QUESTIONNAIRE ON VARIOUS REQUIREMENTS FOR DISCLOSURE RELATING TO GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE IN PATENT APPLICATIONS

QUESTIONNAIRE SUR DIFFÉRENTES EXIGENCES RELATIVES À LA DIVULGATION D'INFORMATIONS EN RAPPORT AVEC LES RESSOURCES GÉNÉTIQUES ET LES SAVOIRS TRADITIONNELS DANS LES DEMANDES DE BREVET

CUESTIONARIO SOBRE LOS DISTINTOS REQUISITOS DE DIVULGACIÓN RELATIVOS A LOS RECURSOS GENÉTICOS Y LOS CONOCIMIENTOS TRADICIONALES EN LAS SOLICITUDES DE PATENTE

(WIPO/GRTKF/IC/Q.3).

PART I

QUESTIONNAIRE ON VARIOUS REQUIREMENTS FOR DISCLOSURE RELATING TO GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE IN PATENT APPLICATIONS
(WIPO/GRTKF/IC/Q.3)

RESPONDENT	**NAME OF REPRESENTATIVE**	**TITLE**
Argentina	Luis María Nogués María Georgina Gerde	Administrador Nacional de Patentes, Instituto Nacional de la Propiedad Industrial
Australia	-	-
Burundi	Aloys Katihabwa	Conseiller au Département de Propriété Industrielle, Ministère du Commerce et de l'industrie
Canada	Robert McDougall	Intellectual Property Policy Officer, Department of Foreign Affairs and International Trade
China	Jianhua Song	Division Director, The State Intellectual Property Office (SIPO)
Czech Republic	Karel Jan Štolc	Ministry of Agriculture
Denmark	-	-
Finland	Riitta Larja	Coordinator, National Board of Patents and Registration of Finland
France	-	-
Germany	Dietrich Welp	Head of the Patent Section, Federal Ministry of Justice
Hungary	Krisztina Kovacs	Deputy Head, Legal Department, Hungarian Patent Office
Italy	Raffaele Foglia	Conseiller Juridique, Ministère de l'extèrieur
Malawi	V. J. Mzumara	Registrar General, Ministry of Justice, Department of the Registrar General

RESPONDENT	NAME OF REPRESENTATIVE	TITLE
Mexico	Josefina Moreni García	Directora de Relaciones Internacionales, Instituto Mexicano de la Propiedad Industrial (IMPI)
Niger	Boukar Attari	Conseiller Volet Diversité Biologique
New Zealand	Kim Connolly-Stone	Senior Advisor, Intellectual Property, Ministry of Economic Development
Philippines	-	-
Portugal	Jaime Serrão Andrez	President of the AC, IINPI - PT
Republic of Korea	Eulsoo Seo	Senior Deputy Director, Korean Intellectual Property Office
Republic of Moldova	Aurelia Ceban	Head of the Preliminary Examination and Methodology Division, State Agency on Industrial Property Protection of the Republic of Moldova (AEGPI)
Romania	Alexandru Cristin Strenc	Deputy Director General, State Office for Inventions and Trademarks
Russian Federation	L. Simonova	Head of Division, Russian Agency for Patents and Trademarks (Rospatent)
Spain	Javier Moreno Ramos	Director Departmento de Coordinación Jurídica y Reaciones Internacionales, Ministerio de Cienca y Tecnología, Oficina Española de Patentes y Marcas
Sweden	Carl Josefsson	Deputy Director, Ministry of Justice
Switzerland	Martin Girsberger	Swiss Federal Institute of Intellectual Property

RESPONDENT	NAME OF REPRESENTATIVE	TITLE
United States of America	Lois E. Boland	Acting Director, Office of International Relations, USPTO
Uruguay	María del Rosario Moreira	Asesora en Relaciones Internacionales, Dirección Nacional de la Propiedad Industrial
Viet Nam	Nguyen Thi Thanh Ha	Deputy Director, Legislation and Management Division, National Office of Industrial Property
European Commission	Ravillard Patrick	Principal Administrator, European Commission
European Patent Office	Bart Claes	Examiner-Member Directorate Patent Law, European Patent Office

QUESTIONNAIRE ON VARIOUS REQUIREMENTS FOR DISCLOSURE RELATING TO GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE IN PATENT APPLICATIONS (document WIPO/GRTKF/IC/Q.3).

Question 1: Please identify any national and/or regional laws and/or regulations which regulate access to genetic resources and/or traditional knowledge (TK) in your national territory. Concerning these laws or regulations, please indicate:

(a) What genetic resources or TK the law and/or regulation applies to;
(b) What requirements are stipulated for obtaining prior informed consent or determining the conditions of access, such as benefit-sharing arrangements;
(c) Whether a distinction has been made between access for non-profit research and access for commercial purposes;
(d) Any requirements for disclosure, reporting or otherwise monitoring of access to genetic resources and associated TK; and
(e) How these laws or regulations have been implemented in your national territory.

Question 2: Please itemize the information that a patent applicant is required to provide in the course of gaining a patent with effect in your country, and indicate the requirements for disclosure of the invention in a patent application. Please indicate the consequence of failure to meet such requirements.

Question 3: Is there a *specific* requirement, in any law and/or regulation that already applies to your country, or in any pending legislation, for a patent applicant to disclose:

(a) Information about any genetic resources used in the development of the claimed invention;
(b) The geographical origin (including country of origin) of genetic resources used in the claimed invention;
(c) An indication or evidence of prior informed consent given by those granting access to genetic resources used in the development of the claimed invention;
(d) The nature or source of associated TK used in isolating or distinguishing the genetic resources used in the claimed invention;
(e) The nature or source of associated TK used in the development of the claimed invention; and
(f) An indication or evidence of prior informed consent given by holders of TK that was used in the development of the claimed invention?

If your answer to all of questions 3(a) to (f) is 'no,' there is no need to answer questions 4 to 10; please go on to answer questions 11 to 14.

Question 4: Do the disclosure or information requirements covered by your answers to question 3 apply only to patent applications for inventions in a particular field or category of technology, or do they apply to patent applications for any inventions, regardless of the nature of the technology involved? Do the requireements apply equally to patent applications by domestic and foreign nationals?

Question 5: Are there particular guidelines defining the relationship that must exist between the genetic resources or TK and the claimed invention in order to trigger the obligation for

disclosure; for example, in the case that access to the genetic resources is necessary for carrying out the invention, or the TK was integral to the invention or was known prior art relevant to the invention?

Question 6: If there is a requirement to disclose the geographical origin of genetic resources, as specified in question 3(b), does it apply only if the genetic resources have been obtained within the legal jurisdiction or territory of your country?

Question 7: If there is a requirement to give evidence of prior informed consent, as specified in questions 3(c) and 3(f), does it apply only if the granters of access to genetic resources or holders of TK are nationals of your country?

Question 8: If there is a requirement to give evidence of prior informed consent, as specified in questions 3(c) and (f), does it specify the required form of such evidence?

Question 9: What are the consequences for the patent applicant or patent holder of any failure to meet any of the requirements covered in your answers to question 3? What means are available for the applicant or patent holder to remedy any failure to meet the requirement(s)? If the initial patent application, as lodged by an applicant, fails to meet these requirements, until what time can this information be subsequently provided?

Question 10: Is all information provided in accordance with these requirements published or available for public inspection, or are there mechanisms for preserving confidentiality of such material; for example, in relation to a confidential contract by which prior informed consent is given?

Question 11: Are there any analogous requirements (similar to questions 3(a)-(f)) in the law that applies in your country for other registered industrial property rights, such as utility models, petty patents, trade marks, or industrial designs?

Question 12: This question concerns the conventional patent disclosure requirements that apply in your country, such as a requirement for the invention to be disclosed in a manner sufficiently clear and complete to enable a person skilled in the art to carry it out, or a requirement to disclose the best mode known to the inventor of carrying out the invention.

(a) Are there circumstances in which these requirements have actually obliged, or may potentially oblige, a patent applicant to disclose any of the categories of information set out in questions 3(a) to (f)?
(b) Do you have information about any particular cases in which patent applicants have disclosed any of the categories of information set out in questions 3(a) to (f) in the normal course of meeting conventional patent disclosure requirements?

Question 13: What provisions apply in the event that information provided in a patent application in your country is false or misleading?

Question 14: If possible, please provide excerpts from or summary details of any legislative provisions, or judicial or administrative findings, that relate to your answers to any of the above questions. (Brief excerpts or quotations would be preferred over full texts of laws or regulations).

[Responses follows]

ARGENTINA

Contact Details

Name:	(1) Luis María Nogués
	(2) María Georgina Gerde
Title:	(1) Administrador Nacional de Patentes
Office/Organization:	Instituto Nacional de la Propiedad Industrial
Member State:	República Argentina
Address:	Paseo Colón N° 717. 2° Piso. Capital Federal. Rep. Arg
Email:	(1) luisnogues@hotmail.com
	(2) ggerde@hotmail.com
Telephone:	(5411) 4344-4917
Facsimile:	(5411) 4344-4919

Response to Question 1(a):
En lo que respecta a la normativa aplicable, cabe agregar que nuestro país está adherido al CONVENIO DE DIVERSIDAD BIOLÓGICA (CDB) pero aún no lo reglamentó, con lo cual nos encontramos frente a un ordenamiento pura y exclusivamente programático.

Response to Question 1(b):
Al no haber relamentación al respecto, no hay requisitos estipulados.

Response to Question 1(c):
Al no haber reglamentación al respecto, no se puede responder la pregunta.

Response to Question 1(d):
No está reglamentado.

Response to Question 1(e):
Al no estar reglamentada la legislación (el CDB) no se puede establecer en que forma opera en nuestro territorio nacional.

Response to Question 2:
El solicitante debe:

(a) presentar una solicitud por medio de la cual requiere una patente, la cual debe estar firmada. (En caso que el solicitante sea una persona física se deberá consignar la firma del mismo en el formulario de la solicitud, salvo que actué directamente a través de su representante legal. En caso que el solicitante sea una persona jurídica, deberá constatar la firma de su representante legal, cuyas facultades de representación de la persona jurídica deberán constar en la presentación). Si la solicitud no está firmada, será rechazada de plano. Si el problema recae sobre la personería invocada, la ley le da un plazo para que acompañe la documentación correspondiente, en caso de no cumplir la solicitud será denegada.

(b) presentar una descripción de la invención y una o varias reivindicaciones. La invención debe ser descripta (divulgada) de manera suficientemente clara y completa para que una persona experta y con conocimientos medios en la materia pueda ejecutarla. Asimismo debe incluir el mejor método (manera) conocido para ejecutar y llevar a la práctica la invención, y los

elementos que se empleen en forma clara y precisa”; es decir los ejemplos de realización que sean imprescindibles para la ejecución práctica de la invención. Ante el incumplimiento de estos requisitos la solicitud se deniega (para ciertas falencias como por ejemplo la falta de claridad la Oficina le va a correr una vista al solicitante para que aclare, subsane, etc.lo que correspondiere, si el requirente no cumple la solicitud pasa a denegarse).

(c) abonar todos los aranceles establecidos por ley (según que arancel no pague la solicitud, se deniega o se desiste).

(d) invocar y presentar las prioridades cuando correspondiere y los documentos de cesión de derechos (cuando fuere menester). Si no los presenta en los plazos establecidos, el solicitante pierde la prioridad.

(e) declarar los datos del depósito de microorganismo cuando correspondiere. Cuando el objeto de la solicitud sea un microorganismo o cuando para su ejecución se requiera un microorganismo no conocido ni disponible públicamente, el solicitante deberá efectuar el depósito de la cepa en una Institución Autorizada para ello. Ante el incumplimiento de este requisito dentro de los plazos establecidos por ley, la solicitud pasa a denegarse.

Response to Question 11:
No.

Response to Question 12:
No.

Response to Question 13:
Si la información proporcionada por el solicitante es falsa, y la falsedad recae sobre alguno de los requisitos de patentabilidad, una vez que la solicitud sea publicada el tercero tiene 60 días para presentar las correspondientes observaciones respecto a la patentabilidad del invento solicitado. Asimismo debe fundamentar su observación y aportar todas las pruebas necesarias. Si bien este tercero no es parte en el expediente, el examinador evaluará lo manifestado por él al momento de realizar el examen de fondo.

Si la información induce a error y esto es advertido por el técnico, el solicitante será intimado a corregirlo bajo apercibimienbto de denegar la solicitud.

Si la información suministrada por el requirente es falsa o induce a error y esto no es advertido en sede administrativa, cualquiera persona puede solicitar la nulidad de la patente por vía judicial.

[End of response of Argentina]

AUSTRALIA

Response to Question 1:
The Federal Government of Australia (Commonwealth of Australia) has prepared draft regulations under the aegis of section 301 of the *Environment Protection and Biodiversity Conservation Act* 1999 for access to, and the utilisation, of the genetic and biochemical resources found in natives species found on federal lands and waters (Commonwealth areas).

The objects of the regulations are to:

(i) promote the conservation of biological resources in Commonwealth areas, including the ecologically sustainable use of the biological resources;
(ii) ensure the equitable sharing of benefits arising from the use of biological resources in Commonwealth areas by providing for benefit-sharing agreements between persons seeking access to biological resources and access providers;
(iii) recognise the special knowledge held by Indigenous people about biological resources;
(iv) establish an access regime designed to provide certainty, and minimise cost, for people seeking access to biological resources; and
(v) seek to ensure that social and economic benefits arising from the use of biological resources in those Commonwealth areas accrue to Australia.

Aspects of management of genetic resources and traditional knowledge, under Australia's federated system, are left to the eight State or Territory governments. Accordingly, the Federal, State and Territory governments of Australia are considering a Nationally Consistent Approach For Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources. This is being undertaken by the inter-governmental Natural Resources Management Ministerial Council. This Nationally Consistent Approach will ensure that genetic resource management is undertaken consistently in all Australian jurisdictions. It picks up world's best practice through the Convention on Biological Diversity's Bonn Guidelines, provides for ecologically sustainable use, and addresses stakeholder issues – particularly those of industry, and the scientific and indigenous communities.

All jurisdictions are also bound by the terms of the National Strategy for the Conservation of Australia's Biological Diversity. This National Strategy specifically deals with traditional indigenous knowledge (Objective 1.8) and with access to genetic resources (Objective 2.8). The full document can be found at: http://www.ea.gov.au/biodiversity/publications/strategy/index.html. Additional Federal Government policy is contained in the National Biotechnology Strategy released by the Commonwealth Biotechnology Ministerial Council in June 2000. Access to genetic resources is dealt with under the Strategy Objective: *The development of measures to enhance access to Australian biological resources* (http://www.biotechnology.gov.au/industry_research/national_strategy/prop-biotech_nat_strategy.pdf.)

Specific answers concerning Commonwealth areas are as follows:

(a) Genetic resources found in native species and the traditional indigenous knowledge of Australia's Indigenous peoples;

(b) Prior informed consent resides with the government of the Australian jurisdiction concerned and may be delegated to a government authority or other entity. It is exercised through the use of permits to exercise control; and commonly by separating benefit-sharing arrangements from the permit system to achieve flexibility and to ensure each case is dealt with on its merits. This is exemplified by the terms of the earlier draft federal regulations as released for public comment;

(c) The Federal Government is considering a mechanism to be included in its regulations that will clearly differentiate between appropriate requirements for commercial scientific research and non- commercial scientific research. It will provide streamlined provisions for dealing with non- commercial scientific research. This mechanism will also ensure that such a differentiation does not weaken compliance with the broader regulatory system;

(d) Monitoring of access is generally done through the administration of the permit process while monitoring of the benefit-sharing agreement is undertaken by the body nominated as the access provider. This is usually a government authority or statutory entity. In certain circumstances the issue of a permit may involve Indigenous communities; and

(e) Federal laws described above are in the process of introduction in accordance with Australian Government procedures. National consistency is being addressed through the Natural Resources Management Ministerial Council.

In addition, each jurisdiction has existing laws under which genetic resources are currently accessed, although these are not generally systematically harmonised. The existing regimes were not designed to regulate access to, and the use of, biological resources in the terms set out in the Convention on Biological Diversity. Accordingly, a number of regulatory regimes already apply to this activity. Individual States and Territories are introducing, reviewing or developing their systems for genetic resource management.

Response to Question 2:
A patent applicant is required to fully describe the invention, and give the best method of performing the invention known to them (section 40(2)(a) of the *Patents Act 1990*). The patent specification must provide an adequate description to allow the invention to be performed by a specialist in the field. If the starting point is biological material, this requirement could be met by a full description of the material in words including where to find the material and how to recognise it. For example, full description of a microorganism means the full morphological, biochemical and taxonomic characteristics of the microorganism known to the applicant. There must be sufficient detail in the specification for a person skilled in the art to distinguish, identify and repeat the invention. Therefore, most commonly, where an invention relates to biological material, this material would be deposited in an International Depository Authority pursuant to the Budapest Treaty (sections 6, 41 and 42 of the *Patents Act*).

A patent application cannot proceed to grant until this information is provided. In addition, once an Australian patent application is accepted, acceptance is advertised. Third parties then have three months in which to oppose the grant of the patent. The grant can be opposed on a number of grounds, including that the applicant has failed to meet the requirements of section 40(2)(a) (section 59(c) of the Patents Act). Once a patent is granted, third parties can apply to the courts for an order revoking the patent, including on the ground that the specification does not meet the requirements of full description (section 138(3)(f) of the Patents Act).

Response to Question 3:
In the context of the Patents Act:
(a) No
(b) No
(c) No
(d) No
(e) No
(f) No

Response to Question 11:
The same answer to question 3 applies to innovation patents (and the former petty patents), trade marks and industrial designs.

Response to Question 12. (a):
The need to disclose the information referred to in question 3 (a) and (b) can/will arise if the invention is for a microorganism and the patent applicant does not use the Budapest Treaty to meet their requirements to provide a full description of the invention.

Response to Question 12. (b):
Such information is not readily available.

Response to Question 13:
If a patent is 'obtained by misrepresentation', it may be revoked on that ground (section 138(3)(d) of the Patents Act). The misrepresentation does not have to be a deliberate misrepresentation. Rather, any representation that was material to the Commissioner of Patents' decision to grant the patent that was in fact not true, is a misrepresentation that can invalidate the patent.

Response to Question 14:
See attachment below for relevant sections from the Patents Act 1990. Also attached is an extract from an opposition under section 59 of the Patents Act (Commonwealth Scientific and Industrial Research Organisation v Bio-care Technology Pty Ltd 45 IPR 483) which discusses the sufficiency requirements of section 40(2)(a) of the Act vis-a-vis microorganism deposits made under the Budapest Treaty and 'reasonably available'.

Provisions referred to in Australian Answers

Patents Act 1990 (Commonwealth)

SECTION 6 - Deposit requirements

For the purposes of this Act, the deposit requirements are to be taken to be satisfied in relation to a micro-organism to which a specification relates if, and only if:

(a) the micro-organism was, on or before the date of filing of the specification, deposited with a prescribed depositary institution in accordance with the rules relating to micro-organisms; and

(b) the specification includes, at that date, such relevant information on the characteristics of the micro-organism as is known to the applicant; and

(c) at all times since the end of the prescribed period, the specification has included:

(i) the name of a prescribed depositary institution from which samples of the micro-organism are obtainable as provided by the rules relating to micro-organisms; and

(iii) the file, accession or registration number of the deposit given by the institution; and

(d) at all times since the date of filing of the specification, samples of the micro-organism have been obtainable from a prescribed depositary institution as provided by those rules.

