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édition

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**AGROCAMPUS OUEST**  
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**RECHERCHE  
EXPÉRIMENTATION  
INNOVATION**

Fruits  
Légumes  
Ornement  
Plantes aromatiques  
et médicinales  
Semences  
Cidriculture  
Viticulture  
Paysage

# NEW REGULATIONS FOR ACCESSING YOUR BIODIVERSITY SAMPLES - PRACTICAL CONSEQUENCES OF THE NAGOYA PROTOCOL ...

Session plénière: Les enjeux de la biodiversité  
Lundi 16 janvier 12h20

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# First steps in Plant sourcing...



Legal Access?



- Protected species (CITES, National, Regional, Local laws...)
- Properties issues (authorization of the land owner)
- Plant health control legislations
- Custom regulations
- **Regulations on Biodiversity Access and Benefit Sharing (A.B.S.)**  
***Accès et Partage des Avantages (A.P.A.)***

# Daunting and unknown issues

Access and Benefit Sharing

**MAT**

Bio Convention

Art. 8 j

Nagoya Protocol

**PIC**

Genetic resources

**CBD**

Penalties

**TK**

**ABS**

Prior Informed Consent

**Biopiracy**

Sovereign rights

Mutually Agreed Terms

Biological resources

Infraction

# Evolution of biodiversity laws



**29 December 1993**

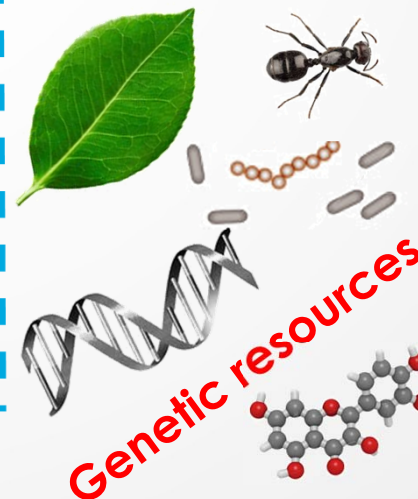
Biodiversity =  
human heritage  
No access  
regulation



