



The implementation of the Nagoya Protocol within surveillance activities

MediLab Secure project – Dakar meeting

- Cindy Dias Vilela
- 22/01/2020

Summary

01

—
Part 1

Presentation of the overall context

02

—
Part 2

Ground principles of the Nagoya
Protocol

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Part 3

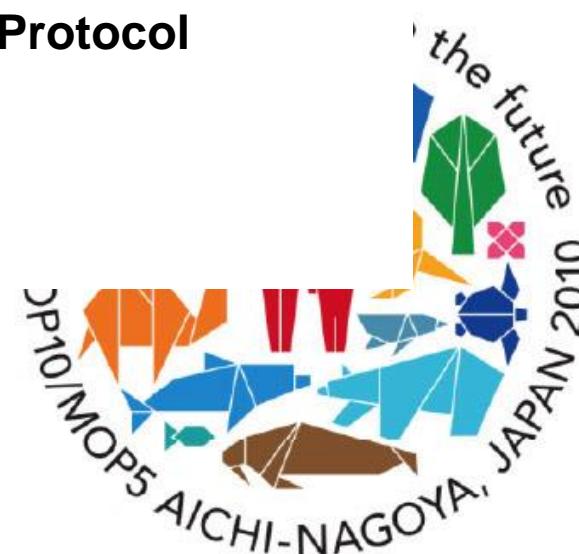
Practical case: surveillance activities





Part 1

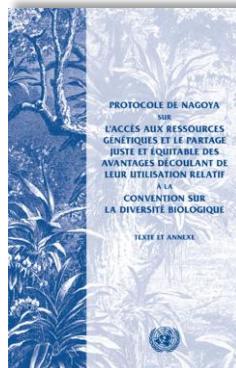
Introduction to the Nagoya Protocol



What is the Nagoya Protocol?

Any material of plant, animal, microbial or other origin containing functional units of heredity

GENETIC RESOURCES



RESEARCH & DEVELOPMENT

Fundamental research
Applied research
Commercial development

Where do surveillance activities stand?

DIAGNOSTIC

SURVEILLANCE
ACTIVITIES

R&D



No international consensus
– depends on the country

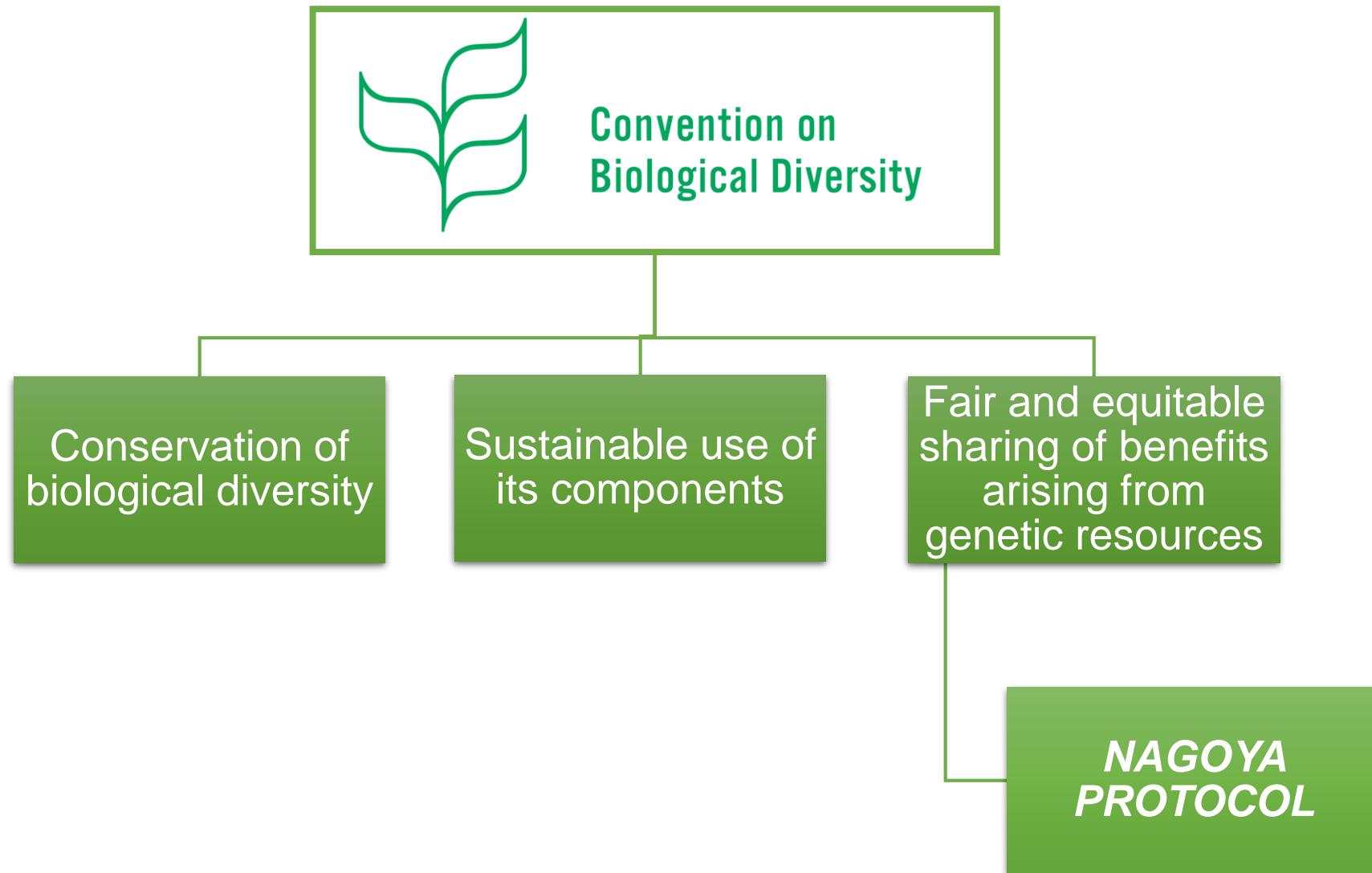
WHO surveys on the
question

Special regime in France



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Why has the Nagoya Protocol been adopted?



Why has the Nagoya Protocol been adopted?

MAIN GOAL

**TO FIGHT AGAINST
BIOPIRACY**



PRINCIPLE

Sovereignty of States over the genetic resources within their territories

CONSEQUENCES



ACCESS REQUEST TO GENETIC RESOURCES



BENEFIT-SHARING

IMPACT ON THE COLLECTION, TRANSFER AND USE OF YOUR SAMPLES



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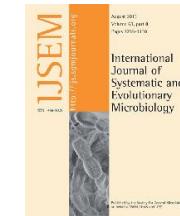
Application to all of your activities

