

Provider Country Measures Taken by Developed Countries

JBA – Tokyo

2019/02/13

Guillaume FAURE

Ministry for an ecological and
solidary transition

Water and biodiversity Department



RÉPUBLIQUE FRANÇAISE

MINISTÈRE
DE LA TRANSITION
ÉCOLOGIQUE
ET SOLIDAIRE

Photo : T. Degen/Terra

Introduction / Plan

- Context
- Historic and legal framework for ABS implementation
 - Excluded genetic resources from access measures
 - A general scheme for wild genetic resources and traditional knowledge associated to genetic resources removed from the french territory, used for research and development activities
 - Specific schemes
 - Specific measures in french overseas territories
- Institutional framework for ABS implementation
- Steps to access genetic resources / associated traditional knowledge
 - Access to genetic resources for research and development without any commercial purpose : a declarative procedure
 - Access for commercial purposes : an authorization procedure
 - Utilisation of traditional knowledge associated to genetic resources (no matter whether the research has a commercial purpose or not) : an authorisation procedure



MINISTÈRE
DE LA TRANSITION
ÉCOLOGIQUE
ET SOLIDAIRE

Introduction / Plan

- Collections
- The European regulation n°511/2014
- Penalties
- Implementation experience in France

Context

- 96 countries have ratified the Nagoya Protocol (NP)
- Rich biodiversity in french overseas territories (Guyana, Wallis and Futuna...)
- Active public research
- Active chemical and cosmetic industries
- France : both a source country and a requesting country

Historic and legal Context

- 1992 : Convention on biological diversity (CDB)
- 2006 : pioneer ABS system in the national park of Amazonia (french Guyane)
- 2010 : Signing of the Nagoya Protocol in Japan (NP)
- 2011 : France signed the Nagoya Protocol
- 2014 : the NP entered into force → Regulation (EU) 511/2014 of the European Parliament and of the Council
- 2016 : « The recapture of nature, landscape and biodiversity law » (« loi n°2016-1087 du 8 août 2016 pour la reconquête de la biodiversité, de la nature et des paysages »)
 - ====> France ratified the NP (art. 46)
 - ====> Implementation in France of the Nagoya Protocol on Access and Benefit Sharing (ABS)
- 2017 : « Decree n°2017-848 of May 9th 2017, regarding the access to genetic resources and traditional knowledge and benefit sharing as a result from their use ”
 - ====> finalisation of the national procedure of declaration and authorisation
 - ====> implementation of the european regulation (due diligence)
 - ====> the national procedure entered into force on 2017, July the 1st



Legal framework for ABS implementation

The 2016 law has excluded a list of genetic resources (out of scope) and distinguished a general scheme and specific schemes.

- Genetic resources excluded from access measures

- human genetic resources,

- genetic resources ruled by specific conventions, such as the International Treaty on Plant genetic Resources for Food and Agriculture (ITPGRFA)

- genetic resources that are not removed from the french territory

- genetic resources issued from species used as models in laboratories

- genetic resources issued from activities dealing with the protection of defense and national security

- * *coming this year : genetic resources issued from micro organisms collected from mainland*

- A general scheme for wild genetic resources and traditional knowledge associated to genetic resources removed from the french territory, used for research and development activities

- Main achievements : a model contract has been issued (timeline, compensation measures...) ; 3 forms regarding declaration and authorisation procedures.



Legal framework for ABS implementation

- Specific schemes

- genetic resources from pathogens collected by laboratories as part of prevention and risk control for human health : the access will be regulated by the ministry of health → text in preparation
- genetic resources from cultivated and wild relative plants, from domestic animals, from domesticated and cultivated microorganisms, from cultivated trees and from pathogens collected by laboratories as part of prevention, monitoring and fight against health danger for animals, plants and health security for food : the ministry for food and agriculture will only regulate access for cultivated trees.

Legal framework for ABS implementation

- Specific measures in french overseas territories

- French Polynesia and New-Caledonia = general competence on environmental affairs, thus they have their own rules.

- . French Polynesia: <http://www.environnement.pf/code-de-l-environnement>

- . New Caledonia (Province Nord): <https://www.biodiversite.nc/attachment/229854/>

- . New Caledonia (Province Sud) :

- <https://www.province-sud.nc/sites/default/files/758331/Code%20de%20l%27environnement-version%20denv-2009-25%20APS%20M31.pdf>

- French Guyane and Wallis-and-Futuna Islands = designated as the 2 territories where local communities may own traditional knowledge.

