

THE CARTAGENA PROTOCOL  
ON BIOSAFETY:  
**A RECORD  
OF THE NEGOTIATIONS**



Secretariat of the  
Convention on  
Biological Diversity



THE CARTAGENA PROTOCOL  
ON BIOSAFETY:  
**A RECORD OF THE NEGOTIATIONS**

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of the Secretariat of the Convention on Biological Diversity concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

The views expressed in this publication are those of the authors and do not necessarily reflect those of the Secretariat of the Convention on Biological Diversity.

This publication may be reproduced for educational or non-profit purposes without special permission from the copyright holders, provided acknowledgement of the source is made. The Secretariat of the Convention would appreciate receiving a copy of any publications that uses this document as a source.

© Secretariat of the Convention on Biological Diversity

ISBN 92-807-2376-6

For more information or additional copies, please contact:

The Secretariat of the Convention on Biological Diversity  
World Trade Centre  
393 St. Jacques, Suite 300  
Montreal, Quebec, Canada H2Y 1N9  
Tel : + 1 (514) 288 2220  
Fax: + 1 (514) 288 6588  
E-mail: [secretariat@biodiv.org](mailto:secretariat@biodiv.org)  
Website: <http://www.biodiv.org>

## PHOTO CREDITS

E. Purnomo/The Image Works (Woman drops rice)  
Chatree Wanasangtham/UNEP - Topham/Ponopresse (field Asia)  
Teuna Van Gysse /UNEP - Topham/Ponopresse (rice field)  
J.Schytte/Still Pictures/Alpha Presse (tomatoes)  
M.Bond/Still Pictures/Alpha Presse (soja)  
J.Douillet/Bios/Alpha Presse (cereal)

# TABLE OF CONTENTS

<b>ABBREVIATIONS</b> .....	<b>5</b>
<b>FOREWORD</b> .....	<b>6</b>
<b>I. INTRODUCTION</b> .....	<b>7</b>
<b>II. BACKGROUND</b> .....	<b>9</b>
<b>III. TEXT OF THE PROTOCOL</b> .....	<b>14</b>
Preamble .....	14
Article 1 Objective.....	17
Article 2 General Provisions .....	19
Article 3 Use of Terms.....	21
Article 4 Scope .....	24
Article 5 Pharmaceuticals .....	26
Article 6 Transit and contained use.....	27
Article 6(1) Transit.....	27
Article 6(2) Contained Use.....	28
Article 7 Application of the Advance Informed Agreement Procedure .....	29
Article 8 Notification.....	32
Article 9 Acknowledgement of Receipt of Notification .....	34
Article 10 Decision Procedure .....	36
Article 11 Procedure for Living Modified Organisms Intended for Direct Use as Food or Feed, or for Processing .....	40
Article 12 Review of Decisions.....	44
Article 13 Simplified Procedure.....	46
Article 14 Bilateral, Regional and Multilateral Agreements and Arrangements.....	48
Article 15 Risk Assessment .....	50
Article 16 Risk Management.....	53
Article 17 Unintentional Transboundary Movements and Emergency Measures .....	55
Article 18 Handling, Transport, Packaging and Identification .....	58
Article 19 Competent National Authorities and National Focal Points .....	61
Article 20 Information Sharing and the Biosafety Clearing-House .....	63
Article 21 Confidential Information .....	67
Article 22 Capacity-building.....	69
Article 23 Public Awareness and Participation.....	72
Article 24 Non-Parties.....	75
Article 25 Illegal Transboundary Movements.....	77
Article 26 Socio-economic considerations .....	79
Article 27 Liability and Redress .....	82
Article 28 Financial Mechanism and Resources.....	85
Article 29 Conference of the Parties serving as the Meeting of the Parties to this Protocol.....	87
Article 30 Subsidiary Bodies .....	90
Article 31 Secretariat.....	91
Article 32 Relationship with the Convention .....	92
Article 33 Monitoring and Reporting .....	93
Article 34 Compliance.....	95
Article 35 Assessment and Review.....	96
Article 36 Signature.....	97
Article 37 Entry into Force.....	98

Article 38	Reservations .....	99
Article 39	Withdrawal .....	100
Article 40	Authentic Texts .....	101
Annex I	Information Required in Notifications under Article 8, 10 and 13 .....	102
Annex II	Information Required Concerning Living Modified Organisms Intended for Direct Use as Food or Feed, or for Processing Under Article 11 .....	105
Annex III	Risk Assessment .....	106
APPENDIX I	DELETED DRAFT ARTICLES .....	110
	Relationship with other international agreements .....	110
	Jurisdictional Scope .....	111
	Notification of Transit .....	111
	Emergency Measures .....	112
	Minimum national standards .....	113
	Non-discrimination .....	114
	Subsequent Imports .....	115
	Ratification, acceptance or approval .....	116
	Accession .....	117
	OTHER PROPOSALS .....	117
	Settlement of Disputes .....	117
	Annex - LMOs that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health .....	118
	Other Annexes .....	118
APPENDIX II	NEGOTIATING SESSIONS AND GROUPS .....	119
APPENDIX III	EVOLUTION OF THE CONTENTS OF THE PROTOCOL .....	121
APPENDIX IV	PROPOSALS FROM GOVERNMENTS .....	128
APPENDIX V	LIST OF DOCUMENTS .....	137
APPENDIX VI	TERMS OF REFERENCE FOR THE OPEN-ENDED AD HOC WORKING GROUP (FROM COP DECISION II/5) .....	140

# ABBREVIATIONS

AIA	Advance informed agreement
BCH	Biosafety Clearing House
BSWG	Open-ended Ad Hoc Working Group on Biosafety
BSWG-1 (BSWG-2...)	First (second.. etc) meeting of the BSWG
CBD	Convention on Biological Diversity
CG-1	Contact Group 1
CG-2	Contact Group 2
CHM	Clearing-house mechanism to promote and facilitate technical and scientific cooperation (Article 18,CBD)
COP	Conference of the Parties
COP1 (COP2...)	First (second... etc) meeting of the COP (of the CBD)
COP/MOP	Conference of the Parties serving as the meeting of the Parties to the Protocol
CNA	Competent national authority (under Article 19, Biosafety Protocol)
EC	European Community
EU	European Union
ExCOP	First extraordinary meeting of the COP
IAEA	International Atomic Energy Agency
ICCP	Intergovernmental Committee for the Cartagena Protocol on Biosafety
ICJ	International Court of Justice
LMO	Living modified organism
LMO-FFP	Living modified organism(s) intended for direct use as food or feed, or for processing
MOP	Meeting of the Parties
NFP	National focal point (under Article 19, Biosafety Protocol)
Resumed ExCOP	Resumed session of the first extraordinary meeting of the COP
SWG-I	Sub-Working Group I
SWG-II	Sub-Working Group II

## DEFINITION OF TERMS

Agenda 21	Agenda 21: Programme of Action for Sustainable Development (UNCED, 1992)
Compromise Group	Negotiating group formed at the Cartagena meeting, comprising Japan, Korea, Mexico, Norway and Switzerland, later joined by Singapore and New Zealand
COP-MOP	Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol
Like-Minded Group	Negotiating group formed at the Cartagena meeting, comprising the G-77 countries and China, with the exception of Argentina, Chile and Uruguay
Madrid Report	The report of the meeting of the Open-ended Ad Hoc Group of Experts on Biosafety (Madrid, 24-28 July 1995) (document UNEP/CBD/COP/2/7)
Miami Group	Negotiating group comprising Argentina, Australia, Canada, Chile, Uruguay and the USA
Rio Declaration	Rio Declaration on Environment and Development (UNCED, 1992)
UNEP Technical Guidelines	United Nations Environment Programme International Technical Guidelines on Safety in Biotechnology
Vienna informal consultations	Consultation meeting held by ExCOP President Juan Mayr, 15-19 September 1999, Vienna, prior to the resumed session of the ExCOP.

# FOREWORD

---

The adoption of the Cartagena Protocol on Biosafety, in the early hours of Saturday, 29 January 2000, marked the end of a four-year long negotiating process that had been often difficult and at times appeared intractable. Three years on, the Protocol has now entered into force, and the commitments it contains have become part of the ever-growing body of international environmental law. At the same time, the work of the Intergovernmental Committee for the Cartagena Protocol on Biosafety, an interim body established by the Conference of the Parties to undertake the preparations necessary for the first meeting of the Parties to the Protocol, has contributed significantly to further advancing the understanding on some of the key issues.

As we look forward to the imminent operationalisation of the Protocol's provisions, aiming to ensure adequate safety in the movement and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity and human health, it seems an appropriate time to look back and reflect upon how the negotiating process developed and how the final text emerged.

The present volume serves as an excellent reference point in this respect. By reflecting the differing views during the genesis of the Protocol and painstakingly charting the negotiation of individual provisions, including draft articles not included in the final agreed text, *The Cartagena Protocol on Biosafety: A Record of the Negotiations* provides us with a history of the gestation and birth of the Protocol to help us understand why it took the final shape that it did.

The record has been meticulously compiled by the Foundation for International Environmental Law and Development and will serve to inform those who did not attend the negotiating sessions and refresh the memories of those who did. I wish to extend my sincere thanks to the members of the FIELD team for their fruitful cooperation and the accuracy and attention to detail displayed in producing this valuable tool. I am confident that it will be of service to all those interested in the evolution and implementation of the Protocol.

Hamdallah Zedan  
*Executive Secretary*

Montreal, September 2003

# I. INTRODUCTION

---

This paper seeks to record the evolution of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity from the initial provision in Article 19(3) of the Convention itself through to the final adoption of the text of the Protocol in January 2000.

The paper aims to contribute to the institutional memory and to the historical record of the Convention on Biological Diversity.<sup>1</sup> It has been developed by the Foundation for International Environmental Law and Development (FIELD) at the request of the Executive Secretary of the Secretariat of the Convention on Biological Diversity (CBD).<sup>2</sup> Drafts of this paper were reviewed by the CBD Secretariat and by a Steering Committee established by the Executive Secretary<sup>3</sup> comprising a number of individual delegates who were closely involved in the negotiations. The contents of the paper, however, remain the responsibility of FIELD and do not necessarily reflect the views of the Secretariat of the Convention on Biological Diversity, or that of any of the reviewers, or of any Party.

This paper is structured as follows:

The Background section provides a brief overview of the process undertaken in respect of Article 19(3) of the Convention, including the work of the Conference of the Parties at its first meeting, the work of the Open-ended Ad Hoc Working Group on Biosafety (BSWG), and the two sessions of the Extraordinary Meeting of the Conference of the Parties (ExCOP). It also provides an overview of the structure of the negotiations, including, for example, the Sub-Working Groups and Contact Groups established by the BSWG, which are referred to throughout the remainder of the document.

At the heart of the paper, in Section III, is an article-by-article analysis of the development of the provisions of the Protocol. The reader will need to bear in mind, however, that the elaboration of the Protocol was not a sequential process. Indeed, it was a complex negotiating process with multiple simultaneous and inter-linked strands, where the resolution of one issue would be contingent upon the agreement on text under another in a sometimes bewildering set of interlocking dependencies and trade-offs.

Section III is based principally upon the official documentation related to the negotiations, that is, the reports of the meetings of the BSWG and the ExCOP, pre-session documents including government submissions, and published reports of consultation meetings. These documents are all available on the website of the Convention on Biological Diversity at <http://www.biodiv.org>. In addition, in relation to some articles, reference is made to the reports of the *Earth Negotiations Bulletin*.<sup>4</sup> For clarification of the numbering of the articles of the Protocol over the course of the negotiations, the reader should refer to Appendix III. The analysis of the elaboration of each article in Section III does not necessarily make specific reference to all government submissions made in respect of the provision in question during the course of the negotiations. However a full list of governments that made submissions to each meeting of the BSWG is contained in Appendix IV.

Appendix I traces the development and fate of draft articles of the Protocol that were proposed and discussed during the course of the negotiations, but that were deleted and are not included in the final text of the Protocol.

---

<sup>1</sup> For a set of personal recollections of some of those involved in the negotiations, see Christoph Bail, Robert Falkner and Helen Marquard (eds.), *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment and Development?* (London, Earthscan, 2002). For a detailed guide to the provisions of the Protocol, see Ruth Mackenzie, Françoise Burhenne-Guilmin, Antonio G.M. La Viña and Jacob Werksman, in cooperation with Alfonso Ascencio, Julian Kinderlerer, Katharina Kummer and Richard Tapper, *An Explanatory Guide to the Cartagena Protocol on Biosafety*, (IUCN Environmental Policy and Law Paper No. 46, 2003). The Secretariat and the United Nations Environment Programme have also produced a simplified guide to the Cartagena Protocol on Biosafety, *Biosafety and the Environment: An Introduction to the Cartagena Protocol on Biosafety* (Belegarde, France, Sadag, SA, 2003), available at <http://www.biodiv.org>.

<sup>2</sup> The FIELD team comprised Fernando Latorre, Ruth Mackenzie, Tony Gross, Elsa Tsioumani, and Catherine McLellan.

<sup>3</sup> The Steering Committee comprised Mr. John Herity (Canada), Mr. Desmond Mahon (Canada), Mr. Cristian Samper (Colombia), Mr. Veit Koester (Denmark), Dr. Tewolde Berhan Gebre Egziabher (Ethiopia), Mr. Gabor Nechay (Hungary), Mr. François Pythoud (Switzerland), and Ms. Helen Marquard (UK).

<sup>4</sup> These reports are available at <http://www.iisd.ca>.



Appendix II records the chronology of meetings, and also sets out the list of chairs and co-chairs of the various bodies established during the negotiations.

Appendix III outlines the evolution of the structure of the Protocol. This Appendix is provided in order to assist the reader, given that over the course of the negotiations the numbering of the articles of the Protocol was revised a number of times as the elaboration of the Protocol progressed.

Appendix IV records the governments that submitted written proposals during the course of the negotiations.

Finally, Appendix V lists the extensive official documentation related to the negotiation of the Protocol. This list does not include in-session documents.

## II. BACKGROUND

---

### The Convention on Biological Diversity

Article 19(3) of the Convention provides that:

The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

This provision resulted from differing views during the negotiation of the Convention. Some countries felt that the Convention should include a provision making mandatory the development of a future protocol on biosafety, whilst others preferred a provision requiring Parties to consider the need for a protocol.<sup>5</sup>

Resolution 2 of the Nairobi Final Act adopting the Convention on Biological Diversity invited UNEP to consider, *inter alia*, Article 19(3) of the Convention. Consequently, Expert Panel IV established by UNEP considered the need for, possible elements of and modalities of a protocol on biosafety. The final report of the Panel was published in April 1993.<sup>6</sup> However the report of Panel IV was not directly taken up and was not part of the formal documentation for the first meeting of the Conference of the Parties to the Convention.

The Nairobi Final Act also established an Intergovernmental Committee on the Convention on Biological Diversity (ICCBD) to prepare for the first meeting of the Conference of the Parties of the Convention. Article 19(3) was taken up in Working Group I of the ICCBD.<sup>7</sup> There was a general agreement in the Working Group on the need for adequate and transparent safety and border control procedures to manage and control the risks associated with the use and release of LMOs

resulting from modern biotechnology, to enable the potential benefits of biotechnology to be maximised, and to gain widespread public acceptance, especially in developing countries.<sup>8</sup> However, there were different views on the need for and modalities of a protocol, and the report of the ICCBD reflects the different views expressed on this issue.<sup>9</sup> The ICCBD recommended that the issue of biosafety should be on the agenda of the first meeting of the Conference of the Parties to the Convention to initiate the process specified in Article 19(3).<sup>10</sup>

### The Conference of the Parties

The first meeting of the Conference of the Parties to the Convention (Nassau, Bahamas, November 1994) decided,<sup>11</sup> as part of its medium-term programme of work, to arrange two meetings in the inter-sessional period prior to its second meeting. The principal meeting was to comprise “an open-ended ad hoc group of experts nominated by Governments without undue delay to consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity.” This group was to meet for a week during 1995 and was to “consider, as appropriate, existing knowledge, experience and legislation in the field of biosafety, including the views of the Parties, subregional, regional and international organisations, with a view to presenting a report for the consideration of the second meeting of the Conference of the Parties, so as to enable the Conference of the Parties to reach an informed decision as to the need for and modalities of a protocol”.

In order to prepare for the work of the group of experts, the COP requested the Secretariat to establish:

---

<sup>5</sup> Mackenzie et al (2003), p.2.

<sup>6</sup> UNEP/Bio.Div./Panels/Inf.4, Report of Panel IV, Nairobi, 28 April 1993.

<sup>7</sup> See UNEP/CBD/IC/2/12, Note by the Interim Secretariat on consideration of the need for and modalities of a protocol on biosafety.

<sup>8</sup> UNEP/CBD/COP/1/4, Report of the Intergovernmental Committee on the Convention on Biological Diversity, para. 223.

<sup>9</sup> *Ibid.*, paras. 223-229.

<sup>10</sup> *Ibid.*, para 229.

<sup>11</sup> Decision I/9, paras.3-8

a panel of 15 experts nominated by Governments, with an equitable geographical representation, in consultation with the Bureau of the COP, assisted by UNIDO, UNEP, FAO and WHO, to prepare a background document to be submitted to the open-ended ad hoc group of experts nominated by Governments based on a consideration, as appropriate, of existing knowledge and experience on risk assessment and management, and guidelines and/or legislation already prepared by the Parties, other Governments and by national and competent subregional, regional and international organisations.<sup>12</sup>

The meeting of the panel of experts took place in Cairo in May 1995 and that of the Ad Hoc Group of Experts in Madrid in July 1995. The Madrid meeting concluded that there was a need for an international framework for safety in biotechnology.<sup>13</sup> The Madrid report identified a number of issues, which, it was agreed, should be addressed within the international framework on biosafety, including a procedure for advance informed agreement.<sup>14</sup> Other issues were identified which, though not yet enjoying consensus, were supported by many delegations, including socio-economic considerations, and liability and compensation.<sup>15</sup> The large majority of delegations favoured the development, within the context of the international framework, of a protocol under the CBD.<sup>16</sup>

The second meeting of the COP (Jakarta, Indonesia, November 1995) considered the report of the Madrid meeting<sup>17</sup> and, after extensive negotiations, agreed to establish an Open-ended Ad Hoc Working Group on Biosafety under the COP to “seek solution to the [...] concerns through a negotiation process to develop, in the field of the

safe transfer, handling and use of living modified organisms, a protocol on biosafety, specifically focusing on transboundary movement, of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedure for advance informed agreement.”<sup>18</sup>

The COP specified the terms of reference of the Working Group in an annex to the decision (see Appendix VI below). The Working Group was to “endeavour to complete its work in 1998.”<sup>19</sup> Decision II/5 also clarified that the subject of the protocol was “living modified organisms resulting from modern biotechnology,” a narrower category of organisms than that referred to in Articles 8 (g) and 19 of the Convention, which use the term “living modified organisms resulting from biotechnology”.

### **The Open-ended Ad Hoc Working Group on Biosafety**

The Open-ended Ad Hoc Working Group (the BSWG) met six times between 1996 and 1999 under the chairmanship of Mr. Veit Koester (Denmark). The first two meetings – BSWG-1 (Aarhus, July 1996) and BSWG-2 (Montreal, May 1997) – constituted a phase of identifying the elements of the future protocol. Appendix III (Evolution of the contents of the Protocol) provides the state of progress after both these meetings by listing the “Possible Contents of the Protocol on Biosafety” identified at BSWG-1 and the “Chairman’s Summary of Elements Presented” contained in the report of BSWG-2.<sup>20</sup>

---

<sup>12</sup> Id.

<sup>13</sup> UNEP/CBD/COP/2/7, Annex I, para. 6.

<sup>14</sup> Ibid., para. 18(a)

<sup>15</sup> Ibid., para. 18(b).

<sup>16</sup> Ibid., para 20.

<sup>17</sup> UNEP/CBD/COP/2/7.

<sup>18</sup> Decision II/5

<sup>19</sup> Decision II/5, Annex, para. 10.

<sup>20</sup> See also, UNEP/CBD/ExCOP/1/3, paras. 29-30.

At BSWG-2, the first of a series of negotiating groups was established, a contact group on definitions. At BSWG-3 this group, which became known as Contact Group 1 (CG-1), had its mandate extended to deal also with annexes to the Protocol, and was supplemented by three other groups. Contact Group 2 (CG-2) was mandated to address institutional matters and final clauses; Sub-Working Group I (SWG-I) was charged with dealing with the advance informed agreement procedure and related issues, including articles on risk assessment and risk management; and Sub-Working Group II (SWG-II) dealt with a diverse range of remaining issues, including capacity-building, the clearing house and socio-economic considerations.<sup>21</sup> Each of these groups was co-chaired by one developed country Party and one developing country Party representative. The sub-working group and contact group structure was maintained until the early phases of BSWG-6 in Cartagena (see below). At BSWG-5 another small group was charged with addressing the issue of liability and redress,<sup>22</sup> and at BSWG-6 a Legal Drafting Group was formed to review draft articles of the Protocol to ensure legal consistency and wording in the text of the Protocol.<sup>23</sup> The issues addressed by the Sub-Working Groups and Contact Groups were clearly closely linked and, during the course of the negotiations, issues moved between the groups. Given the close links between the tasks charged to Contact Group 1 and Sub-Working Group I, it was decided at BSWG-4 to make Contact Group 1 a sub-group of Sub-Working Group I, reporting to it, in order to avoid duplication in the discussions and to ensure coordination of work.<sup>24</sup> A table showing the various sub-groups and contact groups, and their co-chairs, is contained in Appendix II.

At BSWG-3 (Montreal, October 1997) the time pressures began to be felt. Article 28 of the Convention stipulates that the text of the proposed

protocol be communicated to the Contracting Parties at least six months before the meeting to adopt such a protocol. As the Working Group had been asked to complete its work in 1998 and was due to meet for the fourth time in February 1998, and as the COP itself was due to meet in May 1998, there was the possibility of completing the negotiations during this period. However, to meet the requirements of Article 28 a text of the protocol would need to be ready at the end of BSWG-3.

Chair Koester argued that the term "text of a proposed protocol" as contained in Article 28 could be defined as "a draft text of a protocol that all Governments agree constitutes sufficient ground for the completion of the negotiating process and the adoption of the protocol, meaning that all options and elements should be contained in the consolidated draft in legal terms".<sup>25</sup> On this basis BSWG-3 developed the 'consolidated text of draft articles', which constituted the first structured outline of the future protocol and served as the basis for future negotiations. It contained the title, a preamble, 43 articles and five annexes (see Appendix III). (The title at this stage was simply "Biosafety Protocol!")<sup>26</sup>

By BSWG-4 (Montreal, February 1998), while the Working Group entered the negotiating phase,<sup>27</sup> it was clear that the protocol would not be ready for adoption at the fourth meeting of the COP in May 1998. The COP accepted that the Working Group would need more time and approved two further meetings of the Working Group – the first (BSWG-5) to be held in August 1998 and the second (BSWG-6) in February 1999. BSWG-6 would be immediately followed by an extraordinary meeting of the COP (ExCOP) to adopt the text of the protocol.<sup>28</sup>

For BSWG-5 (Montreal, August 1998) the Secre-

---

<sup>21</sup> See UNEP/CBD/BSWG/3/6, paras. 17-25.

<sup>22</sup> This group was established by Contact Group 2. See UNEP/CBD/BSWG/5/3, para. 53. The group was retained at BSWG-6, see UNEP/CBD/ExCOP/1/2, para. 21.

<sup>23</sup> UNEP/CBD/ExCOP/1/2, para. 18. In the earlier phases of the BSWG, a legal drafting function was also carried out by Contact Group 2. See UNEP/CBD/BSWG/5/3, para. 19.

<sup>24</sup> UNEP/CBD/BSWG/4/4, para. 17.

<sup>25</sup> UNEP/CBD/BSWG/3/6, para. 98.

<sup>26</sup> See UNEP/CBD/ExCOP/1/3, para. 31.

<sup>27</sup> UNEP/CBD/ExCOP/1/3, para. 32.

<sup>28</sup> Decision IV/3.

tariat prepared a “revised consolidated text of the draft articles” (see Appendix III). At the end of the meeting, although agreed text on a number of the final clauses had been provisionally adopted, and the Working Group had managed to focus further elements and articles to form the protocol,<sup>29</sup> fifteen of the substantive articles remained entirely in square brackets.

Disagreement on these key provisions persisted throughout BSWG-6 (Cartagena, February 1999), with further consultations taking place among the “Friends of the Chair”, a group of individuals nominated by the regional groups to assist the Chair of the BSWG.<sup>30</sup> However, with no resolution of the outstanding issues, the Chair of the BSWG attempted to resolve the impasse by preparing a “clean text”, containing compromise wording on the outstanding issues, to be transmitted by the Working Group to the ExCOP.<sup>31</sup> This document is frequently referred to in the remainder of this document as the “Chair’s text” or “Chair’s proposed text”. While many delegations expressed concerns about aspects of this text,<sup>32</sup> in the absence of further agreement on its content it was agreed that the BSWG would forward this text with its report to the ExCOP.<sup>33</sup>

### The Extraordinary Meeting of the Conference of the Parties

However, during the ExCOP, which immediately followed BSWG-6, Parties could not agree on the adoption of the Chair’s text, nor on any of the

other proposals put forward by the various negotiating groups. The ExCOP was suspended.<sup>34</sup> However, before the suspension of the meeting, the ExCOP agreed that the title of the Protocol, once finalised and adopted, would be the “Cartagena Protocol on Biosafety.”<sup>35</sup>

Following the suspension of the meeting, the President of the ExCOP, Minister Juan Mayr (Colombia), embarked on a series of informal negotiations involving the five distinct negotiating groups that had emerged during the course of the Cartagena meetings: the Central and Eastern Europe Group, the Compromise Group,<sup>36</sup> the European Union, the Like-minded Group,<sup>37</sup> and the Miami Group.<sup>38</sup>

Informal negotiations took place in Montreal (1 July 1999)<sup>39</sup> and in Vienna (15-19 September 1999).<sup>40</sup> It was during the latter meeting that Minister Mayr’s preferred arrangement of a hexagonal negotiating table, seating the Chair and representatives of the five negotiating groups, with other delegations seated behind, became the locus of the discussions. These arrangements, which had first been used in the later stages of the ExCOP in Cartagena, became known as the “Vienna setting”, and were to be used again in the resumed session of the ExCOP in Montreal in January 2000.

In December 1999, Minister Mayr circulated his draft proposal for addressing the essential core issues: the scope of the protocol (Article 4); application of the advance informed agreement procedure (Article 5) with regard to LMOs intended for direct use as food or feed, or for processing (“com-

<sup>29</sup> UNEP/CBD/ExCOP/1/3, para. 34.

<sup>30</sup> UNEP/CBD/ExCOP/1/2, para. 22.

<sup>31</sup> UNEP/CBD/BSWG/6/L.2. Corrected versions of this document were issued as UNEP/CBD/BSWG/6/L.2/Corr.1 and UNEP/CBD/BSWG/6/L.2/Rev.1, and a further version as revised by the Legal Drafting Group as UNEP/CBD/BSWG/6/L.2/Rev.2. The latter version was annexed to the report of the BSWG to the Extraordinary Meeting of the Conference of the Parties, see UNEP/CBD/ExCOP/1/2, Annex.

<sup>32</sup> UNEP/CBD/ExCOP/1/2, paras.41-45.

<sup>33</sup> UNEP/CBD/ExCOP/1/2, para. 40 and Annex.

<sup>34</sup> Decision EM-I/1, para. 1.

<sup>35</sup> Decision EM-I/1, para. 3.

<sup>36</sup> Japan, Korea, Mexico, Norway and Switzerland, later joined by Singapore and New Zealand.

<sup>37</sup> The G-77 and China (less the three members in the Miami Group).

<sup>38</sup> Argentina, Australia, Canada, Chile, Uruguay and USA.

<sup>39</sup> Informal consultation on the process to resume the ExCOP to adopt a protocol on Biosafety, 1 July 1999, UNEP/CBD/ExCOP/1/INF/2.

<sup>40</sup> Informal consultation on the process to resume the ExCOP to adopt a protocol on Biosafety, 15-19 September 1999, UNEP/CBD/ExCOP/1/INF/3.

modities”); and the relationship of the protocol with other international agreements (Article 31).<sup>41</sup>

Further informal consultations took place in Montreal immediately before the resumed session of the ExCOP. The informal consultations (22-23 January 2000) and the resumed ExCOP (24-28 January 2000) addressed the outstanding “core” issues – those identified in the Chairman’s non-paper – as well as identification and documentation, and reference to the precautionary principle. Contact groups were established addressing, respectively, scope, commodities, and trade issues (including precaution), and one representative was charged with coordinating consultations on

other outstanding “non-core” issues. As noted above, with the exception of formal plenary sessions, and negotiations in the contact groups and in consultations, the resumed session of the ExCOP was held in the Vienna Setting.

With more than thirty Ministers taking part in the negotiations, the final compromise was reached on the core issues, and the text of the Cartagena Protocol on Biosafety was adopted at 4:50 a.m. on 29 January 2000.<sup>42</sup>

---

<sup>41</sup> “Non-paper” dated 21 December 1999, conveyed to all CBD National Focal Points and to the spokespersons of the five negotiating groups.

<sup>42</sup> The final text of the Protocol was contained in document UNEP/CBD/ExCOP/1/L.5, submitted to the plenary of the ExCOP by the Legal Drafting Group. One further amendment to Article 18(2)(a) was introduced orally by the President, on the basis of final consultations, prior to the adoption of the Protocol. See UNEP/CBD/ExCOP/1/3, paras. 90-92, The text of the Protocol is annexed to decision EM-1/3 adopted by the Conference of the Parties, Decision EM-1/3, para. 1.

### III. TEXT OF THE PROTOCOL

#### Preamble

The Parties to this Protocol,  
*Being* Parties to the Convention on Biological Diversity, hereinafter referred to as “the Convention”,  
*Recalling* Article 19, paragraphs 3 and 4, and Articles 8 (g) and 17 of the Convention,  
*Recalling* also decision II/5 of 17 November 1995 of the Conference of the Parties to the Convention to develop a Protocol on biosafety, specifically focusing on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedures for advance informed agreement,  
*Reaffirming* the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development,  
*Aware* of the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health,  
*Recognising* that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health,  
*Recognising* also the crucial importance to humankind of centres of origin and centres of genetic diversity,  
*Taking* into account the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with living modified organisms,  
*Recognising* that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,

***Emphasising* that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements,  
*Understanding* that the above recital is not intended to subordinate this Protocol to other international agreements,  
Have agreed as follows:**

A number of countries prepared text or submitted views on the preamble prior to BSWG-2.<sup>43</sup> The African group in its draft preambular text introduced several elements that would be reflected in the final text. For example, it referred to Article 8(g) of the Convention, acknowledged the rapid expansion of biotechnology and growing public concern over potential adverse effects, acknowledged the limited capabilities of developing countries to cope with associated risks, and recalled the precautionary principle. The precautionary principle was referred to by Canada, the EU and, implicitly by Norway. The EU also recalled decision II/5 of COP 5 (as did Australia) and referred to Article 19 paragraphs 3 and 4 of the Convention (as did the African group and Norway). Norway noted the advantages and potential of biotechnology but recognised that significant gaps in knowledge had been identified and, along with the African group and the EU, pointed out the threat of significant reduction or loss of biological diversity. The African group also referred to social and economic welfare. On the other hand, Switzerland proposed that the Protocol should only deal with safety issues complementary to existing international instruments, in particular the WTO, and that socio-economic implications of biotechnology be addressed in other frameworks. Both Switzerland and the EU called for a flexible system to amend the Protocol so that it could adapt to appropriate scientific and technical developments.

BSWG-2, however, did not discuss the preamble and it was agreed not to prepare any text at that stage.<sup>44</sup>

At BSWG-3, the Working Group decided that the Chair should prepare a draft preamble on the

<sup>43</sup> UNEP/CBD/BSWG/2/2, pp. 2-7, contains the submissions of the African group, Australia, Canada, the EU, Norway, Switzerland and the US.

<sup>44</sup> UNEP/CBD/BSWG/2/6, para. 166.

basis of government submissions and elements suggested by the Chairman himself, for consideration at the following meeting.<sup>45</sup> The consolidated text at the end of BSWG-3 included three options reproducing in their entirety the submissions of the African group, the EU and Norway respectively.<sup>46</sup>

Prior to BSWG-4, the US submitted further draft text, the focus of which was to base the Protocol on scientific risk assessment whilst avoiding unnecessary delays to bringing the benefits of biotechnology.<sup>47</sup> It also referred to Article 17 of the Convention (Exchange of Information).

At BSWG-4, the preamble was discussed in CG-2 and the draft text was reduced to a short and a long option.<sup>48</sup> The short option included text recognising the value of modern biotechnology and the limited capacity of some countries to deal with its risks. The long version included the main elements of the various proposals and referred to the UNEP Technical Guidelines<sup>49</sup> and to Agenda 21; the precautionary principle; significant gaps in scientific knowledge; capacity building; and adequate compensation for damages arising from the handling and transfer of LMOs. It also called for the avoidance of unnecessary delays, in particular unwarranted administrative requirements, whilst acknowledging public concern over potential adverse effects (including socio-economic effects). As disagreement remained on the level of detail, the Contact Group decided to leave the draft preamble open and subject to further amendment, pending finalisation of the entire text of the Protocol.<sup>50</sup> In addition, there were a number of important issues in relation to which it had not yet been decided whether they should be

the subject of separate articles or instead included in the preamble. These included: socio-economic considerations, capacity-building, public awareness and participation, non-Parties, non-discrimination, and relationship with other conventions.<sup>51</sup>

At BSWG-5, Ambassador Ashe, Co-Chair of CG-2, reiterated the decision to defer any consideration of the preamble until BSWG-6, when an overall general framework of the Protocol would be in place.<sup>52</sup>

During the first discussion of the preamble by CG-2 at BSWG-6, delegates agreed to insert language on the importance of centres of origin and of genetic diversity.<sup>53</sup> A footnote indicating that additional language could be added only if agreed upon by other negotiating groups (including those considering the precautionary principle, socio-economic considerations, and liability and redress) was also added.<sup>54</sup> Both the long and the short options for the Preamble prepared at BSWG-4 were considered, and text from the longer version was later added to the shorter.<sup>55</sup> Although some delegates supported reference to the precautionary principle, socio-economic considerations, and liability and redress, they agreed to allow the sub-groups discussing those issues to decide whether or not to include them in the preamble. The single version that was finally agreed included the precautionary "approach" as contained in the Rio Declaration, while omitting references to socio-economic considerations and liability. The Chair's text<sup>56</sup> contained this language, including references to: Articles 8(g), 17 and 19 of the Convention; decision II/5 of the COP; the precautionary approach; the expansion of biotechnology and growing public concern

<sup>45</sup> UNEP/CBD/BSWG/3/6, para. 84.

<sup>46</sup> *Ibid.*, Annex I, see Preamble.

<sup>47</sup> UNEP/CBD/BSWG/4/3, pp. 1-2.

<sup>48</sup> UNEP/CBD/BSWG/4/4, para. 29; Annex III.

<sup>49</sup> United Nations Environment Programme International Technical Guidelines on Safety in Biotechnology.

<sup>50</sup> UNEP/CBD/BSWG/4/4, para. 29.

<sup>51</sup> See now sections on Articles 26, 22, 23 and 24 below.

<sup>52</sup> UNEP/CBD/BSWG/5/3, para. 52.

<sup>53</sup> ENB Vol. 9 No. 112, p. 2.

<sup>54</sup> *Id.*

<sup>55</sup> ENB Vol. 9 No. 117.

<sup>56</sup> UNEP/CBD/BSWG/6/L.2/Rev.1, see the Preamble.



over potential adverse effects on biodiversity and human health; the potential of biotechnology for human well-being; the importance of centres of origin and genetic diversity; and the limited capabilities of many countries to cope with risks associated with LMOs.

Ms. Kummer (Switzerland), Co-Chair of CG-2, reported the satisfactory conclusion of the work of the Group on the preamble during BSWG-6.<sup>57</sup> However, a significant addition to the text would take place at a later stage. Following the informal consultations that took place in Montreal and Vienna prior to the resumed ExCOP, President Mayr prepared a non-paper which suggested deleting the article on Relationship of the Protocol with other International Agreements (then Article 31), and instead reflecting its content in the preamble.<sup>58</sup> The non-paper proposed that the preamble should note that “there are other

international agreements relevant to sustainable development”, that “trade and environment agreements should be mutually supportive” and that the “Protocol and other international agreements are of equal status”.

There was further discussion on the core cluster of trade issues (Articles 31 and 22 (Non-discrimination)) at the resumed ExCOP. Based on the President’s non-paper, the contact group on Articles 31 and 22 proposed in a working paper that those articles be deleted and their content reflected in three preambular paragraphs.<sup>59</sup> The group then sought to reach agreement on these preambular paragraphs.<sup>60</sup> Following further discussions and high-level consultations,<sup>61</sup> the final text of the Protocol was submitted by the Legal Drafting Group to the plenary and was adopted on 29 January 2000.

---

<sup>57</sup> UNEP/CBD/ExCOP/1/2, para. 31.

<sup>58</sup> Draft Chairman’s Proposal for Addressing the Essential Core Issues of the Scope of the Protocol (Article 4), Application of the Advance Informed Agreement (Article 5) with regard to Living Modified Organisms intended for Direct Use as Food or Feed or for Processing (“Commodities”) and Relationship of the Protocol with Other International Agreements (Article 31). Non-paper dated 21 December 1999.

<sup>59</sup> UNEP/CBD/ExCOP/1/3, para. 63.

<sup>60</sup> *Ibid.*, para. 85.

<sup>61</sup> *Ibid.*, para. 87.

## Article 1: Objective

**In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.**

The first exploratory discussions on the Protocol's objective took place at BSWG-2, with a number of delegations submitting written proposals.<sup>62</sup> The EU suggested language reflecting Decision II/5, which included many of the elements appearing in the final text, namely ensuring an adequate level of protection from LMOs resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biodiversity, specifically focusing on transboundary movement. Norway introduced the term of safe transfer, handling and use of LMOs, while Malaysia made reference to risks to human health, to agriculture and to socio-economic welfare. The African region proposal called for a broader objective to encompass safeguarding human and animal health, the environment, biodiversity and the socio-economic welfare of societies from the potential risks of LMOs and products thereof. The

negotiations revealed a lack of consensus and the issue remained to be revisited at BSWG-3.

BSWG-3 delegates considered government submissions<sup>63</sup> and debated references to human health, socio-economic conditions and 'products thereof'.<sup>64</sup> SWG-II worked on reducing the number of alternatives and developing a framework for the drafting of the article. The framework<sup>65</sup> referred to the need for the Protocol to contain a separate article on objectives, which should: be broad, reflect the language from Decision II/5; and cover all the issues required to protect biodiversity, the environment and human health. References to animal health and social well-being were bracketed. Developing a draft bracketed article did not prove possible, so eight options incorporated government submissions.<sup>66</sup> Most texts included reference to human health, with the exception of that of Australia, while animal health was referred to in the African region and South African proposals, and 'products thereof' in the African and Brazilian proposals. The African and Malaysian proposals also included socio-economic imperatives. The Norwegian and South African texts referred to the principle of sustainable development.

A number of delegations submitted text prior to BSWG-4,<sup>67</sup> and the Chairman's note prepared for BSWG-4<sup>68</sup> synthesised divergent views into six options. At BSWG-4, negotiations in SWG-II did not make significant progress. The main contentious issues included references to: impacts on human and/or animal health, and on socio-economic welfare, and references to capacity building,<sup>69</sup> to the principle of sustainable development, and to 'products thereof'.

<sup>62</sup> UNEP/CBD/BSWG/2/2, pp. 43-44, contains the submissions of the African group, EU, Japan, Norway and Switzerland. The submissions of Cuba and Malaysia are contained in UNEP/CBD/BSWG/2/Inf.6 and Inf.7 respectively.

<sup>63</sup> UNEP/CBD/BSWG/3/5.

<sup>64</sup> UNEP/CBD/BSWG/3/6, paras. 69-73.

<sup>65</sup> UNEP/CBD/BSWG/3/6, p. 32.

<sup>66</sup> *Ibid.*, Annex I, see Article 1. The options reflected the submissions of the African region, Australia, Brazil, EC, Malaysia, Norway, South Africa and Switzerland.

<sup>67</sup> UNEP/CBD/BSWG/4/2 contains the submissions of the African region, Argentina, Bolivia, Chile, Colombia, Guinea, Japan, Malaysia, South Africa, Switzerland and the US.

<sup>68</sup> UNEP/CBD/BSWG/4/Inf.2, p. 2.

<sup>69</sup> As suggested by Colombia, see UNEP/CBD/BSWG/4/2, p. 2.

Reference to the precautionary principle emerged at BSWG-5, when the EC proposed its inclusion.<sup>70</sup> Following negotiations in SWG-II, the result at the end of BSWG-5 was a single bracketed text,<sup>71</sup> with the references to the precautionary principle, 'products thereof', risks to human health and socio-economic imperatives still remaining to be resolved in Article 1, as well as in other parts of the Protocol.<sup>72</sup> Consensus was not reached on whether the Protocol would deal with LMO-related activities other than transboundary movement, while references to animal health and sustainable development were removed.

During BSWG-6, delegates in SWG-II were unable to make further progress. The issue was transferred to a Friends of the Chair group in BSWG-6. The final text<sup>73</sup> may be seen as a compromise between the opposing views. There are thus references to the precautionary 'approach' rather than 'principle', linked to a reference to Principle 15 of the Rio Declaration, and to risks to human health. References to 'products thereof' and 'socio-economic imperatives' were removed. The text then remained unaltered until it was adopted at the resumed ExCOP in January 2000.

---

<sup>70</sup> UNEP/CBD/BSWG/5/2, p. 15.

<sup>71</sup> UNEP/CBD/BSWG/5/3, Annex, see Article 1.

<sup>72</sup> UNEP/CBD/BSWG/6/8, p. 14.

<sup>73</sup> UNEP/CBD/ExCOP/1/2, p. 18.

## Article 2: General Provisions

**1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.**

**2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.**

**3. Nothing in this Protocol shall affect in any way the sovereignty of States over their territorial sea established in accordance with international law, and the sovereign rights and the jurisdiction which States have in their exclusive economic zones and their continental shelves in accordance with international law, and the exercise by ships and aircraft of all States of navigational rights and freedoms as provided for in international law and as reflected in relevant international instruments.**

**4. Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law.**

**5. The Parties are encouraged to take into account, as appropriate, available expertise, instruments and work undertaken in international forums with competence in the area of risks to human health.**

An article on general provisions was included in some, but not all, proposals on the possible contents of the future Protocol,<sup>74</sup> and some written suggestions were submitted prior to BSWG-2.<sup>75</sup> The submissions of the African region and Norway included language on taking appropriate "legal, administrative and other measures to implement and enforce the provisions of this Protocol, including measures to prevent and punish conduct in contravention of the Protocol." These proposals constitute the origin of the first paragraph of the final text. The starting point of the article's second paragraph can be traced to the African region proposal, which however, went further by referencing risks to human and animal health, biological diversity, the environment and socio-economic welfare of societies.<sup>76</sup> Finally, the African region text also included language on Parties imposing additional requirements that are consistent with the Protocol and in accordance with the rules of international law, providing the basis for the fourth paragraph of the final text. BSWG-2 delegates held no discussions on this issue, but agreed to retain it and address it at a later stage.<sup>77</sup>

A number of delegations submitted text for consideration at BSWG-3.<sup>78</sup> The EC's proposal included language on the sovereignty of States over their territorial sea, drawn from Article 4.12 of the Basel Convention on the Control of Transboundary Movement of Hazardous Wastes and their Disposal. This provision remained unaltered in the final text.<sup>79</sup> By the end of the meeting, delegates had agreed to consolidate options submitted by the African region, Australia, Brazil, Colombia, the EC, Norway, South Africa and Switzerland.<sup>80</sup> SWG-II was then requested to define elements or develop legal text.

<sup>74</sup> UNEP/CBD/BSWG/1/4, Annex.

<sup>75</sup> UNEP/CBD/BSWG/2/2, pp. 48-51, contains the submissions of the African region, Norway and Switzerland.

<sup>76</sup> UNEP/CBD/BSWG/2/2, p. 43.

<sup>77</sup> UNEP/CBD/BSWG/2/6, para. 176.

<sup>78</sup> UNEP/CBD/BSWG/3/5 contains the submissions of the African region, Australia, Brazil, Colombia, EC, South Africa and Switzerland.

<sup>79</sup> See Article 2(3).

<sup>80</sup> UNEP/CBD/BSWG/3/6, para. 82, and Annex I, see Article 1bis.

