tool (GIZ)



Search is carried out using following keywords and/or their combinations:

- Biological resources
- Biological resource + India
- Biological resource + India + Source, Obtained, Procured, Acquired, Market, Purchased, etc. (City names)
- Agricultural GI s [synonyms and its constituent components]

4. Please reflect on your experience operationalized the system to monitoring genetic resources in your country. What are some of your main challenges, most serious concerns, important questions or greatest accomplishments?

Foreign Patent Office	No. of cases
EPO	19
USPTO	18
Canada	9
China	1
Japan	1
WIPO	1
Australia	5
Taiwan	1
Total	55

Monitoring Indian Patents			
Division	March	April	May
Biotechnology	88	40	53
Agrochemical	52	21	22
TK - Biotech	5	2	3
Microbiology	26	15	16
Biochemistry	41	15	21
Food	37	28	29
Pharmaceuticals	273	103	215
Total	522	224	359
NBA approval required	101	38	45

5. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to monitoring utilization of genetic resources?

Patent	Formulation comprising of plant molecules or extracts for treatment of inflammation, osteoarthritis, allergy, neuro degenerative disorder, diabetes	
Bioresources	Curcuma Longa , Ocimum Basilicum, Zingiber Officinale Moringa Oleifera, Murraya Koenigii	
Patents Filed	India, WIPO, EPO, US, BR, PH, AU, EP	
Third Party Observation under Art.115, EPC filed	02/08/2016	
Transmittal of TPO to applicant	09/08/2016	
First response from Patent applicant	29/08/2016	
ABS agreement signed	21/06/2017	
IRCC generated from ABSCH and uploaded to patent office databases		

5. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to monitoring utilization of genetic resources?

S. No.	Patent Office	No. of cases
1	European Patent Office (EPO)	19
2	US Patent and Trademark Office	18
3	Canadian Intellectual Property Office	9
4	State Intellectual Property Office	1
5	Japan Patent Office (JPO)	1
6	World Intellectual Property Office (WIPO)	1
7	Australian Patent Office	5
8	Taiwan Patent Office	1
	Total	55

Monitoring utilization

5. Please reflect on your experience operationalized the system to monitoring genetic resources in your country. What are some of your main challenges, most serious concerns, important questions or greatest accomplishments?

4. Please reflect on your experience operationalized the system to monitoring genetic resources in your country. What are some of your main challenges, most serious concerns, important questions or greatest accomplishments?

- Challenge:
 - Identifying users (no databases of Nagoya-Protocol users exist)
- Concern:
 - Finding & understanding information about PIC/MAT requirements of provider states in order to decide whether an institution falls within scope or not
- Accomplishment:
 - So far 33 risk-based checks, incl. 3 on-the-spot audits & 1 check based on substantiated concerns
 - Identification of 1 case of non-compliance

Can you explain more?

5. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to monitoring utilization of genetic resources?

Control Checks – Implementation in Practice

- Step 1: 8 sectors differentiated (pharma, cosmetics, biotech, etc.)
- Step 2: 20 institutions per sector pre-selected on random basis
- Step 3: 10 institutions filtered based on expert analysis
 - Expert analysis develops profile for each institution

Annual reports
- R&D expenses
- R&D location
- Strategies



- Step 4: Send questionnaire to identified institutions
 - 1st round of general questions (measures taken, origin of material, etc.)
 - Followed by 2nd round of individual follow-up questions (clarification of open questions)
- Step 5: On-the-spot checks (if necessary)



4. Please reflect on your experience operationalized the system to monitoring genetic resources in your country. What are some of your main challenges, most serious concerns, important questions or greatest accomplishments?

- It is difficult to raise awareness and sensitize users of GR for their obligations, mostly from small businesses or in academia

- It is not very clear yet how the gained insight into utilization could be useful for protection of biodiversity.

What do you think?
Can someone answer this question?



4. Please reflect on your experience operationalized the system to monitoring genetic resources in your country. What are some of your main challenges, most serious concerns, important questions or greatest accomplishments?
-

Challenges that the country used to face:

- The user would collect more than what is approved in terms of quantity.
- Sourcing of species from non-compliant suppliers/middleman.

Please explain more

Accomplishments:

- In order to deal with the above mentioned challenges, the Department established a unit responsible for Biodiversity Compliance Monitoring and Law Enforcement.
- The Department does not issue permit to the users who source raw material from non-complaint suppliers or middleman, but provide the user with the list of compliant suppliers.

