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**Committee on Trade and Environment** 

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#### **REVIEW OF ARTICLE 27.3(b)**

### Communication from Brazil

This document was circulated by Brazil in the TRIPS Council as document IP/C/W/228 (24 November 2000). Brazil has requested that it also be circulated in the CTE.

- 1. At the TRIPS Council meeting held on 21 March 2000, the Chair set out a list of issues to structure discussions on the review of Article 27.3(b) of the TRIPS Agreement. The list of issues is the following:
  - The link between the provisions of Article 27.3(b) and development;
  - Technical issues relating to patent protection under Article 27.3(b);
  - Technical issues relating to *sui generis* protection of plant varieties;
  - Ethical issues relating to patentability of life forms;
  - The relationship to the conservation and sustainable use of genetic material; and
  - The relationship with the concepts of traditional knowledge and farmers' rights.
- 2. We consider that the establishment of a list of issues is most important as a means of facilitating the discussions and moving forward the review of Article 27.3(b) of the TRIPS Agreement. Such a list should not be exhaustive and should be without prejudice to the position of individual countries on those issues.
- 3. Brazil would like to refer to the issues of the checklist, taking into account the discussions undertaken so far at the TRIPS Council as well as possible elements for future discussion. This document is a first contribution of Brazil to the review of Article 27.3(b). Taking into account the developments in the exercise of review, we may bring further clarifications and complements to the issues contained in this document.

### I. THE LINK BETWEEN THE PROVISIONS OF ARTICLE 27.3(b) AND DEVELOPMENT

4. The first item of that checklist ("The links between the provisions of Article 27.3(b) and development") relates to cross-cutting issues that will be elaborated in more detail in the further items and future discussion. The generic nature of this item should serve to ensure that the progress in the review takes into account the needs of developing countries, having in mind the decision by the

General Council in February 2000 that the mandated reviews, including those of the TRIPS Agreement, give due consideration to the impact on development. A good basis for discussion on this topic has already been provided by the African Group (IPC/C/W/206) and by India<sup>1</sup>.

## II. TECHNICAL ISSUES RELATING TO PATENT PROTECTION UNDER ARTICLE 27.3(b)

- 5. Brazilian legislation excludes from patentability all or part of plants and animals, except transgenic micro-organisms that satisfy the three requirements of patentability novelty, inventive step and industrial application and which are not mere discoveries. The same provision establishes that "for the purposes of this Law, transgenic microorganisms are organisms, except for all or part of plants or animals, that express, by means of direct human intervention in their genetic composition, a characteristic normally not attainable by the species under natural conditions".<sup>2</sup>
- 6. Brazil considers that the review of Article 27.3(b) should preserve Members' flexibility to exclude plants and animals from patentability. Such a review, however, demands clarification on the scope of the exceptions set out in that Article.
- 7. As suggested by other Members, we are open to consider a definition of the term "microorganisms", as well as "essentially biological" and "non-biological and micro-biological". Such definition would be useful to ensure a clear distinction between plants and animals exempted from patentability in the TRIPS Agreement. It has been suggested that Article 27.3(b) establishes an artificial distinction between plants and animals, on the one hand, and microorganisms, on the other. In document IP/C/W/209, the United States considers that a quotation from an English dictionary would be sufficient to provide a definition of the term "microorganism". We consider that a more precise and scientific definition is required not merely for the sake of establishing "what name is given the biological material on which the invention is based", as suggested by the United States, but for the purposes of providing a clear definition of the scope of exceptions to patentability set out in Article 27.3(b).
- 8. The US paper also affirms that "the key to what should be patentable as a microorganism is (...) the subject matter claimed; is that subject matter new, does it involve an inventive step, and is it capable of industrial application" and that "to be patentable, a microorganism cannot be as it exists in nature". Nevertheless, there is evidence that patent offices in some developed countries do not necessarily follow such a policy and they tend to accept overly broad claims on genetic resources that could lead to the grant of patents with a broad scope. In such cases, for instance, the process of isolation of a naturally occurring microorganism can often be accepted as a fulfilment of the three conditions established in Article 27.1 to grant patents over them. However costly it may be today to isolate a microorganism, in many instances it may correspond better to a mere discovery than an invention. Furthermore, it is unclear that some patents claimed over microorganisms, for instance, adequately fulfill the requirement of industrial application, as the usefulness of the "invention" is often unclear even to the patent applicant.
- 9. Such "broad patents" over microorganisms pose a series of other problems. Loose criteria to establish novelty, inventive step and industrial application undermine the patent system as a whole, since they yield legal uncertainty. Furthermore, while some countries argue that patents on microorganisms are an important element to encourage research in biotechnology, too broad patents may actually restrict research, as the patent holder has the exclusive rights to exploit the genetic

<sup>2</sup> Law n° 9,279 of May 14, 1996, Article 18, II.