More submissions were received prior to BSWG-4,<sup>81</sup> and Chair Koester consolidated different options to facilitate negotiations.<sup>82</sup> With several delegations calling for brevity, discussions resulted in the retention of four bracketed options,<sup>83</sup> including a zero (no provision) option as suggested by the US.<sup>84</sup>

Prior to BSWG-5, a number of governments submitted their views.<sup>85</sup> Debate in SWG-II focused on the need for such a provision and the level of detail required. The outcome of the discussions at BSWG-5 was a single bracketed option with paragraphs on: implementation measures; cooperation for implementation; prohibition of LMO exports until an AIA is obtained;<sup>86</sup> prevention or reduction of risks to biological diversity; the sovereignty of States over their territorial sea; and the right of a Party to take action that is more protective of biodiversity.<sup>87</sup>

The article on general provisions took its final form in the Chair's proposed text<sup>88</sup> at BSWG-6. The fifth paragraph, on Parties taking into account available expertise in the area of risks to human health, was added as part of a compromise related to the inclusion of a reference to risks to human health in the Protocol's objective. Following revision by the Legal Drafting Group, the title of the provision was changed to "General Provisions."<sup>89</sup> Delegates in the resumed ExCOP addressed the article's fourth paragraph as part of the thematic cluster related to the relationship of the Protocol to other international agreements,<sup>90</sup> and the second paragraph in the context of discussions under Article 18 (Handling, Transport, Packaging and Identification). However, the language remained unaltered and only editorial corrections were made prior to the article's final adoption on 26 January 2000.

---

<sup>81</sup> UNEP/CBD/BSWG/4/2, pp. 3-9 contains the submissions of the African region, Chile, Colombia, Ethiopia, Guinea, India, Japan, South Africa, Switzerland and the US.

<sup>82</sup> UNEP/CBD/BSWG/4/Inf.2, p. 2-8.

<sup>83</sup> UNEP/CBD/BSWG/4/4, Annex II, see Article 1bis.

<sup>84</sup> UNEP/CBD/BSWG/4/2, p. 9.

<sup>85</sup> UNEP/CBD/BSWG/5/2, pp. 16-22 contains the submissions of Ecuador, Kenya, Mexico, New Zealand, Peru, Slovenia, Thailand and Venezuela.

<sup>86</sup> As suggested earlier by the African region, see UNEP/CBD/BSWG/3/5, p. 8.

<sup>87</sup> UNEP/CBD/BSWG/5/3, Annex, Article 1bis.

<sup>88</sup> UNEP/CBD/BSWG/6/L.2, see Article 2.

<sup>89</sup> UNEP/CBD/BSWG/6/L.2/Rev.2, see Article 2.

<sup>90</sup> UNEP/CBD/ExCOP/1/3, para. 33.

## Article 3: Use of Terms

For the purposes of this Protocol:

- (a) 'Conference of the Parties' means the Conference of the Parties to the Convention;
- (b) 'Contained use' means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;
- (c) 'Export' means intentional transboundary movement from one Party to another Party;
- (d) 'Exporter' means any legal or natural person, under the jurisdiction of the Party of export, who arranges for a living modified organism to be exported;
- (e) 'Import' means intentional transboundary movement into one Party from another Party;
- (f) 'Importer' means any legal or natural person, under the jurisdiction of the Party of import, who arranges for a living modified organism to be imported;
- (g) 'Living modified organism' means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;
- (h) 'Living organism' means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;
- (i) 'Modern biotechnology' means the application of:
  - a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
  - b. Fusion of cells beyond the taxonomic family, that overcome natural physiologi-

cal reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

(j) 'Regional economic integration organisation' means an organisation constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Protocol and which has been duly authorised, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it;

(k) 'Transboundary movement' means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties.

The definition of terms was an item included in all proposals on the possible contents of the future Protocol,<sup>91</sup> and discussion started in BSWG-1 with some delegations stressing the need to use definitions found in existing instruments.<sup>92</sup> Following the compilation of such terms by the Secretariat,<sup>93</sup> governments submitted additional definitions contained in national or regional legislation for consideration at BSWG-2.<sup>94</sup> A contact group, chaired by Dr. Gert Willemse (South Africa) and Dr Helen Marquard (United Kingdom), reviewed available definitions in order to recommend action, as delegations had decided that there would be no attempt to define terms at that stage. The contact group recommended preparation of an alphabetical list of terms requiring definition, with country submissions for each, for consideration at BSWG-3. The group stressed that the terms appearing on the list would not necessarily mean that they would need to be defined in the Protocol and that any definitions would need to be developed to reflect their use in the Protocol and the context in which they appeared.<sup>95</sup>

<sup>91</sup> UNEP/CBD/BSWG/1/4, Annex, p. 22.

<sup>92</sup> UNEP/CBD/BSWG/1/4, paras. 74 – 76.

<sup>93</sup> UNEP/CBD/BSWG/2/5.

<sup>94</sup> UNEP/CBD/BSWG/2/2, pp. 8-15 contains the submissions of the African region, Australia, Canada, Cuba, EU, Norway, Switzerland and the US. UNEP/CBD/BSWG/2/Inf.7, pp. 3-5 contains the views of Malaysia.

<sup>95</sup> UNEP/CBD/BSWG/2/6, paras. 161 – 164.

At BSWG-3, the contact group on definitions, now Contact Group 1, resumed its work. CG-1 continued discussions on definitions at BSWG-3 on the basis of the revised compilation of terms<sup>96</sup> and additional country submissions.<sup>97</sup> Delegates identified about thirty terms that would need to be defined as a priority, on the understanding that, in the course of negotiations, the elaboration of other terms might be required.<sup>98</sup> The identified terms at that stage were: accidental release; competent authority; contained use; deliberate release; export and import; exporter; field trial; focal point; illegal traffic; importer; liability; LMO; notification; novel traits; organism; party of export; party of import; party of transit; party concerned; party of origin; potential receiving environment; product; receiving party; transboundary movement; transboundary release; unconfined release; unintended release; and unintended transboundary movement. The African region's suggestion for the definition of an LMO included 'parts thereof',<sup>99</sup> so Contact Group 1 briefly addressed the issue of 'LMOs and products thereof', but noted that it was not within the group's mandate to enter into such a discussion.<sup>100</sup> The Co-Chairs of CG-1 then prepared a draft consolidating suggestions for each term, and delegates bracketed text and proposed further options.<sup>101</sup> This draft was used as the basis for CG-1 deliberations in BSWG-4, while Colombia and the US submitted additional suggestions.<sup>102</sup>

At BSWG-4, CG-1 noted that its deliberations had to be approached from a purely scientific and

technical point of view, in order to provide SWG-I with the least possible number of options.<sup>103</sup> CG-1 worked in collaboration with CG-2, where necessary, regarding the legal questions of definitions, as well as in close contact with SWG-I, which provided comments.<sup>104</sup> CG-1 deliberations resulted in a bracketed list of terms containing: LMO; organism; transboundary movement; export; import; exporter; importer; Party of export; and Party of import.<sup>105</sup> Regarding the definitions of terms relating to export, import and transboundary movement, CG-1 and CG-2 noted that further progress could only be made after the resolution of fundamental issues, such as the Protocol's application to transit or to movements between Parties and non-Parties.<sup>106</sup> For that reason, the bracketed definitions of export and import excluded transit, and references to Parties or States also remained bracketed.<sup>107</sup> CG-1 also addressed the definition of "LMO", considering whether to focus on process or on the result of modification, and deciding to include both in the draft definition.<sup>108</sup>

Further country submissions were received prior to BSWG-5.<sup>109</sup> CG-1 focused on the definition of "LMO", deciding to develop definitions for: LMO; living organism; and modern biotechnology. The definitions were refined following input by SWG-I, while a pending issue was whether modern biotechnology covered cell fusion techniques.<sup>110</sup> The definitions of other terms were forwarded to BSWG-6 as agreed upon at BSWG-4. An informal discussion on 'products thereof' was held in paral-

<sup>96</sup> UNEP/CBD/BSWG/3/Inf.1 is a revised version of UNEP/CBD/BSWG/2/5 containing definitions used in other international agreements as well as in national and regional legislation, and additional definitions as submitted by the African region, Australia, Belarus, Canada, China, Cuba, EU, India, Japan, Malaysia, New Zealand, Norway, Peru and Switzerland.

<sup>97</sup> UNEP/CBD/BSWG/3/5 contains the submissions of the African region, Belarus, Colombia, Malaysia, Mexico, South Africa and Sri Lanka.

<sup>98</sup> UNEP/CBD/BSWG/3/6, para. 92.

<sup>99</sup> UNEP/CBD/BSWG/3/Inf.1, p. 18.

<sup>100</sup> UNEP/CBD/BSWG/3/6, para. 93.

<sup>101</sup> UNEP/CBD/BSWG/3/6, Annex, see Article 2.

<sup>102</sup> UNEP/CBD/BSWG/4/3, pp. 2-5.

<sup>103</sup> UNEP/CBD/BSWG/4/4, para. 22.

<sup>104</sup> UNEP/CBD/BSWG/4/4, para. 27.

<sup>105</sup> UNEP/CBD/BSWG/4/4, Annex IV.

<sup>106</sup> UNEP/CBD/BSWG/4/4, para. 27.

<sup>107</sup> UNEP/CBD/BSWG/4/4, Annex IV.

<sup>108</sup> *Id.*

<sup>109</sup> UNEP/CBD/BSWG/5/2, pp. 22-29, contains the submissions of Ecuador, Japan, Mexico, New Zealand, Panama, Peru, Slovenia, Thailand, the US, Uruguay and Venezuela.

<sup>110</sup> UNEP/CBD/BSWG/5/3, para. 36.

lel, influencing deliberations on the use of terms. The provision was put in brackets, to reflect the fact that the issue of 'products thereof' was still pending.<sup>111</sup> The list of terms forwarded to BSWG-6 contained: LMO; living organism; modern biotechnology; transboundary movement; export; import; exporter; importer; Party of export; and Party of import.<sup>112</sup>

BSWG-6 concluded work on the use of terms, with CG-1 agreeing definitions of "LMO", "living organism", and "modern biotechnology".<sup>113</sup> The term 'contained use' was introduced and CG-1 held discussions on its definition. CG-2 then discussed the definitions of: export; exporter; import; importer; regional economic integration organisation; and transboundary movement. As the issue of transit was involved, these were forwarded to SWG-I. Following resolution of the issue, delegates substituted "Parties" for "States" in the definitions of export, import and transboundary movement. With respect to the definition of "transbound-

ary movement", the Chair's text<sup>114</sup> contained an additional cross-reference to the provisions on: bilateral, regional and multilateral agreements and arrangements; unintentional transboundary movements and emergency measures; and non-Parties (then Articles 11, 14 and 21 respectively).

On 17 February 1999, BSWG-6 provisionally adopted the definitions of exporter, importer, LMO, living organism, modern biotechnology and regional economic integration organisation.<sup>115</sup> During the deliberations of the resumed ExCOP, the reference to the provision on bilateral, regional and multilateral agreements and arrangements under the definition of transboundary movement was excluded. Article 3 was adopted in its final form on 26 January 2000.

---

<sup>111</sup> UNEP/CBD/BSWG/5/3, para. 38.

<sup>112</sup> UNEP/CBD/BSWG/5/3, Annex, see Article 2.

<sup>113</sup> UNEP/CBD/ExCOP/1/2, para. 30.

<sup>114</sup> UNEP/CBD/BSWG/6/L.2, see Article 3(j).

<sup>115</sup> UNEP/CBD/ExCOP/1/2, para. 38.



## Article 4: Scope

**This Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.**

The scope of the Protocol proved to be a highly contentious issue, the debate having been initiated during COP-2, and at the expert meetings held prior to the COP, over the scope of the negotiating mandate of BSWG. The language of decision II/5 was apparently a compromise between the preference of developing countries for a Protocol on biosafety in the field of “safe transfer, handling and use of LMOs” and that of developed countries for a focus on “transboundary transfer of any LMO.”

Following initial discussions in BSWG-1, where the EU suggested the exclusion of LMOs identified as being unlikely to have adverse effects on biodiversity,<sup>116</sup> written proposals were submitted for consideration at BSWG-2.<sup>117</sup> Differences of opinion were apparent: the African proposal included LMOs and ‘products thereof’, while Switzerland favoured a Protocol limited to the intentional transboundary movement of LMOs to be introduced in the environment, excluding contained use and trade in commodities. The EU and Japan called for the exclusion of LMOs unlikely to have adverse effects, while Japan also wished to exclude the transboundary transfer of LMOs covered by other international agreements. The EU and Norway included a reference to risks to human health. Canada suggested that the scope of the Protocol be determined at a later stage.

The issue was not discussed in BSWG-3, although some delegations made submissions.<sup>118</sup> The issue formed part of the mandate of SWG-I, established at BSWG-3. Discussion in BSWG-4 revolved around whether and how the scope of the Protocol as a whole would differ from the scope of application of the AIA procedure. The options contained in the consolidated text<sup>119</sup> at the end of BSWG-4 provided for: no provision on scope; scope equivalent to the scope of the AIA procedure; and bracketed language detailing activities covered and not covered by the Protocol. Regarding the latter option, the transboundary movement of LMOs was covered, with reference to human health, but handling and use were bracketed. A second paragraph excluded LMOs not likely to have adverse effects, requirements for transport operations, transit and movement destined for contained use.

BSWG-5 did not make significant progress. A number of delegations had submitted their views,<sup>120</sup> and SWG-I agreed to work on the option detailing the areas of applicability of the Protocol. At the end of the negotiations in SWG-I, the article on scope had been clarified but major questions remained to be resolved: provisions related to “products thereof”; handling and use of LMOs; reference to human health; socio-economic impacts; and exceptions, with reference to LMOs unlikely to have adverse effects, transport operations, contained use and transit.<sup>121</sup>

Positions were polarised in BSWG-6. SWG-I agreed to delete the bracketed reference to transport operations being excluded from the Protocol’s scope. However, they could not reach consensus on the remaining unresolved issues. Negotiations in the informal groups created to discuss contained use, ‘products thereof’ and human health also failed to reach agreement.

<sup>116</sup> UNEP/CBD/BSWG/1/4, p. 18.

<sup>117</sup> UNEP/CBD/BSWG/2/2, pp. 44-48 contains the submissions of the African region, Canada, EU, Japan, Norway and Switzerland.

<sup>118</sup> UNEP/CBD/BSWG/3/5 contains the submissions of Australia, Brazil, EC, Mexico and Switzerland.

<sup>119</sup> UNEP/CBD/BSWG/4/4, Annex I, see Article 3A.

<sup>120</sup> UNEP/CBD/BSWG/5/2 contains the submissions of Ecuador, Kenya, New Zealand, Peru, Slovenia, Thailand and Venezuela.

<sup>121</sup> UNEP/CBD/BSWG/5/3, para. 31; and Annex, see Article 3A; UNEP/CBD/BSWG/6/8, Annotated Draft Negotiating Text of a Protocol on Biosafety, see Article 4. See also section on Article 5 below.

The Chair's proposed text attempted to draft compromise language.<sup>122</sup> The Chair's text presented to the BSWG retained references to handling and use, as well as to human health, while omitting the references to 'products thereof' and socio-economic well-being. A general statement was introduced into the paragraph on exceptions, to preserve the right of Parties to subject all LMOs to risk assessment prior to decisions on import. The exceptions included transboundary movements of LMOs unlikely to have adverse effects, and of LMOs which are pharmaceuticals for humans. Transit and contained use were covered in certain articles only. On February 19, the Chair's text was reviewed by the Friends of the Chair group, as well as by informal and regional groups, which expressed general dissatisfaction. It became apparent that the issue of scope could stall finalisation of the Protocol. At Minister Mayr's initiative, a Friends of the Minister group continued negotiations on February 20, without however reaching agreement. The text was not altered, and with a minor adjustment made by the Legal Drafting Group, was submitted for the consideration of the ExCOP.<sup>123</sup> Following the suspension of the ExCOP, negotiations on the issue continued in the informal consultations ahead of the resumption of the ExCOP.

According to the Chairman's summary of the Vienna informal consultations,<sup>124</sup> the negotiating groups retained their initial positions. Most groups could accept the text as it stood, apart from the Like-Minded Group, which then proposed a single paragraph which provided for the Protocol to apply to the transboundary movement, transit and handling and use of all LMOs that may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health. Exceptions would

then be addressed under specific articles.<sup>125</sup> Since most groups needed time to examine the proposal, consultations did not progress any further. Suggested texts were incorporated into Chair Mayr's non-paper in December 1999, to assist the negotiation progress.

During the Montreal consultations before the resumption of the ExCOP in January 2000, a contact group was created specifically to address the issue of scope.<sup>126</sup> The Like-Minded Group reiterated its position of retaining a comprehensive provision to cover all LMOs and addressing exceptions under other articles. Other groups preferred to retain the text from Cartagena.<sup>127</sup> A small group was established to address exceptions and to develop language on scope. On January 23, one day before the beginning of the resumed ExCOP, the group came up with an agreed single paragraph to address all LMOs, although reference to transit was still bracketed. New articles were drafted to address exceptions.

Negotiations in the contact group on scope, chaired by Mr. John Herity (Canada) continued during the resumed ExCOP. As the negotiation progressed the contact group on commodities (see section on Article 11) and on scope were merged under the joint chairmanship of Mr. Herity and Mr. François Pythoud (Switzerland).<sup>128</sup> Delegates finally agreed to a provision addressing the transboundary movement, transit, handling and use of all LMOs that may have adverse effects on the conservation and sustainable use of biodiversity, taking also into account risks to human health. Following this agreement, the negotiations focused mainly on the new draft articles on pharmaceuticals, transit and contained use.<sup>129</sup> Article 4 on scope was adopted with the rest of the Protocol on 29 January 2000.

<sup>122</sup> UNEP/CBD/BSWG/6/L.2, see Article 4.

<sup>123</sup> UNEP/CBD/ExCOP/1/2, Appendix I, see Article 4.

<sup>124</sup> UNEP/CBD/ExCOP/1/INF/3, p. 4.

<sup>125</sup> UNEP/CBD/ExCOP/1/INF/3, Informal consultations on Biosafety Protocol, Vienna 15-19 September 1999, Chairman's Summary, p.5.

<sup>126</sup> UNEP/CBD/ExCOP/1/3, para. 12.

<sup>127</sup> UNEP/CBD/ExCOP/1/2, Appendix I, see Article 4.

<sup>128</sup> UNEP/CBD/ExCOP/1/3, para. 53.

<sup>129</sup> UNEP/CBD/ExCOP/1/3 pp. 26, 28-29 and 31. See sections on Articles 5 and 6 below.

## Article 5: Pharmaceuticals

**Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to the making of decisions on import, this Protocol shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organisations.**

Discussion on pharmaceuticals started at BSWG-5, during the debate on scope (see section on Article 4). A footnote was then inserted into the bracketed paragraph on the areas of non-applicability of the Protocol which included “LMOs which are pharmaceuticals for humans” in the annex of LMOs unlikely to have adverse effects,<sup>130</sup> and consequently exclude them from the Protocol’s scope. On 15 February 1999, during SWG-I negotiations at BSWG-6, the footnote was replaced with a reference in the text of the article, excluding the “transboundary movements of LMOs that are pharmaceuticals for humans.” The Chair’s text<sup>131</sup> produced at BSWG-6, also excluded from the scope of the Protocol transboundary movements of LMOs that are pharmaceuticals for humans.

The creation of a separate article on pharmaceuticals originated from the proposal of the Like-Minded Group presented during the Vienna informal consultations, to have a comprehensive provision on scope to cover all LMOs and address the exceptions in other articles.<sup>132</sup> This group suggested including language in the article on the application of the AIA procedure,<sup>133</sup> allowing the Party of import to decide not to apply the AIA procedure to LMOs that are pharmaceuticals for human use.

When the consultations continued in Montreal, it became clear that a compromise would be difficult to reach. The negotiating groups had opposing views: the Miami Group expressed the view that pharmaceuticals would not have adverse effects on biodiversity, while the EU noted other international bodies that could cover future developments. On the other hand, the Like-Minded Group did not wish to exclude pharmaceuticals. In an attempt to reconcile these views, the contact group on scope at the resumed ExCOP drafted language on 23 January 2000, exempting the transboundary movement of pharmaceuticals for humans, without prejudicing the rights of Parties to subject all LMOs to a risk assessment prior to a decision on import.

The issue was finally resolved during the resumed ExCOP following negotiations in the contact group on scope and intense informal consultations.<sup>134</sup> While some delegations noted that the World Health Organisation would be the competent forum to deal with the issue of LMOs that are pharmaceuticals for humans, the Like-Minded Group expressed concern regarding developments in pharmaceutical applications, such as gene-therapy, for which no other standards or institutional provisions existed. While the Chair of the contact group on scope continued informal discussions to explore flexibility on the issue, it was suggested that the exemption should be qualified by limiting the exemption to LMOs that are covered by other international agreements and organisations or that would not be intentionally introduced into the environment. These provisions remained in brackets. The first of these suggestions was included in the final text adopted on 29 January 2000.

<sup>130</sup> UNEP/CBD/BSWG/5/3, Annex, see Article 3A, footnotes; see also Appendix I to this document on ‘Deleted Draft Articles’.

<sup>131</sup> UNEP/CBD/BSWG/6/L.2, see Article 4(c).

<sup>132</sup> UNEP/CBD/ExCOP/1/INF/3, Informal consultations on Biosafety Protocol, Vienna 15-19 September 1999, Chairman’s Summary, p.5.

<sup>133</sup> See section on Article 7 below.

<sup>134</sup> UNEP/CBD/ExCOP/1/3 paras. 28, 45, 51 and 61.

## Article 6: Transit and contained use

**1. Notwithstanding Article 4 and without prejudice to any right of a Party of transit to regulate the transport of living modified organisms through its territory and make available to the Biosafety Clearing-House, any decision of that Party, subject to Article 2, paragraph 3, regarding the transit through its territory of a specific living modified organism, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to living modified organisms in transit.**

**2. Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import.**

### Article 6(1): Transit

At BSWG-2 initial discussions were held on transit together with the issues of handling, transport and packaging.<sup>135</sup> By the end of BSWG-2, realising its complexity, delegations agreed to treat the question of transit of LMOs separately.<sup>136</sup> The debate started in BSWG-3, at which the EC's submission proposed excluding transit from the Protocol's scope.<sup>137</sup>

Diverging views became apparent at BSWG-4. CG-1 and CG-2 considered that the issue of whether the Protocol should apply to LMOs in transit was one of the fundamental questions to be resolved in order for the negotiations to progress.<sup>138</sup> The issue was incorporated into the discussions on scope,<sup>139</sup> application of the AIA procedure, and notification, during BSWG-4, 5 and 6.

In the Chair's proposed text at BSWG-6,<sup>140</sup> transit was excluded from the scope of the Protocol, except as regards the provisions on Parties' general obligations (Article 2), unintentional transboundary movements and emergency measures (then Article 14), and handling, transport, packaging and identification (then Article 15). The Miami Group questioned the latter reference<sup>141</sup> and, in the general disagreement over the scope of the Protocol, the issue of transit remained pending.

According to the Like-Minded Group's proposal, submitted at the Vienna informal consultations in September 1999, transit of LMOs would have been included in the scope of the Protocol<sup>142</sup> and notification of transit of LMOs would have been required. The issue remained under negotiation during the Montreal informal consultations. While the contact group on scope agreed on a comprehensive provision to address all LMOs, reference to transit under the provision on scope remained bracketed and discussion started on the development of a new provision. Requirements for advance notification and necessary documentation for transit also caused intense disagreement.

Following extensive discussions in the contact group on scope during the resumed ExCOP, as well as informal consultations, delegations agreed to include LMOs in transit in the Protocol's scope. They also started drafting a new provision to address the issue. On 26 January 2000, the contact group was presented with a text based on infor-

<sup>135</sup> UNEP/CBD/BSWG/2/6, paras. 145-149.

<sup>136</sup> UNEP/CBD/BSWG/2/6, Annex II, Item I.

<sup>137</sup> UNEP/CBD/BSWG/3/5.

<sup>138</sup> UNEP/CBD/BSWG/4/4, para. 27.

<sup>139</sup> UNEP/CBD/BSWG/4/4, Annex I, see Articles 3A, 3B and 4.

<sup>140</sup> UNEP/CBD/BSWG/6/L.2, see Article 4.

<sup>141</sup> UNEP/CBD/ExCOP/1/3, Annex III, p. 17.

<sup>142</sup> See section on Article 4 above.

mal consultations, which suggested that the AIA procedure would not apply to LMOs in transit. The text was accepted. The final issue to be resolved was the right of a State to regulate LMOs in transit through its territory. Following resolution of this issue, the provision was adopted on 29 January 2000.

### Article 6(2): Contained Use

Early discussions during BSWG-2 indicated the complex nature of this issue, as Canada, the EU, Norway and Switzerland suggested excluding LMOs destined for contained use from the Protocol's scope, while most developing country delegations supported inclusion of all intended uses.<sup>143</sup> At BSWG-3, Norway proposed language on minimum national regulations for biosafety,<sup>144</sup> including the development of an annex on national measures applied to contained use. This proposal was withdrawn during BSWG-6. Norway maintained however that the Protocol should include a provision to ensure that Parties guaranteed safety in the contained use of LMOs.<sup>145</sup>

Following negotiations at BSWG-4, language proposed, but not agreed, on scope and on the application of the AIA procedure, excluded contained use.<sup>146</sup> At the beginning of BSWG-6, Chair Koester identified contained use as one of the key issues requiring resolution, as there seemed to be no point of agreement. SWG-I held lively discussions on whether LMOs destined for contained use should be excluded from the AIA procedure.<sup>147</sup> Many developing country delegations stressed that LMOs in containment should be subject to the same provisions as other LMOs, while other delegations argued that such transboundary movements should not be covered by the AIA

procedure, or even that LMOs destined for contained use should be outside the scope of the Protocol. Discussion continued in an informal group, co-chaired by Australia and Peru, but did not progress further than crystallising the three positions noted above. The lack of an agreed definition of contained use, in light of the fact that discussion in the contact group on definitions were still continuing, further complicated discussions.<sup>148</sup>

At BSWG-6, in the Chair's proposed text,<sup>149</sup> LMOs destined for contained use were not covered by the AIA procedure. They were only partially covered by the Protocol's scope, with reference to the provisions on general obligations of Parties (Article 2), unintentional transboundary movements and emergency measures (then Article 14), handling, transport, packaging and identification (then Article 15), and some paragraphs of Article 17 on information-sharing and the Biosafety Clearing-House.<sup>150</sup> The Like-Minded Group expressed its concern,<sup>151</sup> calling for the inclusion of LMOs destined for contained use in the Protocol's scope and in the AIA procedure. In its proposal submitted during the Vienna informal consultations, the Like Minded Group suggested that, while the scope of the Protocol should cover all LMOs, the Party of import could decide not to apply the AIA procedure to LMOs destined for research in contained use.<sup>152</sup>

As discussions on the issue continued during the resumed ExCOP, both informally and in the contact group on scope, delegations reached general agreement on scope and on 25 January 2000, started exploring options for dealing with contained use. On 26 January, new Article 6 was presented. The provision was adopted on 29 January 2000.

<sup>143</sup> UNEP/CBD/BSWG/2/6, paras. 33-34.

<sup>144</sup> UNEP/CBD/BSWG/3/5.

<sup>145</sup> UNEP/CBD/ExCOP/1/2, para. 24.

<sup>146</sup> UNEP/CBD/BSWG/4/4, Annex I, see Article 3B.

<sup>147</sup> See section on Article 7 below.

<sup>148</sup> See section on Article 3 above.

<sup>149</sup> UNEP/CBD/BSWG/6/L.2, see Article 5.

<sup>150</sup> *Ibid.*, see Article 4(b).

<sup>151</sup> UNEP/CBD/ExCOP/1/3, Annex IV.

<sup>152</sup> UNEP/CBD/ExCOP/1/INF/3, Informal Consultation on Biosafety Protocol, Vienna 15 – 19 September 1999, Chairman's Summary, p.5.

## Article 7: Application of the Advance Informed Agreement Procedure

**1. Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.**

**2. 'Intentional introduction into the environment' in paragraph 1 above, does not refer to living modified organisms intended for direct use as food or feed, or for processing.**

**3. Article 11 shall apply prior to the first transboundary movement of living modified organisms intended for direct use as food or feed, or for processing.**

**4. The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.**

An advance informed agreement procedure was identified as a priority consensus element in the meeting of the Open-ended Ad Hoc Group of Experts on Biosafety before COP 2 in 1995.<sup>153</sup> The scope of the AIA procedure was addressed at BSWG-1.<sup>154</sup> Switzerland, supported by New Zea-

land and the US, suggested that the AIA procedure should apply only to the first transboundary movement of LMOs intended for use in the environment, while notification would be sufficient for subsequent movements. Following remarks by Australia and the EU, delegations also had initial discussions on the categorisation of LMOs according to the degree of potential risk to biodiversity and the relevance of such categorisation to the application of the AIA procedure.

A more extensive debate took place at BSWG-2<sup>155</sup> and BSWG-3, on the basis of country submissions.<sup>156</sup> As discussion focused on the two above issues, most developing countries expressed the view that the AIA procedure should apply to all movements, initial and subsequent, while Brazil, Norway and the US, among others, suggested a simpler procedure for subsequent movements. During BSWG-3, SWG-I prepared an elements paper,<sup>157</sup> drawing from country submissions. The paper compiled options for elements of the scope of the application of the AIA procedure. It was suggested that the procedure cover: all LMOs; all first time transboundary movements of LMOs; all LMOs except those explicitly excluded and exempted; and specific LMOs based on detailed criteria or on criteria listed in an annex. A further option left it to the discretion of the importing State as to whether the exporter should apply national regulations or the Protocol. Chair Koester streamlined these options for BSWG-4,<sup>158</sup> where discussions focused on: the scope of AIA in relation to the scope of the Protocol; the application of the AIA procedure only to specific categories of LMOs; its application to LMOs in transit or destined for contained use; the exemption of low-risk LMOs and the type of agreement required for this exemption.

<sup>153</sup> UNEP/CBD/COP/2/7, Annex I, para 18(a).

<sup>154</sup> UNEP/CBD/BSWG/1/4, paras. 39-43.

<sup>155</sup> UNEP/CBD/BSWG/2/6, paras. 23-72.

<sup>156</sup> UNEP/CBD/BSWG/2/2, pp. 15-28 contains the submissions of the African region, Australia, Canada, Japan, Norway and the US. UNEP/CBD/BSWG/3/3 contains the submissions of the African region, Belarus, Brazil, Colombia, Cuba, EC, India, Japan, Madagascar, Malaysia, Mexico, Norway, Peru, South Africa, Sri Lanka, Switzerland and the US.

<sup>157</sup> UNEP/CBD/BSWG/3/6, para. 85; and Annex I, see Article 3.

<sup>158</sup> UNEP/CBD/BSWG/4/Inf.1, pp. 2-4.

By the end of BSWG-4, it was agreed to draft separate provisions on the scope of the Protocol and on the application of the AIA procedure. Discussions resulted in four options for the application of the AIA procedure.<sup>159</sup> These covered: all LMOs defined in the Protocol; the first movement of an LMO unless an exemption was provided for; specific categories of LMOs listed within the article; or LMOs covered by criteria listed in an annex.

During BSWG-5, a drafting group produced a single bracketed option for consideration by SWG-I: This text contained a detailed paragraph on LMOs to be covered by the AIA (positive list) and another on exemptions (negative list). Although some delegations commented on the two draft paragraphs' contradictory approaches and called for their consolidation, the group could not agree on whether to include a positive or a negative list, so both paragraphs were retained.<sup>160</sup> Discussion then focused on the application of the AIA procedure to transit and contained use, and the scope of exemptions in general. The issue of whether the AIA would apply to all transboundary movements of LMOs or only the first transboundary movement also remained unresolved. A number of footnotes indicated the remaining pending issues.<sup>161</sup>

As a result, the bracketed text submitted to BSWG-6 contained two paragraphs, the first detailing the categories of LMOs to which AIA would apply and the second addressing the exemptions from the AIA procedure. Regarding the first paragraph, the issue of whether AIA would apply to the first or to all transboundary movements, and the inclusion of 'products thereof,' remained bracketed. LMOs covered by the AIA procedure were those

intended for field testing or deliberate release in the Party of import, those banned in the Party of export and those destined for contained use. Categories to be excluded from the AIA procedure were: LMOs in transit; those exempted under the domestic regulatory framework; those destined for contained use; those identified in a decision of the Meeting of the Parties as not likely to have adverse effects on biodiversity;<sup>162</sup> and, under conditions, those destined for placing on the market of the Party of import.<sup>163</sup>

The application of the AIA procedure to commodities caused intense debate during and following BSWG-6.<sup>164</sup> Some developed countries argued that LMOs intended for human or animal consumption would not pose a significant threat to biodiversity and called for their exclusion, while many developing countries advocated application of the AIA procedure to all LMOs, stressing the possibility of accidental releases. On 17 February 1999, delegations agreed that the AIA procedure would apply to the first transboundary movement of an LMO. However, the issue of commodities remained unresolved. According to the Chair's proposed text at BSWG-6, the AIA procedure would cover the first transboundary movement of LMOs "destined for growth, reproduction and propagation in the environment."<sup>165</sup> It would not apply to LMOs not likely to have adverse effects on biodiversity, taking into account risks to human health, as identified in a decision of the MOP, nor to LMOs destined for placing on the market in the Party of import under certain conditions. Parties could, under domestic law, require procedures consistent with the AIA procedure for other LMOs.<sup>166</sup> This latter provision implied that

<sup>159</sup> UNEP/CBD/BSWG/4/4, Annex I, see Article 3B.

<sup>160</sup> UNEP/CBD/BSWG/5/3, Annex, see Article 3B.

<sup>161</sup> UNEP/CBD/BSWG/5/3, para. 31, and Annex, see Article 3B.

<sup>162</sup> The possibility for the Meeting of the Parties to the Protocol to exclude LMOs from the application of the AIA originated from language proposed by Japan., see UNEP/CBD/BSWG/3/3, p. 6. The concept remained in the final text. It should be noted that during the negotiations frequent references were made to future decisions by the 'Meeting of the Parties' or the 'Conference of the Parties' to the Protocol. As discussions on what became Article 29 of the Protocol progressed, these references were amended to refer to the 'Conference of the Parties, serving as the Meeting of the Parties to this Protocol.' This is commonly abbreviated to "COP/MOP". See section on Article 29 below.

<sup>163</sup> UNEP/CBD/BSWG/6/2, pp. 7-9.

<sup>164</sup> The treatment of commodities in relation with the AIA procedure had implications for several provisions of the Protocol. See Background above, and section on Article 11 below.

<sup>165</sup> UNEP/CBD/BSWG/6/L.2, see Article 5.

<sup>166</sup> UNEP/CBD/BSWG/6/L.2, See Article 5.

commodities could be covered by AIA procedures under national legislation. In the revised version of the document containing the Chair's text, the phrase "growth reproduction and propagation in the environment" was replaced by "intentional introduction into the environment." It was specified that this term did not refer to "LMOs intended for direct use as food or feed, or for processing" (LMO-FFPs), the phrase used thereafter to refer to commodities.<sup>167</sup>

Following review by the Friends of the Chair, as well as regional and informal groups, the provision remained under negotiation in the Friends of the Minister group, the most difficult issue remaining whether or not the AIA procedure would apply to commodities.

Delegations reacted to the Chair's proposed text as revised by the Legal Drafting Group on 22 February.<sup>168</sup> The issue of the application of the AIA procedure to LMO-FFPs remained a core focus of discussion in the first session of the ExCOP. The various negotiating groups put forward different proposals for addressing the issue. The Like-Minded Group proposed subjecting the first transboundary movement of all LMOs to AIA, but allowing Parties of import not to apply AIA to LMO-FFPs.<sup>169</sup> The Miami Group supported the Chair's text on this issue,<sup>170</sup> and the EU proposed that the first meeting of the Parties to the Protocol should decide how the AIA procedure should apply to LMO-FFPs.<sup>171</sup>

The application of the AIA procedure to commodities remained one of the core pending issues at the suspension of the first session of the ExCOP, and was further examined during the Vienna informal consultations, when the Compromise Group presented a concept paper to facilitate discussion on developing an alternative procedure for commodities.<sup>172</sup> It was proposed that reference to this alternative procedure in the provision on the application of the AIA procedure would replace the reference to domestic legislation. All groups found the proposal constructive and agreed to consider it,<sup>173</sup> with the Like-Minded Group insisting on a procedure as robust as the AIA procedure. This proposal created the basis for developing a separate provision on LMO-FFPs.<sup>174</sup> Negotiations continued in Montreal, both informally and during the resumed ExCOP, where a contact group, chaired by Mr. François Pythoud (Switzerland) discussed as a cluster the issues of the application of the AIA procedure, development of an alternative procedure for commodities, and the provision on handling, transport, packaging and identification. As the provision on the application of the AIA procedure depended on resolution of the debate on LMO-FFPs,<sup>175</sup> the text of Article 7 was finalised in parallel with Article 11 on a procedure for LMO-FFPs. Therefore, the final text of Article 7, which excludes LMO-FFPs from the application of AIA, referencing Article 11, was adopted on 29 January 2000.

---

<sup>167</sup> UNEP/CBD/BSWG/6/L.2/Rev.1, see Article 5.

<sup>168</sup> UNEP/CBD/ExCOP/1/2, para. 40.

<sup>169</sup> UNEP/CBD/ExCOP/1/3, Annex IV.

<sup>170</sup> UNEP/CBD/ExCOP/1/3, Annex III.

<sup>171</sup> UNEP/CBD/ExCOP/1/3, Annex II.

<sup>172</sup> UNEP/CBD/ExCOP/1/INF/3, Informal Consultations on Biosafety Protocol, Vienna, 15-19 September 1999, Chairman's Summary, p. 3.

<sup>173</sup> *Id.*

<sup>174</sup> See now Article 11.

<sup>175</sup> See section on Article 11 below.



## Article 8: Notification

**1. The Party of export shall notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1. The notification shall contain, at a minimum, the information specified in Annex I.**

**2. The Party of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter.**

Following a general discussion of the AIA procedure at BSWG-1,<sup>176</sup> the African region submitted to BSWG-2 a detailed text on the notification procedure prior to a transboundary movement of LMOs.<sup>177</sup> Part of the first paragraph of the African proposal required the State of export to notify, or require the exporter to notify by application in writing through the channel of the competent authority of the State of export, the competent authority of the States concerned and the Biosafety Clearing-House, of any proposed transboundary transfer of LMOs or products thereof. Such applications were to contain the declarations and information to be specified in Annex I to the Protocol. Elements of the final text can be recognised in this early proposal. BSWG-2 delegates discussed who should trigger the notification procedure: the Party of export, the exporter or the receiving entity in the Party of import.<sup>178</sup>

Several written proposals were submitted to BSWG-3.<sup>179</sup> India's submission included language on notification to the Clearing House, as well as on the requirement for the accuracy of information provided by the exporter, while Canada, whose proposal favoured notification by the importer to the Party of import, suggested that each Party make its importers responsible for the accuracy of provided information. The options resulting from both the written submissions and the discussion were consolidated for consideration by BSWG-4.<sup>180</sup> The Chairman's note for BSWG-4<sup>181</sup> further organised these options. The primary issue of whether the exporter or the importer would trigger the notification procedure was still to be resolved.

BSWG-4 discussions in SWG-I revolved mainly around the issue of who should trigger the notification procedure. The questions of who should bear the responsibility for accuracy of the provided information, and whether the required information should be specified in an Annex or in a list to be established by the meeting of the Parties, also provoked some debate. The outcome was a consolidated bracketed text merging different options. On the requirement for accuracy of information, the zero (no provision) option was retained.<sup>182</sup> Discussions on the content of the required information were held in parallel in CG-1.<sup>183</sup>

BSWG-5 did not make significant progress on this issue. Some governments submitted views<sup>184</sup> and discussions took place in SWG-I, while CG-2 addressed the question of how other international agreements referred to the issue of triggering notification.

<sup>176</sup> UNEP/CBD/BSWG/1/4, paras. 39-43.

<sup>177</sup> UNEP/CBD/BSWG/2/2, p. 53. The document also contains the submissions of the EU, Japan and Norway on notification. UNEP/CBD/BSWG/2/Inf.7, pp. 7-8 contains the submission of Malaysia.

<sup>178</sup> UNEP/CBD/BSWG/2/6, paras. 62-65.

<sup>179</sup> UNEP/CBD/BSWG/3/3, pp. 8-15, contains the submissions of the African Group, Australia, Belarus, Brazil, Canada, Colombia, Cuba, EC, India, Japan, Madagascar, Malaysia, Norway, Peru, South Africa, Sri Lanka, Switzerland, and the US.

<sup>180</sup> UNEP/CBD/BSWG/3/6, Annex I, see Articles 4, 5, 6, and 7.

<sup>181</sup> UNEP/CBD/BSWG/4/Inf.1, pp. 4-5.

<sup>182</sup> UNEP/CBD/BSWG/4/4, Annex I, see Article 4.

<sup>183</sup> See section on Annex I below.

<sup>184</sup> UNEP/CBD/BSWG/5/2 contains the submissions of Ecuador, New Zealand, Peru, Thailand, US, Uruguay, and Venezuela.

Many delegations in SWG-I expressed the view that responsibility for notification should fall on the exporter, or that the Party of export should ensure that the exporter notified the Party of import. Since others still preferred placing responsibility on the importer, no agreement was reached. The question of responsibility for the accuracy of information was not resolved either. The requirement to notify the Biosafety Clearing-House, which was deleted in BSWG-4, was also re-introduced. By the end of the session, delegates deleted the zero (no provision) option regarding responsibility for accuracy of information, and agreed that notification should include, at a minimum, the information specified in Annex I to the Protocol. The rest of the provision remained bracketed to reflect the different options.<sup>185</sup>

BSWG-6 discussions mainly revolved around the question of notification to the Biosafety Clearing-House, which was finally excluded, and the requirement for accuracy of information. As the issue was not resolved in SWG-I, consultation continued in the Friends of the Chair group. The Chair's text produced at BSWG-6 contained compromise language on the issue.<sup>186</sup> The text of the provision then remained unaltered until its adoption on 29 January 2000.

## Notification of transit

The issue of notifying transit countries arose in BSWG-3, with a number of delegations submitting text for a separate provision on notification of transit.<sup>187</sup> Some governments had also included related language in their proposals on notification.<sup>188</sup>

The options were consolidated for BSWG-4,<sup>189</sup> while the US suggested that no provision on notification of transit was necessary.<sup>190</sup> During the debate, other delegations also viewed the provision as unnecessary, while others suggested text requiring the Party of export to obtain consent from Party and non-Party transit States. Both the zero (no provision) option and text providing for notification to the transit State, acknowledgement of notification and documentation for LMOs in transit, were retained in the consolidated text at the end of BSWG-4.<sup>191</sup>

Further views were submitted to BSWG-5.<sup>192</sup> Delegations debated deleting the provision, but most developing countries objected to this option. Following discussions in SWG-I and work in a drafting group, delegations finally agreed to deletion of this provision, on the basis that these elements could be adequately addressed under the provisions on notification, acknowledgement of receipt of notification, decision procedure for AIA, handling, transport and packaging, and liability and compensation.<sup>193</sup>

Following the deletion of the provision, a debate on notification of transit was held under the general provision on notification in BSWG-6, resulting in its final exclusion.<sup>194</sup>

<sup>185</sup> UNEP/CBD/BSWG/5/3, Annex, see Article 4.

<sup>186</sup> UNEP/CBD/BSWG/6/L.2, see Article 6.

<sup>187</sup> UNEP/CBD/BSWG/3/3, pp. 23-25, contains the submissions of Australia, Brazil, Mexico, Peru, Malaysia and Norway.

<sup>188</sup> UNEP/CBD/BSWG/3/3, pp. 8-13. The submissions of the African group and India proposed a reference to "States concerned"; while Colombia and Peru included specific reference to Parties or countries of transit.

<sup>189</sup> UNEP/CBD/BSWG/3/6, Annex I, see Article 8.

<sup>190</sup> UNEP/CBD/BSWG/4/3, p. 9.

<sup>191</sup> UNEP/CBD/BSWG/4/4, Annex I, see Article 8.

<sup>192</sup> UNEP/CBD/BSWG/5/2, pp. 47-49, contains the submissions of Ecuador, New Zealand, Peru, Slovenia, Thailand and Venezuela.

<sup>193</sup> UNEP/CBD/BSWG/5/3, para. 32, and Annex, see Article 8.

<sup>194</sup> UNEP/CBD/ExCOP/1/2, para. 39.

