

## TITLE V

### ACCESS TO GENETIC RESOURCES, FAIR AND EQUITABLE BENEFIT SHARING

# Courtesy translation

**Warning: in the event of any legal inconsistency between the English courtesy translation and the French version, the French version of the law n°2016-1087 shall prevail**

<https://www.legifrance.gouv.fr/eli/loi/2016/8/8/DEV1400720L/jo/texte>

## **Title V: ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS**

### Article 37

Chapter II of Title I of Book IV of the French Environmental Code is amended as follows:

- 1) It is entitled: "Regulation of the uses of natural heritage"
- 2) At the beginning an additional Section 1 is added, entitled: "Activities subject to authorization or declaration" and it includes article L. 412-1
- 3) Section 2 is inserted and entitled: "Utilisation of non-domestic species of animals for scientific purposes" and it includes Article L. 412-2;
- 4) Section 3 is added and reads as follows:

#### "Section 3

"Access to genetic resources and associated traditional knowledge and sharing of the benefits arising from their utilisation

"Art. L. 412-3.- This section aims to determine the conditions for access to the genetic resources being part of the Nation's common heritage, defined under Article L. 110-1, for utilisation, and to ensure the fair and equitable sharing of the benefits arisen from their utilisation and, where applicable, the utilisation of associated traditional knowledge in accordance with the Convention on Biological Diversity adopted in Nairobi on 22 May 1992.

#### "Subsection 1

##### "Definitions

"Art. L. 412-4.-Within the meaning of this section, the following terms should be understood as follows:

"1) Utilisation of genetic resources: means to conduct research and development activities on the genetic or biochemical composition of a part or the whole animals, whole plants or parts thereof, whole micro-organisms or all other biological material containing functional units of hereditary or parts thereof, in particular through the application of biotechnologies, as well as the valorization of these genetic resources and applications and the resulting marketing

"2) Utilisation of traditional knowledge associated with genetic resources: their study and their valorization

"3) Sharing of benefits: the fair and equitable sharing of the benefits arisen from the utilization of genetic resources and associated traditional knowledge, understood as the results of the research and of the promotion and the benefits resulting from

their commercial or non-commercial utilisation, with the State detaining sovereign rights over these resources or with the traditional communities regarding traditional knowledge associated with these resources.

The sharing of benefits may consist in:

“a) The contribution or preservation of biodiversity in situ or ex situ, ensuring its sustainable utilisation.

“b) Protection of traditional knowledge associated with genetic resources through the creation, where applicable, of databases on the traditional knowledge of the traditional communities concerned, with their prior informed consent as well as the protection of other traditional practices and know-how protecting biodiversity;

“c) A contribution, at local level, to the creation of jobs for the local population and the development of branches associated with the sustainable utilisation of genetic resources or of associated traditional knowledge or the ones allowing for the valorization of biodiversity, linked to the territories that have contributed to the conservation of these resources;

“d) The collaboration, cooperation or contribution to activities in the area of research, education, training and raising awareness with the public and local professionals, or know how or technologies transfers;

“e) The maintenance, conservation, management, supply or restoration of ecosystem services over a given territory;

“f) The payment of financial contributions.

The actions a) to d) mentioned above are examined by priority;

“4) Traditional Communities: all communities of inhabitants who traditionally draw their means of subsistence from the natural environment and embodying traditional lifestyle relevant for the conservation and sustainable utilisation of biodiversity;

“5) Traditional knowledge associated with a genetic resource: the knowledge, innovations and practices relating to the genetic or biochemical properties of this resource, its utilisation or characteristics, which have been held from ancient times and continuously by one or more traditional communities mentioned under 4), along with the modifications in this knowledge and practices where they are made by these communities.

“6) Domestic or cultivated species: any species in which the evolutionary process has been influenced by humans to meet their needs ;

“7) Related wild species: any animal species with the capacity to sexually reproduce with domesticated species, along with any plant species used in cross-breeding with a species cultivated in the context of varietal selection;

“8) Collection: a group of samples of genetic resources collected and the related information, gathered and stored, whether it is held by public or private entities.