FUNDINGS



Horizon 2020
European Union Funding
for Research & Innovation

PUBLICATIONS



PATENTS



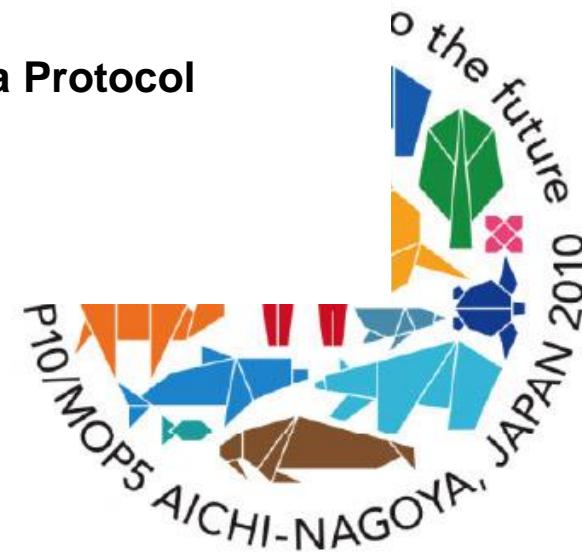
FUTURE COMMERCIAL APPLICATIONS





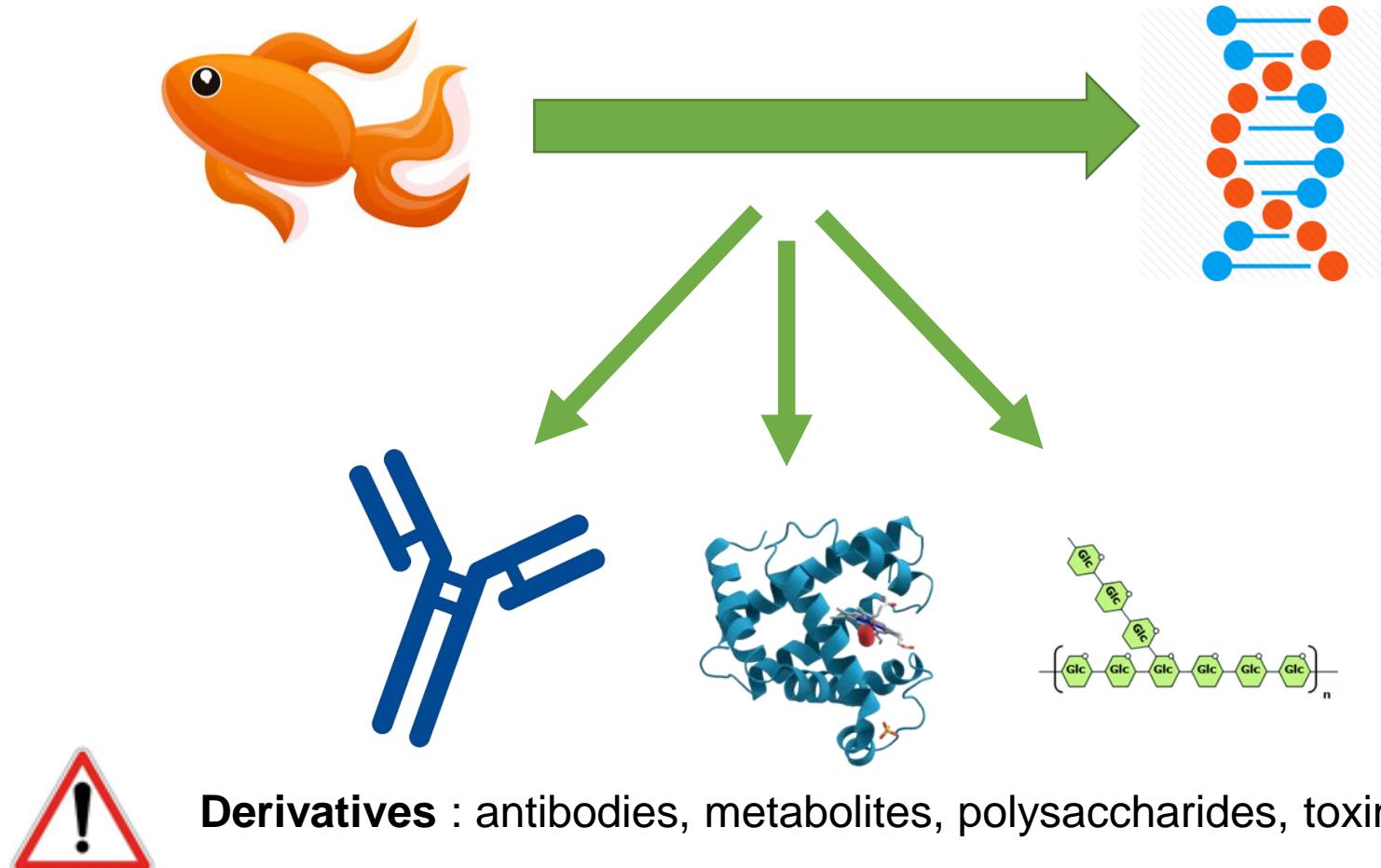
Part 2

Ground principles of the Nagoya Protocol



1/4 – Genetic resources

Broad scope: **any biological material as a whole or any part of it (e.g. DNA)**



Exclusions: human samples, PIP Framework, international waters...



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1/4 – Associated Traditional Knowledge



Indigenous and local communities

Traditional way of life

Relevance for the
conservation and
sustainable use of
biological diversity



2/4 – Country of origin's rules application



[<https://absch.cbd.int/>]



THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE

The Access and Benefit-Sharing Clearing-House (ABSCH) is a platform for exchanging information on ABSCH and a key tool for facilitating the implementation of the Nagoya Protocol. [1](#)