- French overseas departments : Ministry for an ecological and solidary transition (MTES) is the competent national authority (CNA) for those territories.



Institutional framework for ABS implementation

- *PIC granted:*
 - *genetic resources removed from the french territory : MTES grants it ;*
 - *access to traditional knowledge associated with genetic resources : a public entity representing the local community grants it.*
- **CNA :**
 - general ABS scheme : MTES, through DEB, is the CNA ; it is also the CNA to receive declarations of due diligence (european regulation) at the stage of final development of a product developed via the utilisation of genetic resources or traditional knowledge associated with such resources

apa@developpement-durable.gouv.fr

- declarations of due diligence (european regulation) from all recipients of research public fundings involving the use of genetic resources and traditional knowledge associated with genetic resources :
Ministry of Research

si.apa@recherche.gouv.fr

Focal point :

MTES, through the International and european affairs department :

anca.leroy@developpement-durable.gouv.fr



Steps to access genetic resources / associated traditional knowledge

Access to genetic resources for research and development without any commercial purpose : a declarative procedure

▪ the applicant must fulfill a form : imprimé « CERFA » n°15786*01

(https://www.formulaires.modernisation.gouv.fr/gf/cerfa_15786.do),

or on line :

– legal entities: <https://www.demarches-simplifiees.fr/commencer/apa-declaration-pmorale>;

– individuals: <https://www.demarches-simplifiees.fr/commencer/apa-declaration-pphysique>

▪ preliminary and technical instruction by MTES : examination of the file completion ? in the scope ?

▪ decision within 2 months : rejection or agreement by a voucher sent to the applicant. The voucher is then published (« Bulletin officiel ») and sent to the ABS clearing house.