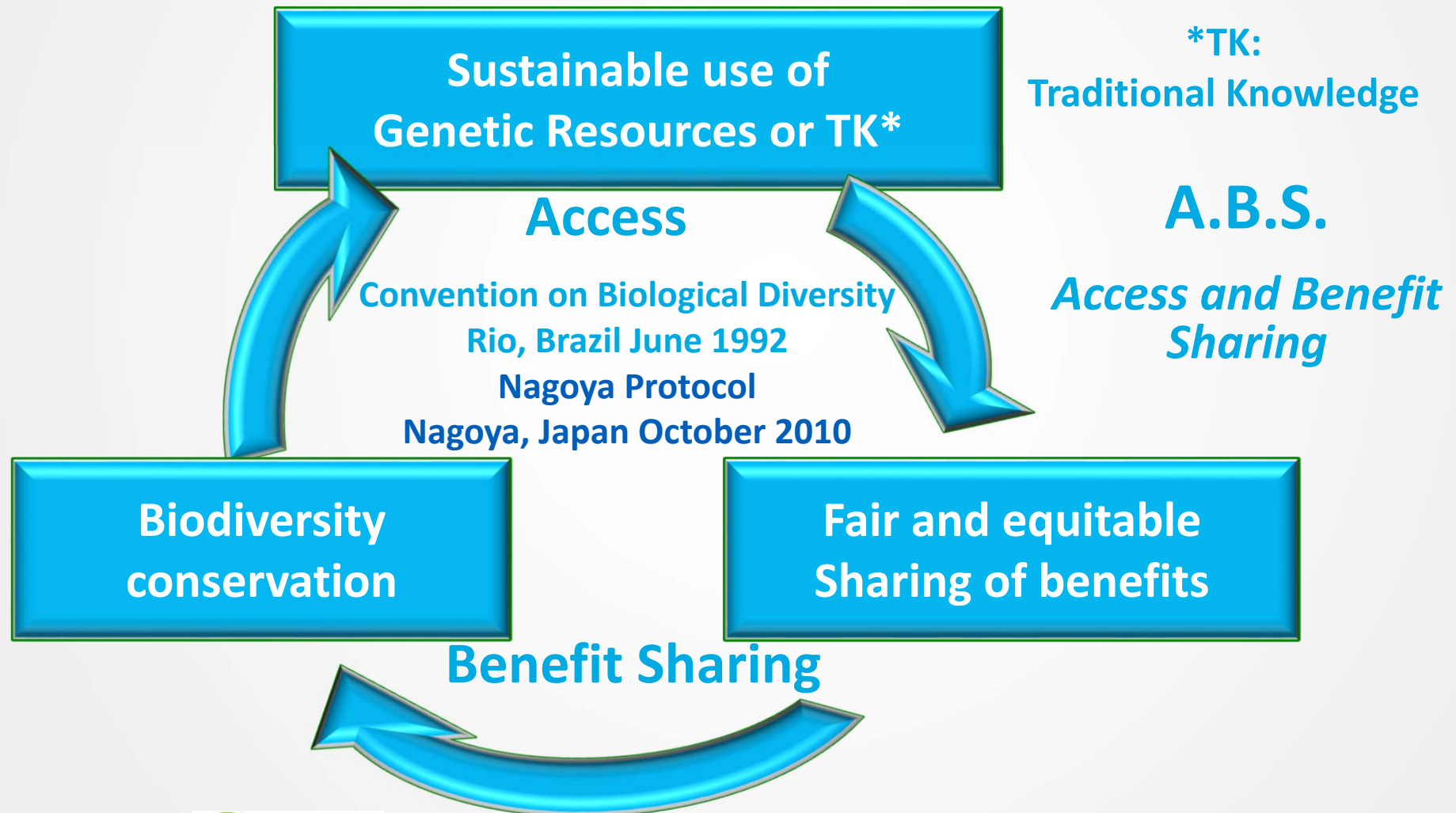
**12 October 2014**

Genetic resources  
+ traditional knowledge  
regulated access !

Genetic + biological resources  
+ traditional knowledge  
Regulated access for R&D !



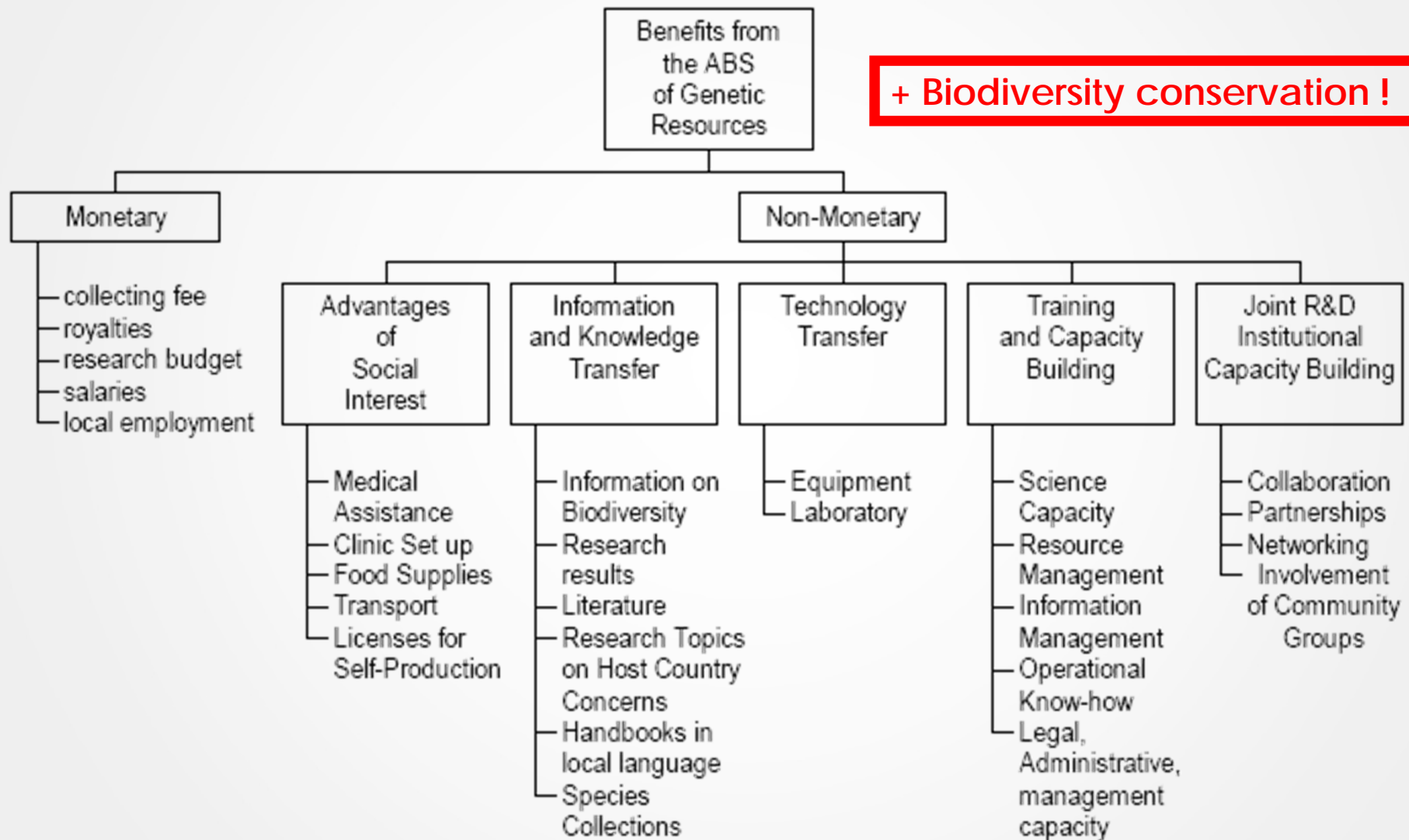
# Virtuous circle of the Convention on Biological Diversity & Nagoya Protocol