[*Note: see sections 41 and 42*]

SECTION 40 - Specifications

(1) A provisional specification must describe the invention.

(2) A complete specification must:

(a) describe the invention fully, including the best method known to the applicant of performing the invention; and

(b) where it relates to an application for a standard patent—end with a claim or claims defining the invention; and

(c) where it relates to an application for an innovation patent—end with at least one and no more than 5 claims.

(3) The claim or claims must be clear and succinct and fairly based on the matter described in the specification.

(4) The claim or claims must relate to one invention only.

SECTION 41 - Specifications: micro-organisms

(1) To the extent that an invention is a micro-organism, the complete specification is to be taken to comply with paragraph 40(2)(a), so far as it requires a description of the micro-organism, if the deposit requirements are satisfied in relation to the micro-organism.

(2) Where:

(a) an invention involves the use, modification or cultivation of a micro-organism, other than the micro-organism mentioned in subsection (1); and

(b) a person skilled in the relevant art in the patent area could not reasonably be expected to perform the invention without having a sample of the micro-organism before starting to perform the invention; and

(c) the micro-organism is not reasonably available to a person skilled in the relevant art in the patent area;

the specification is to be taken to comply with paragraph 40(2)(a), so far as it requires a description of the micro-organism, if, and only if, the deposit requirements are satisfied in relation to the micro-organism.

(3)For the purposes of this section, a micro-organism may be taken to be reasonably available to a person even if it is not so available in the patent area.
(4)Where:
(a) the requirements specified in paragraph 6(c) or (d) cease to be satisfied in relation to a micro-organism; and
(b) steps are taken at a later time within the prescribed period in accordance with such provisions (if any) of the regulations as are applicable; and
(c) as a result of those steps, if the period during which those requirements are not satisfied is disregarded, those requirements would be satisfied at that later time;
those requirements are to be taken to have been satisfied during the period mentioned in paragraph (c), and such provisions as are prescribed have effect for the protection or compensation of persons who availed themselves, or took definite steps by way of contract or otherwise to avail themselves, of the invention during that period.
[*Note: see also section 6 in relation to satisfaction of deposit requirements*.]

SECTION 42 - Micro-organisms ceasing to be reasonably available

(1)Where:
(a) a complete application has been made for a patent, or a patent has been granted for an invention of a kind mentioned in paragraph 41(2)(a); and
(b) the relevant micro-organism was, at the date of filing of the complete specification, reasonably available (within the meaning of section 41) to a skilled person working in the relevant art in the patent area; and
(c) the micro-organism has ceased to be so available;
a prescribed court or the Commissioner, on application made in accordance with the regulations, or the Commissioner, on his or her own motion, may declare that the specification does not comply with section 40 unless the deposit requirements are satisfied in relation to the micro-organism.
(2)Where a declaration is made under subsection (1):
(a) this Act has effect in relation to the specification accordingly; and
(b) section 6 applies as if the references in that section to the date of filing of the specification were references to a date specified in the declaration for the purposes of this subsection.
(3)Subsection (2) does not limit the operation of section 223.
(4)Where:
(a) an application is made under subsection (1); or
(b) the Commissioner proposes to make a declaration under that subsection on his or her own motion;
the applicant for the patent, or the patentee, as the case may be, must be notified, in accordance with the regulations, of the application or proposal and is entitled to appear and be heard.
(5)A declaration by the Commissioner must be made in accordance with the regulations.
(6)An office copy of a declaration by a prescribed court must be served on the Commissioner by the Registrar or other appropriate officer of the court.
(7)An appeal lies to the Federal Court against a decision of the Commissioner under subsection (1).
[*Note: see also section 6 in relation to satisfaction of deposit requirements*.]

SECTION 59 - Opposition to grant of standard patent

The Minister or any other person may, in accordance with the regulations, oppose the grant of a standard patent on one or more of the following grounds, but on no other ground:
(a) that the nominated person is either:

(i) not entitled to a grant of a patent for the invention; or
(ii) entitled to a grant of a patent for the invention but only in conjunction with some other person;

(b) that the invention is not a patentable invention because it does not comply with paragraph 18(1)(a) or (b);
(c) that the specification filed in respect of the complete application does not comply with subsection 40(2) or (3);
(d) that the invention is not a patentable invention under subsection 18(2).

SECTION 138 - Revocation of patents in other circumstances

(1)Subject to subsection (1A), the Minister or any other person may apply to a prescribed court for an order revoking a patent.
(1A) A person cannot apply for an order in respect of an innovation patent unless the patent has been certified.
(2)At the hearing of the application, the respondent is entitled to begin and give evidence in support of the patent and, if the applicant gives evidence disputing the validity of the patent, the respondent is entitled to reply.
(3)After hearing the application, the court may, by order, revoke the patent, either wholly or so far as it relates to a claim, on one or more of the following grounds, but on no other ground:
(a) that the patentee is not entitled to the patent;
(b) that the invention is not a patentable invention;
(c) that the patentee has contravened a condition in the patent;
(d) that the patent was obtained by fraud, false suggestion or misrepresentation;
(e) that an amendment of the patent request or the complete specification was made or obtained by fraud, false suggestion or misrepresentation;
(f) that the specification does not comply with subsection 40(2) or (3).

Commonwealth Scientific and Industrial Research Organisation v Bio-care Technology Pty Ltd (45 IPR 483) extract from pages 492-493

From my reading of the Act the intent of Section 41 is to maintain the " quid pro quo" in the patent system whereby a patentee is granted rights contingent upon disclosure to the public of their invention and how to put that invention into practice. The provision has its origin in the difficulties which can be associated with completely and unequivocally describing a microorganism in written form and issues of repeatability in relation to inventions involving microorganisms. In some, but not all, instances these issues can only be addressed by reference to a sample of the microorganism itself.

If an invention involving a microorganism can be fully described, and is repeatable, normal patent procedure applies. Otherwise, the invention is only fully described if the deposit requirements are met.

Section 41 exists to ensure an overriding purpose of the Act is met, that in return for the exclusive right, the patentee provides information sufficient for a person skilled in the art to be able to perform the invention. More specifically it is directed at ensuring access to microorganisms for inventions which involve microorganisms per se or their use, modification or cultivation. This would allow the public to conduct appropriate experimentation during the

currency of patent proceedings and to make use of the invention following the cessation of any patent rights.

Obviously the ideal solution to the problem of adequately describing a microorganism and reliably repeating the invention comes in the form of a deposit under the Budapest Treaty, which is the "deposit requirements" referred to at the end of paragraph 41(2). In this context it is pertinent at this point to note there are instances where a microorganism is not freely (ie unconditionally) available but is regarded as being reasonably available under the provisions of the Act. The Budapest Treaty and subregulation 3.25 make specific provision for conditional access to samples of microorganisms during the currency of a patent application. The treaty also contains provisions for access to deposits after the expiration of any rights.

The term "reasonably available" as referred to in Section 41 of the Act must be construed in light of the issues I have outlined above. The term itself clearly alludes to the notion of equitable access to a microorganism which either itself, or by its use, is the subject of a patent application. When the overriding intent of the Patents Act is considered, I take the term to encompass equitable and/or impartial access to the microorganism for appropriate experimental use during the prosecution of an application. I also take the term to include conditional access during prosecution of matters relating to the validity of the grant itself as well as access after the cessation of patent rights, if any.

[End of response of Australia]

BURUNDI

Contact details

Name:	Aloys Katihabwa
Title:	Conseiller au Département de Propriété Industrielle
Office/Organization:	Ministère du Commerce et de l'Industrie
Member State:	Burundi
Address:	BP 492 Bujumbura
Email:	alokati2001@yahoo.fr
Telephone:	(257) 244 880
Facsimile:	(257) 225 595

Response to Question 1:
Il n'y a pas de loi ni de réglements nationaux régissant l'accès aux ressources génétiques et aux savoirs traditionnels.

Response to Question 2:
Les renseignements demandés au déposant d'une demande de brevet sont notamment: la description de l'invention, les revendications; l'abrégé et éventuellement les dessins.

Response to Question 3:
Il n'y a pas de disposition spécifique en vigueur ni un projet de loi en préparation.

Response to Question 11:
Des exigences existent pour d'autres titres de propriété industrielle.
- Pour les marques, la marque ne doit pas être descriptive ni trompeuse. Le déposant doit aussi fournir un cliché.
- Pour les dessins et modèles industriels, le déposant doit fournir un échantillon ou une esquisse du dessin ou du modèle.

Response to Question 12 (a):
Oui, pour le cas d'une invention portant sur les médicaments traditionnels.

Response to Question 12 (b):
Le cas à signaler est celui d'un guérisseur traditionnel qui a déposé une demande de brevet pour protéger son savoir. Quand l'administration compétente lui a demandé de décrire le procédé de fabrication de ses médicaments l'intéréssé a refusé de les divulguer. Vous comprenez qu'il ne pouvait pas avoir son brevet.

Response to Question 13:
Dans le cas de faux renseignements, l'office ne délivre pas de brevet.

Response to Question 14:
L'article 10 de la loi du 20 août 1964 stipule en son article 10 point c) que "le brevet sera déclaré nul par les tribunaux, pour les causes suivantes:
(a) …
(b) …

(c) lorsque le breveté, dans la description jointe à sa demande aura, avec intention, omis de faire mention d'une partie de son secret ou l'aura indiqué d'une manière inexacte.

L'article 1er de l'arrêté ministériel n° 040/750 portant mesures d'exécution de la loi du 20 août 1964 sur les brevets, précise aussi en son point a) que: "au moment d'introduire sa demande, le requérant ou son mandataire déposera la description de l'objet inventé, accompagné éventuellement des dessins qui seraient nécessaires pour l'intelligence de la description, le tout en double exemplaire".

L'article 1er point b) stipule en outre que "le requérant ou son mandataire déposera un résumé établi en double exemplaire, énonçant d'une manière précise et concise, les caractères distinctifs qui constituent la nouveauté de l'invention, si le résumé comprend un dessin, deux exemplaires supplémentaires du dessin seront fournis ainsi qu'un cliché métallique…".

[End of response of Burundi]

CANADA

Contact Details

Name:	Robert McDougall.
Title:	Intellectual Property Policy Officer.
Office/Organization:	Department of Foreign Affairs and International Trade .
Member State:	Canada.
Address:	Lester B. Pearson Building,125 Sussex Drive, Ottawa, Ontario K1A 0G2.
Email:	robert.d.mcdougall@dfait-maeci.gc.ca
Telephone:	(613) 944-0381
Facsimile:	(613) 944-0066

Response to Question 1(a):
Access to genetic resources in Canada is regulated through federal, provincial and territorial legal regimes governing access to land.

With respect to lands owned by the federal crown, a number of Ministries have the responsibility for regulating access to lands under their administration. Additionally, access to genetic resources is also governed by environmental laws or sectoral laws (e.g. forestry and fisheries). The domestic legal regime governing Aboriginal rights to use natural resources may have an impact on access to genetic resources on these lands.

Response to Question 1(b):
Genetic resources on federal, provincial and territorial lands are the property of these different levels of government. The *Federal Real Property Act* applies to genetic resources on federal lands. Various federal Ministries are responsible for administering access to federal lands.

Response to Question 1(c):
Commercial activity is prohibited in certain protected areas and parks.

Response to Question 1(d):
The Biodiversity Convention Office of Environment Canada in particular, other federal ministries, and other levels of government each play a role in their respective areas of responsibility in monitoring access to genetic resources.

Response to Question 1(e):
Canada has not enacted a specific national law governing access and benefit-sharing but rather the existing legal regime governing property rights, government lands, environmental protection, resource management and Aboriginal rights are applicable.

Response to Question 2:
In order to obtain a patent, a patent applicant must submit an application which includes:
(a) an indication in English or French that the granting of a Canadian patent is sought;
(b) the name of the applicant;
(c) the address of the applicant or of a patent agent of the applicant;
(d) a document, in English or French, that on its face appears to describe an invention; and

(e) the application fee.
[Section 93 of the Patent Rules, Section 28(1) of the Patent Act.]

The patent application must also contain:
(a) a petition;
(b) an abstract;
(c) a sequence listing (where required);
(d) a copy of a sequence listing in computer readable form (where required);
(e) a claim or claims;
(f) any drawing referred to in the description;
(g) an appointment of a patent agent (where required);
(h) an appointment of an associate patent agent (where required);
(i) an appointment of a representative (where required).

If these elements are not provided at the time of filing, the applicant has up to fifteen months from the earliest filing date to submit any missing elements to the Canadian Patent Office.
[Section 94 of the Patent Rules.]

The specification of the application (description and claims) must:

(a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;
(b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it;
(c) in the case of a machine, explain the principle of the machine and the best mode in which the inventor has contemplated the application of that principle; and(d) in the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions.
[Section 27(3) of the Patent Act.]

The claim or claims must define in distinct and explicit terms the subject-matter of the invention for which an exclusive privilege or property is claimed.
[Section 27(4) of the Patent Act.]

Applications failing to comply with the above requirements are not entitled to patent protection.

Response to Question 3(a)-(f):
No.

Response to Question 11:
No.

Response to Question 12:
No.

Response to Question 13:
Under Section 76 of the Patent Act, every person who, in relation to the purposes of this Act and knowing it to be false,

(a) makes any false representation,
(b) makes or causes to be made any false entry in any register or book,
(b.1) submits or causes to be submitted, in an electronic form, any false document, false information or document containing false information,
(c) makes or causes to be made any false document or alters the form of a copy of any document, or
(d) produces or tenders any document containing false information, is guilty of an indictable offence and liable on conviction to a fine not exceeding five hundred dollars or to imprisonment for a term not exceeding six months or to both.

Response to Question 14: Legislative provisions provided directly in the responses to the questions.

[End of response of Canada]

CHINA

Contact Details

Name:	JianhuaSong
Title:	Division Director
Office/Organization:	The State Intellectual Property Office
Member State:	P.R.China
Address:	6 Xitucheng Road, Haidian District, Beijing 100088, China
Email:	songjianhua@sipo.gov.cn
Telephone:	86-10-62093608
Facsimile:	86-10-62093625

Response to Question 2:

According to the Chinese Patent Law and its Implementing Regulations, a patent application should include the following information:

(1) The request of a patent application shall state the title of the invention, the name of inventor(s), the nationality, name and address of applicant(s), the name and address of patent agency, and where the priority of an earlier application is claimed, the relevant matters.

(2) The description of a patent application shall set forth the invention in a manner sufficiently clear and complete so as to enable a person skilled in the relevant field of technology to carry it out. The description shall generally be consisted of the following: technical field of the invention, background art, contents of the invention, and mode of carrying out the invention.

(3) Where a patent application contains disclosure of one or more nucleotide and /or amino acid sequences, the description shall contain a sequence listing in compliance with the standard prescribed by the State Intellectual Property Office (SIPO). The sequence listing shall be submitted as a separated part of the description, and a copy of the said sequence listing in machine-readable form shall also be submitted.

(4) Where an invention for which a patent is applied for concerns a new biological material which is not available to the public and which cannot be described in the application in such a manner as to enable the invention to be carried out by a person skilled in the art, the applicant shall deposit a sample of the biological with a depositary institution designated by SIPO before, or at the latest, on the date of filing (or the priority date), and submit a receipt of deposit and the viability proof from the depositary institution. Where they are not submitted within the specified time limit, the sample of the biological material shall be deemed not to have been deposited.

(5) The applicant is also required to furnish pre-filing date reference materials concerning the invention when he or it requests for substantive examination to the application. For an application that has been already filed in a foreign country, SIPO may ask the applicant to furnish, within a specified time limit, documents concerning any search made for the purpose of examining that application, or concerning the results of any examination made, in that country. If, at the expiration of the specified time limit, without any justified reason, the said documents are not furnished, the application shall be deemed to have been withdrawn.

Response to Question 11:
At present, there are no analogous requirements (similar to question 3) applied to the applications for granting or registering utility models or industrial designs.

Response to Question 12 (a):
No

Response to Question 12 (b):
Yes, it's said that in some cases the applicants have disclosed such information.

Response to Question 13:
Under the Chinese patent legislation, in general, there is no expressed provision concerning the false or misleading information provided in a patent application and the legal consequences thereof.

Response to Question 14:
Chinese Patent Law

Article 26. Where an application for a patent for invention or utility model is filed, a request, a description and its abstract, and claims shall be submitted.

The request shall state the title of the invention or utility model, the name of the inventor or creator, the name and the address of the applicant and other related matters.

The description shall set forth the invention or utility model in a manner sufficiently clear and complete so as to enable a person ski11ed in the re1evant field of techno1ogy to carry it out; where necessary, drawings are required. The abstract shall state briefly the main technical points of the invention or utility model.

The claims sha1l be supported by the description and shal1 state the extent of the patent protection asked for.

Article 36. When the applicant for a patent for invention requests examination as to substance, he or it shall furnish pre-filing date reference materials concerning the invention.

For an application for a patent for invention that has been already filed in a foreign country, the patent administration department under the State Council may ask the app1icant to furnish within a specified time limit documents concerning any search made for the purpose of examining that application, or concerning the results of any examination made, in that country. If, at the expiration of the specified time limit, without any justified reason, the said documents are not furnished, the application sha1l be deemed to have been withdrawn.

The Implementing Regulations of the Patent Law

Rule l7. "Other related matters" in the request referred to in Article 26, paragraph two of the Patent Law means:

(1) the nationality of the applicant;

(2) where the applicant is an enterprise or other organization, the name of the country in which the applicant has the principal business office;

(3) where the applicant has appointed a patent agency, the relevant matters which shall be indicated; where no patent agency is appointed, the name, address, postcode and telephone number of the liaison person;

(4) where the priority of an earlier application is claimed, the relevant matters which shall be indicated;

(5) the signature or seal of the applicant or the patent agency;
(6) a list of the documents constituting the application;
(7) a list of the documents appending the application; and
(8) any other related matter which needs to be indicated.

Rule l8. The description of an application for a patent for invention or utility model shall state the title of the invention or utility model, which shall be the same as it appears in the request. The description shall include the following:

(1) technical field: specifying the technical field to which the technical solution for which protection is sought pertains;

(2) background art: indicating the background art which can be regarded as useful for the understanding, searching and examination of the invention or utility model, and when possible, citing the documents reflecting such art;

(3) contents of the invention: disclosing the technical problem the invention or utility model aims to settle and the technical solution adopted to resolve the problem; and stating, with reference to the prior art, the advantageous effects of the invention or utility model;

(4) description of figures: briefly describing each figure in the drawings, if any;

(5) mode of carrying out the invention or utility model: describing in detail the optimally selected mode contemplated by the applicant for carrying out the invention or utility model; where appropriate, this shall be done in terms of examples, and with reference to the drawings, if any;...

