

Egypt

Jordan

Lebanon

Lybia

Palestine



Regional meeting



May 16-19th, 2022

Dead Sea, Jordan



Funded by the European Union



The implementation of the Nagoya Protocol within surveillance activities

Summary

01

—
Part 1

Presentation of the overall context

02

—
Part 2

Ground principles of the Nagoya
Protocol

03

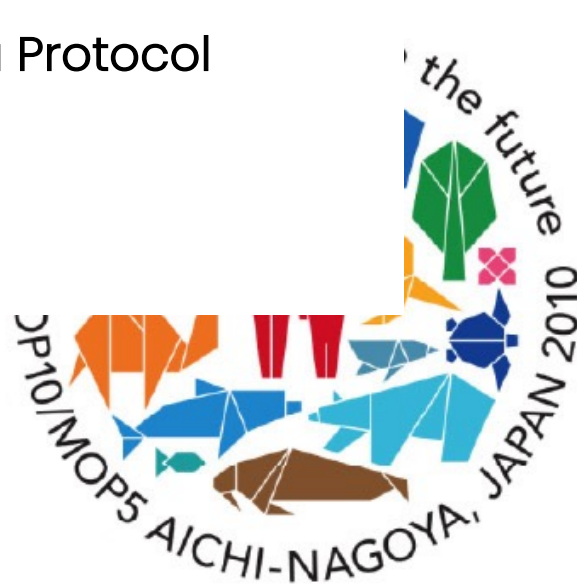
—
Part 3

Practical case: surveillance activities

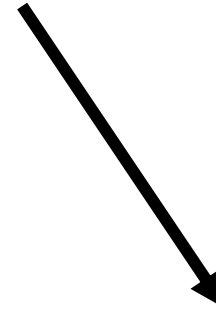
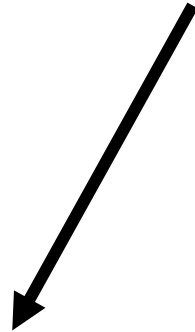
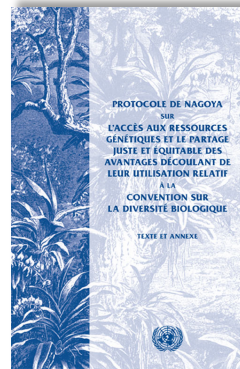


Part 1

Introduction to the Nagoya Protocol



What is the Nagoya Protocol?

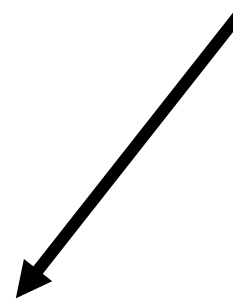
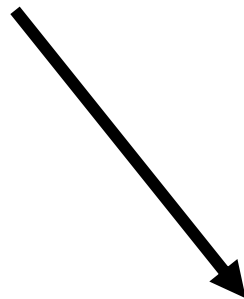


GENETIC RESOURCES

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

RESEARCH & DEVELOPMENT

Conduct of R&D activities on the genetic and/or biochemical composition of genetic resources



Where do surveillance activities stand?



