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Item 13 of the provisional agenda*

SUBSIDIARY BODIES (ARTICLE 30)

"Compilation of views submitted by Parties and other Governments on the need for subsidiary bodies to address scientific issues including risk assessment and risk management" **

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* UNEP/CBD/BS/COP-MOP/2/1

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SUBMISSIONS FROM PARTIES AND OTHER GOVERNMENTS

ARGENTINA [13 SEPTEMBER 2005]
[SUBMISSION: SPANISH]

Con respecto a la solicitud de opiniones a las Partes y otros gobiernos contenida en la Decisión BS-II/14 sobre la necesidad de establecer un órganos subsidiario permanente que provea asesoramiento científico y técnico a la Conferencia de las Partes sirviendo como Reunión de las Partes del Protocolo, incluyendo evaluación y gestión de riesgos, la República Argentina desea manifestar su opinión al respecto.

La Argentina considera que no es necesaria la designación de un cuerpo subsidiario permanente que deba ocuparse de asuntos relacionados con la evaluación y la gestión de riesgos. Esto se debe a que:

(I) no se considera necesaria ninguna acción destinada a extender la orientación ya existente en el texto del Protocolo, en particular, el procedimiento científico establecido en el Anexo III, referido a la evaluación de riesgos para determinar los posibles efectos adversos de los OVM en la conservación y uitilización sustentable de la diversidad biológica en el medio receptor. Dado que el Protocolo requiere que las Partes también tengan en cuenta los riesgos de los OVM para la salud humana, la Argentina considera que los riesgos relacionados con el consumo directo de OVM (inocuidad alimentaria) ya son objeto de tratamiento por los países en otros ámbitos, principalmente en el Codex Alimentarius, por lo cual no estima conveniente reiterar su consideración en el contexto del Protocolo de Cartagena.

(II) se considera que cada país debe crear su propio cuerpo científico abocado a la evaluación y gestión de riesgos. De conformidad con el artículo 22, el Protocolo puede contribuir a la creación de capacidades en los países en desarrollo.

CANADA [15 SEPTEMBER 2005]
[SUBMISSION: ENGLISH]

As per decision MOP BS-II/14 (3), Canada submits the following views regarding the need to designate or establish a permanent subsidiary body to provide the COP-MOP with timely advice on scientific and technical issues arising in relation to the implementation of the Protocol including risk assessment and risk management.

It is Canada's view that there is no need for the establishment of a subsidiary body to provide advice on scientific and technical issues regarding the Protocol, as there are already a number of existing organizations which are examining such scientific and technical issues relevant to LMOs (e.g. FAO, WHO, UNEP, IPPC, OECD). The work of these organizations could be taken advantage of, in order to avoid duplication of work.

In addition, Canada is not convinced that a standing subsidiary body would be a cost-effective alternative to the current practice of designating more specific working groups.

EUROPEAN COMMUNITY AND ITS MEMBER STATES

[9 SEPTEMBER 2005]
[SUBMISSION: ENGLISH]

EU Submission regarding the need to designate or establish a permanent subsidiary body to provide the Conference of the Parties serving as the meeting of the Parties to the Protocol with timely advice on scientific and technical issues arising in relation to the implementation of the Protocol including risk assessment and risk management, and also views regarding the nature of any such body should it be established and particular issues that it could address, such as issues related to paragraph 5 of Article 16, for inclusion in a synthesis report to be considered by the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol

The EU does not at this point see a need for the establishment of a subsidiary body, and though there may be a case for the establishment of such a subsidiary body in the future, currently the EU believes that the case has yet to be made. We feel that it is better to focus on specific issues, and to set up ad hoc time-limited bodies with a precise remit to address scientific and technical issues arising from the Protocol. This then gives a better chance of drawing up focused agendas and achieving specific outcomes. The EU is happy however to consider the views on this issue of other Parties submitted to the Executive Secretary in advance of COPMOP/3. The EU also suggests that COPMOP/3 take into account the experiences gained with ad hoc technical expert groups which have met or will meet before COPMOP/3.

