



**FOREIGN
AFFAIRS AND
TRADE**

International Organisations and Legal
Division

31 October 2000

Hamdallah Zedan
Executive Secretary
Secretariat
Convention on Biological Diversity

Dear Mr Zedan

CARTAGENA PROTOCOL ON BIOSAFETY: CAPACITY BUILDING

Australian comments on the draft Annotated Outline of an Indicative Framework for Capacity Building under the Cartagena Protocol on Biosafety

Thank you for the opportunity to comment on the draft Annotated Outline of the Indicative Framework for Capacity Building under the Cartagena Protocol.

Australia considers that the draft document contains some very useful elements and identifies a number of key issues relevant to setting up a framework for capacity building under the Protocol. The Secretariat's efforts in this regard are appreciated.

Australia would like to make some comments relating to three main areas: use of "risk management" terminology in the draft outline, national legal frameworks, and the role of social science. In view of these comments, we would like to suggest an alternative format for Table 1 in the draft outline.

Use of "Risk Management" terminology in the draft outline

Australia recognises that the term "risk management" in the current draft is intended to refer broadly to the way a country manages risks through policies, laws, regulations, community action etc. However, "risk management" can also be understood as a component of a case-by-case risk analysis process for a particular biotechnology organism or product. We consider that it would be less confusing and more constructive if the paper referenced risk management in the latter way. This would help to achieve consistency in terminology across multilateral rules and guidelines for regulating living modified organisms.

National legal frameworks

It would be useful if the paper encouraged countries to analyse their existing policy/legal/regulatory frameworks to determine if there is already legal capacity to implement the Protocol. The text and table as currently drafted appear to assume that countries will need to develop an entirely new legal framework. A key recommendation made by Pacific-region countries at a capacity building workshop on Biosafety in Fiji in December 1999 was that in-country analysis of the adequacy of existing frameworks be undertaken.

The role of social-science

It is not acceptable to include social science analysis as a component of risk assessment as this is not consistent with the internationally accepted science-based, case-by-case approach used in other regulatory systems which protect human, animal and plant life or health. Social science issues are taken into account in government policy at the broader level, that is, through environment and trade policies, quarantine and biosecurity policies. In this way social policy assists in determining the level of risk that the country is willing to accept (appropriate level of protection in SPS agreement language).

Table 1

In view of the comments above, Australia suggests that the table and discussion follow the format in attachment 1. The points included under the headings of the table as currently drafted are useful and could be incorporated under the suggested alternative headings. The suggested format would also allow for new issues to be incorporated unproblematically, including the need for countries to analyse their legal systems and assess the need for amending existing in-country laws.

Capacity building activities in the field of Biosafety: Australian Submission

I would also like to take this opportunity to draw your attention to a short submission, prepared in response to the Secretariat's request, which sets out Australian views and activities on capacity building in the field of biosafety.

Yours sincerely

Ralph Hillman
Ambassador for the Environment

Attachment: Proposed Alternative Table 1

Legal, regulatory, administrative, institutional and social policy framework	Risk analysis process				Monitoring and feedback
	Initiation/ Notification	Risk Assessment	Risk Management	Risk Communication	
. Assess existing legal/regulatory frameworks to establish whether they are adequate to implement the Protocol					