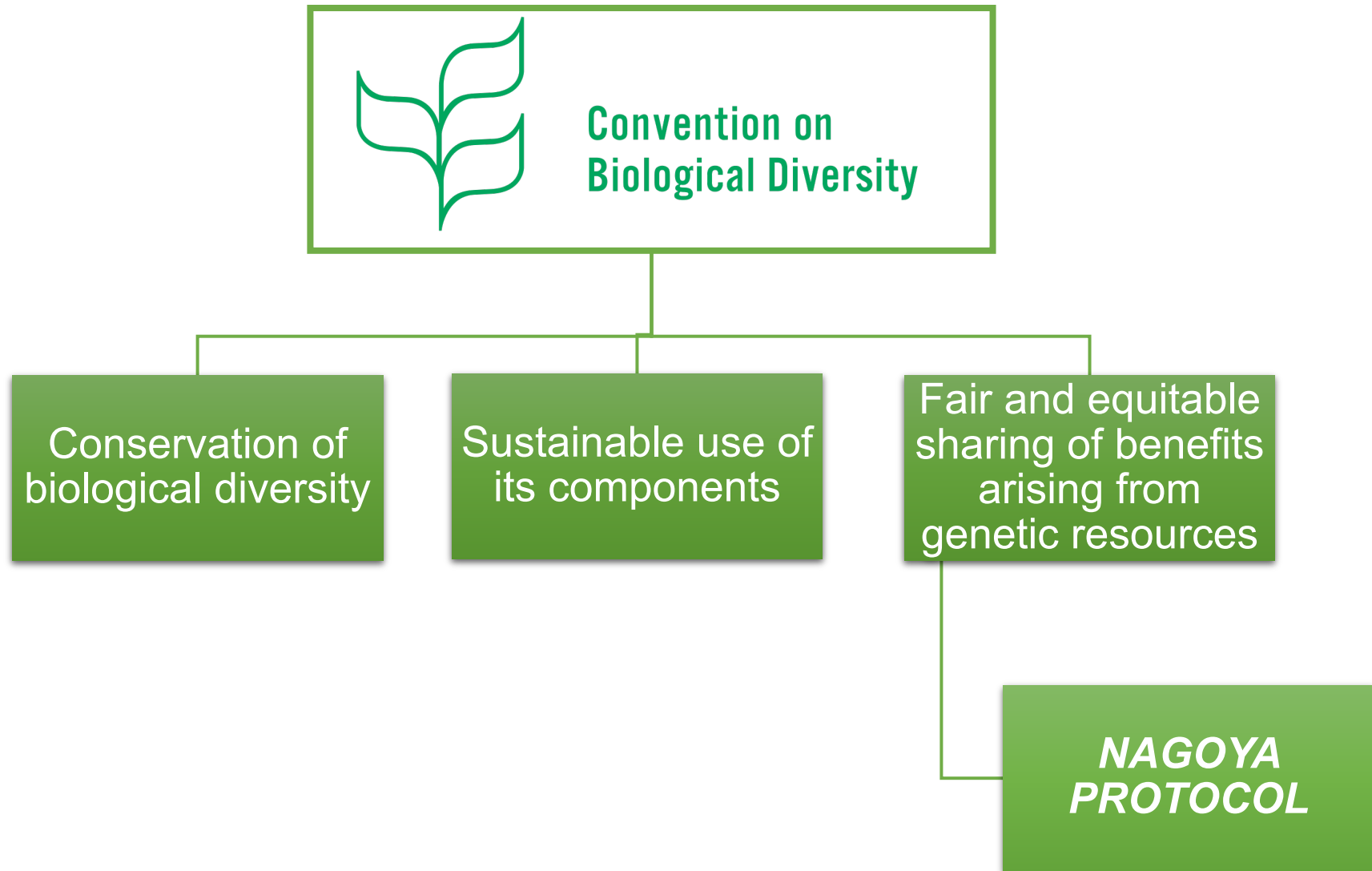
No international consensus
– depends on the country

WHO surveys on the
question

Special regime in France



Why has the Nagoya Protocol been adopted?



Why has the Nagoya Protocol been adopted?