Where an application for a patent for invention contains disclosure of one or more nucleotide and/or amino acid sequences, the description shall contain a sequence listing in compliance with the standard prescribed by SIPO.

Rule 25. biological material

[End of response of China]

CZECH REPUBLIC

Contact Details

Name:	Karel Jan Štolc
Title:	Ing., PhD.
Office/Organization:	Ministry of Agriculture
Member State:	Czech Republic
Address:	Těšnov 17, 171 05 Prague
Email:	stolc@mze.cz
Telephone:	+42 2 2181 2536
Facsimile:	+42 2 2481 0097

Response to Question 1:

The Czech law – No. 527/1990 Coll. On Inventions and Rationalization Proposals, as follows from amendments implemented by Act No. 519/1991 Coll., Act No. 116/2000 Coll. And Act No. 207/2000 Coll. does not regulate access to genetic resources and/or traditional knowledge.

Response to Question 2:

- Patents shall be granted for any inventions which are new, which involve an inventive step and which are susceptible of industrial application (*section 3 (1) above mentioned regulation*);

- The following in particular shall not be regarded as inventions:
  (a) discoveries, scientific theories and mathematical methods;
  (b) aesthetic creations;
  (c) schemes, rules and methods for performing mental acts, playing games or doing business and programs for computers;
  (d) presentations of information (*section 3(2) above mentioned regulation*);

- Patents shall not be granted in respect of :
  (a) inventions the exploitation of which would be contrary to “order public” or morality; this fact may not be concluded merely because the exploitation of invention is prohibited by law;
  (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes and the products thereof (*section 4 above mentioned regulation*);

- The invention must be disclosed in the invention application in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Where the invention concerns an industrial micro-organism for the purposes of production, the micro-organism must be kept in a public collection as from the date on which the applicant’s priority right begins (*section 26 (2) above mentioned regulation*);

- Special provisions on the application of biotechnological invention see enclosure (section 5 of the Act No. 206/200 Col.)

If the application does not fulfill the above conditions of substantive law, it shall be refused.

- The formal conditions:
  An application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Where a group of inventions is claimed in one and the same patent application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” shall mean those features which define a contribution which each of the claimed inventions considered as a whole makes the prior art (*section 26 (1) above mentioned regulation*);

- Subsequent conditions (See *section 6-10 of the Decree No. 21 /2001 Coll. Which is changing the Decree No. 550/1990 Col.*).

If the application does not fulfill the formal conditions above, the Office shall terminate the procedure.

Response to Question 3:
No.

Response to Question 11:
No.

Response to Question 12 (a) - (b):
No.

Response to Question 13:
The application shall be refused if it contains false or misleading information (see Question 2).

[End of response of Czech Republic]

DENMARK

Response to Question 1:
No national law or regulation regulates access to genetic resources and TK.

Response to Question 2:
With regard to the response to this question Denmark shall refer to document WIPO/GRTKF/IC/4/11 item 37. The Danish legislation is in line with the general terms refered to under item 37 with the addition of the last intent of item 38 concerning special provisions on description or deposit of microorganisms or biological materials.

Response to Question 3 (a) and (b):
If an invention concerns or makes use of biological material of vegetable or animal origin the patent application shall include information on the geographical origin of the said material, if known. If the applicant does not know the geographical origin of the material, this shall be indicated in the application. Lack of information on the geographical origin of the material or on the ignorance hereon does not affect the assessment of the patent application or the validity of the rights resulting from the granted patent.

Response to Question 4:
The requirements apply to any invention and apply equally to domestic and foreign nationals.

Response to Question 5 and 6
No

Response to Question 9:
There are no consequences of failure to meet the requirements with regard to the grant of the patent. Wrong information may be liable to criminal sanctions as wrongful information to a public authority. The information may be filed until date of grant.

Response to Question 11:
The response to this question is no.

Response to Question 12:
The responses to the questions under items (a) and (b) are no.

Response to Question 13:
According to the Danish Patent Law false or misleading information may probably lead to the rejection of an application or the invalidation of a granted patent. The reason for rejection or invalidity would then, however, be that the criteria for patentability were not met, and not the fact of false or misleading information as such.

[End of response of Denmark]

FINLAND

Contact Details

Name:	Riitta Larja
Title:	Coordinator
Office/Organization:	National Board of Patents and Registration of Finland
Member State:	Finland
Address:	Arkadiankatu 6 A, 00100 Helsinki, Finland
Email:	riitta.larja@prh.fi
Facsimile:	+ 358 9 6939 5556

Response to Question 1 (a):
Patent legislation is applied to all genetic material and traditional knowledge which is the object of a patent application.

Finland has implemented the Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions into its national legislation by Act No. 650/2000 on Amending the Patents Act. Plant varieties are protected in compliance with the legal practice followed by UPOV by Act No. 789/1992 on the Plant Breeder's Right, as amended by Act No. 651/2000.

Response to Question 1 (b):
Finnish patent laws contain no conditions relating to obtaining prior informed consent or to benefit-sharing

Response to Question 1 (c):
The exclusive right conferred by a patent relates to commercial exploitation alone. (Patents Act, Section 3(3)).

When theNordic gene bank delivers gene bank material, it applies the material transfer agreement, in which the material is delivered to be used in research and plant breeding. However, the agreement is not based on any law.

Response to Question 1 (d):
See answer to question 2.

Response to Question 1 (e):
The Parliament is responsible for legislation, also for the part of implementation.
See question 1(a).

Response to Question 2:
Requirements for disclosure relating to genetic resources and traditional knowledge in patent applications:

The description of an invention disclosed in a patent application shall be sufficiently clear to enable a person skilled in the art, with the guidance thereof, to carry out the invention. (Patents Act, Section 8(2))

The Administrative Instructions issued by the National Board of Patents and Registration concerning the interpretation of this point lay stipulate as follows:

Biological material which has earlier been described in a commonly available publication, can be identified in accordance with the established practice in the field, for instance by using the taxonomic name, complemented, where necessary, by a reference to the literature in the field where the systematic description of the biological material has been presented. (Patent Instructions, Section 98(1)).

Biological material that has not been described previously must be identified with such minuteness of detail that it cannot be mixed with other biological material. (Patent Instructions, Section 98(2)).

On commonly available biological material information must be given how you can obtain it. (Patent Instructions, Section 99).

Section 8(2) of the Patents Act stipulates that:
An invention relating to a biological material or involving the use of biological material when being carried out shall be regarded, in the cases referred to in Section 8a, as disclosed with sufficient clarity only if the requirements set out in that Section are also satisfied.

Whereas Section 8a(1) of the Patents Act states that:
Where an invention concerns biological material or the carrying out thereof involves the use of a biological material which neither is available to the public nor can be described in the application documents in such a manner as to enable a person skilled in the art to carry out the invention, a sample of the biological material shall be deposited no later than on the date the application was filed.

Section 17a of the Patents Decree specifies:
Deposits under the first paragraph of Section 8 a of the Patents Act shall be made with an institution that is an international depositary authority under the Budapest Treaty (done at Budapest on April 28, 1977). Deposits shall be made in accordance with the Budapest Treaty.

According to Section 17 b of the Patents Decree
Where biological material has been deposited, the applicant shall inform the Patent Office in writing of the institution with which the deposit has been made and of the access code given to the deposit by the that institution.

The Finnish Patents Act contains no mention of the information on the geographical origin mentioned in the recital (27) of EU Directive No. 98/44/EC.

The consequences following a failure to satisfy the requirements are
- dismissal of the application (Patents Act, Section 15(1))
- revocation of the application (Patents Act, Section 25(1)(2))
- that the court declares the patent invalid on account of an opposition (Patents Act, Section 52(1)(2).

Response to Question 11:
The same requirements are applied to utility models as are applied to patents.

Response to Question 12 (a):
See answer to question 2.

Response to Question 12 (b):
No

Response to Question 13:
According to Section 13 of the Patents Act, an application for a patent may not be amended in such a way that protection is claimed for matter not disclosed in the application at the time it was filed.

Consequently, amendments and corrections are not allowed. The applicant has to file a new application in which the mistakes have been corrected.

It is also stated that disputes regarding the ownership of an invention are decided in courts. According to Section 17 of the Patents Act, if a person claims before the Patent Authority that he has proper title to the invention and if the circumstances are held to be uncertain, the Patent Authority may invite such person to institute proceedings before a court of law within a period of time to be laid down. If proceedings for proper title to an invention are pending before a court, the patent application may be suspended until a final decision is given by the court.

Response to Question 14:
See the Finnish Patents Act and the Patents Decree.

[End of response of Finland]

FRANCE

Response to Question 1:
Il n'existe pas de législation nationale spécifique à l'accès aux ressources génétiques qui restent régi par les diverses réglementations pertinentes (régime de la propriété, droit de l'environnement, droit des contrats…).

Un travail est cependant en cours pour clarifier l'état du droit applicable dans ce domaine, sous l'égide du Bureau des Ressources Génétiques (BRG), correspondant national dans le cadre de la CBD.

Response to Question 2:
En vertu de l'article R. 612-10 du code de la propriété intellectuelle (CPI), la requête en délivrance doit contenir les renseignements suivants:

- la nature du titre de propriété industrielle demandé;
- le titre de l'invention faisant apparaître de manière claire et concise la désignation technique de l'invention et ne comportant aucune dénomination de fantaisie;
- la désignation de l'inventeur : toutefois, si le demandeur n'est pas l'inventeur ou l'unique inventeur, la désignation est effectuée dans un document séparé contenant les nom, prénoms et domicile de l'inventeur ainsi que la signature du demandeur ou de son mandataire;
- les nom et prénoms du demandeur, sa nationalité, son domicile ou son siège;
- le nom et l'adresse du mandataire, s'il en est constitué.

De plus, la description de l'invention doit être exposée dans la demande de brevet de façon suffisamment claire pour qu'un homme du métier puisse l'exécuter. Elle doit comprendre les éléments suivants :

- l'indication du domaine technique de l'invention;
- l'indication de l'état de la technique antérieure faisant ressortir le problème technique posé;
- un exposé de l'invention permettant la compréhension de la solution technique qui est apportée au problème technique posé; cet exposé doit donc mentionner toutes les caractéristiques techniques propres à l'invention et en particulier, celles qui seront énoncées dans les revendications;
- une brève présentation des différentes figures constituant les dessins, s'il en existe;
- un exposé détaillé d'au moins un mode de réalisation de l'invention précisant, le cas échéant la structure des différentes parties constituant l'invention ainsi que leur agencement et leur fonctionnement; il convient de se référer aux dessins, s'il en existe, et d'expliciter tous les numéros de référence qui y sont portés;
- l'indication de la manière dont l'invention est susceptible d'application industrielle.

Response to Question 3:
(a) des renseignements sur les ressources génétiques utilisées directement ou indirectement pour la mise au point de l'invention revendiquée;
(b) l'origine géographique (notamment le pays d'origine) des ressources génétiques utilisées dans l'invention revendiquée;
(c) une indication ou la preuve du consentement préalable donné en connaissance de cause par ceux qui sont habilités à autoriser l'accès aux ressources génétiques utilisées dans l'invention revendiquée;

(d) la nature ou la source des savoirs traditionnels utilisés comme moyen d'isoler ou de distinguer les ressources génétiques utilisées dans l'invention revendiquée;
(e) la nature ou la source des savoirs traditionnels connexes utilisés pour la mise au point de l'invention revendiquée;
(f) une indication ou une preuve du consentement préalable donné en connaissance de cause par les détenteurs des savoirs traditionnels utilisés pour la mise au point de l'invention revendiquée?

Au niveau national, il n'existe aucune disposition spécifique prévoyant la divulgation de ce type d'informations.

Response to Question 11:
Il n'existe aucune obligation d'information du type de celles citées dans la question 3) a à f) pour les autres DPI enregistrés.

Response to Question 12:
La législation française prévoit en effet que "l'invention doit être exposée dans la demande de brevet de façon suffisamment claire pour qu'un homme du métier puisse l'exécuter…" (*cf.* article L. 612-5 du CPI). En particulier, pour les micro-organismes et matières biologiques, la législation française (article L. 612-5 du CPI) prévoit que "lorsque l'invention concerne l'utilisation d'un micro-organisme auquel le public n'a pas accès, la description n'est pas considérée comme exposant l'invention d'une manière suffisante si une culture de micro-organisme n'a pas fait l'objet d'un dépôt auprès d'un organisme habilité."

Par ailleurs, la législation française prévoit également qu'un mode de réalisation de l'invention doit être exposé de manière suffisamment détaillée (cf. article R 612-12 du CPI). Cependant, il ne doit pas nécessairement s'agir du meilleur mode de réalisation.

Response to Question 12 (a):
En théorie, il n'est pas exclu que l'exigence de suffisance de description puisse contraindre un déposant à divulguer une des informations recensées dans la question 3 a) à f). Par exemple, la composition ou la structure de la ressource génétique sont indispensables pour que ce qui constitue l'objet breveté soit précisément décrit.

Response to Question 12 (b):
Nous ne disposons pas d'exemple concret de cas où le demandeur a été contraint de divulguer ce type d'informations.

Response to Question 13:
Conformément à la législation française (cf article L 613-25 b) du CPI), l'exigence de suffisance de description est sanctionnée par la nullité du brevet. Par conséquent, lorsque les informations contenues dans le brevet sont fausses ou ambiguës et qu'elles ne sont donc pas suffisantes pour qu'un homme du métier puisse exécuter l'invention, le brevet pourra être frappé de nullité.

[End of response of France]

GERMANY

Contact Details

Name:	Dr. Dietrich Welp
Title:	Head of the Patent Section
Office/Organization:	Federal Ministry of Justice
Member State:	Germany
Address:	Mohrenstr. 37, D-10117 Berlin
Email:	welp-di@bmj.bund.de
Telephone:	+493 020259324
Facsimile:	+493 020258251

Response to Question 1(a):
So far in Germany there are no such laws or regulations in the context of IP rights.

Response to Question 2:
According to § 34 (3) of the German patent law a patent applicant has to provide the following information:

(1) the name of the applicant;
(2) a request for the grant of a patent, which shall designate the invention clearly and concisely;
(3) one or more claims defining the matter for which protection is sought;
(4) a description of the invention;
(5) any drawings referred to in the claims or the description.

§ 34 (4) provides, that applications shall disclose the invention in a manner sufficiently clear and complete to enable a person skilled in the art to carry out the invention.
If these requirements are not met, no patent will be granted.

The EPC provides for similar requirements with regard to European patents.

Response to Question 3:
There is no such specific requirement in our national law. Disclosure of origin is stipulated in the preamble of the EC Directive 98/44/EC on the legal protection of biotechnological inventions, although without making it a binding requirement.

Response to Question 11:
No.

Response to Question 12 (a):
In general an indication of the origin etc. is not necessary to enable a person skilled in the art to carry out the invention. This might be different, where the source is unique and essential to put the invention into practice.

Response to Question 13:
The patent can be revoked, if the patent requirements are in fact not met.

[End of response of Germany]

HUNGARY

Contact Details

Name:	Ms. Krisztina Kovacs
Title:	Deputy Head, Legal Department
Office/Organization:	Hungarian Patent Office
Member State:	Hungary
Address:	1054, Budapest, Garibal u. 2, Hungary
Email:	kovacs@hpo.hu
Telephone:	+36 (1) 474 5767
Facsimile:	+36 (1) 331 6596

Response to Question 1:
Hungary has no legislation regulating the access to genetic resources and/or TK.

Response to Question 2:
Under Hungarian legislation patent applicants are required to provide the following information in patent applications:

(a) a *request for grant*, containing
- the name and address of the applicant;
- if there are several applicants, the shares of their entitlement if they are not equal;
- a declaration that the applicant is the inventor or his/her successor in title;
- the name and address of the inventor;
- if there are several inventors, the shares of authorship if they are not equal;
- the name and address of the representative, if any;
- a declaration on claiming convention, internal or exhibition priority, if such priority is claimed;
- a declaration on a derived or divisional application, if such an application is filed;
- a request for the grant of a patent;

(b) a *description* of the invention with one or more claims, the description containing
- the title of the invention;
- a short specification of the subject matter and the field of application of the invention;
- the indication of the background art by describing the solutions which are closest to the invention and by citing, where possible, the documents reflecting such art, as well as the description of deficiencies the improvement of which is aimed at by the invention;
- the description of the most general mode for carrying out the invention;
- the description of the advantageous modes where necessary, in compliance with the dependent claims;
- the enumeration of the figures by indicating their subject
- one or more examples supporting the scope of protection claimed
- the indication of the advantageous effects of the invention with reference to the background art;

(c) one or more drawings where necessary for the understanding of the invention;

(d) an abstract, containing the title of the invention and a short summary - preferably 50 to 150 words - of the invention as disclosed in the description, the claims and the drawings, allowing the clear understanding of the gist of the solution of the problem through the invention and the principal use of the invention;

(e) the document appointing the representative, in any;

(f) a deed of assignment, if the applicant is the successor in title of the inventor;
(g) a priority document where convention priority is claimed;
(h) in the case of an invention involving the use of a microorganism which is not available to the public and cannot be disclosed in the patent application, a receipt concerning the deposit of the said microorganism.

In the case of applications concerning plant varieties these provisions apply with the following differences:

- the title of the invention shall contain the variety denomination, the common name, and the Latin name of the species between parentheses; in the case of State qualified varieties, the denomination registered in the course of qualification shall be used;
- the description shall characterise the plant variety to an extent necessary for identification, by indicating those essential morphological and other measurable characteristics which may distinguish it from the commonly known variety that is the most similar to the claimed variety;
- the commonly known varieties may be referred to in the description and in the claims by the variety denomination as well;
- the statement of the claim shall contain the variety denomination, the common name of the variety as well as its origin and known features, the characterising portion shall contain those features which distinguish the plant variety from the commonly known variety that is the most similar to the claimed variety;
- the plant variety shall be presented, by showing as far as possible the important distinctive features disclosed in the description, on photos.

The substantial requirement for *disclosure of the invention* is that the patent application must disclose the invention in a manner sufficiently clear and detailed for it to be carried out by a person skilled in the art on the basis of the description and the drawings.

Consequences of failing to meet formal requirements as to the contents of the application:
(1) The filing date of the application is not accorded if the application does not contain

- an indication that a patent is sought, or
- information identifying the applicant, or
- a description and the drawing referred to therein, even though they do not comply with other requirements, or - in place of the filing of a description and drawings - reference to a priority document.

If the date of filing cannot be accorded, the applicant is invited to correct the defects within 30 days. If the applicant complies with that invitation within the specified time limit, the date of receipt of the correction is accorded as the date of filing. Failing which, the patent application is considered withdrawn.
If the culture of a microorganism is deposited after the filing of the patent application, the date of deposit shall be regarded as the date of filing.

(2) Where the application does not comply with formal requirements other than those mentioned in point 1 above, the applicant is invited to correct the defects. The patent application is rejected if, in spite of correction or comments, it still does not comply with such requirements. Where the applicant does not reply to the invitation within the fixed time limit, the patent application is considered withdrawn.

Consequences of failing to meet the substantial requirement as to disclosure of the invention:
If a patent application as filed does not disclose the invention in a manner sufficiently clear and detailed for it to be carried out by a person skilled in the art, the patent application is rejected in whole or in part.