<sup>&</sup>lt;sup>1</sup> Non-paper JOB(00)/6091.

<sup>&</sup>lt;sup>3</sup> The Concise Oxford English Dictionary: "an organism not visible to the naked eye, e.g., bacterium or virus".

material. Research institutions, for instance, would have to pay licensing fees to work on the genetic material, thus limiting the access to it. Finally, but not less important, broad patents over genetic material from another country may result in conflicts between the TRIPS Agreement and the Convention on Biological Diversity (this element is elaborated below in more detail under items V and VI).

10. Consequently, as part of the review of Article 27.3(b), we consider that discussions on definitions and on criteria to clarify the scope of the term "microorganism" would be relevant to ensure greater legal certainty in the application of the TRIPS Agreement as the use of those terms is different, according to whether they are used in scientific, legal or market contexts.

### III. TECHNICAL ISSUES RELATING TO SUI GENERIS PROTECTION OF PLANT VARIETIES

- 11. Brazil considers that the review of Article 27.3(b) should preserve Members' flexibility to decide on the most effective means of *sui generis* system for protection of plant varieties. Brazil established a Law on the Protection of New Varieties of Plants in 1997 and has recently adhered to the 1978 Act of the Convention on the Protection of New Varieties of Plants (UPOV 1978). The *sui generis* protection resulted in an effective protection of new plant varieties that have been developed in Brazil. Although we are of the opinion that the UPOV system could be considered as a reference under the review of Article 27.3(b), it does not follow that this system should be considered as the only one to fulfill the criterion of effectiveness set out in Article 27.3(b).
- 12. While membership in the 1991 Act of UPOV is increasing, it is a well-known fact that a large number of developing countries are resisting this instrument on account of its less flexible elements than the previous Act. Such inflexibility could result in conflicts with governments' public policy objectives. One of the main points of concern is related to farmers' rights: UPOV 1978 allows farmers' traditional practice of saving, exchanging, and to a limited degree selling seeds of protected varieties. UPOV 1991 turns these actions into privileges and exceptions, at the discretion of governments' decision on whether or not to permit farmers to save seed for use on their own holdings. The food security of local communities in most developing countries depends largely on their saving, sharing and replanting seeds from the previous harvest. These communities may constitute a large part of the population in developing countries and are basically rural. Consequently, for many of those countries, the possibility of requiring the payment of fees for the purpose of saving seeds for replanting, as permitted in UPOV 1991, would affect negatively small rural producers and result in social imbalances. On the other hand, UPOV 1991 limits exhaustion of rights to sales or otherwise marketing made within the national territory of the Contracting Party concerned, which might disturb the negotiated balance of Article 6 of the TRIPS Agreement.
- 13. Other international instruments are also relevant as references in the review of the issue of plant variety protection. The International Undertaking (IU) of the Food and Agriculture Organization (FAO) is an important reference to ensure that *sui generis* systems for plant variety protection take into account international commitments on farmers' rights. In light of the fact that the FAO International Undertaking is to become a legally binding instrument, consistency between the TRIPS Agreement and the IU is particularly important. The Convention on Biological Diversity is another important reference, as it also relates to the biological materials contained in seeds and establishes the principles of benefit sharing and prior informed consent. Currently, the FAO International Undertaking is being reviewed in order to bring it into harmony with the CBD. We understand that the review of Article 27.3(b) should be part of the international effort to establish a coherent and harmonious relationship among those instruments.

