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## INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE

**Sixteenth Session**  
**Geneva, May 3 to 7, 2010**

POLICIES, MEASURES AND EXPERIENCES REGARDING INTELLECTUAL  
PROPERTY AND GENETIC RESOURCES: SUBMISSION BY MEXICO

*Document prepared by the Secretariat*

1. At its fifteenth session, held from December 7 to 11, 2009, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee'):

“invited Member States and observers to make available to the Secretariat papers describing regional, national and community policies, measures and experiences regarding intellectual property and genetic resources before February 12, 2010, and requested the Secretariat to make these available as information documents for the next session of the Committee.” [...]

2. Further to the decision above, the WIPO Secretariat issued a circular to all Committee participants, dated January 15, 2010, recalling the decision and inviting participants to make their submissions before February 12, 2010.

3. Pursuant to the above decision, the Delegation of Mexico submitted a document entitled “Policies, Measures and Experiences regarding Intellectual Property and Genetic Resources” and requested it be made available as an information document for the sixteenth session of the Committee.

*4. The document is reproduced in the form received and contained in the Annex to this document.*

[Annex follows]

## ANNEX

## POLICIES, MEASURES AND EXPERIENCES REGARDING INTELLECTUAL PROPERTY AND GENETIC RESOURCES IN MEXICO

Article 28 of the Political Constitution of Mexico enshrines the rights of authors, artists and inventors with respect to the production of their works or to the exclusive use of their creations.

Similarly, in Mexican Law, there are three laws related to the protection of works or inventions which are the Law on Industrial Property (LIP), the Federal Law on Copyright (FLC) and the Federal Law on Plant Varieties (FLPV), which contain provisions to regulate, promote and protect inventions (patents, industrial designs, utility models, plant breeder's rights, etc.), as well as all types of literary or artistic works in all their forms, which have been created by individuals, regardless of their legal status. In the case of biological or genetic materials, the directly related national laws are the FLPV and the LIP.

In Mexico, the competent national authority as regards industrial property is the Mexican Institute of Industrial Property (IMPI), to which, pursuant to the LIP, the following applies<sup>1</sup>:

*III. process applications for and, where appropriate, grant patents and registrations of utility models, industrial designs, trademarks and advertising slogans, issue declarations to the effect that marks are well known, issue declarations of protection for appellations of origin, authorize the use thereof, publish trade names and also record renewals thereof and the transfer or licensing of their use and exploitation, and such other powers as are conferred on it by this Law and the Regulations thereunder, for the recognition and preservation of industrial property rights;*

Of the legal forms administered by IMPI, patents is the one directly related to genetic and biological resources.

#### Patent Protection of Genetic and Biological Resources

Mexico is party to different international agreements and treaties which directly or indirectly are related to intellectual property as well as genetic and biological resources. As regards industrial property, the most relevant treaties and agreements are the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure and the Paris Convention for the Protection of Industrial Property.

As regards national laws, specific provisions regarding industrial property are established in the Law on Industrial Property, particularly patents in which the link with the use of genetic or biological resources or materials or products derived therefrom is clear.

Article 15 of the Law establishes the following:

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<sup>1</sup> Article 6(III) of the Law on Industrial Property.

*Article 15.- Any human creation that allows matter or energy existing in nature to be transformed for use by man for the satisfaction of his specific needs shall be considered an invention.*

Pursuant to said Article, any human creation which transforms nature and can be used by man to meet his concrete needs, regardless of the nature or origin of these needs, is thus considered an invention.

In this respect, if an application refers to an invention in the language of Article 15 of the LIP, then it may be considered patentable as long as it fulfils the remaining requirements established in the said Law.

As regards biological or genetic materials, Articles 16, 19 and 47 of the LIP are particularly relevant in as much as these are explicitly related to such genetic materials.

In Article 16 of the LIP, exceptions to patentability are thus provided for, some of which are related to genetic resources, biological materials, or biological resources. In Article 16 it states:

*Article 16.- Inventions that are new, the result of an inventive step and industrially applicable under the terms of this Law shall be patentable, with the exception of:*

- I. essentially biological processes for obtaining, reproducing and propagating plants and animals;*
- II. biological and genetic material as found in nature;*
- III. animal breeds;*
- IV. the human body and the living matter constituting it; and*
- V. plant varieties.*

Similarly, Article 19 of the Law establishes what subject matter is not considered an invention and which therefore cannot be protected by a patent.