## “Subsection 2

“Rules regarding access to genetic resources and associated traditional knowledge within the national territory, and the sharing of benefits arisen from their utilisation.

### “Paragraph 1

“Scope of application

“Art. L. 412-5.

“I.-The following activities are subject to this section:

“1) Access to genetic resources for utilisation

“2) Utilisation of traditional knowledge associated with genetic resources.

“II.-This section does not apply:

“1) To the activities mentioned under I when they relate to:

“a) Human genetic resources

“b) Genetic resources collected outside the national territory and areas under French sovereignty or French jurisdiction

“c) The genetic resources covered by specialised international instruments for access and benefit sharing that meet the objectives of the Convention on Biological Diversity adopted in Nairobi on 22 May 1992, and which are not in violation thereof;

“d) The genetic resources of species utilised as models in research and development. A joint administrative decision by the ministers responsible for the environment, agriculture, research, health and defence will give the list of such model species;

“e) Traditional knowledge associated with genetic resources that cannot be attributed to one or more traditional communities ;

“f) The traditional knowledge associated with genetic resources whose properties are well known and have been used for a long time and repeatedly, outside of the traditional communities;

“g) The knowledge and traditional techniques associated with the promotion methods defined under Article L. 640-2 of the French Rural and Maritime Fishing Code that are likely to benefit agricultural, forestry or food and seafood products;

“2) The exchange and utilisation for personal or non-commercial purposes of genetic resources and associated traditional knowledge within and between traditional/local communities ;

“3) The activities mentioned under I of this article related to the protection of defence and national security interests.

“III.-Paragraphs 2 to 5 of this subsection do not apply to the genetic resources listed under 1) to 5) of this point III, which are under specific regimes on access to genetic resources and associated traditional knowledge on the national territory, and the sharing of the benefits arisen from their utilisation:

“1) Genetic resources arising from domesticated or cultivated species as defined under 6) of Article L. 412-4;

“2) The genetic resources of related wild plant species as defined under 7) of the same Article L. 412-4;

“3) The genetic resources that are subject to forestry as governed by Article L. 153-1-2 of the French Forestry Code;

“4) The genetic resources collected by laboratories in the context of prevention, surveillance and fighting the health risks concerning animals, plants and food health safety within the meaning of 1) and 2) of Article L. 201-1 of the French Rural and Maritime Fishing Code;

“5) The genetic resources collected by the laboratories to prevent and control the serious risks for human health as governed by Article L. 1413-8 of the French Public Health Code.

“Paragraph 2

“Collections

“Art. L. 412-6.-In the case of collections of genetic resources or associated traditional knowledge established before the publication of Act No. 2016-1087 of 8 August 2016 for the restoration of biodiversity, nature and landscapes, the procedures for access and benefit sharing arising from the utilisation of genetic resources under sovereign rights of the State and of the traditional knowledge associated with these genetic resources apply:

“1) To any subsequent access that follows the publication of said Act for the purposes mentioned under I of Article L. 412-7;

“2) To any new utilisation for other purposes.

“A new utilisation is defined as any research and development activity with a direct commercial development objective and for which the activity area stands out from the initial one of the same user with the same genetic resource or associated traditional knowledge.

## “Declaration procedures

“Art. L. 412-7.-I. Shall be subject to a declaration to the competent administrative authority: the access to genetic resources for their utilisation for the purposes of knowledge of biodiversity, conservation in a collection or promotion without a direct commercial development objective

“When the access to genetic resources mentioned in the first paragraph of Point I takes place on the territory under local authority where live traditional communities as defined under Article L. 412-4, the competent administrative authority shall inform traditional communities through an information procedure organized by the public legal entity mentioned under article L. 412-10.

“II.-The applicant is obliged to return to the public legal entity mentioned under this same Article L. 412-10 the information and knowledge, with the exception of the confidential information that constitutes industrial or commercial secrets, accessed from genetic resources collected on the territory under the competence of a local authority where one or more traditional communities are present.