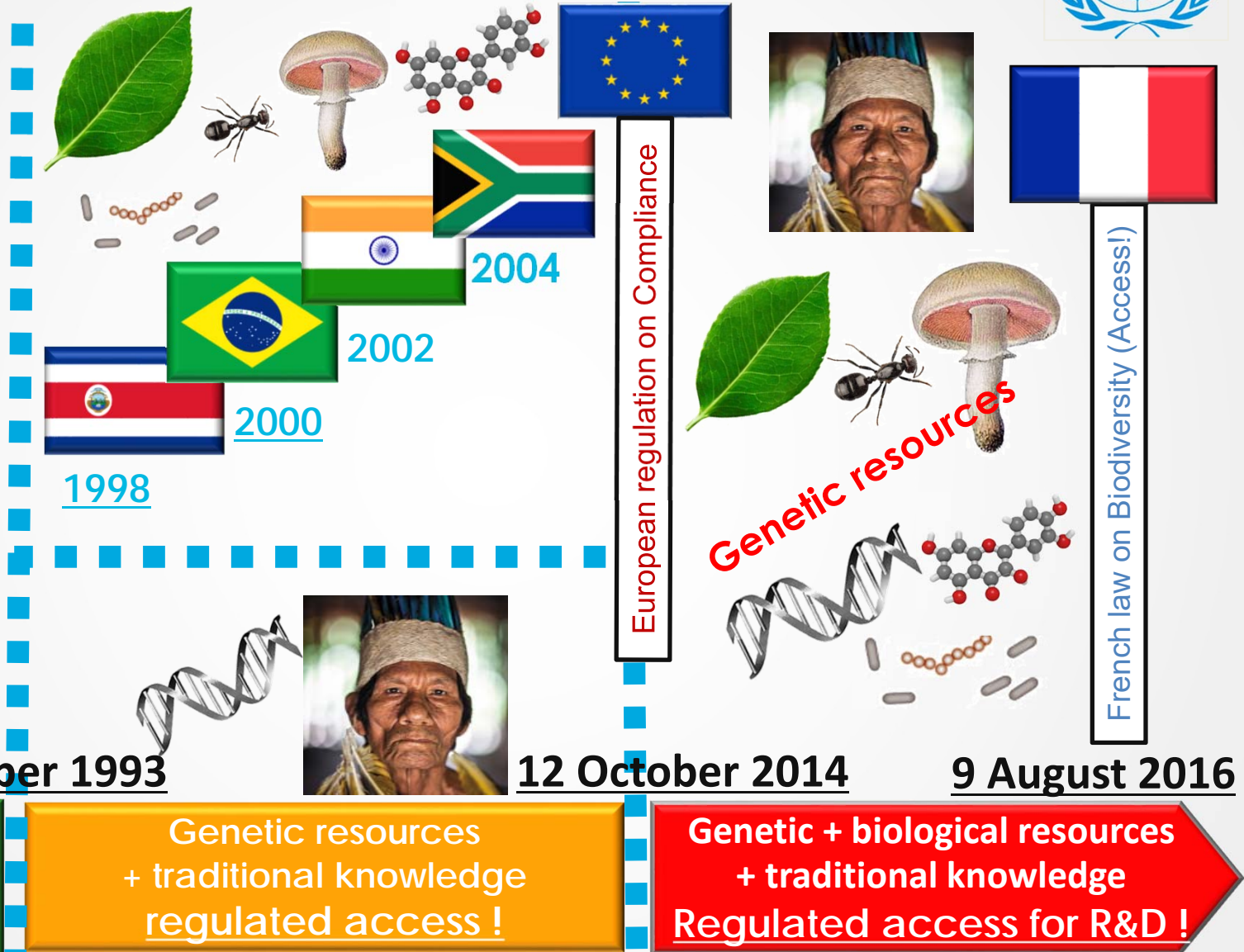
# Examples of Benefit Sharing



**+ Biodiversity conservation !**



# Calendar of