## Article 9: Acknowledgement of Receipt of Notification

**1. The Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt.**

**2. The acknowledgement shall state:**

**(a) The date of receipt of the notification;**  
**(b) Whether the notification, prima facie, contains the information referred to in Article 8;**

**(c) Whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in Article 10.**

**3. The domestic regulatory framework referred to in paragraph 2 (c) above, shall be consistent with this Protocol.**

**4. A failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an intentional transboundary movement.**

The time limit for the response of the importing country and the consequences of a failure to acknowledge receipt were the major contentious issues under this provision. Discussions on the issue of the time limit started in BSWG-2, although there was no clear distinction at the time between acknowledgement of receipt of notification and response, including decision, of the importing Party.<sup>195</sup> While some noted the importance of time limits, most developing country delegations were opposed to prescriptive time limits after which implicit consent might be assumed, while some agreed to consider an indicative time period for the acknowledgement of receipt of notification.<sup>196</sup>

On the basis of written submissions,<sup>197</sup> BSWG-3 consolidated different options for elements of the AIA procedure as a whole. Elements identified as relevant to the acknowledgement of receipt of notification<sup>198</sup> included: its time frame, information to be given to the notifier, and consequences of a failure to respond in a specified time frame. These options were further organised in the Chairman's note prepared for BSWG-4.<sup>199</sup> The note contained: a zero (no provision) option, as suggested by some developing countries; an option with language on acknowledgement of receipt, which would include confirmation that the notification contains *prima facie* the information required for notification,<sup>200</sup> the date of receipt,<sup>201</sup> advice on carrying out a risk assessment and/or a request for further information where necessary; an option with language on review of the content of the request in a specific time period; and language on informing the notifier to proceed according to the AIA procedure or the domestic regulatory framework, provided that this included a control mechanism consistent with the Protocol. All references to time frames remained open and bracketed.

Discussions in BSWG-4 revolved around the same issues, with several delegations still opposing a precise time period for responding to notification. The zero option was retained and the remaining suggestions were consolidated into a single option.<sup>202</sup> The text mainly addressed acknowledgement of receipt, but also included language on informing the notifier about proceeding with or without written consent, which would later be introduced into the provision on decision procedure.<sup>203</sup> On the consequences of a failure to acknowledge receipt, some developing countries supported text stating that failure to acknowledge receipt would not result in any consequences, nor would it imply consent to a transboundary

<sup>195</sup> See also section on Article 10 below.

<sup>196</sup> UNEP/CBD/BSWG/2/6, paras. 56 - 58.

<sup>197</sup> UNEP/CBD/BSWG/3/3, pp. 19-23 contains the submissions of Australia, Belarus, Brazil, Canada, Colombia, EC, Japan, Malaysia, Norway, South Africa, Sri Lanka, Switzerland and the US. UNEP/CBD/BSWG/3/3/Add.1 contains the submission of Madagascar.

<sup>198</sup> UNEP/CBD/BSWG/3/6, Annex I, see Article 5.

<sup>199</sup> UNEP/CBD/BSWG/4/Inf.1, p. 6.

<sup>200</sup> As suggested by Canada, see UNEP/CBD/BSWG/3/3, p. 19.

<sup>201</sup> As suggested by Japan, see UNEP/CBD/BSWG/3/3, p. 21.

<sup>202</sup> UNEP/CBD/BSWG/4/4, Annex I, see Article 5.

<sup>203</sup> See section on Article 10 below.

movement. Similar language had been suggested earlier by Belarus<sup>204</sup> and Switzerland.<sup>205</sup>

Following submission of new government proposals<sup>206</sup> and some discussion at BSWG-5 on the need for the provision, delegations in SWG-I agreed to delete the zero option.<sup>207</sup> Debate focused on the time frame: with several delegations calling for acknowledgement of receipt within 30 days, and others preferring reference to a “reasonable” period of time, the group finally double-bracketed a compromise option of 90 days. Delegations then agreed that the acknowledgement should state the date of receipt of the notification and whether the notification, *prima facie*, contained the information specified under the provision on notification, as well as agreeing that failure to acknowledge receipt upon notification would not

imply consent. Regarding the requirement for the acknowledgement to state whether to proceed according to the AIA procedure or the domestic regulatory framework, delegations debated moving this to the provision on the decision procedure, but ultimately retained and bracketed the reference. The debate continued at BSWG-6, where delegations agreed to keep such language. The remaining outstanding issue of the time limit was also resolved at BSWG-6. Delegations agreed to the previously bracketed 90 day time frame and the provision was adopted with the rest of the Protocol on 29 January 2000.

---

<sup>204</sup> UNEP/CBD/BSWG/3/3, p. 19.

<sup>205</sup> UNEP/CBD/BSWG/3/3, p. 23.

<sup>206</sup> UNEP/CBD/BSWG/5/2, pp. 34-36, contains the submissions of Ecuador, New Zealand, Peru, Slovenia, Thailand and Venezuela.

<sup>207</sup> UNEP/CBD/BSWG/5/3, Annex, see Article 5.

## Article 10: Decision Procedure

1. Decisions taken by the Party of import shall be in accordance with Article 15.

2. The Party of import shall, within the period of time referred to in Article 9, inform the notifier, in writing, whether the intentional transboundary movement may proceed:

(a) Only after the Party of import has given its written consent; or

(b) After no less than ninety days without a subsequent written consent.

3. Within two hundred and seventy days of the date of receipt of notification, the Party of import shall communicate, in writing, to the notifier and to the Biosafety Clearing-House the decision referred to in paragraph 2 (a) above:

(a) Approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism;

(b) Prohibiting the import;

(c) Requesting additional relevant information in accordance with its domestic regulatory framework or Annex I; in calculating the time within which the Party of import is to respond, the number of days it has to wait for additional relevant information shall not be taken into account; or

(d) Informing the notifier that the period specified in this paragraph is extended by a defined period of time.

4. Except in a case in which consent is unconditional, a decision under paragraph 3 above, shall set out the reasons on which it is based.

5. A failure by the Party of import to communicate its decision within two hundred and seventy days of the date of receipt of the notification shall not imply its consent to an intentional transboundary movement.

6. Lack of scientific certainty due to insuff-

icient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimise such potential adverse effects.

7. The Conference of the Parties serving as the meeting of the Parties shall, at its first meeting, decide upon appropriate procedures and mechanisms to facilitate decision-making by Parties of import.

The AIA procedure is at the core of the Protocol, and its importance was reflected in a long and complex negotiation process. The time limit for communication of the decision of the importing Party, the consequences of a failure to communicate a decision, as well as the inclusion of the precautionary principle in the article on the decision procedure caused lengthy debates.

The AIA procedure was identified as a consensus element in the Madrid report<sup>208</sup> before COP2 and in decision II/5. BSWG-1 discussed it as a priority,<sup>209</sup> noting procedures set out in other international instruments as well as the differentiated capacity of countries to carry out risk assessment and risk management. Some delegations submitted their general views on the AIA procedure for consideration at BSWG-2.<sup>210</sup> At that meeting, a debate was initiated on the time limit for the response of the importing Party and the consequences of a failure to communicate a decision.<sup>211</sup> Many developing country delegations opposed time limits for a decision and the interpretation of a failure to communicate a decision as implicit consent, stressing capacity constraints. Norway proposed a 90-day time limit;<sup>212</sup> the US preferred a specified period to

<sup>208</sup> UNEP/CBD/COP/2/7, Annex I, para 18(a).

<sup>209</sup> UNEP/CBD/BSWG/1/4, paras. 39 - 43.

<sup>210</sup> UNEP/CBD/BSWG/2/2, pp. 15-28, contains the submissions of the African region, Australia, Canada, Japan, Norway and the US.

<sup>211</sup> UNEP/CBD/BSWG/2/6, Annex II, Item A. See also section on Article 9 above.

<sup>212</sup> UNEP/CBD/BSWG/2/2, p. 54.

respond, after which consent would be deemed to have been given.<sup>213</sup> The EU and Japan suggested flexible time limits depending on various factors, such as the need for further information.<sup>214</sup> Delegations also discussed the range of possible actions to be taken by the importing Party following notification, outlining prohibition of the import, approval with or without conditions, and request for further information. Proposed elements were presented in the Chairman's summary of elements.<sup>215</sup>

Following an invitation for new submissions to BSWG-3,<sup>216</sup> a number of delegations submitted their views.<sup>217</sup> During the meeting, a drafting group consolidated the different options for approval by SWG-I.<sup>218</sup> Elements relevant to this article in its final form were outlined under provisions on response to notification and on the decision by the Party of import. Chair Koester organised the different options further, with a view to reducing them for BSWG-4.<sup>219</sup> The draft provision on response to AIA notification contained options on interim response, time period for decision, and extension of this time period. The draft provision on decision by the Party of import contained options on the basis and content of the decision, on information to be included in the decision, and on the obligations of the Party of export. This note was the basis for the negotiations in BSWG-4, while Colombia and the US submitted additional written proposals.<sup>220</sup>

During BSWG-4, discussion in SWG-I focused on the time limit for the decision, as well as on its basis, with several delegations supporting reference to scientific evidence, risk assessment and socio-economic imperatives. On the time limit, most developing country delegations opposed implicit consent to a transboundary movement in the case of a failure to meet the time limit. The outcome<sup>221</sup> of discussions in SWG-I at BSWG-4 included bracketed paragraphs on: the basis of the decision; informing the notifier whether to proceed with or without written consent; cooperation among Parties with a view to deciding when a transboundary movement could not proceed without an explicit consent; informing the notifier whether the notification contained *prima facie* the required information;<sup>222</sup> the time period for the decision of the Party; notifying approval, prohibition, or request for additional information; treatment of and notification for subsequent imports; extension of the time period; prohibition of an import when the provided information was not sufficient, with reference to the precautionary principle;<sup>223</sup> authorisation of the receiving Party for all transboundary movements; stating reasons for prohibiting a movement, imposing conditions or requesting additional information; and three options on the consequences of a failure to respond.

Further proposals were submitted prior to BSWG-5<sup>224</sup> and, although delegates held long discussions both in SWG-1 and in a drafting group,

<sup>213</sup> UNEP/CBD/BSWG/2/2, p. 27.

<sup>214</sup> UNEP/CBD/BSWG/2/6, Annex II, Item A.

<sup>215</sup> *Id.*

<sup>216</sup> UNEP/CBD/BSWG/2/6, p. 33.

<sup>217</sup> UNEP/CBD/BSWG/3/3, pp. 15-23 contains the submissions of the African group, Australia, Belarus, Brazil, Colombia, India, Madagascar, Malaysia, Mexico, Norway, Peru, South Africa, Sri Lanka, Switzerland and the US regarding the decision procedure; and the submissions of Australia, Belarus, Brazil, Canada, Colombia, EC, Japan, Malaysia, Norway, South Africa, Sri Lanka, Switzerland and the US regarding the response to AIA notification. UNEP/CBD/BSWG/3/3/Add.1, p.2 contains the submission of Madagascar.

<sup>218</sup> UNEP/CBD/BSWG/3/6, Annex I, see Articles 4, 5, 6 and 7.

<sup>219</sup> UNEP/CBD/BSWG/4/Inf.1, pp. 8-10.

<sup>220</sup> UNEP/CBD/BSWG/4/3, pp. 6-9.

<sup>221</sup> UNEP/CBD/BSWG/4/4, Annex I, see Article 6.

<sup>222</sup> See now Article 9(2)(b).

<sup>223</sup> South Africa (UNEP/CBD/BSWG/3/3, p. 14) and Norway (*ibid.*, p. 17) had suggested similar language with no explicit reference, however, to the precautionary principle. Such reference emerged during BSWG-4 discussions.

<sup>224</sup> UNEP/CBD/BSWG/5/2, pp. 36-41, contains the submissions of Ecuador, Kenya, New Zealand, Peru, Slovenia, Thailand and Venezuela.

SWG-1 Co-Chair Schoonejans (France) reported at the end of the meeting that the provision had been consolidated, but still required further consideration.<sup>225</sup> Topics of debate included: whether or not to replace the language on the basis of the decision with reference to the provision on risk assessment; the time limit for communication of the decision, with some favouring 90 days from the acknowledgement of receipt and many developing country delegations supporting reference to a reasonable time period; and the consequences of a failure to respond, particularly regarding a provision stating that the Party of export would then have no obligations under the Protocol. The provision remained largely bracketed.

Negotiations at BSWG-6 centred on the issues of time limits and implicit consent as a result of a failure to communicate a decision. Delegations debated the options of a 180 or 270 days time limit, or “a reasonable period of time” from the date of receipt of notification. An informal group addressed the issue, eliminating the open reference to a reasonable period of time, but unable to decide between the two remaining options. Following discussions in SWG-I and informal consultations, the Chair’s proposed text at BSWG-6,<sup>226</sup> opted for the time limit of 270 days as the time limit for communication of the decision. Implicit consent in case of a failure to communicate a decision was excluded.<sup>227</sup> The draft article also contained a provision which would not appear in the final text: a paragraph on cooperation among the Parties with a view to deciding to what extent and in which cases, a transboundary movement could not proceed without explicit consent.<sup>228</sup>

There were also differences in the provision on decision-making in the case of lack of scientific certainty,<sup>229</sup> which stated that lack of full scientific certainty or of scientific consensus to determine the potential adverse effects of an LMO, would not prevent the Party of import from prohibiting the import of the LMO in question. With these two major differences, as well as some linguistic and editorial amendments, and with the reference to the precautionary principle emerging as a highly controversial issue, the text of the draft article remained under negotiation at the end of BSWG and the first session of the Ex-COP.

The precautionary principle was not addressed as a separate issue in the Vienna informal consultations in September 1999.<sup>230</sup> At the resumed ExCOP, the Compromise Group suggested that the issue of the precautionary principle in the decision procedure should be considered in the thematic cluster of trade-related issues.<sup>231</sup> On the other hand, the Like-Minded Group proposed its separate treatment.<sup>232</sup> The contact group on trade-related issues initially did not consider precaution, and on 26 January 2000 the Miami Group reiterated the need to address the issue.<sup>233</sup> The Miami Group representative suggested deleting the reference under the provision on decision making, arguing that it was superfluous and was expressed differently from Principle 15 of the Rio Declaration.<sup>234</sup>

On 27 January, the President of the ExCOP called for comments on the provision, in the light of the work of the contact group on trade-related issues. The Miami Group reiterated its position on deletion,<sup>235</sup> while the EU and the Compromise

<sup>225</sup> UNEP/CBD/BSWG/5/3, para. 31.

<sup>226</sup> UNEP/CBD/BSWG/6/L.2, see Article 8.

<sup>227</sup> *Ibid.*, see Article 8(5).

<sup>228</sup> UNEP/CBD/ExCOP/1/2, see Article 8(b).

<sup>229</sup> *Ibid.*, see Article 8(7).

<sup>230</sup> Informal Consultations on Biosafety Protocol, Vienna 15 - 19 September 1999, Chairman’s Summary, UNEP/CBD/ExCOP/1/INF3, p.5.

<sup>231</sup> UNEP/CBD/ExCOP/1/3, para 36.

<sup>232</sup> *Ibid.*, para. 38.

<sup>233</sup> *Ibid.*, para. 55.

<sup>234</sup> UNEP/CBD/ExCOP/1/3, para 66.

<sup>235</sup> *Ibid.*, para. 76.

Group called for finding appropriate wording.<sup>236</sup> The CEE and the Like-Minded Group stated they could accept the wording on precaution in the article on the decision procedure (then Article 8(7)) as it stood at that time.<sup>237</sup> President Mayr then extended the mandate of the contact group on trade-related issues, chaired by Ambassador Yang (Cameroon), to include the provision under consideration. The contact group held extensive discussions, co-chaired by Ambassador Yang and Mr François Pythoud (Switzerland). Delegations reached the final compromise language on

what is now Article 10(6), following the informal consultations held on Friday, 28 January. At the same time, delegations also agreed to delete the provision on cooperation with a view to deciding when a transboundary movement could not proceed without explicit consent (then Article 8(6)). The article took its final form and was adopted on 29 January 2000.

---

<sup>236</sup> *Ibid.*, paras. 77-78.

<sup>237</sup> UNEP/CBD/ExCOP/1/2, paras. 79-80.



## Article 11: Procedure for Living Modified Organisms Intended for Direct Use as Food or Feed, or for Processing

1. A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House. This information shall contain, at a minimum, the information specified in Annex II. The Party shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House. This provision shall not apply to decisions regarding field trials.

2. The Party making a decision under paragraph 1 above, shall ensure that there is a legal requirement for the accuracy of information provided by the applicant.

3. Any Party may request additional information from the authority identified in paragraph (b) of Annex II.

4. A Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.

5. Each Party shall make available to the Biosafety Clearing-House copies of any national laws, regulations and guidelines applicable to the import of living modified organisms intended for direct use as food or feed, or for processing, if available.

6. A developing country Party or a Party with an economy in transition may, in the absence of the domestic regulatory framework referred to in paragraph 4

above, and in exercise of its domestic jurisdiction, declare through the Biosafety Clearing-House that its decision prior to the first import of a living modified organism intended for direct use as food or feed, or for processing, on which information has been provided under paragraph 1 above, will be taken according to the following:

(a) A risk assessment undertaken in accordance with Annex III; and

(b) A decision made within a predictable timeframe, not exceeding two hundred and seventy days.

7. Failure by a Party to communicate its decision according to paragraph 6 above, shall not imply its consent or refusal to the import of a living modified organism intended for direct use as food or feed, or for processing, unless otherwise specified by the Party.

8. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimise such potential adverse effects.

9. A Party may indicate its needs for financial and technical assistance and capacity-building with respect to living modified organisms intended for direct use as food or feed, or for processing. Parties shall cooperate to meet these needs in accordance with Articles 22 and 28.

The treatment of LMO-FFPs was one of the most controversial issues throughout the negotiation process, with implications for several provisions of the Protocol.<sup>238</sup> The term LMO-FFPs only came

<sup>238</sup> See sections on Articles 4, 7, 18, 20 and Annex II.

into usage towards the end of BSWG-6.<sup>239</sup> Until that point, discussions on this issue generally referred to commodities. Following initial discussion over whether LMO-FFPs would be included within the scope of the Protocol,<sup>240</sup> which resulted in a comprehensive provision addressing all LMOs, debate focused on whether LMO-FFPs would be subject to the AIA procedure.<sup>241</sup> Article 11 reflects the outcome of these negotiations.

An early debate in BSWG-2 revolved around the preparation of a report by the Secretariat on the scale of commodity transactions involving LMOs. After the suggestion of Canada and the US that the Secretariat prepare such a study, the G-77 and China called for four other studies, on the socio-economic implications of biotechnology, and on the impacts of LMOs on animals, fisheries and indigenous farming. No studies were prepared, but two roundtables on commodities and on socio-economic implications of biotechnology were organised at BSWG-3.

Delegations began specifically addressing the treatment of commodities in more detail during BSWG-6, when an informal group was formed to address the issue. The Secretariat had identified this as one of the topics requiring resolution under the provision on scope.<sup>242</sup> The informal group focused on the applicability of the AIA procedure. Delegations discussed the obligations of the exporting Party and methods for making information available, on the basis of a Canadian non-paper, which recommended that Parties share information about domestic approvals of LMO-FFPs. Another proposal, presented by the SWG-I Co-Chairs, suggested potential differentiation in the level of risk between LMOs intended

for deliberate release and LMO-FFPs. While some delegations supported such differentiation, arguing that LMO-FFPs did not pose significant threat to biodiversity, many developing country delegations suggested instead that the AIA procedure should apply to all LMOs, and stress the possibility of accidental release and planting in the environment. SWG-I forwarded all options to BSWG Chair Koester.

The Chair's proposed text<sup>243</sup> subjected LMOs destined for "growth, reproduction and propagation in the environment" to the AIA procedure. It provided that Parties might, under domestic law, require procedures consistent with the AIA procedure for other LMOs, implying that such domestic procedures could cover LMO-FFPs. The revised Chair's text<sup>244</sup> stated that the AIA procedure would apply prior to the first intentional transboundary movement of LMOs for intentional introduction into the environment of the Party of import and explicitly excluded LMO-FFPs from the AIA procedure. The possibility for Parties to require procedures consistent with AIA for other LMOs remained. The issue of the application of the AIA procedure to LMO-FFPs remained a core focus of discussion in the first session of the ExCOP. The various negotiating groups put forward different proposals for addressing the issue. The Like-Minded Group proposed subjecting the first transboundary movement of all LMOs to AIA, but allowing Parties of import not to apply AIA to LMO-FFPs.<sup>245</sup> The Miami Group supported the Chair's text on this issue,<sup>246</sup> and the EU proposed that the first meeting of the Parties to the Protocol should decide how the AIA procedure should apply to LMO-FFPs.<sup>247</sup>

<sup>239</sup> The term first appears in the revised Chair's text: UNEP/CBD/BSWG/6/L.2/Rev.1, see Article 5(2).

<sup>240</sup> See section on Article 4 above.

<sup>241</sup> See section on Article 7.

<sup>242</sup> UNEP/CBD/BSWG/6/8, p. 2.

<sup>243</sup> UNEP/CBD/BSWG/6/L.2, see Article 5.

<sup>244</sup> UNEP/CBD/BSWG/6/L.2/Rev.1, see Article 5.

<sup>245</sup> UNEP/CBD/ExCOP/1/3, Annex IV

<sup>246</sup> UNEP/CBD/ExCOP/1/3, Annex III.

<sup>247</sup> UNEP/CBD/ExCOP/1/3, Annex II.

The application of the AIA procedure to commodities was further examined during the Vienna informal consultations. All negotiating groups presented their positions and outlined major components of the issue, reiterating a general acceptance that commodities should be included in the scope of the Protocol. The Compromise Group then presented a concept paper to facilitate discussion aimed at developing an alternative procedure for commodities.<sup>248</sup> All groups found the proposal constructive and agreed to consider it, so a small contact group was established to agree on a set of alternative provisions for LMO-FFPs. The results of the contact group's work were contained in the Chairman's Summary of the Vienna meeting<sup>249</sup>

President Mayr's non-paper in December 1999, consolidating these concepts and intended to facilitate resumed negotiations in Montreal in January 2000, included draft text on an alternative procedure for LMO-FFPs, as well as a new draft annex on information required for LMO-FFPs.<sup>250</sup> This text provided the basis for the final language of Article 11. It contained three paragraphs addressing:

- Provision of information by Parties to the Biosafety Clearing-House and, if requested by a Party, to its national focal point, on domestic approvals and decisions for placing on the market of an LMO-FFP, containing, at a minimum, the information to be specified in an Annex;
- Declarations by Parties through the Biosafety Clearing-House, or in writing to the national focal point of the Party which has provided the information, within 90 days from the date the information has been provided, that the import of the LMO-FFP is subject to domestic legal, administrative and other measures, or that the Party will take a decision regarding such import in accordance with the provisions of the Protocol; requests for additional

information; or indications of its needs for technical assistance and cooperation;

- Proceeding with the transboundary movement of the LMO-FFP to all Parties, which had not reacted according to the above provisions in 270 days from the communication to the BCH or the national focal point.

In the run-up to the resumed ExCOP, the issue of commodities was one of the core pending issues. The informal consultations prior to the meeting were held on the basis of the draft text of the Protocol<sup>251</sup> and ExCOP President Mayr's December 1999 non-paper. While the Miami Group expressed general satisfaction with the draft text in the non-paper, the Like-Minded Group called for a procedure as robust as the AIA procedure and re-stated its concern over the issue of implicit consent. The Compromise Group also noted that failure to respond should not imply consent. A contact group on commodities was established<sup>252</sup> on 23 January 2000. Its chair Mr. François Pythoud (Switzerland) submitted a new draft of a procedure for LMO-FFPs and a new annex on required information. The draft included separate paragraphs on additional information, as well as financial and technical assistance and capacity building. As the basis for the decision on importing an LMO-FFP would be the domestic regulatory system, delegations held extensive discussions on how to address the situation of Parties that had no regulatory system in place, and, in particular, whether specific procedures should be set out in the Protocol, or whether the emphasis should be on capacity building and collaboration between countries.<sup>253</sup>

On 25 January 2000, the contact group on commodities started considering the draft text paragraph by paragraph. The reference to domestic legal, administrative and other measures was replaced by a reference to the domestic regulatory framework. Delegations then debated a ref-

<sup>248</sup> UNEP/CBD/ExCOP/1/INF/3, p. 3.

<sup>249</sup> *Id.*

<sup>250</sup> See now Annex II.

<sup>251</sup> UNEP/CBD/ExCOP/1/2.

<sup>252</sup> UNEP/CBD/ExCOP/1/3, para. 12.

<sup>253</sup> UNEP/CBD/ExCOP/1/3, para. 27.

erence to the need for the domestic framework to be consistent either with the Protocol or its objective, as well as the possibility for merging the provisions on Parties that did and those that did not have a domestic regulatory framework.

The contact group co-chair<sup>254</sup> reported on 27 January 2000 that some of the pending issues on commodities might not be resolved in the contact group but would be submitted to the plenary. A key outstanding issue was the treatment of LMO-FFPs in the article on handling, transport, packaging and identification (then Article 15).<sup>255</sup> The posi-

tion of the article in the Protocol also had to be decided,<sup>256</sup> on the basis of a suggestion by the EU to place it after the AIA procedure. The outcome of these consultations is reflected in the final text, adopted on 29 January 2000.

---

<sup>254</sup> Following the combination of the contact groups on scope and commodities.

<sup>255</sup> See section on Article 18 below.

<sup>256</sup> UNEP/CBD/ExCOP/1/3, para. 74.

## Article 12: Review of Decisions

**1. A Party of import may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a decision regarding an intentional transboundary movement. In such case, the Party shall, within thirty days, inform any notifier that has previously notified movements of the living modified organism referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.**

**2. A Party of export or a notifier may request the Party of import to review a decision it has made in respect of it under Article 10 where the Party of export or the notifier considers that:**

**(a) A change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based; or**

**(b) Additional relevant scientific or technical information has become available.**

**3. The Party of import shall respond in writing to such a request within ninety days and set out the reasons for its decision.**

**4. The Party of import may, at its discretion, require a risk assessment for subsequent imports.**

Discussions on this issue began at BSWG-2, when Australia suggested addressing whether an exporter could request review of a decision of the importing country.<sup>257</sup> In the discussion that followed, Norway proposed that the Party of import could review its decision and that an exporter should be able to ask for review, on the basis of new information. Many delegations noted that the importing Party had a right to modify a consent on the basis of new information, and suggested communication of such a change, as well as its reasons, to the notifier. Others suggested joint review by the importing and the exporting Party.<sup>258</sup>

A number of countries submitted written proposals to BSWG-3,<sup>259</sup> and the different options were consolidated.<sup>260</sup> The Australian<sup>261</sup> and the Brazilian<sup>262</sup> proposals included language allowing exporting Parties to request review of import decisions in cases of changes in circumstances that might influence the outcome of the risk assessment, or of additional relevant scientific or technical information. Furthermore, the above proposals included language on the response, in writing, of the Party of import, within a reasonable period of time.<sup>263</sup>

Chair Koester consolidated the options for BSWG-4.<sup>264</sup> Delegations identified two main issues: conditions upon which the Party of import could review its decision; and conditions upon which a Party of export could request a review. The outcome included bracketed language on: prohibition of a transboundary movement by the Party of import in light of new information; notification

<sup>257</sup> UNEP/CBD/BSWG/2/2, p. 21.

<sup>258</sup> UNEP/CBD/BSWG/2/6, paras. 66-70, and Annex II, see Item A.

<sup>259</sup> UNEP/CBD/BSWG/3/3, pp. 25-26, contains the submissions of the African group, Australia, Brazil, Malaysia, Peru, South Africa and Sri Lanka.

<sup>260</sup> UNEP/CBD/BSWG/3/6, Annex I, see Articles 4, 5, 6 and 7.

<sup>261</sup> UNEP/CBD/BSWG/3/3, p. 25.

<sup>262</sup> UNEP/CBD/BSWG/3/3, p. 26.

<sup>263</sup> See now Article 12(3).

<sup>264</sup> UNEP/CBD/BSWG/4/Inf.1, pp. 10-11.

of such a decision to the notifiers or the Parties concerned and to the Secretariat or the Biosafety Clearing-House within 15 or 30 days; requests by a Party of export for review of an import decision on the basis of a change of circumstances or additional information or evidence that the decision had not been based on scientific, socio-economic, cultural or the precautionary principles; supply of additional information by exporting Parties if relevant to the review of the import decision; and the importing Party's right to unilaterally review its decision.<sup>265</sup>

Some delegations submitted further textual proposals to BSWG-5.<sup>266</sup> In SWG-I, delegations identified the review of decision by the Party of import in light of new scientific information as a central issue, and a drafting group consolidated related language.<sup>267</sup> Debate then focused on bracketed text allowing for review of the decision by the Party of import in the case of reasonable evidence that the decision had not been based on scientific, socio-economic, cultural or the precautionary principles and supported by the best available scientific evidence,<sup>268</sup> as well as the timeframe for response of the Party of import to a request for review by a Party of export. Delegations finally bracketed options for response within "a reasonable period of time" and "90 days". Following discussion on risk assessment for subsequent imports, delegations produced bracketed text referencing the cases of change in the LMO's intended use, variation in the receiving environment, change in the import volume resulting in increase of risk, condition of the first import and other relevant factors likely to affect the risk assessment.<sup>269</sup>

During BSWG-6, delegations in SWG-I concentrated on negotiating language on risk assessments for subsequent imports, and on whether a Party of export or a notifier could request review of an import decision. No agreement was reached and the text was forwarded to the Chair without amendment. The Chair's proposed text<sup>270</sup> incorporated all the elements of the final text of the provision. The possibility for review in cases where there was reasonable evidence that the decision had not been based on a scientific, socio-economic or cultural basis or the precautionary principles was deleted. Detailed language on the conditions of a risk assessment for subsequent imports was also deleted and this possibility was left to the discretion of the Party of import.<sup>271</sup> During the ExCOP, the Miami Group suggested removing the reference to risk assessment for subsequent imports,<sup>272</sup> however the reference was retained. A number of editorial changes were made and the final text was adopted on 29 January 2000.<sup>273</sup>

<sup>265</sup> UNEP/CBD/BSWG/4/4, Annex I, see Article 7.

<sup>266</sup> UNEP/CBD/BSWG/5/2, pp. 43-45, contains the submissions of Ecuador, New Zealand, Peru, Slovenia, Thailand and Venezuela.

<sup>267</sup> UNEP/CBD/BSWG/5/3, Annex, see Article 7.

<sup>268</sup> Australia had suggested that exporting Parties might request review when there was reasonable evidence that the decision had not been based on scientific principles and supported by the best available scientific evidence. See UNEP/CBD/BSWG/3/3, p. 25. At BSWG-4, bracketed references were added to socio-economic, cultural or the precautionary principles.

<sup>269</sup> UNEP/CBD/BSWG/5/3, Annex, see Article 7.

<sup>270</sup> UNEP/CBD/BSWG/6/L.2, see Article 9.

<sup>271</sup> See now Article 12(4).

<sup>272</sup> UNEP/CBD/ExCOP/1/3, Annex III.

<sup>273</sup> UNEP/CBD/ExCOP/1/3, p. 48.

## Article 13: Simplified Procedure

**1. A Party of import may, provided that adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms in accordance with the objective of this Protocol, specify in advance to the Biosafety Clearing-House:**

**(a) Cases in which intentional transboundary movement to it may take place at the same time as the movement is notified to the Party of import; and**

**(b) Imports of living modified organisms to it to be exempted from the advance informed agreement procedure.**

**Notifications under subparagraph (a) above, may apply to subsequent similar movements to the same Party.**

**2. The information relating to an intentional transboundary movement that is to be provided in the notifications referred to in paragraph 1 (a) above, shall be the information specified in Annex I.**

The first discussions on this issue were held at BSWG-2. Some delegations suggested a provision permitting a unilateral or bilateral deviation from the AIA procedure through the use of a simplified procedure.<sup>274</sup> It was also noted that such a procedure was to be understood as a way of simplifying the requirements for an agreement, not as eliminating them.

Some written proposals were submitted for consideration at BSWG-3.<sup>275</sup> The proposal by the EC included elements that would be incorporated into the final text. It proposed: that a Party of import might specify in advance to other Parties cases for which the intentional transboundary movement could take place at the same time as the movement was notified to the Party of import; that such notifications might apply to subsequent similar movements to the same Party; and that the information to be provided in the notification was specified in Annex I. However, there was no substantive discussion, and different options, including a zero (no provision) option, were consolidated into the report of the meeting.<sup>276</sup>

BSWG-4 delegates held discussions on the basis of a note prepared by Chair Koester, which further consolidated different options.<sup>277</sup> BSWG-4 retained the bracketed text, including the zero option.<sup>278</sup>

Following the submission of several written proposals,<sup>279</sup> BSWG-5 delegates discussed the possibility of deleting the article and including its elements in other provisions, such as that on the application with the AIA procedure, without reaching agreement. The article was retained with brackets and with a note that it could be deleted in the future, depending on the outcome of the negotiations on the application of the AIA procedure.<sup>280</sup> It contained all the elements that appear in the final text, with the additional reference to the best available scientific knowledge and other relevant information as the basis for the implementation of the simplified procedure, as well as a

<sup>274</sup> UNEP/CBD/BSWG/2/6, paras. 59-60.

<sup>275</sup> UNEP/CBD/BSWG/3/3, pp. 27-28, contains the submissions of the African group, EC, India, Japan, Norway and South Africa.

<sup>276</sup> UNEP/CBD/BSWG/3/6, Annex I, see Article 9.

<sup>277</sup> UNEP/CBD/BSWG/4/Inf.1, pp. 13-14.

<sup>278</sup> UNEP/CBD/BSWG/4/4, Annex I, see Article 9.

<sup>279</sup> UNEP/CBD/BSWG/5/2, pp. 51-52, contains the submissions of Ecuador, New Zealand, Peru, Slovenia, Thailand and Venezuela.

<sup>280</sup> UNEP/CBD/BSWG/5/3, Annex, see Article 9, footnote 23.

requirement for a Party of import to give reasons for selecting a simplified procedure.<sup>281</sup>

The debate on whether or not to delete the provision continued briefly in SWG-I during BSWG-6. Some delegations argued that the article was unnecessary; others noted that all LMOs should be subject to the AIA procedure; and others called for its retention. Accordingly it was agreed to transmit the text to Chair Koester without modifications, but with the brackets removed. The Chair's proposed text<sup>282</sup> retained most elements, but removed the reference to the best available

scientific knowledge, as well as the requirement for the Party of import to give reasons for selecting the simplified procedure.<sup>283</sup>

Although the Miami Group suggested the deletion of this article at the ExCOP,<sup>284</sup> the provision was retained and, with some editorial changes and rearrangements of text, it was adopted on 29 January 2000.

---

<sup>281</sup> *Ibid.*

<sup>282</sup> UNEP/CBD/BSWG/6/L.2, see Article 10.

<sup>283</sup> UNEP/CBD/BSWG/6/8, p. 31.

<sup>284</sup> UNEP/CBD/ExCOP/1/3, Annex III.



## Article 14: Bilateral, Regional and Multilateral Agreements and Arrangements

**1. Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms, consistent with the objective of this Protocol and provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the Protocol.**

**2. The Parties shall inform each other, through the Biosafety Clearing-House, of any such bilateral, regional and multilateral agreements and arrangements that they have entered into before or after the date of entry into force of this Protocol.**

**3. The provisions of this Protocol shall not affect intentional transboundary movements that take place pursuant to such agreements and arrangements as between the parties to those agreements or arrangements.**

**4. Any Party may determine that its domestic regulations shall apply with respect to specific imports to it and shall notify the Biosafety Clearing-House of its decision.**

The list of possible contents of the Protocol prepared at BSWG-1 included "mechanisms for bilateral agreements."<sup>285</sup> Japan submitted draft text on this issue for BSWG-2.<sup>286</sup> This proposed that Parties could enter into bilateral, multilateral or regional agreements with Parties or non-Parties regarding transboundary transfer of LMOs falling under the scope of the Protocol when such agreements did not derogate from the necessary risk management required by the Convention. It further proposed that the contents of such agreements should be notified to the Secretariat.

BSWG-2 considered bilateral agreements in relation to a number of cross-cutting issues, in particular unilateral and bilateral derogations to the general AIA procedures which would later result in the provision for a "simplified procedure."<sup>287</sup>

Most of the elements of the final text of the provision were introduced through written proposals on bilateral and regional agreements submitted by a number of countries for consideration by BSWG-3.<sup>288</sup>

The texts from Australia, the EC and Switzerland supported Japan's previous proposal that Parties might enter into bilateral, regional or multilateral agreements or arrangements and notify the Secretariat of any such agreement entered into before or after the entry into force of the Protocol. However, the texts differed with regard to the conditions for entering into such agreements. Australia proposed that such agreements should provide for adequate measures to ensure the safe transboundary movement of LMOs in accordance with the objectives of the Protocol. The EC proposed the requirement that such agreements should not result in a "lower level of protection than the one provided for by the Protocol". Switzerland proposed the requirement that such arrangements should not derogate from the environmentally sound management of LMOs as required under the Protocol.

The US proposed language to allow Parties to enter into bilateral or multilateral agreements or arrangements in respect of requirements governing the import and export of LMOs, in place of the AIA procedure. The US also proposed that a Party could notify the Secretariat at any time that the AIA procedure would not apply with respect to its imports of LMOs.

The submission of the African group addressed international cooperation to assist developing countries in the implementation of the Protocol and proposed that Parties could enter into bilat-

<sup>285</sup> UNEP/CBD/BSWG/1/4, Annex.

<sup>286</sup> UNEP/CBD/BSWG/2/2, pp. 67.

<sup>287</sup> UNEP/CBD/BSWG/2/6, paras. 59-60. See also section on Article 13.

<sup>288</sup> UNEP/CBD/BSWG/3/3, pp. 33-34, contains the submissions of the African group, Australia, EC, Switzerland and the US.

eral or multilateral agreements or arrangements for this purpose. These concerns would later be taken up under the consideration of capacity-building.<sup>289</sup>

The draft text developed by SWG-I at BSWG-3 included all the above elements, with the exception of the second part of the US proposal (which it would later resubmit).<sup>290</sup> The elements were ordered into five categories: zero (no provision) option; types of agreements or arrangements; notification of the agreement or arrangement; international cooperation; and regional economic integration organisations.<sup>291</sup> Types of arrangements were further divided into bilateral, regional, and/or multilateral; multilateral; and bilateral or multilateral.

During the discussions at BSWG-4, several delegations supported exemption from the AIA procedure where such agreements existed, provided that the standards of the Protocol were maintained.<sup>292</sup> The resulting draft text contained two options: no provision; and a heavily bracketed option that included all the elements described above and allowed Parties to enter into such agreements, provided these were consistent with the provisions of the Protocol.<sup>293</sup>

Little progress was made at BSWG-5, where the discussion focused on the relationship between this provision and the provision on the application of the AIA procedure (then draft Article 3B).<sup>294</sup> The provision remained in square brackets, since no consensus was reached on whether this provision should remain or whether its elements should be incorporated elsewhere.<sup>295</sup>

Discussions at BSWG-6, in SWG-I, were also unsuccessful in finalising this provision. The Chair's proposed text provided that: agreements or arrangements entered into by Parties must be consistent with the objectives of the Protocol, and not result in a lower level of protection than that provided for by the Protocol; Parties must notify the Biosafety Clearing-House of any agreements or arrangements they had entered into before or after the Protocol's entry into force; and the Protocol's provisions would not affect transboundary movements taking place pursuant to such agreements or arrangements.<sup>296</sup> The Article also allowed for an importing Party to determine that its domestic regulations shall apply to its imports, provided that the Biosafety Clearing-House was notified.<sup>297</sup> The earlier paragraph allowing a regional economic integration organisation to declare that the Protocol did not apply to movements within its territory was deleted.

Minor corrections were made by the Legal Drafting Group, leaving the text of the article to be adopted in January 2000.<sup>298</sup>

---

<sup>289</sup> See now Article 22.

<sup>290</sup> UNEP/CBD/BSWG/4/3 p. 10, contains the submissions of Colombia and the US.

<sup>291</sup> UNEP/CBD/BSWG/3/6, Annex I, see Article 11.

<sup>292</sup> ENB Vol. 9 No. 85, p. 4.

<sup>293</sup> UNEP/CBD/BSWG/4/4, Annex I, see Article 11.

<sup>294</sup> UNEP/CBD/BSWG/5/3, para 32.

<sup>295</sup> *Id.*

<sup>296</sup> UNEP/CBD/BSWG/6/L.2, see Article 11.

<sup>297</sup> *Id.*

<sup>298</sup> UNEP/CBD/BSWG/6/L.2/Rev.2, see Article 11.

## Article 15 - Risk Assessment

- 1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognised risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.**
- 2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment.**
- 3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires.**

Consideration of mechanisms for risk assessment and risk management began at BSWG-1, where several delegations stressed the importance of scientific data, or proposed the inclusion of a reference to risks to human health and welfare. Others recommended the UNEP International Technical Guidelines for Safety in Biotechnology as a valuable source of guidance.<sup>299</sup>

A more extensive discussion took place at BSWG-2 on the basis of submissions on the question of risk assessment and risk management.<sup>300</sup> Australia pointed to the importance of such mechanisms for the Protocol's AIA procedure, while noting

that such mechanisms would not necessarily form part of the Protocol, given that national systems provided for a diverse range of regulatory measures for undertaking risk assessment and risk management, and that a number of international guidelines existed. It proposed a number of general guiding principles for risk assessment on biosafety and stressed the importance of allocating responsibilities for risk assessment to both the exporting and the importing parties.

Switzerland emphasised the need for harmonisation of national structures and recommended that basic principles of risk assessment and risk management be included in the Protocol. Japan stressed the importance of equal treatment of imported and domestic LMOs. Norway proposed that such assessments be carried out by designated national or regional authorities prior to the transfer, handling and use of LMOs.

In addition to referring to human health, the submissions of the African group and of Malaysia<sup>301</sup> proposed consideration of risks to "the environment, biological diversity and the socio-economic welfare of societies".<sup>302</sup> The African group proposed that the documentation to be submitted should at a minimum meet certain provisions ("Risk assessment parameters").<sup>303</sup> Additionally, it suggested: making the outcome of the risk assessment the basis for decision making; requiring risk assessment on a case by case basis; undertaking appropriate management of the risks identified; and submitting all LMOs to a period of observation.<sup>304</sup>

These were included in the Chairman's summary of draft elements, which distinguished between risk assessment and risk management.<sup>305</sup>

<sup>299</sup> UNEP/CBD/BSWG/1/4, paras. 57-63.

<sup>300</sup> UNEP/CBD/BSWG/2/2 pp. 19, 20, 54-57, contains the submissions of Australia, EU, Japan, Switzerland, the African region and Norway.

<sup>301</sup> UNEP/CBD/BSWG/2/Inf.7.

<sup>302</sup> UNEP/CBD/BSWG/2/2, see submission of the African region.

<sup>303</sup> *Id.* See also the section on Annex III below.

<sup>304</sup> *Id.*

<sup>305</sup> UNEP/CBD/BSWG/2/6, Annex I, see Item F. See also section on Article 16 below.

Lengthy procedural discussions took place at BSWG-3 on the basis of the numerous government submissions of draft text on risk assessment.<sup>306</sup> Most of the drafts agreed on the importance of undertaking risk assessments based on up-to-date scientific data and taking into account the information identified in an Annex on Risk Assessment.<sup>307</sup> However, most developing countries supported the view that the assessment should be based not only on scientific data but also on data concerning possible impacts on the conservation and sustainable use of biological diversity, socio-economic factors and the risks to agriculture and human health. Such assessments would, as a consequence, need to be multidisciplinary.<sup>308</sup> Many developing countries also supported the view that risk assessment should be undertaken on a case-by-case basis.<sup>309</sup> Japan called for the establishment of a minimum standard of risk assessment of LMOs. Australia and Brazil also addressed the issue of risk assessment for subsequent imports of the same LMO. Australia considered such assessments unnecessary, except when the intended use, the receiving environment or other factors likely to affect the evaluation had changed. Brazil argued that this should be at the discretion of the receiving Party.

Although most countries proposed assigning the responsibility for such evaluation to the competent authority of the Party of import, Malaysia favoured risk assessment by the Party of export or individual persons or entities under its jurisdiction. It proposed that, when the receiving Party lacked the necessary financial and technical capacity, the exporting Party should assist it and collaborate in the evaluation.

The consolidated text at the end of BSWG-3 brought together all these elements under a number of headings: aim of risk assessment; when risk assessment was required; basic parameters; further specifications concerning parameters; subsequent risk assessments; information to be provided; additional information; responsibility for risk assessment; financial responsibility and financial and technical assistance.<sup>310</sup>

At BSWG-4, SWG-I worked in parallel with CG-1 to facilitate its work on the Annex on risk assessment.<sup>311</sup> As most delegations supported detailing the parameters of risk assessment in an Annex on Risk Assessment, some of the text of the draft article was replaced with a reference to that Annex. On the question of whether the annex should detail the minimum or maximum risk assessment requirements, most delegations preferred keeping them to a minimum.<sup>312</sup>

The consolidated text at the end of BSWG-4 included numerous bracketed options addressing, for example: how, when, and on what, basis risk assessment should be undertaken; its aim; who should undertake the risk assessment; national institutional arrangements; responsibility for reliability of information; financial responsibility; assistance to developing countries and countries with economies in transition; treatment of micro-organisms;<sup>313</sup> and international harmonisation of risk assessment procedures. A zero (no provision) option was also included.<sup>314</sup>

At BSWG-5, negotiations in SWG-I led to the zero option being deleted.<sup>315</sup> The debate also focused on whether risk assessment should be limited to

<sup>306</sup> UNEP/CBD/BSWG/3/3, pp. 34-42, contains the submissions of the African group, Australia, Belarus, Brazil, Canada, Colombia, Cuba, EC, India, Japan, Madagascar, Malaysia, Mexico, Norway, Peru, Sri Lanka, Switzerland and USA.