EU

Argentina

JS map by amCharts Disclaimer

120 Parties to the Nagoya Protocol

3 Ratified, not yet Party [1](#)

78 Non-Parties

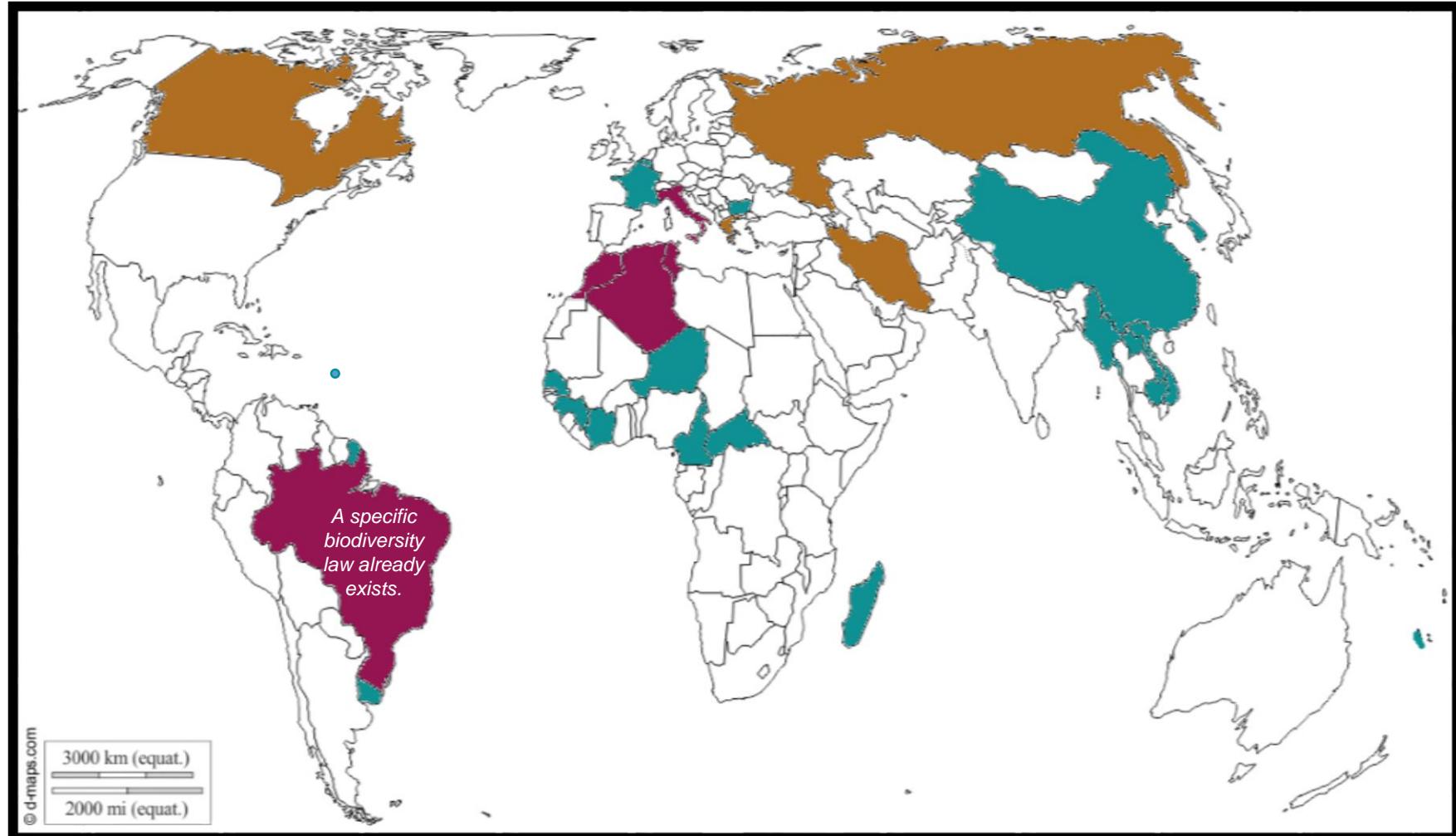
Argentina

- Party to the Nagoya Protocol
- 1 ABS National Focal Point
- 1 Competent National Authority
- 0 Legislative, Administrative or Policy Measure
- 0 ABS Procedure
- 0 National Model Contractual Clause
- 0 Internationally Recognized Certificates of Compliance
- 0 National Websites or Databases



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2/4 – The Nagoya Protocol within the RIIP



PARTY

Nagoya Protocol applies!

SIGNED

Nagoya Protocol will soon apply!

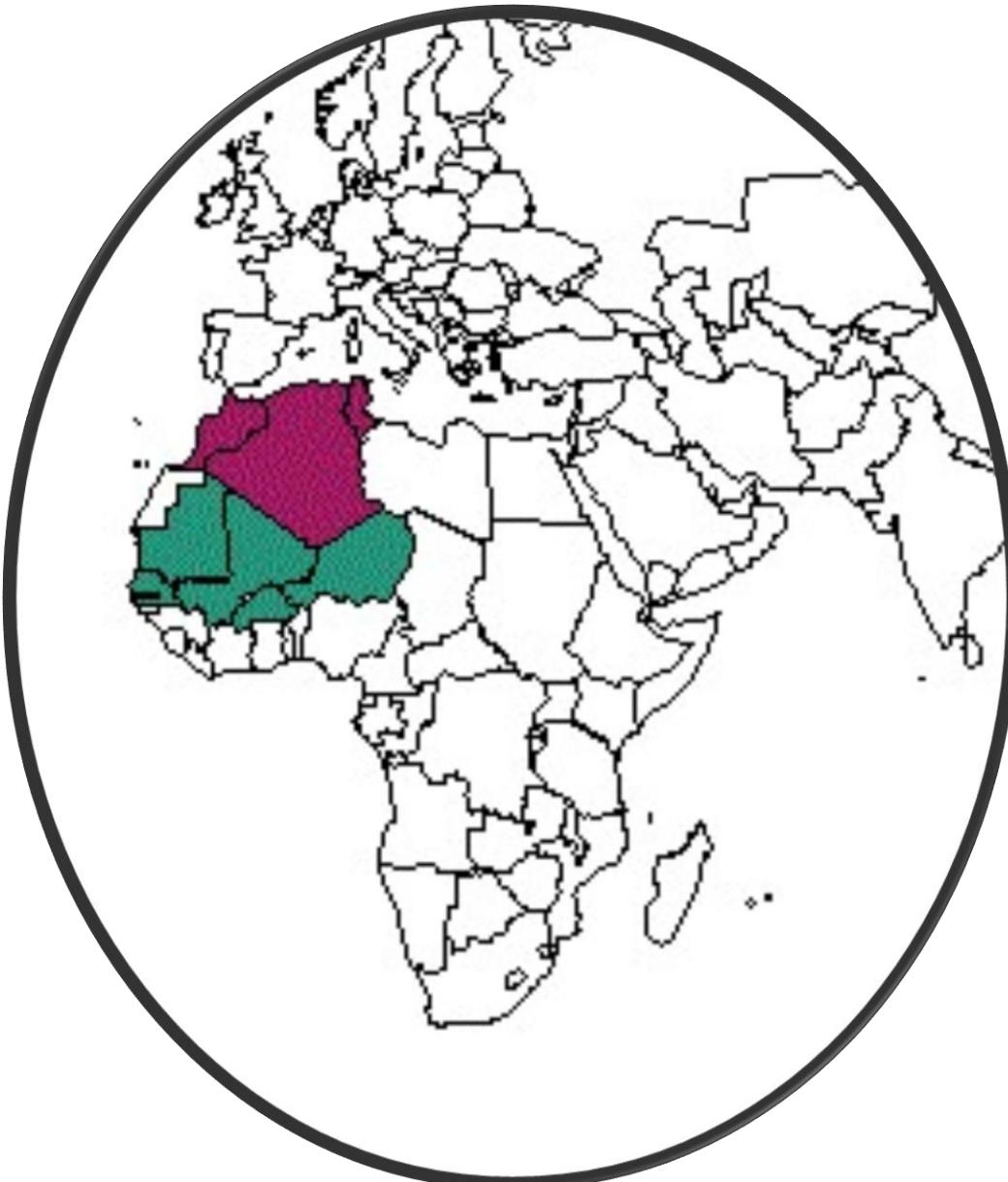
NOT PARTY

Nagoya Protocol does not apply!



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2/4 – The Nagoya Protocol within MediLab Secure



P A R T Y

Nagoya Protocol applies!

S I G N E D

Nagoya Protocol will soon apply!



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2/4 – The Nagoya Protocol within MediLab Secure

| COUNTRY | STATUS | ENTRY INTO FORCE | NATIONAL FOCAL POINT |
|---------------|---|-------------------|--|
| Senegal | Bill | June 1, 2016 | M. Babacar Ngor Youm (Directeur adjoint) Direction des Parcs Nationaux Ministère de l'environnement et du développement durable B.P. 4055 Dakar bacaryoum@yahoo.fr ; youmbaba@yahoo.fr ; +221 33 859 14 40 |
| Mauritania | Existing texts, but no specific measure | November 16, 2015 | M. Moussa Ba (Conseiller Juridique) Ministère de l'Environnement et du Développement Durable Rue 21-185 - No 838 – Ksar Nouakchott bamouss14@gmail.com ; +222 46 01 31 31; +222 27 31 09 52 |
| Mali | N/A | November 29, 2016 | M. Thièman Drame (Ingénieur) Direction Nationale des eaux et forêts Ministère de l'Environnement, de l'assainissement et du développement durable B.P. 275 Bamako vieuxthiemdrame@yahoo.fr ; thiemdrame@gmail.com ; +223 20 23 36 95 +223 20 23 36 97 |
| Burkina Fasso | Law on phylogenetic resources for food and agriculture (2019) | October 12, 2014 | M. Daogo Léon Ouoba Secrétariat Permanent du Conseil National pour le Développement Durable Ministère de l'environnement de l'économie verte et du changement climatique 01 BP 6486 Ouagadougou daogoleon@yahoo.fr ; +70 65 02 49 |
| Niger | No measure | October 12, 2014 | Mr. Boukar Attari (Conseiller) Conseil National de l'Environnement pour un Développement Durable (CNEDD) B.P. 10 193 Niamey biocnedd@intnet.ne ; attariboukar@yahoo.fr ; +227 20 72 25 59 |

PARTY

Nagoya Protocol applies!