biodiversity laws



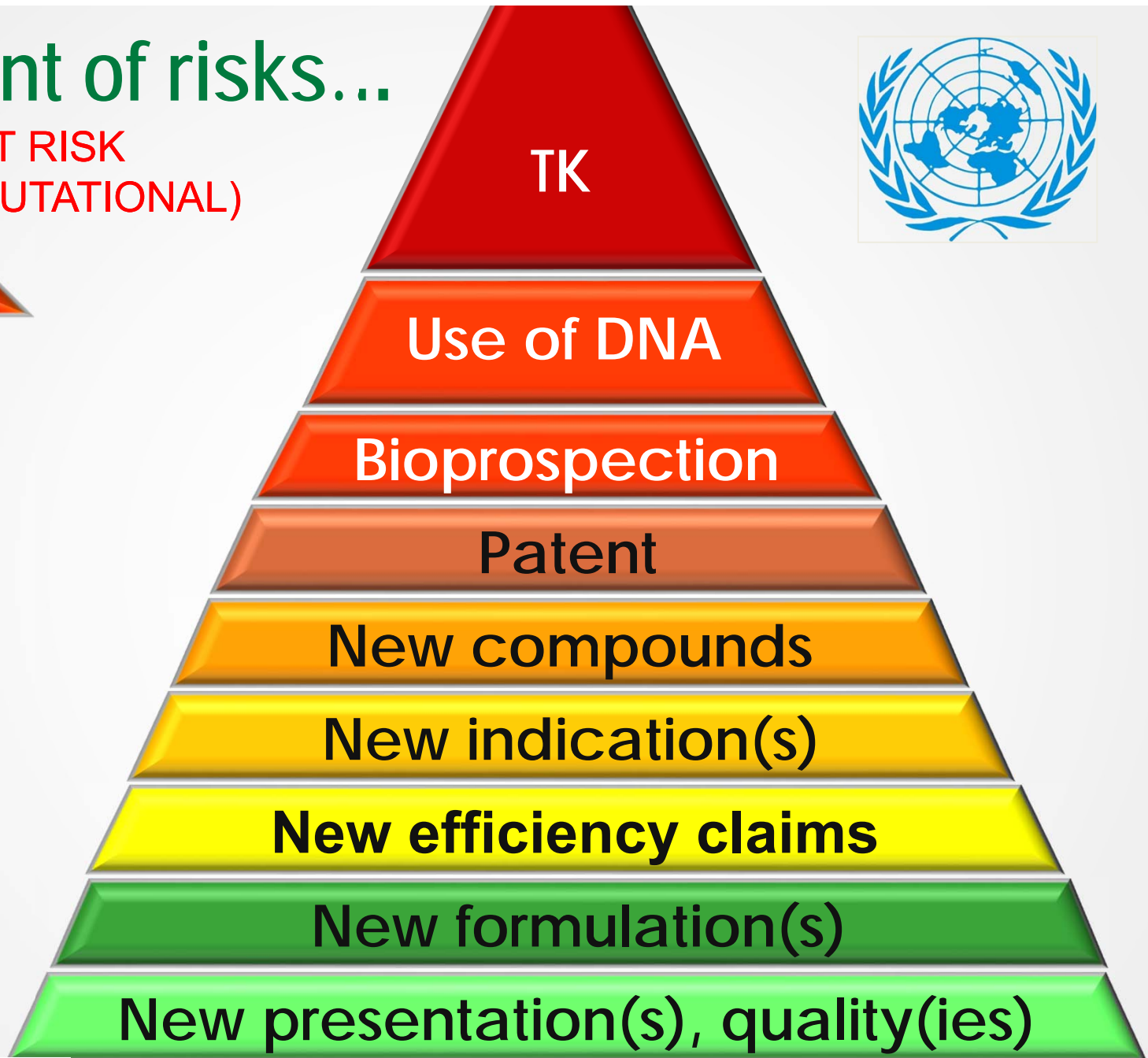
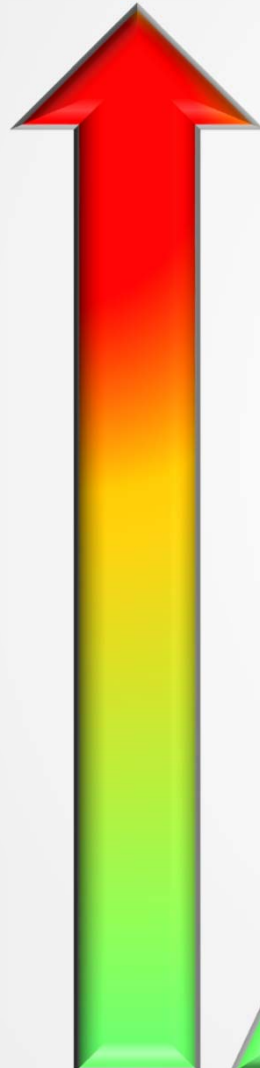
# Consequences for the users