“III.- Shall be subject to declaration: Access to genetic resources in emergency situations relating to human health, animal health or plant health other than those governed by article L. 1413-8 of the French Public Health Code.

“IV.-When the applicant considers that the general terms for benefit sharing applying to his/her activity are not adapted to the specific case of his/her file, he/she can request that his/her activity be subject to authorization.

## “Paragraph 4

### “Authorization procedure for access to genetic resources

“Art. L. 412-8.-I.-Shall be subject to the authorization by the competent administrative authority, the access to genetic resources for utilisation for purposes other than those mentioned under I and III of Article L. 412-7. Starting from the date of the agreement on the benefit sharing, the period for examining the authorization request may not exceed two months.

“When access to the genetic resources mentioned in the first paragraph of point I involves an access from in situ sampling within the geographic limits of a national park defined under Article L. 331-1, the competent authority has to send the authorization request file for access to genetic resources received in application of this point I to the Managing Board of the public establishment of the national park concerned by the in situ sampling. The Managing Board has to issue a reasoned opinion.

If no reply is received within a period of two months, the opinion shall be deemed favourable.

“When the access to genetic resources mentioned in the first paragraph of Point I takes place on the territory under a local authority’s competence where traditional communities live as defined under Article L. 412-4, the competent administrative authority shall have an information procedure for the traditional communities organized by the public legal entity mentioned under Article L. 412-10.

“II.-The authorization specifies the conditions of utilisation for the genetic resources for which it is granted, along with the terms for the sharing of benefits arising from this utilisation, through a contract between the applicant and the competent authority.

“III.-The applicant is obliged to return to the public legal entity mentioned under Article L. 412-10 the information and knowledge, with the exception of the confidential information that constitutes industrial or commercial secrets, accessed from genetic resources collected on the territory of a local authority where one or more traditional communities are present.

“IV.-The authorization can be refused if:

“1) The applicant and the competent authority fail to reach an agreement on the sharing of benefits, where applicable after the implementation of the reconciliation process specified under point VII of this Article

“2) The sharing of benefits offered by the applicant clearly does not correspond to his technical and financial capacities;

“3) The activity or its potential applications run the risk of significantly impacting biodiversity, restricting the sustainable utilisation of this resource or exhausting the genetic resource for which access for its utilisation is requested.

“The rejection is justified.

“V.-The financial contributions likely to be paid by users are calculated based on a percentage of the global annual turnover achieved before tax and other revenue, irrespective of its type, perceived from the products or processes obtained from the genetic resources that are the subject matter of the authorization.

“This percentage shall not exceed 5%, irrespective of the number of genetic resources covered by the authorization.

“Below a threshold set by the *Conseil d'Etat* decree as specified under Article L. 412-19, no financial contribution is requested.

“VI.- If the sharing of the benefits arising from the utilisation of genetic resources involves a financial benefit, this is allocated to the French Agency for Biodiversity, which shall use it exclusively to fund projects that meet the objectives listed under a to d of 3) of Article L. 412-4.

“The French Agency for Biodiversity takes into consideration the important biodiversity from overseas within the national biodiversity and guarantees the fair and equitable sharing of financial benefits.

“If a financial benefit results from the utilisation of genetic resources from a national collection, a national reference laboratory, a biological resource centre or a collection that make its samples available free of charge and this collection is not owned by the user, the French Agency for Biodiversity distributes a share part - defined by contract - to the holder of said collection, for storage and conservation purposes.

“VII.-The *Conseil d'Etat* decree as foreseen under Article L. 412-19 determines the terms and conditions for a reconciliation procedure that can be implemented if the applicant and the competent authority fail to reach an agreement on the sharing of benefits either within a period predefined by the parties or at the initiative of one or other of the parties.

“Paragraph 5

“Authorization procedures for the utilisation of traditional knowledge associated with genetic resources

“Art. L. 412-9.-I.-The utilisation of traditional knowledge associated with genetic resources is subject to authorization, which can only be granted at the end of the procedure defined under articles L. 412-10 to L. 412-14. This procedure aims to obtain the prior informed consent of the traditional communities concerned.