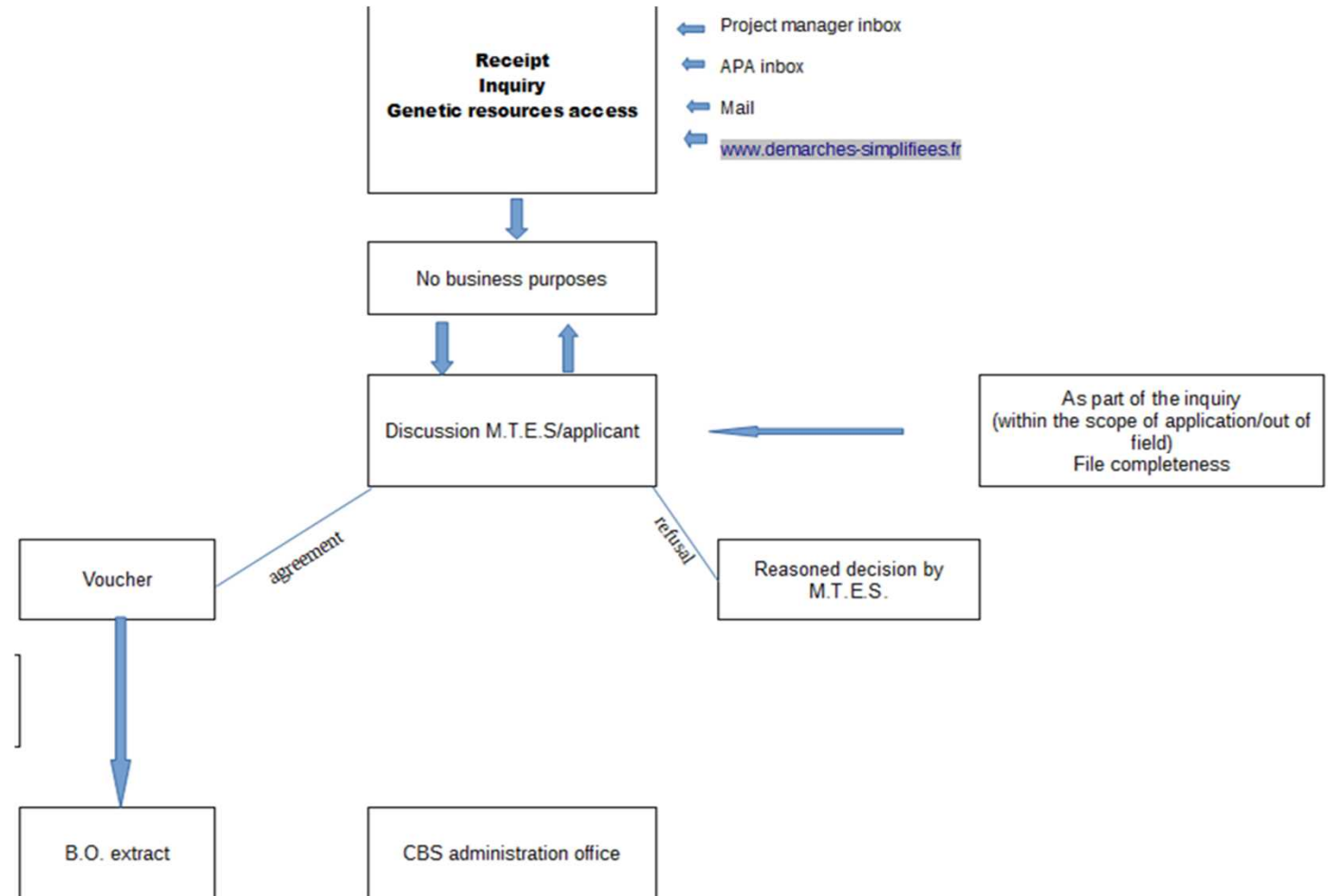
▪ benefit sharing : non-monetary



Steps to access genetic resources / associated traditional knowledge

Declaration

- file by applicant
- inquiry by MTES
- voucher



Steps to access genetic resources / associated traditional knowledge

Access for commercial purposes : an authorization procedure

▪ The applicant must fulfill a form : « imprimé CERFA » n° 15785*01

(https://www.formulaires.modernisation.gouv.fr/gf/cerfa_15785.do),

or on line :

– legal entities : <https://www.demarches-simplifiees.fr/commencer/apa-autorisation-pmorale>

– individuals : <https://www.demarches-simplifiees.fr/commencer/apa-autorisation-pphysique>

▪ preliminary and technical instruction by MTES : examination of the file completion ? in the scope ?

▪ the applicant and the MTES must negotiate an ABS agreement (4 months). In case of non agreement, the authorisation is rejected ;

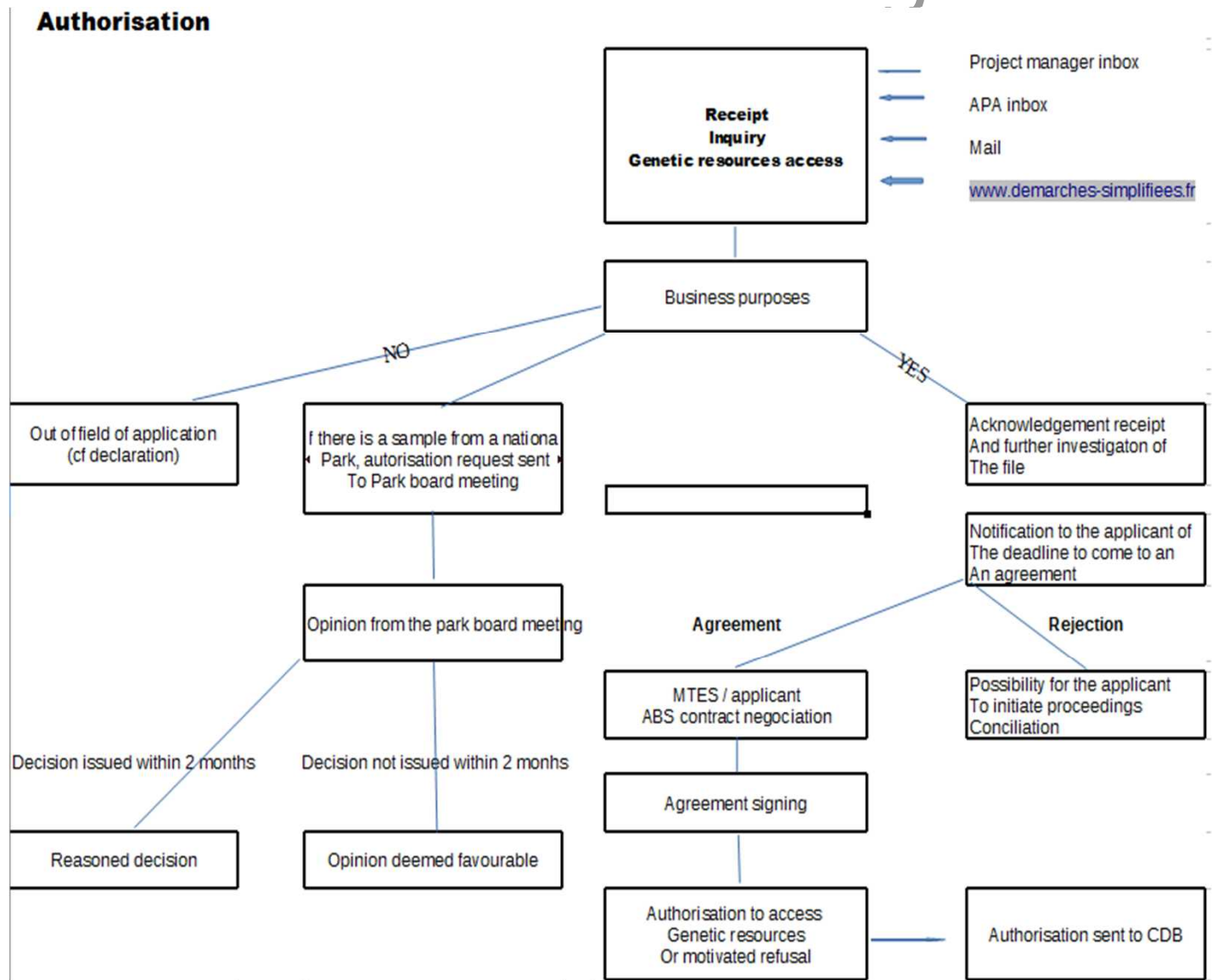
Steps to access genetic resources / associated traditional knowledge