Response to Question 3:
Our answer to all questions (a) to (f) is no.

Response to Question 11:
There are no analogous requirements for other industrial property rights either.

Response to Question 12(a) - (b):
The Hungarian Patent Office forms its practice in compliance with the practice of the European Patent Office, in which, as far as the Hungarian Patent Office is aware, the application of the existing standard requirements in a way actually obliging patent applicants to disclose any of the said categories of information has not been introduced.

Reponse to Question 13:
Under Hungarian patent legislation there is no expressed provision concerning the legal consequences of false or misleading information in a patent application in general. However, where such information relates to the inventor, provisions on moral rights of the inventor and provisions on the right to a patent apply. It is to be pointed out that unless a final court decision rules to the contrary, the person mentioned as such in the application filed at the accorded filing date is deemed to be the inventor, and that the right to a patent belongs to the inventor or his successor in title. Therefore, if false information is given on the inventor in the patent application, this necessitates the initiation of court proceedings for a party to have such false indication corrected in the patent documents and, as the case may be, thus also establish his/her right to the patent. A similar legal presumption relates to the shares of authorship of a joint invention being those as stated in the application filed at the accorded filing date; consequently if such indication is false, its correction necessitates court proceedings. Also, where the subject matter of a patent application or a patent has been taken unlawfully from the invention of another person, the injured party or his successor in title may claim a statement to the effect that he is entitled wholly or partly to the patent and may claim damages under the rules of civil liability. In other words remedies are*de iure* available under existing patent provisions to TK holders who are not mentioned in a patent application relating to relevant TK, whose shares of authorship is falsely indicated, or whose TK has been misappropriated.

Response to Question 14:
Please find excerpts from the 1995 Patents Act and the 1995 ministerial decree on detailed formalities of patent applications in the Annex to this response.

Annex to response of Hungary

Excerpts are given below from Law XXXIII of 1995 on the protection of inventions by patents (Act) and Decree 20/1995. (XII.26.) IM on the detailed formalities of patent application (Decree) in order of occurrence in the replies.

Question 2:

Filing of Patent Application and Requirements

Article 57(2) [Act]

A patent application shall contain a request for the grant of patent, a description of the invention with one or more claims, an abstract, drawings where necessary, and other relevant documents.

The Patent Application

Section 1(1) [Decree]

The patent application shall contain:
a) a request,
b) a description with one or more claims,
c) one or more drawings where necessary for the understanding of the invention,
d) an abstract,
e) the document appointing the representative, if any,
f) a deed of assignment, if the applicant is the successor in title of the inventor,
g) a priority document where convention priority is claimed,
h) where a statement on the display of the invention at an exhibition is made, the relevant certificate,
i) in the case of an invention involving the use of a microorganism which is not available to the public and cannot be disclosed in the patent application, a receipt concerning the deposit of the said microorganism,
j) a fee for administrative services prescribed by special decree.

The Request

Section 2 [Decree]

(1) The request shall be filed in one copy and shall contain:
a) the name and address of the applicant; if there are several applicants, the shares of their entitlement if they are not equal,
b) the title of the invention (short and precise indication of its subject matter),
c) a declaration that the applicant is the inventor or his/her successor in title,
d) the name and address of the inventor; if there are several inventors, the shares of authorship if they are not equal,
e) the name and address of the representative, if any,
f) when claiming convention or internal priority, a declaration to this effect, indicating the filing date, country and number of the foreign patent application in the case of convention priority, or the filing date and reference number of the pending application in the case of internal priority,
g) in the case of displaying the invention at an exhibition, a statement to this effect,

h) in the case of derivation or division, a declaration to this effect, indicating the reference number, as well as the filing and priority dates of the original application,
i) a petition for the grant of a patent,
j) a list indicating the documents attached to the request,
k) the signature of the applicant (of all of the applicants) or of the representative.
(2) The request may also be prepared by completing a form which may be obtained from the Hungarian Patent Office free of charge.

The Description and the Claims

Section 3(2) [Decree]

The patent description shall:
a) contain the title of the invention,
b) specify shortly the subject matter and the field of application of the invention,
c) indicate the background art by describing the solutions which are closest to the invention and by citing, where possible, the documents reflecting such art, further it shall describe the deficiencies the improvement of which is aimed at by the invention,
d) indicate the technical problem to be solved by the invention,
e) set forth the most general mode for carrying out the invention, in compliance with the main claim,
f) describe the advantageous modes when necessary, in compliance with the dependent claims,
g) enumerate the figures by indicating their subject,
h) contain one or more examples supporting the scope of protection,
i) state the advantageous effects of the invention with reference to the background art.

Date of Filing

Article 58 [Act]

(1) The filing date of an application shall be the date on which the application filed with the Hungarian Patent Office contains at least:
a) an indication that a patent is sought,
b) information identifying the applicant,
c) a description and the drawing referred to therein, even though they do not comply with other requirements.
(2) In place of the filing of a description and drawings, reference to a priority document shall suffice to accord a date of filing for the application.

Disclosure of Invention, Claims and Abstract

Article 60 [Act]

(1) A patent application shall disclose the invention in a manner sufficiently clear and detailed for it to be carried out by a person skilled in the art on the basis of the description and the drawings.

Deposit and Availability of Microorganisms

Article 63 [Act]

(1) If an invention involving the use of a microorganism which is not available to the public cannot be disclosed in the patent application, as required by Article 60(1), a certificate shall be filed attesting to the fact that a culture of the microorganism has been deposited under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.
(2) If the culture of a microorganism is deposited after the filing of the patent application, the date of deposit shall be regarded as the date of filing.

Examination on Filing

Article 65 [Act]

Following the filing of a patent application, the Hungarian Patent Office shall examine whether
a) the application satisfies the requirements for according a date of filing (Article 58),
b) the filing fee and the search fee have been paid (Article 57(4)),
c) the description, the abstract and the drawings have been filed in the Hungarian language (Article 57(5)).

Article 66 [Act]

(1) If a date of filing cannot be accorded, the applicant shall be invited to correct the defects within 30 days.
(2) If the applicant complies with that invitation within the specified time limit, the date of receipt of the correction shall be accorded as the date of filing. Failing which, the patent application shall be considered withdrawn.

Examination as to Formal Requirements

Article 68 [Act]

(1) If a patent application satisfies the requirements examined under Article 65, the Hungarian Patent Office shall examine whether the formal requirements of Article 57(2) and (3) have been satisfied.
(2) Where the application does not comply with the requirements examined under paragraph (1), the applicant shall be invited to correct the defects.
(3) The patent application shall be rejected if, in spite of correction or comments, it still does not comply with the requirements under examination. An application may be rejected only for grounds precisely and expressly stated in the invitation.
(4) Where the applicant does not reply to the invitation within the fixed time limit, the patent application shall be considered withdrawn.

Substantive Examination

Article 74 [Act]

(1) The Hungarian Patent Office shall carry out a substantive examination of the published patent application at the request of the applicant.
(2) The substantive examination shall ascertain
a) whether the invention meets the requirements of Articles 1 to 5 and whether it is not excluded from patent protection under Article 6(2) and
b) whether the application complies with the requirements laid down by this Law.

Article 76 [Act]

(1) If a patent application does not meet the requirements examined under Article 74(2), the applicant shall be invited, according to the nature of the objection, to correct the defects, to submit comments or to divide the application.
(2) A patent application shall be rejected in whole or in part if it does not meet the examined requirements even after the correction of the defects or the submitting of comments.
(3) An application may be rejected only on grounds that have been precisely and expressly stated and duly reasoned in the invitation. Where necessary, a further invitation shall be issued.
(4) If the applicant fails to reply to the invitation or to divide the application, he shall be considered to have relinquished the provisional patent protection.

Question 13:

Moral Rights of the Inventor and his Rights Concerning the Disclosure of the Invention

Article 7 [Act]

(1) The person who has created an invention shall be deemed to be the inventor.
(2) Unless a final court decision rules to the contrary, the person mentioned as such in the application filed at the accorded filing date shall be deemed to be the inventor.
(3) If two or more persons have made an invention jointly, their shares of authorship shall be regarded as equal in the absence of an indication to the contrary.
(4) Unless a final court decision rules to the contrary, the shares of authorship stated in the application filed at the accorded filing date or as determined under paragraph (3) shall be deemed applicable.
(5) The inventor shall have the right to be mentioned as such in the patent documents. Published patent documents shall not mention the inventor if he so requests in writing.
(6) The inventor shall be entitled to institute legal proceedings under the Civil Code against any person contesting his authorship or otherwise infringing his moral rights deriving from the invention.
(7) Prior to the publication of the patent application, an invention may only be disclosed with the consent of the inventor or his successor in title, as appropriate.

Right to a Patent

Article 8 [Act]

(1) The right to a patent shall belong to the inventor or his successor in title.
(2) Unless a final court decision or other official decision rules to the contrary, the right to a patent shall belong to the person who filed the application with the earliest date of priority.
(3) If two or more persons have created an invention jointly, the right to the patent shall belong to them or their successors in title jointly. Where two or more persons are entitled to the right, it shall be deemed to belong to them equally unless otherwise provided.
(4) If two or more persons have created an invention independently of each other, the right to the patent shall belong to the inventor, or his successor in title, who filed the application with the earliest date of priority.

Infringement of Inventions

Article 34 [Act]

Where the subject matter of a patent application or a patent has been taken unlawfully from the invention of another person, the injured party or his successor in title may claim a statement to the effect that he is entitled wholly or partly to the patent and may claim damages under the rules of civil liability.

[End of response of Hungary]

ITALY

Contact Details

Name:	Cons. Raffaele Foglia
Title:	Conseiller juridique
Office/Organization:	Ministère de l' extèrieur, Roma
Member State:	Italy
Address:	Via Reno, 35 – 00198 ROMA
Email:	r.foglia@mclink.it
Telephone:	003906 – 855.57.75
Facsimile:	003906 – 855.57.75

Response to Question 1(a):
There is any [sic] knowledge of national laws protecting genetic resources.

Response to Question 1(b):
Relating to "Traditional Knowledge", it is a question of the acknowledgement of the certificate of origin. The applicable law is the above mentioned community one (cfr. Reg. 2081/92) which concerns only agricultural goods and foodstuff.

The Rules included in Reg. 2081/92/CEE can be directly applied in Italy. No kind of consent for access or benefit-sharing is provided in favour of different parties from the owners of the certificate of origin.

Response to Question 1(c):
There is no rule in favour of No profit associations.

Response to Question 1(d):
The basic rule is observing the description of an invention concerning use of raw materials brought from specific geographical areas and/or use of a particular know-how.

Response to Question 1(e):
Community Regulation is directly applied in Italy.

Response to Question 3 : There is no patent law protection for genetic resources and for traditional knowledge. Neither the patent applicant are required to disclose the genetic resources or traditional knowledge that have been used.

Response to Question 10:
No answer.

Response to Question 11:
Informations about genetic resources or Traditional Knowledge that have been used are not required from the utility patent, patty patent, industrial design and trademark applicants.

Response to Question 12:
The answer is negative in any case

Response to Question 13:
The sanction in case of false or misleading information can be, according to the specific case, invalidity or loss of right, as well as damages' compensation.

Response to Question 14:
See art. 59 RD June 29th 1939, n. 1127 (Patent Act), as well as Art. 41 and 47 RD June 21st 1942, n. 929 (Trademark Act) and formers changes.

[End of response of Italy]

MALAWI

Contact Details

Name:	Mr. V. J. Mzumara
Title:	Registrar General
Office/Organization:	Ministry of Justice, Department of the Registrar General
Member State:	Malawi
Address:	P.O. Box 100, Blantyre, Malawi
Email:	reg@malawi.net
Telephone:	(265) 01624355
Facsimile:	(265) 01621686

Response to Question 1:
None

Response to Question 2:
On the application form the applicant should:

(i) indicate name of applicant,
(ii) state an address for service,
(iii) name of the inventor in case the applicant is not the inventor himself/herself,
(iv) convention country/date if any,
(v) disclosure of an invention.

Failure to meet the above requirements results in the rejection of the patent.
Ref.: Laws of Malawi Patent Act: Cap.49:02; Section 12, 13 and 14.

Response to Question 3(a) - (f):
No.

Response to Question 11:
No.

Response to Question 12(a) - (b):
No.

Response to Question 13:
Liable to revocation.

[End of response of Malawi]

MEXICO

Contact Details

Name:	Josefina Moreno García
Title:	Directora de Relaciones Internacionales
Office/Organization:	Instituto Mexicano de la Propiedad Industrial (IMPI)
Member State:	México
Address:	Arenal 550, Col. Tepepan, Del Xochimilco C.P. 16020 México, DF
Telephone:	5334 0704
Facsimile:	5555 4056

Response to Question 1:
En México, a la fecha no existe legislación que regule el acceso a recursos genéticos o conocimiento tradicional.

Existen algunos casos aislados donde se ha optado por un contrato de acceso al recurso genético por las partes.

Response to Question 2:
La descripción de una solicitud de patente debe de contener come lo señala la Ley de la Propiedad Industrial:

(a) el ámbito de la tecnología a la que se aplica (campo de la invención),
(b) el estado de la técnica conocida (antecedentes la invención),
(c) la divulgación de la invención (descripción detallada de la invención), si es necesario,
(d) la referencia y explicación de los dibujos y sus partes (descripción de los dibujos o figuras) y, en el caso de que se requiera,
(e) ejemplos que indiquen la mejor manera que el solicitante conoce para llevar a cabo la invención.

Response to Question 3:
En la Ley de Propiedad Industrial, no existe ningún requerimiento específico para informar por parte del solicitante, acerca del origen del recurso genético usado en la invención, ni evidencia de consentimiento previo informado, ni de la naturaleza o fuente de conocimiento tradicional asociado.

Response to Questions 4-10:
No aplican.

Response to Question 11:
No existen requerimientos del tipo mencionados en la pregunta 3 para ninguna figura jurídica de propiedad industrial.

Response to Question 12 (a) - (b):
No.

Response to Question 13:
Ninguna

Response to Question 14:
Ninguna

[End of response of Mexico]

NIGER

Contact Details

Name:	Boukar Attari
Title:	Conseiller Volet Diversité Biologique
Office/Organization:	Conseil National de l'Environnement pour un développement Durable (CNEED)
Member State:	Niger
Address:	Secrétariat Exécutif du CNEDD BP 10193
Email:	attarib@caramail.com / biocnedd@intnet.ne
Telephone:	722 559
Facsimile:	722 981

Response to Question 1:
Pour le moment, il n'y a pas de législation qui régissent l'accès aux ressources génétiques et aux savoirs traditionnels au Niger. Cependant des travaux préliminaires sont en cours pour la rédaction d'un rapport national sur les ressources génétiques des animaux domestiques du Niger a été crée en mai 1999.

Response to Question 2:
Néant dans le domaine des ressources génétiques et des savoirs traditionnels.

Response to Question 3:
Idem que réponse Question 2.

Response to Question 10:
Néant.

Response to Question 11:
Dans la législation en vigueur notamment l'ordonnance portant sur le droit d'auteur, droits voisins et expression du folklore, il n' y a pas d'exigences analogues (à celles visées dans les question 3 (a)).

Response to Question 12 (a):
Les dispositions de ce type ne sont prises dan la législation nationale citée ci dessus.

Response to Question 13:
Les dispositions de ce type ne sont prises dans la législation nationale citée ci dessus.

[End of response of Niger]

NEW ZEALAND

Contact Details

Name:	Kim Connolly-Stone
Title:	Senior Advisor, Intellectual Property
Office/Organization:	Ministry of Economic Development
Member State:	New Zealand
Address:	33 Bowen Street, PO Box 1473, Wellington, New Zealand
Email:	kim.connolly-stone@med.govt.nz
Telephone:	64 4 474 2751
Facsimile:	64 4 471 2658

Response to Question 1(a):
None.

Response to Question 1(b):
None.

Response to Question 1(c):
No.

Response to Question 1(d):
None.

Response to Question 1(e):
Not Applicable.

Response to Question 2:
1. Applicant's name, address and nationality;
2. The true and first inventor's name, address and nationality; and
3. Every complete specification is required to:
    3.1 particularly describe the invention and the method by which it is to be performed;
    3.2 disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and
    3.3 end with a claim or claims defining the scope of the invention claimed.

Failure to provide this information will result in the application for patent protection being refused.

Response to Questions 4 - 10:
Not Applicable.

Response to Question 11:
There are no analogous requirements similar to questions 3(a) - (f) that applies to any other registered industrial property rights. A new Trade Marks Bill, however, currently before Parliament will provide an absolute ground for not registering a trade mark where the use or registration of the trade mark is, or is likely to be, offensive to a significant section of the community include Maori.

Response to Question 12 (a):
Under section 17 of the Patent Acts 1953, the Commissioner of Patents may refuse a patent application where the use of the invention is contrary to morality. Where an invention is either derived from or uses of traditional knowledge, or relates to an indigenous flora or fauna, or products extracted therefrom, applicants are asked to provide an indication or evidence of prior informed consent being given by a relavent Maori group. This requirement is not specifically included in the Patents Act, but is required as a matter of internal office procedure.

These issues have been argued in respect of only one application (NZ 501679). The case concerned an application to use oil extracted from kiwi (a rare indigenous flightless bird, and a national icon) to manufacture insect repellent. In that case the patent attorney for the applicant argued that use of kiwi to manufacture insect repellent was not culturally offensive, and declined to seek consent from any Maori tribe. The application was, however, later amended with all reference to kiwi being deleted from the patent specification.

Response to Question 12 (b):
None.

Response to Question 13:
A third party may oppose the granting of a patent or seek revocation of a patent in the event that certain information provided is false or misleading.

Response to Question 14:
Under section 21 of the Patents Act 1953, third parties may oppose the granting of a patent where the applicant or the person named as the true and first inventor obtained the invention or any part of it from another person, or that the invention (or the method by which it is performed) is not sufficiently or fairly described. Altenatively, under section 42 of the Patents Act, third parties may seek revocation of a patent on the same grounds within 12 months of the patent being granted.

Third parties may also apply, under section 42 of the Patents Act, to the High Court to seek revocation of a patent on a number of grounds including:
(1) The patent was granted to a person not entitled under under the provisions of the Patents Act to apply therefore;
(2) The complete specification does not particularly describe the invention and the method by which it is to be performed nor disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and
(3) The patent was obtained on a false suggestion or representation.

[End of response of New Zealand]

PHILIPPINES

Response to Question 1 (a):
Executive Order No. 247 (PRESCRIBING GUIDELINES AND ESTABLISHING A REGULATORY FRAMEWORK FOR THE PROPSPECTING OF BIOLOGICAL AND GENETIC RESOURCES, THEIR BY-PRODUCTS AND DERIVATIVES, FOR SCIENTIFIC AND COMMERCIAL PRUPOSES; AND FOR OTHER PURPOSES).