#### IV. ETHICAL ISSUES RELATING TO PATENTABILITY OF LIFE FORMS

- 14. Brazil considers that ethical, cultural and religious concerns relating to patentability of life forms are an important element to ensure that public interest is adequately reflected in the context of the review of Article 27.3(b). This element would be consonant with the Principles of the TRIPS Agreement set out in Article 8.1. The issue also relates to Article 27.2, which allows for exclusion of patentability of "inventions, within their territory of the commercial exploitation of which is necessary to protect ordre public or morality (...)".
- 15. Ethical, cultural and religious beliefs concerning patents on life forms vary among countries and often even *within* a country and therefore should be taken into account in the review process. Property rights over life forms are accepted in most cultures or religions, through private ownership of individual animals and plants such as cattle, domestic animals, crops etc. Patents over life forms, including microorganisms, however, do not limit control over individual living beings, but over the whole group of specimen, which may be considered morally wrong for some cultures.
- 16. Some developed country Members have argued in previous meetings that moral and ethical consequences of inventions are better dealt with directly that is, by inhibiting the development of the technologies themselves instead of creating obstacles to their patentability. A great number of developed country Members emphasize that intellectual property rights aim at encouraging research and development of new technologies. Whenever a Member considers that some specific technologies related to patents on technology are contrary to ethical, cultural or religious standards, Article 27.3(b) should consider the possibility of providing flexibility for Members to limit or to deny intellectual property rights over such technologies, in order to prevent that their development is encouraged.
- 17. Finally, this item is also related to issues discussed under other items of the checklist, such as biopiracy, protection of traditional knowledge and farmers' rights. Future discussions on this item could also take into account health, human rights and agricultural concerns. We may bring future contributions in this respect in the review process.

# V. THE RELATIONSHIP TO THE CONSERVATION AND SUSTAINABLE USE OF GENETIC MATERIAL

- 18. Brazil attaches particular importance to this item, which enshrines several issues concerning the relationship between the Convention on Biological Diversity and the TRIPS Agreement that demand clarification by the Council for TRIPS. Clarification on the relationship of both agreements will be one of the key elements of the review of Article 27.3(b).
- 19. Article 15.1 ("Access to Genetic Resources") of the Convention on Biological Diversity states that "Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation". Further, Article 16.5 ("Access and Transfer of Technology") of the Convention also establishes that "The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives" (emphasis added).
- 20. We believe that such provisions, along with other relevant provisions of the CBD (such as Article 8(j), which will be discussed in more detail in item VI), are closely connected to the scope of the TRIPS Agreement in general and to the review of Article 27.3(b) of the Agreement in particular.

- Brazil considers that TRIPS and the CBD should be mutually supportive and promote the sustainable use of resources. At the implementation level, however, conflicts could arise, for instance, in the case of patents claimed over naturally-occurring genetic resources, which are protected by the CBD. Some examples are already well known to the general public: in its paper on "Protection of Biodiversity and Traditional Knowledge" (IP/C/W/198), for instance, India reports its experience with cases of patents claimed over turmeric, karela, basmati and the neem tree; another example is the case of the avahuasca vine (a native plant of the Amazonian rainforest used by thousands of indigenous peoples of the Amazon for sacred religious and healing ceremonies). Broad patents over microorganisms, plants and animals may result in monopoly rights for the exploitation of the patent's subject matter, thus restricting exploitation of such resources. Additionally, patents over a Member's genetic resource, but granted outside its territory raises the issue of potential conflict with the principle of the sovereignty of the Contracting Parties of the CBD over their own genetic resources. Such patents claimed over genetic resources are generally obtained without the prior informed consent of the government or of the traditional community that holds the knowledge on that material. Moreover, no fair and equitable benefit sharing from the exploitation of the subject matter is established by the right holder of the patent.
- 22. In the absence of clear standards defining the scope of patentability of micro-organism (as discussed above) and a framework in TRIPS that clarifies the relationship of that Agreement with Members' obligations under the CBD, implementation of the TRIPS Agreement may result in conflicts with the Convention. With a view to avoiding conflicts in the implementation of both instruments and what is more, to ensure a mutually supportive relationship Brazil considers that amending Article 27.3(b) of the TRIPS Agreement to accommodate principles of the CBD will be a necessary outcome of the review of that Article. Failure to clarify this relationship may turn out to be detrimental to both instruments.
- 23. In order to explore a mutually beneficial relationship, one important step would be to ensure that patenting of genetic resources plants, animals or microorganisms does not run counter to the basic principles of the CBD. Some of those principles are the sovereignty of the Contracting Parties of the CBD over their genetic resources; the principle of benefit sharing; and the principle of prior informed consent. The CBD also has the objective of ensuring protection, at the national level, of traditional knowledge. Today, several countries have to tackle the problem of unauthorized bioprospection and patenting of genetic resources over which, according to Article 15.1 of the CBD, they have sovereign rights. Several countries today are putting in place legislation to regulate access to genetic resources<sup>4</sup>, many of which may contain intellectual property-related provisions, in line with Article 16 of that Convention. In Brazil, for instance, in June 2000, legislation entered in force to regulate the access to genetic resources, protection and access to associated traditional knowledge, sharing of benefits and access to and transfer of technology for its conservation and use, among other provisions.
- 24. We fully agree with the arguments expressed by India in its paper (IP/C/W/198) that it would be less cost-effective to establish an internationally accepted solution to prevent biopiracy than to divert national resources to expensive judicial processes for the revocation of patents that include illegal genetic resources. Developing countries do not have the resources to follow each and every patent issued outside their territories on the use of their resources.
- 25. In this connection, Brazil considers that Article 27.3(b) should be amended in order to include the possibility of Members requiring, whenever appropriate, as a condition to patentability: (a) the identification of the source of the genetic material; (b) the related traditional knowledge used to

