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CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY SERVING AS THE MEETING OF THE PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY
Second meeting
Montreal, 30 May-3 June 2005
Item 16 of the provisional agenda*

OTHER SCIENTIFIC AND TECHNICAL ISSUES THAT MAY BE NECESSARY FOR THE EFFECTIVE IMPLEMENTATION OF THE PROTOCOL

Compilation of submissions by Gouvernments and organizations pursuant to paragraph 4 of decision BS-I/11 **

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SUBMISSIONS FROM GOVERNMENTS

CANADA

[5 JANUARY 2005]
[SUBMISSION: ENGLISH]

In the period since the Cartagena Protocol was adopted Canada has sought clarity on several issues on which the Protocol is either silent or could lead to alternative interpretations. One such issue is the obligations and rights of transit states that are a Party to the Protocol.

In negotiating the Protocol, much discussion occurred around the rights and obligations of transit states. It is Canada's recollection that whereas many transit states would like to ensure that documentation accompanies shipments in transit through their territory, there was a clear indication that they did not wish to take on obligations for generating documents themselves for such shipments.

This could be of particular importance for a Party acting as a transit state when the transiting shipments originate from a state that is not a Party and as such has no obligations under the Protocol. In our view, this situation should not result in the Party in which LMOs are in transit being considered as a Party of export under the Protocol. Were this to be the case, transit states would have an undue burden to ensure accurate information is provided to meet the Protocol documentation requirements.

Therefore, it is Canada's view that a Party when acting as a transit state should not take on the Party of export obligations and is not required to generate documentation to accompany a shipment that is in transit through its territory

As Canada is an exporter of LMO products, but also acts as a transit state for the international movement of FFP-LMOs, it is important for Canada to have a clear view on the obligations within the Protocol for a transit state. We believe this is an important issue since many Parties will, at least initially, not be exporters of LMOs, but may well act as transit states in the international movement of LMOs. It is our belief that an early MOP decision that clarifies the obligations and rights of transit states, especially regarding the issue of documentation to accompany shipments of LMOs is necessary for the effective implementation of the Protocol.

Article 18 requires that Parties take measures to require specific documentation to accompany transboundary movements of LMOs. The decision from the first Meeting of the Parties refers to the responsibilities of exporters and importers regarding documentation.

Notwithstanding that a country may have requirements under its domestic legislation, Article 6 of the Protocol exempts shipments in transit from advanced informed agreement requirements, which Canada supports. However, the Protocol is silent on the obligations of transit states regarding other Protocol provisions, particularly documentation for shipments intended for food, feed or processing (Article 18.2(a)).

Canada is interested in seeking a clear interpretation of this issue, preferably through a decision at MOP 2. Such a decision could usefully consist of two parts: i) a decision that provides a clear definition of transit and ii) clarification that a Party acting as a transit state does not take the obligations of the Party of export, particularly those relating to Article 18.2(a).

As an example, a definition of transit could be drawn from an existing broadly agreed international agreement such as the definition in GATT Article V(1), which has been in force for over fifty years:

> LMO shipments shall be deemed to be in transit across the territory of a Party when the passage across such territory, with or without trans-shipment, warehousing, breaking of bulk, or change in the mode of transport, is only a portion of a complete journey beginning and terminating beyond the frontier of the Party across whose territory the LMO shipment passes.

As bulk commodities, some of which are LMOs, often transit through territories of Parties and non-Parties (e.g., EU Member States, South Africa, Singapore, Bahamas, Canada) en route to Parties of import, this issue requires greater clarity.

Canada considers it important for the effective implementation of the Protocol that the second Meeting of the Parties agree on a decision to clarify the obligations and rights of transit states, particularly regarding documentation, and to reach agreement on a common and clear definition of what is, and is not, a transit shipment. Canada would recommend that this issue could be appropriately considered under Agenda item 16 of the Second Meeting of the Parties to the Protocol.