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2/4 – The Nagoya Protocol within MediLab Secure

| COUNTRY | STATUS | ENTRY INTO FORCE | NATIONAL FOCAL POINT |
|---------|--------------|------------------|---|
| Tunisia | Bill | N/A | M. Abdelhakim Issaoui Direction Générale de l'Environnement et de la Qualité de la Vie Ministère des Affaires Locales et de l'Environnement Boulevard de la Terre Centre Urbain Nord 1080 Cedex Tunis hakissaoui@yahoo.fr +216 70 728 493 +216 9890 5322 |
| Algeria | N/A | N/A | Melle Assia Azzi Sous-directrice, Gestion et police forestière Direction Générale des Forêts Ministere de l'Agriculture et du Developpement Rural Chemin Doudou Mokhtar Ben Aknoun Alger azziassia@yahoo.fr +213 560 94 42 32 |
| Morocco | Bill n°56-17 | N/A | M. Mohammed Mehdi Chef du Service de la Prévention des Risques Biotechnologiques Direction du Changement Climatique, de la Diversité Biologique et de l'Économie Verte Secrétariat d'Etat Chargé du Développement Durable 9, Avenue Al Araar, Section 16 Hay Ryad 10100 Rabat mehdi.s3e@gmail.com +212 6 73 08 23 17 |

S I G N E D

Nagoya Protocol will soon apply!



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3/4 – Date of genetic resources collection



Website

[<https://www.cbd.int/abs/nagoya-protocol/signatories/>]

Date to remember:
October 12th 2014



Nagoya Protocol

About the Nagoya Protocol

Nagoya Protocol Text

History

Parties

Becoming a Party

List of Parties

National information - country profiles

Key Steps towards implementation

Key Protocol issues

ABS Clearing-House

Assessment and review

Awareness-raising

Capacity-building and development

Compliance with the Protocol

Cooperation

> Access and Benefit-sharing > Parties > Signatories

Parties to the Nagoya Protocol

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization was adopted by the Conference of the Parties to the Convention on Biological Diversity at its tenth meeting on 29 October 2010 in Nagoya, Japan. In accordance with its Article 32, the Protocol was opened for signature from 2 February 2011 to 1 February 2012 at the United Nations Headquarters in New York by Parties to the Convention. The Protocol entered into force on 12 October 2014.

The list below provides information on date of signature and the status of ratification, acceptance, approval or accession. Visit also the country profiles and national information available in the ABS-Clearing-House

Nagoya Protocol on Access and Benefit-sharing : 112 Parties (116 Ratifications) (92 Signatures)

* Note : rtf = Ratification, acs = Accession, acp = Acceptance, apv = Approval, scs = Succession

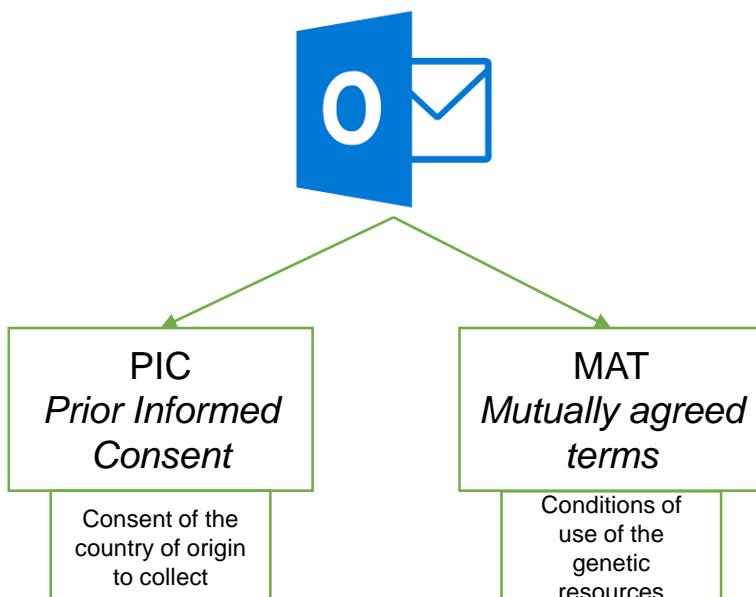
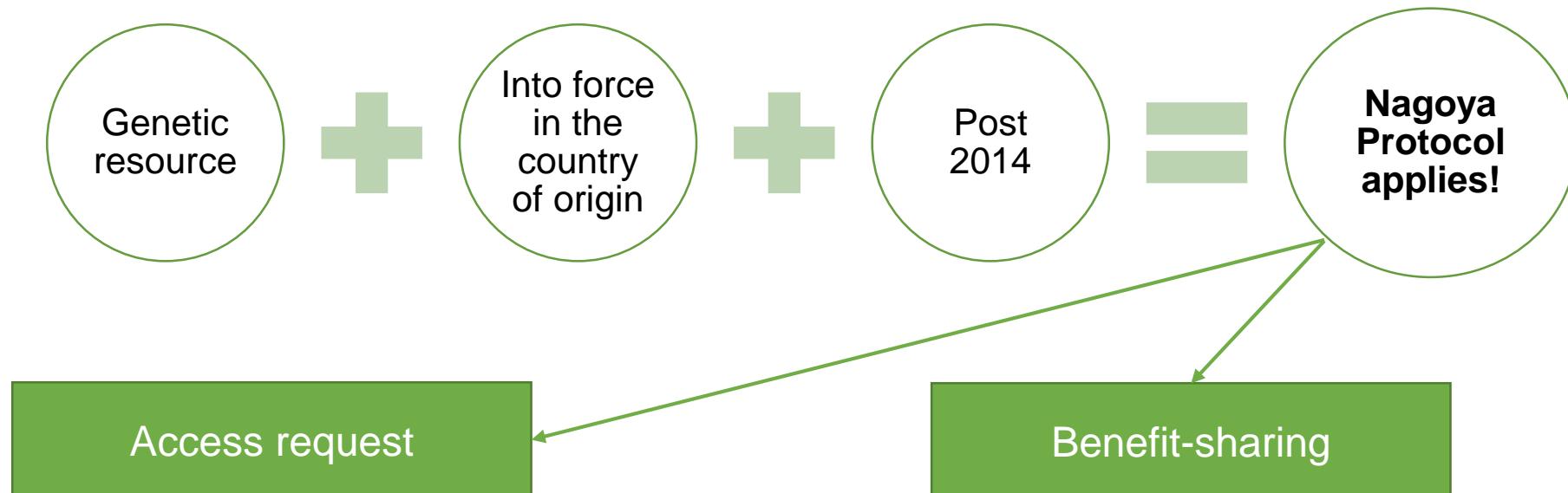
| No. | Country Name | Signed | Ratification | Party |
|------|------------------------------------|------------|--------------|-------|
| 1. | Afghanistan | | 2018-06-06 | acs |
| 2. | Albania | | 2013-01-29 | acs |
| 3. | Angola | | 2017-02-06 | acs |
| 4. | Antigua and Barbuda | 2011-07-28 | 2016-12-12 | rtf |
| 5. | Argentina | 2011-11-15 | 2016-12-09 | rtf |
| 6. | Austria | 2011-06-23 | 2018-07-20 | rtf |
| 7. | Belarus | | 2014-06-26 | acs |
| 8. | Belgium | 2011-09-20 | 2016-08-09 | rtf |
| 9. | Benin | 2011-10-28 | 2014-01-22 | rtf |
| 10. | Bhutan | 2011-09-20 | 2013-09-30 | rtf |
| 11. | Bolivia (Plurinational State of) | | 2016-10-06 | acs |
| 106. | United Republic of Tanzania | | 2018-01-19 | acs |
| 107. | Uruguay | 2011-07-19 | 2014-07-14 | rtf |
| 108. | Vanuatu | 2011-11-18 | 2014-07-01 | rtf |
| 109. | Venezuela (Bolivarian Republic of) | | 2018-10-10 | acs |
| 110. | Viet Nam | | 2014-04-23 | acs |
| 111. | Zambia | 2016-05-20 | 2016-08-18 | acs |
| 112. | Zimbabwe | | 2017-09-01 | acs |
| | Algeria | 2011-02-02 | | |
| | Andorra | | | |
| | Armenia | | | |
| | Australia | 2012-01-20 | | |
| | Azerbaijan | | | |
| | Bahamas | | | |
| | Bahrain | | | |
| | Bangladesh | 2011-09-06 | | |
| | Barbados | | | |
| | Belize | | | |
| | Bosnia and Herzegovina | | | |
| | Brazil | 2011-02-02 | | |
| | Brunei Darussalam | | | |
| | Cabo Verde | 2011-09-26 | | |
| | Canada | | | |

