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

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POLICIES, MEASURES AND EXPERIENCES REGARDING INTELLECTUAL PROPERTY AND GENETIC RESOURCES: SUBMISSION BY THE EUROPEAN UNION AND ITS MEMBER STATES

Document prepared by the Secretariat

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

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

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

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- 3. Pursuant to the above decision, the Delegation of Spain, on behalf of the European Union and its Member States, submitted a document entitled "Situation in the European Union and its Member States" and requested it be made available as an information document for the sixteenth session of the Committee.
 - 4. The document is reproduced in the form received and contained in the Annex to this document.

[Annex follows]

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ANNEX

SITUATION IN THE EUROPEAN UNION AND ITS MEMBER STATES

European Union

Disclosure of geographical origin is dealt with under EC Directive 98/44, on the legal protection of biotechnological inventions. Recital 27 of the Directive's preamble states that:

"Whereas 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; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents."

On this basis some EU Member States have introduced a disclosure requirement but it is not obligatory and failure to comply does not affect the granting or enforceability of patents, without prejudice to the outcome of international negotiations on this issue.

Voluntary requirements

In some MS disclosure is encouraged by voluntary requirements, and so there are no legal consequences for non-compliance.

Mandatory requirements

Other EU Member States have instituted a mandatory disclosure requirement within their patent laws. This has been implemented through a stand-alone disclosure requirement. For reasons of legal certainty non-compliance of this provision does not prevent patentability or enforceability of a patent. Rather, any legal consequences of non-compliance lie outside the scope of patent law.

With respect to plant variety protection, Council Regulation 2100/94 on Community Plant Variety Rights requires applicants of a community plant variety right to state the geographic origin of the variety (article 50).

Situation In Certain Member States

<u>Austria</u>

Austrian Patent Office

In the Austrian patent law, nothing is provided - neither a mandatory divulgation of the origin of genetic resources nor a voluntary divulgation of origin.

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Federal Ministry of Agriculture, Forestry, Environment and Water Management

Concerning plant variety protection, a request for protection of a new variety has to be filed at the AGES agency. The applicant has to fill in a questionary where he has to indicate the origin of the plants of hybridation.

Belgium

Belgium has adopted national legislation to include disclosure of origin in (Belgian) applications for patents where the subject matter of the application makes use of genetic resources in its development.

Belgium has amended its patent law of 28 march 1984 (BPL) in function of the implementation of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. The requirement (article 15, § 1, 6 BPL) "that patent applications must contain the geographic source of the plant or animal material, if known, that formed the basis for the development of the invention" is a formal requirement that aims to contribute to transparency with regard to the geographic origin of the genetic source on which the invention is directly based. The standard form for national patent applications provides for tick boxes that obliges the applicant to declare (Yes or No) wether use has been made of genetic ressources in the sense of article 15, § 1, 6 BPL. He further is invited to provide information on the geographical source or he can declare that he is not aware of it. This measure provides for a mere formality that does not put any burden on the work of the patent office, i.e. the patent office does not make a research to the geographic source of the material. The information is available for the public by means of inclustion of the application form in the public part of the patent file.

Denmark

The Danish requirement is provided in Chapter 2, 2(4), of the Danish Order on Patents and Supplementary Protection Certificates, Order No. 93 of 29 January 2009. This is an implementation of the Directive 98/44, Recital 27.

Germany

According to sec. 34a of the German Patent Code a patent application for an invention which is based on plant or animal biological material should contain information on the geographical origin of such material if the origin is known to the applicant. This is without prejudice to the examination of patent applications and the validity of rights arising from the patents.

This provision was introduced into German patent law in the course of the implementation of the EC Directive 98/44. Turning Recital 27 into German law was meant to enhance transparency and not to prejudge any possible outcome of international negotiations on the issue of disclosure of origin in patent applications.

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The Netherlands

The Netherlands has no requirement to disclose the origin or source of genetic resources. The Netherlands refers to and still fully supports the proposal made by the EU in this regard (WIPO/GRTKF/IC/8/11). Spain

Spain has no mandatory requirement to disclose the origin or source of genetic resources in patent applications.

Sweden

Disclosure requirement in patent applications in Sweden, including procedure at the Swedish Patent and Registration Office

If an invention relates to biological material from animals or plants, a patent application should include information on the geographical origin of said material. If the origin is not known this should be indicated. An absence of information regarding the origin of biological material provided is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.¹

This demand is unsanctioned and does not affect the examining of patent applications or the validity of the rights conferred with a granted patent.²

Therefore, there is no particular procedure, e.g. a form that shall be filled in by the applicant or a notification sent to a provider of resources, regarding disclosure and the compliance is not actively sought for during examination of patent applications. As a consequence no figures regarding the exact number of applications can be presented. All patent applications are published 18 month after the filing, thus enabling third party to search for e.g. biological material subject to benefit sharing agreements.

It is stated in the government bill³ that the object of this regulation is to facilitate for countries providing genetic resources to monitor compliance with regulations and contracts regarding access to and sharing of benefits from genetic resources, such as the Bonn-guidelines.

[End of Annex and of document]

¹ Swedish Patents Decree, Section 5a.

² Certifying untruthful information can be a crime, penalized under the Swedish Penal Act Chapter 15, Section 11. However, withholding information in a patent application is not a criminal act in Sweden. This means that if the applicant leaves out information on geographical origin of a biological material he/she can not be penalized.

³ Government bill 2003/04:55- implementation of directive 98/44/EC on the legal protection of biotechnological inventions, page 134.