CONSIDERATION OF PROPOSALS FOR AMENDMENT OF APPENDICES I AND II

A. Proposal

Inclusion of a new paragraph after paragraph 4 in the Interpretation section of the Appendices, to read as follows (with the following paragraphs being renumbered):

5. The following are not subject to the provisions of the Convention:

   a) *in vitro* cultivated DNA* that does not contain any part of the original from which it is derived;
   b) cells or cell lines** cultivated *in vitro* that theoretically at a molecular level do not contain any part of the original animal or plant from which they are derived;
   c) urine and faeces;
   d) medicines and other pharmaceutical products such as vaccines, including those in development and in process materials +, that theoretically at a molecular level do not contain any part of the original animal or plant from which they are derived; and
   e) fossils.

* That is DNA that is assembled from its constituent materials, not solely extracted directly from plants and animals.

** That is cultures of plant or animal cells, that are maintained and/or propagated in artificial conditions and do not contain any significant part of the original plant or animal from which they are derived.

\+ That is products subject to a research or manufacturing process such as medicines, potential medicines and other pharmaceuticals such as vaccines that are produced under conditions of research, diagnostic laboratory or pharmaceutical production and do not depend for their production in bulk solely on material extracted from plants or animals and do not contain any significant part of the original plant or animal from which they are derived.

B. Proponent

Ireland (on behalf of the Member States of the European Community)

C. Supporting statement

Background

At its 46th meeting (Geneva, 12-15 March 2002), the Standing Committee reviewed document SC46 Doc. 12, containing recommendations of a working group on time sensitive research samples, and agreed that proposals should be prepared for consideration at the 12th meeting of the Conference of the Parties (CoP12) (Santiago, 2002). Annex 1 of that document contained a proposed annotation to the Appendices, which was then finalized and was submitted by the Depositary Government at the request of the Standing Committee.

Unfortunately the proposal submitted by the Depositary Government contained a technical error, in referring to annotation º607, which relates only to corals, although the intention of the proposal was to refer to all species. It was noted that a strict application of the Rules of Procedure prevented the scope of the proposal being extended to cover all species and the Depositary Government therefore withdrew the proposal and stated that a new one would be submitted for consideration at the next meeting.

The representative of the Depositary Government referred the matter to the 49th meeting of the Standing Committee and a revised version was considered at the 50th meeting and referred to CoP13 for approval.

Consideration

Although the Depositary Government's proposal addresses many of the concerns raised, the EU is not satisfied that the language adequately defines the type of specimens covered by the annotation. It also believes that the annotation should be extended to cover synthetically produced cell lines, as these are also widely used by the pharmaceutical industry in the production of vaccines and other medicines.

Having consulted with representatives from the pharmaceutical industry, and taking into account the concerns raised by the World Health Organisation at the last Conference (COP12, Inf 19), regarding the need to ensure timely access by individuals and communities to life saving vaccines and other biological products, the EU remains concerned that the text proposed by the Depositary Government does not reflect the terminology currently in use within the industry. It fears that there may be scope for misinterpretation or misunderstanding as to the nature and extent of the derogation. There are also concerns that immunisations programmes worldwide may be put at risk if vaccines have to be made subject to the CITES permitting process. We therefore believe that the annotation should be amended to define terms such as in vitro DNA and pharmaceutical products. We also believe that it should be made clear that the term pharmaceutical products applies only to those in development and in process materials and that are subject to a research or manufacturing process, produced under conditions of research, diagnostic laboratory or pharmaceutical production.

Although no one has actually managed to detect the presence of original genetic material in vaccines or other pharmaceutical products it is not technically feasible to guarantee that small amounts of such material are not present. It is for this reason that we would prefer to refer to specimens that theoretically at a molecular level do not contain any part of the original animal or plant genetic material from which they are derived. These proposed changes also make it clear that the annotation only applies to specimens derived from a manufacturing process and will not utilise original genetic material.

The draft annotation has been carefully worded to ensure that products derived from original genetic material are not included in the derogation. This should help to reassure those Party States who fear that an annotation of this kind would undermine their efforts to protect their intellectual property rights in genetic material derived from native species.

Finally it should be noted that millions of vaccines and tens of thousands of cultivated cell lines are traded worldwide every year. Cell lines are widely used in medical research and health protection programmes. They are also widely used as an alternative to using live animals in medical experiments. Issuing permits for these specimens would not only add greatly to existing workloads, it would also place an unnecessary financial burden on the pharmaceutical industry thereby putting vital medical research at risk. There is no conservation benefit to be gained from controlling these specimens and these products should therefore exempt from the CITES controls.