- in case of genetic resources collected *in situ* in a national park, the park board meeting must give a formal opinion within 2 months ;
- decision within 2 months after the agreement : authorization to access genetic resources. The authorization is then published (« Bulletin officiel ») and sent to the ABS clearing house.
- The benefit sharing may be monetary or non monetary (negotiated in the agreement).

Steps to access genetic resources / associated traditional knowledge

Authorization (Genetic resources)

- file by applicant (business purposes)
- inquiry by MTES
- negotiation with the applicant
- agreement for benefit sharing
- authorization delivery



Steps to access genetic resources / associated traditional knowledge

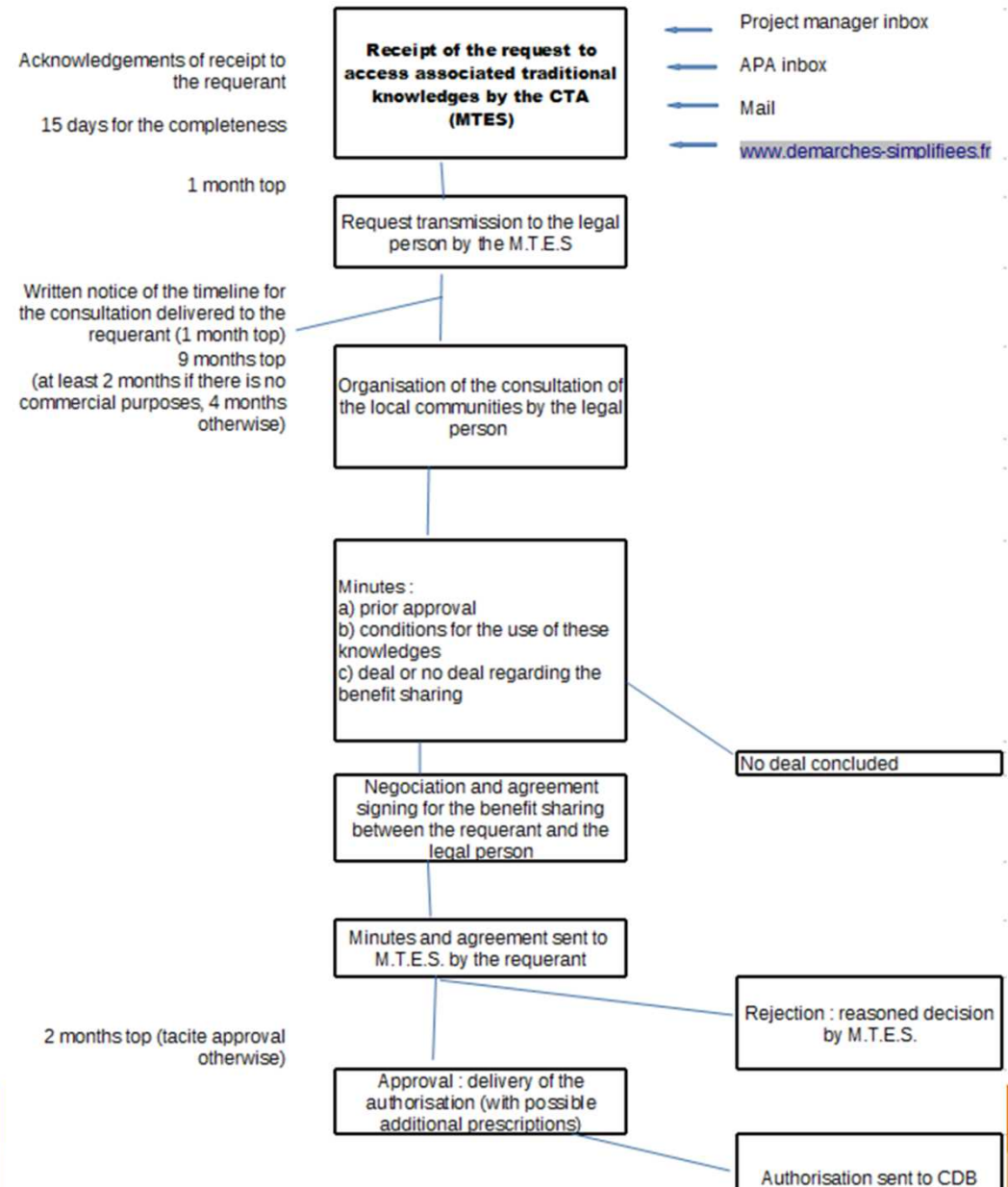
Utilization of traditional knowledge associated to genetic resources (no matter whether the research has a commercial purpose or not) : an authorization procedure.