Republic Act No. 8371 (AN ACT TO RECOGNIZE, PROTECT AND PROMOTE THE RIGHTS OF INDIGENOUS CULTURAL COMUNITIES/INDIGENOUS PEOPLES; CREATING A NATIONAL COMMISSION ON INDIGENOUS PEOPLES, ESTABLISHING IMPLEMENTING MECHANISMS, APPROPRIATING FUNDS THEREFOR, AND FOR OTHER PURPOSES); and

NCIP Administrative Order No.01-98 (RULES AND REGULATIONS IMPLEMENTING REPUBLIC ACT NO. 8371)

Indigenous peoples/indigenous communities have the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including indigenous knowledge systems and practices. Access to biological and genetic resources and to indigenous knowledge related to conservation, utilization and enhancement of these resources shall be allowed within ancestral lands and domains of the indigenous peoples and communities only with a free and proper informed consent of such communities, obtained in accordance with customary laws of the concerned community.

Prospecting of biological and genetic resources shall be allowed only within the ancestral lands and domains of indigenous cultural communities only with the proper informed consent of concerned local communities; obtained in accordance with the customary laws of the concerned community.

Executive Order No. 247 distinguishes AcademicResearch Agreement and Commercial Research Agreement. Only duly recognized Philippine universities and academic institutions, domestic government entities and intergovernmental entities may apply for an academic research agreement.

Response to Question 2:
The patent application, in general, shall contain a request for the grant of patent, a description of the invention, drawings necessary for teh4 understanding of the invention, one or more claims and an abstract. The application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Where the application concerns a microbiological process or the product thereof and involves the use of a microorganism which cannot be sufficiently disclosed in the application in such a way as to enable the invention to be carried out by a person skilled in the art, and such material is not available to the public, the application shall be supplemented by a deposit of such material with an international depository institution (Sections 32 and 35 of Republic Act No. 8293, IP Code). The application shall be deemed withdrawn upon failure to meet such requirements.

Response to Question 3
No.

Response to Question 11:
As regards utility model and industrial designs and trademarks, there are no analogous requirements.

Response to Question 12:
No.

Response to Question 13:
As regards pending applications, the examiner may notify the applicant of his action thereon which could be a preliminary rejection, The examiner shall state the reasons for any adverse action or objection or requirement and such information or references will be given as may be useful in aiding the applicant to judge the propriety of continuing the prosecution of his application. Part 9 of the Rules and Regulations on Inventions sets out the guidelines in the examination of application, nature of proceedings in the examination of an application for a patent and general considerations.

As regards granted applications, the provision on cancellation of patent under Section 61 of the IP Code applies whenever false or misleading information are provided in the applications.

Response to Question 14:
Intellectual Property Code of the Philippines. Sec. 61 Cancellation of Patents.- 61.1. Any interested person may, upon payment of the required fee, petition to cancel the patent or any claim thereof, or parts of the claim, on any of the following grounds:

(a) That what is claimed as the invention is not new or patentable;
(b) That the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by any person skilled in the art; or
(c) That the patent is contrary to public order or morality.

61.2 Where the grounds for cancellation relate to some of the claims or parts of the claim, cancellation may be effected to such extent only.

Please see Executive Order No. 247, series of 1995, Republic Act No. 8371, and Part 9 of the Rules and Regulations on Inventions.

[End of response of the Philippines]

PORTUGAL

Contact Details

Name:	Jaime Serrão Andrez
Title:	President of the AC
Office/Organization:	IINPI - PT
Member State:	Portugal
Address:	Campo das Cebolas, 1149-035 Lisboa, Portugal
Email:	cadm@inpi.pt
Telephone:	+ 351 21 881 81 02
Facsimile:	+ 351 21 886 00 66 / + 351 21 887 53 08

Response to Question 1 (a):
Decree Law 118 - 2002

Response to Question 2:
Article 59 of Portuguese Patent Law (DL 16/95 of 24th January). If the applicant fail to meet such requirements the application shall be refused.

Response to Question 3 (a):
Yes

Response to Question 3 (b) - (f):
No.

Response to Question 4:
Only to patent applications concerning biotechonological inventions. Yes.

Response to Question 5:
No.

Response to Question 9:
The patent shall be refused if the applicant, after notification, not provide the requirements.This information shall be submitted within 16 months after tha date of the application filed in Portugal or, if a priority is claimed, after the priority date.

Response to Question 10:
This information is available for public inspection after the date of publication of the application.

Response to Question 11:
No.

Response to Question 12 (a) - (b):
No.

[End of response of Portugal]

REPUBLIC OF KOREA

Contact Details

Name:	Eulsoo Seo
Title:	Senior Deputy Director
Office/Organization:	Korean Intellectual Property Office
Member State:	Republic of Korea
Address:	Government Complex Building 4, 920 Dunsan-dong, Seo-gu, Daejeon, 302-701 Korea
Email:	sesetor@kipo.go.kr
Telephone:	+82 42 481 5072
Facsimile:	+82 42 472 3459

Response to Question 2:
According to the Korean Patent Law, a patent applicant should provide the name and address of the applicant and the inventor, the title of the invention, a specification, drawing if necessary, and an abstract. The specification shall contain a detailed description of the invention, disclosing the invention in a manner that would enable a person having ordinary skill in the art to which the invention pertains to carry out the invention.

Response to Question 11:
No.

Response to Question 12 (a):
A patent applicant of an invention relating to microorganisms shall provide detailed information about any microbial material used in the development of the invention so that a person skilled in the art could easily carry out the invention.

[End of response of Republic of Korea]

REPUBLIC OF MOLDOVA

Contact Details

Name:	Mrs. Aurelia Ceban
Title:	Head of the Preliminary Examination and Methodology Division
Organization:	State Agency on Industrial Property Protection of the Republic of Moldova (AGEPI)
Member State:	The Republic of Moldova
Address:	24/1 Andrei Doga Street, MD-2024, Chisinau, Republic of Moldova
Email:	office@agepi.md
Telephone:	(3732) 44-32-53
Facsimile:	(3732) 44-00-94

Response to Question 1:

The access to genetic resources is regulated by the Law of the Republic of Moldova No 461/1995 on Patent for Inventions and the Regulations on Applying this Law, also by the Law of the Republic of Moldova No. 915/1996 on the Protection of Plant Varieties and the Regulations on Applying this Law.

(a) The above mentioned Laws are applied to every biological material which contains genetic information and is capable of reproducing itself or is reproduced in a biological system, and to processes of production and use of the said material, with the exception of human body and processes of cloning human beings.

(b) There are no provisions on this matter.

(c) According to the Rules 3-9 of the Law No. 461/1995, the use of human embryos for non-medical industrial and commercial purposes is forbidden.

(d) The requirement for disclosure concerning the reproducible biological material is stipulated in the Law No. 461/1996, Art. 10 (4): if the invention concerns reproducible biological material which cannot be disclosed in such a manner as to enable a person skilled in the art to reproduce it or if such material is not freely accessible, an attestation shall be attached to the application concerning the deposit of the material with the depository institute designated by the Government or with a body having the status of international depository authority. The deposit must have been made prior to the filing date of the patent application.

The access to the deposited biological material is regulated by the Regulations on Applying the Law No. 461/1995, Rules 30.4-306:

30.4 Access to the deposited biological material shall be provided through the supply of a sample:

(a) up to the first publication of the patent application:
- at the AGEPI request, if this sample is necessary for patentable procedure or if the patent application is subject of a trial before the AGEPI;
- to applicant, at his request;
- to any authority or natural or legal person, authorized by the applicant.

(b) between the publication of the application and the granting of the patent, to anyone requesting it or, if the applicant so requests, only to an independent expert;

(c) after the patent has been granted, and notwithstanding revocation or cancellation of the patent, to anyone requesting it.

30.5 The sample shall be supplied only if the person requesting it undertakes, for the term during which the patent is in force:
(a) not to make the sample or any material derived from it available to third parties;
(b) not to use the sample or any material derived from it except for experimental purposes, unless the applicant for or proprietor of the patent, as applicable, expressly waives such an undertaking.

30.6 At the applicant's request, where an application is refused or withdrawn, access to the deposited material shall be limited to an independent expert for twenty years from the date on which the patent application was filed.

Response to Question 2:
The Law No. 461/1995, Art 10(2) (b) stipulates: a description of the invention shall disclose it in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. The applicant shall indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

Concerning the reproducible biological material, there is a special requirement for depositing the said material that has been already mentioned above. The insufficiency of disclosure of an invention could constitute as ground for rejection of the application for reason of unsuitability of industrial applicability requirement, also can serve as ground for invalidation of the patent according to Art 28 (c) of the Law No. 461/1995: throughout its term of validity, a patent may be opposed and invalidated in whole or in part if the subject matter of the invention is not disclosed in a sufficiently clear and complete manner in the description.

Response to Question 3 (a):
The applicant is required to disclose in an application referring to a biological material the information concerning the cultural-morphological, physiological- biochemical, hemo- and geno- taxonomical, cariological and biotechnological characteristics of the material; the characteristic of the pattern material; the hybridization principle; the genealogy of colonies; the conditions of cultivation and other characteristics, as well as the process of production of the said material.

Response to Question 3 (b) - (f):
No specific provisions.

Response to Question 11:
There is a requirement for appellations of origin and namely: the applicant shall indicate the geographical origin and area of production of the raw material, the existence of some particular conditions for its production and the description of the method of production of the said product.

Response to Question 12 (a):
We consider that in order to comply with the requirement for an invention to be disclosed in a manner sufficiently clear and complete, the applicant should furnish also information containing in questions 3 (a), (b), and (d), the last point - only where the isolation or the distinguish of the biological material can not be disclosed otherwise.

Response to Question 12 (b):
No.

Response to Question 13:
According the Regulations on Applying the Law No. 461/1995, the Agency has the right to require the applicant additional information and evidence where the Agency may reasonable doubt the veracity of any information provided by the applicant.

Response to Question 14:
Excerpts from the legislation of the Republic of Moldova in the field of industrial property protection were enclosed to the above answers.

[End of response of the Republic of Moldova]

ROMANIA

Contact Details

Name:	Dr. eng. Alexandru Cristian Strenc
Title:	Deputy Director General
Office/Organization:	State Office for Inventions and Trademarks
Member State:	Romania
Address:	5, Ion Ghica Street, Sector 3, 70018 Bucharest, Romania
Email:	office@osim.ro
Telephone:	4021-315.90.66
Facsimile:	4021-312.38.19

Response to Question 3:
A draft Regulation for applying the Law 64/1991 completed and ammended the Law 203/2002 is currently under approval according to rule 14c from the draft Regulation "…when the state of the art includes also traditional knowledges they shall be clearly indicated in the description including their source, when known." There are no consequences in case of non-compliance.

Response to Question 4:
The disclosure or information requirements apply to patent applications for any inventions, regardless of the nature of the technology involved. Yes the requirements apply equally to patent applications by domestic and foreign nationals.

Response to Question 9:
No.

Response to Question 10:
No.

Response to Question 11:
The possibility to include similar provisions in the draft Instructions for applying the future legislation regarding industrial designs.

Response to Question 12 (a):
No. A patent applicant discloses the information set out in questions 3(a) to (f) if the information is known to him.

Response to Question 12 (b):
No.

Response to Question 13:
There are no provisions.

[End of response of Romania]

RUSSIA

Contact Details

Name : L. Simonova
Title : Head of Division
Office/Organization : Russian Agency for patents and trademarks (Rospatent)
Member State : Russia
Address : 30-1, Berezhkovskaya nab., 123995 Moscow, Russia
Email : lsimonova@rupto.ru
Telephone : 240 34 57
Facsimile : 956 43 74

Response to Question 1 (a):

Genetic resources:

(a) of animal origin – Federal Law No. 52-FZ on the Animal World, of April 24, 1995.
(b) of plant origin – Law No. 5605-1 on Selection Achievements, of August 6, 1993.

Response to Question 1 (b):

Federal Law No. 52-FZ on the Animal World, of April 24, 1995, establishes:

- types and methods of use of the animal world (article 34);
- conditions of use of the animal world (article 35);
- provision for use of the animal world (article 36);
- procedure for granting licenses (article 37);
- right to use traditional methods for obtaining subjects of the animal world and the products of its vital activity (article 48);
- right to priority use of the animal world (article 49);
- system of payments for use of the animal world (article 52);
- fee for granting licenses for use of the animal world (article 53);
- administrative, civil law and criminal liability for infringing laws of the Russian Federation on protection and use of the animal world (article 55);
- the non-validity of acts infringing the laws of the Russian Federation and the laws of subjects of the Russian Federation in the field of protection and use of subjects of the animal world (article 58);

Law No.5605-1 on Selection Achievements, of August 6, 1993 defines: The right of the patent owner (article 13): "The exclusive right of the patent owner shall consist in that any person shall receive from the patent owner a license for carrying out, with seeds and breeding material of a protected selection achievement, the following acts:

(a) production and reproduction;
(b) bringing up to an appropriate seeding level for further propagation;
(c) offer for sale;
(d) normal and other types of sale;
(e) export from the territory of the Russian Federation;
(f) import into the territory of the Russian Federation;
(g) storage for the purposes listed above.

Conditions of use of a selection achievement.

Licensing agreement (article 16)

Conditions of a licensing agreement for restriction of a licensee's rights (article 18)
Open license (article 19)
Compulsory license (article 20)

Response to Question 1 (c):
Article 14 of the Law on Selection Achievements defines acts which are not recognized as infringements of a patent owner's right: the following acts, carried out in relation to a protected selection achievement shall not be recognized as infringements of a patent owner's right:

(a) acts carried out for personal and non-commercial purposes;
(b) acts carried out for experimental purposes.

Response to Question 1 (e):
The provisions of the Federal Law on the Animal World are implemented by State authorities of the Russian Federation in the field of protection and use of the animal world (article 5); State authorities of subjects of the Russian Federation in the field of protection and use of subjects of the animal world (article 6); local government authorities in the field of protection and use of subjects of the animal world (article 8); and with the participation of indigenous minorities and ethnic communities in the protection and use of subjects of the animal world, and the preservation and renewal of the environment in which they live (article 9).

The unified policy in the field of legal protection for selection achievements in the Russian Federation is implemented by the State Commission of the Russian Federation for the Testing and Protection of Selection Achievements (hereinafter – State Commission) and, in accordance with this Law, considers applications for selection achievements, examines and tests those achievements, keeps the State Register of Protected Selection Achievements and the State Register of Selection Achievements Acceptable for Use, grants patents and inventor's certificates, publishes official information relating to the protection of selection achievements, issues rules and clarifications regarding the application of this Law, and performs other duties.

Response to Question 2:
In accordance with article 4.1 of the Patent Law of the Russian Federation of October 14, 1992, and article 3.2 of the Rules for Drafting, Filing and Examining Applications for the Grant of Patents, which came into force on October 19, 1998:
The description of an invention must disclose the invention in a sufficiently complete manner for it to be carried out.

The description begins with the name of the invention (and also, in accordance with the headings of the current edition of the International Patent Classification (IPC), to which the claimed invention relates, the index of these headings) and contains the following sections:

- the technical field to which the invention relates;
- the prior art;
- the essential features of the invention;
- a list of diagrams, drawings and other materials (if attached);
- information confirming that the invention can be carried out;
- a list of the sequences of nucleotides and amino acids (if such sequences are used to characterize the invention).

It shall not be permitted to replace the description section with a reference to the source containing essential information (literary source, description in a previously filed application, description attached to a protected document, and so on).

The essential features of the invention are disclosed insofar as they are sufficient to achieve a technical result.

In accordance with section 3.3.6, in a claim characterizing a strain of a micro-organism, the cell cultures of plants and animals shall comprise the generic and specific name of the biological subject in Latin with an indication of the surname(s) of the inventor(s) of the type and, if the strain has been deposited, the name or abbreviation of the collection-depositary, registration number attributed by the collection to the deposited subject, and the designation of the strain.

In accordance with article 8(21) of the Law, a request for additional materials, including amended claims, shall be sent to the applicant where, without such materials, it is not possible to carry out a substantive examination of the application, including the taking of a decision. If within the prescribed period the applicant does not submit the requested materials or a request to extend the period for their submission, the application may be recognized as withdrawn and the applicant shall be informed accordingly. Processing of the application shall be terminated. Processing may be continued where a period which has lapsed has been renewed by the Patent Office (section 15 of the Rules).

Response to Question 11:
No.

Response to Question 12(a) and (b):
No.

Response to Question 13:
The accuracy of information is verified during the examination of compliance with the criterion of "industrial applicability." In accordance with Article 4(1) of the Law, an invention shall be industrially applicable, if it can be used in industry, agriculture, healthcare and other sectors of activity.

When establishing the possibility of use of an invention, it shall be verified whether the application materials contain an indication of the designation of the claimed subject matter of the invention.

It shall also be verified whether the primary application materials contain a description of the means and methods by which the invention may be carried out in the form in which it is characterized in any of the claims. In the absence of such information in the application materials, it is permissible for the means and methods in question to be described in the source which has become generally accessible before the priority date of the invention.

If it is established that on the priority date of the invention all the requirements in question have been satisfied, the invention may be recognized as complying with the requirement of industrial applicability.

If one or more of the requirements in question are not satisfied, it shall be concluded that the invention does not meet the requirement of industrial applicability. In this case, the applicant may be requested to draft the corresponding arguments and to express his own opinion on these arguments as well as correcting the claims (if, in the examiner's opinion, the application materials permit such a correction, as a result of which the conclusion in question may be

modified). In this connection, the request may contain specific recommendations for correcting the claims. In relation to an invention, which has been determined not to meet the requirement of industrial applicability, novelty and inventive step shall not be verified, and a decision shall be taken to refuse to grant a patent with an explanation of the appropriate grounds therefor.

Response to Question 14:
The corresponding provisions of the Laws in question will be submitted as soon as possible.

[End of response of Russia]

SPAIN

Contact Details

Name :	Javier Moreno Ramos
Title :	Director Departamento de Coordinación Jurídica y Relaciones Internacionales
Office/Organization :	Ministerio de Ciencia y Tecnología, Oficina Española de Patentes y Marcas
Member State :	España
Address :	Panamá, 1, 28071 Madrid
Email :	javier.moreno@oepm.es
Telephone :	+34 91 3496802
Facsimile :	+34 91 5722741

Response to Question 2:

* Datos bibligráficos:
- Nombre y dirección del solicitante
- Nombre del inventor
- Nombre y dirección del Agente de la Ppdad : Industrial (en su caso)
- Forma de adquisición del derecho
- Datos de prioridad (en su caso)

* Título de la invención
* Resumen de la invención
* Descripción de la invención (por triplicado). Debe contener:
- Título de la invención
- Indicación del sector de la técnica al que se refiere la invención
- Indicación del estado de la técnica anterior a la fecha de prioridad, conocido por el solicitante y que pueda ser útil para la comprensión de la invención y para la elaboración del informe sobre el estado de la técnica, citando, en la medida de lo posible, los documentos que sirvan para reflejar el estado de la técnica anterior.
- Una explicación de la invención, que permita una comprensión del problema técnico planteado así como la solución al mismo, indicándose, en su caso las ventajas de la invención en relación al estado de la técnica anterior.
- Breve descripción de los dibujos si los hubiera
- Exposición detallada de, al menos, un modo de realización de la invención
- Indicación de la manera en que la invención es susceptible de aplicación industrial, a no ser que ésta se derive de manera evidente de la naturaleza de la invención o de la explicación de la misma.
-

Cuando la invención se refiera a un procedimiento microbiológico, la descripción deberá cumplir los siguientes requisitos (art. 25.2 LPE y art 5.4 Regl.):
- Que la descripción contenga las informaciones de que disponga el solicitante sobre las características del microorganismo.
- Que el solicitante hubiere depositado no más tarde de la fecha de presentación de la solicitud un cultivo de microorganismos en una Institución autorizada para ello, conforme a los Convenios internacionales, vigentes en España sobre esta materia. Asimismo, el solicitante deberá indicar en la descripción el nombre de la Institución autorizada donde haya

depositado una muestra del cultivo del microorganismo y consignar el número o clave de identificación de dicho microorganismo por la Institución autorizada.