“II.- After fair and equitable sharing, the benefits arisen from the utilisation of the traditional knowledge associated with genetic resources are allocated to projects benefiting directly the traditional communities concerned. These projects are undertaken with the involvement of the traditional communities.

“Art. L. 412-10.-A decree designates -in each area where a traditional community lives as defined under 4) of Article L. 412-4, a public legal entity responsible for organizing the consultation of the traditional community or communities owning traditional knowledge associated with genetic resources, under the conditions defined in Articles L. 412-11 to L. 412-14. This legal entity may be a public environmental cooperation body as specified under Article L. 1431-1 representing the French General Local Authorities Code, an Advisory Council as specified under Article L. 71-121-1 of the same code or, failing that, the State or one of its competent public establishments in the area of the environment.

“This public legal entity is also responsible for negotiation and signature, taking into account the report mentioned under 6) of article L. 412-11 of this code, the benefit sharing contract concluded with the user and depending on circumstances, monitoring the goods attributed by the contract.



“Art. L. 412-11.

For each access application for the utilisation of traditional knowledge associated with genetic resources, the public legal entity mentioned under Article L. 412-10, asked on by the administrative authority competent to issue the authorization, defines and notify the applicant of the maximum length of the consultation, including the steps listed under 1) to 6) of this article.

The public legal entity:

“1) Identifies the traditional community or communities concerned by the request and assesses where applicable within their representative structures the existence of customary or traditional structures, competent to give an assessment on the utilisation of traditional knowledge associated with the genetic resources detained by them and on the sharing of the benefits arising from their utilisation.

“2) Determines the appropriate terms and conditions for informing and involving the traditional communities concerned;

“3) Proceeds to notify;

“4) Proceeds, as appropriate, the consultation of any public institution, association or foundation acting for the public interest competent on the content of the request or the traditional communities concerned;

“5) Ensures the involvement of all traditional communities concerned and seeks to reach a consensus;

“6) Records in a report the conduct of the consultation and its result, in particular:

“a) Prior informed consent given for the utilisation of their knowledge or refusal to give prior informed consent;

“b) Terms and conditions for utilisation of this knowledge;

“c) Agreement or the absence of an agreement on the sharing of the benefits arisen from this utilisation, as well as the terms and conditions for this benefit sharing;

“7) Transmits a copy of the report to the representative structures of the traditional communities concerned.

“Art. L. 412-12.-I.-In the light of the report, the administrative authority grants or refuses - in whole or partially - the utilisation of traditional knowledge associated with genetic resources.

“II.-The utilisation of associated traditional knowledge is limited to the purposes and conditions specifically mentioned in the authorization.

“Art. L. 412-13.-I.-The public legal entity mentioned under article L. 412-10 negotiates and signs with the user, in the light of the report mentioned under 6) of Article L. 412-11, the contract for the benefit sharing concluded by the parties during the consultation.

Modification to contracts on benefit sharing may be concluded under the same conditions.

“II.- Any exclusivity clauses in a contract regarding access to or utilisation of a part of traditional knowledge associated with genetic resources are deemed to be not written.

“III.-A standard benefit sharing contract is established by decree of the *Conseil d’Etat* under Article L. 412-19.

“Art. L. 412-14.-I.-If the benefits arisen from the utilisation of traditional knowledge are not assigned for the benefit of another beneficiary on the basis of the benefit sharing contract, they are transmitted by the user to the public legal entity mentioned under Article L. 412-10, which ensures the management and eventual devolution of the benefit of the traditional community or communities concerned. These benefits are the subject of separate accounting. They shall be assigned to projects benefiting directly the traditional community or communities concerned and in accordance with the opinion of community or communities.

“II.-The public legal entity mentioned under Article L. 412-10 ensures that the benefits arisen from the utilisation of the traditional knowledge is in compliance with the criteria set under point I of this article and with the content of the benefit sharing contract for the duration specified for this utilisation in the contract. It may file a civil suit in the event that this section is violated.

“III.-The benefit sharing contract may state that in the event of the disappearance of the recipient of the benefits initially designated by the contract, the public legal entity mentioned under Article L. 412-10 can act as proxy.