<sup>307</sup> This was Annex II at the time of these negotiations. The Risk Assessment annex was renumbered Annex III at the conclusion of the negotiations.

<sup>308</sup> See Malaysia's submission in UNEP/CBD/BSWG/3/3, also expressly supported by the African group, Colombia, Cuba, India, Madagascar, Mexico and Sri Lanka.

<sup>309</sup> The African group, Belarus, Cuba, India and Malaysia.

<sup>310</sup> UNEP/CBD/BSWG/3/6, Annex I, see Article 12.

<sup>311</sup> ENB Vol. 9 No. 85, p. 3.

<sup>312</sup> *Ibid.*, p. 4.

<sup>313</sup> Reflecting earlier draft text from Colombia in UNEP/CBD/BSWG/3/3.

<sup>314</sup> UNEP/CBD/BSWG/4/4, Annex I, see Article 12.

<sup>315</sup> ENB Vol. 9 No. 100, p. 1.

scientific principles or whether the precautionary principle, socio-economic, human health and ethical factors should also be considered. The Co-Chair of SWG-I, Mrs Wint (Jamaica) reported to the BSWG that the article had been considerably reduced but retained issues that required further discussion such as the type of information necessary for risk assessment, responsibility for carrying out risk assessment and financial responsibility.<sup>316</sup> Although many supported the removal of the paragraphs concerning financial responsibility for the risk assessment, these were retained in brackets in the consolidated negotiating text at the end of BSWG-5.<sup>317</sup> The various options specifying who should undertake the risk assessment and the paragraph requiring that risk assessment and management of micro-organisms should be conducted in contained conditions also remained in brackets.<sup>318</sup>

Reference in the article to “appropriate risk assessment techniques developed by relevant international organisations” was replaced by “recognised” techniques at BSWG-6.<sup>319</sup> Delegations also agreed to include language reflecting that the assessment should be based on information provided in accordance with the article on Notification (then Article 6), but they remained divided on whether the responsibility should lie exclusively with the importer or whether the latter could require the exporter to conduct the assessment.<sup>320</sup> Consensus was not reached on the question of financial responsibilities, nor on the inclusion of references

to human health, socio-economic considerations, and the conservation and sustainable use of biodiversity. These matters were thus transferred to the Friends of the Chair for further consultations.<sup>321</sup>

The Chair’s proposed text<sup>322</sup> provided for risk assessment to be based at a minimum on information provided in accordance with the Article on Notification (then Article 6). The Legal Drafting Group later amended this, reinstating the previous reference to the annex on risk assessment (then Annex II),<sup>323</sup> and the reference to the purpose of identifying and evaluating possible adverse effects on the conservation and sustainable use of biodiversity, taking also into account risks to human health. The article linked the risk assessment to the decision under Article 8 (Decision procedure for AIA) and noted that the Party of import may require the exporter to carry out the risk assessment. Finally, it assigned the financial responsibility for risk assessment to the notifier if the Party of import so required.

A final revision in the resumed ExCOP, which took place in the informal consultations, coordinated by Ambassador Nobs (Switzerland), on the so-called ‘non-core issues’ at the ExCOP, adjusted the references to the articles and replaced the term “financial responsibility” with “cost.”<sup>324</sup>

<sup>316</sup> UNEP/CBD/BSWG/5/3, para. 32.

<sup>317</sup> UNEP/CBD/BSWG/5/3, Annex, see Article 12.

<sup>318</sup> *Id.*

<sup>319</sup> ENB Vol. 9 No. 113, p. 1.

<sup>320</sup> *Id.*

<sup>321</sup> ENB Vol. 9 No. 113, pp. 1-2.

<sup>322</sup> UNEP/CBD/BSWG/6/L.2, see Article 12.

<sup>323</sup> UNEP/CBD/BSWG/6/L.2/Rev.2, see Article 12.

<sup>324</sup> ENB Vol. 9 No. 137, p. 8; and UNEP/CBD/ExCOP/1/3, para. 86.

## Article 16: Risk Management

**1. The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.**

**2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.**

**3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.**

**4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.**

**5. Parties shall cooperate with a view to:**  
**(a) Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and**

**(b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.**

The Chairman's summary of draft elements at the end of BSWG-2 separated risk assessment and risk management into two provisions.<sup>325</sup> Malaysia had previously made this distinction in its submission, and had called for risk management strategies and measures to be included in the risk assessment report. Elements identified for a provision on risk assessment included reference to Article 8(g) of the Convention and to the guidance provided by the UNEP Technical Guidelines and other sources, as well as options on the legal status of the provision and on responsibility for the risk management procedures.<sup>326</sup>

A significant part of the language reflected in the final text of this provision was already reflected in governments' submissions to BSWG-3.<sup>327</sup> Australia called on Parties to "establish or maintain national means to regulate, manage or control risks associated with the safe use, handling and transboundary movement of living modified organisms, in accordance with Article 8(g) of the Convention," which with minor rephrasing would appear as the first paragraph of the final text. Canada proposed that these measures should be imposed "to the extent necessary to prevent the adverse effects of the living modified organism on the conservation and sustainable use of biological diversity within the territory of the Party of import."<sup>328</sup> The African group and Madagascar, in a separate submission, proposed that any LMO "whether imported or locally developed shall undergo a period of observation commensurate with its life cycle or generation time as the case may be before it is put to its intended use."<sup>329</sup>

<sup>325</sup> UNEP/CBD/BSWG/2/6, Annex II, Item F. See also section on Article 15 above.

<sup>326</sup> UNEP/CBD/BSWG/2/6, Annex II, Item F.

<sup>327</sup> UNEP/CBD/BSWG/3/3, pp. 42-45, contains the submissions of the African group, Australia, Belarus, Canada, Colombia, Cuba, India, Madagascar, Malaysia, Norway, Sri Lanka and Switzerland.

<sup>328</sup> See paragraph 2 of the final text of the Article.

<sup>329</sup> See now Article 16(4).

Several proposals advocated the reduction of risks to acceptable levels.<sup>330</sup> A number of countries suggested including a minimum type<sup>331</sup> or examples<sup>332</sup> of risk management, while others called for cooperation in the development and harmonisation of risk management procedures.<sup>333</sup> In a similar fashion, Malaysia supported language on technical and financial assistance, as it had done in the provision on risk assessment. Finally, Norway called for the phasing out of antibiotic resistance marker genes by 2002. All these options were included in the consolidated text at the end of BSWG-3 approved by the Plenary.<sup>334</sup> These were then re-arranged by the Secretariat into: requirements; cooperation; observation period; and antibiotic resistance markers.<sup>335</sup>

Discussions continued in SWG-I at BSWG-4 on the need for this provision, and on the need for global and regional standards.<sup>336</sup> Options in the consolidated text at the end of BSWG-4 were reduced to two: no provision and a provision enshrining the elements previously identified, obliging Parties to establish measures to regulate, manage and control risks associated with LMOs in accordance with Article 8 of the Convention or criteria stipulated in the Protocol. A more detailed option was also provided.<sup>337</sup>

During the course of BSWG-5 the zero (no provision) option was removed and SWG-I, in light of the discussions on categories of transboundary movements, introduced a new paragraph calling upon Parties to take appropriate measures to

prevent unintentional transboundary movements of LMOs.<sup>338</sup> All the text was bracketed, with the most contentious issues being the provision for financial assistance, reference to the precautionary principle, and the phasing out of antibiotic resistance marker genes.<sup>339</sup>

After unsuccessful initial discussions at BSWG-6, work on the article was assigned to an informal group with a mandate to report to SWG-I.<sup>340</sup> However, further discussions in SWG-I failed to achieve consensus and the issue was referred to the Friends of the Chair.<sup>341</sup> In the Chair's proposed text, the references to the precautionary principle, financial assistance, antibiotic resistance markers, and to the annex developing the criteria for risk management, were deleted.<sup>342</sup> The paragraph on cooperation was amended to read: "identifying [LMOs] or specific traits of [LMOs] that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health" and with the insertion of "with a view to taking appropriate measures on the treatment of such [LMOs] or specific traits."<sup>343</sup>

The Legal Drafting Group would later review this text and make some amendments. The paragraph on cooperation was divided into two parts.<sup>344</sup> The draft article was then retained without amendment and incorporated into the final text of the Protocol.

<sup>330</sup> African group, Belarus, Cuba, India, Madagascar and Sri Lanka.

<sup>331</sup> African group, India and Sri Lanka.

<sup>332</sup> Norway.

<sup>333</sup> Australia and Switzerland.

<sup>334</sup> UNEP/CBD/BSWG/3/6, Annex I, see Article 13.

<sup>335</sup> UNEP/CBD/BSWG/4/Inf.1, see Article 13.

<sup>336</sup> ENB Vol. 9 No. 85, p. 4.

<sup>337</sup> UNEP/CBD/BSWG/4/4, Annex I, see Article 13.

<sup>338</sup> UNEP/CBD/BSWG/5/3 para. 32.

<sup>339</sup> ENB Vol. 9 No. 108, p. 6; UNEP/CBD/BSWG/5/3, para 32 and Annex, see Article 13.

<sup>340</sup> ENB Vol. 9 No. 111, p. 1.

<sup>341</sup> ENB Vol. 9 No. 112, p. 1 and No. 113, p. 2.

<sup>342</sup> UNEP/CBD/BSWG/6/L.2, see Article 13.

<sup>343</sup> *Id.*

<sup>344</sup> UNEP/CBD/BSWG/6/L.2/Rev.2, see Article 13.

## Article 17: Unintentional Transboundary Movements and Emergency Measures

1. Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organisations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States. The notification shall be provided as soon as the Party knows of the above situation.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, make available to the Biosafety Clearing-House the relevant details setting out its point of contact for the purposes of receiving notifications under this Article.

3. Any notification arising from paragraph 1 above, should include:

(a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organism;

(b) Information on the circumstances and estimated date of the release, and on the use of the living modified organism in the originating Party;

(c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures;

(d) Any other relevant information; and  
(e) A point of contact for further information.

4. In order to minimise any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party, under whose jurisdiction the release of the living modified organism referred to in paragraph 1 above, occurs, shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures.

A number of governments presented draft text on emergency procedures prior to BSWG-2.<sup>345</sup> These proposals, with the exception of that of Japan, which referred the matter to Article 14(1)(d) and (e) of the Convention, included a general commitment to immediately inform affected countries; introduce appropriate measures and procedures; and identified information to accompany the notification (including the identity of the LMO, the quantities and circumstances of the release, and emergency measures needed to be taken). The views of the African Group and Norway reflected their concerns about the possible effects of the accident on human health and the environment. The African group also added consideration of animal health and biodiversity. Norway proposed the need for consultations on the part of the affected States.

The question of unintentional transboundary movement of LMOs (including accidents and emergency cases) was considered at BSWG-2.<sup>346</sup> The above elements were reflected in the Chair's summary of elements, which also referred to consultation with and information to landlocked/neighbouring countries, and notification of unintentional releases to the BCH and to directly involved third parties.<sup>347</sup> The main elements and structure of this provision were thus already identified at this early stage.

<sup>345</sup> UNEP/CBD/BSWG/2/2, pp. 58-59, contains the submissions of the African group, Japan and Norway, and UNEP/CBD/BSWG/2/Inf. 7 contains the submissions of Malaysia.

<sup>346</sup> UNEP/CBD/BSWG/2/6, paras. 137-144.

<sup>347</sup> Ibid. Annex II, Item G.



Governments submitted further text for BSWG-3 under two different provisions: unintentional transboundary movements and emergency measures (then Articles 16 and 17 respectively).<sup>348</sup> In addition to the above elements, Australia and Brazil proposed extending the scope of Article 16 to include “known unintentional domestic releases of [LMOs]”. Brazil also included reference to a Party that suspected that an unintentional transboundary movement into its territory had occurred. Malaysia proposed consideration of socio-economic imperatives and risks to agriculture, and Mexico proposed resolution of these issues under “the rules governing international responsibility of the State for damage to the environment”. The US specified the national focal point as the authority to be notified of the release. Of the submissions addressing emergency measures, Peru held the view that in cases of accidents the responsibility to take immediate action lay with the insurer and the competent authorities.

All these elements were incorporated into the consolidated text prepared by SWG-II.<sup>349</sup>

A submission by Colombia for BSWG-4 reflected previous text from Malaysia on mitigating adverse effects. Colombia supplemented this with the obligation to “prevent future unintentional transboundary movements” and to minimise risks once such a movement had occurred.<sup>350</sup> The article on unintentional transboundary movements (then Article 15), as considered by BSWG-4, addressed the responsibilities and rights of Parties in respect of unintentional transboundary movements, covering: knowledge required to trigger responsibility; actions required; scope of information required; notification to the BCH; and confidentiality of information provided.<sup>351</sup> The article on emer-

gency measures (then Article 16), contained text that called for either the establishment of national measures and procedures, or the incorporation of appropriate measures into the risk management strategies established under the article on risk management (then Article 13).<sup>352</sup>

The draft articles on unintentional transboundary movements and emergency measures were merged during the course of BSWG-4, on the basis of a draft prepared by the Co-Chairs of SWG-II. Delegations agreed on the need for the provision and consolidated text on the elements to be included in the notification.<sup>353</sup> There was no consensus on the remaining text covering: actions required by the Party of origin; an affected Party’s right to request emergency assistance from the Party of origin; an affected Party’s right to request consultation among concerned Parties; and whether Parties should avoid actions with potential impacts on freshwater and marine ecosystems.<sup>354</sup>

Discussions at BSWG-5 considered, among other issues, whether to use the term “accident” or “unintentional release,”<sup>355</sup> socio-economic considerations, and the necessity for and details of provisions on emergency measures. However, progress was hampered as difficulties arose with liability and responsibility issues.<sup>356</sup> Text prepared by a drafting group reinserted the earlier paragraph on confidentiality and, in the subsequent discussions, “point of contact” was inserted to distinguish it from National Focal Point and National Competent Authority.<sup>357</sup> The ensuing text no longer made reference to releases of aquatic LMOs, assistance in emergency measures, or action at the expense of the Party of origin to minimise adverse impacts and prevent further releases.<sup>358</sup> The text required Parties to take preventative measures, notify

<sup>348</sup> UNEP/CBD/BSWG/3/3, see Articles 16 and 17, contains submissions by African group, Australia, Belarus, Brazil, EC, India, Malaysia, Mexico, Norway, Peru, Sri Lanka, Switzerland and USA.

<sup>349</sup> UNEP/CBD/BSWG/3/6, Annex I, see Articles 15 and 16.

<sup>350</sup> UNEP/CBD/BSWG/4/3, pp. 11-12.

<sup>351</sup> UNEP/CBD/BSWG/4/Inf. 2, see Article 15.

<sup>352</sup> *Ibid.*, see Article 16.

<sup>353</sup> ENB Vol. 9 No. 85, p. 6.

<sup>354</sup> *Id.*

<sup>355</sup> ENB Vol. 9 No. 99, p. 2.

<sup>356</sup> ENB Vol. 9 No. 102, p. 2.

<sup>357</sup> ENB Vol. 9 No. 106, p. 2.

<sup>358</sup> UNEP/CBD/BSWG/5/3, Annex, and UNEP/CBD/BSWG/4/4, Annex II, see Merger of Article 15 and 16.

affected Parties and relevant international organisations (and listing the type of information to be provided), make available to the BCH the details of the relevant point of contact, and consult each other to determine appropriate action.<sup>359</sup>

Remaining contentious issues, including prevention of unintentional releases, linkages with the article on risk assessment, confidential information and responsibility for triggering actions to minimise impacts, impeded the attempts to remove the brackets from this draft article during BSWG-6.<sup>360</sup> The Co-Chair of SWG-I introduced a proposal under which the paragraph on confidential information in this provision was transferred to the article on Confidential Information, (then Article 21), and consensus was reached on the information to be included in the notification of unintentional transboundary movements.

The Chair's proposed text deleted the references to prevention of unintentional releases, socio-economic well-being (retaining references to biological diversity and human health), and 'products thereof'; and favoured reference to information on risk management measures rather than risk assessment.<sup>361</sup> The draft article specified the measures that Parties had to take in the event of an unintentional transboundary movement of LMOs, including notification, provision of information, consultation with the affected and potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures. A subsequent revision of the text amended the final paragraph of this article and re-ordered the list of required information.<sup>362</sup>

---

<sup>359</sup> UNEP/CBD/BSWG/5/3, see Merger of Article 15 and 16.

<sup>360</sup> ENB Vol. 9 No. 112, p. 2.

<sup>361</sup> UNEP/CBD/BSWG/6/L.2, see Article 14.

<sup>362</sup> UNEP/CBD/BSWG/6/L.2/Rev. 2, see Article 14.

## Article 18: Handling, Transport, Packaging and Identification

1. In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.

2. Each Party shall take measures to require that documentation accompanying:

(a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they “may contain” living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;

(b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned; and

(c) Living modified organisms that are intended for intentional introduction into

the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.

3. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, in consultation with other relevant international bodies.

The Chair’s Summary of draft elements prepared at the end of BSWG-2, covered the main issues raised in the discussions and written proposals.<sup>363</sup> Options in the Summary included: the packaging and labelling of LMOs to maintain safety levels during transport, consideration of existing international recommendations and agreements on transport, the need for coverage of transit,<sup>364</sup> adoption of the precautionary approach, development of general principles on labelling, packaging and transport, and the labelling of LMOs intended for food purposes.<sup>365</sup> Switzerland had called for international harmonisation and a study of appropriate technical details,<sup>366</sup> and the Summary acknowledged that international instruments such as the UN Recommendations on the Transport of Dangerous Goods and the WHO Labour Safety Manual did not adequately cover the transport and handling of LMOs.

<sup>363</sup> UNEP/CBD/BSWG/2/6, para. 145-149; Annex II, Item I.

<sup>364</sup> As proposed by Malaysia (UNEP/CBD/BSWG/2/Inf.7).

<sup>365</sup> As proposed by Norway (UNEP/CBD/BSWG/2/2).

<sup>366</sup> UNEP/CBD/BSWG/2/2, p.63.

Submissions were received for BSWG-3.<sup>367</sup> Australia, Brazil and Sri Lanka proposed that shipments containing LMOs should be clearly identified, handled and packaged to prevent accidental releases and should include contact details of the relevant focal point. Belarus and India called for specific labelling of food products incorporating LMOs, with Belarus further proposing that other LMOs should be labelled according to environmental, health and ethical concerns. Norway's proposal required the inclusion of a movement document from the point of departure to the point of use. Cooperation with the World Customs Organisation (WCO) in assigning a universal identification code for products covered by the Protocol was suggested by Colombia. Japan proposed that the Conference of the Parties elaborate guidelines on the issue, while Malaysia recommended adoption of precautionary measures and the right of Parties to impose the necessary terms and conditions for the protection of the environment (including socio-economic imperatives and risks to agriculture and human health). Mexico referred to the needs of developing countries and countries with economies in transition. Peru favoured insurance policy cover and specified requirements on language, size, location and use of symbols in the labelling.

The Consolidated Text at the end of BSWG-3 contained the above proposals, except those of Mexico and Peru.<sup>368</sup> The options went from a general requirement of safe transfer to a requirement to establish specific documentation and labelling procedures. Some options called for the development by the COP of the necessary standards, while others foresaw drawing upon existing international standards.

The Chair's Note on this article, prepared for BSWG-4, reduced the number of options to four.<sup>369</sup> These were two short options, one requiring transport to be undertaken in safe conditions to avoid adverse effects and the other obliging Parties to establish or promote measures in conformity with international rules and standards or standards under the Protocol. Of the two longer options, one reflected a new submission by Colombia<sup>370</sup> proposing the inclusion of a safety information sheet containing information to be specified in an Annex to the Protocol and calling again for cooperation with the WCO; and the other reflected the elements of the existing Consolidated Text.<sup>371</sup>

During BSWG-4 further consolidated text was prepared containing two options developed by SWG-II.<sup>372</sup> The first required exporting Parties to develop appropriate measures for the handling, transport and packaging of LMOs. The second option, which listed Parties' obligations (to be developed in an annex to the Protocol), received much support.<sup>373</sup> In addition, a zero (no provision) option was favoured by some delegations to avoid possible conflict with the WTO.<sup>374</sup> Substantial progress was made at BSWG-4, although a number of contentious issues remained. These included: the need for the provision; its scope; reliance on international rules and standards versus national measures; development of new international standards; and the information to accompany transport (including labelling).<sup>375</sup>

The text was reduced to a single bracketed option in BSWG-5 covering scope; need for identification (including possible consideration of relevant international rules); accompanying documentation; and development of standards by the COP.<sup>376</sup> At

<sup>367</sup> UNEP/CBD/BSWG/3/3, pp. 51-54, contains the submissions of the African group, Australia/Brazil/Sri Lanka, Belarus, Colombia, Cuba, India, Japan, Mexico, Norway, Peru, Switzerland and USA.

<sup>368</sup> UNEP/CBD/BSWG/3/6, Annex I, see Article 17.

<sup>369</sup> UNEP/CBD/BSWG/4/Inf. 2, see Article 17.

<sup>370</sup> UNEP/CBD/BSWG/4/3, pp. 13-14.

<sup>371</sup> UNEP/CBD/BSWG/3/6, Annex I, see Article 17, Option 1.

<sup>372</sup> ENB Vol. 9 No. 81, p. 2.

<sup>373</sup> *Id.*

<sup>374</sup> UNEP/CBD/BSWG/4/4, Annex II, see Article 17.

<sup>375</sup> *Id.*

<sup>376</sup> UNEP/CBD/BSWG/5/3, Annex, see Article 17.

this stage, the draft Article still addressed all LMOs in the same manner, an approach that would be changed in later negotiations.

At BSWG-6, initial discussions focused on a text prepared by the Co-Chairs of SWG-II. Although some delegations were satisfied with the text, others offered suggestions for improvement.<sup>377</sup> According to the Earth Negotiations Bulletin, most developing country delegations supported, *inter alia*: language on risks to human health and ‘products thereof’; labelling in addition to identification; and the development of new standards under the Protocol.<sup>378</sup> Some developed country delegations held the view that new standards and requirements for documentation to accompany LMOs would duplicate other international rules and create unnecessary bureaucracy.<sup>379</sup> Delegations differed as to whether the article applied to all LMOs within the scope of the Protocol or only to LMOs subject to the AIA procedure.<sup>380</sup> In the informal group, convened by Co-Chair Herity, some delegations noted the linkage with the articles on objectives and scope of AIA, and many considered labelling for consumers to be an internal policy issue. Others disagreed, citing the objective of the Protocol and Article 19(3) of the Convention.<sup>381</sup>

The Chair’s proposed text replaced all references to “labelling” with “identification,” maintained the reference to human health, required the COP to determine if standards needed to be developed, and extended the scope of the provision to all LMOs within the scope of the Protocol.<sup>382</sup> No agreement was reached on this provision during the remainder of BSWG-6 and the first session of the ExCOP. The Miami Group proposed that the article should only cover LMOs within the scope of the AIA procedure,

not all those within the scope of the Protocol.<sup>383</sup> The EU proposed new text for the article (then Article 15), which would differentiate documentation requirement depending on the intended use of the LMO concerned.<sup>384</sup> This approach, though not the precise formulation of the EU proposal, would be reflected in the final text.

In the Vienna consultations, discussions on the Compromise Group concept paper on LMO-FFPs resulted in a framework under which adequate and differentiated documentation requirements for LMO-FFPs would be developed.<sup>385</sup>

The discussions by the contact group on commodities, chaired by Mr François Pythoud (Switzerland),<sup>386</sup> during the resumed ExCOP resulted in text differentiating between the different intended uses of LMOs (LMO-FFPs, LMOs for contained use, and LMOs for intentional introduction into the environment) and accompanying documentation.<sup>387</sup> However, disagreement remained on the specific elements and language for identification of LMO-FFPs.<sup>388</sup> In final high-level consultations, a compromise was reached under which it was agreed that the documentation accompanying LMO-FFPs should clearly identify that they “may contain” LMOs and “are not intended for intentional introduction into the environment.” Future consideration of detailed requirements by the meeting of the Parties was also mandated. This was the last issue to be agreed by the ExCOP. When the ExCOP President introduced to the plenary the final text of the Protocol submitted by the Legal Drafting Group,<sup>389</sup> he introduced an oral amendment to Article 18. With this amendment, the Protocol was adopted.<sup>390</sup>

<sup>377</sup> ENB Vol. 9 No. 112, p. 1.

<sup>378, 379, 380, 381</sup> *Id.*

<sup>382</sup> ENB Vol. 9 No. 114, p. 1; and UNEP/CBD/BSWG/6/L.2, see Article 15.

<sup>383</sup> UNEP/CBD/ExCOP/1/3, Annex III.

<sup>384</sup> UNEP/CBD/ExCOP/1/3, Annex II.

<sup>385</sup> UNEP/CBD/ExCOP/1/INF/3, Informal Consultations on Biosafety Protocol, Vienna, 15-19 September 1999, p.4.

<sup>386</sup> ENB Vol. 9 No. 134, p. 2.

<sup>387</sup> ENB Vol. 9 No. 135, p. 1.

<sup>388</sup> *Id.*, and ENB Vol. 9 No. 136, p. 1.

<sup>389</sup> UNEP/CBD/ExCOP/L.5.

<sup>390</sup> UNEP/CBD/ExCOP/1/3, paras. 90-92.

## Article 19: Competent National Authorities and National Focal Points

**1. Each Party shall designate one national focal point to be responsible on its behalf for liaison with the Secretariat. Each Party shall also designate one or more competent national authorities, which shall be responsible for performing the administrative functions required by this Protocol and which shall be authorised to act on its behalf with respect to those functions. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.**

**2. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for which type of living modified organism. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the name and address or responsibilities of its competent national authority or authorities.**

**3. The Secretariat shall forthwith inform**

**the Parties of the notifications it receives under paragraph 2 above, and shall also make such information available through the Biosafety Clearing-House.**

Views on this issue were first submitted for BSWG-2.<sup>391</sup> The African group proposal<sup>392</sup> included language on the obligation of a Party to inform the Secretariat of the designated agency or of any changes regarding this designation.

The debate in BSWG-2 revolved around the number of competent national authorities and focal points, the possibility of establishing a single entity to fulfil the functions of both, and the possibility of establishing regional focal points. Some minimum tasks and responsibilities of these bodies were suggested, as well as a timeframe for their designation.<sup>393</sup> A Chair's summary outlined the options for the number and type of competent authorities/focal points, the timeframe for designation and their responsibilities.<sup>394</sup>

During BSWG-3, SWG-II discussed the issue on the basis of government submissions.<sup>395</sup> Most submissions stated that Parties should designate the national competent authority(ies) and focal point, and notify the Secretariat and the BCH of this designation and any related changes. A few submissions outlined various tasks that the competent national authorities and focal points should perform. Colombia, Norway and the US suggested language providing for the Secretariat to inform the Parties of notifications received. The obligation to provide information on the responsibilities of each competent authority where there was more than one, as suggested by the US, is also reflected in the final text.

<sup>391</sup> UNEP/CBD/BSWG/2/2, p. 60 contains the submissions of the African region, EU, Japan, Norway and Switzerland. UNEP/CBD/BSWG/2/Inf.7, pp. 5-6, contains the submissions of Malaysia.

<sup>392</sup> UNEP/CBD/BSWG/2/2, p. 60.

<sup>393</sup> UNEP/CBD/BSWG/2/6, paras. 73-79.

<sup>394</sup> UNEP/CBD/BSWG/2/6, Annex II, see Item B.

<sup>395</sup> UNEP/CBD/BSWG/3/3, pp. 54-61, contains the submissions of the African Group, Australia, Belarus, Brazil, Colombia, Cuba, EC, India, Japan, Madagascar, Malaysia, Mexico, Norway, Peru, South Africa, Sri Lanka, Switzerland and the US. UNEP/CBD/BSWG/3/5 also contains the submission of Indonesia.

The outcome of BSWG-3 discussions included five options, derived from government submissions.<sup>396</sup> All options contained text on the designation of one or more competent authorities, but differed on the number of focal points. There were also different possibilities regarding the timeframe for the Party's obligation to notify the Secretariat of the designation: with the deposit by the Party of its instrument of ratification; by the entry into force of the Protocol for the Party; or within three months of the Protocol's entry into force for the Party. The level of detail of the proposed language also differed when outlining the tasks of the bodies. One of the options further included text on ensuring sufficient resources for the efficient performance of the focal point's tasks.

Following Chair Koester's initial attempt to synthesise similar options for BSWG-4, reducing them to three,<sup>397</sup> the main contentious issues at BSWG-4 included: the number of focal points per Party; the timeframe for notifying the Secretariat of the designation of competent authorities and focal points; and whether or not to include detailed reference to their tasks. SWG-II negotiations in BSWG-4 resulted in a single bracketed text, the above issues still remaining unresolved. Delegations agreed that the national focal point "shall be responsible for liaison with the Secretariat".

BSWG-5 discussions focused on the number of focal points and the timeframe for designation.<sup>398</sup> SWG-II agreed that the timeframe for designation was to be no later than the date of entry into force of the Protocol for the Party in question. Delegations also agreed that the Secretariat should inform Parties of notifications received and make such information available through the BCH, and affirmed that Parties should provide relevant information on the respective responsibilities of their competent national authorities and, if applicable, on which competent national authority was responsible for which type of LMO. The final text was streamlined into three paragraphs.<sup>399</sup> The issue of whether a Party could designate more than one focal point remained bracketed<sup>400</sup> and was finally resolved in BSWG-6, where delegates agreed to the designation of one national focal point<sup>401</sup> and provisionally adopted the article.<sup>402</sup> It remained unchanged thereafter, although the article was renumbered when the Protocol was agreed in its final form.

---

<sup>396</sup> UNEP/CBD/BSWG/3/6, Annex I, see Article 18.

<sup>397</sup> UNEP/CBD/BSWG/4/Inf. 2, p. 12.

<sup>398</sup> UNEP/CBD/BSWG/5/2, pp. 76-78 contains the submissions of Ecuador, New Zealand, Peru, Slovenia, Thailand and Venezuela.

<sup>399</sup> UNEP/CBD/BSWG/5/3, Annex, see Article 18.

<sup>400</sup> UNEP/CBD/BSWG/6/8, p.44.

<sup>401</sup> UNEP/CBD/ExCOP/1/2, Appendix I, see Article 16.

<sup>402</sup> UNEP/CBD/ExCOP/1/3, para. 51.

## Article 20: Information Sharing and the Biosafety Clearing-House

1. A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to:

(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and

(b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

2. The Biosafety Clearing-House shall serve as a means through which information is made available for the purposes of paragraph 1 above. It shall provide access to information made available by the Parties relevant to the implementation of the Protocol. It shall also provide access, where possible, to other international biosafety information exchange mechanisms.

3. Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the Biosafety Clearing-House under this Protocol, and:

(a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;

(b) Any bilateral, regional and multilateral agreements and arrangements;

(c) Summaries of its risk assessments or environmental reviews of living modified organisms generated by its regulatory process, and carried out in accordance with Article 15, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

(d) Its final decisions regarding the importation or release of living modified organisms; and

(e) Reports submitted by it pursuant to Article 33, including those on implementation of the advance informed agreement procedure.

4. The modalities of the operation of the Biosafety Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

Prior to BSWG-2, three government submissions were made.<sup>403</sup> The African group called for the establishment of a Biosafety Clearing-House to provide information relating to the implementation of the Protocol and composed of recognised experts. It also proposed that the modalities of establishment should be considered and decided at the first meeting of the Parties, a proposal which would be reflected in the fourth paragraph of the final text. As in other provisions, the African group supported the inclusion of information on “products thereof” as well as on LMOs. The proposal specified the duties and types of information to be collected and disseminated by the BCH, including assistance to developing countries. Switzerland acknowledged this mechanism as an essential tool to implement the Protocol and called for it to host information on scientific references for risk assessment and management,

<sup>403</sup> UNEP/CBD/BSWG/2/2 pp.65-67 contains the submissions of the African group, Canada and Switzerland.



national procedures on risks, databanks on related experiments, and information on transboundary movements and AIA. It also suggested following the model of the BIOBIN project which UNIDO and OECD had jointly developed.

Canada noted that the term 'clearing-house' needed to be defined once the type of information that would be considered, resources and processing of information were known. This could include how or whether to track decisions to approve, conditionally approve or prohibit transboundary movements of LMOs and sharing of information on risks. The US proposed facilitating information-sharing through a centralised clearing-house or database, coordinated by an existing organisation. Parties could make available to the clearing-house mechanism publicly available information on domestic laws/regulations applicable to the production and/or use of LMOs; and on risk assessments or environmental reviews generated by the regulatory process.<sup>404</sup>

At BSWG-3, new submissions on the clearing-house were considered.<sup>405</sup> A number of governments suggested using the Clearing-house Mechanism under the Convention as the clearing-house for the Protocol,<sup>406</sup> while one saw the Protocol's clearing-house as an integral part of the CHM.<sup>407</sup> A number of countries proposed that the object of the mechanism should be the information to be identified under an annex to the Protocol ("Information to be provided to the Secretariat under Information Sharing/Clearing House").<sup>408</sup> Some developed country delegations raised the issue of confidentiality of data,<sup>409</sup> while some developing countries advocated the inclusion of socio-economic information or research.<sup>410</sup>

Cooperation with an International Registry on LMOs was suggested by Cuba, and Malaysia called for cooperation with existing international agencies, organisations, mechanisms and networks for the dissemination of biosafety-related information. The US proposed that Parties should make information on their decisions on importation, field tests and commercial use of LMOs publicly available. Switzerland called for Parties to ensure the inclusion of information on intentional movements subject to AIA and on unintentional movements. The views of the US regarding the need for a centralised database or clearing house, holding information on domestic laws, regulations and guidelines, and risk assessments would become incorporated into the draft text at BSWG-5.

An annex was compiled listing the types of information that countries had proposed.<sup>411</sup> In addition to the above, Colombia and Japan proposed to include the provision by Parties of information on any bilateral, regional and multilateral agreements and on unilateral declarations of exemption from or simplification of the AIA procedures. Japan also suggested periodic reporting on the implementation of the AIA procedure. Both proposals would feature in the final text.

SWG-II reduced the options to seven which differed on the following points: acknowledgement of the special needs of developing countries; nature and structure of the clearing-house/centralised database; types of information to be handled by the mechanism; respect for confidential information and extent of access to and availability of such information.<sup>412</sup>

<sup>404</sup> *Ibid*, pp. 31-32

<sup>405</sup> UNEP/CBD/BSWG/3/3, pp. 61-67, contains the submissions of the African group, Australia, Belarus, Brazil, Canada, Colombia, Cuba, EC, India, Japan, Madagascar, Malaysia, Mexico, Norway, Peru, South Africa, Sri Lanka, Switzerland and USA.

<sup>406</sup> India and Colombia.

<sup>407</sup> Madagascar.

<sup>408</sup> Australia, Canada, EC and Norway.

<sup>409</sup> Belarus, Canada, EC, Norway and Switzerland.

<sup>410</sup> African group, Cuba, India, Sri Lanka.

<sup>411</sup> UNEP/CBD/BSWG/3/3, Annex IV, contains the submissions of the African group, Australia, Belarus, Brazil, Canada, Colombia, EC, Japan, Madagascar, Norway, Peru and Sri Lanka.

<sup>412</sup> UNEP/CBD/BSWG/3/6, Annex I, see Article 19.

The consolidated text at the end of BSWG-4 reduced the text to three options addressing the objective and establishment of the mechanism, its content, and information-sharing obligations of the Parties.<sup>413</sup>

At BSWG-5, SWG-II considered whether the mechanism in question should be a database or a clearing-house.<sup>414</sup> To assist the discussions, the Secretariat defined the term “clearing-house” as a “decentralised transactional system with responsibility for information residing with the information providers” and further noted that “using the [Convention’s CHM], a network of networks, would not be burdensome, but establishing a new database would be.”<sup>415</sup>

Some developed countries had expressed a preference for a simple electronic database mechanism, while many developing countries supported a clearing-house separate from the CHM, mainly because of access difficulties to the Internet. The Co-Chair of SWG-II mandated a working group to outline a common concept of the clearing-house.<sup>416</sup> The working group decided that a clearing-house was a means through which information was made available, by providing access to information provided by Parties.<sup>417</sup> The Co-Chair referred to three existing biosafety information systems: UNIDO’s Biosafety Information and Advisory System, UNEP’s International Registry on Biosafety, and OECD’s BioTrack.<sup>418</sup> Delegations agreed to use the term “clearing-house” rather than “database.”<sup>419</sup>

The Co-Chair of SWG-II noted the interpretation of a decentralised clearing-house as one that would not collect information, but rather would point to it.<sup>420</sup> Delegations decided to remove brackets from language on the protection of confidential information in exchange for deleting a reference to publicly available information.<sup>421</sup> The reference to information on unintentional transboundary movements was deleted as it was covered under the article on Unintentional Transboundary Movements (then Article 15).<sup>422</sup> However, the references to reports on implementation under the article on Monitoring and Compliance, (then Article 35) and to a decision by the first MOP with regard to the arrangements for the mechanism were retained.<sup>423</sup> Paragraphs on decisions regarding clearing-house modalities and reports on its operation were merged. The reference to existing international biosafety information exchange mechanisms had the brackets removed.<sup>424</sup>

As the much debated issue of “products thereof” touched upon many other provisions, it was dealt with separately at a general consultation and referred to CG-1.<sup>425</sup>

The draft text emerging from BSWG-5 contained the options outlined above and was similar in content and lay out to the text of the article as finally adopted.<sup>426</sup>

During negotiations at BSWG-6 a number of issues were still pending: the relationship between a biosafety clearing-house and the CBD CHM; references to “products thereof” and confidential infor-

<sup>413</sup> UNEP/CBD/BSWG/4/4, Annex II, see Article 19.

<sup>414</sup> ENB Vol. 9 No. 108, p. 7.

<sup>415</sup> ENB Vol. 9 No. 100, pp. 1-2.

<sup>416</sup> ENB Vol. 9, No. 100, p.2

<sup>417</sup> ENB Vol. 9, No. 101, p.2.

<sup>418</sup> ENB Vol. 9, No. 104, p. 2.

<sup>419</sup> ENB Vol. 9, No 103, p.2.

<sup>420</sup> ENB Vol. 9 No. 105, p. 2

<sup>421</sup> *Id.*

<sup>422</sup> *Id.*

<sup>423</sup> *Id.*

<sup>424</sup> *Id.*

<sup>425</sup> UNEP/CBD/BSWG/5/3, para. 28.

<sup>426</sup> *Ibid.*, Annex, see Article 19.

mation; and the relationship with the provisions on risk assessment and on AIA procedures.<sup>427</sup> The ad hoc discussion on LMOs and “products thereof” resulted in an agreement to substantially reduce the number of references to the term “products thereof” in the Protocol. However the term remained in this draft article, accompanied by a definition.

The Chair’s proposed text at BSWG-6, established the Biosafety Clearing-House as part of the CBD clearing-house mechanism and included a reference to the protection of confidential information.<sup>428</sup> The previous text, regarding the obligation of Parties to provide summaries of risk assessments, as well as reports on their implementation of the AIA procedures, had the brackets removed.

The revised Chair’s text included language to assist countries that are centres of origin.<sup>429</sup> During this revision the first reference to “products thereof”, in the context of the facilitation of exchange of scientific, technical, environmental and legal information, was removed. Additionally, the reference to “the Parties ...at their first meeting” was replaced by the “Conference of the Parties serving as the meeting of the Parties to this Protocol” to reflect discussions on institutional provisions of the Protocol.

Some minor adjustments, such as the amendment of the wording “national laws” to “any existing laws”, were made immediately prior to the final adoption of the text in January 2000.

---

<sup>427</sup> ENB Vol. 9 No. 113, p. 2.

<sup>428</sup> UNEP/CBD/BSWG/6/L.2, see Article 17.

<sup>429</sup> UNEP/CBD/BSWG/6/L.2/Rev.2, see Article 17. The final text of the Protocol would also include the phrase “and centres of genetic diversity”.

## Article 21: Confidential Information

1. The Party of import shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the Party of import as part of the advance informed agreement procedure of the Protocol that is to be treated as confidential. Justification shall be given in such cases upon request.

2. The Party of import shall consult the notifier if it decides that information identified by the notifier as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the notifier of its decision, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure.

3. Each Party shall protect confidential information received under this Protocol, including any confidential information received in the context of the advance informed agreement procedure of the Protocol. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms.

4. The Party of import shall not use such information for a commercial purpose, except with the written consent of the notifier.

5. If a notifier withdraws or has withdrawn a notification, the Party of import shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the Party and the notifier disagree as to its confidentiality.

6. Without prejudice to paragraph 5 above, the following information shall not be considered confidential:

- (a) The name and address of the notifier;
- (b) A general description of the living modified organism or organisms;
- (c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
- (d) Any methods and plans for emergency response.

The issue of confidential information was briefly addressed in discussions at BSWG-1<sup>430</sup>

The Chair's summary of elements at BSWG-2 identified the need to define confidentiality; to protect confidential data and relative proprietary rights without hindering information-sharing amongst Parties; to avoid undermining the ability of the competent national authority to take informed decisions; and to disclose information to the public.<sup>431</sup>

Governments submitted written proposals for consideration at BSWG-3.<sup>432</sup> Colombia proposed to exclude from confidentiality provisions information on, *inter alia*, contingency plans and methods of preventing or mitigating accidents, and a summary of the risk assessment with respect to the effects on biodiversity including human health. These proposals would be reflected in the final text. Similarly, the EC suggested excluding, in addition to Colombia's exemptions, the general description of the LMO and its name, the address of the notifier and the purpose of movement. The EC also proposed that the notifier should indicate any part of the submitted information which was confidential and justify this. The competent national authority or national focal point would decide what information to keep confidential, following consultation with the notifier and after informing it of the decision. Finally, the EC's text provided that, in the event that a notification was withdrawn, the confidentiality of the information

<sup>430</sup> UNEP/CBD/BSWG/1/4, para. 46.

<sup>431</sup> UNEP/CBD/BSWG/2/6, Annex II, Item. C.

<sup>432</sup> UNEP/CBD/BSWG/3/3 contains the submissions of Australia, Brazil, Colombia, EC, Madagascar, Mexico, Norway, Sri Lanka and USA.

supplied would be respected. The US introduced the element concerning the establishment of appropriate internal procedures to protect the information received. The two options drafted by SWG-II at BSWG-3 retained the above proposals.<sup>433</sup>

Prior to BSWG-4, governments submitted further draft text.<sup>434</sup> The US proposed new text introducing additional elements. It prohibited the use of confidential information for a commercial purpose and obliged Parties receiving confidential information to protect confidentiality in a manner no less favourable than the treatment of confidential information on domestic LMOs.

Contentious issues that arose during the debate included: the balance between protecting confidential information and the need to provide adequate information for handling emergencies; the balance between the rights and obligations of both receiving and providing parties; and wording that might obstruct technological development.<sup>435</sup>

The draft proposed by the Co-Chair of SWG-II had a single substantive option (with bracketed text) comprising the following elements:<sup>436</sup> identification by the notifier of confidential information; consultation by the importing Party in cases of disagreement on questions of confidentiality; protection of confidential information through procedures no less favourable than those applicable to domestic LMOs; prohibition on using such information for commercial purposes; respect for the confidentiality of information submitted in the event of withdrawal of notification; and information not considered confidential.

Further proposals were made in advance of BSWG-5.<sup>437</sup> Discussions at BSWG-5 focused on the need for the provision.<sup>438</sup> Most developing countries preferred the zero (no provision) option, arguing that it would be redundant given international agreements and given that the issue was trade-related. Other developing countries and most developed countries supported the draft provision as a means of safeguarding information and reassuring the private sector.<sup>439</sup> As no consensus could be reached the entire article was placed in brackets.

In the consolidated text transmitted to BSWG-6, a number of adjustments were made, of which two are worthy of note. First, the zero option was removed. Second, the text provided that, when communicating its decision to the notifier that it believed that the relevant information did not qualify to be treated as confidential, the party of import was obliged to provide "reasons on request and an opportunity for consultation and for an internal review of the decision."<sup>440</sup>

The Chair's proposed text produced at BSWG-6 was almost identical to the previous draft but with the brackets removed.<sup>441</sup> On the final contentious issue of whether to include a list of types of information that "should not generally" or "in no case may" be considered confidential, the Chair's text used "may not."<sup>442</sup> However, the revised text used the phrase "shall not."<sup>443</sup> The text then remained unchanged until its final adoption.

<sup>433</sup> UNEP/CBD/BSWG/3/6, Annex I, Article 20.

<sup>434</sup> UNEP/CBD/BSWG/4/3.

<sup>435</sup> ENB Vol. 9 No. 85, p. 7.