The EU suggests that COPMOP/3 should also take into account any lessons drawn by the CBD's Ad Hoc Open-ended Working Group on Review of Implementation of the Convention (WGRI), which is scheduled to meet in September 2005. This group has a mandate, among other things: to review the impacts and effectiveness of existing processes under the Convention, such as meetings of the Conference of the Parties, the Subsidiary Body on Scientific, Technical and Technological Advice, national focal points, and the Secretariat, as part of the overall process for improving the operations of the Convention and implementation of the Strategic Plan.

JAPAN

[6 DECEMBER 2005]
[SUBMISSION: ENGLISH]

Under the existing system of the Protocol, there are in place Biosafety Clearing-House (BCH) and Biosafety Information Resource Centre, which provide information on scientific and technical issues, including risk assessment and risk management. Also, measures to facilitate capacity building like Roster of Experts (ROE) have been established. Therefore we think specific issues arising in relation to the implementation of the Protocol can be addressed by using these instruments.

In addition, there is few materials to consider the nature of a permanent subsidiary body and particular issues that it could address, because the COP/MOP has not encountered scientific and technical issues on which such body needs to provide advice. Therefore we believe that at this moment there is no need to urgently designate or establish a permanent subsidiary body.

Naturally, there will be a possibility of reconsidering the designation or establishment of a permanent subsidiary body when needed in the future. In such case, we should take into account not only the needs but also ways of sustainable finance, because the establishment and management of such body will need additional human and financial resources, but on the other hand it seems difficult for each country to assume such additional costs, bearing in mind the past discussion on the costs of the Secretariat services for the Protocol.

NEW ZEALAND

[30 OCTOBER 2005]
[SUBMISSION: ENGLISH]

In light of the request to Parties and other Governments to submit views to the Executive Secretary, regarding the need to designate or establish a permanent subsidiary body for the Biosafety Protocol, for inclusion in a synthesis report to be considered by the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

New Zealand submits that there is not sufficient demonstrable need to designate or establish a permanent subsidiary body at this time. Given the significant resource implications inherent in establishing a permanent subsidiary body, New Zealand would not be in a position to support such a proposal. New Zealand submits that rather than establishing a permanent body, ad hoc groups can be established to provide advice on specific issues as the need arises.

NORWAY

[14 SEPTEMBER 2005]
[SUBMISSION: ENGLISH]

(Secretariat note: The following are responses in Norway's interim national report to questions 56, 30 and 23)

(a) Question 56: Please use this box to provide any other information related to articles of the Protocol, questions in the reporting format, or other issues related to national implementation of the Protocol.

Answer:
As stated in the answers to questions 23 and 30 above, Norway is in favour of a scientific committee being appointed with the task of providing scientific and technical guidance on risk assessment guidelines, ARMG in GMO and other tasks that might be considered important for the fulfilment of the objectives of the Protocol, such as tasks pursuant to Article 18(3).

The scientific committee should be appointed to fulfil specific tasks, not on a permanent basis. It should receive funding from the core budget and each Party should be entitled to appoint one expert to participate in its meetings. We call upon the Secretariat to make a budget proposal for the establishment of such a committee that could meet annually or biannually as the need may be.

(b) Question 30: Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 18, including any obstacles or impediments encountered.

Answer:

The Norwegian legal framework on GMO also addresses handling, transport, packaging and identification requirements pursuant to Article 18. The following are relevant to the implementation of Article 18:

- Regulations of 2 September 2005 on labeling, transport, import and export of GMO.
- Regulations of 7 November 2002 No. 1290 on feedstuffs (labeling requirements)
- Regulations of 21 December 1993 No. 1385 on labeling of foodstuffs.

As concerns Article 18(1), the existing Norwegian legislation contains appropriate rules on the safe transport, handling and packaging of GMO. These rules are contained in:

- Regulations of 11 November 2002 on transport of dangerous goods by road and rail
- Regulations of 13 November 1998 No. 1066 on transport and import of GMO, which were replaced by Regulations of 2 September 2005 on labeling, transport, import and export of GMO without major changes relating to obligations pursuant to Article 18(1).