“Paragraph 6

“Provisions specific to the overseas local authorities regarding competent administrative authority

“Art. L. 412-15.-Thee regional councils of Guadeloupe and La Réunion, the assemblies of French Guiana and Martinique and the departmental council of Mayotte may decide in their territory deliberating to perform the administrative functions mentioned under I of Articles L. 412-7, L. 412-8 and L. 412-9 for the

requests to access and utilize genetic resources and associated traditional knowledge concerning their territory.

“Paragraph 7

“Collections

“Art. L. 412-16.- A decree defines a simplified annual declaration procedure for the holders of scientific collections.

“Paragraph 8

“Common provisions

“Art. L. 412-17.-I. The applicant indicates to the competent administrative authority which parts of the information provided in the declaration file, authorization request file and benefit sharing agreement concluded must remain confidential. If not, their dissemination would be a breach of industrial or commercial secrecy. Information likely to jeopardize the safeguarding of defence and national security interests shall not be provided in the aforementioned files or agreement.

“II.- Authorizations and declaration acknowledgment of receipt are registered by the administrative authority in on the Clearing House Mechanism created by the conference of the parties of the Convention on Biological Diversity, adopted in Nairobi on the 22 May 1992 in accordance with the stipulations of paragraph 3 of Article 18 of said Convention.

The registration gives the authorizations and declaration receipt slips the status of international recognized certificate of compliance as meant in paragraph 2 of article 17 of the the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, as of the entry into force of this protocol for France.

“III.-The transfer to third parties by the user of genetic resources or associated traditional knowledge for their utilisation must be accompanied by the transmission by the user of the authorization or declaration receipt slip, along with the associated obligations if they apply to the new user. The latter is obliged to declare this transfer to the competent administrative authority.

“A change in utilisation not anticipated in the initial authorization or declaration shall require a new authorization request or a new declaration.

“IV.-The benefits will be directed to the conservation of genetic resources and the associated traditional knowledge, as well as their local promotion and sustainable use.

### “Subsection 3

“Rules regarding the utilisation of genetic resources and associated traditional knowledge

“Art. L. 412-18.-I.-This subsection does not apply within the framework of the utilisation of genetic resources from animal selection operations - including operations for the conservation of animal species - performed in application of Chapter III of Title V of Book VI of the French Rural and Maritime Fishing Code, and does also not apply within the framework of the use of plant varieties that are or have been legally commercialised.

“II.-A decree designates one or more competent authorities responsible for applying (EU) Regulation No. 511/2014 of the European Parliament and of the Council of 16 April 2014 on measures concerning compliance by users in the EU of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, in particular the functions described under Articles 5, 7 and 9 to 13 of this Regulation, as well as under Articles 3 to 7 of (EU) Implementing Regulation 2015/1866 of the Commission of 13 October 2015 stating the terms and conditions for application of (EU) Regulation No. 511/2014 of the European Parliament and the Council regarding the registration of collections, the supervision of compliance with the rules by the user and the best practices.

“Users of genetic resources and associated traditional knowledge submit to the competent authority or authorities mentioned in the first paragraph of this Point II the information specified under article 4 of aforementioned EU Regulation No. 511/2014 of 16 April 2014, in the following cases:

“1) When they receive funding for research involving the utilisation of genetic resources and traditional knowledge associated with genetic resources.

“The administrative document granting the public funding contains a reimbursement clause for the sums paid to support the research works using genetic resources or associated traditional knowledge in the event of non compliance with the obligations defined in this Point II;

“2) At the final stage of the development of a product elaborated on the basis of the utilisation of genetic resources and traditional knowledge associated with genetic resources.

“If this utilisation leads to a patent application, the information mentioned in the first paragraph of this point II is sent to the National Institute of Industrial Property on the declaring party’s sole initiative. The National Industrial Property Institute proceeds with the standard examination of the patent application and gives the date of the deposit of the file and transmits the information without examining it to the competent authority responsible for the application of the European Union regulation aimed at ensuring that each Member State checks that the users of genetic resources and where applicable, traditional knowledge associated with these resources on its territory, has had access them in compliance with all legislative and regulatory provisions applicable at the time.