<sup>&</sup>lt;sup>4</sup> An informal survey by IUCN of 1998 identifies 30 countries considering legislation on access to genetic resources – see Glowka, Lyle: *A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources*. Gland, Switzerland: IUCN.

obtain that material; (c) evidence of fair and equitable benefit sharing; and (d) evidence of prior informed consent from the Government or the traditional community for the exploitation of the subject matter of the patent. An interpretative note to Article 27.3(b) should also be made in order to clarify that discoveries or naturally occurring material shall be excluded from patentability.

- 26. For the sake of legal consistency, such amendments would be necessary to ensure compatibility between the TRIPS Agreement and the Convention on Biological Diversity. Several countries already establish the abovementioned requirements in their national legislation as a means of implementing the CBD.
- 27. Concerning similar suggestions made in other fora, the United States has mentioned in its document that requirements to identify the source of the genetic resource in the patent application would be "a legal and administrative nightmare". We are of the view that such concern is exaggerated and unjustified. Fulfilling such requirements, besides addressing a crucial problem of coherence between two binding international agreements, would not be any more burdensome than any other regular requirement in the already existing patent application procedures. Furthermore, evidence of the legitimacy of the access to biological resources and/or to associated traditional knowledge should be imposed only where the Administration has reasonable grounds to suspect that national legislation on the protection of biodiversity has been violated by the patent applicant. This element would restrict the application of the requirement to a few patent applications and would represent a mechanism of biodiversity law enforcement. The burden, therefore, would not normally be imposed on law-compliant companies and individuals. The US also questions whether such a system would actually ensure benefit sharing from the exploitation of any product or process that might be developed from the resource or knowledge. In this respect, Brazil is of the view that once Article 27.3(b) is amended as proposed in paragraph 25, the TRIPS Agreement itself would provide the adequate enforcement of such requirements through its dispute settlement mechanism.
- 28. The proposed amendment would have the clear benefit of providing a predictable environment for Governments, investors, traditional communities and researchers. As a consequence, research and development in biotechnology in developing countries would be encouraged, which would be in line with the objectives of the TRIPS Agreement to promote technological innovation and the transfer and dissemination of technology.

## VI. THE RELATIONSHIP WITH THE CONCEPTS OF TRADITIONAL KNOWLEDGE AND FARMERS' RIGHTS

- 29. Discussions among Members under the review of Article 27.3(b) have already demonstrated that traditional knowledge may bring significant benefits for several industrial sectors, in particular the pharmaceutical and agricultural sectors. It is a well-known fact that traditional knowledge may bring significant contributions for several industrial sectors. Particularly in the pharmaceutical sector, for instance, traditional knowledge may play a key role in the pre-scanning phase to identify the active substances of medicines. If such active substances were to be developed synthetically, it would take years and large amounts of investment in research and development in laboratories.
- 30. Article 8(j) of the Convention on Biological Diversity establishes that "each Contracting Party shall, as far as possible and as appropriate, (...) subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices."