As concerns Article 18(2)(a), it follows from Sections 18 and 19 of the Regulations of 2. September 2005 on labeling, transport, import and export of GMO that exporters are required to provide the following information on a label or in a document accompanying GMO intended for direct use as food or feed, or for processing, and transmit it to the importer receiving the GMO:

- that it contains GMO;
- the unique identification code assigned to the GMO if such codes exist;
- the common, scientific and - if it exists - commercial name of the product;
- a contact point for further information;
- a declaration stating that the GMO are intended for direct use as food or feed, or for processing and not intended for deliberate release into the environment; and

For products consisting of or containing mixtures of GMO to be used only and directly as food or feed, or for processing, the unique identification code may be replaced by a list of unique identification codes for all the GMO used to constitute the mixture.

Regulations of 7 November 2002 No. 1290 on feedstuffs and Regulations of 21 December 1993 No. 1385 on labeling of foodstuffs contain rules on labeling of all GM food and feed. Any intentional use of GM ingredients in food at any level must be labeled. Labeling requirements do not apply to conventional products with traces of GMO or genetically modified material up to 0,9 %, provided the presence of this material is adventitious or technically unavoidable.

If necessary, the Regulations mentioned above will be revised when detailed requirements are adopted in accordance with the second sentence of Article 18(2)(a).

As concerns Article 18(2)(b), it follows from Sections 18 and 19 of the Regulations of 2. September 2005 on labeling, transport, import and export of GMO that exporters are required to provide the following information on a label or in a document accompanying GMO destined for contained use, and transmit it to the importer receiving the GMO:

- that it contains GMO;
- the unique identification code assigned to the GMO if such code exist;
- that it is destined for contained use;
- the common and scientific name of the product;
- any requirements for the safe handling, storage, transport and use of the GMO; and
- a contact point for further information, including the name and address of the individual or institution to whom or which the GMO is consigned.

As concerns Article 18(2)(c), it follows from Sections 18 and 19 of the Regulations of 2. September 2005 on labeling, transport, import and export of GMO that exporters are required to provide the following information on a label or in a document accompanying GMO intended for deliberate release into the environment, and transmit it to the importer receiving the GMO:

- that it contains GMO;
- the unique identification code assigned to the GMO if such code exist;
- a declaration by the exporter that the transport is in conformity with the requirements of the Cartagena Protocol applicable to the exporter;
- the common and scientific name of the GMO and its characteristics;
- any requirements for the safe handling, storage, transport and use of the GMO; and
- contact point for further information, including name and address of the importer and exporter.

Furthermore, the following EC Acts are in the process of being incorporated into the EEA Agreement and consequently implemented in the Gene Technology Act and Regulations adopted pursuant to it:

- Regulation (EC) 1829/2003 of 22 September 2003 on genetically modified food and feed;
- Regulation (EC) 1830/2003 of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.
- Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003; and
- Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms.

We refer to the report from the EC for a detailed description of these Acts.

Norway is of the opinion that a standardized format for documentation and identification requirements for inclusion in a stand-alone document, should be developed in order to secure clearest possible identification and avoid the difficulties for traders that would result from different countries requiring different formats.

Norway is furthermore of the opinion that the question of thresholds and sampling and detection methods are important, albeit difficult matters that merit further consideration by the Parties.

Given the technical nature of these issues, Norway is therefore in favour of a scientific committee being appointed with the task of providing scientific and technical guidance on these matters. The nature and composition of such a committee is commented upon under Question 56 of this Report.

Question 23: Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Articles 15 and 16, including any obstacles or impediments encountered

Answer:

Further details q.18: Norway did not take a decision regarding article 10 during the reporting period.

Further details q. 20: The Norwegian Food Safety Authority collects samples from imported food, feed and seed which are analysed for content of GMO. The analyses of the samples are carried out by The Norwegian Veterinary Institute which has an extensive cooperation with other European GMO-detection laboratories to develop and validate GMO-detection protocols.