<sup>436</sup> UNEP/CBD/BSWG/4/SWG.II/CRP5.

<sup>437</sup> UNEP/CBD/BSWG/5/2 contains the submissions of Ecuador, New Zealand, Peru, Slovenia, Thailand and Venezuela.

<sup>438</sup> UNEP/CBD/BSWG/5/3, para. 43.

<sup>439</sup> ENB Vol. 9 No. 100, p. 2 and No. 108, p. 7.

<sup>440</sup> UNEP/CBD/BSWG/5/3, Annex, see Article 20.

<sup>441</sup> UNEP/CBD/BSWG/6/L.2, see Article 18.

<sup>442</sup> UNEP/CBD/BSWG/6/L.2, see Article 18(6)

<sup>443</sup> UNEP/CBD/BSWG/6/L.2/Rev.2, see Article 18(6); and UNEP/CBD/ExCOP/1/2, see Article 18(6).

## Article 22: Capacity-building

**1. The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition, including through existing global, regional, subregional and national institutions and organisations and, as appropriate, through facilitating private sector involvement.**

**2. For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs of developing country Parties, in particular the least developed and small island developing States among them, for financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity-building in biosafety. Cooperation in capacity-building shall, subject to the different situation, capabilities and requirements of each Party, include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety. The needs of Parties with economies in transition shall also be taken fully into account for such capacity-building in biosafety.**

During the discussions at BSWG-1, all delegations stressed the importance of capacity-building for the success of the Protocol.<sup>444</sup> However views differed regarding the form and content of the provision. Some delegations suggested that such measures should be undertaken to give effect to Article 8(g) of the Convention, while others proposed to include the provisions of Article 18(2) of the Convention. The importance of the issue and of adequate funding and transfer of technology was generally stressed.

Prior to BSWG-2, some governments submitted draft text<sup>445</sup> which would later feature in the Chairman's summary of draft elements.<sup>446</sup> The African group proposed that Parties design policies and take measures to strengthen and develop human resources and institutional capacities in biosafety and biotechnology. In its view, the BCH should assist developing countries to identify their requirements and secure the necessary funds. Bolivia stressed the importance of training and capacity-building regarding risk assessment and management. In the view of the EU, the issue was one of information exchange, training, education and institutional capacities essential for the functioning of the Protocol. Malaysia pointed out the importance of the ability to benefit from the potential of biotechnology. Norway listed the four main elements of the issue: development and strengthening of capacities to implement the Protocol; development of national biosafety legislation; awareness, assessment and management of LMO-related risks; and safety in the transboundary movement of LMOs.

More governments submitted text for BSWG-3, many of which reiterated existing proposals.<sup>447</sup> However, Cuba introduced two new elements: technical and scientific cooperation, and an international registry of LMOs. It called for the promotion of international cooperation in the handling and use of LMOs and in the implemen-

<sup>444</sup> UNEP/CBD/BSWG/1/4, para. 70.

<sup>445</sup> UNEP/CBD/BSWG/2/2 contains the submissions of the African group, Bolivia, Canada, EU, Norway. See also submission of Malaysia, UNEP/CBD/BSWG/2/Inf.7.

<sup>446</sup> UNEP/CBD/BSWG/2/6.

<sup>447</sup> UNEP/CBD/BSWG/3/3 contains the submissions of the African group, Australia, Belarus, Brazil, Canada, Colombia, Cuba, EC, India, Madagascar, Malaysia, Mexico, Norway, Peru, Sri Lanka, Switzerland, and US.

tation of national policies. The proposed registry would become the basis for a global information network on LMOs which would also provide assistance, training and consultancy services to developing countries on implementation and for fostering scientific research.

Six options were produced by SWG-II, including a zero (no provision) option.<sup>448</sup> Generally, the options combined most of the main elements suggested by governments in their submissions and included: the development and implementation of regional and global capacity building programmes and with securing funds by the Secretariat and the BCH; the establishment of centres of training and capacity building with financial mechanisms; cooperation in the training of personnel, exchange of experts, informational exchange and institutional capacity-building to perform risk assessment and management; maximising the use of existing multilateral, regional and bilateral mechanisms and encouraging the assistance of the private sector; enhancing the capacity of developing countries, their local technological and institutional competence to contribute to the distribution of benefits from the potential of biotechnology.

While some argued that other international agreements had mandates to participate in capacity building, others favoured the development of a provision within the Protocol. The differences between the options included: the degree of clarity on financial assistance and capacity-building implementation and planning; inclusion of capacity development in biotechnology as well as biosafety; and emphasis on capacity and risk assessment and management procedures.<sup>449</sup>

At BSWG-4, delegations agreed to retain the article on capacity building.<sup>450</sup> In the resulting draft,<sup>451</sup> the options were reduced to two: a single paragraph option, and a six-paragraph option, which removed the repetition of the previous options and included new wording proposal by Colombia<sup>452</sup> stressing the importance of “new and additional financial resources”. The first option simply required Parties to design appropriate policies and take effective measures to build capacity, through international, regional and national institutions and to take into account the needs of developing countries. The other option called for maximising the use of existing multilateral, regional and bilateral mechanisms, development of national law and guidelines on biosafety, development of risk assessment and risk management mechanisms, establishment of new and additional financial resources, distribution of benefits from the potentials of biotechnology, and involvement of the Secretariat in developing and implementing capacity-building programmes, securing funds and providing information.

The single provision that emerged at the end of BSWG-5 had been condensed to five elements, mostly bracketed:<sup>453</sup> an obligation to cooperate in capacity building in developing countries and in countries with economies in transition; identification of capacity building needs; needs of countries with economies in transition; and involvement of the private sector (as proposed by some developed countries).<sup>454</sup> The reference to the role of the Secretariat was deleted. The text on financial matters was referred to CG-2 for discussion under the article on the Financial Mechanism (then Article 26).<sup>455</sup> Among the contentious issues that remained unresolved was the reference to “biotechnology to the extent that it relates to biosafety” in the provision.

<sup>448</sup> UNEP/CBD/BSWG/3/6, Annex I, see Article 21.

<sup>449</sup> ENB Vol. 9 No. 74, p.8.

<sup>450</sup> ENB Vol. 9 No. 85, p.7.

<sup>451</sup> UNEP/CBD/BSWG/4/4, Annex II, see Article 21.

<sup>452</sup> UNEP/CBD/BSWG/4/3.

<sup>453</sup> UNEP/CBD/BSWG/5/3, Annex, see Article 21.

<sup>454</sup> ENB Vol. 9 No. 104, p. 2.

<sup>455</sup> *Id.*

At BSWG-6, discussions took place in SWG-II, and in a sub-group of SWG-II and CG-2.<sup>456</sup> The article was considered in conjunction with the article on Financial Mechanism and Resources (then Article 26). The general reference to capacity-building on biotechnology and biosafety was amended to refer to “biotechnology to the extent that it is required for biosafety.”<sup>457</sup> Despite disagreements, the reference to facilitating private sector involvement was retained in the Chair’s text.<sup>458</sup> Language addressing access to financial resources, technology and know-how, cooperation to enhance

technological and institutional capacities, and assistance in areas of risk assessment and risk management, which had been supported by most developing countries,<sup>459</sup> also featured in the Chair’s text.

The article then remained unchanged until its final adoption in January 2000.

---

<sup>456</sup> ENB Vol. 9 No. 117, p. 7.

<sup>457</sup> UNEP/CBD/BSWG/6/L.2, see Article 19.

<sup>458</sup> *Id.*

<sup>459</sup> ENB Vol. 9 No. 110, p. 2.



## Article 23: Public Awareness and Participation

### 1. The Parties shall:

(a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;

(b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.

2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.

3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House.

Discussions on public awareness and participation started at BSWG-2.<sup>460</sup> The Chair's summary of elements<sup>461</sup> reflected the views expressed during the debates and governments' prior submissions of draft text<sup>462</sup>.

On public awareness, the following elements were identified: whether to address public awareness in the Protocol; the provision by Parties of adequate information on the safe transfer, handling and

use of LMOs to the public; the development and implementation of public awareness mechanisms by national competent authorities/ national focal points, together with the private sector and NGOs; whether decisions on such mechanisms should only be taken at the national level; facilitating educational and public awareness programmes on safety in biotechnology; and respecting confidentiality in public-awareness mechanisms.

On public participation, the elements included were: whether to include a provision on public participation in the Protocol (noting that Article 14(1) of the Convention already addressed public participation in the context of impact assessment); whether to reflect both public awareness and public participation in a single provision; whether to encourage but not mandate public awareness under the Protocol; whether to carry out a public hearing in cases subject to AIA; whether to decide the level of public participation at the national level; and whether to include the participation of NGOs, citizens, consumer protection groups and stakeholders.

A number of written proposals were received for BSWG-3,<sup>463</sup> including a proposal for a general commitment to ensure that adequate information on the transfer, handling and use of LMOs was provided to the public. Many countries also proposed the development of educational and public awareness programmes on biosafety.<sup>464</sup>

Delegations considered the need for a provision on this issue in the Protocol at BSWG-3. Some recommended including a reference in the preamble, since the article on Information Sharing/Biosafety Clearing House, (then Article 19) also touched on the issue. Others noted that the CBD already addressed the issue.<sup>465</sup>

The Co-Chairs' text from SWG-II took up many of the written submissions. It referred to the provi-

<sup>460</sup> UNEP/CBD/BSWG/2/6, paras. 80-113.

<sup>461</sup> UNEP/CBD/BSWG/2/6, Annex II, Item E.

<sup>462</sup> UNEP/CBD/BSWG/2/2, pp. 64-65, contains the submissions of the African group, Bolivia, Canada and Norway.

<sup>463</sup> UNEP/CBD/BSWG/3/3, pp. 74-78, contains submissions of the African group, Australia, Belarus, Brazil, Canada, Cuba, India, Japan, Malaysia, Mexico, Norway, Peru, Sri Lanka, Switzerland,

<sup>464</sup> For example, India, Mexico, Malaysia, Sri Lanka and Switzerland.

<sup>465</sup> ENB Vol. 9 No. 74, p. 8.

sion of adequate information to the public; the development of educational programmes on biosafety; the opportunity for public hearings for the approval of a release, transfer or use of LMOs (as proposed by the African group); the protection of commercial confidential information while promoting public understanding of biosafety issues and making risk assessments publicly available (as proposed by Brazil); cooperation with other States (as suggested by Cuba); and the disclosure of information on biosafety and impacts of releases to the public (as in Malaysia's submission).

The Consolidated Text at the end of BSWG-3<sup>466</sup> included five options: no provision; inclusion in the preamble; the entire Co-Chairs' text; and two options containing a general obligation to take appropriate measures for public awareness and public participation.

By the end of BSWG-4, delegations had settled on inclusion of a bracketed provision on public awareness and participation reflecting different views.<sup>467</sup> The resulting single text comprised all the elements of the Co-Chairs' text approved at the third meeting.<sup>468</sup>

The negotiations in SWG-II during BSWG-5 revolved around the nature of the public's role in the decision-making process.<sup>469</sup> Some countries preferred to provide the public with "the opportunity for involvement in the decision-making process" while others favoured providing "the results of the decision-making process."<sup>470</sup> In response to concerns about implementing such a provision at the national level, the proviso "where appropriate"

was added to both.<sup>471</sup> The reference to national laws, regulations and administrative measures was also contentious.<sup>472</sup>

The majority of developing countries suggested taking human health into account when developing and implementing public awareness programmes on the safe transfer, handling and use of LMOs, and also called for inclusion of "products thereof" in addition to LMOs.<sup>473</sup> Many developing countries advocated the removal of the reference to confidential information.<sup>474</sup> One developed country proposed restricting Parties' obligations to facilitating public participation to "intentional" transboundary movements of LMOs, whereas others suggested using "release of LMOs" to simplify language related to LMOs.<sup>475</sup> Most delegations supported provisions on international cooperation for promotion and development of educational and public awareness programmes.<sup>476</sup>

All these options were reflected in the bracketed text approved for consideration at BSWG-6.<sup>477</sup>

At BSWG-6, agreement could not be reached on the bracketed language of the provision and the Co-Chairs of SWG-II drafted new text.<sup>478</sup> However, the subsequent debate did not succeed in bringing together the different views. The main contentious issues at this stage were: whether to protect confidential information at all; whether complete, or only appropriate, information needed to be provided to the public; and whether information related only to the "release, safe transfer and handling and use of LMOs" or also to the results of the decision-making process regarding such activi-

<sup>466</sup> UNEP/CBD/BSWG/3/6, Annex I, see Article 22.

<sup>467</sup> ENB Vol. 9 No. 85, p. 7.

<sup>468</sup> UNEP/CBD/BSWG/4/4, Annex II, see Article 22.

<sup>469</sup> ENB Vol. 9 No. 108, p. 8.

<sup>470</sup> *Id.*

<sup>471</sup> *Id.*

<sup>472</sup> *Id.*

<sup>473</sup> ENB Vol. 9 No. 103, p. 2.

<sup>474</sup> *Id.*

<sup>475</sup> ENB Vol. 9 No. 108, p. 8.

<sup>476</sup> ENB Vol. 9 No. 100, p. 2.

<sup>477</sup> UNEP/CBD/BSWG/5/3, Annex, see Article 22.

<sup>478</sup> ENB Vol. 9 No. 113, p. 2.

ties.<sup>479</sup> A small group was created to deal with the issue and produced text that included bracketed references to human health, “products thereof” and “release, safe transfer, handling and use.”<sup>480</sup>

The Chair’s proposed text at BSWG-6<sup>481</sup> contained language referencing human health and respect for confidential information, but excluding public information on “release” of LMOs. This article, which was by now very close to the text finally approved, required Parties to: promote and facilitate public awareness, education and participation in the implementation of the Protocol, and, in doing so, cooperate with other States and international organisations; consult the public in the decision-making process and provide the results of such decisions, while respecting confidential information; and inform the public about how to access the BCH.

The revised Chair’s text replaced the reference to cooperation with “international organisations” to “international bodies.”<sup>482</sup> The final text adopted at the resumed ExCOP included a final adjustment stipulating that Parties’ obligations to consult with the public in the decision-making process be carried out in accordance not only with their respective laws, but also with their regulations.

---

<sup>479</sup> *Id.*

<sup>480</sup> ENB Vol. 9 No. 117, p. 7.

<sup>481</sup> UNEP/CBD/BSWG/6/L.2, see Article 20.

<sup>482</sup> UNEP/CBD/BSWG/6/L.2/Rev.2, see Article 20.

## Article 24: Non-Parties

**1. Transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol. The Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements.**

**2. The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Biosafety Clearing-House on living modified organisms released in, or moved into or out of, areas within their national jurisdictions.**

Although some reference had already been made to the issue of non-Parties, it was agreed at BSWG-2 that it was premature to prepare text on the topic.<sup>483</sup>

The resumed debate at BSWG-3 focused on whether to include a provision on this issue or not and it was agreed that an element paper should be prepared reflecting the views expressed.<sup>484</sup> The consolidated text included an element paper, which addressed the topics of non-Parties, trade with non-Parties and existing government submissions.<sup>485</sup> Substantive elements proposed under the non-Parties section allowed for Parties to enter into bilateral or regional agreements, compatible with the Protocol, and required such agreements to be made available to other Parties through the CHM and the Secretariat. On trade with non-Parties, options included permitting such trade if adequate measures to ensure safe

movement were taken; limitation of restrictions to those no more stringent than under the WTO; permission with flexibility; and submission of non-Parties to arbitration mechanisms provided under the Protocol.

In discussions in SWG-II at BSWG-4, some delegations expressed their concern over non-parties gaining trade advantages, and over the need for incentives to ratify the Protocol.<sup>486</sup> Some delegations requested a definition of “non-Party”.<sup>487</sup> The resulting draft text included the following options: no provision needed; no trade of LMOs between Parties and non-Parties; non-discriminatory trade (through bilateral, regional or multilateral arrangements) if in compliance with the substantive provisions of the Protocol or if conducted under a regulatory framework as stringent as the Protocol’s; and consideration of trade restrictions with non-Parties five years after the entry into force of the Protocol.<sup>488</sup>

At BSWG-5, the provision was discussed in CG-2 together with the provisions on non-discrimination/national treatment and on the relationship with other international agreements, as these were considered interlinked.<sup>489</sup> However, the discussions showed delegations maintaining their positions, namely: to have no provision; to ban trade with non-Parties; or to subject such trade to bilateral, regional or multilateral arrangements.<sup>490</sup> The text approved for inclusion in the consolidated negotiating text for BSWG-6 streamlined the previous options into three bracketed paragraphs reflecting these positions.<sup>491</sup>

After deciding to include the provision in the Protocol and to withdraw the language banning trade with non-parties, the Chair’s proposed text produced at BSWG-6 subjected transboundary

<sup>483</sup> UNEP/CBD/BSWG/2/6, para. 175.

<sup>484</sup> UNEP/CBD/BSWG/3/6, paras. 53-64.

<sup>485</sup> *Ibid.*, Annex I, see Article 23.

<sup>486</sup> ENB Vol. 9 No. 79, p. 2.

<sup>487</sup> *Id.*

<sup>488</sup> UNEP/CBD/BSWG/4/4, Annex II, see Article 23.

<sup>489</sup> UNEP/CBD/BSWG/5/3, para. 40.

<sup>490</sup> ENB Vol. 9 No. 105, p. 2, and No. 107, p. 2.

<sup>491</sup> UNEP/CBD/BSWG/5/3, Annex, see Article 23.

movements of LMOs between Parties and non-Parties to a requirement of consistency with the objectives and principles of the Protocol.<sup>492</sup> The second paragraph of the article also encouraged Parties to conduct such dealings in accordance with bilateral, regional and multilateral agreements or arrangements with non-Parties, and required Parties to encourage non-Parties to adhere to the Protocol and “to contribute appropriate information to the BCH on LMOs released in and moved into or out of, their territory.” In its proposal at the ExCOP, the EU proposed that trade with non-Parties should be “consistent with the objectives” of the Protocol.<sup>493</sup> The Miami Group proposed a similar amendment and, in addition, the deletion of the second paragraph of the article.<sup>494</sup>

By 27 January 2000 at the resumed ExCOP, the Chair of the informal consultations on unresolved non-core issues, Ambassador Nobs (Switzerland), recognised that no solution had yet been found on the contentious aspects of the provision.<sup>495</sup> After further consultations final text was prepared. The article allowed trade with non-Parties “consistent with the Protocol’s objective” and bilateral, regional and multilateral agreements and arrangements for that purpose. The second paragraph was maintained, requiring Parties to encourage non-Parties to adhere to the Protocol and to contribute appropriate information to the BCH.

---

<sup>492</sup> UNEP/CBD/BSWG/6/L.2, see Article 21.

<sup>493</sup> UNEP/CBD/ExCOP/1/3, Annex II.

<sup>494</sup> *Ibid.* Annex III.

<sup>495</sup> UNEP/CBD/ExCOP/1/3 para. 86.

## Article 25: Illegal Transboundary Movements

**1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalising transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements.**

**2. In the case of an illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the living modified organism in question by repatriation or destruction, as appropriate.**

**3. Each Party shall make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements pertaining to it.**

Of the written submissions made prior to the BSWG-2, only the African region presented text on illegal traffic in LMOs.<sup>496</sup> The African group proposed as illegal traffic under the Protocol any transfer of LMOs or products thereof: without notification to, or AIA of, all States concerned; with AIA obtained from the States concerned through falsification, misrepresentation or fraud; or with AIA not conforming “in a material way with the documents submitted” or resulting in the deliberate release of LMOs in contravention of the Protocol and of the general principles of international law. In such cases, the State of import would have had the right to destroy or dispose of the organisms or products in question. Lastly, the African submission suggested that Parties should adopt

appropriate domestic legislation to prevent and punish illegal traffic and should cooperate with other Parties in this respect.

However, BSWG-2 considered that, as “illegal traffic” was related to “monitoring and compliance”, it was too early to begin drafting text on this item.<sup>497</sup>

Further draft text was presented before BSWG-3 by Australia, Malaysia and South Africa.<sup>498</sup> Malaysia and South Africa essentially endorsed Africa’s earlier proposal. Malaysia added that the person responsible for the illegal traffic could be required to remove the LMO from the environment. Australia’s text was similar, first defining illegal traffic and then calling for national legislation to address this, which could include the re-export of the LMO or the imposition of additional penalties.

Following the request from BSWG-3,<sup>499</sup> the Secretariat prepared a compilation of the main elements identified in the submissions by governments. This was then considered by SWG-II which turned the elements into six options, which were then included in the consolidated text.<sup>500</sup>

The draft text emerging from BSWG-4 included options for: no provision; development of domestic legislation and cooperation; and a longer option reflecting governments’ proposals on domestic legislation, together with a number of provisions for information sharing.<sup>501</sup>

During BSWG-5, debate revolved around the need for the provision, which was not supported by most developed countries which felt that a general reference to Parties’ obligations existed in the article on General Obligations, (then Article 1bis), and which considered illegal traffic to be a matter for domestic legislation.<sup>502</sup> Developing

<sup>496</sup> UNEP/CBD/BSWG/2/2, pp. 63-64.

<sup>497</sup> UNEP/CBD/BSWG/2/6, para 174.

<sup>498</sup> UNEP/CBD/BSWG/3/5, see Article 20.

<sup>499</sup> UNEP/CBD/BSWG/3/6, para 52.

<sup>500</sup> UNEP/CBD/BSWG/3/6 pp. 85-87

<sup>501</sup> UNEP/CBD/BSWG/4/4, Annex II, see Article 25.

<sup>502</sup> ENB Vol. 9 No. 108, p. 8.

countries generally favoured the article, noting that its scope should extend to “products thereof” and that it should include references to informing the Secretariat and the BCH, to developing national legislation and to cooperation among Parties.<sup>503</sup> Some developing countries introduced text regarding the right of the affected Party to request the Party of origin to dispose of the LMOs in question at its own expense, which was opposed by several developed countries.<sup>504</sup>

CG-2 developed a definition of illegal traffic and SWG-II then drew on this to produce further draft text for discussion.<sup>505</sup> The definition was sent for consideration under the article on Use of Terms, (then Article 2).<sup>506</sup> The resulting text, which did not include a definition of illegal traffic, included brackets around the term “products thereof” and around the reference to the nature of the information to be conveyed to the BCH.<sup>507</sup>

The Chair’s proposed text at BSWG-6 changed “illegal traffic” to “illegal transboundary movement” but retained an explanation of the term and the provision for the affected Party to request the Party of origin to dispose of the LMOs at its own cost.<sup>508</sup> The text called for Parties to adopt appropriate domestic measures to prevent and penalise such transboundary movements, allowed the affected Party to request the disposal of the LMOs in question by the Party of origin, and obliged Parties to make available to the BCH information concerning such cases. The text was revised by the Legal Drafting Group,<sup>509</sup> which made a few adjustments and finalised the text of the article that was adopted.

---

<sup>503</sup> *Id.*

<sup>504</sup> *Id.*

<sup>505</sup> ENB Vol. 9 No. 104, p. 2, and UNEP/CBD/BSWG/5/3, para 45.

<sup>506</sup> ENB Vol. 9 No. 108, p. 8.

<sup>507</sup> UNEP/CBD/BSWG/5/3, Annex, see Article 25.

<sup>508</sup> UNEP/CBD/BSWG/6/L.2, see Article 23.

<sup>509</sup> UNEP/CBD/BSWG/6/L.2/Rev.2, see Article 23.

## Article 26: Socio-economic considerations

**1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.**

**2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.**

Socio-economic considerations were one of the issues on which there was no consensus at the Madrid Experts Meeting in July 1995.<sup>510</sup>

At BSWG-1, most developed countries considered the subject of little relevance and believed that further studies on the matter were not necessary. Some developing countries expressed the opposite view and noted that, "in addition to economic impacts such as income distribution, the negative socio-economic impacts of LMOs could include erosion of agricultural and other biological diversity; risks to sustainable use of existing biodiversity; and the threats of transgenic animals and plants to the cultural and religious order of some countries."<sup>511</sup> It was proposed that the Secretariat prepare a study on the socio-economic impacts of biotechnology, but after extensive discussion no agreement was reached. Instead, the BSWG requested the Secretariat to compile a bibliogra-

phy of relevant literature regarding both positive and negative potential socio-economic effects of biotechnology.<sup>512</sup>

The bibliography on potential socio-economic impacts of biotechnology prepared by the Secretariat<sup>513</sup> was considered at BSWG-2, together with written submissions from governments.<sup>514</sup> The African Group presented the most comprehensive submission on socio-economic factors, incorporated into a number of draft provisions throughout the Protocol: objectives, general obligations, notification procedure, risk assessment and management, liability and compensation. The draft article on socio-economic considerations proposed by the African group included taking into account the length of time before such impacts may be manifested and proposed a seven year notification period prior to export. The African group proposal contained an extensive list of socio-economic considerations to be included in a risk assessment: anticipated changes in the existing social and economic patterns; possible threats to biological diversity, traditional crops or other products and, in particular, farmers' varieties and sustainable agriculture; impacts likely to be posed by the possibility of substituting traditional crops, products and indigenous technologies through modern biotechnology outside of their agro-climatic zones; anticipated social and economic costs due to loss of genetic diversity, employment, market opportunities and, in general, means of livelihood of the communities; disruptions to social and economic welfare; and possible effects contrary to the social, cultural, ethical and religious values of communities.<sup>515</sup> It constituted the most detailed list of socio-economic considerations to be taken into account by the Protocol.<sup>516</sup>

Bolivia's submission noted that the introduction of LMOs in countries rich in biodiversity or that are centres of genetic diversity could result in

<sup>510</sup> UNEP/CBD/COP/2/7, Annex I, para. 18(b).

<sup>511</sup> UNEP/CBD/BSWG/1/4, para 88.

<sup>512</sup> *Ibid.*, para 111.

<sup>513</sup> UNEP/CBD/BSWG/2/4.

<sup>514</sup> UNEP/CBD/BSWG/2/2, contains the submissions of the African Group, Bolivia, Canada, the EU and Japan.

<sup>515</sup> *Ibid.* p. 84.

<sup>516</sup> It was retained in the draft text until BSWG-4, where it was section 12 of Annex II. See UNEP/CBD/BSWG/4/4, p. 73



the depletion of that diversity. A breakdown of agricultural systems and genetic erosion would threaten livelihoods.<sup>517</sup>

A request by the G-77 and China to the Secretariat to prepare a study on the socio-economic implications of biotechnology was later withdrawn, but that Group asked the Secretariat instead to facilitate a round-table discussion on socio-economic considerations at BSWG-3.<sup>518</sup>

At this stage, socio-economic considerations, as well as ethical considerations, were discussed in the context of risk assessment. Here the debate focused on whether such assessments should be based solely on scientific data.

Governments submitted draft text prior to BSWG-3.<sup>519</sup> In addition to earlier suggestions, Mexico stressed the importance of addressing impacts on the recipient environment and, in particular, on centres of origin. Concern over impacts on social and economic welfare was expressed by Madagascar and Sri Lanka, amongst others.

It was agreed at BSWG-3 that socio-economic considerations would not be the subject of a further element paper, but would be included in the consolidated text of draft articles, with the texts already submitted by governments being set out as various options.<sup>520</sup>

Four substantive options were drafted (in addition to the zero (no provision) option). One option basically reflected the previous submission by the African group, in which socio-economic factors featured as an element of risk assessment and management and which included a period of observation of the potential impacts and the requirement for seven years' advance notifica-

tion of export of an LMO. Another option called for socio-economic imperatives to be taken into consideration at all levels in the Protocol, including risk assessment and management and for particular attention to be paid to the displacement of particular agricultural resources, cultures or livelihood and to the prevention and mitigation of possible adverse effects. A further option simply acknowledged that socio-economic considerations varied considerably from Party to Party and therefore encouraged research on the issue.<sup>521</sup>

At this stage, the debate revolved around the need to include these considerations in the text of the Protocol at all. Generally speaking, developing countries felt the issue was at the heart of the Protocol itself, whereas developed countries considered the concept too vague and specific to each country's circumstances to be enshrined in a separate provision.<sup>522</sup>

At BSWG-4 there was little change to the text, with the exception of some bracketing and reordering.<sup>523</sup> The Chair called for a reduction of options in the draft text.<sup>524</sup> The resulting draft contained two substantive options (as well as a zero option): one simply calling for appropriate consideration of socio-economic consequences of adverse consequences of using LMOs, while the second specified a series of measures to be taken that reflected the concerns of developing countries.<sup>525</sup>

Negotiations were again difficult at BSWG-5, with few concessions made from either standpoint. Preferences varied from a mention of the subject in the preamble, references in the articles dealing with risk assessment and risk management, or as an independent article.

<sup>517</sup> *Id.*

<sup>518</sup> UNEP/CBD/BSWG/2/6, paras. 183 and 190.

<sup>519</sup> UNEP/CBD/BSWG/3/3, contains, *inter alia*, the submissions on risk assessment and on risk assessment parameters of the African group, Belarus, India, Madagascar, Malaysia, Mexico and Sri Lanka.

<sup>520</sup> UNEP/CBD/BSWG/3/6, para 27.

<sup>521</sup> *Ibid.*, pp.87-88.

<sup>522</sup> *Ibid.*, paras. 29-38.

<sup>523</sup> UNEP/CBD/BSWG/4/4.

<sup>524</sup> ENB. Summary. Vol. 9 No. 85, p. 9

<sup>525</sup> UNEP/CBD/BSWG/4/4, p. 48

The draft was reduced to one option with many brackets by merging a number of the previous paragraphs, which included many of the submissions of developing countries, to produce a compromise provision. This draft referred to prevention and mitigation of socio-economic impacts, an assessment and management of risks with a long observation period, while also encouraging research on the topic. It also called for Parties exporting commodities-LMOs to notify affected Parties sufficiently in advance to allow appropriate measures to be taken, providing special assistance when the affected Party was a developing country. Annex II was reduced to a call for "information on the potential impacts on the socio-economic patterns of the importing country".<sup>526</sup>

The meeting noted that there "appeared to be a shared sympathy for the subject, but not about the need, place and the manner of handling the issue under the Protocol".<sup>527</sup> The issue had a bearing on the scope and other provisions for the Protocol and needed to be considered carefully by delegations before the sixth meeting of the Working Group.<sup>528</sup>

The Chair's proposed text at BSWG-6 contained significant changes. It provided that Parties should take into account socio-economic implications of adverse impacts, also taking into account human health, "especially in regard to the indigenous and local communities as referred to in Article 8(j) of the Convention". It further encouraged Parties to cooperate on research and information exchange, "including the need for the early warning to such local and indigenous communities that may be affected economically".<sup>529</sup>

The text was revised and amended to form the draft transmitted by BSWG-6 to the ExCOP.<sup>530</sup> Although many delegations, especially developing countries, were initially unhappy with the Chair's proposed text, the wording on socio-economic considerations was ultimately accepted with little discussion.

A requirement for Parties' decisions on import to be "consistent with their international obligations" was added. Socio-economic considerations arising from the "impact" of LMOs could now be taken into account (instead of "adverse impact"). The reference to "risks to human health" was deleted. The phrase "the value of biological diversity to indigenous and local communities" was added and, similarly, regarding research and information exchange, a general reference to "any socio-economic impacts of LMOs, especially on indigenous and local communities" was included in place of earlier language on early warning and economic effects on local and indigenous communities. Any reference to socio-economic considerations in Annex II was deleted.

At the resumed ExCOP, a final addition made during the last informal consultations conducted by Ambassador Nobs added a reference to Parties' domestic measures to implement the Protocol with regard to socio-economic considerations.<sup>531</sup>

<sup>526</sup> *Id.*; Text submitted to plenary by the co-chairs of SWG II (UNEP/CBD/BSWG/5/CRP.32).

<sup>527</sup> UNEP/CBD/BSWG/5/3, para. 46.

<sup>528</sup> *Id.*

<sup>529</sup> UNEP/CBD/BSWG/6/L.2, see Article 24.

<sup>530</sup> UNEP/CBD/ExCOP/1/2, Appendix 1

<sup>531</sup> ENB Vol. 9 No. 137, p. 9.

## Article 27: Liability and Redress

**The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.**

Liability was another issue on which there was no consensus at the Madrid Experts Meeting in July 1995.<sup>532</sup> At BSWG-1, several delegations, noting that the issue of liability and compensation had been addressed by a number of international conventions, recommended that the Secretariat prepare a working paper on the matter. It was noted that Article 14(2) of the Convention gave the COP a mandate to address the issue of liability and redress, including compensation for damage to biodiversity.<sup>533</sup>

A document prepared by the Secretariat for BSWG-2 on existing international agreements relevant to biosafety,<sup>534</sup> addressed liability and compensation with reference to Article 14(2) of the Convention, paragraph 18(b) of Annex I to the report of the Open-ended Ad Hoc Group of Experts<sup>535</sup>, and decision II/5 of the COP.<sup>536</sup> The document noted that, although most of the international agreements examined avoided matters relating to liability and compensation and left these to domestic law makers, there were some agreements that addressed damage to persons, property and the environ-

ment arising from potentially hazardous activities, the most developed regimes being those addressing oil pollution damage and damage caused by nuclear incidents. Those regimes indicated that there were essentially three functions of liability in international law, namely: a corrective function (ex post facto enforcement), a preventive function (ex ante facto incentive) and a reparative function. The document listed a series of elements including: scope of activities and substances; definition of environmental damage; establishment of a standard of care and of measurement of the damages; locus standi; determination of available remedies; defences; adequate insurance; and designation of forum and enforcement of judgments that a liability regime under the Biosafety Protocol might consider.

Some governments made submissions for BSWG-2.<sup>537</sup> Generally speaking, while developed countries were opposed to having an article on liability and preferred to rely on international law and Article 14(2) of the Convention to cover the issue, many developing countries wanted to include a provision and some submitted draft text. It was decided that liability and compensation should be discussed at the following meeting on the basis of the government submissions of draft text.<sup>538</sup>

The Consolidated Text of Draft Articles at the end of BSWG-3 included, under Article 27 (Liability and Compensation), seven options deriving from the main elements of the submissions by governments.<sup>539</sup> Option 1 was to have no provision, while Option 2 referred work on the matter to the development of Article 14(2) of the CBD.

Option 3 obliged the state or states of origin of the harm to negotiate with the affected state or states on the legal consequences. It also required them to bear the costs of restoration or compensation

<sup>532</sup> UNEP/CBD/COP/2/7, Annex 1, para. 18(b).

<sup>533</sup> UNEP/CBD/BSWG/1/4, paras. 95-97.

<sup>534</sup> UNEP/CBD/BSWG/2/3.

<sup>535</sup> UNEP/CBD/COP/2/7.

<sup>536</sup> UNEP/CBD/BSWG/2/3, paras. 121- 123.

<sup>537</sup> UNEP/CBD/BSWG/2/2, contains the submissions of the African group, Bolivia, Canada, EU, Japan and Norway.

<sup>538</sup> UNEP/CBD/BSWG/2/6, para. 177.

<sup>539</sup> UNEP/CBD/BSWG/3/6, Annex, see Article 27.

in cases of detriments to human or animal health, biodiversity or socio-economic welfare of the state, and to make payments in the case of personal or property damages. It also encouraged Parties to further elaborate liability rules and allowed Parties to undertake further actions, such as submitting a claim to arbitration or to the International Court of Justice. Under Option 4 exporting Parties would be liable for any negative effects unforeseen on the basis of the information provided for the first import, for breach of the Protocol obligations, for illegal traffic and for unintentional transboundary movements. Option 5 stated that exporter would be liable for any damage deriving from the transboundary movement of LMOs and for full compensation. Option 6 called on Parties to cooperate in adopting appropriate rules and procedures on liability and redress in accordance with Article 14(2) of the Convention. Finally, Option 7 covered the responsibility of Parties to meet their international obligations on conservation and sustainable use biodiversity, to ensure that recourse was available in accordance with their legal system, to provide compensation from damage by LMOs. It provided for further cooperation between Parties for the further development of international law on liability, the settlement of related disputes, and the development of criteria and procedures for payment of compensation, compulsory insurance and compensation funds.

At BSWG-4, debate still revolved around whether to include a provision on liability or not, or whether to leave the matter to be addressed by the CBD COP (under Article 14 (2) CBD) or by the meeting of the Parties to the Protocol. Keeping the options open, the draft text of SWG-II<sup>540</sup> amalgamated the proposals received into several

options, taking account of the recent government submissions on the topic.<sup>541</sup> The options ranged from no article, to consideration at the first meeting of the Parties, to the inclusion of an article on liability and compensation. The main new feature was the itemisation of possible different elements of the provision: liability; civil liability; compensation; measures for reinstatement; prescription of liability; emergency fund and exceptions. Other proposals for substantive text included strict liability of the state of origin, liability for breach of due diligence, and the establishment of an Emergency Compensation Fund.

Developed and developing countries in general advanced opposing views during BSWG-5. Some developed country delegations expressed concern about the length of time that had been spent in developing liability regimes under other international agreements, and others suggested that the matter could be dealt with by domestic frameworks on product liability.<sup>542</sup> Most developing countries stressed the importance of a substantive provision on liability and redress. It was suggested that it would be illogical to develop a regulatory framework to ensure safety without considering the consequences of accidents. Other developing countries noted the absence of a general international law of liability and called for a tailor-made regime.<sup>543</sup>

At BSWG-5, SWG-II referred the issue to CG-2 where a small drafting group was set up to clarify positions and reach agreement on text.<sup>544</sup> The text that was sent to BSWG-6 was entirely bracketed in order to combine all the variations into a single option.<sup>545</sup>

<sup>540</sup> UNEP/CBD/BSWG/4/4, pp. 49 - 53.

<sup>541</sup> UNEP/CBD/BSWG/4/2, contains the submissions of the African region, Bolivia, Chile, Colombia, India, Japan, Malaysia, Norway, South African and Switzerland.

<sup>542</sup> ENB, Vol. 9 No. 108, p.9.

<sup>543</sup> *Id.*

<sup>544</sup> UNEP/CBD/BSWG/5/3, paras. 40 and 53.

<sup>545</sup> *Id.*

At BSWG-6, the Chair of the drafting group on liability, Ms. Kate Cook (United Kingdom), sought to identify the middle ground between polarised positions, which called either for a strong liability regime or for deletion of the article. After lengthy discussions, many delegations agreed that this complex issue could not be resolved at the meeting and supported a non-paper from the Chair of the drafting group to include an article that would enable future work on the issue.<sup>546</sup> The debate then focused on the level of commitment to such work and possible timeframes for action.

The drafting group discussed the issue and submitted text calling upon Parties to “examine the modalities of establishing and developing rules and procedures on liability and redress” and mandating them to start, at the first MOP, a process to elaborate rules and procedures to develop a

regime within six years. A revised text merged the two paragraphs and deleted the reference to “studies to be carried out.”<sup>547</sup> Additionally, the text now called upon the first meeting of the COP/MOP “to adopt a process with respect to the appropriate elaboration of international rules and procedures” on liability. This process should take account of “the ongoing process in international law on these matters” and was to be completed in four years, rather than six. The final text,<sup>548</sup> revised by the Legal Drafting Group, was presented to the plenary of the ExCOP and remained unchanged until the final adoption of the Protocol at the resumed ExCOP in January 2000.

---

<sup>546</sup> ENB Vol. 9 No. 111, p. 2 and No. 112, p. 2.

<sup>547</sup> UNEP/CBD/BSWG/6/L.2/Rev.1, see Article 25.

<sup>548</sup> UNEP/CBD/BSWG/6/L.2/Rev.2, see Article 25.

## Article 28: Financial Mechanism and Resources

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

2. The financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for this Protocol.

3. Regarding the capacity-building referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need for financial resources by developing country Parties, in particular the least developed and the small island developing States among them.

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed and the small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building requirements for the purposes of the implementation of this Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, *mutatis mutandis*, to the provisions of this Article.

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in

transition avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multi-lateral channels.

The issue of funding and other financial considerations relating to implementation of the Protocol was discussed at BSWG-1.<sup>549</sup> As with the issue of capacity-building, some delegations argued that appropriate financial mechanisms were already established under other international agreements, while others favoured including a specific provision within the Protocol, including reference to Articles 20 and 21 of the Convention (Financial Resources and Financial Mechanism, respectively).

Prior to BSWG-2, some governments presented their views in writing.<sup>550</sup> The African group called upon Parties to agree on a scale of contributions to the budgets of the Secretariat and the BCH at the first meeting of the Parties to the Protocol. It also proposed the establishment of a contingency fund for cases of accidents arising from the use, release and transfer of LMOs and voluntary funding mechanisms to cover the costs of capacity-building centres. Norway supported the idea that financial resources for application of the Protocol should be in accordance with Article 20 of the Convention (as the EU also suggested) and the use of the Convention's financial mechanism under Article 21 (which Japan also proposed).

It was agreed that the Secretariat should draft articles on "financial issues" and "institutional framework", including different options if appropriate.<sup>551</sup>

Further draft text was submitted to BSWG-3, under the provisions on capacity-building, in which developing countries generally emphasised the importance of a financial mechanism to ensuring and strengthening capacity-building.<sup>552</sup>

<sup>549</sup> UNEP/CBD/BSWG/1/4, paras. 98 – 100.

<sup>550</sup> UNEP/CBD/BSWG/2/2, pp. 71-72 contains the submissions of the African region, EU, Japan and Norway.

<sup>551</sup> UNEP/CBD/BSWG/2/6, para. 170

<sup>552</sup> UNEP/CBD/BSWG/3/3, pp. 69-74, contains submissions of Canada, Colombia, Cuba, EU, India, Madagascar and Sri Lanka.

Following the request from BSWG-2, the Secretariat prepared two draft articles on financial resources and the financial mechanism.<sup>553</sup> Both took up many of the elements of the previous government proposals, including the establishment of a funding mechanism of a voluntary nature and a revolving fund to assist in emergency situations.

The draft article on financial resources obliged developed country Parties to provide new and additional financial resources to enable developing country Parties to meet the costs of implementing measures taken under the Protocol. It also encouraged developed country Parties to provide, and developing country Parties to avail themselves of, financial resources through bilateral, regional and other multilateral channels. Particular attention was to be paid to the special needs of least developed countries and small island states.

Another draft article established a mechanism for the provision of financial resources to developing country Parties, accountable to and operating under the authority of the Meeting of the Parties. The financial mechanism would constitute a trust fund. The Meeting of the Parties would determine the policy, strategy and programme of access to and utilisation of these resources. The draft also encouraged Parties to strengthen existing financial institutions in order to provide financial resources for the Protocol.

The consolidated text prepared by CG-2 at BSWG-3 included two options.<sup>554</sup> Both established the opportunity for developed countries to provide financial and technological resources to developing countries. One specified that the financial mechanism and institutional structure referred to in Article 21 of the Convention would also serve the Protocol and would be accountable to and function under the authority of the Conference of the Parties.

Both options were retained after BSWG-4, although a new paragraph was added to the longer of the two options clarifying that the “guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties ... shall apply *mutatis mutandis* to the provisions of this Article.”<sup>555</sup>

Progress was made during BSWG-5, where CG-2 prepared a consolidated text containing brackets. During the discussions, delegates deleted a paragraph that required developed countries to provide new and additional resources to the financial mechanism, as this would duplicate Article 20 of the Convention.<sup>556</sup> Similarly, in order to avoid repetition of Article 21 of the Convention, the paragraph detailing the financial mechanism’s accountability to the COP was removed.<sup>557</sup> The consolidated text also included two new paragraphs alluding to the needs of developing countries, and in particular least developed countries and small island states, for capacity-building for implementation of the Protocol and for the development and implementation of programmes, particularly on risk assessment and management.<sup>558</sup>

At BSWG-6, the draft article was provisionally adopted at the second plenary session on 17 February 1999.<sup>559</sup> The brackets in the first paragraph, linking financial resources under the Protocol to Article 20 of the Convention, had been removed. The paragraph referring to capacity-building and implementation had been retained, while the bracketed provision on risk assessment and risk management was deleted.<sup>560</sup>

Two final adjustments were made, re-numbering the reference to the number of the article on capacity building in the third paragraph and changing the references to small island states to “small island developing states”.

<sup>553</sup> UNEP/CBD/BSWG/3/4, pp. 2-3.

<sup>554</sup> UNEP/CBD/BSWG/3/6, pp. 90 – 91.

<sup>555</sup> UNEP/CBD/BSWG/4/4, pp. 56 – 57.

<sup>556</sup> ENB Vol. 9 No. 104, p. 2.

<sup>557</sup> *Id.*

<sup>558</sup> UNEP/CBD/BSWG/5/3, pp. 43 -44.

<sup>559</sup> UNEP/CBD/ExCOP/1/2, para. 38.