*Article 19.- The following shall not be considered inventions for the purposes of this Law:*

- I. theoretical or scientific principles;*
- II. discoveries that consist in making known or revealing something that already existed in nature, even though it was previously unknown to man;*
- III. diagrams, plans, rules and methods, for carrying out mental processes, playing games or doing business, and mathematical methods;*
- IV. computer programs;*
- V. methods for presenting information;*

VI. *aesthetic creations and artistic or literary works;*

VII. *methods of surgical, therapeutic or diagnostic treatment applicable to the human body and to animals; and*

VIII. *juxtaposition of known inventions or mixtures of known products, or alteration of the use, form, dimensions or materials thereof, except where in reality they are so combined or merged that they cannot function separately or where their particular qualities or functions have been modified so as to produce an industrial result or use not obvious to a person skilled in the art.*

For its part, Article 47 explicitly establishes the requirements regarding disclosure of the invention, particularly as regards genetic and biological materials as follows:

*Article 47.- The patent application shall be accompanied by:*

I. *A description of the invention, which shall be sufficiently clear and complete to be fully understood and, where appropriate, to serve as a guide for a person with average skill in the art to make it; it shall also mention the best method known to the applicant of carrying out the invention, when this is not clear from the description of the invention.*

*In the case of biological material where the description of the invention cannot itself be sufficiently detailed, the application shall be completed with a record of the deposit of the material at an institution recognized by the Institute, in accordance with the provisions of the Regulations under this Law;*

II. *the drawings required for the description to be understood;*

III. *one or more claims, which shall be clear and concise and may not exceed the contents of the description; and*

IV. *an abstract of the description of the invention, which shall serve solely for the publication thereof and as an element of technical information.*

IMPI procedures and actions regarding applications for the protection of inventions related to genetic or biological resources

In IMPI, patent applications in which the invention is directly related to biological or genetic materials are examined case by case, with different requirements and ways of dealing with the substantive examination of such applications depending on the subject matter described and claimed.

A way of dealing with a patent application as regards such genetic or biological resources or materials, is thus from the start to consider whether the subject matter described and claimed is an invention in the language of Article 19 of the LIP or whether it is excluded from patentability pursuant to Article 16 of the LIP.

In accordance with what is established in Article 16 of the LIP, in Mexico it is not possible to grant patent protection to biological or genetic materials in their natural state, that is, to those biological or genetic materials, irrespective of their origin, which have not been

isolated from their natural environment or whose properties have not been modified so as to give them a specific industrial application.

Conversely, biological or genetic materials which have been developed or obtained by means of non-essentially biological processes (that is, biotechnological processes) and whose characteristics have been modified as regards genetic or biological materials as they occur in nature, can be protected by means of a patent as long as these materials are not considered animal breeds or plant varieties and provided that the remaining patentability requirements established in the LIP are met.

Where an invention claimed in a patent application is related to biological or genetic material the subject matter described in the application and in the prior art is studied during the substantive examination to determine whether the said invention is *directly linked* to biological or genetic material, that is, *whether there is a direct connection between the resource and the invention in itself*.

During the substantive examination of a patent application there are thus different triggers which oblige patent examiners to identify whether the invention contained in a patent application is directly linked to genetic or biological material:

- Where a patent application contains claims to genetic material or biological material *in itself* (for instance, a microorganism).
- Where genetic material or biological material is used to bring about *in itself* a specific method or process (for instance, plasmid cloning).
- Where genetic material or biological material is used to bring about *with itself* a specific method or process (for instance, in a fermentation process).
- Where genetic material or biological material, whether directly or by means of a method or process, is used to *obtain a specific product derived from it* (for instance, obtaining an extract or manufacturing a protein).

