From: Ploeger-He@bmj.bund.de Sent: vendredi, 26. février 2010 11:28

To: Grtkf

Subject: C. 7795

Dear ladies and gentlemen,

on behalf of the German Ministry of Justice I thank you for the opportunity to further comment on the documents WIPO/GRTKF/IC/16/4 Prov., WIPO/GRTKF/IC/16/5 Prov. and WIPO/GRTKF/IC/16/6 Prov. which I would like to do as follows:

TK and TCEs

We think that future discussions may well be based on documents WIPO/GRTKF/IC/9/4 and WIPO/GRTKF/IC/9/5, however they should not be the only basis for future work. As stated by the EU on IGC 14, the discussions should be based on the entire work carried out by the Committee, not documents. particular document **Documents** excluding anv or WIPO/GRTKF/IC/14/4 and WIPO/GRTKF/IC/14/5 contain comprehensive lists of other documents with possible relevance for future discussions. Just to pick two, the gap analyses contained in documents WIPO/GRTKF/IC/13/4(b) and WIPO/GRTKF/IC/13/5(b) Rev. should also be referred to, since they contain valuable information on the general characteristics of TCEs and of TK respectively.

It has always been our position that any discussion on secondary priority issues has to be based on a resilient common understanding in the Committee of the objective of protection for TK, TCEs and GR. Therefore Germany supports comments on p.16 of document WIPO/GRTKF/IC/16/5 (ex 9/5) asking for greater clarification what actually should be the objective and subject of protecting TK through Article 1. The same holds true for TCEs in document WIPO/GRTKF/IC/16/4 (ex 9/4). Germany reserves its right to make additional comments on the other substantive provisions once this upstream issue has been clarified sufficiently. This does not imply that Germany accepts the substantive provisions contained in the Annexes of documents WIPO/GRTKF/IC/16/4 and WIPO/GRTKF/IC/16/5 as the only basis for future discussions.

GR

We think that future discussion may well be based on document WIPO/GRTKF/IC/11/8(a), however it should not be the only basis for future work. As stated by the EU on IGC 14, the discussions should be based on the entire work carried out by the Committee, not excluding any particular document or documents. Document WIPO/GRTKF/IC/14/7 contains a comprehensive list of other documents with possible relevance for future discussions. Just to pick one, document WIPO/GRTKF/IC/8/9 (updated by document WIPO/GRTKF/IC/13/8(B)) should also be taken into consideration since it provides general information on the Committee's activities relating to genetic resources and intellectual property (IP).

We consider that the Committee should continue primarily to explore substantive

intellectual property issues concerning the relationship between intellectual property and genetic resources as summarized in the three substantial clusters mentioned in document WIPO/GRTKF/IC/13/8 with the following priority:

- 1) IP issues in mutually agreed terms for the fair and equitable sharing of benefits arising from the use of genetic resources. Our results could certainly enrich the discussions in the other international fora.
- 2) The interface between the patent system and genetic resources, particularly defensive protection;
- 3) IP issues concerning disclosure requirements and alternative proposals for dealing with the relationship between intellectual property and genetic resources.

Best Regards

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SWITZERLAND

Please find below the comments of Switzerland on the draft documents WIPO/GRTKF/IC/16/4 Prov., WIPO/GRTKF/IC/16/5 Prov., and WIPO/GRTKF/IC/16/6 Prov. We apologize for the delay in submitting these comments and any inconveniences this may have caused.