* Un a o más reivindicaciones (por triplicado)
* Dibujos (en su caso)

En este momento en España coexisten dos procedimientos de consesión de patentes, uno sin examen de fondo en el que no son objeto de examen la novedad, la actividad inventiva ni la suficiencia de la descripción, y otro en el que sí se examinan estos requisitos por lo que una patente se puede denegar si falta alguno de ellos.

Response to Question 3:
No.

Response to Question 11:
No.

Response to Question 12 (a):
En invenciones en las que esté implicada una materia de origen vegetal o animal que sea endémica de un lugar concreto se puede considerar necesaria a divulgación del origen geográfico concreto de dicho material para que la descripción sea suficientemente clara y completa para que un experto en la materia pueda ejecutarla.

Response to Question 12 (b):
Tenemos casos concretos de solicitudes de patente españolas en las que se divulga el origen geográfico del material animal o vegetal patentado. Como ejemplo, se pueden citar los siguientes números de patentes:
ES 2049666 (EP 0447706) (Extractos de *Commiphora mukul*)
ES 2012104 (Extractos de *Mimosa tenuiflora*)
ES 2124675 (Extractos de *Phlebodium decumanum*)
ES 2137900 (Extractos de *Phlebodium decumanum*)
ES 2146555 (Extractos de *Phlebodium decumanum*)

Response to Question 13:
Incurriría en falsedad en documento público.

Response to Question 14:
Article 25.1 (Ley española de patentes):
"La invención debe ser descrita en la solicitud de patente de manera suficientemente clara y completa para que un experto sobre la materia pueda ejecutarla."

Article 5 (Reglamento de Ejecución de la Ley española de patentes):
Se refiere al contenido de la descripción, y establece que deberá contener: "…una explicación de la invención, que permita una comprensión del problema técnico planteado así como la solución al mismo, indicándose, en su caso las ventajas de la invención en relación al estado de la técnica anterior…. "

Exposición de Motivos de la Ley española de patentes:
"…Cuando una invención tenga por objeto una materia biológica de origen vegetal o animal o que utilice una materia de este tipo, la descripción relativa a dicha invención deberá incluir, en su caso, información sobre el lugar de origen geográfico de origen de dicha materia, cuando éste sea

conocido, y ello sin perjuicio del examen de las solicitudes de patente y de la validez de los derechos que se deriven de las patentes expedidas.”

[End of response of Spain]

SWEDEN

Contact Details

Name:	Carl Josefsson
Title:	Deputy Director
Office/Organization:	Ministry of Justice
Member State:	Sweden
Address:	103 33 STOCKHOLM
Email:	carl.josefsson@justice.ministry.se
Telephone:	+46 8 405 47 41
Facsimile:	+46 8 405 36 01

Response to Question 1:
There are no laws or regulations applicable in Sweden in this respect.

Response to Question 2:
According to the Swedish Patent Act (SFS 1967:837), Section 8, second paragraph, a patent application shall contain a description of the invention, also comprising drawings if such are necessary. The description shall be so clear as to enable a person skilled in the art to carry out the invention with the guidance thereof.

In addition, according to Section 8 a of the Act, if in the carrying out of an invention a microorganism is to be used which is neither available to the public nor can be described in the application documents so as to enable a person skilled in the art to carry out the invention with the guidance thereof, a culture of the organism shall be deposited no later than the date of the filing of the application. The culture shall thereafter be continuously on deposit. A deposited culture may be replaced by a new culture of the same organism, if it ceases to be viable or if samples from the culture cannot be supplied for other reasons.

Further, the Patents Decree (SFS 1967:838) (Sections 17 – 17 c) and the Guidelines of the Swedish Patent and Registration Office (Sections 5 –10) contain regulations in detail regarding matters related to description and deposition.

Failure of compliance with requirements regarding the application will be followed by the dismissal of the application (Section 15 of the Act). However, the applicant shall in advance be notified and be given the possibility of correction. Further, a correction of a dismissed application within a certain time will reinstate the application.

During the ongoing implementation of the EC-Directive on the Legal Protection of Biotechnological Inventions (98/44/EC), some amendments of the above mentioned Sections of the Patent Act are being considered. These amendments should be made in order to bring the Swedish legislation in line with the Directive. According to a Government Memorandum on the implementation (Ds 2001:49), Section 8 a of the Act will be amended so as to encompass not only microorganisms, but all inventions involving the use of or concerning biological material (cf. Article 13 of the Directive). (A Government Bill on the implementation is being prepared and will be submitted to the Parliament, probably later this year.)

Response to Question 3 (a):
No.

Response to Question 3 (b):
The above mentioned Government Memorandum on the implementation of the EC-Directive (98/44/EC) proposes a draft new Rule 5 a of the Patents Decree. The draft Rule mainly reiterates paragraph 27 of the Preamble of the EC-Directive and contains provisions on the disclosure of the geographical origin of biological material as follows:

"If an invention is based on biological material of plant or animal origin or if it uses such material, the patent application shall include information on the geographical origin of such material, if known. If the origin is unknown, this shall be said.

Lack of information on the geographical origin or on the knowledge of the applicant in this respect is without prejudice to the processing of patent applications or the validity of rights arising from granted patents."

Response to Question 3 (c) - (f):
No.

Response to Question 4 :
The information requirements covered by the note to question 3(b) would apply to patent applications for any inventions based on biological material of plant or animal origin or using such material, regardless of the technology involved. The requirements would apply equally to patent applications by domestic and foreign nationals.

Response to Question 6:
The draft Rule mentioned in the note to question 3 (b) would apply regardless of where the biological material was obtained.

Response to Question 9:
As regards the draft Rule mentioned in the note to question 3 (b) there would be no consequences for the patent applicant or patent holder of any failure to meet the requirements of disclosure of the geographical origin of the biological material.

Response to Question 10:
The information on geographical origin would be available to anyone when the patent was granted (or when eighteen months had passed from the filing date or from the date from which priority was claimed). Information which does not concern the invention for which patent is sought or has been granted and which regards business secrets could however on request be kept secret.

Response to Question 11:
No.

Response to Question 12:
No such circumstances or cases are known.

Response to Question 13:
There are no specific regulations within the realm of Swedish patent law in this respect. False or misleading information could probably lead to the rejection of an application or the invaliditation of a granted patent. The reason for rejection or invalidity would then however be that the criteria for patentability not were met, not the fact of false or misleading information as such.

[End of response of Sweden]

SWITZERLAND

Contact Details

Name:	Dr. jur. Martin Girsberger
Office/Organization:	Swiss Federal Institute of Intellectual Property
Member State:	Switzerland
Address:	Einsteinstrasse 2, 3003 Bern
Email:	martin.girsberger@ipi.ch
Telephone:	+41 31 324 48 63
Facsimile:	+41 31 350 05 66

Response to Question 1 (a):
In Switzerland, access to genetic resources and TK is governed by property law (that is, statutory and customary law regarding real estate and movables). This law exists at the national, cantonal and municipal level. Basically, this law covers all forms of genetic resources and traditional knowledge. There is thus no special access legislation regarding genetic resources and traditional knowledge in Switzerland.

Response to Question 1 (b) - (e):
See reply to question 1(a) above.

Response to Question 2:
In this regard, the applicable provisions include: The Swiss Federal Law on Patents for Inventions (LPI), the Swiss Federal Ordinance on Patents for Inventions, the European Patent Convention (EPC), and the Patent Cooperation Treaty (PCT). The majority of the patents with effect in Switzerland are granted according to the provisions of the EPC.

The following conditions apply: According to Arts. 49(2) LPI and 78(1) EPC, a patent application must contain (1) a request, (2) a description of the invention, (3) one or more patent claims, (4) drawings, and (5) an abstract. Furthermore, according to Arts. 5(1) LPI and 81 EPC, the applicant must designate the inventor in the patent application.

The application must disclose the invention in a manner sufficiently clear and complete, enabling a person skilled in the art to carry out the invention (Arts. 50(1) LPI and 83 EPC). If an invention is not disclosed sufficiently clear and complete for it to be carried out by a person skilled in the art, this is a ground for revocation (Arts. 26(1)(3) LPI and 138(1)(b) EPC).

Response to Question 11:
No.

Response to Question 12 (a):
The invention must be disclosed in a manner sufficiently clear and complete to enable a person skilled in the art to carry out the invention. If any information about the genetic resource or traditional knowledge is indispensable in this regard, it must be disclosed. In particular, this may be the case if a genetic resource used in an invention only occurs in a particular location.

Response to Question 12 (b):
We are not aware of any such particular cases. In this regard, the following should be noted:

- The number of patent applications deposited according to the provisions of the LPI that concern inventions that are based on or use genetic resources is very small.
- We have no information about any such patent applications that concern inventions that are based on or use traditional knowledge.

Response to Question 13:
The consequences depend on what kind of information is false or misleading. If, for example, the inventor named in the invention is not the true inventor, this may be grounds for revocation of the patent (Art. 26(1)(6) LPI). Furthermore, the provisions of the criminal law may apply (e.g., forgery of documents). Competent in this regard are the civil and criminal courts.

Response to Question 14:
Excerpt of the Swiss Federal Law on Patents for Inventions:

SWISS FEDERAL LAW ON PATENTS FOR INVENTIONS

Article 5(1) LPI:
"The applicant shall file a written designation of the inventor with the Federal Institute of Intellectual Property."

Article 26(1)(3) LPI:
"On request, the court shall declare a patent to be invalid:
[...]
(3) where the invention is not disclosed in the patent specification in such a way that a person skilled in the art could carry it out[.]"

Article 49(2) LPI:
"The application shall contain:

(a) a request for the grant of the patent;
(b) a description of the invention;
(c) one or more claims;
(d) the drawings to which the description or claims refer;
(e) an abstract."

Article 50(1) LPI:
"The invention shall be disclosed in the patent applicatiion in such a way that a person skilled in the art may carry it out."

EUROPEAN PATENT CONVENTION (EPC):

Article 78(1) EPC:
"A European patent application shall contain:

(a) a request for the grant of a European patent;
(b) a description of the invention;
(c) one or more claims;
(d) any drawings referred to in the description or the claims;
(e) an abstract."

Article 81 EPC:
“The European patent application shall designate the inventor. If the applicant is not the inventor or is not the sole inventor, the designation shall contain a statement indicating the origin of the right to the European patent.”

Article 83 EPC:
“The European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.”

Article 138 (1)(b) EPC:
“(1) Subject to the provisions of Article 139, a European patent may only be revoked under the law of a Contracting State, with effect for its territory, on the following grounds:
[...]
(b) if the European patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art[.]”

[End of response of Switzerland]

UNITED STATES OF AMERICA

Contact Details

Name:	Mrs. Lois E. Boland
Title:	Acting Director
Office/Organization:	Office of International Relations, USPTO
Member State:	United States of America
Address:	Box 4, Department of Commerce, Washington, DC 20231
Email:	Lois.Boland@uspto.gov
Telephone:	+1 703/305-9300
Facsimile:	+1 703/305-8885

Response to Question 1 (a):
In the United States, property and contract law govern, inter alia, access and benefit sharing of genetic resources. In general, the owner of land owns the genetic resources found on or in it. Ownership of animals or plants on land may be controlled by a third party. The U.S. federal government, state and local governments, tribes, corporations, individuals and non-U.S. nationals can and do own land, animals and plants. In the case of Federal National Parks, under the jurisdiction of the U.S. Department of the Interior, for example, the National Parks Omnibus Management Act of 1998 (PL 105-391) encourages use of parks for science, encourages publication of the results of research conducted in parks, and requires that research conducted in parks be consistent with park laws and mangement policies. This law also requires that research be conducted in a manner that poses no threat to park resources or public enjoyment. National Park Service Management Policies state that research activities that might disturb resources or visitors that require the waiver of any regulation, or that involve the collection of specimens may be allowed only pursuant to terms and conditions of an appropriate permit. Regulations promulgated under the authority of this law include 26 Code of Federal Regulations (CFR) 2.5 which requires researchers wishing to conduct research involving such acts as removing, digging, or disturbing plants, etc. from their natural state, to obtain a specimen collection permit. Scientific and research agreements, such as the Cooperative Research and Development Agreements (CRADAs) may also be concluded. A copy of the policy of the National Park Service is attached.

Contract law is also well developed in this area. A party to a contract, including one involving access to genetic resources and the sharing of benefits from commercialization of relevant resources may seek damages or specific performance for a breach of contract in state courts. There may also be criminal law implications.

With respect to tradtitional knowledge, state trade secret law may provide protection where the knowledge is not generally known by others, the indigenous or local community has sought to protect such knowledge from disclosure and the knowledge is commercially valuable because it is secret.

Response to Question 1 (b) - (d):
Depends on the nature of the ownership of the land and resource, as well as the specific contract negotiated.

Response to Question 1 (e):
The laws and regulations described above are implemented in the United States and are effectively enforced by U.S. Government regulatory agencies and state and federal courts.

Response to Question 2:
Generally, for an invention to be patentable in the U.S., it must be statutory subject matter, new, useful, non-obvious, enabled, and fully described. The pertinent provisions are discussed below.

Section 112, 1st paragraph of title 35 of the United States patent law requires a patent specification to "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention." This provision of the patent law contains three separate and distinct requirements- the written description requirement, the enablement requirement and the best mode requirement of a patent application.

Written Description Requirement

The basic inquiry of the written description requirement is whether one skilled in the art would reasonably conclude that the inventor was in possession of the claimed invention at the time the application was filed. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claim is not explicitly described in the specification, then the requirement for an adequate written description is met.

Enablement

An invention is considered enabled if the specification teaches one skilled in the art how to make and how to use the invention without undue experimentation. Undue experimentation is determined based on a weighing of several factors. These are: the nature of the invention, the breadth of the claims, the state of the art, the level of skill in the art, the predictability or unpredictability of the art, the amount of direction or guidance provided in the specification, the presence or absence of working examples provided in the specification and the quantity of experimentation necessary to make the claimed invention.

Best Mode

The description of an application must set forth the best mode of the invention. The best mode requirement is a safeguard against the desire on the part of some people to obtain patent protection without making a full disclosure as required by the statute. There are two distinct analyses under best mode. The first, a subjective requirement of whether, at the time the inventor filed his patent application, he knew of a mode of practicing the claimed invention better than any other. Secondly, if the inventor in fact contemplated such a preferred mode, whe the disclosure by applicant enabled one skilled in the art to practice the best mode or, whether the inventor concealed the preferred mode from the public. Deficiencies related to disclosure of the best mode for carrying out the claimed invention are not usually encountered during examination of an application because evidence to support such a deficiency is seldom in the record.

35 USC 102 states that a person is not entitled to a patent if:
(a) the invention was known or used by others in this country, or patented or

described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent; or (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States; or (f) he did not himself invent the subject matter sought to be patented.

The USPTO does administer a re-examination procedure under 35 U.S.C. 302 where any party can request re-examination of an issued U.S. patent based on prior art that was not considered during the original examination procedure. The case of turmeric demonstrates that reexamination based on prior art can be effective.

A patent is not granted if applicant fails to meet the above statutory requirements.

Response to Question 11:
No.

Response to Question 12 (a):
Yes. Patent applicants sometimes voluntarily provide information about the genetic resources used in the invention, including the source of origin, in order to meet the written description, enablement or best mode requirements. (Also, see question 2 answer.)

Additionally, 37 C.F.R. 1.56 requires a duty to applicants and their representatives for candor, good faith, and disclosure. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the USPTO, which includes a duty to disclose to the Office all information known to that individual to be material to patentability. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. This duty extends to all dealings with the USPTO, and is not limited to representations to or dealings with the examiner. For example, the duty would extend to proceedings before the Board of Patent Appeals and Interferences and the Office of the Assistant Commissioner for Patents.

Response to Question 12 (b):
In light of the greater than 365,000 patent applications received by the USPTO per year, a search for this information is beyond the available resource limitations. Nevertheless, based on experience, the USPTO is aware that patent applicants, at times, provide information about the genetic resources used in their invention, including the source of origin, in order to meet the written description, enablement or best mode requirement.

Response to Question 13:
Questions of fraud, inequitable conduct, candor, and good faith are generally handled by our courts. Specifically, 37 C.F.R. 1.56 imposes a duty on applicants and their representatives for candor, good faith, and disclosure. (See answer to question 12.)

Response to Question 14:
Gemveto Jewelry Co. v. Lambert Bros., Inc., 542 F. Supp. 933, 216 USPQ 976 (S.D. N.Y. 1982) wherein a patent was held invalid or unenforceable because patentee's foreign counsel did not disclose to patentee's United States counsel or to the Office prior art cited by the Dutch Patent Office in connection with the patentee's corresponding Dutch application. The court stated, 542 F. Supp. at 943, 216 USPQ at 985: Foreign patent attorneys representing applicants for U.S. patents through local correspondent firms surely must be held to the same standards of conduct

which apply to their American counterparts; a double standard of accountability would allow foreign attorneys and their clients to escape responsibility for fraud or inequitable conduct merely by withholding from the local correspondent information unfavorable to patentability and claiming ignorance of United States disclosure requirements.

Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1258, 1259, 43 USPQ2d 1666, 1670-71 (Fed. Cir. 1997) (patent held unenforceable due to inequitable conduct based on patentee's failure to disclose a relevant reference and for failing to disclose ongoing litigation).

Semiconductor Energy Laboratory Co. v. Samsung Electronics Co., 204 F.3d 1368, 54 USPQ2d 1001 (Fed. Cir. 2000). During prosecution patentee submitted an untranslated 29-page Japanese reference as well as a concise explanation of its relevance and an existing one-page partial English translation, both of which were directed to less material portions of the reference. The untranslated portions of the Japanese reference "contained a more complete combination of the elements claimed [in the patent] than anything else before the PTO." 204 F.3d at 1374, 54 USPQ2d at 1005. The patentee, whose native language was Japanese, was held to have understood the materiality of the reference. "The duty of candor does not require that the applicant translate every foreign reference, but only that the applicant refrain from submitting partial translations and concise explanations that it knows will misdirect the examiner's attention from the reference's relevant teaching." 204 F.3d at 1378, 54 USPQ2d at 1008.