Once it is established that the invention is directly related to a genetic resource, it is determined whether such genetic or biological material may be described or listed in itself as established in the second paragraph of Article 47(I) of the Law which states:

*Article 47.- The patent application shall be accompanied by:*

*I. a description of the invention, which shall be sufficiently clear and complete to be fully understood and, where appropriate, to serve as a guide for a person with average skill in the art to make it; it shall also mention the best method known to the applicant of carrying out the invention, when this is not clear from the description of the invention.*

*In the case of biological material where the description of the invention cannot itself be sufficiently detailed, the application shall be completed with a record of the deposit of the material at an institution recognized by the Institute, in accordance with the provisions of the Regulations under this Law.*

The triggers to request a record of the deposit to which the above Article 47 of the Law refers, are found in Article 37 of the Regulations, which states that:

*Article 37.- For the purposes of the second paragraph of Article 47(I) of the Law, a record of the deposit of biological material shall be required in the following cases:*

- I. where a microorganism is claimed in itself;*
- II. where the biological material referred to in the application is not publicly available; and*
- III. where the description that has been given of the biological material is insufficient for a person skilled in the art to reproduce it.*

It is noteworthy that the above triggers and legal conditions are limited to the different legal obligations in force and in no circumstances is there a trigger or legal obligation which is related to undertaking specific actions or legal regulations regarding the acquisition or use of genetic or biological material outside the scope of the patent system itself.

As established in Article 47(I) of the LIP, where such biological or genetic material may not be described in detail, that is, the technical features which define it are insufficient for the same results to be achieved by a person skilled in the art to obtain or replicate it, then the applicant is obliged to supplement the patent application with a record of deposit of said material issued by an institution recognized by IMPI, pursuant to what is established in the Regulations under the LIP (particularly Articles 28, 34, 35 and 37 of said Regulations), whether on the date of filing the application with IMPI or during its substantive examination.

The institutions referred to in the Law and the Regulations thereunder as regards the deposit of biological or genetic materials are those which are recognized as International Depositary Authorities (IDA) for the purposes of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (the Budapest Treaty, to which Mexico is party) or those national institutions which fulfill the relevant internationally accepted criteria and rules, as established in Article 35 of the Regulations.

*Article 35.- For the purposes of the second paragraph of Article 47(I) of the Law, the Institute shall accord recognition to institutions that have the character of international depositary authorities for biological material, and also to national institutions, in accordance with relevant internationally recognized criteria and rules.*

*The Institute shall publish a list of institutions recognized under this Article in the Diario Oficial (Official Gazette).*

In this way, where during the substantive examination it is ascertained that the record of deposit of genetic or biological material is required in the language of Article 37 of the LIP Regulations for the purposes of Article 47(I) of the LIP, then that record of deposit is examined to see whether it was filed in a timely manner and in keeping with Article 34 of the Regulations under the Law or if submitting a deposit of such material is required in the language established in the same Law and the Regulations thereunder.

The legal language and time limits in which said record of deposit should be submitted are covered by Article 34 of the Regulations, which establishes:

*Article 34.- The record of deposit of biological material referred to in the second paragraph of Article 47(I) of the Law shall be submitted within six months following the date on which the applicant files the corresponding patent application, and the said applicant shall retain the right to recognition by the Institute of the date and hour of the handing over of the application as the date and hour of filing, provided that the record of deposit shows that the deposit occurred prior to the date and hour of the handing over of the application, failing which the date on which the record was shown to the Institute shall be recognized as the filing date of the application.*

*Where the applicant fails to show the record in the specified period, the application shall be considered abandoned.*

Where during the substantive examination of an application it is ascertained that the record of deposit of genetic or biological material is required and no such record was filed along with the application on the date of filing with IMPI, alternative provisions for its fulfillment may apply. Where the applicant is required to submit a record of deposit and this has not occurred, then the applicant may submit a late filing, in which case the provisions of Article 38 of the Regulations apply, namely:

*Article 38.- The Institute shall recognize the date on which a patent application is handed over to it by the applicant as the date and hour of its filing, provided that the said application complies with the requirements laid down in Articles 47(I) to (III), 179 and 180 of the Law, and also with the provisions of Article 5(III) and (VII) of the Regulations.*

*Where the application does not comply with one or other of the legal and regulatory requirements specified in the foregoing paragraph, the Institute shall recognize only, as the date and hour of its filing, except in the case referred to in Article 180 of the Law, the date and hour of receipt of the submission by which the applicant complies with the requirements specified in the first paragraph above that were not complied with in the application, or otherwise remedies the failure to comply with the said requirements.*

Where the applicant, even with the prerogatives established in the LIP and the Regulations thereunder, does not submit a record of deposit then it is considered that the requirements of the Law established in Article 47(I) of the LIP have not been fulfilled and therefore the respective patent is refused.