<sup>560</sup> *Id.*

## Article 29: Conference of the Parties serving as the Meeting of the Parties to this Protocol

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

(a) Make recommendations on any matters necessary for the implementation of this Protocol;

(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

(c) Seek and utilise, where appropriate, the services and cooperation of, and information provided by, competent international organisations and intergovernmental and non-governmental bodies;

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 33 of this Protocol and consider such informa-

tion as well as reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, *mutatis mutandis*, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held in conjunction with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialised agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party



**to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.**

The African group, Australia, Cuba and the USA, submitted views on the Meeting/Conference of the Parties for consideration at BSWG-2.<sup>561</sup> The African group proposed language on the first, subsequent and extraordinary meetings of the Conference of the Parties, most of which would find reflection in the final text of the provision. It proposed to convene the first meeting of the Parties not later than one year after the date of entry into force of the Protocol, in conjunction with a meeting of the Conference of the Parties to the Convention if one was scheduled within the same period. It also suggested that subsequent ordinary meetings of the Parties should be held, unless the Parties decided otherwise, in conjunction with the meetings of the Conference of the Parties to the Convention. Finally, it proposed that extraordinary meetings of the Parties should be held when deemed necessary by a meeting of the Parties, or at the written request of any Party, when supported by at least one third of the Parties within six months of the request.

Australia considered that the Conference of the Parties to the Convention could serve concurrently as the meeting of the Parties to the Protocol and pointed out the possible confusion if the same name was kept. It also argued that the provisions of Article 32(2) of the Convention, which stipulate that decisions under any Protocol to the Convention shall be taken only by Parties to that Protocol, should apply.

As requested by BSWG-2, the Secretariat prepared draft text on institutional matters including a provision on Meetings of the Parties.<sup>562</sup> The proposed text from the African group on first, subsequent and extraordinary meetings was retained, together with the issues it had identified to be addressed at the first meeting: rules of procedure, financial provisions related to the financial mechanism; and designation of the Secretariat. The Secretariat text also listed a number of functions of the Meeting of the Parties, and noted that the UN, its agencies and the IAEA could participate in the sessions as observers, as well as any other organisation meeting the relevant criteria. In addition to a general statement that Parties might review the Protocol and its implementation, a list of functions of the Meeting of the Parties was proposed, including obligations in respect of implementation, rules of procedure, budget, subsidiary bodies and amendment of the Protocol or its annexes.

However, the provision on the Conference of the Parties developed by BSWG-3 on the basis of text introduced by the Chair and followed by a few alternatives,<sup>563</sup> took up few of the elements proposed by the Secretariat. This consolidated text simply established the Conference of the Parties of the Convention as the Protocol's supreme body and referred to the voting procedures under Article 32(2) of the CBD, representation on the Bureau of the Conference of the Parties, and decisions to be made at its first meeting.<sup>564</sup>

<sup>561</sup> UNEP/CBD/BSWG/2/2, pp. 36-39; UNEP/CBD/BSWG/2/Inf.6..

<sup>562</sup> UNEP/CBD/BSWG/3/4, pp. 4-5.

<sup>563</sup> UNEP/CBD/BSWG/3/6, p. 28.

<sup>564</sup> *Ibid.*, pp. 125-126.

During BSWG-4 the discussion drew on precedents in other international environmental agreements, notably the Kyoto Protocol to the UN Framework Convention on Climate Change. This used the institutional device of the Conference of the Parties serving as the Meeting of the Parties.<sup>565</sup> The draft article prepared by CG-2, and incorporated into the new consolidated draft text, was largely derived from the earlier texts drafted by the Secretariat reflecting government submissions.<sup>566</sup> Hence, Article 29 contained the previous paragraphs on the first meeting of the Parties (but without a timeframe), subsequent ordinary meetings and extraordinary meetings. The text of the draft prepared by the Secretariat on observers was also incorporated, as well as earlier text on representation on the Bureau and on review of the implementation of the Protocol. The article now clarified that the procedural and financial rules of the Convention would apply "*mutatis mutandis*" to the Protocol, except as otherwise decided by consensus, and listed a shorter number of functions. Four of these functions had been

already proposed by the Secretariat, namely, making recommendations on the implementation of the Protocol: establishing the necessary subsidiary bodies; considering and adopting proposals for amendment of the Protocol and annexes; and exercising any other functions required for the Protocol's implementation. Two new functions were added: to seek to utilise services, cooperation and information from international organisations and bodies; and to establish the form and the intervals for transmitting information in reports and reports from subsidiary bodies. The text of the draft article was provisionally adopted by BSWG-5 at its second plenary session on 19 August 1998.<sup>567</sup>

This text remained unchanged until BSWG-6 where it was provisionally adopted<sup>568</sup> and re-titled "Conference of the Parties serving as the Meeting of the Parties to the Protocol."<sup>569</sup> It remained unchanged until finally adopted at the resumed ExCOP.

---

<sup>565</sup> UNEP/CBD/BSWG/4/4, para. 23.

<sup>566</sup> *Ibid.*, p. 57-58.

<sup>567</sup> UNEP/CBD/BSWG/5/3, para. 26.

<sup>568</sup> UNEP/CBD/ExCOP/1/2, para. 38.

<sup>569</sup> UNEP/CBD/ExCOP/1/2 p. 9. This change was also reflected in other provisions of the Protocol which had previously referred to "the Meeting of the Parties".

## Article 30: Subsidiary Bodies

**1. Any subsidiary body established by or under the Convention may, upon a decision by the Conference of the Parties serving as the meeting of the Parties to this Protocol, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.**

**2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under the Protocol shall be taken only by the Parties to the Protocol.**

**3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to the Protocol, shall be substituted by a member to be elected by and from among the Parties to the Protocol.**

Although the first draft text addressing subsidiary bodies was only prepared by the Secretariat for BSWG-3, Australia had already expressed its views in writing before BSWG-2. It proposed that the Subsidiary Body on Scientific Technical and Technological Advice (SBSTTA) of the Convention should provide similar services to the Protocol, if similar advice was considered necessary, and that non-Parties to the Protocol should be enabled to participate.<sup>570</sup>

Following BSWG-2, the Secretariat developed draft text concerning institutional matters, which provided for the Meeting of the Parties to establish such subsidiary bodies as deemed necessary for the implementation of the Protocol and, at its first session, to adopt rules of procedure for such subsidiary bodies.<sup>571</sup>

<sup>570</sup> UNEP/CBD/BSWG/2/2, p.38.

<sup>571</sup> UNEP/CBD/BSWG/3/4, pp. 4-5.

<sup>572</sup> ENB Vol. 9 No. 74, p. 9.

<sup>573</sup> *Id.*

<sup>574</sup> UNEP/CBD/BSWG/4/4, Annex III, see Article 30.

At BSWG-3, the Contact Group on Institutional Matters and Final Clauses (CG-2) addressed these issues and developed draft text including a provision on subsidiary bodies.<sup>572</sup> The text was later approved by the plenary and incorporated into the consolidated text.<sup>573</sup> Elements included: the use of the Convention's subsidiary bodies and mechanisms as subsidiary bodies and mechanisms of the Protocol; and that decisions of the subsidiary bodies while exercising their functions were to be taken by the Parties to the Protocol.

At BSWG-4, CG-2 considered precedents on institutional matters from other international environmental agreements and prepared draft text that, with the exception of minor amendments, was almost identical to the final text.<sup>574</sup> Article 30 on subsidiary bodies called for subsidiary bodies under the Convention to serve the Protocol, subject to a decision by the meeting of the Parties. The provision also provided for the participation of non-Parties to the Protocol that are Parties to the CBD as observers in subsidiary bodies of the Protocol without the right to participate in decision-making. Finally, the article stated that members of the Bureau of a subsidiary body to the Convention representing a non-Party to the Protocol should be substituted by a member representing a Party to the Protocol when such a body operated under the Protocol.

The provision was subsequently approved by CG-2 of BSWG-5.<sup>575</sup> The text of the draft article was provisionally adopted by BSWG-5 at its second plenary session on 14 August 1998.<sup>576</sup>

Following the review by the Legal Drafting Group of the Chair's text at BSWG-6, the reference, in the first paragraph, to the "meeting of the Parties" was replaced with "Conference of the Parties serving as the meeting of the Parties to this Protocol" (COPMOP), in accordance with the agreement reached on that article.<sup>577</sup> The article on subsidiary bodies was provisionally adopted at BSWG-6<sup>578</sup> and remained unchanged until the final adoption of the Protocol at the resumed ExCOP.

<sup>575</sup> ENB Vol. 9 No. 100 p. 2.

<sup>576</sup> UNEP/CBD/BSWG/5/3, para.26.

<sup>577</sup> UNEP/CBD/BSWG/6/L.2/Rev.2, see Article 28; see also section on Article 29 above.

<sup>578</sup> UNEP/CBD/ExCOP/1/2, para. 38.

## Article 31: Secretariat

**1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.**

**2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, *mutatis mutandis*, to this Protocol.**

**3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.**

Views on the secretariat of the Protocol were first submitted to BSWG-2.<sup>579</sup> Although submissions generally suggested that the administration of the Protocol should be undertaken by the Secretariat of the Convention, the African group proposed a number of additional functions. These included giving the Secretariat the responsibility to: compile and disseminate, in collaboration with the BCH, information regarding any living modified organisms or products thereof; receive and convey information from and to Parties on capacity building; assist Parties to identify cases of illegal traffic; and cooperate with Parties and relevant international organisations in providing experts and equipment for the purpose of emergency assistance. In addition, Cuba proposed that the Secretariat encourage non-Parties to participate as observers in the meetings of the Parties and to act in conformity with the Protocol, as well as notify Parties of any request for scientific or technical cooperation in conformity with an article of the Protocol on Technical and Scientific Cooperation.<sup>580</sup>

The Secretariat prepared draft text for consideration at BSWG-3, which referred to Art 24(2) of the Convention and provided for the Secretariat of the Convention to serve as the Secretariat of the

Protocol.<sup>581</sup> A number of additional functions were also listed, including those proposed by the African group and functions equivalent to those of the Secretariat of the Convention, such as reporting to the Meeting of the Parties on work carried out.

The Consolidated Text of the article on the Secretariat resulting from the meetings of CG-2 at BSWG-3 referred to the costs of Secretariat services and proposed the establishment of a Trust Fund, with the option that Parties meet the costs voluntarily.<sup>582</sup>

At BSWG-4, CG-2 developed text that was almost identical to the article as finally adopted.<sup>583</sup> The first and second paragraphs established that the Secretariat of the Convention would serve as the Secretariat to the Protocol and that its functions would apply "*mutatis mutandis*" to the Protocol. The third paragraph, in brackets, provided that the costs of the services of the Secretariat of the Protocol should be met by the Parties to the Protocol, and that the Conference of the Parties to the Protocol at its first meeting would decide the related necessary financial arrangements. No further reference to the proposed Trust Fund was made.

At BSWG-5 two adjustments were made, replacing "Conference of the Parties" with "Meeting of the Parties" and "financial arrangements" with "budgetary arrangements".<sup>584</sup> The bracketed text was accepted and the whole provision was agreed by CG-2.<sup>585</sup> The text of the draft article was provisionally adopted by BSWG-5 at its second plenary session on 19 August 1998.<sup>586</sup>

The revision by the Legal Drafting Group of the Chair's text at BSWG-6 changed "Meeting of the Parties" to "Conference of the Parties serving as the meeting of the Parties to this Protocol"<sup>587</sup>. The article was provisionally adopted by BSWG-6 at its second plenary session on 17<sup>th</sup> February 1999,<sup>588</sup> and remained unchanged until the final adoption of the Protocol at the resumed ExCOP.

<sup>579</sup> UNEP/CBD/BSWG/2/2, pp. 36-39, contains the submissions of the African region, Australia, EU, Japan and Norway on the Secretariat.

<sup>580</sup> UNEP/CBD/BSWG/2/Inf.6.

<sup>581</sup> UNEP/CBD/BSWG/3/4, pp. 5-6.

<sup>582</sup> UNEP/CBD/BSWG/3/6, Annex I.

<sup>583</sup> UNEP/CBD/BSWG/4/4, Annex III.

<sup>584</sup> UNEP/CBD/BSWG/5/3, Annex.

<sup>585</sup> ENB Vol. 9 No. 100, p. 2.

<sup>586</sup> UNEP/CBD/BSWG/5/3, para. 26.

<sup>587</sup> UNEP/CBD/BSWG/6/L.2/Rev.2, see Article 29.

<sup>588</sup> UNEP/CBD/ExCOP/1/2, para. 38.

## Article 32 - Relationship with the Convention

**Except as otherwise provided in this Protocol, the provisions of the Convention relating to its Protocols shall apply to this Protocol.**

Early proposals favoured the inclusion of a statement on the relationship between the Protocol and the Convention in the preamble (Australia), in a provision on jurisdictional scope (US),<sup>589</sup> or in a separate provision (African group).<sup>590</sup>

However, the first draft for a provision on the issue was prepared during BSWG-3 by CG-2 on institutional matters and final clauses.<sup>591</sup> The Consolidated Text prepared at the end of that meeting included the same text of the article as would finally be adopted.<sup>592</sup> The provision remained unchanged during the subsequent negotiations, was provisionally adopted at BSWG-6,<sup>593</sup> and finally adopted at the resumed ExCOP in January 2000.<sup>594</sup>

---

<sup>589</sup> UNEP/CBD/BSWG/2/2, p. 4 and p. 31.

<sup>590</sup> UNEP/CBD/BSWG/2/Inf.2.

<sup>591</sup> UNEP/CBD/BSWG/3/6, see Article 33.

<sup>592</sup> *Id.*

<sup>593</sup> UNEP/CBD/ExCOP/1/2, para. 38.

<sup>594</sup> UNEP/CBD/ExCOP/1/3.

## Article 33 – Monitoring and Reporting

**Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement the Protocol.**

Although submissions for BSWG-2 on this issue were compiled under the heading “Monitoring and Compliance”, only Canada proposed the inclusion of a new article to cover compliance. (The issues of monitoring and compliance were subsequently split into two different articles at BSWG-4, see further below).<sup>595</sup>

The African group called for Parties to report annually to the Secretariat and to the BCH on the implementation of the Protocol (including in particular information on the status of the LMOs deliberately released and on the operation of the AIA procedure), and to ensure that users monitored activities and products at regular intervals and reported to the competent national authority. The EU noted the need for a cooperative and transparent process based on good faith and full participation. Norway proposed the establishment of monitoring programmes on the use of LMOs and distinguished monitoring during the research period from monitoring after an LMO had been put on the market. It also noted that compliance procedures should be developed in addition to dispute settlement procedures.

BSWG-2, however, concluded that any drafting on the item was premature.<sup>596</sup> Hence in his summary of “monitoring”, the Chair merely reflected the above elements, together with consideration of Article 26 of the Convention and decision II/17, and of the problems of capacity-building and similar issues encountered during implementation.<sup>597</sup> With regard to “compliance”, the main elements identified were the possibilities of establishing a standing or *ad hoc* body in charge of compliance reviews, obtaining formal findings of non-compliance, taking into account similar procedures in international legal instruments, and establishing a cooperative and conciliatory advisory procedure where confidentiality was safeguarded.<sup>598</sup>

During BSWG-3, CG-2 prepared draft text on monitoring and compliance, which the BSWG agreed to incorporate into the consolidated text, together with the proposals of the African group.<sup>599</sup> Thus, the first two options prepared by CG-2 called upon Parties “to determine at their first meeting how to establish procedures and institutional mechanisms for determining non-compliance with the provisions of this Protocol and for the treatment of Parties found in non-compliance” or to consider whether to establish those procedures. The third option consisted of new text submitted by the African group requesting Parties “to introduce, implement and enforce national compliance and monitoring systems”, taking into account international standards and guidelines, and to provide information on national monitoring and compliance systems, as well as information on any significant incidents of illegal traffic to the BCH.<sup>600</sup> The fourth option was the earlier proposal submitted by the African group.

CG-2 agreed to split the article into two at BSWG-4: Monitoring and Reporting (then Article 35) and Compliance (then Article 35bis).<sup>601</sup> The first

<sup>595</sup> UNEP/CBD/BSWG/2/2 p. 69-71 contains the submissions of the African group, Canada, EU and Norway. See also section on Article 34 below.

<sup>596</sup> UNEP/CBD/BSWG/2/6, paras. 150-160.

<sup>597</sup> *Ibid.* Annex II, Item H.

<sup>598</sup> *Id.*

<sup>599</sup> UNEP/CBD/BSWG/3/6 paras. 96 - 97.

<sup>600</sup> UNEP/CBD/BSWG/3/5.

<sup>601</sup> UNEP/CBD/BSWG/4/4, Annex III, see Articles 35 and 35 bis.

two options from the previous draft formed the basis for Article 35bis,<sup>602</sup> while the remaining two options were integrated into the provision on monitoring and reporting. The article on monitoring and reporting thus required Parties to monitor their implementation of the Protocol, to establish or maintain systems for that purpose, and to report to the meeting of the Parties on these measures, at intervals to be determined by the meeting of the Parties.<sup>603</sup> At this point, the text contained the elements of the article that would finally be adopted, albeit with minor changes.

At BSWG-5, notwithstanding further submissions (notably that of the EC which advocated linking this article to the article on Decision Procedure for AIA, (then Article 6) by encouraging Parties to provide assistance to Parties of import and

proposing the establishment of a standing body of experts operating a monitoring and assistance process),<sup>604</sup> the previous two paragraphs were merged into one and language on establishing and maintaining mechanisms was deleted.<sup>605</sup> The article was provisionally adopted at the second plenary session at BSWG-5 on 19 August 1998.<sup>606</sup> References to the “meeting of the Parties” were replaced by “the Conference of the Parties serving as the meeting of the Parties to this Protocol” once this matter was settled at BSWG-6, and the article was provisionally adopted.<sup>607</sup> The article was reviewed by the Legal Drafting Group,<sup>608</sup> and remained unchanged thereafter.

---

<sup>602</sup> See now section on Article 34 below.

<sup>603</sup> UNEP/CBD/BSWG/4/4, Annex III, see Article 35.

<sup>604</sup> UNEP/CBD/BSWG/5/2 contains the submissions of EC, New Zealand, Peru, Slovenia, Thailand and Venezuela. See Article 35.

<sup>605</sup> UNEP/CBD/BSWG/5/3, Annex, see Article 35.

<sup>606</sup> UNEP/CBD/BSWG/5/3, para. 26.

<sup>607</sup> UNEP/CBD/ExCOP/1/2, para. 38.

<sup>608</sup> UNEP/CBD/BSWG/6/L.2/Rev.2, see Article 32.

## Article 34: Compliance

**The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms established by Article 27 of the Convention.**

The issue of compliance was discussed and addressed in an article together with the issue of monitoring until BSWG-4 where the items were split into two separate articles.<sup>609</sup> Three early drafts would constitute the core of this article: the options prepared by CG-2 at BSWG-3 whereby Parties would “determine at their first meeting how to establish procedures and institutional mechanisms for determining non-compliance with the provisions of this Protocol and for the treatment of Parties found in non-compliance” or consider whether to establish those procedures;<sup>610</sup> the EC proposal for cooperation, advice and assistance;<sup>611</sup> and the Norwegian submission proposing a distinction between dispute settlement and compliance procedures.<sup>612</sup>

At BSWG-4, Article 35bis on compliance simply reflected, in bracketed text, the options prepared

by CG-2 during BSWG-3, and included the possibility of no provision.<sup>613</sup>

Following work on this provision by CG-2 at BSWG-5, language was developed which, in itself, was not the object of dispute and included the essence of the three elements of the final provision.<sup>614</sup> However, the entire article was bracketed to reflect a lack of consensus on whether the provision should be included in the Protocol at all.<sup>615</sup> At this stage Article 35bis required Parties to consider and approve, at their first meeting, procedures and institutional mechanisms to promote compliance with the Protocol and to address cases of non-compliance.<sup>616</sup> This text also noted that those procedures and mechanisms were to be separate from, and without prejudice to, the dispute settlement procedure established under Article 27 of the Convention.<sup>617</sup> Furthermore, they could include provisions to offer advice or assistance, where appropriate.<sup>618</sup>

At BSWG-6, an amendment was introduced to the text by CG-2 in order to reach a compromise and allow the plenary to provisionally adopt the article.<sup>619</sup> Thus, the procedures to be established to promote compliance were qualified as “cooperative”, and with this, the brackets around the article were removed.<sup>620</sup> A final revision by the Legal Drafting Group replaced the reference to the “meeting of the Parties” by “the Conference of the Parties serving as the meeting of the Parties to this Protocol”.<sup>621</sup> The article remained unchanged until its final adoption by the resumed ExCOP.

<sup>609</sup> See section on Article 33 above.

<sup>610</sup> UNEP/CBD/BSWG/3/6, Annex I.

<sup>611</sup> UNEP/CBD/BSWG/2/2 p. 70.

<sup>612</sup> *Id.*

<sup>613</sup> UNEP/CBD/BSWG/4/4, Annex III, see Article 35 bis.

<sup>614</sup> UNEP/CBD/BSWG/5/3, para. 55.

<sup>615</sup> *Id.*

<sup>616</sup> *Ibid.* Annex, see Article 35 bis.

<sup>617</sup> *Id.*

<sup>618</sup> *Id.*

<sup>619</sup> UNEP/CBD/ExCOP/1/2, para. 38.

<sup>620</sup> ENB Vol. 9 No. 117, p. 9.

<sup>621</sup> UNEP/CBD/BSWG/6/L.2/Rev.2, see Article 33.



## Article 35: Assessment and Review

**The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, five years after the entry into force of this Protocol and at least every five years thereafter, an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes.**

Japan and Norway submitted views on the issue of “review and adaptation” prior to BSWG-2.<sup>622</sup> Norway proposed that the Protocol establish flexible procedures to allow adaptation to scientific and technical progress<sup>623</sup>, and Japan recalled paragraph 5(c) of the annex to Decision II/5, which envisaged the establishment of a review mechanism.

The first draft text on the issue, together with other institutional matters and final clauses, was prepared by the Secretariat for BSWG-3.<sup>624</sup> Two options envisaging amendments to the Protocol were then developed. One was lengthy and included detailed language on procedures for amendment by the Secretariat and the Meeting of the Parties to the Protocol. This text was discussed by CG-2,<sup>625</sup> which prepared another draft in its place, later contained in the Consolidated Text at the end of BSWG-3.<sup>626</sup> (The superseded draft would later re-appear in the discussions on the article on the Conference of the Parties, which would include provisions for amending the Protocol and its annexes).<sup>627</sup> The draft had been proposed by Switzerland and was based on Article

5 of the Montreal Protocol on Substances that Deplete the Ozone Layer.<sup>628</sup> It called upon Parties to assess the Protocol on the basis of available scientific, environmental and technical information at a certain date and at least every five years thereafter. It further specified that at least one year before each assessment, the Parties would convene appropriate panel of experts, and that the panels would report their conclusions to other Parties within a year, through the Secretariat.

Two more options were added at BSWG-4, including the removal of the provision and a shorter provision calling for the regular evaluation of the effectiveness of the Protocol, three years after the entry into force and at least every six years thereafter.<sup>629</sup>

At BSWG-5, the article was considered by SWG-I, which agreed that the concept of the article was in line with provisions set out under the CBD, and reduced the article to a short text with two sets of square brackets.<sup>630</sup> References to “five” years and “at least every five years thereafter” were included, in brackets, in a text that largely reflected the shorter option from BSWG-4.<sup>631</sup> Text assigning the assessment to an expert panel was removed, but the reference to an assessment of the procedures and annexes was maintained.<sup>632</sup>

The bracketed text was accepted by SWG-I during BSWG-6<sup>633</sup> and was provisionally adopted.<sup>634</sup> The reference to the “meeting of the Parties” was replaced by “the Conference of the Parties serving as the meeting of the Parties to this Protocol” following revision by the Legal Drafting Group.<sup>635</sup> The provision then remained unchanged until final adoption at the resumed ExCOP.

<sup>622</sup> UNEP/CBD/BSWG/2/2, p. 74.

<sup>623</sup> A view also expressed by the EC (UNEP/CBD/BSWG/2/2, p. 42).

<sup>624</sup> UNEP/CBD/BSWG/3/4, pp. 10 – 11.

<sup>625</sup> ENB Vol. 9 No. 74, p. 9.

<sup>626</sup> UNEP/CBD/BSWG/3/6, Annex I, see Article 36.

<sup>627</sup> See section on Article 29 above.

<sup>628</sup> UNEP/CBD/BSWG/3/5, see Article 19 of the Swiss submission.

<sup>629</sup> UNEP/CBD/BSWG/4/4, Annex III, see Article 36.

<sup>630</sup> UNEP/CBD/BSWG/5/3, para. 32.

<sup>631</sup> *Ibid*, Annex, see Article 36.

<sup>632</sup> *Id.*

<sup>633</sup> ENB Vol. 9 No. 113, p. 1.

<sup>634</sup> UNEP/CBD/ExCOP/1/2, para. 38.

<sup>635</sup> UNEP/CBD/BSWG/6/L.2/Rev.2, see Article 34.

## Article 36: Signature

**This Protocol shall be open for signature at the United Nations Office at Nairobi by States and regional economic integration organisations from 15 to 26 May 2000, and at United Nations Headquarters in New York from 5 June 2000 to 4 June 2001.**

Only the African region submitted draft text on this topic prior to BSWG-2.<sup>636</sup> It proposed what would become the final text (except for the dates, which were, of course, at that stage omitted).

The text on final clauses for BSWG-3 prepared by the Secretariat used this text, but referred to “any” regional economic integration organisation.<sup>637</sup> The provision remained unchanged and it was provisionally adopted by BSWG-5 on 19 August 1998,<sup>638</sup> and then by the plenary of BSWG-6.<sup>639</sup>

Dates (“24 May 1999 to 23 May 2000”) were first included in this provision in the Chair’s proposal text at BSWG-6.<sup>640</sup> At the resumed ExCOP in Montreal the final draft of the Protocol submitted by the Legal Drafting Group revised the dates and provided for signature in Nairobi during the fifth meeting of the CBD COP, as well as at the UN Headquarters.<sup>641</sup>

---

<sup>636</sup> UNEP/CBD/BSWG/2/2, p. 74.

<sup>637</sup> UNEP/CBD/BSWG/3/4, see Article K.1.

<sup>638</sup> UNEP/CBD/BSWG/5/3, para. 26.

<sup>639</sup> UNEP/CBD/ExCOP/1/2, para. 38.

<sup>640</sup> UNEP/CBD/BSWG/6/L.2, see Article 35.

<sup>641</sup> UNEP/CBD/ExCOP/1/L.5.

## Article 37: Entry into Force

**1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organisations that are Parties to the Convention.**

**2. This Protocol shall enter into force for a State or regional economic integration organisation that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force pursuant to paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organisation deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organisation, whichever shall be the later.**

**3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organisation shall not be counted as additional to those deposited by member States of such organisation.**

Both the African group and Australia submitted draft text before BSWG-2 on this subject.<sup>642</sup> The African proposal included a schedule for the entry into force of the Protocol (ninety days after the date of deposit of the sixteenth instrument of ratification, acceptance, approval or accession). Australia referred to Article 36 of the Convention, which sets out the provisions for the entry into force of the Convention, and for protocols to it.

The draft text on final clauses prepared by the Secretariat for BSWG-3 merged both proposals (but omitted the number of instruments of ratification, acceptance, approval or accession that would be required to trigger entry into force), and added a third paragraph to clarify that instruments deposited by regional economic integration organisations should not be counted as additional to those of each Member State of such organisation.<sup>643</sup>

At BSWG-4 the text was reviewed by CG-2, which removed the reference to Article 36 of the Convention and, regarding the entry into force of the Protocol for Parties, amended the last sentence to refer to the Convention instead of the Protocol. This reflected the requirement that Parties to the Protocol had to be Parties to the Convention.<sup>644</sup>

The text was provisionally approved at BSWG-5<sup>645</sup> and at BSWG-6<sup>646</sup> but the number of ratifications required (fifty) was first included in the subsequent Chair's proposed text.<sup>647</sup> A reference to regional economic integration organisations was also inserted in the first paragraph on the entry into force of the Protocol.<sup>648</sup> This was later extended by the Legal Drafting Group to the second paragraph on entry into force of the Protocol for a State or a regional economic integration organisation.<sup>649</sup> The article then remained unchanged until its final adoption by the resumed ExCOP.

<sup>642</sup> UNEP/CBD/BSWG/2/2, p. 75, contains the submissions of the African region and Australia.

<sup>643</sup> UNEP/CBD/BSWG/3/4, see Article K.4.

<sup>644</sup> UNEP/CBD/BSWG/4/4, Annex III, see Article 40.

<sup>645</sup> UNEP/CBD/BSWG/5/3, para. 26.

<sup>646</sup> UNEP/CBD/ExCOP/1/2, para. 38.

<sup>647</sup> UNEP/CBD/BSWG/6/L.2, see Article 36.

<sup>648</sup> *Id.*

<sup>649</sup> UNEP/CBD/BSWG/6/L.2/Rev.2, see Article 36.

## Article 38: Reservations

**No reservations may be made to this Protocol.**

Only the African region presented text on “reservations and declarations” for BSWG-2.<sup>650</sup> It proposed that no reservations could be made to the Protocol and this language was retained in the final text of the Protocol.

The draft text on final clauses prepared for BSWG-3 by the Secretariat employed the same text;<sup>651</sup> however the Consolidated Text, following discussion by CG-2, also included the option of not having an article on this issue.<sup>652</sup>

At BSWG-5, the option for no provision was replaced by bracketing a single option.<sup>653</sup> The brackets were removed at BSWG-6<sup>654</sup>. The text remained unchanged until the adoption of the final draft of the Protocol at the resumed ExCOP.

---

<sup>650</sup> UNEP/CBD/BSWG/2/2, pp. 75-76.

<sup>651</sup> UNEP/CBD/BSWG/3/4, see Article K.5.

<sup>652</sup> UNEP/CBD/BSWG/3/6, see Article 41.

<sup>653</sup> UNEP/CBD/BSWG/5/3, Annex, see Article 41.

<sup>654</sup> UNEP/CBD/BSWG/6/L.2, see Article 37.

## Article 39: Withdrawal

**1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from the Protocol by giving written notification to the Depositary.**

**2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.**

The African group made the only submission on this issue at BSWG-2. This submission, with the exception of the timeframes, was the same as the text finally adopted.<sup>655</sup> The text stated that a Party could withdraw from the Protocol by notifying the Depositary after two years from the date on which the Protocol had entered into force for that Party. A second paragraph specified that the withdrawal would become effective three years after its receipt by the Depositary or at any other later date specified in the notification of withdrawal.

Almost identical text was proposed by the Secretariat's draft on final clauses for BSWG-3, with the exception of the second timeframe being changed to "one year after the date of receipt" (as provided in the final text), and the inclusion of a third paragraph providing that any Party that withdrew from the Protocol would also be considered as having withdrawn from the Convention.<sup>656</sup>

The provision remained unchanged until BSWG-4, where it was revised by the CG-2 which removed the third paragraph.<sup>657</sup>

The same text was provisionally adopted at BSWG-5<sup>658</sup> and at the second session of the plenary at BSWG-6,<sup>659</sup> and was finally approved at the resumed ExCOP.

<sup>655</sup> UNEP/CBD/BSWG/2/2, p. 76.

<sup>656</sup> UNEP/CBD/BSWG/3/4, p. 13.

<sup>657</sup> UNEP/CBD/BSWG/4/4, Annex III, see Article 42.

<sup>658</sup> UNEP/CBD/BSWG/5/3, para. 26.

<sup>659</sup> UNEP/CBD/ExCOP/1/2, para. 38.

## Article 40: Authentic Texts

**The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.**

Only the African group submitted text on this issue prior to BSWG-2,<sup>660</sup> and this reflected the text as finally approved. The Secretariat used the same draft text in its document on final clauses prepared for BSWG-3.<sup>661</sup> The text was later agreed by CG-2 at BSWG-4,<sup>662</sup> and remained unchanged until its provisional adoption at BSWG-5<sup>663</sup> and at BSWG-6,<sup>664</sup> and final adoption at the resumed ExCOP in Montreal on 29 January 2000.

---

<sup>660</sup> UNEP/CBD/BSWG/2/2, pp. 76-77.

<sup>661</sup> UNEP/CBD/BSWG/3/4, p.13.

<sup>662</sup> ENB Vol. 9 No. 80, p. 2.

<sup>663</sup> UNEP/CBD/BSWG/5/3, para. 26.

<sup>664</sup> UNEP/CBD/ExCOP/1/2, para. 38.

## **Annex I: Information Required in Notifications under Article 8, 10 and 13**

- (a) Name, address and contact details of the exporter.
- (b) Name, address and contact details of the importer.
- (c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.
- (d) Intended date or dates of the transboundary movement, if known.
- (e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
- (f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
- (g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
- (h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.
- (i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.
- (j) Quantity or volume of the living modified organism to be transferred.
- (k) A previous and existing risk assessment report consistent with Annex III.
- (l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

ding, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

(m) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.

(n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.

(o) A declaration that the above-mentioned information is factually correct.

The African group proposed a comprehensive list of information required in notifications under the Advance Informed Agreement (AIA) procedure for consideration by BSWG-2.<sup>665</sup> Many of the elements of the final text were already included in this list and, taken together with the list of information related to the LMO which the African region included in its proposed Annex II on risk assessment, all the information referred to in this Annex had been identified at this stage, with the exception of element (l).<sup>666</sup>

Many countries submitted draft text for BSWG-3<sup>667</sup> that, in most cases, was not as detailed as the African proposal, but was in a similar vein. Cuba, however, put forward an extensive set of lists covering information relating to the LMO (classified by characteristics of the donor, recipient or parent organism, vector, modified organism); information relating to the conditions of release and the receiving environment; information relating to the interactions between the LMOs and the environment; and information on monitoring, control, waste treatment and emergency response plans.<sup>668</sup> It also proposed an additional annex covering information required in cases of

<sup>665</sup> UNEP/CBD/BSWG/2/2, p. 77.

<sup>666</sup> See section on Annex III below.

<sup>667</sup> UNEP/CBD/BSWG/3/3, pp. 79-90, contains the submissions of the African region, Australia, Brazil, Canada, Colombia, Cuba, India, Norway, Peru, South Africa, Sri Lanka, Switzerland and the US.

<sup>668</sup> *Ibid.* pp. 84-88.

notification for placing on the market. Colombia also specified information relating to the parent organism, to include toxicity and allergenicity for humans, mechanisms used by the organism to survive, and information pertaining to the host organism, to include methods of detecting it and its potential to affect ecosystem conditions. However, these types of information would be later transferred to the annex on risk assessment under which possible adverse effects were to be identified and their likelihood evaluated.<sup>669</sup> The US submission proposed the qualification that such assessments had to be “known and available”, language which was retained until BSWG-6.

The draft texts submitted by Norway, South Africa and Switzerland introduced the elements of contingency plans and information on experiences with previous releases. Sri Lanka referred to risk management requirements. South Africa also called for the observation of any differences between the environment of the exporting country and the environment of the release.

The Contact Group on Definitions and Annexes (CG-1) established at BSWG-3,<sup>670</sup> having considered the draft text in submissions and the issues raised during the discussions, encapsulated the main elements in the Consolidated Text.<sup>671</sup> This text referred to points (a)-(d), (h)-(m), and (o) of the final text.<sup>672</sup> The precise formulations however, differed. The list in the Consolidated Text also envisaged the inclusion of information relating to insurance (as proposed by Africa, India and Sri Lanka), differences between the environment of the exporting country and the environment of the release, contingency plans, requirements for risk management, experiences with previous releases, contact details of person(s) responsible for plan-

ning and carrying out the release, and information on the training of such personnel.

At BSWG-4, CG-1 first reviewed and simplified the draft Annex I, then referred it to SWG-I.<sup>673</sup> During the discussion it was pointed out that some of the submissions were more detailed regarding risk assessment. The need for an Annex II on risk assessment parameters was also discussed.<sup>674</sup> The issue was sent back to CG-1, where drafts of Annex I and Annex II (risk assessment) were prepared.<sup>675</sup> In order to facilitate the work on annexes at BSWG-5, CG-1 also prepared a list of annexes based on those discussed at the meeting, annexes identified in government submissions, and annexes referred to in the text of articles discussed by the sub-working groups at the meeting.<sup>676</sup>

Discussions in CG-1 addressed the uncertain legal status of the Annex and its level of detail, and it was agreed to seek guidance from SWG-I.<sup>677</sup> Delegations debated whether an AIA notification should include a risk assessment report in every case, and whether such a risk assessment would be undertaken according to the parameters listed in Annex II.<sup>678</sup> CG-1 also responded to concerns raised in SWG-I about “intended use of LMO” and “intended dates of transfer” where delegates noted that specific dates might not always be known, and an exporter requesting AIA might not have complete information about intended use of an LMO in the country of import.<sup>679</sup> The consolidated text listed categories of information to be provided in an AIA notification, including the taxonomic status of the recipient organism, methods to ensure safe handling, a risk assessment report, intended dates of transfer, and intended use of the LMO.<sup>680</sup> Two footnotes were included to clarify and allow for further development of the

<sup>669</sup> See section on Annex III below.

<sup>670</sup> UNEP/CBD/BSWG/3/6, paras. 21-22.

<sup>671</sup> *Ibid.* paras. 92-95, see Annex I.

<sup>672</sup> *Id.*

<sup>673</sup> UNEP/CBD/BSWG/4/4, para. 22.

<sup>674</sup> *Ibid.* paras. 22 and 28. See also ENB Vol. 9 No. 79, p. 1.

<sup>675</sup> UNEP/CBD/BSWG/4/4, para. 28.

<sup>676</sup> UNEP/CBD/BSWG/4/4, Annex V.

<sup>677</sup> ENB Vol. 9 No. 85, p. 5.

<sup>678</sup> *Id.*

<sup>679</sup> *Id.*

<sup>680</sup> UNEP/CBD/BSWG/4/4, see Annex I.



provision: a first note retained the possibility of re-considering the inclusion of information on the applicable laws, procedures and guidelines of the State of export, as well as of available information, including purpose, about any notification to other governments on the import or development of the LMO.<sup>681</sup> Both of these would be included at BSWG-5. The second footnote simply noted that responsibility for declaring the factual correctness of the information needed to be clarified.<sup>682</sup>

At BSWG-5 discussions of the annexes by CG-1 began with the consideration of the 19 annexes forwarded by BSWG-4.<sup>683</sup> Although the list would be carried forward to BSWG-6, it was agreed that the Protocol should contain no more than four annexes, of which Annexes I (Information required for notification for AIA) and II (Risk Assessment) had strong support.<sup>684</sup>

In draft Annex I (Information), the number of elements was increased from 12 to 15.<sup>685</sup> The footnotes were removed as the elements they addressed were inserted into the text. Following Norway's proposal to include language on the "regulatory status of the LMO" to address the issue of applicable laws referred to in the earlier footnote, this element was inserted.<sup>686</sup> A new element concerning the "intended date of the transboundary movement, if known" was also included.<sup>687</sup> Finally, regarding the reference to centres of origin, "a description of the habitats where the organism may persist or proliferate" was introduced in brackets, consistent with earlier proposals.<sup>688</sup> Other brackets that were

kept at this stage referred to: "products thereof"; availability of risk assessments; and reference to either "the exporter/importer or applicant/receiving company/institution/individual", respectively. Their removal was dependent upon discussions on issues and terminology in other groups.<sup>689</sup> But, with the exception of these few brackets, the number and content of elements were those that would feature in the final text.

Discussions continued at BSWG-6, where the Chair noted that the heavy workload of the CG-1 precluded consideration of any annexes additional to the two already contained in the draft negotiating text.<sup>690</sup> By the end of 16 February 1999, discussions on Annex I had been completed<sup>691</sup> except for the sub-paragraph on risk assessment, which was transferred to the discussions on Annex II (Risk Assessment).<sup>692</sup> Annex I was completed the next day when delegates agreed to text providing for "a previous and existing risk assessment report consistent with Annex II"<sup>693</sup> Once the more general pending issues were resolved, the Chair's text included a single reference to "products thereof" in sub-paragraph (i) on intended use.<sup>694</sup> Annex I was then provisionally adopted by the BSWG.<sup>695</sup> The remaining brackets had been removed in this text, now identical to the final text except for minor corrections made by the Legal Drafting Group,<sup>696</sup> and Annex I was finally adopted at the resumed ExCOP.<sup>697</sup>

<sup>681</sup> *Id.*

<sup>682</sup> *Id.*

<sup>683</sup> UNEP/CBD/BSWG/5/3, paras. 36-37, and UNEP/CBD/BSWG/5/Inf.1.

<sup>684</sup> *Id.*

<sup>685</sup> UNEP/CBD/BSWG/5/3, see Annex I.

<sup>686</sup> UNEP/CBD/BSWG/5/2, pp. 132-134, contains new submissions from New Zealand, Norway, Peru, Slovenia and Thailand.

<sup>687</sup> *Id.* As New Zealand, Slovenia and Thailand proposed in their submissions.

<sup>688</sup> UNEP/CBD/BSWG/3/3, see the submissions from Colombia, Cuba, Norway and South Africa.

<sup>689</sup> UNEP/CBD/BSWG/5/3, para. 37.

<sup>690</sup> UNEP/CBD/ExCOP/1/2, p. 7.

<sup>691</sup> *Ibid.* p. 8.

<sup>692</sup> ENB Vol. 9 No. 112, p. 2.

<sup>693</sup> ENB Vol. 9 No. 113, p. 2.

<sup>694</sup> UNEP/CBD/BSWG/6/L.2. See Annex I.

<sup>695</sup> UNEP/CBD/ExCOP/1/3, para. 51.

<sup>696</sup> UNEP/CBD/BSWG/6/L.2/Rev.2. See Annex I.

<sup>697</sup> UNEP/CBD/ExCOP/1/3.

## **Annex II: Information Required Concerning Living Modified Organisms Intended for Direct Use as Food or Feed, or for Processing Under Article 11**

- (a) The name and contact details of the applicant for a decision for domestic use.
- (b) The name and contact details of the authority responsible for the decision.
- (c) Name and identity of the living modified organism.
- (d) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.
- (e) Any unique identification of the living modified organism.
- (f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
- (g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
- (h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
- (i) Approved uses of the living modified organism.
- (j) A risk assessment report consistent with Annex III.
- (k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

The development of an annex on information requirements for LMO-FFPs resulted from the agreement to develop an alternative procedure for LMO-FFPs given their exclusion from the AIA procedure.<sup>698</sup> An annex covering the information to be provided under the new article on LMO-FFPs (then Article 9bis) was first proposed in President Mayr's non-paper for the resumed ExCOP.<sup>699</sup> This proposal reduced the elements of Annex I (Information required to obtain AIA) to six,<sup>700</sup> namely: name, address and contact details of developer and/or notifier; name, identity and domestic classification of the biosafety level of the LMO (not in Annex I); description of the modification and resulting characteristics; centres of origin and description of habitats of proliferation; intended use; and risk assessment.<sup>701</sup>

Discussions at the resumed ExCOP were held on the basis of the draft Protocol text and the President's non-paper. The contact group on commodities at the resumed session of the ExCOP agreed to add several new elements to the list in this Annex, including, *inter alia*, unique identification of LMOs and suggested methods for safe handling, storage and transport.<sup>702</sup> When this proposal was further considered, contact group Chair Pythoud reported a consensus on extending the differentiated approach to the accompanying documentation.<sup>703</sup> Further elements from draft Annex I were included: taxonomic status, and characteristics of recipient and donor organisms. In the final draft of the Protocol submitted by the Legal Drafting Group, the references to "intended uses" was replaced by "approved uses" and the name and contact details were amended to become the "applicant for a decision on domestic use" and the "authority responsible for the decision."<sup>704</sup> The Annex was then adopted as part of the final text of the Protocol as Annex II. This resulted in a renumbering of the remaining Annex on Risk Assessment, which became Annex III.

<sup>698</sup> See sections on Article 7 and Article 11.

<sup>699</sup> Draft Chairman's proposal for addressing the essential core issues of the scope of the Protocol of 21 December 1999, see Annex 1B.

<sup>700</sup> See section on Annex I above.

<sup>701</sup> *Id.*

<sup>702</sup> ENB Vol. 09 No. 132, p. 2.

<sup>703</sup> ENB Vol. 09 No. 135, p. 2 and No. 136, p. 1.

<sup>704</sup> UNEP/CBD/ExCOP/1/L.5, see Annex III.

## Annex III: Risk Assessment

### Objective

1. The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

### Use of risk assessment

2. Risk assessment is, *inter alia*, used by competent authorities to make informed decisions regarding living modified organisms.

### General principles

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organisations.