LITHUANIA

[14 DECEMBER 2004]
[SUBMISSION: ENGLISH]

The essential scientific and technical issue concerned with risk assessment.
Scientific subjects are following:

Participation in scientific research programmes which could benefit risk assessment;
Cooperation on GMO scientific matters;
Risk assessment of genetically modified higher plants and non-plant GMOs.

Technical capacity building:

Public awareness;
Consumer attitude to GMO and biotechnology;
Information sharing and sub-regional cooperation.

Regulation of Risk Assessment of the GMOs to human health, the environment or agriculture adopted by the Order of the Ministers of Environment, Agriculture, Health and the Director of State Food and Veterinary Service in December 2002, amended in 2004. The order establishes the main principles, methods and performance procedured for the activities related to the risk assessment of GMO and GMP, consisted of GMO, posed to human health and environment. The national order has been approximated according to the requirements of Europe Union (EU) Directive 2001/18/EC decision No. 2002/623/EC.

The order applies to all natural and legal persons, releasing into environment or placing on the market genetically modified organism's or genetically modified product's in the territory of the Republic of Lithuania. There are provisions from the respective annexes of EU Directive 2001/18/EC regarding general principles, steps and methodology of risk assessment. The general principles and criteria for establishing the National GMO Experts Scientific Committee outlined in the annex for the above mentioned order. The Ministry of Environment, the Ministry of Health and State Food and Veterinary Service are responsible for implementation of this order.

The Ministry of Environment, upon receipt of the notification and request for deliberate release into environment or placing on the market GMOs or GMPs, without delay, but no later than 10 days informs and delivers the dossier to the GMO management and GMO Experts Committee requesting them

to submit possible risk assessment posed by GMOs and GMPs to human health and environment and preliminary findings.

SLOVENIA [4 JANUARY 2005]
[SUBMISSION: FRENCH]

Slovenia is participating in EU wide effort to fulfil this point.

SWITZERLAND [23 DECEMBER 2004]
[SUBMISSION: FRENCH]

b-1 Procédure concernant le mouvement transfrontière des organismes vivants modifiés qui sont des produits pharmaceutiques à usage vétérinaire qui ne sont pas destinés à être introduits intentionnellement dans l'environnement

Le Protocole de Cartagena ne contient aucune référence spécifique aux mouvements transfrontières des organismes vivants modifiés qui sont des produits pharmaceutiques à usage vétérinaire qui ne sont pas destinés à être introduits intentionnellement dans l'environnement:

- Ils ne sont pas exclus du champ d'application du Protocole comme les mouvements transfrontières des organismes vivants modifiés qui sont des produits pharmaceutiques à usage humain qui relèvent d'autres organisations ou accords internationaux pertinents et,
- A l'opposé des organismes vivants destinés à être utilisés directement pour l'alimentation humaine ou animale, ou à être transformés, ils ne sont pas exclus spécifiquement de la procédure d'accord préalable en connaissance de cause (voir article 7 paragraphe 2) quand bien même ils ne sont pas destinés à être introduits intentionnellement dans l'environnement.

Le manque de clarté concernant le statut des organismes vivants modifiés qui sont des produits pharmaceutiques à usage vétérinaire qui ne sont pas destinés à être introduits intentionnellement dans l'environnement pose des difficultés lors de la mise en œuvre du Protocole de Cartagena au niveau national. Cela peut avoir en effet des implications importantes sur les obligations de la Partie exportatrice en matière de mise à disposition d'information et sur les exigences en matière d'information dans la documentation accompagnant le mouvement transfrontière.