Having ascertained whether the described and claimed invention is directly related to a biological or genetic resource, and once it is established that said material has been deposited with an IDA or its description is sufficiently clear and complete, then it is ascertained whether said material, or its directly related invention, is new (Articles 16 and 12(I) of the LIP), involves an inventive step (Article 16 and 12(III) of the LIP), is industrially applicable (Article 16 and 12(IV) of the LIP) and the same results can be achieved by a person skilled in the art (Article 47(I) of the LIP and Article 28 of the Regulations thereunder) and determine whether the respective patent may proceed or not.

Disclosure of origin or source of biological or genetic material directly related to an invention contained in a patent application



In Mexico, applicants for patents in which the invention claimed is directly related to biological or genetic materials state, in most cases, the country or countries of origin of said materials even though the LIP or the Regulations thereunder do not contain specific articles which necessitate such disclosure. The reasons for disclosing the country of origin in patent applications came about in the general scope obligations relating to the requirement to provide a sufficient description contained in the Law and the Regulations thereunder and which applies to all patent applications, regardless of the technical field concerned.

As mentioned above, where the invention claimed in a patent application is directly related to biological or genetic material, there is an obligation to ascertain whether said deposit is required or sufficient to define and carry out the claimed invention. Where the deposit is determined to be sufficient, then a patentability analysis is carried out as regards its novelty, inventive step and industrial applicability.

The reasons for identifying that a claimed invention does not require a deposit of the biological material with an IDA may include:

- the applicant has described in the application the taxonomy of the organism from which the genetic or biological material of the invention was obtained.
- the applicant has described in the application the fact that the genetic material of the invention is already known in the prior art, and cites the supporting references or bibliography.
- the applicant has described in the application the fact that the genetic material has been filed previously with an IDA (whether by himself or by others), and cites the filing number of the deposit of said material and the date on which said deposit was made.
- the applicant has described in a clear and complete manner the genetic material of the invention, for instance, by disclosing the complete sequence of said genetic material (for instance, genomes of viruses, phagocytes, plasmids, etc.).

Considering the above, during the substantive examination of patent applications whose invention is related to biological or genetic materials, a search in specific national or international databases is carried out on genetic resources (GRs) or biological resources (BRs). The aim of searching the databases may be one of the following:

- To ascertain whether the genetic or biological material directly related to the invention is described in the prior art. This is to establish whether said material is new or inventive.
- To ascertain whether the genetic or biological material directly related to the invention is referred to in accordance with international taxonomy, for the purposes of establishing whether its classification in the application corresponds to the description for such material and thus determine whether its description in the application is clear and complete so that a person skilled in the art could carry out the claimed invention or whether the material deposited corresponds to the description in the application.

– To ascertain whether the taxonomy classification of the genetic or biological material directly related to the invention is universally known or whether there are synonyms of the material, so that where synonyms exist, it may be established whether the GR or BR from which the genetic or biological material was obtained has already been described in different scientific terms and consequently ascertain whether the described material is clear and complete, as well as establishing whether the invention is new and inventive.

– To ascertain whether the genetic or biological material is in accordance with the technical specifications, in keeping with the databases, for the purposes of establishing whether the description in the application is clear and complete.

– To ascertain which genetic or biological materials belong to the same taxon or the taxon closest to the subject matter of the invention, with the aim of establishing whether other materials belonging to the said taxon have been used in prior art to carry out the same or a similar invention to that claimed and establish whether said invention involves an inventive step.

Once a search in the database has been performed an analysis of the claimed subject matter is carried out to determine its patentability pursuant to the requirements established in the Law.