DATE OF
ENTRY INTO
FORCE OF
THE
PROTOCOL
IN EACH
PARTY



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4/4 – Access request and benefit-sharing



| Monetary | Non-monetary |
|--|---|
| <ul style="list-style-type: none">➤ Access fees/fee per sample collected or otherwise acquired➤ Up-front payments ; Milestone payments; Payment of royalties➤ Licence fees in case of commercialization➤ Research funding➤ Joint ownership of relevant intellectual property rights. | <ul style="list-style-type: none">➤ Sharing of research and development results➤ Collaboration and contribution in scientific research and development programs➤ Collaboration, cooperation and contribution in education and training;➤ Strengthening capacities for technology transfer;➤ Institutional capacity-building |



4/4 – Traceability is key!

Annexe X – Informations relatives à l'accès au Matériel et au partage des avantages découlant de son utilisation

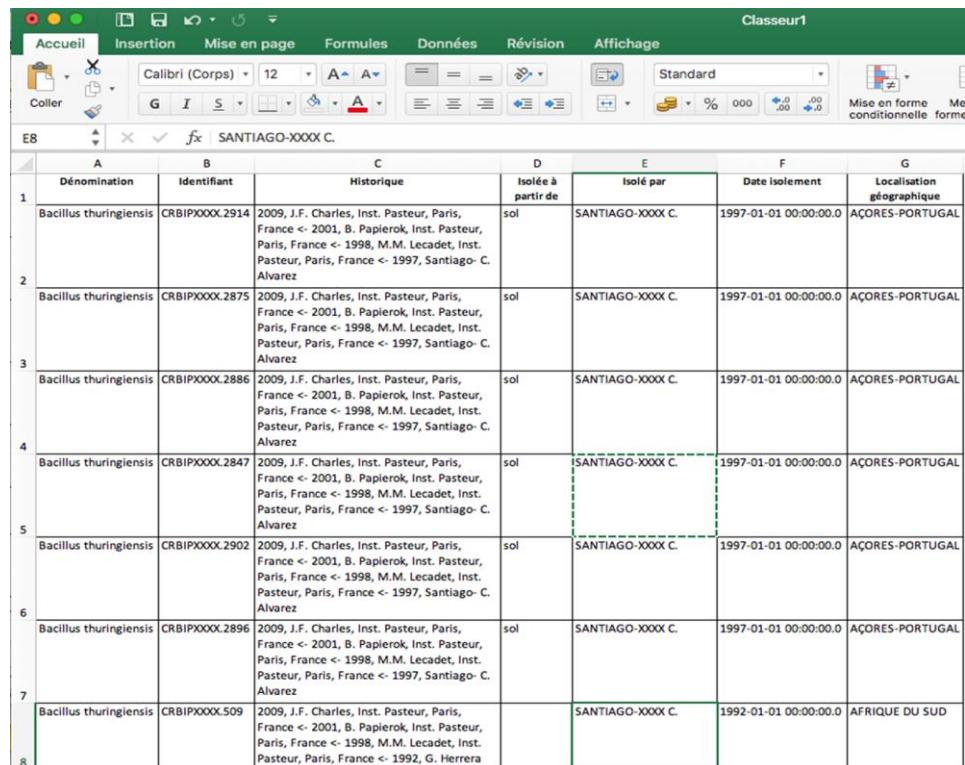
Matériel: XXX

1. Information de diligence nécessaire

| | |
|---|------------------------------|
| Pays de collecte initiale du Matériel : | Année de collecte initiale : |
|---|------------------------------|

2. Autorisation d'accès et conditions d'utilisation

| Autorisation du pays d'origine à accéder au Matériel | <input type="checkbox"/> Non | <input type="checkbox"/> Oui | Autorité ayant délivré l'autorisation : |
|--|------------------------------|--|--|
| | NA | Autorisation | <input type="checkbox"/> IRCC (<i>International Recognized Certificates of Compliance</i>) <input type="checkbox"/> PIC (<i>Prior Informed Consent</i>) <input type="checkbox"/> Autre: XXX Date de délivrance : Référence : |
| | NA | Conditions d'utilisation | Champ d'utilisation autorisé (ex.: utilisation commerciale) : Autorisation de transfert (ex.: droit au transfert à un tiers) : |
| | NA | Conditions convenus d'un commun accord (MAT) | <input type="checkbox"/> Oui <input type="checkbox"/> Non Date de délivrance : Conditions et modalités du partage des avantages (ex.: type de partage des avantages) : |