Monitoring utilization

6. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to monitoring utilization of genetic resources

Monitoring utilization



in 3 minutes or less

5. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to monitoring utilization of genetic resources?

Stolen crotons from the airport!

- The user stepped out of the airport during a layover and clipped plants and placed them in his bag.
- He took them back to his “country” (he did not tell us where) and then asked us if we were interested in the results of the study



5. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to monitoring utilization of genetic resources?

- A User was in the process of obtaining an ABS Permit and when the permit application was still under consideration in the Department, the User decided to export finished products without a ABS permit and a validation of the CITES permit.
- The consignment was confiscated at the Airport and triggered law enforcement.
- The ABS Permit process was put on hold until the law enforcement process was completed.

5. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to monitoring utilization of genetic resources?



The [Baringo County](#) has confirmed recent [media reports](#) that residents living around Lake Bogoria in Baringo County have received the sum of KES 2.3 Million in royalties from a Dutch bio-enzyme company. According to [Baringo County news](#), this royalties deal comes after “successful negotiation between the Kenya Wildlife Service (KWS) and Novozyme – a foreign company that took an enzyme drawn from a Bacteria in Lake Bogoria hot springs about 15 years ago”. It is reported that the royalties will be partly used as bursaries for over 200 local students while part of the funds will be deployed to fund other development projects in the area. However, local civil society organisations have reportedly demanded full disclosure of all the money from the royalties deal.

5. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to monitoring utilization of genetic resources?
-

We met a user eager to become the first person in the UK to submit an in-scope Due Diligence Declaration but had not yet reached the first checkpoint. We have not had the heart to tell him that he has been beaten to it...



5. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to monitoring utilization of genetic resources?
-

- We have a cocoa plantation (*Theobroma cacao* L.) in our ministry that expresses the genetic variability of a producing region of our country, and we can contact the interaction of the crop with a group of squirrels. There we enjoy seeing the children impressed with these animals in their habitat, and as we are interested in the games that the squirrels play in the trees.

5. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to monitoring utilization of genetic resources?



Compliance

Checkpoint checklist

Obligation for Parties: ✓ Parties have an obligation to designate of one or more checkpoints relevant to the utilization of genetic resources

Function: ✓ Checkpoints collect or receive information on PIC, MAT, source, and utilization.

Where they are placed: ✓ The information is collected at any stage of research, development, innovation, pre commercialization or commercialization.