Where an applicant has omitted the description of the genetic or biological material of the invention referring to it by a common name, he is required to amend the application in such a way as to include the scientific name in line with the international taxonomic classification. Where the said scientific name is not described using the correct taxonomic convention, he is required to amend the application in such a way as to change it in line with the internationally accepted taxonomy for said genetic or biological material (or biological or genetic resource from which it was sourced).

In any of the above cases, the deposit with an IDA, the description of the technical characteristics which define the genetic or biological material (or the genetic or biological resource from which it was sourced), the bibliographical references for the said material or resource, or its taxonomic classification, in most cases, allow the origin (geographical or other) of the said material to be established.

Where the biological or genetic material has not been previously described (whether because it is exotic, rare or completely new to science) and therefore is unavailable to the public, applicants in general provide a deposit to an IDA and mention the origin, geographical or other, of said material in the patent application. This is all due to the fact that if this were not done, the description would not be clear and complete and could not be carried out by a person skilled in the art.

In applications in which the applicants have used a biological or genetic material to carry out an invention (with or without having deposited the genetic or biological material with an IDA or described said material in terms of its technical characteristics, for instance, its general description, as well as genus and species) but have not described its geographical origin or from where it was sourced, and during the substantive examination it is established that the disclosure of such origin or source is required, then the applicant is required to remedy such an omission.

The legal bases for dealing with the above requirements are listed in Article 47 of the LIP and Article 28 of the Regulations thereunder, which state:

*Article 47.- The patent application shall be accompanied by:*

*I. a description of the invention, which shall be sufficiently clear and complete to be fully understood and, where appropriate, to serve as a guide for a person with average skill in the art to make it; it shall also mention the best method known to the applicant of carrying out the invention, when this is not clear from the description of the invention.*

*In the case of biological material where the description of the invention cannot itself be sufficiently detailed, the application shall be completed with a record of the deposit of the material with an institution recognized by the Institute, in accordance with the provisions of the Regulations under this Law;*

*II. the drawings required for the description to be understood;*

*III. one or more claims, which shall be clear and concise and may not exceed the contents of the description; and*

*IV. an abstract of the description of the invention, which shall serve solely for the publication thereof and as an element of technical information.*

*Article 28.- The description shall be drafted according to the following rules:*

*I. it shall give the name or title of the invention as it appears in the application;*

*II. it shall specify the field of technology to which the invention relates;*

*III. it shall mention the prior art known to the applicant in the state of the art to which the invention belongs, and shall preferably specify the documents that reflect the said state of the art;*

*IV. it shall describe the invention, as claimed, in clear and accurate terms that permit the technical problem, even where it is not expressly mentioned as such, to be understood, and shall give the solution to the problem, and explain the advantages of the invention, if any, over the prior art.*

*The description shall be concise, but as complete as possible, and it shall avoid digressions of any kind; the description shall point to the respects in which the invention being disclosed differs from similar inventions that are already known;*

*V. where the deposit of biological material is required under the provisions of the second paragraph of Article 47(I) of the Law, it shall mention that the said deposit has been made and shall state the name and address of the depositary institution, the date on which the deposit was made and the number allocated to it by the said institution, and describe also, to the extent possible, the nature and characteristics of the deposited material in so far as they are relevant to the disclosure of the invention;*

*VI. it shall contain a list of the various figures constituting the drawings, referring to them and to the various parts of which they are composed;*

*VII. it shall mention the best known method, or the applicant's intended best means, of carrying out the claimed invention; where this is sufficient, the mention shall take the form of practical examples or specific applications of the invention that are not of a nature that is alien to the invention described, and with references to the drawings, if any; and*

*VIII. it shall expressly state, when this is not apparent from the description or from the nature of the invention, the manner in which it may be produced or used, or both.*

*The description shall be presented in the form and order specified in this Article, except where, owing to the nature of the invention, a different form or order makes for better understanding and more practical presentation.*

*Each of the chapters in the description referred to in items II to VII above shall be preceded by a heading.*

Along with the cited legal bases, and depending on the specific case, there are various technical reasons for invoking the requirement to disclose the geographical origin or source of the genetic or biological material, including the following:

- It is evident (whether from prior or current art) that the invention could not have been carried out with all of the specimens of the same species and can only be carried out using biological or genetic materials obtained from a species from a particular geographical area.
- The invention described only refers to one species or genus in particular but it is evident (whether in the application description or in the current prior art) that the genetic or biological material was obtained from a particular species or lower ranking taxon.
- It is evident (whether from prior or current art) that the genus or species from which the biological or genetic material was obtained or derived has a wide range of genotype and phenotype variations which prevent it from being determined with the described subject matter whether said material may in all cases indicate the origin of the claimed invention.
- It is evident (whether from prior or current art) that in other genera and species, or lower ranking taxons, similar or identical genetic materials to those described have been obtained but their geographical origin or source does not match what the applicant has declared.