MAIN GOAL

**TO FIGHT AGAINST
BIOPIRACY**



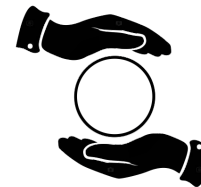
PRINCIPLE

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

Application to all of your activities

FUNDINGS



Horizon 2020
European Union Funding
for Research & Innovation

PUBLICATIONS



PATENTS



FUTURE COMMERCIAL APPLICATIONS





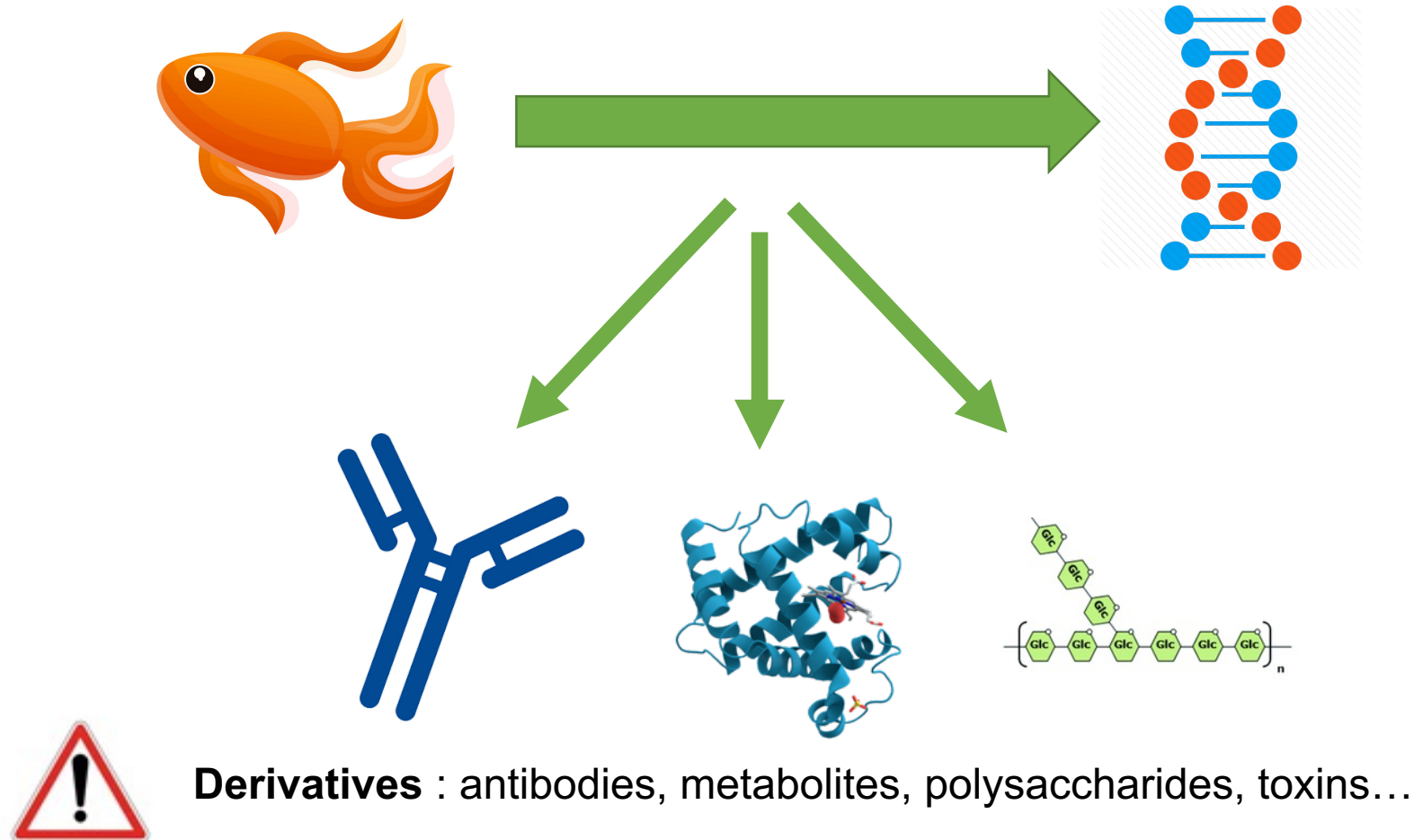
Part 2

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...

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

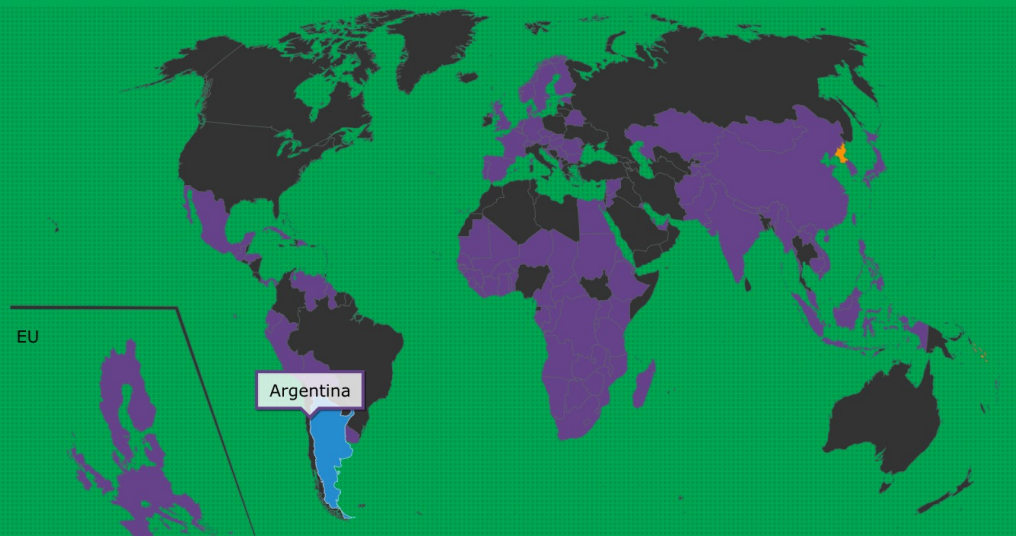
 **ABSCH WEBSITE** [<https://absch.cbd.int/>]

 **ABSCH** THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE

 Convention on Biological Diversity

[Home](#) | [About the ABSCH](#) | [Search](#) | [Submit](#) | [Country Profiles](#) ▾ | [National Reports](#)

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. 