La Suisse demande dès lors que la Conférence des Parties siégeant en tant que Réunion des Parties au Protocole clarifie dans une décision le statut du mouvement transfrontière des organismes vivants modifiés qui sont des médicaments vétérinaires qui ne sont pas destinés à être introduits intentionnellement dans l'environnement et précise les informations devant figurer dans la documentation d'accompagnement

b-2 Responsabilité des états de transit en ce qui concerne la documentation accompagnant le mouvement transfrontière des organismes vivants modifiés

Lors de la 1ère Conférence des Parties siégeant en tant que Réunion des Parties au Protocole, un certain nombre d'états avaient soulevé la question de la responsabilité des états de transit en ce qui concerne les exigences en matière de documentation accompagnant le mouvement transfrontière des organismes vivants modifiés (article 18 paragraphe 2 du Protocole) et demandé une clarification à ce sujet de la part de la Conférence des Parties siégeant en tant que Réunion des Parties au Protocole. La

Suisse soutient le traitement de cette question, propre à faciliter la ratification et la mise en œuvre du Protocole par un certain nombre d'états, par la 2ème Conférence des Parties siégeant en tant que Réunion des Parties au Protocole.

UNITED STATES OF AMERICA (USA) [21 JANUARY 2005]
[SUBMISSION: ENGLISH]

Based on the expectation that other scientific and technical issues may need to be addressed as a matter of priority for the effective implementation of the Protocol, and in particular, in preparation for the 30 May – 3 June 2005 second Meeting of the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP/MOP-2), the following issues are likely to arise in this regard and we offer the following views.

Testing and Detection

At present, there are no internationally recognized sampling and testing methodologies for LMOs. Furthermore, no global consensus exists as to whether such standardized methodologies can or should be established as a means of enforcing biosafety systems as these systems vary from country to country. Additionally, LMO sampling and detection entail an economic cost that must be taken into account. In this regard, countries considering implementation of a testing regime should consider the following basic points:

1) Testing should be done with a clear objective for biosafety; and
2) The costs of testing should factor into a cost-benefit analysis (i.e. more costly methodologies do not necessarily reduce risk).
3) Testing should be science-based and transparent;
4) Testing should be reliable and validated.

Even with identical testing protocols, repeated sampling and testing of the same cargo could and often does produce different results. Sampling variance and normal testing variables contribute to such differences. The potential impact on trade from varying or opaque standards could be significant.

Biosafety Thresholds and Adventitious Presence

The term "adventitious presence" has several different meanings depending on context. At such time as the COP/MOP considers this issue, it is imperative that the COP/MOP agree on a clear definition of and context for the term "adventitious presence". The United States believes that the only relevant definition for this term within the context of the scope and objectives of the Cartagena Protocol is the "unintentional presence of approved LMOs in a non-LMO shipment". This definition then makes possible an informed discussion of how to determine what constitutes a non-LMO shipment for the purposes of meeting the documentation requirements under Article 18.

Given the realities of the global bulk grain production, handling and transportation systems that freely commingle commodities with similar qualities, and the ever increasing global acreage planted to bioengineered crop varieties, it is unrealistic to speak of a "zero threshold" for approved LMOs in a non-LMO commodity shipment. The bulk commodity systems simply cannot guarantee that non-LMO shipments will not contain small amounts of other materials, including approved LMOs. Therefore, the

COP/MOP must focus on a determination of what is a realistic and practical level for determining whether a shipment is considered non-LMO or is subject to Article 18 documentation requirements.

It was clear from the Bonn Workshop that there is a wide divergence of views about the appropriate "purity level" necessary for a shipment to be considered non-LMO and how that definition might be derived. Unsupportable low levels are impractical and costly from an economic perspective, as demonstrated by some recent studies, and the COP/MOP should consider carefully the burden that such low levels would impose.

Finally, the COP/MOP should bear in mind that the "may contain" language in Article 18 is intended to inform authorities in the country of import, but is not intended to be the basis of regulatory decisions on the importation of specific products. Therefore, a reasonable and practical definition will serve to meet the objectives of the Protocol and to permit the global grain trade (and delivery of food aid) to flow.