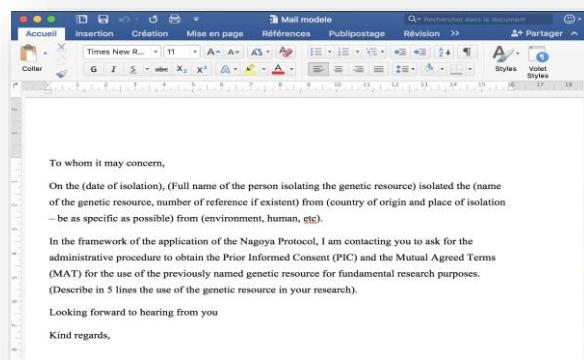
| A | B | C | Historique | | E | F | G |
|---|------------------------|----------------|---|-----|------------------|-----------------------|---------------------------|
| | Dénomination | Identifiant | Historique | | Isolé par | Date isolement | Localisation géographique |
| 1 | Bacillus thuringiensis | CRBIPXXXX.2914 | 2009, J.F. Charles, Inst. Pasteur, Paris, France <- 2001, B. Papierok, Inst. Pasteur, Paris, France <- 1998, M.M. Lecadet, Inst. Pasteur, Paris, France <- 1997, Santiago- C. Alvarez | sol | SANTIAGO-XXXX C. | 1997-01-01 00:00:00.0 | AÇORES-PORTUGAL |
| 2 | Bacillus thuringiensis | CRBIPXXXX.2875 | 2009, J.F. Charles, Inst. Pasteur, Paris, France <- 2001, B. Papierok, Inst. Pasteur, Paris, France <- 1998, M.M. Lecadet, Inst. Pasteur, Paris, France <- 1997, Santiago- C. Alvarez | sol | SANTIAGO-XXXX C. | 1997-01-01 00:00:00.0 | AÇORES-PORTUGAL |
| 3 | Bacillus thuringiensis | CRBIPXXXX.2886 | 2009, J.F. Charles, Inst. Pasteur, Paris, France <- 2001, B. Papierok, Inst. Pasteur, Paris, France <- 1998, M.M. Lecadet, Inst. Pasteur, Paris, France <- 1997, Santiago- C. Alvarez | sol | SANTIAGO-XXXX C. | 1997-01-01 00:00:00.0 | AÇORES-PORTUGAL |
| 4 | Bacillus thuringiensis | CRBIPXXXX.2847 | 2009, J.F. Charles, Inst. Pasteur, Paris, France <- 2001, B. Papierok, Inst. Pasteur, Paris, France <- 1998, M.M. Lecadet, Inst. Pasteur, Paris, France <- 1997, Santiago- C. Alvarez | sol | SANTIAGO-XXXX C. | 1997-01-01 00:00:00.0 | AÇORES-PORTUGAL |
| 5 | Bacillus thuringiensis | CRBIPXXXX.2902 | 2009, J.F. Charles, Inst. Pasteur, Paris, France <- 2001, B. Papierok, Inst. Pasteur, Paris, France <- 1998, M.M. Lecadet, Inst. Pasteur, Paris, France <- 1997, Santiago- C. Alvarez | sol | SANTIAGO-XXXX C. | 1997-01-01 00:00:00.0 | AÇORES-PORTUGAL |
| 6 | Bacillus thuringiensis | CRBIPXXXX.2896 | 2009, J.F. Charles, Inst. Pasteur, Paris, France <- 2001, B. Papierok, Inst. Pasteur, Paris, France <- 1998, M.M. Lecadet, Inst. Pasteur, Paris, France <- 1997, Santiago- C. Alvarez | sol | SANTIAGO-XXXX C. | 1997-01-01 00:00:00.0 | AÇORES-PORTUGAL |
| 7 | Bacillus thuringiensis | CRBIPXXXX.509 | 2009, J.F. Charles, Inst. Pasteur, Paris, France <- 2001, B. Papierok, Inst. Pasteur, Paris, France <- 1998, M.M. Lecadet, Inst. Pasteur, Paris, France <- 1992, G. Herrera | | SANTIAGO-XXXX C. | 1992-01-01 00:00:00.0 | AFRIQUE DU SUD |
| 8 | | | | | | | |

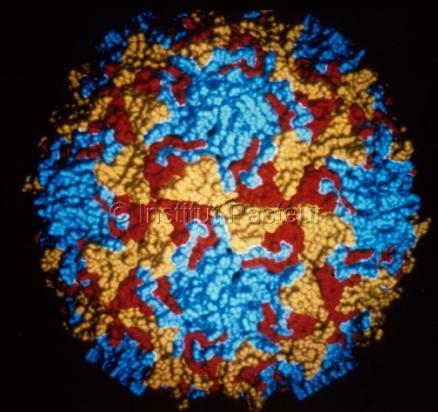
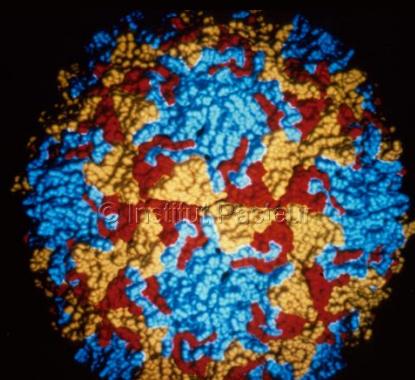
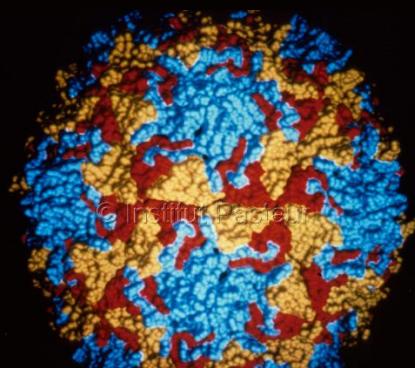
Track sheet Excel table Software



How to implement ABS requirements in my institution?

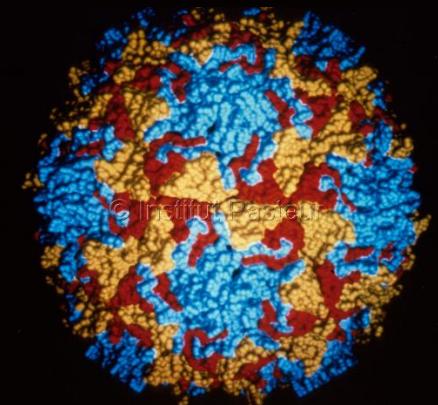
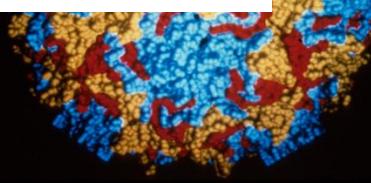
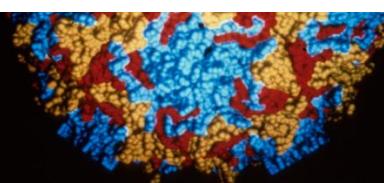
- Process - institution policy -
Sample management
- Access request email template
- Tracking sheet
- Contracts :
 - ✓ *Material Deposit Agreements*
 - ✓ *Material Transfer Agreements...*



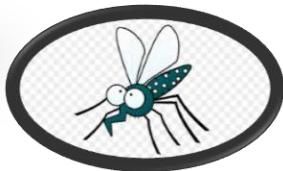


Part 3

Practical case: MediLab Secure project - surveillance activities



1/6 – Surveillance activities – R&D



Prospective collection of genetic resources

- Email to National Focal Point of the country of origin
- Mention of the surveillance objective
- Transfer to another lab (abroad)