- the applicant must fulfill a form : « imprimé CERFA » n°15784*01 (https://www.formulaires.modernisation.gouv.fr/gf/cerfa_15784.do);
- preliminary and technical instruction by MTES : examination of the file completion ? in the scope ?
- a public local entity (in French Guyane and Wallis-and Futuna-Islands) that is still to be designated, organizes a prior consultation with the local community (2 to 9 months). Once the local community has delivered its consent, it negotiates an agreement with the public local entity.
- decision within 2 months after the agreement : authorisation to access traditional knowledge.

Steps to access genetic resources / associated traditional knowledge

Authorization (Traditional knowledge)

- file by applicant
- inquiry by MTES
- consultation of local communities monitored by the legal person
- minutes & Agreement
- authorization



Collections

For collections established before the publication of the 2016 law, the procedures apply :

- to access, after the publication of the 2016 law, to genetic resources for research and development without any commercial purpose (declaration) ;
- to access genetic resources for commercial purposes (authorisation), only in case of a new use (in case of access to carry on research that have begun before the law, there is no access procedure).

The European regulation n°511/2014

Users obligations

- Exercise due diligence regarding legality of access (and sharing of benefits)
- Seek, keep and transfer to subsequent users :
 - - internationally recognised certificate of compliance, where available
 - - if IRCC not available, information on genetic resources or traditional knowledge associated, date/place of access, source, any rights and obligations, PIC and MAT

The European regulation n°511/2014

Checkpoints

- Monitoring measures : checkpoints
- Two checkpoints :
 - - at the stage of research funding where research involves utilization of genetic resources or traditional knowledge associated
 - - at the stage of pre-commercialisation (final stage of development of the product)
- IT tool developed to facilitate the process of exchange of information (DECLARE)

Penalties

- « Art. L. 415-3-1. (code de l'environnement) :
- I. Shall be punished with one year's imprisonment and a fine of €150,000 :
 - 1) The use of genetic resources or associated traditional knowledge (...) without the documents mentioned under point 3 of article 4 of (EU) Regulation (2014)
 - 2) Failure to search for, keep or send to subsequent users the relevant information on access and sharing of benefits for genetic resources or associated traditional knowledge (...). The fine shall be increased to one million euros if use of the genetic resources or associated traditional knowledge has led to a commercial use
- II. The individuals or legal entities guilty of the offences specified under I of this article shall also suffer a ban for a period, that may not exceed five years, on requests for an authorisation to access genetic resources and associated traditional knowledge with a view to its commercial use. »

Implementation experience

- To this point :

- more than 100 vouchers have been delivered in order to access genetic resources for research and development without any commercial purposes
- 50 more are being inquired
- only a few authorization requests have been submitted until now (to access genetic resources) and are being inquired ; no authorization requests for traditional knowledge have been submitted until now
- no agreement has been yet signed



Any question ? apa@developpement-durable.gouv.fr

Thanks for your attention



Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

MINISTÈRE
DE LA TRANSITION
ÉCOLOGIQUE
ET SOLIDAIRE