SUBMISSIONS FROM ORGANIZATIONS

GLOBAL INDUSTRY COALITION (GIC)

[21 DECEMBER 2004]
[SUBMISSION: ENGLISH]

Pursuant to the request in Paragraph 5 of Decision MOP BS-I/11, the following provides the views and comments of the users and developers of biotechnology concerning the other scientific and technical issues that may need to be addressed as a matter of priority in order to formulate common approaches towards these issues and to promote the effective implementation of the Protocol.

1. *Inclusion of Information on Biosafety Research in the Protocol Process*

As more governments develop regulatory systems and engage in science-based risk assessments following entry into force of the Protocol, they will require not only information about the regulatory status of LMOs and risk assessment undertaken by other governments but also *concrete and reliable information about biosafety research.* Awareness of the nature and results of the extensive and growing body of biosafety research through facilitated information exchange will be critical to build the capacities necessary for the effective implementation of the Protocol. These include the following key capacity building elements identified in the Action Plan for Building Capacities for the Effective Implementation of Protocol:

- *Legislative and Policy Frameworks*: Knowledge of the results of biosafety research conducted to date and ongoing efforts in this regard are fundamental to formulating sound, science-based policies and regulatory systems.
- *Monitoring and Assessment Mechanism*: Effective and efficient risk assessment and establishment of appropriate monitoring requirements can only be accomplished when those responsible for such activities are well informed about the results of state-of the-art biosafety research and the extensive experience with LMOs that has accrued around the world to date. As reflected in paragraph 5 of Annex III of the Protocol, this includes scientific evidence about the nature, characteristics and risks of LMOs as well as the consideration of these risks "in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment."
- *Human Resources Development and Training and Scientific, Technical and Institutional Collaboration*: Building human capacity in biosafety as well as ensuring scientific collaboration includes the need to ensure awareness of and access to results and, ultimately, involvement in ongoing biosafety research. Ensuring that capacity building includes undertakings related to information sharing and collaboration in the field of biosafety research also will facilitate the transfer of technology and know-how to countries desiring it.
- *Information Exchange and Data Management*: For all of the foregoing reasons, it is important to ensure that biosafety research is among the information shared by the international community.

2. *Coordination of Biosafety Research Information Exchange*

The omission of biosafety research information exchange as a basis for capacity building also is reflected in the Coordination Mechanism for the Action Plan in which "lessons learned" focuses exclusively on what can be learned from capacity building exercises such as workshops on regulatory systems, not what can be learned through sharing technical knowledge. This is another issue that should be addressed as a priority in order to promote the effective implementation of the Protocol.

While the Secretariat need only play a procedural role with respect to the posting of information on the BCH by countries concerning their regulatory frameworks, decisions and other information required by the Protocol, an effective information exchange mechanism for biosafety research results would require a well-managed quality control mechanism. Several options exist for such a mechanism, whether it is created as part of the BCH or is accomplished through a link from the BCH to another appropriate site. One approach could be to establish an editorial board of reputed scientists to ensure scientific integrity of posted results and exchanges of views. Ideally, the BCH space devoted to biosafety research would allow for scientific experts to submit not only results of research but scientific view points as is done, for example, in the correspondence pages of publications by Nature and Science. The PRELEX system of the European Commission also provides a good model for establishing an issue-based system that allows for new information and exchange of views.

3. *Consideration of Biotechnology Development Activities in the Public Research Sector*

The Protocol implementation process must take into account biotechnology development activities funded by the international community to support the activities of public research institutions such as the International Agricultural Research Centres, the national research institutions of developing countries and academic research centres in general. Currently there is no forum to communicate the work being conducted by such institutes to the Parties to the Protocol so that Parties may consider the scientific input of those developing biotechnology products that address the needs of their countries and regions. Efforts should be made to include those conducting public goods research in the implementation process to ensure that these public research institutions are able to carry out their mandate consistent with the new constraints being developed under the Protocol.