Transfer of genetic resources

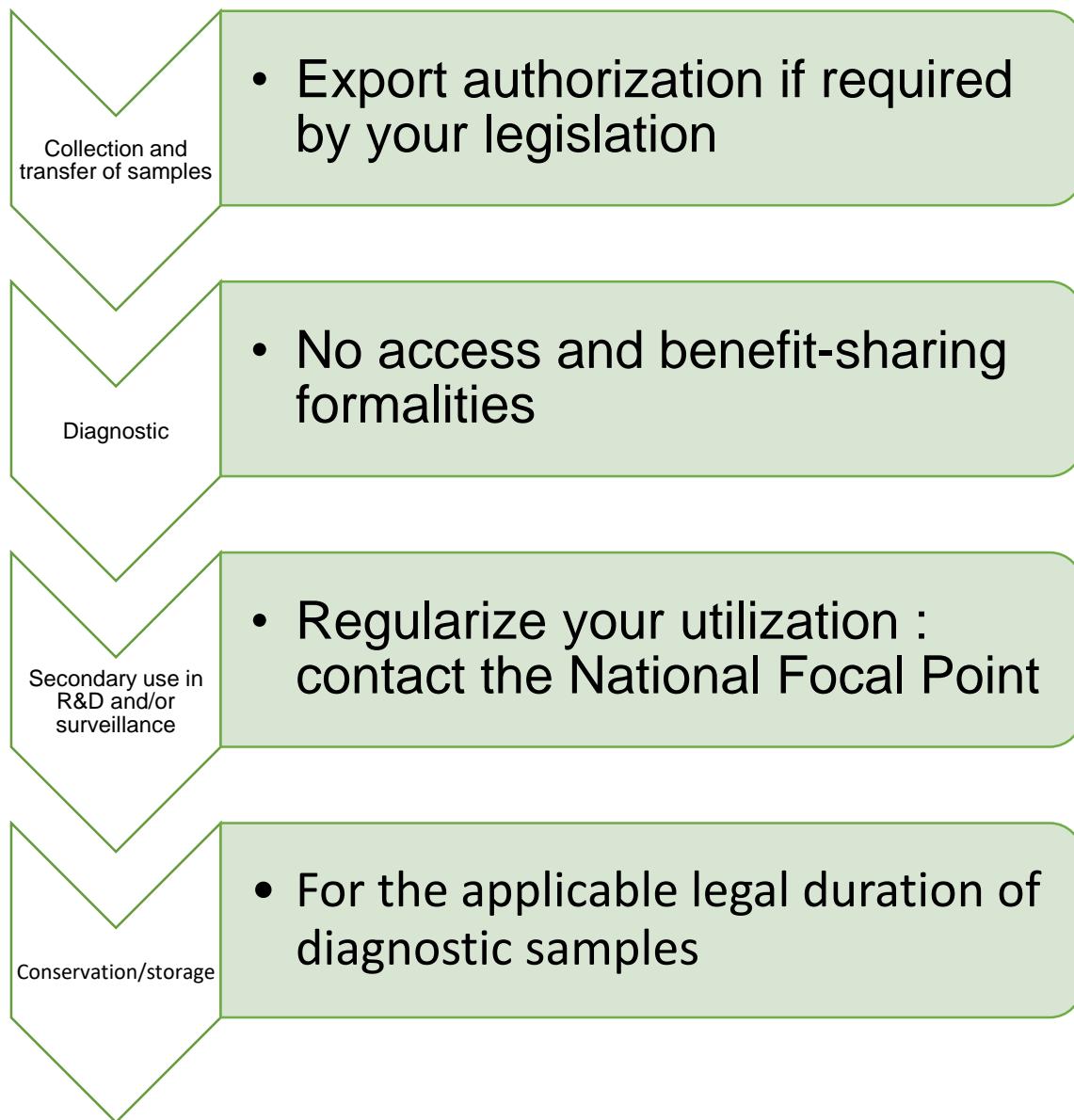
- In case of research project or focal point requirement, conclusion of an MTA:
 - costs of transfer
 - intellectual property and publications
 - access and benefit-sharing obligations

Use of genetic resources

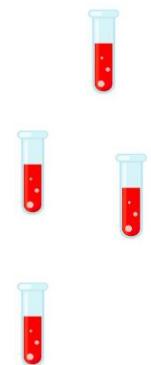
- Within the scope authorized by the National Competent Authority
- Keep record of use (e.g. tracking sheet) for future benefit-sharing and secondary transfers



2/6 – Technical exchange in diagnostic activities



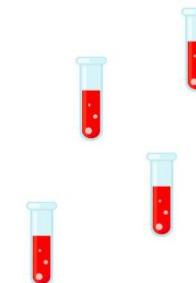
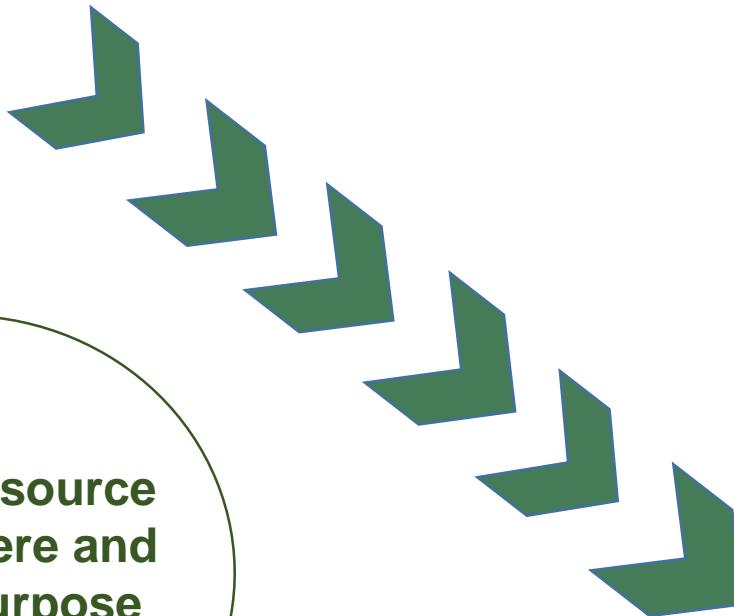
3/6 – Diagnostic & technical training