It is desirable to call such applications to the attention of the examiner even if there is only a question that they might be "material to patentability" of the application the examiner is considering. It is desirable to be particularly careful that prior art or other information in one application is cited to the examiner in other applications to which it would be material. Do not assume that an examiner will necessarily remember, when examining a particular application, other applications which the examiner is examining, or has examined. See Armour & Co. v. Swift & Co., 466 F.2d 767, 779, 175 USPQ 70, 79 (7th Cir. 1972); KangaROOS U.S.A., Inc. v. Caldor, Inc., 585 F. Supp. 1516, 1522, 1528-29, 222 USPQ 703, 708, 713-14 (S.D. N.Y. 1984), vacated and remanded, 778 F.2d 1571, 228 USPQ 32 (Fed. Cir. 1985). While vacating the summary judgment and remanding for trial in KangaROOS, the Court of Appeals for the Federal Circuit stated that a "lapse on the part of the examiner does not excuse the applicant." 778 F.2d at 1576, 228 USPQ at 35.

It may be desirable to submit information about prior uses and sales even if it appears that they may have been experimental, not involve the specifically claimed invention, or not encompass a completed invention. See Hycor Corp. v. The Schlueter Co., 740 F.2d 1529, 1534-37, 222 USPQ 553, 557-559 (Fed. Cir. 1984). See also LaBounty Mfg., Inc. v. U.S. Int 'l Trade Comm 'n, 958 F.2d 1066, 22 USPQ2d 1025 (Fed. Cir. 1992).

These are just a few excerpts. The USPTO Manuel of Patent Examining Procedure available over the Internet at www.uspto.gov provides many other examples.

APPLICATION PROCEDURES AND REQUIREMENTS FOR

SCIENTIFIC RESEARCH AND COLLECTING PERMITS

United States Department of the Interior
National Park Service

POLICY AND GENERAL REQUIREMENTS

The National Park Service (NPS) welcomes your interest in considering national parks for your research site. The NPS is responsible for protecting in perpetuity and regulating use of our National Park areas (parks, monuments, battlefields, seashores, recreation areas, etc.). Preserving park resources unimpaired and providing appropriate visitor uses of parks require a full understanding of park natural resource components, their interrelationships and processes, and visitor interests that can be obtained only by the long term accumulation and analysis of information produced by science. The NPS has a research mandate to provide management with that understanding, using the highest quality science and information. Superintendents increasingly recognize that timely and reliable scientific information is essential for sound decisions and interpretive programming. NPS welcomes proposals for scientific studies designed to increase understanding of the human and ecological processes and resources in parks and proposals that seek to use the unique values of parks to develop scientific understanding for public benefit.

When is a permit required?

A Scientific Research and Collecting Permit is required for most scientific activities pertaining to natural resources or social science studies in National Park System areas that involve fieldwork, specimen collection, and/or have the potential to disturb resources or visitors. When permits are required for scientific activities pertaining solely to cultural resources, including archeology, ethnography, history, cultural museum objects, cultural landscapes, and historic and prehistoric structures, other permit procedures apply. The park's Research and Collecting Permit Office or Headquarters can provide copies of NPS research-related permit applications and information regarding other permits. Federally funded collection of information from the public, such as when formal surveys are used, may require approval from the Office of Management and Budget.

NPS superintendents may authorize their staff to carry out official duties without requiring an NPS research and collecting permit. NPS staff must comply appropriately with professional standards and with all conditions normally associated with scientific research and collecting permits issued by the park. All other natural and social science research and data collection in a park requires a Scientific Research and Collecting Permit and will be allowed only pursuant to the terms and conditions of the permit.

Additional required permits, approvals, and agreements

In some cases, other federal or state agency permits or approvals may be required before NPS staff can process an application for a Scientific Research and Collecting Permit. Examples include U.S. Fish and Wildlife Service threatened and endangered species

permits and migratory bird permits and approvals by an Institutional Animal Care and Use Committee. It is the responsibility of the principal investigator to provide NPS with copies of such permits when they submit an application. Applicants are encouraged to contact park staff to determine if additional permits may be required in conjunction with a proposed study.

Separate agreements between the investigator and NPS are required when proposed studies or collected specimens are intended to support commercial research activities.

Who may apply?

Any individual may apply if he/she has qualifications and experience to conduct scientific studies or represents a reputable scientific or educational institution or a federal, tribal, or state agency.

When to apply?

We recommend that you apply at least 90 days in advance of your first planned field activities. Projects requiring access to restricted locations or proposing activities with sensitive resources, such as endangered species or cultural sites, usually require extensive review and can require 90 days or longer for a permitting decision. Simple applications can often be approved more quickly.

How and where to apply?

An individual may obtain application materials via the Internet (find "Research Permit and Reporting System" at <http://science.nature.nps.gov/research> or through <www.nps.gov>) or by contacting the park in which the work will be conducted. Addresses for NPS areas are listed on the NPS Internet web site (<www.nps.gov>) or may be obtained by contacting the NPS Public Affairs Office via telephone number 202-208-4747. All application materials must be submitted to the NPS area in which you plan to work. You may submit this information via Internet or traditional postal service.

Study proposals

Applications for Research and Collecting Permits must include a research proposal. Proposals must include, as appropriate, all elements outlined in the separate document *Guidelines to Researchers for Study Proposals.*

Review of proposals

Each proposal will be reviewed for compliance with National Environmental Policy Act (NEPA) requirements and other laws, regulations, and policies. The superintendent may also require internal and/or external scientific review, depending on the complexity and sensitivity of the work being proposed and other factors. You can expedite review of your proposal by providing photocopies of existing peer reviews, or by providing names, mailing addresses, and email addresses of persons that you wish to recommend to review your proposal. Specific details about the review process may be included with the application materials provided by that park.

Facilitating a favorable decision

The superintendent makes a decision to approve a research and collecting permit based on an evaluation of favorable and unfavorable factors (see examples, below), and on an assessment of perceived risks and benefits. While park managers will work with applicants to arrive at a mutually acceptable research design, there may be activities where no acceptable mitigating measures are possible and the application may be denied.

The time and effort required to review the permit application and accompanying study proposal will be proportional to the type and magnitude of the proposed research. For example, a single visit for a non-manipulative research project will often require a relatively simple proposal and the permitting decision should be relatively fast. A highly manipulative or intrusive investigation, however, with the potential to affect non-renewable, rare, or delicate resources, needing detailed planning or logistics, would receive more extensive review. Some of the predisposing factors that influence permitting decisions are outlined below.

Favorable factors

The proposed research:
- contributes information useful to an increased understanding of park resources, and thereby contributes to effective management and/or interpretation of park resources; provides for scheduled sharing of information with park staff, including any manuscripts, publications, maps, databases, etc., which the researcher is willing to share;
- addresses problems or questions of importance to science or society and shows promise of making an important contribution to humankind's knowledge of the subject matter;
- involves a principal investigator and support team with a record of accomplishments in the proposed field of investigation and with a demonstrated ability to work cooperatively and safely, and to accomplish the desired tasks within a reasonable time frame;
- provides for the investigator(s) to prepare occasional summaries of findings for public use, such as seminars and brochures;
- minimizes disruption to the park's natural and cultural resources, to park operations, and to visitors;
- discusses plans for the cataloging and care of collected specimens;
- clearly anticipates logistical needs and provides detail about provisions for meeting those needs; and
- is supported academically and financially, making it highly likely that all fieldwork, analyses, and reporting will be completed within a reasonable time frame.

Unfavorable factors

The proposed research:
- involves activities that adversely affect the experiences of park visitors;
- shows potential for adverse impact on the park's natural, cultural, or scenic resources, and particularly to non-renewable resources such as archeological and fossil sites or special-status species (the entire range of adverse impacts that will be considered also includes construction and support activities, trash disposal, trail conditions, and mechanized equipment use in sensitive areas);
- shows potential for creating high risk of hazard to the researchers, other park visitors, or environments adjacent to the park;

- involves extensive collecting of natural materials or unnecessary replication of existing voucher collections; requires substantial logistical, administrative, curatorial, or project monitoring support by park staff; or provides insufficient lead time to allow necessary review and consultation;
- is to be conducted by a principal investigator lacking scientific institutional affiliation and/or recognized experience conducting scientific research; and
- lacks adequate scientific detail and justification to support the study objectives and methods.

Park response

The principal investigator should receive notice of the approval or rejection of the application by written correspondence via mail, electronic mail, or facsimile. If modifications or changes in a study proposal initially deemed unacceptable would make the proposal acceptable, the park may suggest them at this time. If the application is rejected, the applicant may consult with the appropriate NPS Regional Science Advisor to clarify issues and assess the potential for reconsideration by the park.

Permittee response

If your permit request is approved by the park, you will receive a copy of the permit that you must sign and return to the park via mail or fax. Once the park receives a copy of the permit that you have signed, appropriate NPS officials will validate it and return an approved copy to you. You must carry a copy of the approved permit at all times while performing your research or collecting in the park.

Permit stipulations

General Conditions (requirements and restrictions) will be attached to all Research and Collecting Permits issued. These conditions must be adhered to by permit recipients. Additional Park-specific Conditions may also be included that address unique park resources or activities. An NPS permit is valid only for the activities authorized in the permit. The principal investigator must notify the NPS in writing of any proposed changes. Requests for significant changes may necessitate re-evaluation of the permit conditions or development of a revised proposal.

Access permit requirements

Some NPS areas require access permits for off-road travel, camping, and other activities. Access to many areas is limited and popular destinations can be booked several months in advance. Please contact the park's Research and Collecting Permit Office to obtain information on any needed access permits.

Research products and deliverables

Researchers working in NPS areas are required to complete an NPS Investigator's Annual Report form for each year of the permit, including the final year. The NPS maintains a system enabling researchers to use the Internet to complete and submit the Investigator's Annual Report. NPS staff will contact permit holders near the beginning of each calendar year to request the prior year's report and explain how to access and use the system. Investigator's Annual Reports are used to consistently document accomplishments of research conducted in parks. Principal

investigators are responsible for the content of their reports. NPS staff will not modify reports received unless requested to do so by the principal investigator responsible for the report.

Park research coordinators may request copies of field notes, data, reports, publications and/or other materials resulting from studies conducted in NPS areas. Additional deliverables may be required of studies involving NPS funding or participation.

Privacy Act and Paperwork Reduction Act

NPS regulations (36 CFR 2.1) prohibit possessing, destroying, injuring, defacing, removing, digging, or disturbing from their natural state in any form animals, plants, paleontological, or mineral resources. NPS regulations (36 CFR 2.5) require researchers wishing to conduct research involving acts prohibited by other regulations, such as CFR 2.1, to obtain a specimen collection permit. The National Parks Omnibus Management Act of 1998 (Public Law 105-391) encourages use of parks for science, encourages publication of the results of research conducted in parks, and requires that research conducted in parks be consistent with park laws and management policies. This law also requires that research be conducted in a manner that poses no threat to park resources or public enjoyment. National Park Service Management Policies state that research activities that might disturb resources or visitors, that require the waiver of any regulation, or that involve the collection of specimens may be allowed only pursuant to terms and conditions of an appropriate permit.

The information you submit in your Application for a Scientific Research and Collecting Permit will be used by park managers to determine whether or not to issue you a Scientific Research and Collecting Permit. The information you submit in your Investigator's Annual Report will be used by park managers to inform resource management decision-makers, park visitors, the public, and other researchers about the objectives and progress results of your research.

Parks and park records are public assets. The information you submit in your Application and in your Investigator's Annual Report is not confidential and will be in the public record and available to the public. If you want to receive and maintain a Scientific Research and Collecting Permit, you must respond to both the Application and Investigator's Annual Report collections of information. If you do not respond to the request for information in the Application, you will not be considered for a Scientific Research and Collecting Permit. If you have received a Scientific Research and Collecting Permit and do not respond to the request for information in the Investigator's Annual Report, your permit may be revoked and you may be denied future permits.

The Application for a Scientific Research and Collecting Permit and the Investigator's Annual Report are two parts of one complete process dealing with conducting scientific research and collecting in a unit of the National Park System. The total public reporting burden involved in electronically completing the collection of information process for a single scientific research and collecting activity in a unit of the National Park System includes the burden of reading the informational documents associated with these two information collection forms plus completing and submitting one Application form (approximately 45 minutes), plus the burden of signing and mailing an issued permit back to the park (approximately 15 minutes), plus the burden of completing one associated Investigator's Annual Report form (approximately 15 minutes). Some applicants will experience an additional burden of photocopying and mailing attachments (approximately 15 minutes). Other applicants will experience an additional burden of coordinating with a specimen repository (approximately 30 minutes). The total public reporting

burden experienced by a successful permittee for electronically completing this process for a single scientific research and collecting activity in a unit of the National Park System thus is estimated to range between 1.25 and 2.0 hours per year. The total public reporting burden experienced by an unsuccessful applicant for electronically completing this process is estimated to be about 45 minutes per year because the unsuccessful applicant will not be required to complete the Investigator's Annual Report, mail a signed permit, or respond to other portions of the process. The few applicants who complete these forms manually are expected to experience a somewhat larger annual reporting burden. Direct any comments you may have regarding this burden estimate or any other aspect of this information collection process or of its two forms to the Office of Information and Regulatory Affairs of OMB, Attention Desk Officer for the Interior Department, Office of Management and Budget, Washington, DC 20503; and to the Information Collection Clearance Officer, WASO Administrative Program Center, National Park Service, 1849 C Street, N.W., Washington, DC 20240.

GUIDELINES TO RESEARCHERS FOR STUDY PROPOSALS

UNITED STATES DEPARTMENT OF THE INTERIOR

National Park Service

Your proposal should include each of the required information items listed below, in enough detail that an educated non-specialist can understand exactly what you plan to do. If you have already prepared a relevant proposal for a funding application, work plan, formal agreement, or similar document, then your original proposal likely will satisfy National Park Service (NPS) proposal requirements. The primary area where new information may be necessary concerns the ability of the park to assess what, if any, impacts your research may have on park resources. You should compare your original proposal to these guidelines to be certain that you have provided all the required information. If additional information is required, you can provide it in a cover letter or supplement to your proposal, as appropriate. If a required topic does not apply to your proposed study, simply list the topic and write "not applicable."

The length of your proposal depends primarily on the complexity of the work planned. In some cases, a proposal may consist of a couple of pages for a study expected to have no significant impact on park resources or visitor experiences. However, proposals for lengthy or complex research problems, for extensive collecting, and for work with special status species or sensitive cultural resources are typically longer, more detailed, and well-organized. Incomplete, disorganized, or illegible proposals may be returned for revision.

I. INTRODUCTION

A. Title

B. Date of proposal

C. Investigators - Provide the name, title, address, telephone number, FAX number, email address, and institutional affiliation of the principal investigator and the name and affiliation of all additional investigators listed in the proposal.

D. Table of contents - Recommended for long or complicated proposals.

E. Abstract - Provide a brief summary description of the proposed project. Include up to five keywords that can be used by the NPS to quickly identify the proposal subject (for example, microbiology, geology, ecology).

II. OVERVIEW - Summarize the proposed project by describing in general the problem or issue being investigated as well as any previous pertinent research.

A. Statement of issue - Describe the issue to be investigated and its importance and relevance to science and to the park. Provide relevant background information that clarifies the need for the project and why it is valuable for the research and/or collecting to be conducted in the park.

B. Literature summary - Summarize the relevant literature regarding the issue, problem, or questions that will be investigated.

C. Scope of study - Describe the overall geographic and scientific scope of the project.

D. Intended use of results - Describe how the products will be used, including any anticipated commercial use.

III. OBJECTIVES/HYPOTHESES TO BE TESTED - Describe the specific objectives of the proposed project. Where appropriate, the objectives should be stated as specific hypotheses to be tested.

IV. METHODS - Describe how the proposed methods and analytical techniques will achieve the study objectives or test the stated hypothesis/question. Provide pertinent literature citations.

A. Description of study area – Clearly describe the study area in terms of park name(s), geographic location(s), and place names. Provide maps, park names, or geographic coordinates as appropriate. Indicate whether your work will take place in an area designated or managed as “wilderness” by the NPS.

B. Procedures - Describe the proposed study design that addresses the stated objectives and hypotheses. Explain the methods and protocols to be employed in the field and laboratory.

C. Collections - Describe the type, size, and quantity of specimens or materials to be collected, sampled, or captured, and your plans to remove them from the collecting site. If you are aware specimens of the proposed types already exist in a repository, explain why additional collecting is necessary. Provide scientific nomenclature where possible. Provide information on all other applicable federal or state permits where required.

D. Analysis - Explain how the data from the study will be analyzed to meet the stated objectives or test the hypotheses. Include any statistical techniques or mathematical models necessary to the understanding of the analysis.

E. Schedule - Provide a schedule that includes start of project, approximate dates or seasons of fieldwork, analysis, reporting, and completion dates.

F. Budget - Briefly outline the expenses associated with this project and identify your expected funding source(s). Include the anticipated costs pertaining to the cataloging of collected and permanently retained specimens or materials.

V. PRODUCTS

A. Publications and reports - Describe the expected publications or reports that will be generated as part of this study.

B. Collections – Describe the proposed disposition of collected specimens or materials. If you propose that the NPS lend the specimens or samples to a non-NPS institution for long-term storage, identify that institution and give a brief justification for this proposal.

C. Data and other materials - Describe any other products to be generated as part of the project, such as, photographs, maps, models, handouts, exhibits, software presentations, raw data, GIS coverages, or videos, and the proposed disposition of these materials. If data are to be collected from the public as part of this study, provide a copy of the data collection instrument (survey, questionnaire, interview protocol, etc.).

VI. LITERATURE CITED - Include full bibliographic citations for all reports and publications referenced in the proposal.

VII. QUALIFICATIONS - Provide a background summary or curriculum vitae for the principal investigator and other investigators listed in the proposal. Identify their training and qualifications relevant to the proposed project and their ability to conduct field activities in the environment of the proposed study area. Describe previous research and collecting in NPS areas, including study and permit numbers if available.

VIII. SUPPORTING DOCUMENTATION AND SPECIAL CONCERNS - Provide information on the following topics where applicable. Attach copies of any supporting documentation that will facilitate processing of your application, such as other required federal and state permits, copies of peer reviews, letters of support and funding commitments, and certifications. Collection of information from the public when federal funds are used may require approval from the Office of Management and Budget (OMB). Upon your request, the NPS Social Science Program will advise you on steps needed to obtain this OMB approval.

A. Safety - Describe any known potentially hazardous activities, such as electrofishing, rock climbing, scuba diving, whitewater boating, aircraft use, wilderness travel, wildlife capture, handling or immobilization, use of explosives, etc.

B. Access to study sites - Describe the proposed method and frequency of travel to and within the study site(s). Explain any need to enter restricted areas. Describe duration, location, and number of participants for planned backcountry camping.

C. Use of mechanized and other equipment - Describe any field equipment, markers, or supply caches by type, number, and location. You should explain how long

they are to be left in the field. Explain the need to use these materials in restricted areas and the alternatives that were considered.

D. Chemical use - Identify any chemicals and hazardous material that you propose using within the park. Indicate the purpose, method of application, and amount to be used. Describe plans for storage, transfer, and disposal of these materials and describe steps to remediate accidental releases into the environment. Attach copies of Material Safety Data Sheets.