Obligation for Users: ✓ Users are required to provide information to checkpoints

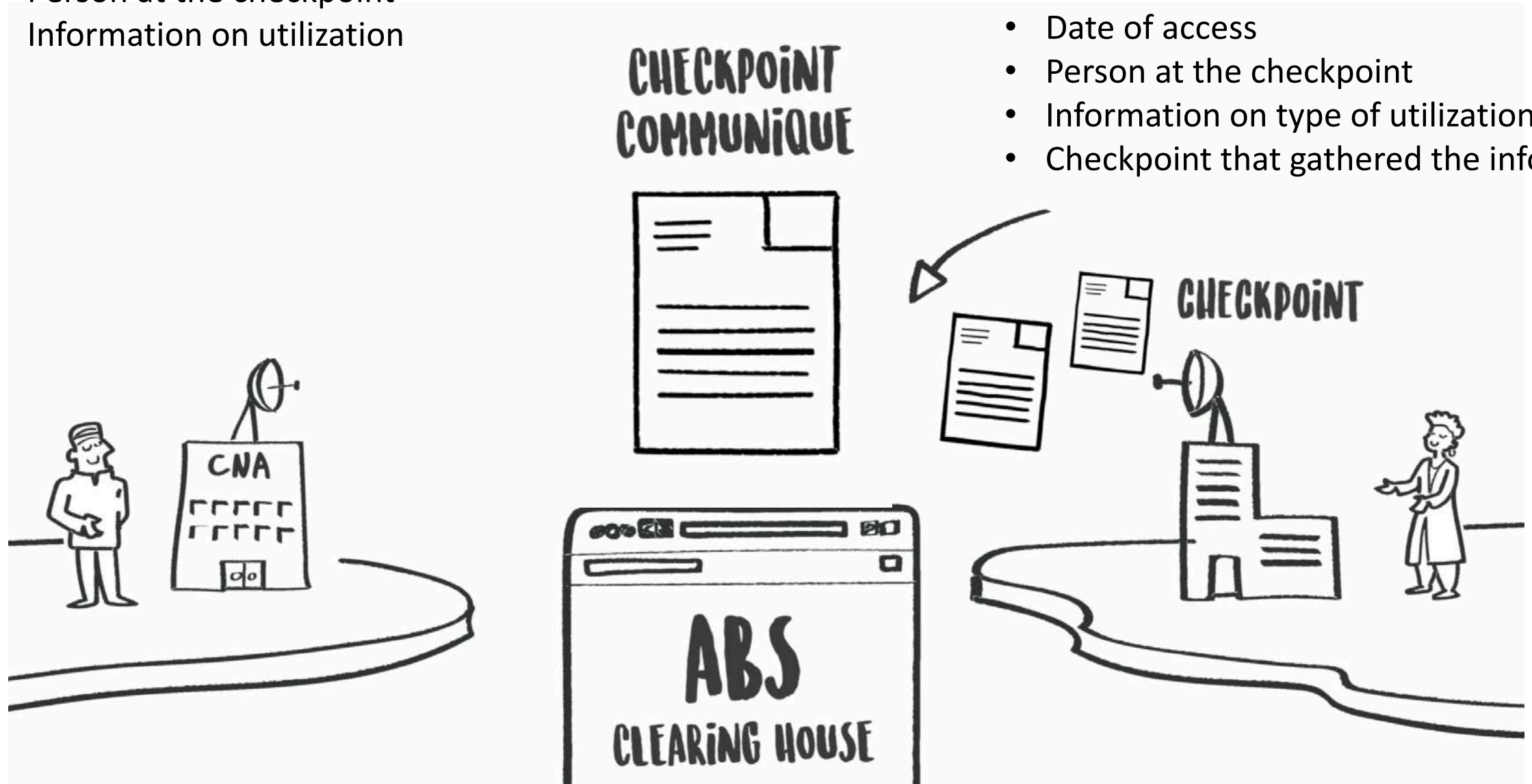
Purpose: ✓ The information gathered is provided to the provider country and ABSCH (checkpoint communique)