As can be seen, regardless of the technical reason concerned, when in an application an invention directly related to a genetic or biological material is described, a declaration of the geographical origin or source of the said material is required for the purposes of ensuring that the invention is clear and complete, and may be carried out by a person skilled in the art, the applicant is required to make the necessary amendments or declarations. If this is not done, the application, which does not fulfill the requirements of the articles of the above-mentioned Law, cannot be granted, because then its cancellation would follow under the terms of Article 56 of the LIP.

Legal actions subsequent to the grant of a patent

There are legal provisions in Mexico which provide for the annulment of a patent where this has been granted in contravention of one of the provisions of the Law, regardless of the technical nature of the invention in question.

As regards inventions relating to genetic or biological materials, the legal bases for annulling a patent in which the description of the genetic or biological material is insufficiently clear and complete on which the patented invention is based or from which it is derived is contained in the articles of Chapter VII *Invalidity and Lapse of Patents and Registrations*, of the LIP, including Article 78 which is particularly relevant and states:

*Article 78.- The patent or registration shall be invalid in the following cases:*

*I. when it is granted in violation of the provisions on the requirements and conditions for the grant of patents or registrations of utility models and industrial designs. For the purposes of the provisions of this subparagraph, the requirements and conditions for the grant of patents and registrations shall be those laid down in Articles 16, 19, 27, 31 and 47;*

*II. when such grant takes place in violation of the provisions of the law in force at the time of grant of the patent or registration.*

*An action seeking invalidation under this subparagraph may not be based on the disputing of the legal representation of the applicant for the patent or registration.*

*III. when abandonment of the application occurs in the course of processing; and*

*IV. when the grant has been invalidated by serious error or negligence, or has been made to a person not entitled to it.*

*An action seeking invalidation, as provided for in subparagraphs I and II above, may be brought at any time; that deriving from the circumstances provided for in subparagraphs III and IV above may be brought within five years following the date on which the publication of the patent or registration in the Gazette becomes effective.*

*Where the invalidation affects only one or some of the claims, or part of a claim, invalidation shall be declared only in respect of the claim or claims affected, or the affected part of a claim. Invalidation may be declared in the form of a limitation or specification of the corresponding claim.*

Thus, where the subject matter has been granted in contravention of the provisions of Article 47 of the Law, which, as previously mentioned, involves and requires the invention to be described in a clear and complete manner, and which therefore triggers the requirement of disclosure of deposit, origin or source of the material where it is necessary to carry out the invention claimed or so that a person skilled in the art might carry it out, then it is possible to declare said patent null and void.

Inventions directly based on, or derived from, biological or genetic materials which may be protected by a patent in Mexico.

Pursuant to the provisions established in the Law on Industrial Property, and particularly considering the flexibilities that said Law and the supranational rules allow (such as TRIPS), in Mexico patent protection may be granted to different inventions which are based on, or directly related to, biological or genetic materials, including:

- Isolated nucleic acid sequences (RNAs, DNAs, ETS, EST, etc.),
- Isolated genes,
- Isolated genomes (for instance viruses, viroids, phagocytes, phagemids, plasmids, vectors),
- Isolated microorganisms (for instance, bacteria or viruses),
- Isolated cells (regardless of their origin),
- Genetically modified organisms (regardless of their taxonomy, except human),
- Isolated proteins,
- Isolated biomolecules,
- Isolated or manufactured tissues

In any case, patent protection may be granted only to any of the said biological or genetic materials when said materials are new, inventive, industrially applicable and, as stated previously, have been described in a clear and complete manner so as to allow the claimed invention to be carried out in practice since, otherwise, it might lead to the respective patent being annulled or rather, having been granted in violation of said provisions, declared null and void.