Further details q. 21: The Norwegian Gene technology Act requires that releases of GMO to the environment should take place stepwise in order to be able to detect unforeseen adverse effects on the environment or human health before a full scale release is granted.

Further details q. 22: Norway cooperates with the European Union in a working group under Directive 2001/18/ EC, with the aim of phasing out GMO with antibiotic resistance marker genes that may have adverse effects on human health or the environment.

Directive 2001/18/EC on the deliberate release of GMO calls for a phasing out of antibiotic resistance marker genes which may have adverse effects on human health and the environment. The Scientific Panel on Genetically Modified Organisms under the European Food Safety authority adopted an opinion in April 2004 that one category (category II) of ARMG that are being used in GMO should be restricted to field trial purposes, and that one other category of ARMG should be restricted to contained use only (category III). The opinion is available on http://www.efsa.eu.int/science/gmo/gmo_opinions/384_en.html

The Norwegian Scientific Committee for Food Safety will deliver "An assessment of potential long-term health effects caused by antibiotic resistance marker genes in GMO based on antibiotic usage and resistance patterns in Norway" ultimo September 2005. According to the preliminary summary the Committee is of the same opinion as EFSA regarding the risk of ARMG in Groups II and III, but expresses somewhat more concern regarding the nptII-gene in Group I. The preliminary summary of the report is enclosed in Annex II. The final report will be made available through the Biosafety Information Resource Center on the Biosafety Clearing House, where further information on horizontal gene transfer can be found.

Further details q. 23: A risk assessment must be carried out by the notifier both for notifications of GMO intended for intentional introduction into the environment and for notifications of GMO intended for direct use as food or feed, or processing, The requirements for the risk assessment are in line with the requirements specified in annex III to the Cartagena Protocol. It should be carried out on a case by case basis, and must be based on the precautionary principle. The Norwegian authorities assesses whether the information in the risk assessment is in line with the national requirements, and ask for further documentation if the information is not sufficient as basis for a decision.

A consent under the Norwegian Gene Technology Act may be granted on condition that the notifier carries out risk management measures such as post market monitoring, isolation distances and provisions ensuring traceability of the GMO.

Norway is of the opinion that further guidelines supplementing Articles 15, 16 and Annex III on Risk Assessment to the Protocol is necessary for a common approach, which again is important to fulfil the objectives of the Protocol. The work to be carried out by the Ad Hoc Technical Expert Group established by MOP BS-II/9 on identifying the relevance of, and gaps in existing approaches to and guidance material on risk assessment and the need for capacity building activities, will be an important contribution towards the development of necessary further guidelines.

Norway is furthermore of the opinion that the reports on antibiotic resistance marker genes (ARMG) mentioned above clearly indicate that such genes are examples of specific traits covered by Article 16(5). The Parties to the Protocol are obliged to identify such traits and take appropriate measures regarding their treatment.

Norway is therefore in favour of a scientific committee being appointed with the task of providing scientific and technical guidance on risk assessment guidelines, ARMG in GMO and other tasks that might be considered important for the fulfilment of the objectives of the Protocol, such as tasks pursuant to Article 18(3) identified by Norway in the answer to Question 30 of this Report.

UNITED STATES OF AMERICA (USA) [16 SEPTEMBER 2005]
[SUBMISSION: ENGLISH]

Summary: The United States does not believe that the need exists to designate or establish a permanent subsidiary body to address scientific or technical issues, primarily because: (1) other resources and institutions exist for this purpose and are at the disposal of Parties; (2) establishing such a body would tax the limited resources of the Protocol; and, (3) it is unclear how Parties will benefit from a subsidiary body in the foreseeable future.

Background: Paragraph 3 of decision BS-II/14 of COP/MOP-2 invites Parties and other Governments to submit views regarding the need to designate or establish a permanent subsidiary body to provide the Parties with timely advice on scientific and technical issues arising in relation to the implementation of the Protocol, including risk assessment and risk management.