 **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

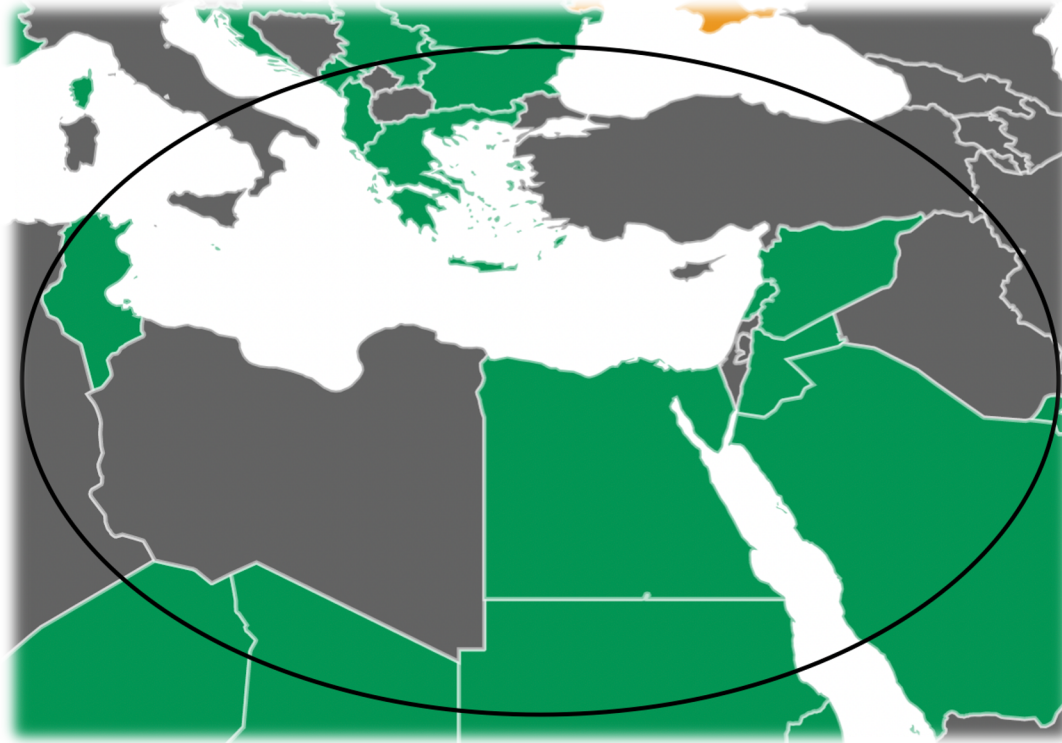
120 Parties to the Nagoya Protocol

3 Ratified, not yet Party 

78 Non-Parties



2/4 – The Nagoya Protocol within MediLab Secure



PARTY

Nagoya Protocol applies!

NON-PARTY

Nagoya Protocol does NOT apply!



2/4 – The Nagoya Protocol within MediLab Secure

COUNTRY	STATUS	ENTRY INTO FORCE	NATIONAL FOCAL POINT
Jordan	A permit must be obtained but no information on a specific text	October 12, 2014	Mr. Bilal Qtishat P.O. Box 1408 Amman 11941 Director Department Nature Protection Directorate Ministry of Environment bqtishat@yahoo.com +962 65560113
Lebanon	N/A	January 18, 2018	Ms. Lara Samaha Lazarieh Building P.O.Box 11-2727 Beirut Head Department Department of Conservation of Natural Wealth Organization Ministry of Environment l.samaha@moe.gov.lb +961 1 976 555 ext 417
Egypt	N/A	October 12, 2014	Mr. Ossama El-Tayeb 30 Maadi Zerae Road, 7th floor Maadi Cairo Scientific Advisor Department Nature Conservation Sector Egyptian Environmental Affairs Agency omtayebom@gmail.com ; drfoudamos@gmail.com +202 3336 3222, +2010 607 7374

2/4 – The Nagoya Protocol within MediLab Secure

COUNTRY	STATUS	ENTRY INTO FORCE	NATIONAL FOCAL POINT
State of Palestine	N/A	N/A	N/A
Lybia	N/A	N/A	Mr. Hamzah Abdulkaber Ahmed P.O. Box 83618 Al Gheran, Janzur Road Tripoli Organization Ministry of Environment hamzanoury986@gmail.com +218 926964911

NON-PARTY

Nagoya Protocol does NOT apply!