#### Competent national authorities as regards genetic and biological resources

As mentioned above, it is a fact that in our country there are patents and patent applications involving genetic or biological materials which may come from the habitats in which they occur, that is, in *in situ* conditions such as scientific collections or uses or simply without having been authorized for collection, or *ex situ* collections, such as herbariums or biological collections.

In Mexico, the body in charge of protecting, preserving and regulating the sustainable use of natural resources<sup>2</sup>, pursuant to the Law on Federal Public Administration<sup>3</sup> is the Secretariat of the Environment and Natural Resources.

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<sup>2</sup> Natural resources include renewable and non-renewable resources. In the field of renewable resources, biodiversity is understood as being three-tiered: ecosystems, species and genes. Therefore it could be argued that genetic resources fall within, or are part of, biological resources and that these, in turn, are natural resources.

<sup>3</sup> Article 32 bis. The Secretariat of the Environment and Natural Resources is in charge of the following matters:

I. Promoting the protection, restoration and conservation of ecosystems and of natural resources as well as environmental goods and services, with a view to bringing about their sustainable use and development;

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As regards the particular situation of genetic resources, there is no specific legislation in our country on access to such resources; however, there are various provisions in different environmental laws. Also, Mexico is party to the Convention on Biological Diversity, one of whose objectives is the fair and equitable sharing of benefits derived from the use of such resources.

Within environmental legislation, there are the following provisions:

- General Law on Ecological Equilibrium and Environmental Protection (GLEEEP): this regulates scientific collection (Article 87) and the authorization for use in biotechnology (Article 87 bis), with biotechnology defined in the Law as any technological application that uses biological resources, live organisms or their derivatives to produce or modify goods or processes for specific uses.
- General Law on Wildlife (GLW) and the Regulations thereunder: These include provisions for scientific collection and for teaching purposes, and do not support use for commercial or biotechnology purposes. In the Regulations under the Law there are five different arrangements relating to scientific collection.
- NOM-126-ECOL-2000: This official Mexican standard is based on the GLW and establishes specifications for the scientific collection of biological material.
- General Law on Sustainable Forest Development (GLSFD) and the Regulations thereunder: provisions cover the collection and use of biological forest resources<sup>4</sup> for scientific purposes<sup>5</sup>, as well as biotechnology collection for commercial purposes<sup>6</sup>.

The absence of specific legislation on access to genetic resources has resulted in:

- some cases of misappropriation of resources (biopiracy), and
- the failure of potentially successful projects which might have been of benefit to Mexico, in particular due to not having been able “to change the intent in the use” of collected resources.

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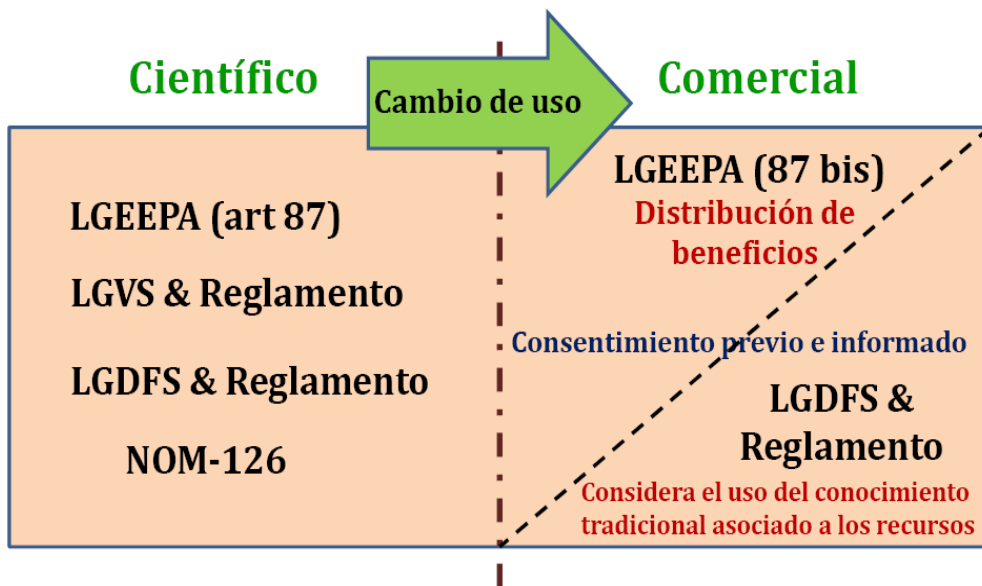
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III. Administrating and regulating the use, and promoting the sustainable use, of natural resources to which the Federation is entitled, with the exception of petroleum and all liquid, solid and gaseous hydrocarbons, as well as radioactive minerals;