Transfer of samples

- Export authorization if required by your legislation

**Genetic resource
is a tool here and
not the purpose
of the study**

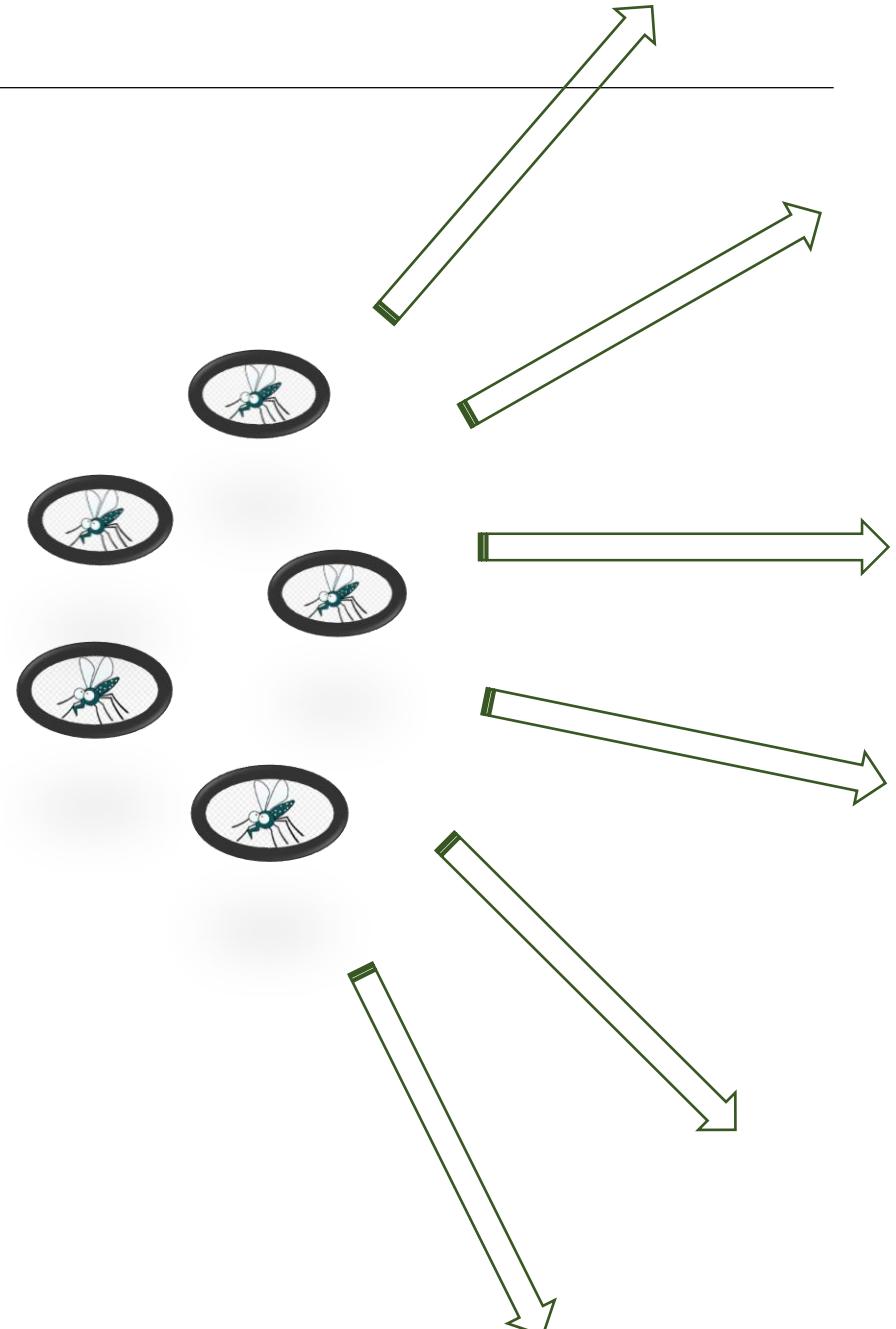


4/6 – EQA

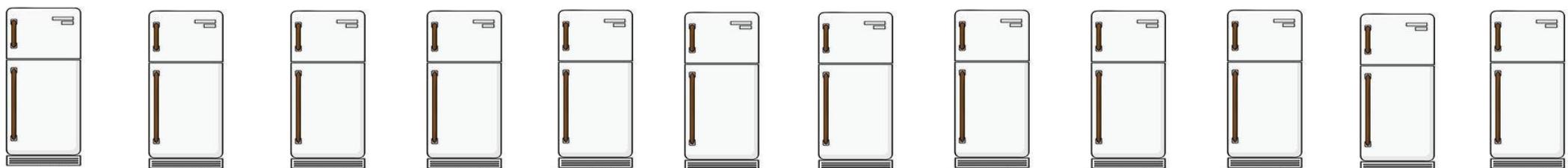


**Genetic resource
is a tool here and
not the purpose
of the study**

**If no destruction
and secondary
use,
regularization of
utilization**



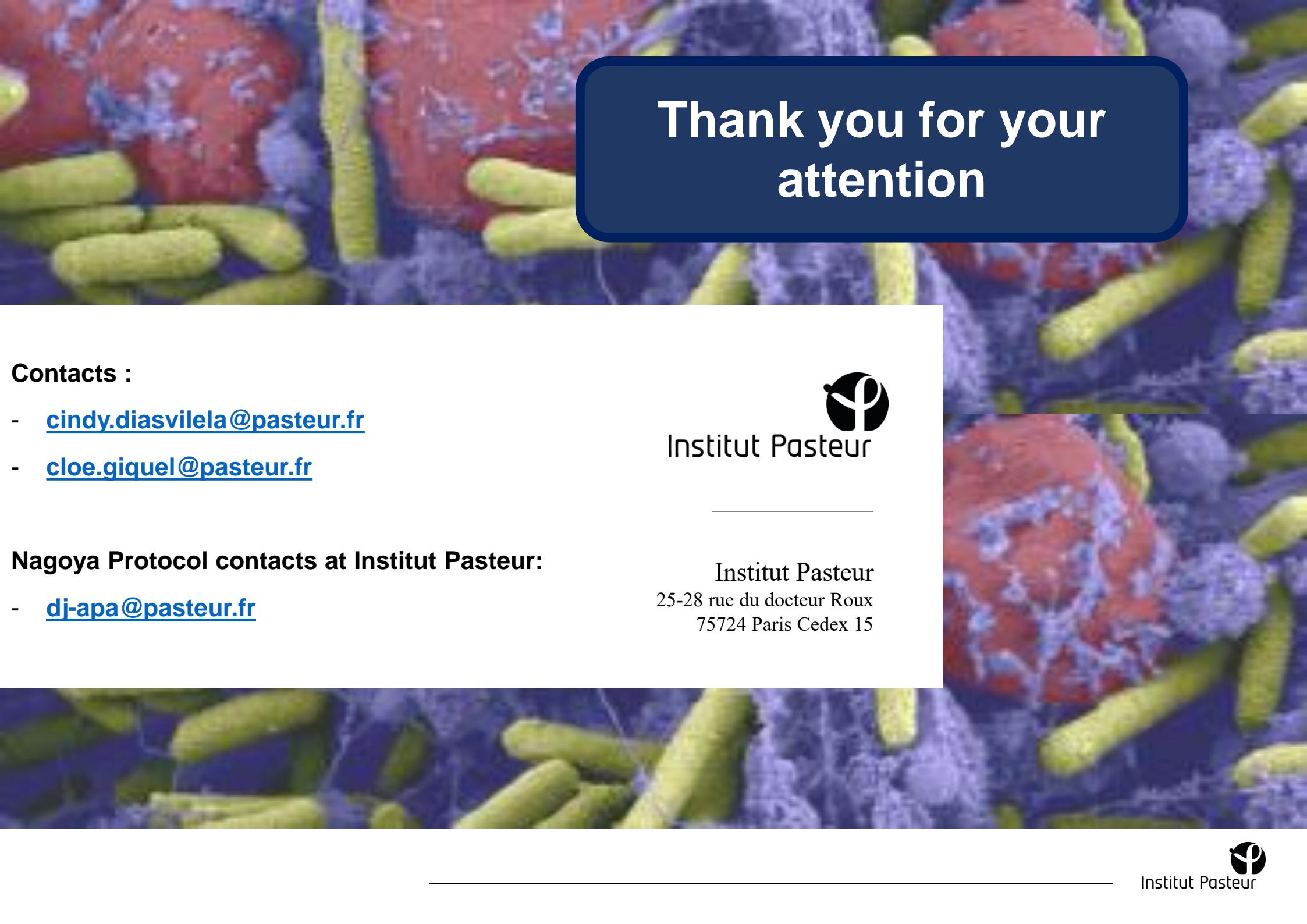
5/6 – Transfer of GR for conservation purposes



6/6 – Data Sequencing Information (DSI)

| DSI = GENETIC RESOURCE | DSI = INTERMEDIAIRY SYSTEM | DSI = NOT A GENETIC RESOURCE |
|--|---|---|
|  <p>Part of Asia and Africa</p> <p>Tangible resource = DSI = synthetic resource</p> <p>The values of the Protocol would be undermined if DSI excluded</p> |  <p>International binding legal instrument?</p> <p>International code of conduct?</p> <p>Convention on Biological Diversity is currently conducting a study</p> |  <p>Europe, USA</p> <p>Not feasible in practice, especially for big data projects</p> <p>No consensus on the determination of the exact geographical origin of DSI</p> <p>Goes against Open Data policies imposed by funders, aren't they already a benefit-sharing for all?</p> |





Thank you for your
attention

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