- 31. The issue of protection of traditional knowledge is addressed under the review of Article 27.3(b) based on several issues: (a) prevention of unauthorized patenting of traditional knowledge; (b) *sui generis* frameworks for the protection of traditional knowledge; and (c) documentation of traditional knowledge. Below are our views on these issues:
- (a) Preventing unauthorized patenting of plants, animals and microorganisms related to traditional knowledge
- 32. This issue is closely related to item V ("The relationship to the conservation and sustainable use of genetic material"), as it addresses the relationship between the TRIPS Agreement and the Convention on Biological Diversity. We consider that the TRIPS Agreement does not ensure that Members may prevent patents claimed without due regard to the provisions set out at the Convention on Biological Diversity, in particular the requirements of benefit sharing and prior informed consent set out in Article 8(j) of the CBD.
- 33. In this context, an amendment to Article 27.3(b) of the TRIPS Agreement, as suggested in paragraph 25, would be a necessary step to prevent biopiracy of genetic resources related to the use of traditional knowledge. As noted among the "Recommendations at the Multilateral Level" of the Expert Meeting on Systems and National Experiences for Protecting Traditional Knowledge, Innovations and Practices, held in UNCTAD from 30 October to 1 November, 2000, "exclusion from patentability of TK [traditional knowledge]-based products in one country, for instance, would not exclude others from granting it a patent"<sup>5</sup>.
- (b) Framework for the protection of traditional knowledge
- Some developed country Members have argued at the TRIPS Council that the status quo already provides for different means of protecting traditional knowledge. Today, for instance, companies can establish inter partes contracts with traditional or indigenous communities. In the absence of any other legal framework to protect such knowledge, we recognize that bilateral contracts can be a possible means of ensuring the prior consent of traditional communities and benefit sharing of their use. Such contractual modalities of protection, however, are not sufficient to protect traditional knowledge, as they are not easily enforceable and are subject to the direct negotiations between the parties involved. Consequently there is no way to ensure that the prior consent obtained from these communities will actually be an informed one. There is no way to ensure, either, that the benefit sharing between a company and a community will actually be fair and equitable. In market, free-enterprise economies, only a proprietary protection of traditional knowledge, even a sui generis one, will ensure that market forces will operate to generate fairness and equity. In addition, a contractual approach, unlike a proprietary one, does not provide protection erga omnes, in the sense that if the knowledge is by some way publicly disclosed, there would be no mechanisms available to prevent their use by innocent third parties. As a matter of course, to oblige the guilty party to compensate the community for damages would not enable the latter to compensate it. In conclusion, a contractual approach is clearly insufficient and could protect only some residual aspects of traditional knowledge transfer. Similar problems arise with other schemes, such as voluntary guidelines to be followed by bioprospecting companies; however constructive the intent to establish such guidelines might be, they may end up being ineffective due to their voluntary nature.
- 35. Brazil notes that nothing in the TRIPS Agreement prevents Members from protecting traditional knowledge at the national level, in accordance with Article 8(j) of the Convention on Biological Diversity. To a limited extent, even the existing legal framework of intellectual property

<sup>&</sup>lt;sup>5</sup> Expert Meeting on Systems and National Experiences for Protecting Traditional Knowledge, Innovations and Practices: *Outcome of the Expert Meeting*, held in UNCTAD from 30 October to 1 November 2000.

rights could provide some protection to traditional knowledge. However useful it may be to explore such options, they are generally considered to be insufficient to provide adequate protection to traditional knowledge.