<sup>4</sup> GLSFD, Article 2(XXIV). Biological forest resources: covers the species and varieties of plants, animals and microorganisms of the forest ecosystems and their biodiversity, and in particular those of scientific, biotechnological or commercial interest;

<sup>5</sup> Regulations under the GLSFD, Article 2(VII). Scientific collection, obtaining or removal of biological forest resources for the purposes of producing basic scientific information and for biotechnology research for non-commercial purposes;

<sup>6</sup> Regulations under the GLSFD, Article 2(VIII). Biotechnology collection for commercial purposes, obtaining or removal of biological forest resources for the purposes of producing chemical compounds, genes, proteins, secondary compounds, molecular structures, metabolic processes, and other results, for profit-making purposes;



**Lo que no sabemos ...**

- Lo que se colecta sin permisos (científica y comercialmente)
- Lo que se colecta con fines científicos con permisos y **cambia de uso** (...a comercial)
- Los recursos genéticos nacionales que se encuentran en colecciones en otros países (*ex situ*) y en el país, y la transferencia a terceros.
- Patentes en México y el mundo que incluyen recursos genéticos y/o conocimiento tradicional
- Cuanto perdemos/ganamos económicamente por la utilización de los recursos genéticos de nuestro país

Scientific	Change of use->	Commercial
GLEEEP (Article 87)		GLEEEP (Article 87 bis)
GLW & Regulations thereunder		<b>Benefit sharing</b>
GLSFD & Regulations thereunder		<b>Prior informed consent</b>
NOM-126		GLSFD & Regulations thereunder
<b>Considers the use of traditional knowledge associated with resources</b>		

**What we do not know ...**

- What is collected without authorization (for science and commercially)
- What is collected for scientific purposes with authorization and **changes use** (...to commercial)
- National genetic resources found in collections in other countries (*ex situ*) and in the country, and the transfer to third parties
- Patents in Mexico and worldwide which include genetic resources and/or traditional knowledge



- How much in economic terms we are losing or earning due to the use of our country's genetic resources

Relationship between the national authorities as regards intellectual property and the competent national authorities regarding genetic or biological resources

In spite of the fact that there are provisions in environmental legislation for collecting for commercial purposes, as well as for preventing the use of genetic resources collected for scientific purposes for other purposes, there are no legislative mechanisms or policy measures shared between the authorities in charge of intellectual property and the environmental body which may verify that genetic resources which run out or are used to obtain intellectual property rights were actually acquired lawfully and that where this is the case, the prior informed consent of their rightful holders has also been given, and in such a case, sharing of the benefits to which the GLEEEP refers has also taken place.

Due to the above it is important for Mexico to develop mechanisms which, not only at the national but at the multilateral level, allow for the detection of genetic or biological resources directly related to the inventions contained in patent applications, patents granted, or in other legal forms relating to intellectual property.

To achieve such an objective, in Mexico it was proposed to carry out an analysis of the forms and mechanisms which would enable the environmental authorities to identify which patent applications are directly related to a genetic or biological resource so that the authorities could identify, as regards access and beyond the scope of industrial property, whether such resources were accessed in accordance with the provisions of applicable national laws and, where this is the case, to proceed according to the sanction mechanisms or the use thereof, as established in such laws.

Similarly, Mexico is party to the negotiations of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore of the World Intellectual Property Organization, and is willing to listen to other country's experiences on this topic and to identify the advantages and disadvantages of an international amendment or adaptation to national laws on disclosing the origin or source of genetic resources in industrial or intellectual property applications.

[End of Annex and of document]