4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

### Methodology

7. The process of risk assessment may on the one hand give rise to a need for fur-

ther information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances. 8. To fulfil its objective, risk assessment entails, as appropriate, the following steps:

(a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;

(b) An evaluation of the likelihood of these adverse effects being realised, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;

(c) An evaluation of the consequences should these adverse effects be realised;

(d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realised;

(e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and

(f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

### Points to consider

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

(a) Recipient organism or parental organisms. The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of ori-

**gin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;**

**(b) Donor organism or organisms. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;**

**(c) Vector. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;**

**(d) Insert or inserts and/or characteristics of modification. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;**

**(e) Living modified organism. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;**

**(f) Detection and identification of the living modified organism. Suggested detection and identification methods and their specificity, sensitivity and reliability;**

**(g) Information relating to the intended use. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and**

**(h) Receiving environment. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.**

The African group's submission prior to BSWG-2<sup>705</sup> included an annex on parameters for risk assess-

ment classified according to: characteristics of the donor and recipient organisms, vectors, living modified organism, resuscitated organisms and genes and fossil DNA, safety considerations for human and animal health, environmental considerations, and socio-economic considerations. The submission also contained an annex on risk management procedures. For the proposed article on risk assessment, the African group proposed that decisions on import should be based on risk assessments undertaken on a case by case basis, language that would later be reflected in this annex.<sup>706</sup>

In its submission, Australia referred to Article 30 of the Convention (Adoption and amendment of annexes). Norway also submitted a comprehensive proposal addressing: information related to the LMO (similar to the African proposal); information related to the intended use, sub-divided into LMOs for contained use and those for deliberate release; and characteristics of the potential receiving environment.

Further submissions were received prior to BSWG-3, the majority containing lists of specific information requirements.<sup>707</sup> The African group, India and Norway proposed extensive listings of the characteristics of the different organisms involved in the genetic modification. The African group and India also proposed information on the genetic stability of the organisms, the potential of the organisms to transfer genes with other organisms, potential pathogenicity to humans and animals, and measures to counteract adverse impacts. Together with Sri Lanka, they also proposed taking into account environmental and socio-economic considerations. Many of the submissions<sup>708</sup> emphasised information on the characteristics of the vector, in contrast to the information required under Annex I.<sup>709</sup> Malaysia referred to preliminary

<sup>705</sup> UNEP/CBD/BSWG/2/2, pp. 78-97, contains the submissions of the African region, Australia and Norway.

<sup>706</sup> *Ibid.*, p. 56. See also section on Article 15 above.

<sup>707</sup> UNEP/CBD/BSWG/3/3, pp. 92-103, contains the submissions of the African region, Australia, Belarus, Brazil, India, Malaysia, Norway, Peru and Sri Lanka.

<sup>708</sup> The African region, Belarus, Brazil, India, Norway and Sri Lanka.

<sup>709</sup> See section on Annex I above.

issues on methodology, advocating a multidisciplinary approach, and specifying the objectives of the risk assessment.

CG-1, having agreed that an annex on risk assessment was necessary but without beginning discussions on its content, compiled these submissions into the Consolidated Text at BSWG-3,<sup>710</sup> by classifying them into general principles and specific information requirements. These in turn were classified according to: characteristics of donor and recipient or parental organisms; characteristics of the vector; characteristics of the LMOs; safety considerations; environmental considerations; release of LMOs for biological control; release experiment of LMO for bioremediation; and socio-economic considerations.<sup>711</sup>

The discussions during BSWG-4 addressed whether some information requirements listed in draft annex I (Information required to obtain AIA) were more appropriate for inclusion in draft annex II (Risk Assessment).<sup>712</sup> The repetition of information in both annexes was also discussed.<sup>713</sup>

Working in parallel with the discussions on the article on Risk Assessment, (then Article 12) in SWG-I, CG-1 prepared a draft of annex II: a short version outlining a general approach and a longer version containing a more detailed approach. This recognised that, whichever approach was taken, no list of risk assessment parameters could fully provide for all factors in all instances of risk assessment.<sup>714</sup> It identified six risk assessment factors to be considered and these, in essence, would constitute the elements that feature in the final text as

the sequence of the risk assessment: identification of hazardous characteristics of the LMO, the extent of the related consequences, the likelihood of the hazard, estimation of the risk posed, application of risk management strategies, and determination of the overall risk of adverse effects.<sup>715</sup> A note was also included to clarify that the information required could vary from LMO to LMO depending on the particular circumstances, which would also appear in the final text (although differently phrased).

Some countries submitted additional text prior to BSWG-5.<sup>716</sup> Australia proposed that the assessment had to be carried out in a scientifically sound and transparent manner, taking into account scientific evidence, expert technical and technological advice, experience, and techniques developed by relevant international organisations. Norway, which advocated an annex on LMOs for contained use,<sup>717</sup> proposed that the precautionary principle should be taken into account in the contained use of LMOs.

While the discussions on the article on risk assessment continued to examine the need for an annex on principles and procedures for risk assessment,<sup>718</sup> CG-1 streamlined the draft annex II down to a framework specifying: the objective, use, general principles, and methodology of risk assessment (including the parameters to be taken into account).<sup>719</sup> The objective, in line with Malaysia's earlier proposal, affirmed that the risk assessment aimed to identify and evaluate the potential adverse effects of LMOs on biodiversity. Further references to human health and socio-

<sup>710</sup> UNEP/CBD/BSWG/3/6, paras. 92 – 95.

<sup>711</sup> *Ibid.* See Annex II.

<sup>712</sup> ENB Vol. 9 No. 78, p. 2.

<sup>713</sup> ENB Vol. 9 No. 79, p. 2.

<sup>714</sup> UNEP/CBD/BSWG/4/4, Annex IV, see Annex II (Revision).

<sup>715</sup> *Id.*

<sup>716</sup> UNEP/CBD/BSWG/5/2, pp. 135-144, contains submissions of Australia, New Zealand, Norway, Peru, Slovenia and Thailand.

<sup>717</sup> See Appendix I below on Deleted Draft Articles: Annex III Contained Use.

<sup>718</sup> ENB Vol. 9 No. 100, p. 1 and No. 104, p. 1.

<sup>719</sup> UNEP/CBD/BSWG/5/3. Annex, see Annex II.

economic considerations remained in brackets. The language on use was new and noted the use of risk assessment by competent authorities in order to make informed decisions about the transboundary movement of LMOs. The general principles language acknowledged the precautionary approach as a guiding principle of the assessment (in brackets), the uncertainty concerning the level of risk when there is lack of scientific knowledge or consensus, and the risk associated with transboundary movements of LMOs or products thereof. It noted that these should be considered in the context of using the non-modified recipients or parental organisms in the receiving environments. Risk assessments should be carried out on a case by case basis, and in a scientifically sound and transparent manner.<sup>720</sup> The section on methodology contained the steps and parameters noted above and included Australia's reference to expert advice and guidelines from international organisations.<sup>721</sup> A footnote indicated that further discussion on the technical details was still pending.<sup>722</sup>

At BSWG-6 agreement on the draft article on risk assessment was dependent upon a resolution of the discussions on annex II. These took place in CG-1, which considered language on general principles including reference to the precautionary approach and lack of scientific knowledge.<sup>723</sup> Language on requesting additional information or implementing appropriate risk management techniques to address uncertainties or increased levels of risk was inserted.<sup>724</sup> Delegates also discussed specific technical and scientific details to be taken into account during risk assessment, including characteristics of recipient/parental

organisms, vector, inserts/modification and donor organisms.<sup>725</sup> Information regarding safety considerations for human health and socio-economic considerations depended on the resolution of discussions by other sub-groups.<sup>726</sup> Similarly, the references to "products thereof" and the precautionary approach were dependent upon discussions in other sub-groups. Following the resolution of these issues, the section on general principles in annex II of the Chair's text could then contain a reference to "products thereof" and an implicit reference to the precautionary approach.<sup>727</sup> Annex II, together with Annex I, was then provisionally adopted by the BSWG.<sup>728</sup>

The Legal Drafting Group at the resumed ExCOP later reviewed this text and made minor editorial changes. The annex was re-numbered and was adopted as Annex III as part of the final text of the Protocol on 29 January 2000.

---

<sup>720</sup> *Id.*

<sup>721</sup> *Id.*

<sup>722</sup> *Id.*

<sup>723</sup> ENB Vol. 9 No. 112, p. 1.

<sup>724</sup> *Id.*

<sup>725</sup> *Id.*

<sup>726</sup> ENB Vol. 9 No. 113, p. 2.

<sup>727</sup> UNEP/BSWG/6/L.2/Rev.1, see Annex II.

<sup>728</sup> UNEP/CBD/ExCOP/1/3, para. 51.

## APPENDIX I: DELETED DRAFT ARTICLES

### Relationship with other international agreements

Prior to BSWG-2, a number of countries submitted views on the relationship between the protocol and other international agreements.<sup>729</sup> Australia recalled that the terms of reference of the BSWG stated that the protocol should “not override or duplicate any other international legal instrument in this area”<sup>730</sup> and stressed that the protocol need not derogate from WTO provisions. Similarly, the US proposed specifying that “nothing in [the protocol] shall affect the rights and obligations of countries under [prior] agreements.” Norway proposed an exemption in cases of “serious damage or threat to biological diversity”. The EU called for “consistency between the Protocol and the Agreements under the WTO” as well as with the relevant international obligations of the Parties, proposing to refer the issue as far as possible to Article 22 of the Convention. At the same time the Secretariat prepared a background document on existing international agreements on biosafety to provide the basis for negotiations,<sup>731</sup> which was subsequently considered at BSWG-3.<sup>732</sup>

The Secretariat also prepared two options of draft text for BSWG-3.<sup>733</sup> The first simply referred the issue to Article 22 of the Convention, while the second reflected the views expressed by Australia and the US, but with the exemption proposed by Norway. A second paragraph required Parties to “implement this Protocol with respect to the marine environment consistently with the rights and obligations of States under the law of the sea”.

The consolidated text at the end of BSWG-3 included both options, although it dropped the second paragraph of the second option.<sup>734</sup>

At BSWG-4, CG-2 continued the preliminary discussions and a third option was added to the consolidated draft text.<sup>735</sup> This provided that, in the event of any inconsistency between the Protocol and the Agreement on Technical Barriers to Trade (TBT) and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), the Protocol would “prevail to the extent of the inconsistency” and that Parties could “waive to this extent their right to bring a complaint against any other Party under [those] agreements”.

Several further submissions were made prior to BSWG-5.<sup>736</sup> At BSWG-5, the issue was addressed by SWG-II in conjunction with draft articles on Non-Parties and Non-discrimination (then Articles 23 and 24).<sup>737</sup> There was disagreement on the relationship between the proposed article on the relationship with other international agreements (then Article 34), and paragraph 5 of the article on General obligations, (then Article 1bis) which referred to the jurisdiction, rights and obligations of States under the law of the sea.<sup>738</sup>

The resulting consolidated negotiating text at the end of BSWG-5 contained a single option.<sup>739</sup>

Consensus could not be reached during BSWG-6 and the issue remained unresolved. Later, following the informal consultations, a non-paper by President Mayr proposed removing the draft article (then Article 31) and reflecting its intent instead in the Preamble.<sup>740</sup> Agreement could not be reached during the resumed ExCOP and the matter was finally resolved by informal negotiations on the last day of the negotiations, which led to the insertion of new preambular provisions on the relationship of the protocol with other international agreements, included in the final text of the Protocol.<sup>741</sup>

<sup>729</sup> UNEP/CBD/BSWG/2/2, pp. 32-35, contains the submissions of Australia, Canada, the European Union, Norway and United States.

<sup>730</sup> Decision II/5, Annex, para. 4(b).

<sup>731</sup> UNEP/CBD/BSWG/2/3.

<sup>732</sup> UNEP/CBD/BSWG/3/Inf.2.

<sup>733</sup> UNEP/CBD/BSWG/3/4, p. 8.

<sup>734</sup> UNEP/CBD/BSWG/3/6, Annex I, see Article 34.

<sup>735</sup> UNEP/CBD/BSWG/4/4, Annex III, see Article 34.

<sup>736</sup> UNEP/CBD/BSWG/5/2, see Article 34, contains the submissions of Ecuador, New Zealand, Peru, Slovenia, Thailand, Uruguay and Venezuela.

<sup>737</sup> UNEP/CBD/BSWG/5/3, para. 40.

<sup>738</sup> *Ibid.*, para. 43.

<sup>739</sup> UNEP/CBD/BSWG/5/3, Annex, see Article 34.

<sup>740</sup> Draft Chairman's Proposal, Non-paper dated 21 December 1999. See also section on the Preamble in section III above.

<sup>741</sup> See also section on Non-discrimination in this Appendix.

## Jurisdictional Scope

A draft article on jurisdictional scope was prepared by the Secretariat for BSWG-3.<sup>742</sup> This proposal included two options for text:

1. "Articles 4 of the Convention on Biological Diversity regarding Jurisdictional Scope shall apply to this Protocol." or
2. "Subject to the rights of other States, and except as otherwise expressly provided in this Protocol, the provisions of this Protocol apply, in relation to each Contracting Party:
  - (a) In the case of components of biological diversity, in areas within the limits of its national jurisdiction; and
  - (b) In the case of processes and activities, regardless of where their effects occur, carried out under its jurisdiction or control, within the area of its national jurisdiction or beyond the limits of national jurisdiction."

The first option reflected a proposal submitted by the EU prior to BSWG-2.<sup>743</sup>

The consolidated text at the end of BSWG-3 retained only the first option.<sup>744</sup>

At BSWG-4, CG-2 decided that this article was redundant and could be deleted.<sup>745</sup> The recommendation was reiterated at BSWG-5, and the draft article ("Article 32 Jurisdictional Scope) was deleted.<sup>746</sup>

## Notification of Transit

A number of governments submitted draft text prior to BSWG-3.<sup>747</sup> Australia and Brazil proposed that Parties could require notification in writing of "other Parties intent to transit an LMO through their territory". According to this proposal, such Parties would be required to provide the BCH with "details of the categories of LMOs for which notification is required" and "information to be provided with the notification". On receipt of the notification, the Party would be required to advise on relevant provisions for transit of the LMOs. Mexico proposed that transit required the issue by the country of transit of a permit to the exporting Party. The exporting Party should also assume "responsibility for any cases of accidental release in [the countries of transit]". Malaysia proposed to define transit as "the temporary stop-over of an LMO which is on a continuous journey to another destination." Norway proposed a detailed procedure with timelines under which the country of transit could "declare in writing whether a notification is required for subsequent transit movements of the same LMO." Peru proposed that the "documentation provided for the transport of LMOs must specify the care needed during their transit".

The Consolidated Text at the end of BSWG-3 included options for a draft article divided into four sections: requirements; acknowledgement/response; treatment of goods in transit; and an option of no specific provision under this article.<sup>748</sup>

At BSWG-4, the need for this article was considered by SWG-I. The resulting two options contained in the consolidated text included an option for no provision and an option requiring the earlier proposed elements, i.e. the notification between Parties of the intent to transit LMOs; acknowledgement of notification by the State of transit; notification by transit States regarding

<sup>742</sup> UNEP/CBD/BSWG/3/4, p. 7.

<sup>743</sup> UNEP/CBD/BSWG/2/2, p. 48.

<sup>744</sup> UNEP/CBD/BSWG/3/6, Annex I, see Article 32.

<sup>745</sup> UNEP/CBD/BSWG/4/4, para. 23.

<sup>746</sup> UNEP/CBD/BSWG/5/3, Annex, p. 46

<sup>747</sup> UNEP/CBD/BSWG/3/3, see Article 7, contains the submissions of Australia, Brazil, Malaysia, Mexico, Norway and Peru.

<sup>748</sup> UNEP/CBD/BSWG/3/6, Annex I, see Article 8.



treatment of subsequent imports; and documentation specifying the necessary care for the LMOs while in transit.<sup>749</sup>

During BSWG-5, SWG-I recommended the deletion of the article on the grounds that its relevant elements were already covered in a number of other articles.<sup>750</sup> The Working Group therefore agreed to the deletion of draft Article 8 (Notification of Transit).<sup>751</sup>

## Emergency Measures<sup>752</sup>

Some governments presented draft text on emergency procedures prior to BSWG-2.<sup>753</sup> These proposals, with the exception of Japan which referred the matter to Article 14(1)(d) and (e) of the Convention, included a general commitment to immediately inform affected countries and to introduce appropriate measures and procedures; and identified information to accompany the notification (including the identity of the LMO, the quantities and circumstances of the release, and emergency measures needed to be taken). The views of the African group and Norway reflected their concerns about the possible effects of an accident on human health and the environment. The African group also added references to animal health and biodiversity and Norway proposed the need for consultations on the part of the affected States.

Further proposals were presented for BSWG-3 under two separate headings: unintentional transboundary movements (then Article 16) and emergency measures (then Article 17).<sup>754</sup> India endorsed the African group's earlier text. Malaysia emphasised the importance of emergency plans as part of risk management strategies under the relevant provision of the protocol and the need for national measures that included contingency plans and emergency measures. Peru held the view that in cases of accidents the responsibility to take immediate action lay with the insurer and the competent authorities.

All the proposed elements were contained in the consolidated text prepared by SWG-II.<sup>755</sup>

At BSWG-4,<sup>756</sup> the renumbered Article 16 on emergency measures contained text that called either for the establishment of national measures and procedures, or for the incorporation of appropriate measures into risk management strategies required under draft article 13 (Risk Management).<sup>757</sup> However, later in the meeting, the draft articles on unintentional transboundary movement and on emergency measures were merged on the basis of a draft prepared by the Co-Chairs of SWG-II.<sup>758</sup> These issues are now addressed in Article 17 of the Protocol.

<sup>749</sup> UNEP/CBD/BSWG/4/4, Annex I, see Article 8.

<sup>750</sup> UNEP/CBD/BSWG/5/3, para. 32.

<sup>751</sup> UNEP/CBD/BSWG/5/3, Annex, see Article 8. See also section on Article 6 in Section III above.

<sup>752</sup> See also section on Article 17 in Section III above.

<sup>753</sup> UNEP/CBD/BSWG/2/2, pp. 58-59, contains the submissions of Africa, Japan and Norway, and UNEP/CBD/BSWG/2/Inf.7 contains the submission of Malaysia.

<sup>754</sup> UNEP/CBD/BSWG/3/3, p. 50, contains the submissions of the African group, India, Malaysia and Peru.

<sup>755</sup> UNEP/CBD/BSWG/3/6, Annex I, see Articles 15 and 16.

<sup>756</sup> Colombia had presented draft text in UNEP/CBD/BSWG/4/3, p. 13.

<sup>757</sup> UNEP/CBD/BSWG/4/Inf.2, see Article 16.

<sup>758</sup> UNEP/CBD/BSWG/4/SWG.II/CRP.1. See now section on Article 17 in Section III above.

### Minimum national standards

By BSWG-3, a number of governments had submitted draft text on minimum standards,<sup>759</sup> following an earlier submission by Norway.<sup>760</sup> These proposals generally agreed with Norway that each “Party shall ensure that appropriate legal, institutional and administrative frameworks with regard to the safe transfer, handling and use of LMOs are in place” and that “[t]he national regulations shall as a minimum fulfil the requirements set out in this Protocol with regard to the safe transfer, handling and use of LMOs”. Norway proposed that such frameworks needed to be established “upon the date of the entry into force of this Protocol for [the Party in particular].”

Canada proposed a requirement for “domestic laws [in so far as to] manage the risks identified under [their] risk assessment procedures [in accordance with the Protocol].” Language from the first two elements would later be included in Article 2 (General Provisions). The draft Consolidated Text at the end of BSWG-3 included the Norwegian and Canadian proposals, as well as an option not to have any provision on this issue.<sup>761</sup>

Chair Koester prepared a note for BSWG-4 based on the three earlier options.<sup>762</sup> This proposed a deadline of “two years after the date of ratification/accession”; the obligation to “cooperate in establishing at the international and regional level, procedures [for] risk assessment”; and that “Parties may impose more stringent or comprehensive requirements based on scientific considerations”. At BSWG-4, SWG-I dealt with this provision and the resulting text contained two options, a zero (no provision) option and an option based on the Chair’s text but allowing the Parties to impose more stringent requirements based on the precautionary principle.<sup>763</sup>

During BSWG-5 views differed on whether to retain this article, delete it, or move it elsewhere, particularly to the draft article on general obligations (then Article 1bis).<sup>764</sup> At the fourth session of the plenary at BSWG-5, the Co-Chair of SWG-I, Mrs Wint (Jamaica), reported that SWG-I had agreed to delete the article if its substance was effectively addressed in Article 1bis.<sup>765</sup>

At BSWG-6, SWG-II considered the draft for inclusion in Article 1bis. After its principal provisions were incorporated into the draft Article 1bis (now Article 2 (General Provisions)), the Working Group agreed to remove the draft Article 16 on minimum national standards.<sup>766</sup>

<sup>759</sup> UNEP/CBD/BSWG/3/3, see Article 15, p. 43, contains the submissions of the African group, Canada, Mexico, Norway and Peru.

<sup>760</sup> UNEP/CBD/BSWG/2/2, p. 59.

<sup>761</sup> UNEP/CBD/BSWG/3/6, Annex I, see Article 14, p. 68.

<sup>762</sup> UNEP/CBD/BSWG/4/Inf.1, see Article 14.

<sup>763</sup> UNEP/CBD/BSWG/4/4, Annex I, see Article 14.

<sup>764</sup> Further submissions were made prior to BSWG-5. (UNEP/CBD/BSWG/5/2, pp. 61-63, contains the submissions of Ecuador, Kenya, New Zealand, Peru, Slovenia, Thailand and Venezuela.

<sup>765</sup> UNEP/CBD/BSWG/5/3, para. 32.

<sup>766</sup> UNEP/CBD/ExCOP/1/2, para. 39.

## Non-discrimination

Following the discussion in plenary at BSWG-3 on non-discrimination, it was decided to prepare an element paper on non-discrimination by SWG-II and include it in the Consolidated Text.<sup>767</sup> Thirteen elements were included in the draft text encompassing views ranging from acknowledging the exercise of sovereign rights by Parties in respect of non-discrimination to ensuring the Protocol's consistency with trade-related international treaties, and in particular, those under the WTO.<sup>768</sup>

A large number of submissions were made prior to BSWG-4.<sup>769</sup> Those from Argentina and Australia stressed that measures regulating the safe transfer, handling and use of LMOs should not "create unnecessary obstacles to, and or constitute means of arbitrary or unjustified discrimination or disguised restrictions on international trade". Argentina also proposed that "Parties shall not discriminate between imported living modified organisms and those produced locally and/or those that have previously authorised to be imported from a third party".

Chile proposed that "Parties may restrict trade of certain living modified organisms while permitting others". Bolivia's submission subjected the introduction of an LMO into a country Party to the Protocol to compliance with the AIA procedure. The text from the US and Japan, following Argentina and Australia, declared that the "importing Party shall ensure that its decisions and actions with respect to the import of a living modified organism are not more restrictive than with regard to the same living modified organism produced domestically or imported from any other country." Japan also proposed that "recipient Contracting Parties may impose specific conditions

when living modified organisms of foreign origin are imported from non-Parties with which [there is] no agreement or arrangement [as provided under the Protocol]".

Malaysia supported the receiving country Party's sovereign right and prerogative to decide on the issue and allowed that "any matter of national interest such as social and ethical matters and sensitivities of the culture and religion prevailing in the receiving country" could be taken into consideration. It also proposed that "[p]revious decisions by the receiving country Party... shall not affect the right of the receiving country Party to make its [own] decisions".

Elements from the proposals from Argentina, Australia, Japan and the USA were included in the two substantive options in the draft text prepared by SWG-II, together with the option to have no provision on non-discrimination.<sup>770</sup>

Additional views were submitted prior to BSWG-5.<sup>771</sup> During BSWG-5, SWG-II discussed a draft article, "Non-discrimination/National Treatment", following a proposal from Mexico<sup>772</sup> as part of a cluster including draft articles on Non-Parties, (then Article 23), and on Relationship with Other International Agreements, (then Article 34). At the heart of the discussion was the question of the extent to which the protocol would address trade issues and what role non-trade concerns would play. A drafting group worked on draft articles on non-discrimination and on non-parties. The resulting consolidated negotiating text at the end of BSWG-5 contained two paragraphs in brackets endorsing non-discrimination and prohibiting unnecessary obstacles/unjustified discriminations/disguised restrictions to trade.<sup>773</sup>

<sup>767</sup> UNEP/CBD/BSWG/3/6, paras. 65-68.

<sup>768</sup> *Ibid.*, p. 85.

<sup>769</sup> UNEP/CBD/BSWG/4/2, pp. 10-11, contains submissions of Argentina, Australia, Bolivia, Chile, Japan, Malaysia, Switzerland and USA.

<sup>770</sup> UNEP/CBD/BSWG/4/4, Annex II, see Article 24.

<sup>771</sup> UNEP/CBD/BSWG/5/2, pp. 97-98, contains the submissions of Ecuador, Mexico, New Zealand, Peru, Thailand, Uruguay and Venezuela.

<sup>772</sup> *Id.*

<sup>773</sup> UNEP/CBD/BSWG/5/3, Annex, see Article 24.

At BSWG-6, a Co-Chair (Canada) of the informal group on trade-related issues, reported to SWG-II that many delegates supported deleting the provision, although one regional group wished to retain it.<sup>774</sup> However, the issue remained unresolved and the draft provision on non-discrimination in the Chair's proposed text at BSWG-6 was modified slightly, although not in substance.<sup>775</sup>

The deletion of this article was proposed in President Mayr's non-paper,<sup>776</sup> in view of the amendments to the preamble<sup>777</sup> and to the then Article 8, paragraph 4bis<sup>778</sup> (Decision procedure).

At the resumed ExCOP, a contact group on articles 31 (Relationship with other international agreements) and 22 (Non-discrimination) was established, chaired by Ambassador Yang (Cameroon), to examine the issues in the non-paper. Ambassador Yang would later report that the group's proposal, set out in a working paper, also suggested deleting these articles and that their content should be reflected in three preambular paragraphs.<sup>779</sup> Further consultations were held but no agreement was reached on the preambular text to replace those articles.<sup>780</sup> The outstanding issues relating to the preambular text were resolved in high-level consultations on the overall text of the Protocol.<sup>781</sup> Reference to non-discrimination was not included in the preamble when the final draft text of the Protocol, as submitted by the Legal Drafting Group, was adopted.

## Subsequent Imports

A number of governments submitted draft text on subsequent imports of LMOs for consideration at BSWG-3.<sup>782</sup> Australia proposed specifying that notification of subsequent imports of the same LMO into the same importing Party should only be required in writing: "where there may be a change in the intended use of the living modified organism; a variation in the receiving environment; or other factors likely to affect the risk assessment or risk management". However Brazil, together with Mexico and Peru, proposed that notification in writing should be required for all subsequent imports of the same LMO into the same importing Party. The EC suggested "a single notification" to cover similar or subsequent transboundary movements to the same Party of import. Norway proposed that a State of import could at any time declare that subsequent imports of a specific LMO into its territory for specified uses or purposes would be exempt from the AIA procedure. Switzerland proposed that the national focal points of the importing party should be informed thirty days in advance of any intended subsequent transboundary movements and that, in cases of no response, the exporter could proceed with such movements.

The draft Consolidated Text at the end of BSWG-3 divided the proposals into three sections: notification (six options); application (two options); and regulation (one option).<sup>783</sup>

<sup>774</sup> ENB, Vol. 9 No. 112, p. 2.

<sup>775</sup> UNEP/CBD/BSWG/3/6/L.2, see Article 22.

<sup>776</sup> Draft Chairman's Proposal, Non-paper dated 21 December 1999.

<sup>777</sup> See sections on the Preamble in Section III above and on Relationship with Other International Agreements in this Appendix.

<sup>778</sup> This new paragraph introduced by President Mayr was later removed. See also section on Article 10 in section III.

<sup>779</sup> UNEP/CBD/ExCOP/1/3, para. 63.

<sup>780</sup> *Ibid.*, para. 85.

<sup>781</sup> *Ibid.*, paras. 87-91.

<sup>782</sup> UNEP/CBD/BSWG/3/3, Article 10, contains the submissions of Australia, Brazil, European Community, Mexico, Norway, Peru and Switzerland.

<sup>783</sup> UNEP/CBD/BSWG/3/6, Annex, Article 10.

At BSWG-4 the options, drawn mainly from the submissions of Australia, Brazil, EC and Norway, were narrowed down to five, including a zero (no provision) option.<sup>784</sup>

However at BSWG-5, SWG-I decided to delete the article on the grounds that its contents were “amply covered in the revised Article 6 [Decision Procedure] para. 3 (a), as contained in UNEP/CBD/BSWG/5/SWG.I/CRP.3 as well as in Articles 9 [Simplified Procedure] and 12 [Risk Assessment], contained in working papers 11 and 4, respectively, of SWG-I.”<sup>785</sup> The Article was provisionally deleted until BSWG-6, when final deletion of the draft Article 10 (Subsequent Imports) was agreed.<sup>786</sup>

### **Ratification, acceptance or approval**

The Secretariat prepared a draft article on ratification, acceptance or approval for BSWG-3.<sup>787</sup> This stated that, in accordance with Article 34 of the Convention, the Protocol would be subject to ratification, acceptance or approval and that the relevant instrument would be deposited with the Depository. Additional provisions regarding the particular case of regional economic integration organisations were also envisaged, mirroring the text of the Convention, in order to clarify that such organisations and their Member States could not exercise rights under the Protocol concurrently.

However, during BSWG-4, CG-2 agreed that draft article 38 on ratification, acceptance and approval was redundant<sup>788</sup> and that it could be deleted.<sup>789</sup> At BSWG-5, draft article 38 on ratification, acceptance and approval was deleted.<sup>790</sup>

---

<sup>784</sup> UNEP/CBD/BSWG/4/4, Annex I, see Article 10.

<sup>785</sup> UNEP/CBD/BSWG/5/3, para. 32; and Annex, see Article 10.

<sup>786</sup> UNEP/CBD/ExCOP/1/2, para. 39.

<sup>787</sup> UNEP/CBD/BSWG/3/4, p. 12.

<sup>788</sup> See Article 34 of the Convention. See also section on Article 37 in section III above.

<sup>789</sup> UNEP/CBD/BSWG/4/4, para. 23.

<sup>790</sup> UNEP/CBD/BSWG/5/3, para. 27.

## Accession

The Secretariat drafted text for BSWG-3 on this issue,<sup>791</sup> which reproduced the relevant provisions from the Convention. The draft read:

1. In accordance with Article 35 of the Convention, this Protocol shall be open for accession by States and by regional economic integration organisations from the date on which the Convention or the protocol concerned is closed for signature. The instruments of accession shall be deposited with the Depository.
2. In their instruments of accession, the organisations referred to in paragraph 1 above shall declare the extent of their competence with respect to the matters governed by the Protocol. These organisations shall also inform the Depository of any relevant modification in the extent of their competence.
3. The provisions of Article [Ratification,] paragraph (b), shall apply to regional economic integration organisations, which accede to this Protocol.

At BSWG-4, CG-2 agreed that Article 39 (Accession) was redundant<sup>792</sup> and could be deleted.<sup>793</sup> BSWG-5 accepted this recommendation and, after provisionally<sup>794</sup> deleting this Article, it was then finally removed.

## OTHER PROPOSALS

### Settlement of Disputes

A number of submissions were made on settlement of disputes prior to BSWG-2.<sup>795</sup> The African group reproduced the text of Article 27 of the Convention on Settlement of Disputes, while the EU invoked Article 27(5) CBD which states that “the provisions of this Article shall apply with respect to any protocol except as otherwise provided in the protocol concerned.” Bolivia called for an international arbitration mechanism under UNEP or another international organisation to be decided by the Convention. Cuba also supported arbitration but under the procedures set down in Annex II of the Convention.

The Secretariat prepared draft text for consideration at BSWG-3<sup>796</sup> containing two options. The first referred to Article 27 and Annex II of the Convention, while the second reproduced the text of Article 27. During the discussions at BSWG-3, it was agreed that the relevant provisions of the Convention should apply and that the Protocol should indicate in its article on Relationship with the Convention (then article 33), by means of a footnote, that “[t]his provision potentially allows for the provisions of the Convention on, for example, settlement of disputes; amendment; adoption and amendment of annexes; and right to vote to apply to the Protocol.”<sup>797</sup>

Draft Article 33 was reconsidered at BSWG-4 and BSWG-5 in light of its relation to other pending issues. Explicit reference to settlement of disputes was finally removed at BSWG-6.<sup>798</sup>

<sup>791</sup> UNEP/CBD/BSWG/3/4, p. 12.

<sup>792</sup> See Article 35 of the Convention. See also sections on Article 37 in section III above, and on Ratification, Acceptance or Approval in this Appendix.

<sup>793</sup> UNEP/CBD/BSWG/4/4, para. 23.

<sup>794</sup> UNEP/CBD/BSWG/5/3, para. 27.

<sup>795</sup> UNEP/CBD/BSWG/2/2, pp. 40-41, contains the submissions of the African region, Australia, Bolivia, Canada and the EU. See also submission of Cuba in UNEP/CBD/BSWG/2/Inf.6.

<sup>796</sup> UNEP/CBD/BSWG/3/4, p. 9.

<sup>797</sup> UNEP/CBD/BSWG/3/6, Annex I, see Article 33.

<sup>798</sup> UNEP/CBD/BSWG/6/L.2, see Article 30.

### **Annex - LMOs that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health**

Following a proposal from the EC before BSWG-3<sup>799</sup> to include an annex listing such LMOs, an “empty” annex was included in the Chair’s proposed text at BSWG-6<sup>800</sup> but then removed during the second revision of the draft.<sup>801</sup>

### **Other Annexes**

A number of other proposed annexes were identified in the Chair’s draft on content of certain articles prepared for BSWG-3. These addressed: information required in order to obtain advance informed agreement; risk assessment parameters; risk management schemes; function of focal points/competent authorities; and information to be provided to the Secretariat under information sharing/clearing-house.<sup>802</sup> CG-1 recommended that these annexes be included in the consolidated draft, and a further list of proposed annexes contained in submissions was also provided.<sup>803</sup>

During BSWG-4, discussions continued on draft annexes I and II and on preparations for discussions on the remainder of the proposed annexes at the following meeting. However, at BSWG-5 the decision was taken to limit the number of annexes to four.<sup>804</sup>

---

<sup>799</sup> UNEP/CBD/BSWG/3/5.

<sup>800</sup> UNEP/CBD/BSWG/6/L.2, see Annex III.

<sup>801</sup> UNEP/CBD/BSWG/6/L.2/Rev.2. For a more detailed account on this proposal see section on Article 4 in section III.

<sup>802</sup> UNEP/CBD/BSWG/3/Inf.4.

<sup>803</sup> UNEP/CBD/BSWG/3/6, para. 94.

<sup>804</sup> UNEP/CBD/BSWG/5/3, para. 37. See also the sections on Annexes I, II and III in section III.

## APPENDIX II: NEGOTIATING SESSIONS AND GROUPS

### OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY

First Meeting (BSWG-1)	Aarhus, 22-26 July 1996	Chairman	Mr. Veit Koester	Denmark
Second meeting (BSWG-2)	Montreal, 12-16 May 1997	Chairman	Mr. Veit Koester	Denmark
Third Meeting (BSWG-3)	Montreal 13-17 October 1997	Chairman	Mr. Veit Koester	Denmark
		Co-Chairs, Sub-Working Group I	Dr. Eric Schoonejans Mrs. Sandra Wint	France Jamaica
		Co-Chairs, Sub-Working Group II	Ms. Hira Jhamtani Mr. David Gamble	Indonesia New Zealand
		Co-Chairs, Contact Group 1	Mr. Gert Willemse Mr. Piet van der Meer	South Africa Netherlands
		Co-Chairs, Contact Group 2	Amb. John Ashe	Antigua and Barbuda
Fourth meeting (BSWG-4)	Montreal 5-13 February 1998	Chairman	Mr. Veit Koester	Denmark
		Co-Chairs, Sub-Working Group I	Dr. Eric Schoonejans Mrs. Sandra Wint	France Jamaica
		Co-Chairs, Sub-Working Group II	Ms. Amarjeet K. Ahuja Mr. John Herity	India Canada
		Co-Chairs, Contact Group 1	Mr. Gert Willemse Mr. Piet van der Meer	South Africa Netherlands
		Co-Chairs, Contact Group 2	Amb. John Ashe Ms. Katharina Kummer	Antigua and Barbuda Switzerland
Fifth meeting (BSWG-5)	Montreal 17-28 August 1998	Chairman	Mr. Veit Koester	Denmark
		Co-Chairs, Sub-Working Group I	Dr. Eric Schoonejans Mrs. Sandra Wint	France Jamaica
		Co-Chairs, Sub-Working Group II	Ms. Amarjeet K. Ahuja Mr. John Herity Mr. Gert Willemse	India Canada South Africa
		Co-Chairs, Contact Group 1	Mr. Piet van der Meer Amb. John Ashe	Netherlands Antigua and Barbuda
		Co-Chairs, Contact Group 2	Ms. Katharina Kummer	Switzerland
		Chair, Drafting Group on Liability and Redress	Ms. Kate Cook	United Kingdom
Sixth meeting (BSWG-6)	Cartagena 15-19 February 1999	Chairman	Mr. Veit Koester	Denmark
		Co-Chairs, Sub-Working Group I	Dr. Eric Schoonejans Mrs. Sandra Wint	France Jamaica
		Co-Chairs, Sub-Working Group II	Mr. Rajen Habib Khwaja Mr. John Herity	India Canada
		Co-Chairs, Contact Group 1	Mr. Osama El-Tayeb Mr. Piet van der Meer	Egypt Netherlands
		Co-Chairs, Contact Group 2	Amb. John Ashe Ms. Katharina Kummer	Antigua and Barbuda Switzerland
		Chair, Legal Drafting Group	Amb. Lynn Holowesko	Bahamas
		Chair, Drafting Group on Liability and Redress	Ms. Kate Cook	United Kingdom



## CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY

First extraordinary meeting (ExCOP)	Cartagena 22-23 February 1999	President	Mr. Juan Mayr Maldonado,	Colombia
Informal consultations	Montreal, 1 July 1999	President	Mr. Juan Mayr Maldonado,	Colombia
Informal consultations	Vienna, 15-19 September 1999	President	Mr. Juan Mayr Maldonado,	Colombia
Informal Consultations	Montreal 22-23 January	President	Mr Juan Mayr Maldonado	Colombia
First extraordinary meeting (Resumed ExCOP)	Montreal 24-29 January 2000	President	Mr. Juan Mayr Maldonado,	Colombia
		Chair, Contact Group (commodities)	Mr. François Pythoud	Switzerland
		Chair, Contact Group (scope)	Mr. John Herity	Canada
		Chair, Legal Drafting Group	Amb. Lynn Holowesko	Bahamas
		Chair, Contact Group (articles 31 and 22)	Amb. Philémon Yang	Cameroon
		Co-ordinator, Consultations on non-core issues	Amb. Beat Nobs	Switzerland

## APPENDIX III: EVOLUTION OF THE CONTENTS OF THE PROTOCOL

### BSWG-1

During BSWG-1 (July 1996) a contact group was established to consolidate proposals for the possible structure of the protocol into a single document, not necessarily the subject of consensus, including in a logical order all the elements put forward.<sup>805</sup> The working paper developed by the contact group contained three sections: items included in all proposals, items included in some but not all proposals, and terms proposed for definition. The working paper was submitted to the final plenary and was included as the annex to the report of the meeting.

#### Possible Contents of the Protocol on Biosafety

##### A. Items included in all proposals:

Title  
 Preamble  
 Use of terms/Definitions  
 Advance informed agreement  
 Information sharing  
 Relationship with other international agreements  
 Institutional framework for the functioning of the Protocol  
 Settlement of disputes  
 Amendment  
 Final clauses

##### B. Items included in some but not all proposals:

Objectives  
 Scope  
 Jurisdictional scope  
 General obligations  
 Criteria to determine the use of AIA and/or notification procedures  
 Notification procedure  
 Considerations for risk assessment and risk management  
 Mechanisms for risk assessment  
 Mechanisms for risk management

Emergency procedures  
 Minimum national standards on biosafety  
 Designation of competent authority and national focal point  
 Capacity building  
 Transport and packaging requirements for the transfer of LMOs  
 Handling, transport and transit requirements for LMOs  
 Transboundary movement between parties  
 Transboundary movement from a party through States which are not parties  
 Illegal traffic  
 Duty to re-import  
 Technical information network  
 Public awareness  
 Clearing-house  
 Mechanisms for bilateral agreements  
 Liability/Liability and compensation  
 Consultations on liability  
 Monitoring and compliance  
 Financial issues  
 Socio-economic considerations  
 Review and adaptation  
 Signature  
 Accession  
 Right to vote  
 Entry into force  
 Reservations and declarations  
 Withdrawal  
 Depository  
 Authentic texts  
 Annexes

#### Appendix I: Terms proposed for definition:

Living Modified Organisms (LMOs)  
 Transboundary movement  
 Transfer  
 Safe transfer  
 Competent authority  
 Familiarity  
 Adverse effects  
 Contained use  
 Intended/deliberate release  
 Unintended release  
 Focal point  
 Risk assessment  
 Risk management  
 Modern biotechnology  
 Advance Informed Agreement/Prior informed consent

<sup>805</sup> UNEP/CBD/BSWG/1/4, paras. 101-102.

Minimum national standards  
 Biosafety  
 Limited field trial  
 Handling of LMOs  
 Use of LMOs  
 Centres of origin  
 Centres of genetic diversity  
 Compensation  
 Accidental release  
 Open environment  
 Open field trial  
 Accidental

(UNEP/CBD/BSWG/1/4)

## BSWG-2

At BSWG-2 (May 1997), the Chair, on the basis of his review of items which had been addressed by submissions of participants, tabled conference room papers or aide-mémoires raising specific questions on which the views of the delegations were sought. These views were compiled by the Chair, and delegations were given an opportunity to add elements that had been proposed or to suggest modifications. It was decided to annex the revised Chair's summary of draft elements to the report of BSWG-2. It was agreed that these revised summaries should not be treated as negotiated documents and that they in no way created a prescriptive framework for negotiations.<sup>806</sup>

### Chairman's Summary of Elements Presented

#### Item A: Procedures in the case of specific transfer of LMOs

Topic: Modalities of the Procedure(s)

Elements: Notification; Information that may be required;  
 Period of time; Review

Topic: For which cases should the procedure(s) apply

Elements: No exceptions/deviations; Exceptions/deviations;  
 Specific cases

Topic: Simplified procedure

Topic: Consent

#### Item B: Competent authority(s)/focal point(s)

Topic: Modalities for competent authority(s)/focal point(s)

Elements: Nomination; Time of designation; Responsibilities of Competent

Authority(s)/Focal Point(s)

#### Item C: Information-sharing

General; Between Parties; Clearing-house; Confidentiality;  
 Common format

#### Item D: Capacity-building

#### Item E: Public awareness/public participation

Public awareness; Public participation

#### Item F: Risk assessment and risk management (including minimum national standards)

Risk Assessment: Provisions; Responsibility; Legal status;  
 Aim/basis

Risk Management: Provisions; Legal status; Responsibility/  
 trigger; Basis

#### Item G: Unintentional transboundary movement of LMOs (including accidental and emergency cases)

#### Item H: Monitoring and compliance

Monitoring

Compliance

#### Item I: Handling, transport/packaging/and transit requirements for transboundary movement of LMOs

(UNEP/CBD/BSWG/2/6)

## BSWG-3

At the end of BSWG-3 (October 1997) a "consolidated text of draft articles" was prepared based on the outcome of the work of the Sub-Working Groups and contact groups and attached to the report of the meeting.<sup>807</sup> The purpose of this was to meet the requirement of the Convention that the text of any proposed protocol be communicated to the Parties by the Secretariat at least six months before the meeting at which it was to be adopted.<sup>808</sup> As the COP had asked the Working Group to complete its work by the end of 1998,<sup>809</sup> and as the COP would next meet in May 1998, this would enable the requirement to be met. The Chairman had defined "text of a proposed protocol" as "a draft text of a protocol that all Governments agree constitutes sufficient ground for the

<sup>806</sup> UNEP/CBD/BSWG/2/6, Annex II.

<sup>807</sup> UNEP/CBD/BSWG/3/6.

<sup>808</sup> Article 28, CBD.