- 36. Protection provided by the conventional IPR regime is limited by operational factors lack of adequate education, awareness and resources, for example and, most importantly, by conceptual factors, since certain aspects of the knowledge produced in most traditional communities are not necessarily within the scope of the TRIPS Agreement. Traditional knowledge is often held collectively, which makes it difficult to determine its title holders. It may also be intergenerational, which may not fit adequately the requirement of novelty. Dissemination of traditional knowledge is often made orally, which makes it difficult to constitute documented prior art.
- 37. In this respect, we fully endorse the "Recommendations at the Multilateral Level" of the above mentioned UNCTAD Expert Meeting on Systems and National Experiences for Protecting Traditional Knowledge, Innovations and Practices, which established that "National sui generis systems by themselves will not be sufficient to adequately protect TK [traditional knowledge]." (...) "Therefore, there is a need for exploring an international mechanism for protecting TK, which may explore minimum standards of an international sui generis system for TK protection. Traditional, local and indigenous communities should be involved in building an international framework for collective rights."
- 38. We recognize that further discussion is necessary to consider adequate means for the multilateral protection of traditional knowledge. Synergies between other organizations such as the CBD, WIPO, FAO and UNCTAD, for instance are most relevant to build up a better understanding and consider developments of a framework on this issue. In this context, in light of its link with development, Brazil considers that the review of Article 27.3(b) is an appropriate exercise to discuss the possibility of establishing minimum standards of protection for traditional knowledge at the multilateral level.
- 39. Some countries might argue that so far relatively few countries have already established legislation on the issue, which would make it difficult to establish an internationally recognized regime to secure benefits arising out of the use of traditional knowledge. It should be recalled, however, that a large number of WTO Members who negotiated the minimum standards of intellectual property rights set out by the TRIPS Agreement have not yet incorporated such minimum standards at their national levels. Consequently, the absence of protection at the national level did not deter WTO Members from negotiating and establishing one of the most ambitious international treaties on intellectual property rights. Bearing this precedent in mind, we consider that Members should not be discouraged from discussing minimum international standards for the protection of traditional knowledge, whatever the forum in which they might be developed.

#### (c) Documentation of traditional knowledge

- 40. Brazil considers that documentation of traditional knowledge would have the clear benefit of providing documentation for patent offices to determine prior art and check against patent claims that are filed without the consent of the holders of traditional knowledge. It should be noted that different Members such as Switzerland (IP/C/M/25, paragraph 81), India (IP/C/W/198, paragraphs 16 to 23) and the United States (IP/C/W/209, paragraph 3 of item 4) have already agreed on the usefulness of documenting traditional knowledge. In this context, we consider that the TRIPS Council should explore further the means of establishing databases to this end.
- 41. It should go without saying that information that belongs to traditional and indigenous communities should never be disclosed in those databanks without their prior informed consent, in accordance with the Convention on Biological Diversity. The establishment of databases and the

process of documentation should not be burdensome or costly. Further consideration needs to be given, however, to the best ways in which determine the final use of information contained in such databases, in order to avoid that they result in the facilitation of biopiracy.

#### VII. CONCLUSION

- 42. Brazil considers that the review of Article 27.3(b) raises several issues that relate to the clarification of its scope as well as to its relationship with obligations undertaken by Members in other international binding agreements, in particular the Convention on Biological Diversity.
- 43. The link of Article 27.3(b) to development issues merits further discussion in order to ensure that its review takes into account the needs of developing country Members.
- 44. We believe that Article 27.3(b) should preserve Members' flexibility to exclude patentability of plants and animals. Clarification may be necessary, however, to establish a more precise definition on terms such as "micro-organism" in order to determine the scope of patentability of Article 27.3(b).
- 45. Article 27.3(b) should also preserve the flexibility of Members to decide on the most effective *sui generis* systems for plant varieties protection. International instruments, such as UPOV (1978 and 1991), FAO and the CBD, as well as national systems, are references for *sui generis* systems of protection of plant varieties.
- 46. The review of Article 27.3(b) should take into account Members' concerns over ethical issues on patentability of life forms.
- 47. Brazil believes that the TRIPS Agreement and the CBD should be mutually supportive and ensure sustainable use of genetic resources. In order to avoid conflicts in the implementation of both agreements, Brazil proposes to amend Article 27.3(b) to include the requirements of: (a) the identification of the source of the genetic material; (b) the related traditional knowledge used to obtain that material; (c) evidence of fair and equitable benefit sharing; and (d) evidence of prior informed consent from the Government or the indigenous community for the exploitation of the subject matter of the patent.
- 48. We are open to discuss adequate ways of protecting traditional knowledge at the multilateral level. In light of its link with development, the review of Article 27.3(b) is an adequate exercise to discuss the establishment of *sui generis* protection systems. Synergies between the TRIPS Council and other fora, such as the CBD, WIPO, FAO and UNCTAD are necessary and should be furthered in concrete ways.