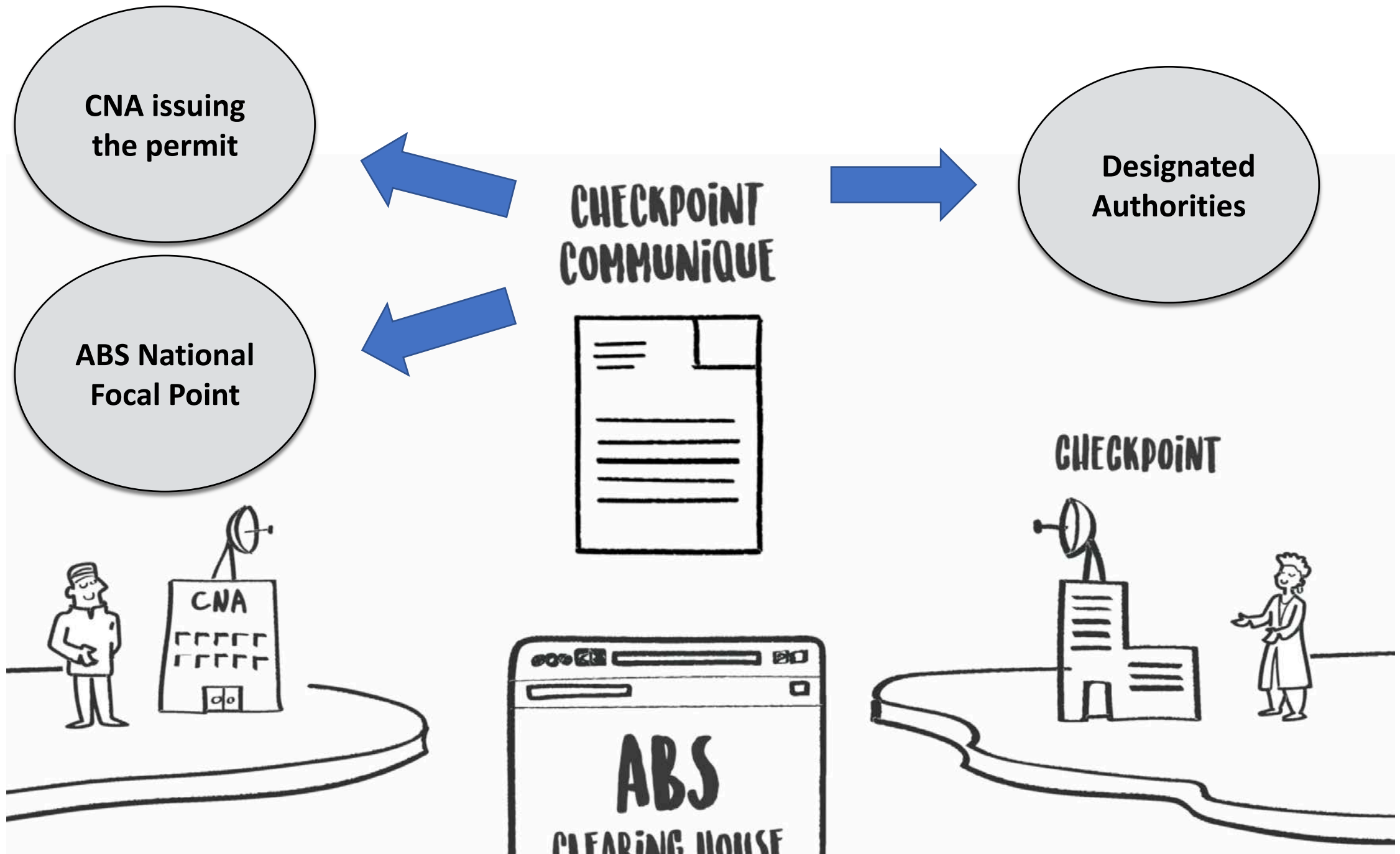
IF THE CERTIFICATE IS AVAILABLE

- Certificate unique ID
- Checkpoint gathering the information
- Person at the checkpoint
- Information on utilization

IF THE CERTIFICATE IS NOT AVAILABLE

- Source
- Subject matter
- Proof of PIC and MAT
- Date of access
- Person at the checkpoint
- Information on type of utilization
- Checkpoint that gathered the info