US Views:

1) **Establishment of a subsidiary body is not prudent as other resources and institutions exist and are at the disposal of the Parties.**

A subsidiary body that addresses scientific issues related to the transboundary movement of LMOs would very likely be duplicative of the efforts of a number of international bodies that are expert on topics of interest to Parties. For instance, with respect to risk assessment and risk management, the United States believes that the International Plant Protection Convention (IPPC) is an appropriate forum for the development of guidance on risk assessment with respect to plant health issues associated with LMOs. In the case of the IPPC, a Memorandum of Cooperation between the IPPC and the CBD was adopted in December 2003 to ensure effective cooperation and reduce duplication of efforts in joint activities. It is worth highlighting that in April 2004, the IPPC adopted guidelines for LMO risk assessment/risk management as a supplement to an existing standard. As risk assessment is an important tool in any science-based framework for decision-making and is a critical element for decisions related to import under the Protocol, the United States would strongly urge Parties to actively participate in the work of the IPPC, which is undertaking relevant work in this area.

2) **Establishing a permanent subsidiary body would tax the limited resources of the Protocol and the signatory Parties**.

The establishment of a subsidiary body at this time would only reduce available resources for much needed individual country capacity building in critical areas, such as risk assessment and risk management. Before taking any decision about the need for a subsidiary body, Parties should consider carefully the true costs of such a body. In this regard, the United States recognizes that many countries need to develop their capacity to conduct risk assessments and supports capacity building activities in this area. The United States has consistently supported efforts to help other countries develop their capacity to conduct risk assessments through bilateral assistance and participation in multilateral institutions such as the IPPC.

3) **It is unclear how Parties will benefit from a subsidiary body in the foreseeable future.**

It is not clear how Parties could benefit from a permanent subsidiary body in the near term. At COP/MOP-2, Parties did not identify any particular scientific or technical issues that warranted additional guidance at this time. The United States believes the establishment of a permanent subsidiary body is premature.

SUBMISSIONS FROM ORGANIZATIONS

GLOBAL INDUSTRY COALITION (GIC) [13 SEPTEMBER 2005]
[SUBMISSION: ENGLISH]

The following provides the views and comments of the users and developers of modern biotechnology regarding the need to designate or establish a permanent subsidiary body to provide the Parties to the Cartagena Protocol on Biosafety (the "Protocol") with scientific and technical advice. While it is recognized that there is a clear need to improve the scientific and technical basis for decisions being made by the Parties, the private sector does not support the establishment of a new subsidiary body for the following reasons:

1. Parties Can Benefit from the Use of Existing Resources and Structures

There exists at the present time an appropriate structure and resource to allow Parties to obtain the scientific and technical advice necessary to allow them to complete the Protocol implementation process. Ad hoc technical expert groups on specific priority issues on the Protocol's programme of work can be established, as required, to respond to requests where specific scientific or technical issues must be addressed for the Parties. Such groups have been both beneficial and practical to date in the Protocol implementation process as they allow Parties to draw on the existing knowledge and competence available within international, regional and national organizations, including the private sector, non-governmental organizations and the scientific community in field relevant to the issue at hand. In addition, these groups are targeted to consider specific scientific or technical issues; thus, they are composed of true experts on those specific issues, rather than general biosafety experts in a generic subsidiary body that may not be able to provide adequate expertise on any one issue area.

In situations where the Parties require sound scientific and technical assistance on issues critical for implementation of the Protocol, technical expert groups can adequately provide responses to issues that the MOP may put to them in a timely manner and without undue expense on behalf of the Secretariat of the Convention on Biological Diversity.

2. A New Body would Divert Resources Necessary to Bring All Parties into Compliance

Protocol implementation work should focus first and foremost on the development of the capacity of all Parties to ensure compliance with the Protocol. Once Parties are in compliance with existing obligations and the Protocol, including its Clearing House, is fully functioning, the question of whether an additional body is required can be reconsidered.