3/4 – Date of genetic resources collection



Website

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

**Date to remember:
October 12th 2014**

Access and Benefit-sharing

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.

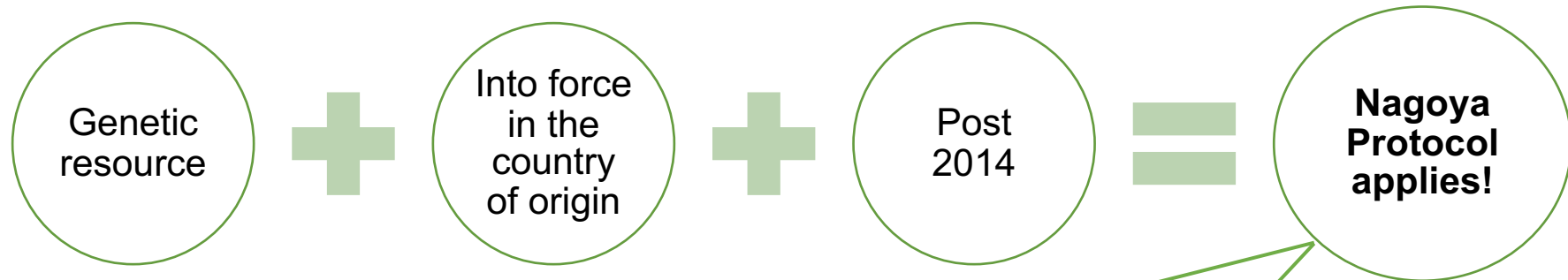
The list below provides information on date of signature and the status of ratification, acceptance, approval or accession. Visit also the country profiles and national information available in the [ABS-Clearing-House](#)

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 2018-09-04
2.	Albania		2013-01-29	acs 2014-10-12
3.	Angola		2017-02-06	acs 2017-05-07
4.	Antigua and Barbuda	2011-07-28	2016-12-12	rtf 2017-03-12
5.	Argentina	2011-11-15	2016-12-09	rtf 2017-03-09
6.	Austria	2011-06-23	2018-07-20	rtf 2018-10-18
7.	Belarus		2014-06-26	acs 2014-10-12
8.	Belgium	2011-09-20	2016-08-09	rtf 2016-11-07
9.	Benin	2011-10-28	2014-01-22	rtf 2014-10-12
10.	Bhutan	2011-09-20	2013-09-30	rtf 2014-10-12
11.	Bolivia (Plurinational State of)		2016-10-06	acs 2017-01-04
106.	United Republic of Tanzania		2018-01-19	acs 2018-04-19
107.	Uruguay	2011-07-19	2014-07-14	rtf 2014-10-12
108.	Vanuatu	2011-11-18	2014-07-01	rtf 2014-10-12
109.	Venezuela (Bolivarian Republic of)		2018-10-10	acs 2019-01-08
110.	Viet Nam		2014-04-23	acs 2014-10-12
111.	Zambia		2016-05-20	acs 2016-08-18
112.	Zimbabwe		2017-09-01	acs 2017-11-30
	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

4/4 – Access request and benefit-sharing



Access request

Benefit-sharing



PIC
Prior Informed Consent

Consent of the country of origin to collect

MAT
Mutually agreed terms

Conditions of use of the genetic resources

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

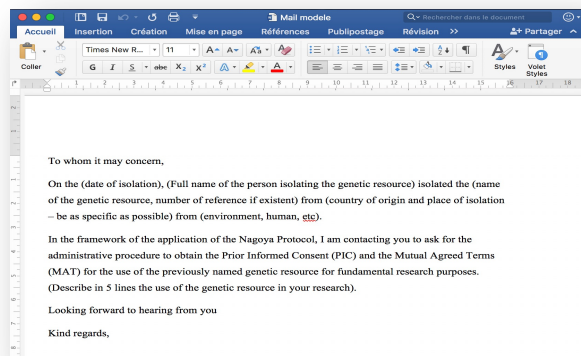
Autorisation du pays d'origine à accéder au Matériel	<input type="checkbox"/> Non <input type="checkbox"/> Oui	Autorité ayant délivré l'autorisation :	
	NA	Autorisation	<input type="checkbox"/> IRCC (<i>International Recognized Certificates of Compliance</i>) <input type="checkbox"/> PIC (<i>Prior Informed 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) :	

