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Trade Negotiations Committee

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DRAFT DECISION TO ENHANCE MUTUAL SUPPORTIVENESS BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY

Communication from Brazil, China, Colombia, Ecuador, India, Indonesia, Peru, Thailand, the ACP Group, and the African Group

The following communication, dated 15 April 2011, is being circulated at the request of the delegations of Brazil, China, Colombia, Ecuador, India, Indonesia, Kenya (on behalf of the African Group), Mauritius (on behalf of the ACP Group), Peru, and Thailand.

Members,

Bearing in mind the principles, objectives and definitions of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement), of the Convention on Biological Diversity (CBD), and of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol);

Reaffirming that States have sovereign rights over their own biological resources¹;

Stressing the need for the TRIPS Agreement and the CBD to be implemented in a manner which is mutually supportive and does not run counter to their respective objectives²;

Recalling that the fair and equitable sharing of benefits arising from the utilization of genetic resources is one of three core objectives of the CBD³;

Stressing the need to ensure that the utilization of genetic resources and/or associated traditional knowledge must comply with the access and benefit-sharing legislation of the Member providing genetic resources and/or associated traditional knowledge, that is, the country of origin of such resources or a Member that has acquired the genetic resources in accordance with the CBD;

Noting that Article 17 of the Nagoya Protocol establishes that Parties shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources, including designating effective check-points to collect or receive, as appropriate, relevant information regarding the utilization of genetic resources at, *inter alia*, any stage of research, development, innovation, pre-commercialization or commercialization;

¹ Paragraph 4 of the Preamble of the CBD.

² Article 16.5 of the CBD and Article 4 of the Nagoya Protocol dealing with "Relationship with International Agreements and Instruments".

³ Article 1 of the CBD.

Noting the extensive discussions in the Council for TRIPS and under the aegis of the Director-General on the introduction into the TRIPS Agreement of a mandatory requirement for the disclosure of origin of genetic resources and/or associated traditional knowledge used in inventions for which intellectual property rights are applied for;

Recognizing that the disclosure requirement in Article 29 of the TRIPS Agreement is incomplete without the disclosure of origin of genetic resources and/or associated traditional knowledge;

Acknowledging that a legal obligation establishing such a mandatory disclosure requirement in patent applications will contribute to prevent both misappropriation of genetic resources and the grant of erroneous patents and also enhance transparency about the utilization of genetic resources and/or associated traditional knowledge;

Decide to amend the TRIPS Agreement by inserting a new Article as follows:

Article 29bis

Disclosure of Origin of Genetic Resources and/or Associated Traditional Knowledge

1. For the purposes of establishing a mutually supportive relationship between this Agreement and the Convention on Biological Diversity, Members shall have regard to the objectives, definitions and principles of this Agreement, the Convention on Biological Diversity, and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, in particular its provisions on prior informed consent for access and fair and equitable benefit sharing.

2. Where the subject matter of a patent application involves utilization of genetic resources⁴ and/or associated traditional knowledge, Members shall require applicants to disclose: (i) the country providing such resources, that is, the country of origin of such resources or a country that has acquired the genetic resources and/or associated traditional knowledge in accordance with the CBD; and, (ii) the source⁵ in the country providing the genetic resources and/or associated traditional knowledge. Members shall also require that applicants provide a copy of an Internationally Recognized Certificate of Compliance⁶ (IRCC). If an IRCC is not applicable in the providing country, the applicant should provide relevant information regarding compliance with prior informed consent and access and fair and equitable benefit sharing as required by the national legislation of the country providing the genetic resources or a country that has acquired the genetic resources and/or associated traditional knowledge, that is, the country providing the genetic resources and/or associated traditional knowledge in accordance with the CBD.

⁴ As mentioned in Article 2 of the CBD, "Genetic resources" means genetic material of actual or potential value and "Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.

⁵ Including details of whom in the providing country such resources were obtained from.

⁶ Article 17.3 of the Nagoya Protocol states that "An internationally recognized certificate of compliance shall serve as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent". Article 17.4 states the minimum information that shall be contained in the IRCC when such information is not confidential.

3. Members shall publish the information disclosed in accordance with paragraph 2 of this Article jointly with the publication of the application or the grant of patent, whichever is made first.

4. Members shall put in place appropriate, effective and proportionate measures so as to permit effective action against the non-compliance with the obligations set out in paragraph 2 of this Article. Patent applications shall not be processed without completion of the disclosure obligations set out in paragraph 2 of this Article.

5. If it is discovered after the grant of a patent that the applicant failed to disclose the information set out in paragraph 2 of this Article, or submitted false and fraudulent information, or it is demonstrated by the evidence that the access and utilization of genetic resources and/or associated traditional knowledge violated the relevant national legislation of the country providing genetic resources and/or associated traditional knowledge, that is, the country of origin of such resources or a country that has acquired the genetic resources and/or associated traditional knowledge in accordance with the CBD, Members shall impose sanctions, which may include administrative sanctions, criminal sanctions, fines and adequate compensation for damages. Members may take other measures and sanctions, including revocation, against the violation of the obligations set out in paragraph 2.