- **If R&D conducted on genetic resources (art. 2c) laws of the source country apply. Negotiate access before beginning studies.**
- Biodiversity (plants, animals, microorganisms and fungi) is under the sovereignty of host nations, which are free to put in place more or less restrictive regulations.
- Antarctic + international waters, human body are "OUT".
- "Nagoya compliance", controls and sanctions by member states on their territory.
- If infringement severe penalties and risks to reputation.

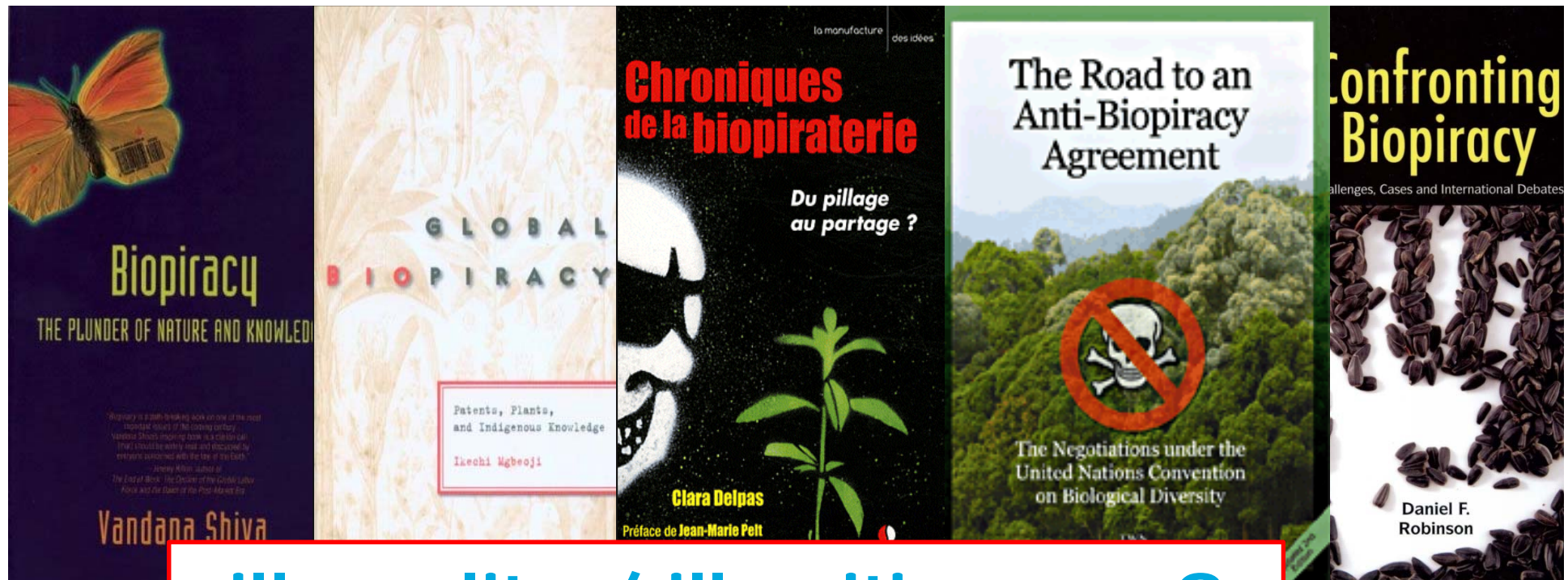
# Gradient of risks...

HIGHEST RISK  
(LEGAL & REPUTATIONAL)



RISK = 0




Existing use(s) (commodity) 9/21







illegality / illegitimacy ?