Dénomination	Identifiant	Historique	Isolée à partir de	Isolé par	Date isolement	Localisation géographique
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
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
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
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
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
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
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

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...*

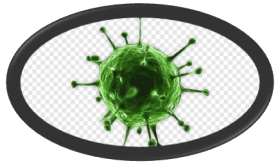




Part 3

**Practical cases: 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
 - acces 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



Collection and transfer of samples

- Export authorization if required by your legislation

Diagnostic

- No access and benefit-sharing formalities

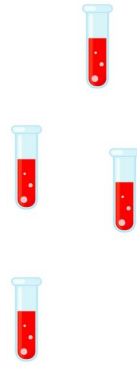
Secondary use in R&D and/or surveillance

- Regularize your utilization : contact the National Focal Point

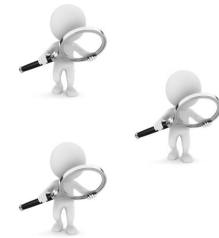
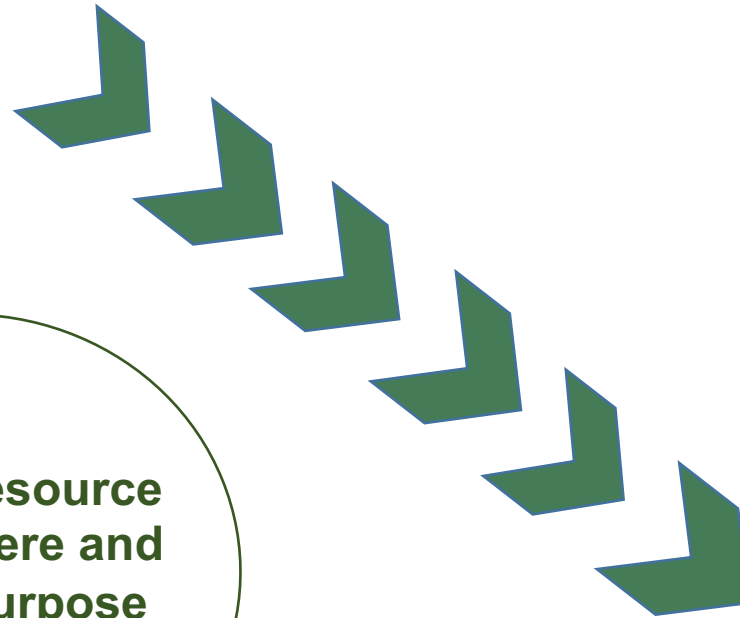
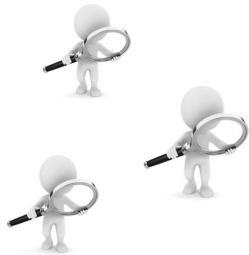
Conservation/storage

- For the applicable legal duration of diagnostic samples

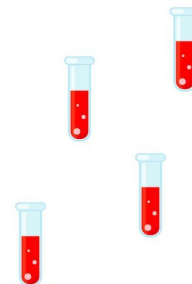
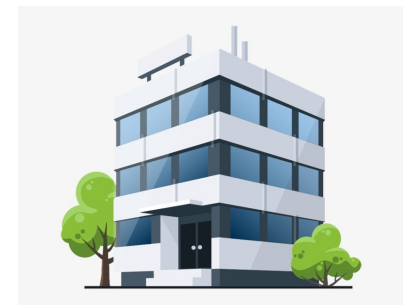
3/6 – Diagnostic & technical training