“If this utilisation leads to a request for a marketing approval, the information mentioned in the same first paragraph is collected by the competent authority for marketing approval, which transmits it without examining it to the competent authority mentioned in the penultimate paragraph of this Point II.

“Art. L. 412-19.-A decree in the Conseil d’Etat, issued after opinions – when they are concerned - from the local authorities governed by article 73 of the Constitution, specifies the conditions for the application of this section.

“Art. L. 412-20.-I.-The holders of a collection can request the approval by the State to all or part of their collection with a view to its inclusion within a European collections register.

“II.-The user of a genetic resource from a collection registered in the European collections register mentioned under Article 5 of (EU) Regulation No. 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization is considered to have been sufficiently diligent to obtain the information listed under Paragraph 3 of Article 4 of this Regulation. In the event of an access prior to the publication of Act No. 2016-1087 of 8 August 2016 for the restoration of biodiversity, nature and landscapes and on the date of approval of the collection, the due diligence shall be under the responsibility of the user.”

## Article 38

Article L. 415-1 of the same code is amended as follows:

- 1) At the beginning of the first paragraph, the following wording is added: “I.-”;
- 2) A point II is added, and reads as follows:

“II.-In addition to the officers mentioned under I of this article, the following shall be competent to search for and to assess violations of Articles L. 412-7 to L. 412-16, as well as of the obligations set down under Article 4 of (EU) Regulation No. 511/2014 of the European Parliament and of the Council of 16 April 2014 on

compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization and the texts drafted for their application:

“1) The officers from the departments of competition, consumption and fraud control who are entitled with competencies specified in Book V of the Consumer Code;

“2) The sworn officers appointed to this end by the Minister of Defence;

“3) The sworn officers appointed to this end by the Minister of Research

“4) The officers mentioned under L. 1421-1, L. 1435-7 and L. 5412-1 of the French Public Health Code

“5) The sworn officers of the regional natural parks;

“6) The sworn and commissioned officers of the local authorities and their groups;

“7) The sworn officers appointed to this end by the Minister of Agriculture.”

#### Article 39

Following article L. 415-3 of the same code, an article L. 415-3-1 is inserted and reads as follows:

“Art. L. 415-3-1.-I.

Shall be punished with one year's imprisonment and a fine of €150,000:

“1) The utilisation of genetic resources or associated traditional knowledge as meant in article L. 412-3 L. 412-4 without possessing the documents mentioned under Point 3 of Article 4 of (EU) Regulation No. 511/2014 of the European Parliament and of the Council of 16 April 2014, as mentioned above if they are compulsory;

“2) Failure to search for, keep or send to subsequent users the relevant information on access to and sharing of the benefits for genetic resources and associated traditional knowledge in application of the same Article 4.

“The fine shall be increased to one million euros if utilisation of the genetic resources or traditional knowledge mentioned under 1) of this point I has led to a commercial use.

“II.-The individuals or legal entities guilty of the offences specified under I of this article may also be convicted - by way of an additional punishment – to a ban for a period that may not exceed five years, to request, in application of Articles L. 412-8 and L. 412-9, for an authorization to access genetic resources or certain categories of them and the associated traditional knowledge with a view to its commercial use.”

## Article 40

Under II of Article L. 173-2 of the same code, the reference: “and L. 412-1” is replaced by the references: “, L. 412-1 and L. 412-7 to L. 412-16”.

## Article 41

In the last paragraph of Article L. 132-1 of the same code, the words: “and the National Forestry Property Centre” are replaced with the words: “, the National Forestry Property Centre, the legal entities designated by the decree in the *Conseil d’Etat* as specified in the first paragraph of article L. 412-10 for gathering the informed prior consent of the traditional communities and associations regularly declared and performing activities related to the conservation of traditional knowledge written into their statutes for at least three years.”