E. Ground disturbance - Describe the type, location, area, depth, number, and distribution of expected ground-disturbing activities, such as soil pits, cores, stakes, or latrines. Describe plans for site restoration of significantly affected areas.

Proposals that entail ground disturbance may require an archeological survey and special clearance prior to approval of the study. You can help reduce the extra time that may be required to process such a proposal by including identification of each ground disturbance area on a USGS 7.5 -minute topographic map.

F. Animal welfare - For vertebrate species that require review by your Institutional Animal Care and Use Committee (IACUC) according to the Animal Welfare Act, please include a photocopy of the study protocol, and IACUC review form and approval.

For vertebrate species not requiring IACUC review, describe your protocol for any capture, holding, marking, tagging, tissue sampling, or other handling of these animals (including the training and qualifications of personnel relevant to animal handling and care). Please discuss alternative techniques considered and outline any procedures to alleviate pain or distress. Include contingency plans to be implemented in the event of accidental injury to or death of the animal.

G. NPS assistance - Describe any NPS field assistance you would like to receive to complete the proposed study, such as use of equipment or facilities or assistance from staff.

H. Wilderness “minimum requirement” protocols - If some or all of your activities will be conducted within a location administered by the NPS as a designated, proposed, or potential wilderness area, your proposal should describe how the project adheres to wilderness “minimum requirement” and “minimum tool” concepts. Refer to the park’s wilderness management plan for further information.

GENERAL CONDITIONS

For
SCIENTIFIC RESEARCH AND COLLECTING PERMIT

United States Department of the Interior
National Park Service

1. Authority - The permittee is granted privileges covered under this permit subject to the supervision of the superintendent or a designee, and shall comply with all applicable laws and regulations of the National Park System area and other federal and state laws. A National Park Service (NPS) representative may accompany the permittee in the field to ensure compliance with regulations.

2. Responsibility - The permittee is responsible for ensuring that all persons working on the project adhere to permit conditions and applicable NPS regulations.

3. False information - The permittee is prohibited from giving false information that is used to issue this permit. To do so will be considered a breach of conditions and be grounds for revocation of this permit and other applicable penalties.

4. Assignment - This permit may not be transferred or assigned. Additional investigators and field assistants are to be coordinated by the person(s) named in the permit and should carry a copy of the permit while they are working in the park. The principal investigator shall notify the park's Research and Collecting Permit Office when there are desired changes in the approved study protocols or methods, changes in the affiliation or status of the principal investigator, or modification of the name of any project member.

5. Revocation - This permit may be terminated for breach of any condition. The permittee may consult with the appropriate NPS Regional Science Advisor to clarify issues resulting in a revoked permit and the potential for reinstatement by the park superintendent or a designee.

6. Collection of specimens (including materials) - No specimens (including materials) may be collected unless authorized on the Scientific Research and Collecting permit.

The general conditions for specimen collections are:

- Collection of archeological materials without a valid Federal Archeology Permit is prohibited.
- Collection of federally listed threatened or endangered species without a valid U.S. Fish and Wildlife Service endangered species permit is prohibited.
- Collection methods shall not attract undue attention or cause unapproved damage, depletion, or disturbance to the environment and other park resources, such as historic sites.
- New specimens must be reported to the NPS annually or more frequently if required by the park issuing the permit. Minimum information for annual reporting includes specimen classification, number of specimens collected, location collected, specimen status (e.g., herbarium sheet, preserved in alcohol/formalin, tanned and mounted, dried and boxed, etc.), and current location.

- Collected specimens that are not consumed in analysis or discarded after scientific analysis remain federal property. The NPS reserves the right to designate the repositories of all specimens removed from the park and to approve or restrict reassignment of specimens from one repository to another. Because specimens are Federal property, they shall not be destroyed or discarded without prior NPS authorization.
- Each specimen (or groups of specimens labeled as a group) that is retained permanently must bear NPS labels and must be accessioned and cataloged in the NPS National Catalog. Unless exempted by additional park-specific stipulations, the permittee will complete the labels and catalog records and will provide accession information. It is the permittee's responsibility to contact the park for cataloging instructions and specimen labels as well as instructions on repository designation for the specimens.
- Collected specimens may be used for scientific or educational purposes only, and shall be dedicated to public benefit and be accessible to the public in accordance with NPS policies and procedures.

- Any specimens collected under this permit, any components of any specimens (including but not limited to natural organisms, enzymes or other bioactive molecules, genetic materials, or seeds), and research results derived from collected specimens are to be used for scientific or educational purposes only, and may not be used for commercial or other revenue-generating purposes unless the permittee has entered into a Cooperative Research And Development Agreement (CRADA) or other approved benefit-sharing agreement with the NPS. The sale of collected research specimens or other unauthorized transfers to third parties is prohibited. Furthermore, if the permittee sells or otherwise transfers collected specimens, any components thereof, or any products or research results developed from such specimens or their components without a CRADA or other approved benefit-sharing agreement with NPS, permittee will pay the NPS a royalty rate of twenty percent (20%) of gross revenue from such sales or other revenues. In addition to such royalty, the NPS may seek other damages to which the NPS may be entitled including but not limited to injunctive relief against the permittee.

7. Reports - The permittee is required to submit an Investigator's Annual Report and copies of final reports, publications, and other materials resulting from the study. Instructions for how and when to submit an annual report will be provided by NPS staff. Park research coordinators will analyze study proposals to determine whether copies of field notes, databases, maps, photos, and/or other materials may also be requested. The permittee is responsible for the content of reports and data provided to the National Park Service.

8. Confidentiality - The permittee agrees to keep the specific location of sensitive park resources confidential. Sensitive resources include threatened species, endangered species, and rare species, archeological sites, caves, fossil sites, minerals, commercially valuable resources, and sacred ceremonial sites.

9. Methods of travel - Travel within the park is restricted to only those methods that are available to the general public unless otherwise specified in additional stipulations associated with this permit.

10. Other permits - The permittee must obtain all other required permit(s) to conduct the specified project.

11. Insurance - If liability insurance is required by the NPS for this project, then documentation must be provided that it has been obtained and is current in all respects before this permit is considered valid.

12. Mechanized equipment - No use of mechanized equipment in designated, proposed, or potential wilderness areas is allowed unless authorized by the superintendent or a designee in additional specific conditions associated with this permit.

13. NPS participation - The permittee should not anticipate assistance from the NPS unless specific arrangements are made and documented in either an additional stipulation attached to this permit or in other separate written agreements.

14. Permanent markers and field equipment - The permittee is required to remove all markers or equipment from the field after the completion of the study or prior to the expiration date of this permit. The superintendent or a designee may modify this requirement through additional park specific conditions that may be attached to this permit. Additional conditions regarding the positioning and identification of markers and field equipment may be issued by staff at individual parks.

15. Access to park and restricted areas - Approval for any activity is contingent on the park being open and staffed for required operations. No entry into restricted areas is allowed unless authorized in additional park specific stipulations attached to this permit.

16. Notification - The permittee is required to contact the park's Research and Collecting Permit Office (or other offices if indicated in the stipulations associated with this permit) prior to initiating any fieldwork authorized by this permit. Ideally this contact should occur at least one week prior to the initial visit to the park.

17. Expiration date - Permits expire on the date listed. Nothing in this permit shall be construed as granting any exclusive research privileges or automatic right to continue, extend, or renew this or any other line of research under new permit(s).

18. Other stipulations - This permit includes by reference all stipulations listed in the application materials or in additional attachments to this permit provided by the superintendent or a designee. Breach of any of the terms of this permit will be grounds for revocation of this permit and denial of future permits.

[End of response of the
United States of America]

URUGUAY

Contact Details

Name:	María del Rosario Moreira
Title:	Asesora en Relaciones Internacionales
Office/Organization:	Dirección Nacional de la Propiedad Industrial
Member State:	Uruguay
Address:	Rincon 717
Email:	dnpiuy@adinet.com.uy
Telephone:	(598 2) 9025771
Facsimile:	(598 2) 9031140

Response to Question 1 (a):
No existe legislacion nacional específica al respecto.

Response to Question 2:
I - De acuerdo al art. 22 de la Ley No. 17.163 de 2 de setiembre de 1999 La solicitud de patente deberá contener:
(a) El nombre del inventor y el solicitante con su domicilio
(b) La clase de patente que se solicita
(c) La denominación atribuida a la invención
(d) La descripción clara y completa de la misma
(e) Una o más reivindicaciones
(f) Un resumen de la descripción
(g) La constancia de pago de derechos
(h) La fecha, el país y el numero de la solicitud de prioridad reivindicada, en su caso
(i) Los documentos de cesión de derechos, cuando corresponda.
Según el art. 25 de dicha ley, en caso de solicitudes relativas a microorganismos, el depósito del material biológico necesario para la descripción de su objeto se realizará en instituciones autorizadas.

II - Según el art. 4 del Decreto No. 11/000 de 13 de enero de 2000, que reglamenta la mencionada ley 17.164, la descripción de la invención contenida en la solicitud de patente, deberá contener:
(a) La indicación del sector de la técnica al que se refiera la invención.
(b) La indicación del estado de la técnica anterior, conocido por el solicitante, necesario para el conocimiento de la invención o para la tarea de exámen, debiendo citarse los documentos conocidos que lo divulguen.
(c) Una explicación de la invención que permita la comprensión del problema técnico planteado, así como la solución dada al mismo, para un técnico con conocimientos medios en la materia, indicando las diferencias con el estado de la técnica anterior.
(d) Una exposición de la forma de llevar la invencion a la práctica, detallando procedimiéntos y/o métodos.
(e) La indicación de la manera en que la invención se puede explotar industrialmente.

Response to Question 11:
No.

Response to Question 12:
No.

Response to Question 13:
Por aplicación de las normas contenidas en la legislación general, así como las de la ley de patentes No. 17.164 mencionada (arts. 22, 32, 33 y 44), la solicitud puede ser desestimada, o la patente concedida puede ser revocada o anulada.

[End of response of Uruguay]

VIET NAM

Contact Details

Name:	Nguyen Thi Thanh Ha
Title:	Deputy Director, Legislation and Management Division
Office/Organization:	National Office of Industrial Property
Member State:	Viet Nam
Address:	386 Nguyen Trai Street, Hanoi, Vietnam
Email:	noip@fpt.vn ha_nguyenthithanh@yahoo.com
Telephone:	84 4 8583069 – Ext. 118
Facsimile:	84 4 5583328

Response to Question 1:
There are not any laws or regulations on access to genetic resources and/or TK

Response to Question 2:
- Required information includes: (i) pior art; (ii) summary of the invention; (iii) detailed description of the invention; and (iv) example of working the invention;
- Requirements for disclosure includes: (i) complete disclosure of the content of the invention; (ii) information enough for the average skilled person to carry out the invention;
- Failure to meet such requirements leads to refusal of patent grant.

Response to Question 3 (a) - (f):
No.

Response to Question 11:
No, there are not.

Response to Question 12:
There are not any particular regulations that oblige applicants to disclose any of the categories. However, in fact, in order to make the applications clearly and completely disclose the content of the inventions, the applicants are required to disclose categories of information set out in question 3 (d) to (f). Applications regarding to genetic resources could be taken as examples where the applicants did so to meet conventional patent disclosure requirements.

With respect to categories of information set out in question 3 (a) to (c), applicants are not required to disclose them.

Response to Question 13:
We do not have any regulations on the event, except for information on the right to apply for a patent, on applicant and invention.

Response to Question 14:
Article 6.3 of Circular No. 3055-TT/SHCN of December 31, 1996 of Ministry of Science, Technology and Environment guiding the implementation of the regulations on the procedures for establishing industrial property rights and other regulations in Decree No. 63-CP of October 24, 1996 of the Government on detailed regulations on industrial property says:

The description must totally reveal the nature o the technical solution requested to be protected. The descripti9on must provide information to such an extent that based on which a person with the average professional level in the corresponding technical area can apply such solution.

The description must clarify the novelty, creativity (if the protection object is an invention) and applicability of the technical solution requested to be protected.

The description must include the following contents:
(i) The international criteria for invention classification (under the Strasbourg Agreement),
(ii) The title of the technical solution,
(iii) The area in which the technical solution is applied or involved in,
(iv) The technical status of the above area at the time of filing the application (the technical solutions already known),
(v) The nature of the technical solution,
(vi) A brief description of the attached drawings (if any),
(vii) A model of application of the technical solution,
(viii) The obtainable benefits (the effectiveness of the technical solution).

[End of response of Viet Nam]

EUROPEAN COMMISSION

Contact Details

Name: Ravillard Patrick
Title: Principal Administrator
Office/Organization: European Commission
Address: B-1049 Brussels
Email: patrick.ravillard@cec.eu.int
Telephone: +32-2/295.27.69
Facsimile: +32-2/299.31.04

Response to Question 1 (a):
Directive 98/44/CE of the European Parliament and of the Council on the legal protection of biotechnological inventions deals indirectly with the above mentioned issues.

Article 2 of the directive states that Biological material means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.

This definition also includes material from plant and/or animal origin.

Response to Question 1 (b):
See answers provided by the Member States of the European Community.

Response to Question 1 (c):
Not specified in Directive 98/44.

Response to Question 1 (d):
Not specified.

Response to Question 1 (e):
Please see possible contributions of the Member States of the European Community as regards the implementation of Recital 27 of Directive 98/44/CE (see below the content of this recital).

Response to Question 2:
According to the European Patent Convention, a European patent shall contain a request for the grant of a European patent; a description of the invention; one or more claims; any drawings referred to in the description or the abstract; and an abstract. The European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. The failure to meet such requirements leads to the rejection of the patent application.

Response to Question 11:
No.

Response to Question 12 (a):
Article 13(1)(b) of Directive 98/44/EC states that where an invention involves the use of or concerns biological material which is not available to the public and which cannot be described in a patent application in such a manner as to enable the invention to be reproduced by a person

skilled in the art, the description shall be considered inadequate for the purpose of patent law unless the application as filed contains such relevant information as is available to the applicant on the characteristics of the biological material deposited.

Response to Question 12 (b):
See answers provided by the Member States of the European Community.

Response to Question 13:
There is no article in the directive 98/44 which is devoted to this issue. However, recital 27 (which is not legally binding) of this directive lays down that, "if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; (…) this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents."

This has to be regarded as being an encouragement to mention the geographical origin of biological material in the patent application, along the lines indicated by Article 16(5) of the Convention on Biological Diversity. However, to provide such information is not an obligation under Community law. Nor does the failure to provide such information have, as such, any legal consequences for the processing of patent applications, or on the validity of rights arising from granted patents.

Response to Question 14:
See explanations given in the answer to question 13.

[End of response of the
European Commission]

EUROPEAN PATENT OFFICE

Contact Details

Name:	Dr. Bart Claes
Title:	Examiner – Member Directorate Patent Law
Office/Organization:	European Patent Office
Address:	D-80298 Munich, Germany
Email:	belaes@epo.org
Telephone:	+49 89 2399 8429 or 5156
Facsimile:	+49 89 2399 5153

Response to Question 1 (a):
The European Patent Office (EPO) has answered this questionnaire on the basis of European patent law as governed by the European Patent Convention (EPC). For questions which deal with issues which go beyond the EPC, the EPO refers to the answered questionnaires from the member states of the European Patent Organisation (at present all EU Member States, MC, CH, LI, CY, TK, CZ, SK, EE, BG).

Response to Question 1 (b):
cfr. member states EPC.

Response to Question 1 (c):
cfr. member states EPO.

Response to Question 1 (d):
cfr. member states EPO.

Response to Question 1 (e):
cfr. member states EPO.

Response to Question 2:
The EPC provisions relevant for the present questionnaire are:

a.1) A European patent (EP) application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC). If an invention involves the use of or concerns biological material and this biological material is not available to the public and cannot be described in such a manner as to enable the invention to be carried out by a person skilled in the art, reference needs to be made to the deposit of this biological material (e.g. under the Budapest Treaty) in accordance with Rule 28 (1),(2) EPC. The deposited biological material shall be available to any person, from the date of publication of the EP application, by the issue of a sample to the person requesting so (Rule 28(3)-(9) EPC).

a.2) If the biological material has been deposited by a person other than the applicant, the EP application needs to identify this person and a document needs to be submitted satisfying the EPO that the latter has authorised the reference to the deposited material and has given his unreserved and irrevocable consent to the deposited material being made available to the public in accordance with Rule 28 EPC.

a.3) Non-compliance with the requirements of Article 83 in conection with Rule 28 EPC results in the refusal of the EP application (Article 97(1), Article 83 EPC).

b) If an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known. This requirement is without prejudice to the processing of patent applications or the validity of rights arising from granted patents (Rule 23b(1) EPC read in conjunction with Recital 27 EU Directive 98/44/EC).
Accordingly, there is no sanction for non-compliance.

c) Rule 27 EPC prescribes the content of the description of EP applications. In particular Rule 27(b),(c) EPC require the applicant to indicate the relevant background art, as far as known to the applicant, and any advantage of the invention over this background art. No sanction is foreseen under the EPC for non-compliance upon filing the application. Relevant prior art (Article 54(2) EPC) discovered during the processing of the application must be indicated in the description. This prior art may include relevant TK.

Response to Question 3:
(b) The geographical origin (including country of origin) of genetic resources used in the claimed invention.

Response to Question 4:
The requirement of Rule 23b(1) EPC read in conjunction with Recital 27 EU Directive 98/44/EC applies to EP applications regardless of the nature of technology involved or the origin or residence of the applicant. The requirement only concerns inventions which are based on biological material of plant or animal origin or which uses such material.

Response to Question 5:
It follows from Recital 27 EU Directive (see answer b) to Question 2) that the requirement only concerns inventions which are based on biological material of plant or animal origin or which use such material.

There are no particular guidelines under the EPC which go beyond the stipulations in the above itemised provision.

Response to Question 6:
No.

Response to Question 9:
The requirement of Recital 27 is without prejudice to the processing of patent applications or the validity of rights arising from granted patents (Rule 23b(1) EPC, Recital 27 EU Directive 98/44/EC).

It is noted here that the national patent and other laws of the member states of the EPO may provide for other consequences with respect to national patent applications or patents.

Response to Question 10:
The indications are included in the EP application or patent as published. Any information filed in relation to this is not exempt of (public) file inspection in accordance with Article 128 EPC.

Response to Question 11:
cfr. member states EPO.

Response to Question 12(a):
It follows from answers a) and c) to Question 2 that in particular cases information as set out in Question 3 may be provided by the applicant.

Response to Question 12(b):
Yes, categories of information as set out in Question 3 are sometimes disclosed in relevant EP applications.

Respnse to Question 13 :
There is no general answer to this question under the EPC. On the one hand mechanisms exist for the correction of obvious errors. On the other hand false or misleading information in the description or with respect to the deposit of biological material may lead to non-compliance with the requirements for European patent applications (Article 83 EPC: lack of sufficiency of disclosure)

It is noted here that the national patent and other laws of the member states of the EPO may provide for other sanctions with respect to national patent applications and patents.

Response to Question 14:
See answer to Question. For the full text of the provisions please consult the EPC at: <http://www.european-patent-office.org>.

[End of response of the
European Patent Office]

[End of Annex]