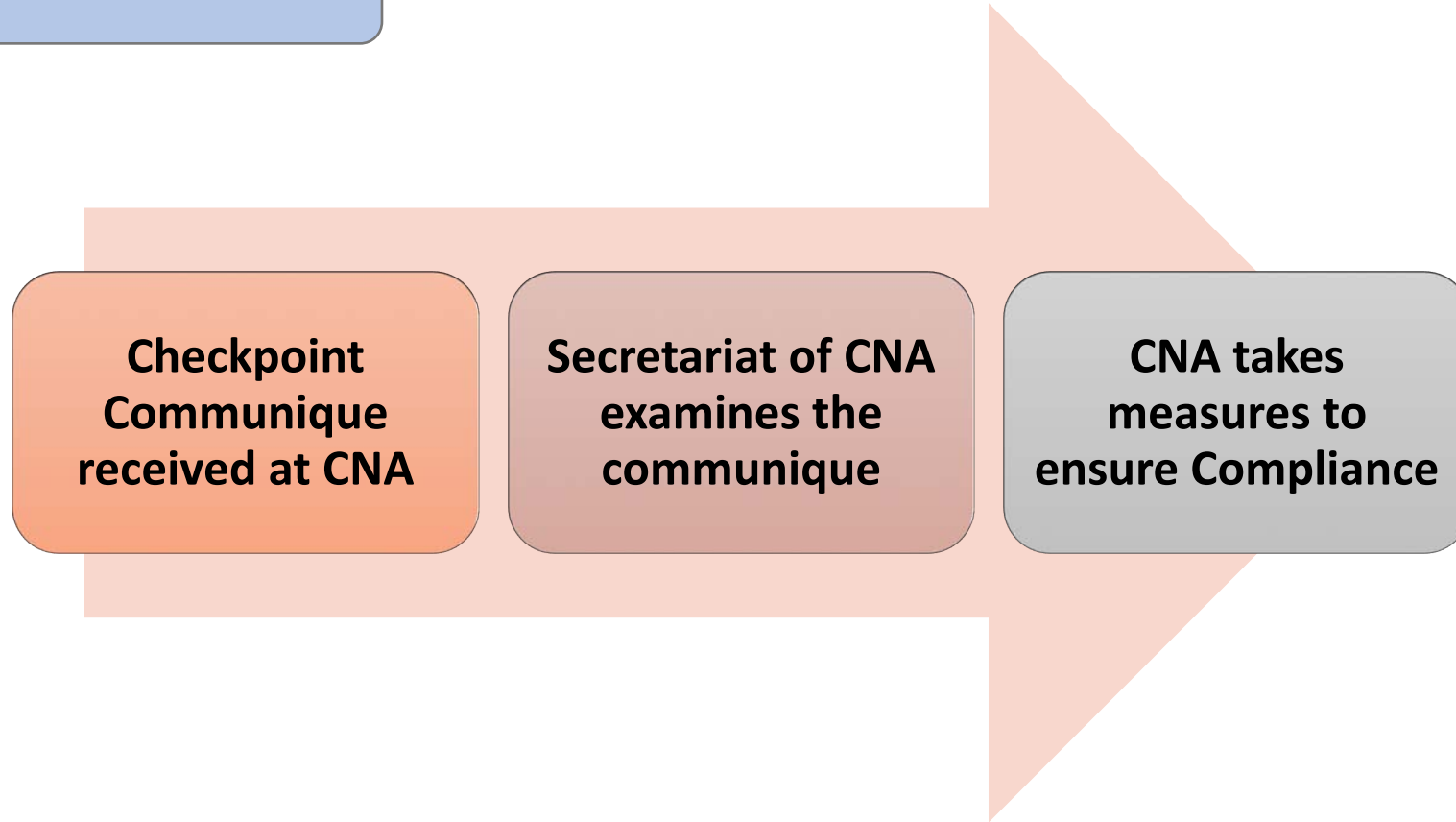


Compliance

1. Describe the (envisioned) process how checkpoint communiqués from ABS Clearing-House will be received and addressed?

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Envisioned Process



1. Describe the (envisioned) process how checkpoint communiqués from ABS Clearing-House will be received and addressed?

- No CPCs will be received by German authorities as no access requirements exist
- However, after receiving a CPC provider state can trigger internat. collaboration:
 - Provider state needs to check whether info in CPC matches any PIC/MAT granted before or not
 - If not, provider state authority may contact BfN & inform about substantiated concerns
 - Such substantiated concerns can trigger compliance check by BfN

In the first communiqué sent to South Africa
can you please explain your experience?



1. Describe the (envisioned) process how checkpoint communiqués from ABS Clearing-House will be received and addressed?

- Once a Checkpoint Communiqué is received, the Competent National Authority will study the content of the communiqué and engage with the designated Checkpoint that generated the communiqué, if clarity or more information is required.
- Once all the information is received, the Competent National Authority will decide if there is a need to refer the matter to the unit responsible for Biodiversity Compliance Monitoring and Law Enforcement for further action.

In the first communiqué sent by Germany
can you please explain your experience?

Countries who have received the CPC issued by the checkpoint of another country:

South Africa, Uganda, Kenya, Peru, Spain, Lao PDR, Vietnam, France, Malawi,

So what happened once you received the communiqué?

Countries that have issued CPC to themselves: Malta, Qatar

What do you think?

1. Describe the (envisioned) process how checkpoint communiqués from ABS Clearing-House will be received and addressed?

-
- Currently IRCC's are sent through the intermediate of the publishing authority.

Note: We still only received two (and they lack information, so first step will be to get them finalized)

Please explain the next steps to finalize them?

Compliance

2. What measures does your country take to ensure users under its jurisdiction are in compliance with ABS requirements from provider countries?

Compliance with domestic legislation activity

Stand up if you have measures in place to implement Article 15 of the Protocol

Do you ensure users under its jurisdiction are in compliance with ABS requirements from provider countries?

- **Yes** - keep standing **No** - sit back down

For your own GR?

- **Yes** - keep standing **No** - sit back down

For GR from other provider countries

- **Yes** - keep standing **No** - sit back down



2. What measures does your country take to ensure users under its jurisdiction are in compliance with ABS requirements from provider countries?

- Visits to companies checks preparedness for fulfilment of due diligence
- Talks at stakeholder association meetings
- Yearly «user» conferences with possibility to ask questions
- informal thematic discussions on open questions for implementation
- Help desk answers questions from users by mail and phone

2. What measures does your country take to ensure users under its jurisdiction are in compliance with ABS requirements from provider countries?