# Examples of biopiracy accusations

Sector	Company	Source Country	Plant	Use	Legal action	Date
Agro chemical	WR Grace (USA)	India 	<i>Azadirachta indica</i> Neem tree	Fungicide	Cancellation of the EU patent (OEB)	1990
Agro chemical	Monsanto (USA)	India 	<i>Solanum melongena</i> Eggplant	Pesticide	Legal action by National Biodiversity Authority	2012
Agro chemical	Monsanto (USA)	Australia Asia 	<i>Glycine max</i> Soybean	Climate adaptation	Action against the UE patent	2015

Sector	Company Institution	Source Country	Plant	Use	Legal action	Date
Pharma	Merck (USA)	Costa Rica 	<i>Bioprospection</i> <i>historical model agreement</i>		NGOs' critics against insufficient local consultations of communities	1991
Pharma	Schwabe (Germany)	South Africa 	<i>Pelargonium sidoides</i>	Bronchitis rhinosinusitis	Cancellation of the EU patent (OEB) Action on liability in Africa	2010
Pharma (Academic)	IRD (France)	French Guyana 	<i>Quassia amara</i> Kouachi	Malaria	NGO action against the French patent	2016

Sector	Company	Source Country	Plant	Use	Legal action	Date
Cosmetic	Greentech (France)	Peru 	<i>Plukenetia volubilis</i> Sacha Inchi	Skincare cream	Action against the French patent Patent has been withdrawn	2009

# Nagoya Protocol implementation

**Pre-Nagoya access regulations:** [Brazil, India, South Africa, Peru, ...](#)

## **Nagoya access regulations (92 + EU):**

Gabon, Jordan, Rwanda, Seychelles, Mexico, Laos, India, Fiji, Ethiopia, Panama, Mauritius, South Africa, Albania, Micronesia, Botswana, Syria, Mongolia, Comoros, Honduras, Tajikistan, Ivory Coast, Bissau Guinea, Indonesia, Bhutan, Norway, Egypt, Myanmar, Burkina Faso, Benin, Kenya, Guyana, Vietnam, Hungary, Denmark, Namibia, European Union (16 May 2014), Samoa, Spain, Guatemala, Uganda, Belarus, Vanuatu, Niger, Burundi, Gambia, Madagascar, Mozambique, Sudan, Peru, Switzerland, **Uruguay (14 July 2014)**, Malawi, United Arab Emirates, Guinea, Marshall Islands, Lesotho, Dominican Republic, Cambodia, DR Congo, Congo, Kyrgyzstan, Kazakhstan, Liberia, Mauritania, Croatia, Cuba, Philippines, Djibouti, Pakistan, Slovakia, Togo, UK, Senegal, Germany, Czech Republic, Zambia, Finland, China, Belgium, Bulgaria, Netherlands, Moldova, France, Mali, Sweden, Swaziland, Bolivia, Luxembourg, Sierra Leone, Cameroon, Malta, Argentina, Antigua and Barbuda ...



**Nagoya Protocol internationally enforced on 12 October 2014**



**European Regulation on Compliance 20 May 2014** (Official Journal of the European Union). **All articles** (including 4, 7 & 9) **applicable since 12 October 2015**



**Access legislation Law 42/2007**  
**art. 71 Application pending**



**Access legislation 8 August 2016**  
**Application pending**

# French biodiversity access law



9 août 2016	JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE	Texte 2 sur 86
<b>LOIS</b>		
LOI n° 2016-1087 du 8 août 2016 pour la reconquête de la biodiversité, de la nature et des paysages (1)		

- Titre V « Accès aux ressources génétiques et partage juste et équitable des avantages » art. 37 à 46
- Loi cadre --> décrets d'application en attente
- Procédures déclarative ou d'autorisation
- Art 110.1 Code Environnement  
Les espaces, ressources et milieux naturels terrestres et marins, les sites, les paysages diurnes et nocturnes, la qualité de l'air, les êtres vivants et la biodiversité font partie du patrimoine commun de la nation. Ce patrimoine génère des services écosystémiques et des valeurs d'usage.
- Sanctions :
  - 1 an d'emprisonnement et 150 000 € d'amende
  - Amende portée à 1 million d'euros en cas d'utilisation commerciale illicite

# Biodiversity access in practice 1

www.cbd.int



2

Convention on Biological Diversity

العربية | English | Español | Français | Русский

Sign up for an account | Sign In

The Convention | Cartagena Protocol | Nagoya Protocol | Programmes | Information | Secretariat