- * Comments on WIPO/GRTKF/IC/16/4 Prov. (TCEs):
- * General comments:
- * As repeatedly stated, Switzerland holds the view that all three substantive issues GR, TK and TCEs should be treated on an equal footing. Accordingly, all three issues should be dealt with at each session of the IGC and be allotted comparable attention and time.
- * We recall our statements at previous IGC sessions on document IC/9/4, in particular the statements made at IGC-15.
- * The renewed mandate refers to document IC/9/4 in its entirety. As we have stated previously, we consider agreement on basic issues such as in particular policy objectives and terminology a prerequisite for successful and meaningful work on substantive provisions. We therefore expect that the IGC will, in addition to Part 3, also discuss Parts 1 and 2 of the Annex to document IC/9/4 in the further course of its negotiations on an international legal instrument or instruments.
- * The renewed mandate states that "[t]he Committee will [...] continue its work and undertake text-based negotiations with the objective of reaching agreement on a text of an international legal instrument (or instruments) which will ensure the effective protection of GRs, TK and TCEs." Switzerland wishes to clarify that the absence of square brackets in the revised document WIPO/GRTKF/IC/16/4 Prov. does not mean that there is consensus in the IGC on any parts of the text, including text not in brackets. Accordingly, the document remains open for discussion in its entirety.
- * With regard to the subheading "Definition of TCEs" (see Annex, p. 14), we suggest to add the following text: "A delegation noted that it considered the establishment of a working definition of "TCEs" to be one of the prerequisites of a substantial discussion. The definition of "TCEs" as contained in Article 1 constituted a good working definition. The IGC could and should revisit this definition during the course of its negotiations to amend or modify the definition if necessary. The delegation highlighted that the definition of "TCEs" should encompass all TCEs, that was, TCEs from developing countries and developed countries."
- * In the context of terminology, we moreover wish to highlight that the IGC should take into account existing relevant international terminology, including the definition of "intangible cultural heritage" of the UNESCO Convention for the Safeguarding of the Intangible Cultural Heritage.
- * With regard to the subheading "Meaning of community" (see Annex, p. 13), we suggest to add the following text: "A delegation suggested that the term "community" should be understood in the same broad and inclusive sense as the term "communities" as described in footnote 23 of the Annex of document IC/9/4."
- * On p. 13, we suggest to include a new subheading "Structure of Article 1" and to add the following text: "One delegation sought to have clarification from the Secretariat

on the structure of Article 1. The delegation asked whether its understanding was correct that all conditions stated in small letters (aa) to (cc) apply to all forms of TCEs described in roman numbers (i) to (iv). If this understanding was correct, the delegation suggested to structure the text accordingly in order to avoid ambiguities. The Secretariat later confirmed the understanding as correct."

- * Comments on WIPO/GRTKF/IC/16/5 Prov. (TK): General comments:
- * As repeatedly stated, Switzerland holds the view that all three substantive issues GR, TK and TCEs should be treated on an equal footing. Accordingly, all three issues should be dealt with at each session of the IGC and be allotted comparable attention and time.
- * We recall our statements at previous IGC sessions on document IC/9/5, in particular the statements made at IGC-15.
- * The renewed mandate refers to document IC/9/5 in its entirety. As we have stated previously, we consider agreement on basic issues such as policy objectives and terminology a prerequisite for successful and meaningful work on substantive provisions. We therefore expect that the IGC will, in addition to Part 3, also discuss Parts 1 and 2 of the Annex to document IC/9/5 in the further course of its negotiations on an international legal instrument or instruments.
- * The renewed mandate states that "[t]he Committee will [...] continue its work and undertake text-based negotiations with the objective of reaching agreement on a text of an international legal instrument (or instruments) which will ensure the effective protection of GRs, TK and TCEs." Switzerland wishes to clarify that the absence of square brackets in the revised document WIPO/GRTKF/IC/16/5 Prov. does not mean that there is consensus in the IGC on any parts of the text, including text not in brackets. Accordingly, the document remains open for discussion in its entirety.
- * Comments on WIPO/GRTKF/IC/16/6 Prov. (Genetic Resources):
- * General comments:
- * As repeatedly stated, Switzerland holds the view that all three substantive issues GR, TK and TCEs should be treated on an equal footing. Accordingly, all three issues should be dealt with at each session of the IGC and be allotted comparable attention and time.
- * We recall our statements at previous IGC sessions on document IC/11/8(a), in particular the statements made at IGC-15.
- * In the context of the "General Commentary on Cluster B" (see Annex 1, pp. 10-13), we recall the proposals on the disclosure of the source of genetic resources and traditional knowledge presented by Switzerland and the several communications it submitted in this regard to WIPO. Apart from footnote 12, however, these proposals and communications are not reflected in this part of the revised document. To more fully reflect these proposals and also to better balance the information given concerning the various proposals and positions expressed in WIPO, we suggest to add the following text:

"In 2003, Switzerland submitted proposals for an amendment of the PCT-Regulations, which would explicitly enable the national legislator to require patent applicants to disclose the source of genetic resources and/or traditional knowledge. The concept of "source" should be understood in its broadest sense possible. This is because according to the relevant international instruments, in particular the CBD, a multitude of entities may be involved in access and benefit sharing. In order for the disclosure requirement to apply, the invention is to be directly based on the genetic resource or traditional knowledge. If patent applicants have no information at hand about the source, they would have to declare that the source is unknown to them or the inventor. In case an international patent application does not contain the required declaration, national law may foresee that in the national phase the application is not processed any further until the required declaration is furnished. If it is discovered after the granting of a patent that the applicant failed to declare the source or submitted false information, this may not be ground for revocation or invalidation of the granted patent; however, other sanctions provided for in national law, including criminal sanctions such as fines, may be imposed. Moreover, Switzerland invited WIPO, in close collaboration with the CBD, to establish an online-list of government agencies competent to receive information about the declaration of source. The office receiving a patent application containing such a declaration would inform the listed government agency about the respective declaration."