- Checks on user compliance (Art. 9 of the EU ABS Regulation)
 - Carried out by Member States
 - Risk-based approach
 - Surveys on users of GR/ TKaGR
 - Awareness-raising as part of the plans
 - Taking into account application of best practice
- Rules on penalties – established at Member State level (Article 11 of the EU ABS Regulation)

2. What measures does your country take to ensure users under its jurisdiction are in compliance with ABS requirements from provider countries?

-
- The Netherlands have implemented the Nagoya Protocol in a special Act. High penalties can apply (max 6 years imprisonment).
 - A survey was made to identify user groups in 2014
 - A target group and risk analysis was made in 2017 as basis for an enforcement strategy.
 - Inspectors have been trained (ongoing)
 - The NVWA are actively carrying out inspections on users since 2017. We started with inspections on the spot, but are now experimenting with digital (remote) inspections, sometimes followed up by a physical inspection.

Compliance

3. Please describe a situation (hypothetical or real) outlining how your country might deal with an issue of non-compliance?



3. Please describe a situation (hypothetical or real) outlining how your country might deal with an issue of non-compliance?

A person convicted of any offence in terms of ABS legislation is liable to :

- Imprisonment not exceeding 5 years
- 10 years for second offences
- Fine not exceeding R5-million
- R10-million for second offences
- Both fine and imprisonment



3. Please describe a situation (hypothetical or real) outlining how your country might deal with an issue of non-compliance?

Cases of non-compliance, identified as a result of the user check, are subject to a financial penalty determined by a decision of the regional inspector competent for the place of residence or the site of the user, or the place of conducting operations related to the utilization of genetic resources:

- For transfer or utilization of GR or TK related to GR without MAT or inconsistently therewith – from PLN 5000 to PLN 100 000 (*1 USD = 3,9 PLN*)
- For failing to seek, keep and transfer to subsequent users information and documents referring to the material or for failing to keep the information relevant to access and benefit sharing for twenty years after the end of the period of utilization - from PLN 1000 to PLN 100 000.
- For utilization of GR despite failure to obtain an access permit or its equivalent and to establish mutually agreed terms - from PLN 10 000 to PLN 200 000.
- For failing to submit a DDD when applying for financing the research - from PLN 1000 to PLN 20 000.
- For failing to submit a DDD or the information from IRCC at the final stage of product development - from PLN 5000 to PLN 100 000.

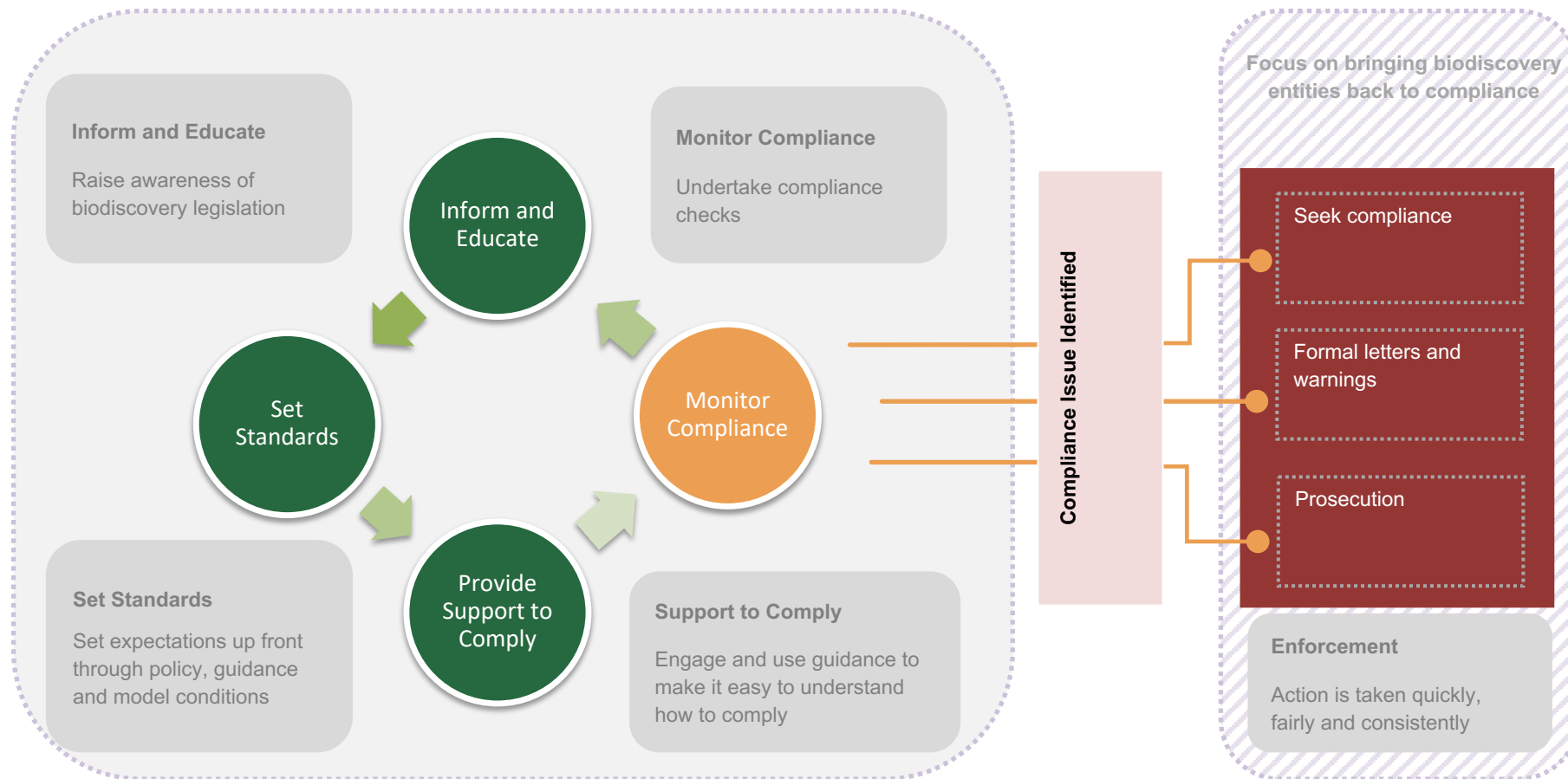
What other things can we do before we
send the user to jail?