Transfer of samples
→ Export authorization if required
by your legislation



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

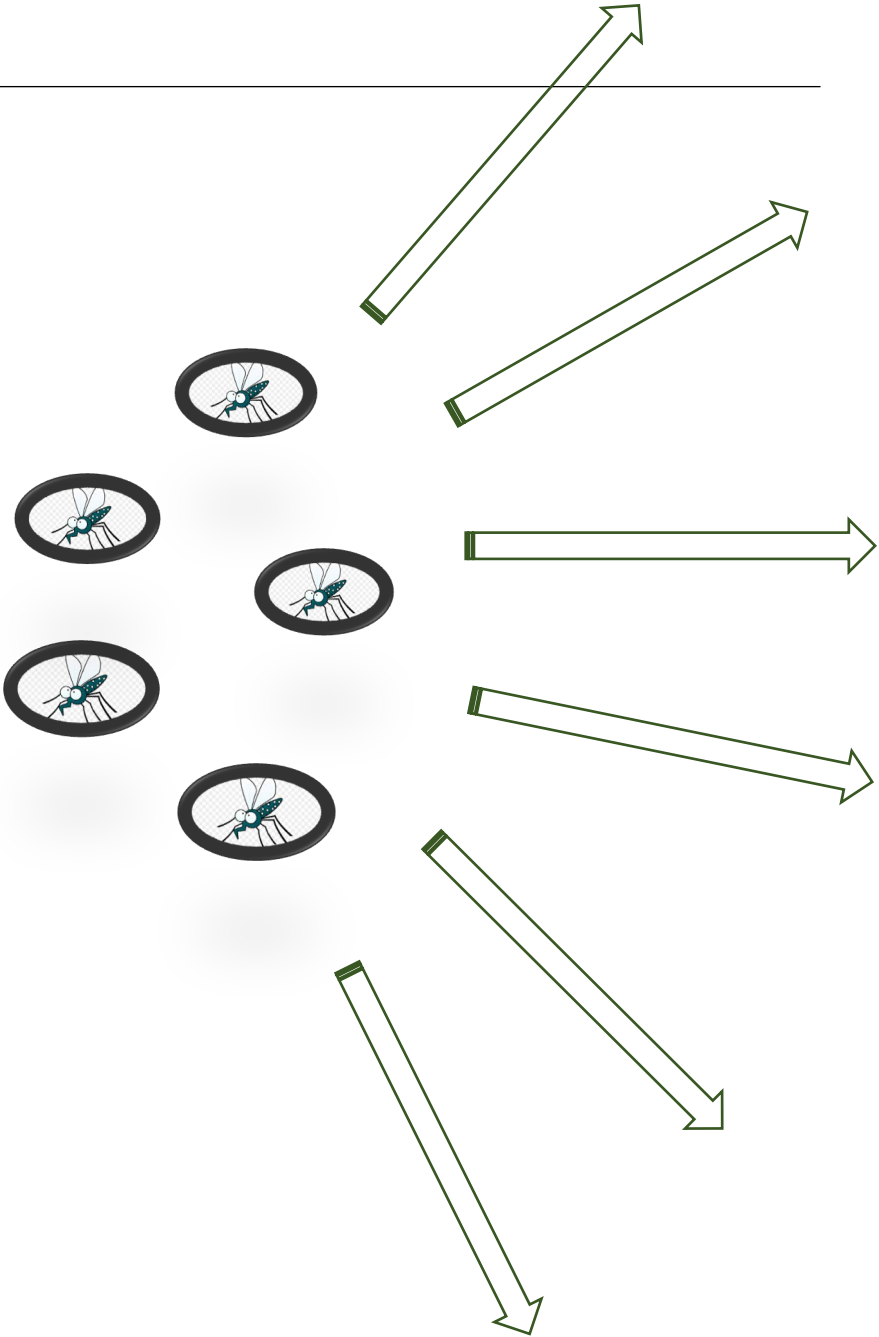


4/6 – EQA

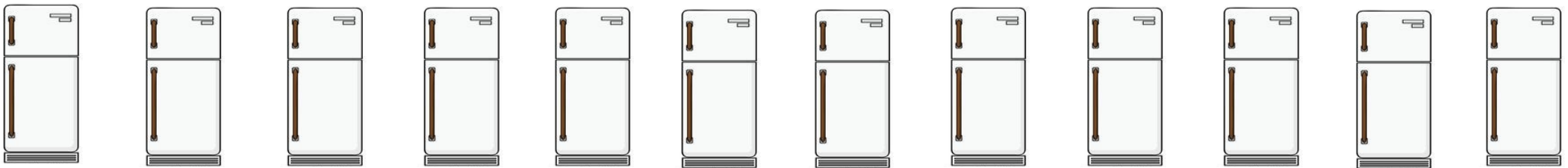
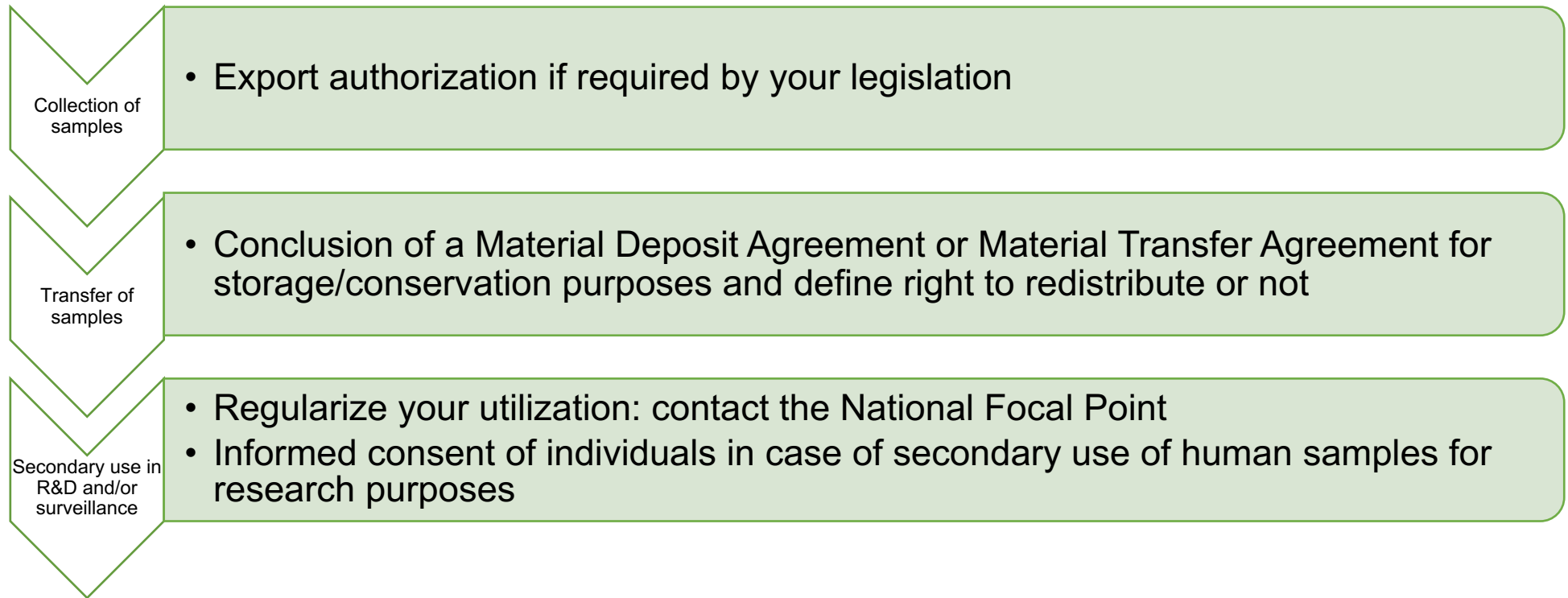


**Genetic resource
is a tool here and
not the purpose
of the study**

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



5/6 – Transfer of GR for conservation purposes



6/6 – Data Sequencing Information (DSI)

ISSUE : DEFINING A FRAMEWORK

What type of data is concerned by this notion? Only newly sequenced ones?

How to link DSI to a tangible genetic resource and a specific country?

No consensus on the determination of the exact geographical origin of DSI

Important matter COP 15

DSI regime in the future WHO treaty?
(2024)

Numerous legal and scientific position papers on the subject

Potential solution: multilateral system, open access, common fund

ISSUE : CONFLICTING INTERETS

Tangible resource = DSI
= synthetic resource

→ The values of the Protocol would be undermined if DSI excluded

BUT

Considering DSI as GR not feasible in practice, especially for big data projects

→ Goes against Open Data policies imposed by funders, aren't they already a benefit-sharing for all?

What do you think?



**Thank you for your
attention**

Contacts :

- cindy.diasvilela@pasteur.fr
- cloe.giquel@pasteur.fr

Nagoya Protocol contacts at Institut Pasteur:

- dj-apa@pasteur.fr



Institut Pasteur

Institut Pasteur
25-28 rue du docteur Roux
75724 Paris Cedex 15