Media Headlines

27 July 2012, Times of Zambia (Ndola)  
'Public should be consulted over GMOs'

3

Parties

List of Parties

National Focal Points

Status of Contributions

Country Profiles

Convention Bodies

Introduction

Conference of the Parties (COP)

Scientific Body (SBST)

Working Group on the Implementation (WGRI)

ICNP

## List of Parties

Note: Information on the Convention on Biological Diversity under the Cartagena Protocol

France



France

Convention

Party since: 1994-09-29  
By: Ratification

Cartagena Protocol

Party since: 2003-09-11  
By: Approval

Nagoya Protocol on Access and Benefit-sharing

Party since: 2016-11-29  
By: Ratification

Nagoya - Kuala Lumpur

Information > Country Profiles > National Focal Points

## France - Country Profile

### Convention on Biological Diversity

#### M. François Lengrand

Bureau biodiversité et milieux  
Direction des affaires européennes et internationales  
Ministère de l'environnement, de l'énergie et de la mer  
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#### Mme Elise Rebut

Pôle biodiversité-forêts-océans, Sous-direction de l'environnement et du climat, Direction du développement durable  
Direction générale de la mondialisation, de la culture, de l'enseignement et du développement international  
Ministère des affaires étrangères et du développement international  
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75732 Paris  
France

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elise.rebut@diplomatie.gouv.fr

5 (Focal points)

Show map

# Practice 2:



# Practice 3: What is requested by Biodiversity Authorities?

- Description of the project / duration
  - Names, roles and relationships between researchers
  - Local institutions, researchers involved
  - Parts confidential when applicable
  - Benefit sharing monetary & non-monetary programme
- 
- Access Permit for the detailed project and researchers (No change of intent, participants...)
  - Duration/ date of issuance, date of expiry
  - Reporting on the results
  - Milestones & Benefit Sharing

# Practice 4:

Recent example from French Academic  
researchers

V. Jullian, N. Fabre.

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RESOLUCIÓN DE DIRECCIÓN GENERAL  
Nº 146 -2016-SERFOR/DGGSPFFS

Lima, 15 ABR 2016

## VISTO:

La solicitud de autorización para realizar investigación científica con colecta de flora silvestre fuera de Áreas Naturales Protegidas y con acceso a recursos genéticos, presentada por la señora Valérie Jullian, y;

## CONSIDERANDO:

Que, mediante solicitud s/n, registrada el 10 de marzo de 2016, la señora Valérie Jullian solicitó a la Dirección General de Gestión Sostenible del Patrimonio Forestal y de Fauna Silvestre la autorización de investigación científica con colecta de flora silvestre y con acceso a recursos genéticos, como parte del Proyecto "Investigación sobre metabolitos secundarios de un boraginacea peruana y sus actividades antimicrobianas", por el periodo entre 1 de abril de 2016 hasta 30 de agosto de 2017;