3. Please describe a situation (hypothetical or real) outlining how your country might deal with an issue of non-compliance?
-

We would first determine what approach the Provider country focal point would like us to take ranging from seizure and repatriation of the resource, attempting to re-negotiate on behalf of the provider or to open a line of communication with the focal point of the Provider country and the user.

3. Please describe a situation (hypothetical or real) outlining how your country might deal with an issue of non-compliance?

- The Queensland Department of Environment and Science has developed a Regulatory Strategy and Enforcement Guidelines to ensure it takes an appropriate, proportionate and repeatable approach to issues of non-compliance



3. Please describe a situation (hypothetical or real) outlining how your country might deal with an issue of non-compliance?

- **CNA undertakes compliance check**
 - Triggered by risk-based plan or
 - Substantiated concerns
- **Check leads to CNA assumption of a situation of non-compliance**
 - CNA requests user to show relevant documents (PIC/MAT)
- **If no relevant documentation provided**
 - **Reactive measures are taken**
 - User asked to remedy non-compliance (get PIC/MAT)
 - Prohibition to further utilize until successful remedy
 - Seizure, confiscation if remedy unsuccessful
 - **Due diligence violation is sanctioned**
 - Regulatory fine up to 50.000 €
 - Regulatory fine may exceed financial benefit that perpetrator has obtained (i.e. 50.000 € may be exceeded, in principle ad infinitum)
 - **NFP / CNA of provider state is informed**

Provider countries – How many of you have the possibility to bring a non-compliant user back into compliance?

3. Please describe a situation (hypothetical or real) outlining how your country might deal with an issue of non-compliance?

- The enforcement strategy is primarily focused on remedial action (Administrative law). For example, if a document is missing, the user will get a reasonable period for getting the document. If this is not possible, but the document is needed, the user can be summoned to stop the use. The Minister can take immediate interim measures to enforce this.
- Serious offences will be forwarded to the prosecutor (Criminal law). Max 6 years imprisonment.
- There have not been cases of non-compliance yet.

3. Please describe a situation (hypothetical or real) outlining how your country might deal with an issue of non-compliance?



- Education
- Informal Warning
- Enforcement undertaking
- Compliance / Enforcement / Stop Notice
- Formal Caution
- Fines
- Product withdrawal / Seizure
- Court Action
- **Publicity**

Bad publicity is the worst

3. Please describe a situation (hypothetical or real) outlining how your country might deal with an issue of non-compliance?