## Article 42

I.-Article L. 1413-8 of the Public Health Code is amended as follows:

- 1) Under 1), the words: “in his possession” are replaced by the words” “held by him”
- 2) In the first sentence of 2), the references: “L. 224-2-1 and L. 231-4” are replaced by the references: “L. 202-1 to L. 202-3”

3) After 2), 3) is inserted and reads as follows:

“3) The biological resources collected by the laboratories responsible for microbiological supervision under the conditions mentioned under 2) of this article are kept in a national collection of biological resources of interest for public health. An administrative order of the minister of health determines the list of establishments responsible for keeping these resources. A decree from the *Conseil d’Etat* determines the terms and conditions for their conservation, their provision and the sharing of benefits arisen from their utilisation.”

II.-Chapter V of Title I of Book I of the third part of the same code has an additional Article L. 3115-6, and reads as follows:

“Art. L. 3115-6.-An administrative decision of the health minister determines the terms and conditions for rapid access to biological resources useful in fighting the international propagation of diseases, with a view to sending these resources to reference laboratories in third countries or countries designated by the World Health Organisation.”

## Article 43

I.-Book VI of the French Environmental Code is amended as follows:

1) Chapter IV of Title I is added to in the form of an Article L. 614-3, worded as follows:

“Art. L. 614-3.-4) and 5) of Article L. 412-4 and II of Article L. 412-9, except for the last sentence, are applicable in New Caledonia.”

2) Chapter IV of Title II is added to in the form of an Article L. 624-5 and reads as follows:

“Art. L. 624-5.-4) and 5) of Article L. 412-4 and II of Article L. 412-9, except for the last sentence, are applicable in French Polynesia.”

3) After Article L. 635-2, an Article L. 635-2-1 is inserted and reads as follows:

“Art. L. 635-2-1.-Section 3 of chapter II of Title I of Book IV, Point II of Article L. 415-1 and Article L. 415-3-1 are applicable in Wallis and Futuna, subject to their competencies and the adaptation of the first paragraph of Article L. 412-10, which reads as follows: “The territorial constituencies governed by Title IV of Act No. 61-814 of 29 July 1961 conferring on Wallis and Futuna the status of an overseas territory or, by default, the State or one of the competent public entities in charge of the environment are responsible for organizing the consultation of traditional communities under the conditions set down under Articles L. 412-11 to L. 412-14.”

4) Title IV is added to in the form of an article L. 640-5, worded as follows:

“Art. L. 640-5.-Section 3 of chapter II of Title I of Book IV, Point II of Article L. 415-1 and Article L. 415-3-1 are applicable to the French Southern and Antarctic Territories.”

II.-Article L. 3115-6 of the French Public Health Code is applicable in Wallis and Futuna, French Polynesia and New Caledonia.

In French Polynesia and New Caledonia, the same Article L. 3115-6 applies under the conditions set respectively by the agreement between the State and French Polynesia and by the agreement between the State and New Caledonia concluded for the application of Chapter V of Title IV of Book VIII of the third part of the same code.

#### Article 44

Article L. 331-15-6 of the French Environmental Code is repealed starting from the latest dates of entry into force of the decrees specified under Section 3 of Chapter II of Title I of Book IV of the same code, in its draft resulting from this Law, and at the latest on 1 January 2018.



#### Article 45

I. Under the conditions specified under Article 38 of the Constitution, the Government is authorized to take any measures falling under the domain of the law through governmental orders (ordinances) so as to:

- 1) Define the terms and conditions for access to the genetic resources mentioned under 1), 2) and 4) of Point III of Article L. 412-5 of the French Environmental Code and the associated traditional knowledge and terms and conditions for the sharing of benefits arisen from their utilisation
- 2) Define the administrative and criminal regime sanctions for situations of non compliance and violations of the obligations foreseen in the governmental orders under this Point I.

II. - The governmental orders specified under point I are taken within a period of eighteen months starting from the enactment of the current law. For each governmental order, a draft ratification bill is brought before Parliament within a period of three months starting from the publication of the said order.

#### Article 46

Shall be authorized the ratification of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization related to the Convention on Biological Diversity signed by France on 20 September 2011.