Assuming that paragraphs 11 to 15 follow a timeline of events, we suggest to add this text as new para. 13bis, since the first communication by Switzerland to the IGC was submitted in 2004.

- * In paragraph 12 (8th line) we suggest to amend the text as follows: "A Two formal proposals has have already been tabled in the Committee WIPO, one for a mandatory disclosure requirement, the other one explicitly enabling the Contracting Parties of the PCT to introduce such a requirement."
- * On page 14 of the Annex, in Chapter "National experiences on disclosure," we suggest to amend the second paragraph concerning Switzerland as follows: "Switzerland has introduced such a mandatory disclosure requirement concerning genetic resources and traditional knowledge at the national level." Additionally, we suggest including a new footnote at the end of this paragraph referring to the communication Switzerland submitted in February 2010 on its provisions on the disclosure requirement at the national level.



International Seed Federation

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World Intellectual Property Organization Attn: Director General F. Gurry 34 Chemin des Colombettes 1211 Geneva, Switzerland

10 February 2010

Disclosure of Origin or Source of Genetic Resources

Dear Director-General Gurry,

The International Seed Federation (ISF) has participated in the fifteenth session of the WIPO Inter-Governmental Committee (IGC) on Intellectual Property, and Genetic Resources, Traditional Knowledge and Folklore (GRTKF) took place in Geneva from Dec. 7-11 2009.

It is with great interest that we have read the WIPO document GRTKF/IC/11/8/a on Genetic Resources and on behalf of ISF we would like to provide a response to this document and specifically to the issue of Disclosure of Origin or Source of Genetic Resources outlined in § 11 of the document.

ISF believes that a disclosure should only be necessary for those materials where the applicable form of Intellectual Property would prevent further research and breeding with that material.

If <u>origin</u> has the meaning of "country of origin" in the sense of the CBD, the disclosure of origin is extremely difficult as in most cases it is impossible to trace the origin of a biological resource. Moreover, it is also very difficult to determine when and where biological materials, in the form received, have developed these distinctive properties. All nations grow, import and export many food and agricultural crop species whose centres of diversity lie outside their national boundaries, and are thus inherently dependent on multiple and foreign genetic resources for food and agriculture. The historic wide spread use of plant genetic resources for food and agriculture is evident in the ancestry of individual crop varieties.

ISF believes disclosure of <u>source</u> of the genetic resource, i.e. where the material was obtained, would be possible when the source is known. Normally the applicant knows and is allowed to indicate this with possible exceptions:

In the breeding community, one reason why the source could not be known is that
the biological material comes from the breeder's nursery and that there is no
record of the original source;

 Sometimes the biological resource has been received in the frame of a confidential contract and the disclosure of the origin would be a breach of that contract.

If the applicant does not know the "source" of the material, or is not allowed to disclose it by contractual agreement, he/she may reasonably be asked to explain why not.

The disclosure of the "source", in the meaning as summarized in the following paragraph, should be an administrative requirement only and thus, the failure to disclose, except in the case of proved fraudulent intention, could not invalidate the title of protection. Therefore the disclosure of origin should never be a criterion for patentability as it is in conflict with paragraph 1 of Art. 27 of the TRIPs agreement, and other international patent treaties.

In summary, ISF could accept the disclosure of the "source" of the biological material, in the sense of where the material has been obtained from, when it is known, and if it is not a breach of a contract.

ISF members are supportive of a central Clearinghouse Mechanism and mutual recognition of information. And last but not least, ISF members also strongly feel that the discussions and decisions on disclosure should be made within a WIPO and TRIPS context and not within any other organisation, such as the CBD.

Yours sincerely

Marcel Bruins Secretary General

CC: Secretariat of the CBD, FAO-IT, UPOV, ICC