- User A takes plant species for scientific research . Checkpoint in User country (research and development) reports non-compliance. Seychelles as provider country contacted through checkpoint communique . Seizure of materials by CNA in user country, return of GR to provider country followed by legal action.

Please explain.



3. Please **describe a situation (hypothetical or real)** outlining how your country might deal with an issue of non-compliance?

- ✓ **Use** the MAT standard terms for Non-Compliance Cases
- ✓ **Apply** Administrative Sanctions
- ✓ **Execution** of the Bond
- ✓ **Notify** the ABS CH



How will you notify the ABSCH on cases of non-compliance?



Compliance

4. Please reflect on your experience regarding compliance (Articles 15 & 16). What are some of your biggest challenges, primary concerns, important questions or greatest accomplishments?

4. Please reflect on your experience regarding compliance (Articles 15 & 16). What are some of your biggest challenges, primary concerns, important questions or greatest accomplishments?

- On the ground checks carried out by the Member States
- EU most advanced in implementation
 - Still – delays in setting up institutional and administrative framework in the MS (infringement action)
 - Early days of implementation:
 - (almost) all MS set up institutional framework
 - not all MS yet carry out checks
- Main challenges (as identified in the Implementation Report, prepared by EC, 2018):
 - Low level of awareness about ABS
 - Users complain about complexity of the system and unclear wording of the obligations
 - Technical file – challenging also for authorities

4. Please reflect on your experience regarding compliance (Articles 15 & 16). What are some of your biggest challenges, primary concerns, important questions or greatest accomplishments?

Main challenge: Identifying potential users – easier for some sectors than others

Main concern: Users report spending a long time chasing up provider countries for details of access measures with little response or clarity – it can delay, restrict or prevent important research. Both users and providers miss out on potential benefits.

Important questions: Issues around scope. Practicalities of inspections. What's to stop users lying about the point of access?

Accomplishments: Our awareness raising and user engagement. User feedback shows increased level of engagement, urgency to develop internal procedures and feeling of “empowerment” (actual quote) rather than being worried about the legislation



4. Please reflect on your experience regarding compliance (Articles 15 & 16). What are some of your biggest challenges, primary concerns, important questions or greatest accomplishments?

-
- Identifying “users” is a challenge.
 - We found that companies/institutions try to comply, but are at the moment risk-avoiding and try not to use genetic resources where access rules apply.
 - Companies fear the administrative burden, but are implementing Nagoya Protocol in their administration.
 - Not getting replies from National Focal Points of provider countries is frustrating users that are trying to comply.
 - Awareness raising first, but carrying out inspections is an important incentive for users to really start implementing the Nagoya Protocol.
 - Implemented new inspection method: digital inspection. Users get an online questionnaire that they are obliged to fill in. This way they have to demonstrate if they are user / no user, what kind of genetic resources, from which countries, how they fulfill their due diligence obligations. Can be followed by a physical inspection. Small group of specialized inspectors and keeping them up-to-date is a challenge.

Compliance

5. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to compliance (Articles 15 & 16)

Compliance



STORY
TIME!

The logo for 'STORY TIME!' features the word 'STORY' in the top row and 'TIME!' in the bottom row. The letter 'O' in 'STORY' is replaced by a yellow clock face with black hands. Each letter is a different color: 'S' is teal, 'T' is pink, 'O' is yellow, 'R' is red, 'Y' is blue, 'T' is orange, 'I' is green, 'M' is purple, 'E' is orange, and the exclamation mark is teal.

in 3 minutes or less



5. Please share a **very interesting real-life story, funny anecdote, amazing case or marvelous example related to compliance (Articles 15 & 16)**

What can we say? Let's just say that getting investigators to comply with legislation requirements has been a tough challenge, full of all types of surprises



5. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to compliance (Articles 15 & 16)

- 1st checkpoint communique published did not include the necessary information about the user...! (not set up in the system properly, despite multiple tests run before)

5. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to compliance (Articles 15 & 16)
-

No matter who runs the workshop, leads a meeting, or gives the presentation, all businesses, without fail, send their enquiries to Katie. Never Rob.



5. Please share a very interesting real-life story, funny anecdote, amazing case or marvelous example related to compliance (Articles 15 & 16)

We think this means that everything will contribute to conservation and sustainable use.



credits

Monitoring Genetic Resources in

PERU

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Monitoring Genetic Resources: What happens in The Dominican Republic?

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Monitoring of genetic resources in



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Monitoring Genetic Resources in INDIA

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Thank you