# Practice 5: Reporting to the source country

## FORMATO DE INFORME DE INVESTIGACIÓN (PARCIAL o FINAL)

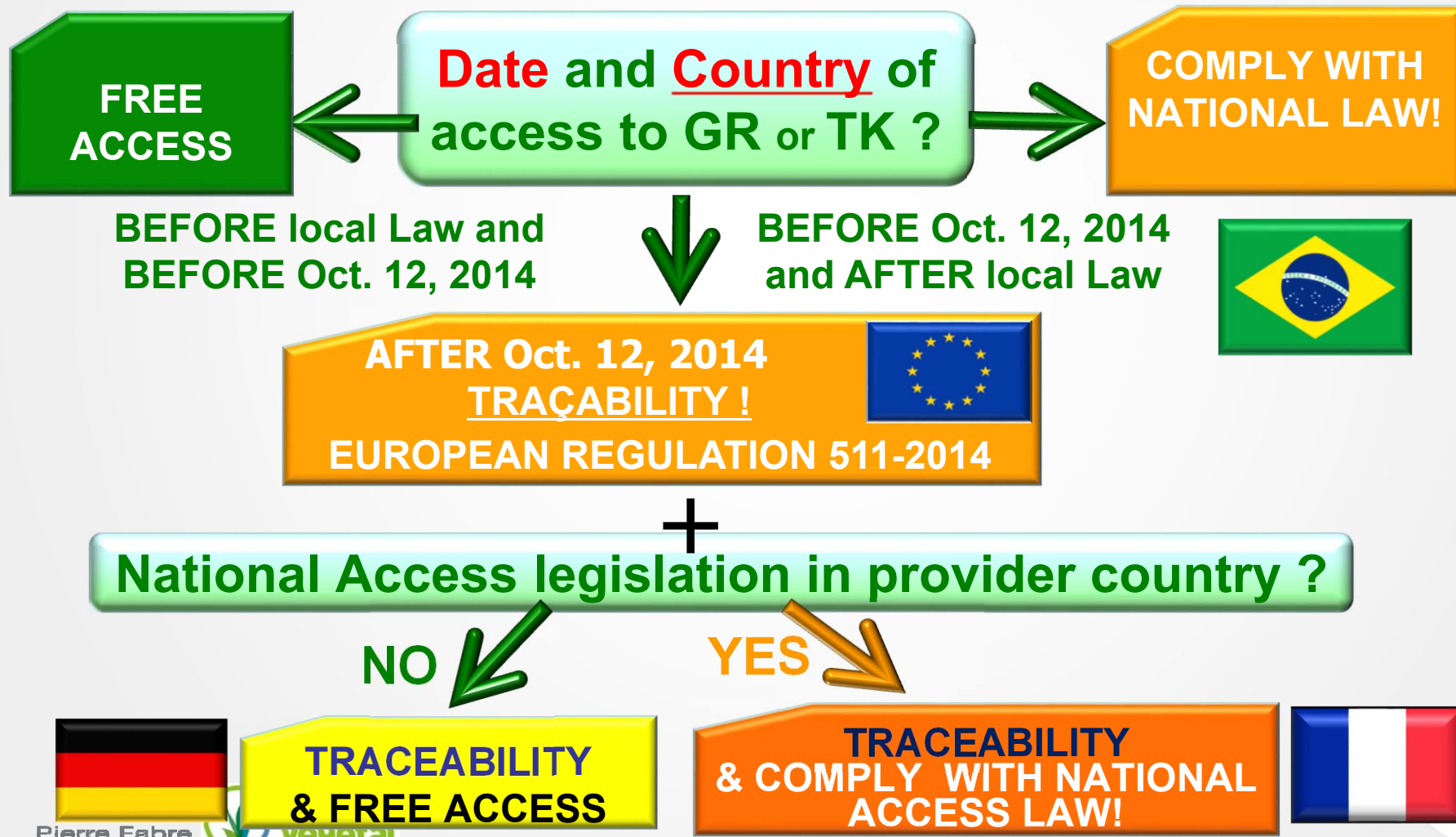
Una vez culminada la investigación autorizada, o al término de un período anual, los investigadores responsables deberán revisar el cumplimiento de los compromisos asumidos, teniendo en cuenta lo siguiente:

- 1) Entregar a la DGGSPFFS del SERFOR una (01) copia del informe parcial o final en idioma español, como resultado de la autorización otorgada, en formato impreso y soporte digital (CD), para ello adjunto el formato de informe a presentar:

- a. Título del Proyecto.
- b. Área estudiada (indicando coordenadas geográficas para todas las zonas de colecta).
- c. N° de Autorización.
- d. Autores.
- e. Institución.
- f. Resumen para ser publicado en la web del SERFOR (donde se deberá señalar los resultados y la relevancia de lo encontrado en forma sintetizada)
- g. Marco teórico.
- h. Material y Métodos.
- i. Resultados.
- j. Discusión.
- k. Conclusiones.
- l. Bibliografía.
- m. Anexos



# In practice 6: use of samples



# ABCD take-home messages

Access

Benefit Sharing

Compliance (EU regulation 511-2014)

Due diligence Obligation (EU Implementing Reg. 2015/1866: annex 2 & 3)

- Access to GR depends on each country which is free to regulate (or not) access and to request Benefit Sharing
- Access to GR and TK is regulated in France since August 2016
- Users in EU need to be compliant and to respect Due Diligence Obligation
- Implementation of Nagoya Protocol should **facilitate access, conservation** and should bring **legal certainty**

# To go further...

Convention on Biodiversity: [www.cbd.int/doc/legal/cbd-en.pdf](http://www.cbd.int/doc/legal/cbd-en.pdf)

Nagoya Protocol: [www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf](http://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf)

Practical information on Countries: <https://absch.cbd.int>

European Regulation No 511/2014:

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0511&from=EN>

Compliance measures of Regulation No 511/2014:

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R1866&from=EN>

French Biodiversity law 8 August 2017

[https://www.legifrance.gouv.fr/jo\\_pdf.do?id=JORFTEXT000033016237](https://www.legifrance.gouv.fr/jo_pdf.do?id=JORFTEXT000033016237)