<sup>809</sup> Decision II/5.

completion of the negotiating process and the adoption of the protocol, meaning that all options and elements should be contained in the consolidated draft in legal terms.<sup>810</sup>

The opportunity would still remain for governments to submit text or amendments to the existing text for inclusion under the following headings in the consolidated draft articles: socio-economic considerations; liability and compensation; illegal traffic; non-Parties; non-discrimination; objectives and general obligations.<sup>811</sup> It was clarified that:

- The draft did not preclude other options than those contained in the current draft;
- The draft did not imply that items addressed in the draft should be contained in the Protocol; and
- The entire consolidated draft should be considered to be in square brackets, and the same applied for everything in the draft.<sup>812</sup>

**Consolidated Text of Draft Articles**

Title  
 Preamble  
 Article 1- Principles/Objectives  
 Article 1 bis. General Obligations  
 Article 2. Use of terms  
 Article 3. Advance Informed Agreement  
 Article 4. Notification Procedure for AIA  
 Article 5. Response to AIA Notification  
 Article 6. Decision Procedure for AIA  
 Article 7. Review of Decision under AIA  
 Article 8. Notification of Transit  
 Article 9. Simplified Procedure  
 Article 10. Subsequent Imports  
 Article 11- Bilateral & Regional Agreements  
 Article 12- Risk Assessment  
 Article 13- Risk Management  
 Article 14- Minimum National Standards  
 Article 15- Unintentional Transboundary Movements  
 Article 16- Emergency Measures

Article 17- Handling Transport Packaging and Labelling  
 Article 18- Competent Authority/Focal Point  
 Article 19- Information Sharing/Biosafety Clearing House  
 Article 20- Confidential Information  
 Article 21- Capacity Building  
 Article 22. Public Awareness / Public Participation  
 Article 23. Non Parties  
 Article 24. Non Discrimination  
 Article 25. Illegal Traffic  
 Article 26. Socio-Economic Considerations  
 Article 27. Liability and Compensation  
 Article 28. Financial Mechanism and Resources  
 Article 29. Conference of the Parties  
 Article 30. Subsidiary Bodies and Mechanisms  
 Article 31. Secretariat  
 Article 32. Jurisdictional Scope  
 Article 33. Relationship with the Convention  
 Article 34. Relationship with other International Conventions  
 Article 35. Monitoring and Compliance  
 Article 36. Assessment and Review of Procedures/Annexes  
 Article 37. Signature  
 Article 38. Ratification, Acceptance, or Approval  
 Article 39. Accession  
 Article 40. Entry into Force  
 Article 41. Reservations  
 Article 42. Withdrawals  
 Article 43. Authentic Texts

**Annexes**

- I. Information required in order to obtain Advance Informed Agreement
- II. Risk assessment parameters
- III. Risk management schemes
- IV. Function of focal points/competent authorities
- V. Information to be provided to the Secretariat under information sharing/clearing house

(UNEP/CBD/BSWG/3/6)

The consolidated text approved at the end of BSWG-3 formed the basis for negotiations at BSWG-4 (February 1998), which approved draft articles resulting from the work of its two Sub-Working Groups and two Contact Groups as a basis for its future work, on the understanding that the Secretariat would incorporate them into

<sup>810</sup> UNEP/CBD/BSWG/3/6, para. 98.

<sup>811</sup> *ibid.*, para. 103.

<sup>812</sup> *ibid.*, Annex II.

the new consolidated draft text of the protocol, to be submitted to BSWG-5.<sup>813</sup>

The report of the fourth meeting contains four annexes with the draft articles as reviewed by the groups:

- Annex I (SWG-I) – Articles 3 to 14
- Annex II (SWG-II) – Articles 1, 1bis and 15 to 27
- Annex III (CG-2) – Preamble and Articles 28 to 43
- Annex IV (CG-1) – Use of Terms.

A fifth Annex contained a list of proposed annexes to the draft protocol: the two previous draft annexes I and II, ten further annexes proposed in government submissions, and six proposed annexes referred to in the consolidated text of the SWGs.

The Secretariat thus prepared a “revised consolidated text of the draft articles” for BSWG-5 (August 1998).<sup>814</sup>

**Revised Consolidated Text of the Draft Articles for BSWG-5.**

Preamble  
 Article 1. Objectives  
 Article 1 bis. General Obligations  
 Article 2. Use of Terms  
 Article 3 A. The Scope of the Protocol  
 Article 3 B. The Application of the AIA Procedure  
 Article 4. Notification [Procedure][for AIA]  
 Article 5. Response to [AIA] Notification  
 Article 6. Decision Procedure for AIA  
 Article 7. Review of Decisions [Under AIA]  
 Article 8. Notification of Transit  
 Article 9. Simplified Procedure  
 Article 10. Subsequent Imports  
 Article 11. [International Cooperation] Multilateral, Bilateral and Regional Agreements [other than the Protocol]  
 Article 12. Risk Assessment  
 Article 13. Risk Management  
 Article 14. Minimum National Standards

Merger of Article 15 and Article 16. Unintentional Transboundary Movements and Emergency Measures  
 Article 17. Handling, Transport, Packaging and Labelling  
 Article 18. Competent National Authority/National Focal Point  
 Article 19. Information Sharing/Biosafety Clearing-House/ [Biosafety Database]  
 Article 20. Confidential Information  
 Article 21. Capacity-Building  
 Article 22. Public Awareness/Public Participation  
 Article 23. Non-Parties  
 Article 24. Non-Discrimination  
 Article 25. Illegal Traffic  
 Article 26. Socio-Economic Considerations  
 Article 27. Liability and Compensation  
 Article 28. Financial Mechanism and Resources  
 Article 29. Conference of the Parties  
 Article 30. Subsidiary Bodies and Mechanisms  
 Article 31. Secretariat  
 Article 32. Jurisdictional Scope  
 Article 33. Relationship with the Convention  
 Article 34. Relationship with other International Agreements  
 Article 35. Monitoring and Reporting  
 [Article 35 bis. Compliance]  
 [Article 36. Assessment and Review of this Protocol]  
 Article 37. Signature  
 Article 38. Ratification, Acceptance, or Approval  
 Article 39. Accession  
 Article 40. Entry into Force  
 Article 41. Reservations  
 Article 42. Withdrawal  
 Article 43. Authentic Texts

**Annexes**

- I. Information Required in Notification for Advance Informed Agreement
- II. Risk Assessment
- III. List of Annexes to the draft Protocol

(UNEP/CBD/BSWG/5/Inf.1)

The draft articles and annexes, as revised and amended by the SWGs and the CGs, were approved for inclusion in the consolidated text to be used as a basis for negotiations at the sixth meeting. It was agreed that the Secretariat would prepare a consolidated text of the draft protocol by making necessary editorial corrections, deleting articles, where

<sup>813</sup> UNEP/CBD/BSWG/4/4, para.30.

<sup>814</sup> UNEP/CBD/BSWG/5/Inf.1.

so agreed, and renumbering, without substantively changing any articles or footnotes, save for the government submissions to be considered in the consideration of the preamble.<sup>815</sup>

The Secretariat thus prepared the “Draft Negotiating Text”<sup>816</sup> for BSWG-6 (February 1999).

## BSWG-6 and the ExCOP

### Draft Negotiating Text for BSWG-6.

Title  
 Preamble  
 Article 1. Objectives  
 Article 2. General Obligations  
 [Article 3. Use of Terms]  
 Article 4. The Scope of the Protocol  
 Article 5. The Application of the AIA Procedure  
 Article 6. Notification  
 Article 7. Acknowledgement of Receipt of Notification [for AIA]  
 Article 8. Decision Procedure for AIA  
 Article 9. Review of Decisions [under AIA]  
 Article 10. Notification of Transit  
 Article 11. Simplified Procedure  
 Article 12. Subsequent Imports  
 Article 13. Multilateral, Bilateral and Regional Agreements  
 [or Arrangements] [other than the Protocol]  
 Article 14. Risk Assessment  
 [Article 15. Risk Management]  
 Article 16. Minimum National Standards  
 Article 17. Unintentional Transboundary Movements and  
 Emergency Measure  
 [Article 18. Handling, Transport, Packaging [and Labelling]  
 Article 19. Competent National Authority/National Focal Point  
 Article 20. Information-Sharing/Biosafety Clearing-House  
 [Article 21. Confidential Information]  
 Article 22. Capacity-Building  
 Article 23. Public Awareness and Participation  
 [Article 24. Non-Parties]  
 [Article 25. Non-Discrimination]  
 [Article 26. Illegal Traffic]  
 [Article 27. Socio-Economic Considerations]  
 [Article 28. Liability and Redress]

Article 29. Financial Mechanism and Resources  
 Article 30. Conference of the Parties  
 Article 31. Subsidiary Bodies and Mechanisms  
 Article 32. Secretariat  
 Article 33. Relationship with the Convention  
 [Article 34. Relationship with other International Agreements]  
 Article 35. Monitoring and Reporting  
 [Article 36. Compliance]  
 Article 37. Assessment and Review of this Protocol  
 Article 38. Signature  
 Article 39. Entry into Force  
 [Article 40. Reservations]  
 Article 41. Withdrawal  
 Article 42. Authentic Texts  
 Annex I. Information Required In Notification for Advance  
 Informed Agreement  
 Annex II. Risk Assessment

(UNEP/CBD/BSWG/6/2)

At the closure of BSWG-6, in light of the unresolved issues, the BSWG agreed to forward to the ExCOP, as a package, the draft articles contained in the Chair’s proposed text<sup>817</sup> and as revised in the Legal Drafting Group,<sup>818</sup> incorporating the articles already provisionally adopted. The extraordinary meeting of the COP (ExCOP) (February 1999) thus considered this draft.

### Draft Protocol on Biosafety submitted to the ExCOP by the BSWG.

Preamble  
 1. Objective  
 2. General provisions  
 3. Use of terms  
 4. Scope  
 5. Application of the advance informed agreement procedures  
 6. Notification  
 7. Acknowledgement of receipt of notification  
 8. Decision procedure  
 9. Review of decisions  
 10. Simplified procedure  
 11. Multilateral, bilateral and regional agreements and  
 arrangements

<sup>815</sup> UNEP/CBD/BSWG/5/3, para.60.

<sup>816</sup> UNEP/CBD/BSWG/6/2.

<sup>817</sup> UNEP/CBD/BSWG/6/L.2/Rev.1.

<sup>818</sup> UNEP/CBD/BSWG/6/L.2/Rev.2.

12. Risk assessment
13. Risk management
14. Unintentional transboundary movements and emergency measures
15. Handling, transport, packaging and identification
16. Competent national authorities and national focal points
17. Information sharing and the Biosafety Clearing-House
18. Confidential information
19. Capacity-building
20. Public awareness and participation
21. Non-Parties
22. Non-discrimination
23. Illegal transboundary movements
24. Socio-economic considerations
25. Liability and redress
26. Financial mechanism and resources
27. Conference of the Parties serving as the meeting of the Parties
28. Subsidiary bodies and mechanisms
29. Secretariat
30. Relationship with the Convention
31. Relationship with other international agreements
32. Monitoring and reporting
33. Compliance
34. Assessment and review
35. Signature
36. Entry into force
37. Reservations
38. Withdrawal
39. Authentic texts

Annexes

- I. Information required in notifications
- II. Risk assessment

(UNEP/CBD/ExCOP/1/2)

There was no consensus at the ExCOP on this draft, or on the three proposals from negotiating groups: the “package proposal” submitted by the EU;<sup>819</sup> the “outstanding issues and necessary revisions to the text of the draft protocol” submitted by the Miami Group;<sup>820</sup> or the “proposal on the text of the draft protocol” submitted by the Like-Minded Group of Countries.<sup>821</sup>

<sup>819</sup> UNEP/CBD/ExCOP/1/3, Annex II.

<sup>820</sup> UNEP/CBD/ExCOP/1/3, Annex III.

<sup>821</sup> UNEP/CBD/ExCOP/1/3, Annex IV.

<sup>822</sup> UNEP/CBD/ExCOP/1/3, decision EM I/1.

<sup>823</sup> UNEP/CBD/ExCOP/1/2, Appendix I.

<sup>824</sup> UNEP/CBD/ExCOP/1/3, Annex.

The resumed ExCOP (January 2000) finally approved the Cartagena Protocol on Biosafety to the Convention on Biological Diversity with the following contents and structure. (The table also indicates when negotiations on the text of each article were concluded.)

**Cartagena Protocol on Biosafety to the Convention on Biological Diversity**

(The title was agreed during the first session of the ExCOP in Cartagena.<sup>822</sup>)

**Preamble**

(The first eight preambular elements were adopted unchanged from the proposed text transmitted by the Chair of the BSWG to the ExCOP on 22 February 1999;<sup>823</sup> the final three (deriving from Articles 22 and 31 in the Chair’s proposed text) were inserted at the close of the resumed ExCOP on 29 January 2000<sup>824</sup>)

**Article 1 Objective**

(Adopted unchanged from Chair’s proposed text)

**Article 2 General provisions**

(Adopted unchanged from Chair’s proposed text)

**Article 3 Use of terms**

(Adopted unchanged from Chair’s proposed text)

**Article 4 Scope**

(Adopted at the close of the resumed ExCOP)

**Article 5 Pharmaceuticals**

(New article inserted during the resumed ExCOP)

**Article 6 Transit and contained use**

(New article inserted during the resumed ExCOP)

**Article 7 Application of the advance informed agreement procedure**

(Former Article 5 in the Chair’s proposed text modified during the resumed ExCOP)

**Article 8 Notification**

(Former Article 6 in the Chair’s proposed text with minor editorial amendments)

**Article 9 Acknowledgement of receipt of notification**

(Former Article 7 in the Chair’s proposed text adopted unchanged (except for re-numbering of internal references to other Article))

**Article 10 Decision procedure**

(Former Article 8 in the Chair’s proposed text with substantive changes introduced during the resumed ExCOP)

**Article 11 Procedure for living modified organisms intended for direct use as food or feed, or for processing**

(New Article proposed by the President prior to the resumed ExCOP, following the informal consultations, and amended by the resumed ExCOP.)

**Article 12 Review of decisions**

(Former Article 9 in the Chair's proposed text with minor editorial amendments)

**Article 13 Simplified procedure**

(Former Article 10 in the Chair's proposed text, internally re-ordered and with editorial amendments)

**Article 14 Bilateral, regional and multilateral agreements and arrangements**

(Former Article 11 in the Chair's proposed text with the reference to "Parties or non-Parties" deleted by the resumed ExCOP)

**Article 15 Risk assessment**

(Former Article 12 in the Chair's proposed text with minor amendments)

**Article 16 Risk management**

(Former Article 13 of the Chair's proposed text, with amendments to the provision on the period of observation)

**Article 17 Unintentional transboundary movements and emergency measures**

(Former Article 14 of the Chair's proposed text with editorial amendments)

**Article 18 Handling, transport, packaging and identification**

(Former Article 15 of the Chair's proposed text, substantially amended and adopted at the close of the resumed ExCOP)

**Article 19 Competent national authorities and national focal points**

(Former Article 16 of the Chair's proposed text adopted unchanged)

**Article 20 Information sharing and the Biosafety Clearing-House**

(Former Article 17 of the Chair's proposed text with minor editorial amendments)

**Article 21 Confidential information**

(Former Article 18 of the Chair's proposed text with minor amendments)

**Article 22 Capacity-building**

(Provisionally adopted at BSWG-6)

**Article 23 Public awareness and participation**

(Former Article 20 of the Chair's proposed text with minor editorial and one substantive amendment)

**Article 24 Non-Parties**

(Former Article 21 of the Chair's proposed text amended during the resumed ExCOP)

**Article 25 Illegal transboundary movements**

(Former Article 23 of the Chair's proposed text with minor amendments)

**Article 26 Socio-economic considerations**

(Former Article 24 of the Chair's proposed text with reference to decisions taken under domestic measures inserted during the resumed ExCOP)

**Article 27 Liability and redress**

(Former Article 25 of the Chair's proposed text adopted unchanged)

**Article 28 Financial mechanism and resources**

(Provisionally adopted at BSWG-6)

**Article 29 Conference of the Parties serving as the meeting of the Parties to this Protocol**

(Provisionally adopted at BSWG-5)

**Article 30 Subsidiary bodies**

(Provisionally adopted at BSWG-5)

**Article 31 Secretariat**

(Provisionally adopted at BSWG-5)

**Article 32 Relationship with the Convention**

(Provisionally adopted at BSWG-5)

**Article 33 Monitoring and reporting**

(Provisionally adopted at BSWG-5)

**Article 34 Compliance**

(Provisionally adopted at BSWG-6)

**Article 35 Assessment and review**

(Provisionally adopted at BSWG-6)

**Article 36 Signature**

(Provisionally adopted at BSWG-5)

**Article 37 Entry into force**

(Provisionally adopted at BSWG-5)

**Article 38 Reservations**

(Adopted unchanged from Chair's proposed text)

**Article 39 Withdrawal**

(Provisionally adopted at BSWG-5)

**Article 40 Authentic texts**

(Provisionally adopted at BSWG-5)

**Annex I Information required in notifications under Articles 8, 10 and 13**

(Adopted with minor editorial changes from Chair's proposed text)

**Annex ii Information required concerning living modified organisms intended for direct use as food or feed, or for processing under Article 11**

(New annex added during the resumed ExCOP)

**Annex III Risk assessment**

(Adopted unchanged from Chair's proposed text)



## APPENDIX IV: PROPOSALS FROM GOVERNMENTS

### A: Governments that submitted proposals to BSWG-2

Title	Australia, Canada, European Union, Malaysia, Norway
Preamble	African region, Australia, Canada, Cuba, European Union, Malaysia, Norway, Switzerland, United States
List of terms/definitions	African region, Australia, Canada, Cuba, European Union, Malaysia, Norway, Switzerland, United States
Advance informed agreement	African region, Australia, Canada, Japan, Malaysia, Norway, United States
Information sharing	African region, Australia, Bolivia, Canada, Cuba, Japan, United States
Relationship with other international agreements	Australia, Canada, Cuba, European Union, Norway, United States
Institutional framework	African region, Australia, Bolivia, Canada, European Union, Japan, Norway, United States
Settlement of disputes	African region, Australia, Bolivia, Canada, Cuba, European Union, Japan, Norway, United States
Amendments	African region, Australia, Cuba, European Union, Norway
Final clauses	Australia, European Union, Malaysia, Norway
Objectives	African region, Cuba, European Union, Japan, Malaysia, Norway, Switzerland
Scope	African region, Canada, European Union, Japan, Norway, Switzerland
Jurisdictional scope	Cuba, European Union
AIA criteria	Canada, European Union
Notification procedure	African region, Japan, Norway
Identification and classification	Malaysia
Centres of origin and of genetic diversity	Malaysia
Considerations for risk assessment and risk management	Cuba, European Union, Japan, Switzerland
Mechanisms for risk assessment	African region, Malaysia, Norway
Mechanisms for risk management	Norway
Emergency procedures	African region, Japan, Malaysia, Norway
Minimum national standards	Norway
Designation of competent national authorities and national focal points	African region, Cuba, European Union, Japan, Malaysia, Norway, Switzerland
Capacity-building	African region, Bolivia, Canada, Cuba, European Union, Malaysia, Norway
Scientific and technical cooperation	Cuba, Malaysia,
Transboundary movement	Cuba
Transport and packaging	African region, Malaysia, Norway, Switzerland
Contained use	Cuba
International register	Cuba
Illegal traffic	African region
Public awareness	African region, Bolivia, Canada, Cuba, Malaysia, Norway
Information and prior informed consent	Cuba
Clearing house	African region, Canada, Switzerland
Technical information network	Malaysia
Mechanisms for bilateral agreements	Japan
Liability and compensation	African region, Bolivia, Canada, Cuba, European Union, Japan, Malaysia
Consultations on liability	Norway
Monitoring and compliance	African region, Canada, Cuba, European Union, Malaysia, Norway
Reports	Cuba
Financial issues	African region, Cuba, European Union, Japan, Malaysia, Norway
Socio-economic considerations	African region, Bolivia, Canada, European Union, Japan, Malaysia
Ethical considerations	Malaysia

### III. TEXT OF THE PROTOCOL

---

Relationship with the Convention	Cuba
Conference of the Parties	Cuba
Secretariat	Cuba
Review and adaptation	Japan, Norway
Adoption and amendment of annexes	Australia, Cuba
Signature	African region, Cuba
Ratification, acceptance or approval	Cuba
Accession	African region, Cuba
Right to vote	African region, Cuba
Entry into force	African region, Australia, Cuba
Reservations and declarations	African region, Cuba
Withdrawal	African region, Cuba
Depositary	African region, Cuba
Authentic texts	African region, Cuba
Annex: Information required in order to obtain AIA	African region, Cuba
Annex: Risk assessment parameters	African region, Norway
Annex: Risk management	African region
Other	Myanmar

Sources: documents UNEP/CBD/BSWG/2/2; UNEP/CBD/BSWG/2/Inf.6; UNEP/CBD/BSWG/2/Inf.7; and UNEP/CBD/BSWG/2/Inf.8.

## B: Governments that submitted proposals to BSWG-3

3: AIA	African region, Australia, Belarus, Brazil, Colombia, Cuba, European Community, India, Japan, Madagascar, Malaysia, Mexico, Norway, Peru, South African region, Sri Lanka, Switzerland, United States
4: Notification procedure for AIA	African region, Australia, Belarus, Brazil, Canada, Colombia, Cuba, European Community, India, Japan, Madagascar, Malaysia, Norway, Peru, South African region, Sri Lanka, Switzerland, United States
5: Decision procedure for AIA	African region, Australia, Belarus, Brazil, Colombia, India, Madagascar, Malaysia, Mexico, Norway, Peru, South African region, Sri Lanka, Switzerland, United States
6: Response to AIA notification	Australia, Belarus, Brazil, Canada, Colombia, European Community [check], Japan, Madagascar, Malaysia, Norway, South African region, Sri Lanka, Switzerland, United States
7: Notification of transit	Australia, Brazil, Malaysia, Mexico, Norway, Peru
8: Review of decisions under AIA	African region, Australia, Brazil, Malaysia, Peru, South African region, Sri Lanka
9: Simplified procedure	African region, European Community, India, Japan, Norway, South African region
10: Subsequent imports	Australia, Brazil, European Community, Mexico, Norway, Peru, Switzerland
11: Confidential information	Australia, Brazil, Colombia, European Community, Madagascar, Mexico, Norway, Sri Lanka, United States
12: Bilateral and regional agreements	African region, Australia, European Community, Switzerland, United States
13: Risk assessment	African region, Australia, Belarus, Canada, Colombia, Cuba, India, Madagascar, Malaysia, Norway, Sri Lanka, Switzerland
14: Risk management	African region, Australia, Belarus, Canada, Colombia, Cuba, India, Madagascar, Malaysia, Norway, Sri Lanka, Switzerland
15: Minimum national standards	African region, Canada, Mexico, Norway, Peru
16: International transboundary movements	Australia, Belarus, Brazil, European Community, Malaysia, Mexico, Norway, Peru, Sri Lanka, Switzerland, United States
17: Emergency measures	African region, India, Malaysia, Peru
18: Handling, transport, packaging and labelling	African region, Australia/Brazil/Sri Lanka, Belarus, Colombia, Cuba, India, Japan, Malaysia, Mexico, Norway, Peru, Switzerland, United States
19: Competent national authority	African region, Australia, Belarus, Brazil, Colombia, Cuba, European Community, India, Japan, Madagascar, Malaysia, Mexico, Norway, Peru, South African region, Sri Lanka, Switzerland, United States
20: Information sharing/clearing house	African region, Australia, Belarus, Brazil, Canada, Colombia, Cuba, European Community, India, Japan, Madagascar, Malaysia, Mexico, Norway, Peru, South African region, Sri Lanka, Switzerland, United States
21: Capacity building	African region, Australia, Belarus, Brazil, Canada, Colombia, Cuba, European Community, India, Madagascar, Malaysia, Mexico, Norway, Peru, Sri Lanka, Switzerland, United States
22: Public awareness/public participation	African region, Australia, Belarus, Brazil, Canada, Cuba, India, Japan, Malaysia, Mexico, Norway, Peru, Sri Lanka, Switzerland
Annex I: Information required in order to obtain AIA	African region, Australia, Brazil, Canada, Colombia, Cuba, India, Norway, Peru, South African region, Sri Lanka, Switzerland, United States
Annex II: Risk assessment parameters	African region, Australia, Belarus, Brazil, India, Malaysia, Norway, Peru, Sri Lanka
Annex III: Risk management schemes	African region, India, Norway
Annex IV: Information to be provided to the Secretariat under information sharing/clearing house	African region, Australia, Belarus, Brazil, Canada, Colombia, European Community, Japan, Madagascar, Norway, Peru, Sri Lanka
Socio-economic considerations	African region, Cameroon, Japan, Malaysia, South African region, Sri Lanka
Liability and compensation	African region, Brazil, Japan, Malaysia, Mexico, Norway, St. Kitts and Nevis, South African region

The Secretariat also submitted recommendations<sup>825</sup> on:

- Financial issues
- Institutional framework
- Jurisdictional scope
- Relationship with other international conventions
- Settlement of disputes
- Review
- Final clauses

Sources: UNEP/CBD/BSWG/3/3; UNEP/CBD/BSWG/3/3/Add.1; UNEP/CBD/BSWG/3/3/Add.3; and UNEP/CBD/BSWG/3/4

---

<sup>825</sup> (UNEP/CBD/BSWG/3/4)

## C: Governments that submitted proposals to BSWG-4

Title	Australia
Preamble	United States
Article 1- Principles/Objectives	African region, Argentina, Bolivia, Chile, Colombia, Guinea, Japan, Malaysia, South African region, Switzerland, United States
Article 1 bis. General Obligations	African region, Chile, Ethiopia, Guinea, India, Japan, South African region, Switzerland, United States
Article 2. Use of terms	Colombia, United States
Article 3. Advance Informed Agreement	Colombia
Article 4. Notification Procedure for AIA	Colombia
Article 5. Response to AIA Notification	Colombia, United States
Article 6. Decision Procedure for AIA	Colombia
Article 7. Review of Decision under AIA	
Article 8. Notification of Transit	Colombia
Article 9. Simplified Procedure	Australia
Article 10. Subsequent Imports	United States
Article 11- Bilateral & Regional Agreements	Colombia, United States
Article 12- Risk Assessment	Colombia
Article 13- Risk Management	Colombia
Article 14- Minimum National Standards	
Article 15- Unintentional Transboundary Movements	Colombia, United States
Article 16- Emergency Measures	Colombia
Article 17- Handling Transport Packaging and Labelling	Colombia, United States
Article 18- Competent Authority/Focal Point	Colombia
Article 19- Information Sharing/Biosafety Clearing House	Australia, Colombia, United States
Article 20- Confidential Information	Australia, Colombia, United States
Article 21- Capacity Building	Colombia
Article 22. Public Awareness / Public Participation	Colombia
Article 23. Non Parties	African region, Argentina, Bolivia, Chile, Ethiopia, India, Japan, Malaysia, Niger, South African region, Switzerland, United States
Article 24. Non Discrimination	Argentina, Australia, Bolivia, Chile, Japan, Malaysia, Switzerland, United States
Article 25. Illegal Traffic	African region, Bolivia, Chile, Colombia, European Community, Guinea, Japan, Malaysia, Niger, South African region, Switzerland
Article 26. Socio-Economic Considerations	African region, Bolivia, Chile, Colombia, Ethiopia, Guinea, Japan, Malaysia, Niger, South African region, Switzerland
Article 27. Liability and Compensation	African region, Bolivia, Chile, Colombia, India, Japan, Malaysia, Norway, South African region, Switzerland
Article 28. Financial Mechanism and Resources	Colombia
Article 29. Conference of the Parties	United States
Article 30. Subsidiary Bodies and Mechanisms	
Article 31. Secretariat	
Article 32. Jurisdictional Scope	
Article 33. Relationship with the Convention	
Article 34. Relationship with other International Conventions	

### III. TEXT OF THE PROTOCOL

---

Article 35. Monitoring and Compliance		
Article 36. Assessment and Review of Procedures/Annexes	United States	
Article 37. Signature		
Article 38. Ratification, Acceptance, or Approval		
Article 39. Accession		
Article 40. Entry into Force	United States	
Article 41. Reservations		
Article 42. Withdrawals	United States	
Article 43. Authentic Texts		
Annexes		
I. Information required in order to obtain Advance Informed Agreement	Colombia, United States	
II. Risk assessment parameters	Norway, United States	
III. Risk management schemes	United States	
IV. Function of focal points/competent authorities	United States	
V. Information to be provided to the Secretariat under information sharing/clearing house		United States
New annex: Contained use	Norway	

Sources: UNEP/CBD/BSWG/4/2 and UNEP/CBD/BSWG/4/3

**D: Governments that submitted proposals to BSWG-5**

General comments	Ecuador, Mexico, Panama, Switzerland, Uruguay, Vanuatu
Title	New Zealand
Preamble	Ecuador, European Community, Georgia, Mexico, New Zealand, Panama, Peru, Thailand
Article 1. Objectives	Ecuador, European Community, Georgia, New Zealand, Slovenia, Thailand, Uruguay, Venezuela
Article 1 bis. General Obligations	Ecuador, Georgia, Kenya, Mexico, New Zealand, Peru, Slovenia, Thailand, Uruguay, Venezuela
Article 2. Use of Terms	Ecuador, Georgia, Japan, Mexico, New Zealand, Panama, Peru, Slovenia, Thailand, United States, Uruguay, Venezuela
Article 3 A. The Scope of the Protocol	Ecuador, Georgia, Kenya, New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 3 B. The Application of the AIA Procedure	Ecuador, Georgia, Kenya, New Zealand, Norway, Peru, Slovenia, Thailand, Uruguay, Venezuela
Article 4. Notification [Procedure][for AIA]	Ecuador, New Zealand, Peru, Thailand, Venezuela, United States
Article 5. Response to [AIA] Notification	Ecuador, Georgia, New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 6. Decision Procedure for AIA	Ecuador, Georgia, Kenya, New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 7. Review of Decisions [Under AIA]	Ecuador, Georgia, New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 8. Notification of Transit	Ecuador, Georgia, New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 9. Simplified Procedure	Ecuador, Georgia, New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 10. Subsequent Imports	Ecuador, Georgia, New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 11. [International Cooperation] Multilateral, Bilateral and Regional Agreements [other than the Protocol]	Australia, Ecuador, Georgia, Japan, New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 12. Risk Assessment	Australia, Ecuador, Georgia, Japan, Kenya, Mexico, New Zealand, Norway, Peru, Slovenia, Thailand, Venezuela
Article 13. Risk Management	Australia, Ecuador, Georgia, New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 14. Minimum National Standards	Ecuador, Georgia, Kenya, New Zealand, Peru, Slovenia, Thailand, Venezuela
Merger of Article 15 and Article 16. Unintentional Transboundary Movements and Emergency Measures	Ecuador, Georgia, New Zealand, Peru, Slovenia, Thailand, United States, Venezuela
Article 17. Handling, Transport, Packaging and Labelling	Ecuador, Georgia, Kenya, New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 18. Competent National Authority/ National Focal Point	Ecuador, Georgia, New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 19. Information Sharing/ Biosafety Clearing-House/[Biosafety Database]	Ecuador, Georgia, Kenya, New Zealand, Peru, Slovenia, Thailand, Uruguay, Venezuela
Article 20. Confidential Information	Ecuador, Georgia, New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 21. Capacity-Building	Ecuador, Georgia, New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 22. Public Awareness/Public Participation	Ecuador, Georgia, New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 23. Non-Parties	Ecuador, Georgia, Japan, New Zealand, Peru, Slovenia, Thailand, Uruguay, Venezuela
Article 24. Non-Discrimination	Ecuador, Georgia, Mexico, New Zealand, Peru, Slovenia, Thailand, Uruguay, Venezuela
Article 25. Illegal Traffic	Ecuador, Georgia, Kenya, New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 26. Socio-Economic Considerations	Ecuador, Georgia, Haiti, Kenya, New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 27. Liability and Compensation	Ecuador, Georgia, Haiti, Kenya, New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 28. Financial Mechanism and Resources	Ecuador, Georgia, New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 29. Conference of the Parties	Georgia, Peru, Slovenia, Thailand, Venezuela
Article 30. Subsidiary Bodies and Mechanisms	Georgia, Peru, Slovenia, Thailand, United States, Venezuela
Article 31. Secretariat	Georgia, Peru, Slovenia, Thailand, Venezuela
Article 32. Jurisdictional Scope	Georgia, New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 33. Relationship with the Convention	New Zealand, Peru, Slovenia, Thailand, Venezuela

### III. TEXT OF THE PROTOCOL

---

Article 34. Relationship with other International Agreements	Ecuador, Georgia, New Zealand, Peru, Slovenia, Thailand, Uruguay, Venezuela
Article 35. Monitoring and Reporting	European Community, Georgia, New Zealand, Peru, Slovenia, Thailand, Venezuela
[Article 35 bis. Compliance]	Ecuador, Georgia, Haiti, Kenya, New Zealand, Peru, Slovenia, Thailand, Venezuela
[Article 36. Assessment and Review of this Protocol]	Ecuador, Georgia, New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 37. Signature	Peru, Slovenia, Thailand, Venezuela
Article 38. Ratification, Acceptance, or Approval	New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 39. Accession	New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 40. Entry into Force	Georgia, New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 41. Reservations	Ecuador, Georgia, New Zealand, Peru, Slovenia, Thailand, Venezuela
Article 42. Withdrawal	Georgia, Peru, Slovenia, Thailand, Venezuela
Article 43. Authentic Texts	New Zealand, Peru, Thailand, Venezuela
Annexes	
I. Information Required in Notification for Advance Informed Agreement	New Zealand, Norway, Peru, Slovenia, Thailand
II. Risk Assessment	Australia, New Zealand, Norway, Peru, Slovenia, Thailand
III. List of Annexes to the draft Protocol	European Community, Thailand
Response to Aide Mémoire from Co-Chairs of CGs 1 and 2	European Community

Sources: UNEP/CBD/BSWG/5/2; UNEP/CBD/BSWG/5/Inf.2; and UNEP/CBD/BSWG/5/Inf.2/Add.1



**E: Governments that submitted proposals to BSWG-6**

Article 1 Objectives	Slovenia
Article 3 Use of Terms	Slovenia
Article 5 Application of AIA procedure	Slovenia
Article 11 Simplified procedure	Slovenia
Article 18 Handling, Transport, Packaging and Labelling	Slovenia
Article 28 Liability and Redress	Slovenia
Settlement of Disputes	Chile

Sources: UNEP/CBD/BSWG/6/Inf.3

The Secretariat also re-circulated previous submissions (see UNEP/CBD/BSWG/6/Inf.2).

## APPENDIX V: LIST OF DOCUMENTS

### Report of Panel IV (UNEP):

UNEP/Bio.Div./Panels/Inf. 4 Consideration of the need for and modalities of a protocol setting out appropriate procedures including, in particular, advance informed agreement in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity

### COP-1 (Nassau, November 1994)

#### Pre-session document:

UNEP/CBD/COP/1/3 Report of the Intergovernmental Committee on the Convention on Biological Diversity on the Work of its First Session (paragraph 1(c), paragraph 18, Annex II-Report of working Group I)

UNEP/CBD/COP/1/4 Report of the Intergovernmental Committee on the Convention on Biological Diversity on the Work of its Second Session (Item 4.2.2, paragraphs 222-232)

#### Report

UNEP/CBD/COP/1/17 Report of the First Meeting of the Conference of the Parties to the Convention on Biological Diversity (contains decision I/9-Medium term programme of work of the Conference of the Parties, paragraphs 3-8)

### COP-2 (Jakarta, November 1995)

#### Pre-session document:

UNEP/CBD/COP/2/7 Report of the Open-Ended Ad Hoc Group of Experts on Biosafety (Madrid, July 1995) also contains (Annex IV) Report of the Panel of Experts on Biosafety (Cairo, May 1995)

#### Report:

UNEP/CBD/COP/2/19 Report of the Second Meeting of the Conference of the Parties to the Convention on Biological Diversity (contains decision II/5 Consideration of the need for and modalities of a protocol for the safe transfer, handling and use of living modified organisms)

### BSWG-1 (Aarhus, July 1996)

#### Pre-session documents:

UNEP/CBD/BSWG/1/1 Draft Provisional Agenda

UNEP/CBD/BSWG/1/1/Add.1 Draft Annotated Provisional Agenda

UNEP/CBD/BSWG/1/2 Terms of reference of the Open-ended Ad Hoc Working Group on Biosafety

UNEP/CBD/BSWG/1/3 Elaboration of the terms of reference of the Open-ended Ad Hoc Working Group on Biosafety

#### Report:

UNEP/CBD/BSWG/1/4 (UNEP/CBD/COP/2/7) Report of the First Meeting of the Open ended Ad Hoc Working Group on Biosafety

### BSWG-2 (Montreal, May 1997)

#### Pre-session documents:

UNEP/CBD/BSWG/2/1 Draft Provisional Agenda

UNEP/CBD/BSWG/2/1/Add.1 Annotations to the Provisional Agenda

UNEP/CBD/BSWG/2/2 Compilation of views of Governments on the contents of the future protocol (18 March 1997)

UNEP/CBD/BSWG/2/3 Background document on existing international agreements related to Biosafety

UNEP/CBD/BSWG/2/4 Potential socio-economic effects of biotechnology: a bibliography

UNEP/CBD/BSWG/2/5 Glossary of terms relevant to a biosafety protocol: results of a preliminary survey

UNEP/CBD/BSWG/2/Inf.1 Information for participants

UNEP/CBD/BSWG/2/Inf.2 Individual Government submissions on the contents of the future Protocol

UNEP/CBD/BSWG/2/Inf.3 Report of the First Meeting

UNEP/CBD/BSWG/2/Inf.4 Enabling the safe use of biotechnology

UNEP/CBD/BSWG/2/Inf.5 UNEP international technical guidelines for safety in biotechnology

UNEP/CBD/BSWG/2/Inf.6 Views of Cuba (6 May 1997)

UNEP/CBD/BSWG/2/Inf.7 Views of Malaysia (6 May 1997)

UNEP/CBD/BSWG/2/Inf.8 Views of Myanmar (6 May 1997)

UNEP/CBD/BSWG/2/Inf.9 List of participants

**Report:**

UNEP/CBD/BSWG/2/6 Report of the Second Meeting of the Open-ended Ad Hoc Working Group on Biosafety

**BSWG-3** (Montreal, October 1997)

**Pre-session documents:**

UNEP/CBD/BSWG/3/1 Draft Provisional Agenda  
 UNEP/CBD/BSWG/3/1/Add.1 Annotated Provisional Agenda  
 UNEP/CBD/BSWG/3/2 Chairman's review of items addressed by country submission at BSWG/2  
 UNEP/CBD/BSWG/3/3 Compilation of government submissions of draft text on selected items  
 UNEP/CBD/BSWG/3/3/Add.1 Advance informed agreement  
 UNEP/CBD/BSWG/3/3/Add.2 Submissions on socio-economic considerations and liability and compensation  
 UNEP/CBD/BSWG/3/3/Add.3 List of country submissions by Articles.  
 UNEP/CBD/BSWG/3/4 Compilation of draft text prepared by the Secretariat on selected items  
 UNEP/CBD/BSWG/3/5 Government submissions  
 UNEP/CBD/BSWG/3/Inf.1 Compilation of definitions and terms relevant to a biosafety protocol (revision of UNEP/CBD/BSWG/2/5)  
 UNEP/CBD/BSWG/3/Inf.1/Add.1 Definitions from the submissions of Malaysia  
 UNEP/CBD/BSWG/3/Inf.2 Background document on existing international agreements related to Biosafety  
 UNEP/CBD/BSWG/3/Inf.3 Study on existing international information sharing systems  
 UNEP/CBD/BSWG/3/Inf.4 Chairman's Draft Content of Text of Items (Article 11, Arts. 15-22)

**Report:**

UNEP/CBD/BSWG/3/6 Report of the Third Meeting of the Open-ended Ad Hoc Working Group on Biosafety

**BSWG-4** (Montreal, February 1998)

**Pre-session documents:**

UNEP/CBD/BSWG/4/1 Draft Provisional Agenda  
 UNEP/CBD/BSWG/4/1/Add.1 Annotated Provisional Agenda  
 UNEP/CBD/BSWG/4/2 Compilation of Government Submissions of Draft Text on Selected Items:

Articles 1, 1 bis and 23–27

UNEP/CBD/BSWG/4/3 Compilation of Government Submissions of Draft Text on Items other than Articles 1, 1 bis and 23–27

UNEP/CBD/BSWG/4/Inf.1 Chairman's Note on Articles 3–10 and 12–14

UNEP/CBD/BSWG/4/Inf.1/Add.1 Chairman's Note on Article 11

UNEP/CBD/BSWG/4/Inf.2 Chairman's Note on Articles 1, 1 bis and 15–27

UNEP/CBD/BSWG/4/Inf.3 Preamble

UNEP/CBD/BSWG/4/Inf.4 Implementation Mechanisms for Information Sharing

UNEP/CBD/BSWG/4/Inf.5 The Consolidated Text from the third meeting

UNEP/CBD/BSWG/4/Inf.6 List of participants

UNEP/CBD/BSWG/4/Inf.8 Chairman's Note on Articles 28–43

**Report:**

UNEP/CBD/BSWG/4/4 Report of the Fourth Meeting of the Open-ended Ad Hoc Working Group on Biosafety

**BSWG-5** (Montreal, August 1998)

**Pre-session documents:**

UNEP/CBD/BSWG/5/1 Draft Provisional Agenda  
 UNEP/CBD/BSWG/5/1/Add.1 Annotated Provisional Agenda  
 UNEP/CBD/BSWG/5/2 Compilation of New Government Submissions of Draft Text (Structured by Article)  
 UNEP/CBD/BSWG/5/Inf.1 Revised Consolidated Text of the Draft Articles  
 UNEP/CBD/BSWG/5/Inf.2 Government Submissions  
 UNEP/CBD/BSWG/5/Inf.2/Add.1 Georgia – Comments on the Revised Consolidated Text  
 UNEP/CBD/BSWG/5/Inf.3 Information Note on 'Products Thereof'  
 UNEP/CBD/BSWG/5/Inf.4 Submission from the Government of Vietnam

**Report:**

UNEP/CBD/BSWG/5/3 Report of the Fifth Meeting of the Open-ended Ad Hoc Working Group on Biosafety

## **BSWG-6** (Cartagena, February 1999)

### **Pre-session documents:**

UNEP/CBD/BSWG/6/1 Draft Provisional Agenda  
UNEP/CBD/BSWG/6/1/Add.1 Annotated Provisional Agenda  
UNEP/CBD/BSWG/6/2 Draft Negotiating Text  
UNEP/CBD/BSWG/6/2/Rev.1 Draft Negotiating Text  
UNEP/CBD/BSWG/6/3 Clusters Analysis  
UNEP/CBD/BSWG/6/4 Preparation of the Draft Negotiating Text of the Protocol on Biosafety  
UNEP/CBD/BSWG/6/5 Development of a Legally Binding Instrument  
UNEP/CBD/BSWG/6/6 Report: Meeting of the Extended Bureau (21–22 October 1998)  
UNEP/CBD/BSWG/6/7 Transshipment  
UNEP/CBD/BSWG/6/8 Overview and Annotated Draft Negotiating Text of the Protocol on Biosafety  
UNEP/CBD/BSWG/6/Inf.1 Compilation of New Government Submissions of Draft Text (structured by Article) [same as UNEP/CBD/BSWG/5/2]  
UNEP/CBD/BSWG/6/Inf.2 Government Submissions on the Preamble and Annexes (submitted prior to BSWG5)  
UNEP/CBD/BSWG/6/Inf.3 Proposition of the Government of Chile: Settlement of Disputes  
UNEP/CBD/BSWG/6/Inf.4 Resolutions on Biodiversity and the Environment (ACP-EU Joint Assembly, 24 Sept. 1998, Brussels, Belgium)  
UNEP/CBD/BSWG/6/Inf.5 Comments by the United Nations Economic and Social Council's Committee of Experts on the Transport of Dangerous Goods on the Draft Protocol on Biosafety  
UNEP/CBD/BSWG/6/Inf.6 Remarks submitted by Slovenia  
UNEP/CBD/BSWG/6/Inf.7 Remarks submitted by the Office International des Épizooties  
UNEP/CBD/BSWG/6/Inf.8 Note by the Co-Chairs of Contact Group I: Programme of Work  
UNEP/CBD/BSWG/6/Inf.9 Note from the Co-Chairs of Contact Group II to the Extended Bureau

### **Report:**

UNEP/CBD/ExCOP/1/2 Report of the Sixth Meeting of the Open-ended Ad Hoc Working Group on Biosafety

## **ExCOP-1** (Cartagena, February 1999, and resumed session in Montreal, January 2000)

### **Pre-session documents:**

UNEP/CBD/ExCOP/1/1 Draft Provisional Agenda  
UNEP/CBD/ExCOP/1/1/Rev.1 Draft Provisional Agenda  
UNEP/CBD/ExCOP/1/1/Rev.2 Provisional revised agenda  
UNEP/CBD/ExCOP/1/1/Add.1 Annotated Provisional Agenda  
UNEP/CBD/ExCOP/1/1/Add.1/Rev.1 Annotated provisional agenda  
UNEP/CBD/ExCOP/1/1/Add.1/Rev.2 Annotations to the provisional revised agenda  
UNEP/CBD/ExCOP/1/4 Proposed interim arrangements for the Intergovernmental Committee of the Protocol on Biosafety  
UNEP/CBD/ExCOP/1/INF.1 Documentation containing draft text of the Protocol for the resumed session: explanatory note by the Secretariat  
UNEP/CBD/ExCOP/1/INF.2 Aide-mémoire: Chairman's summary of informal consultations held in Montreal on 1 July 1999  
UNEP/CBD/ExCOP/1/INF.3 Chairman's summary of informal consultations held in Vienna from 15 to 19 September 1999

### **Report:**

UNEP/CBD/ExCOP/1/L.2/Rev.1 Draft report of the ExCOP (first session)  
UNEP/CBD/ExCOP/1/3 Report of the Extraordinary Meeting of the Conference of the Parties for the adoption of the Protocol Biosafety  
UNEP/CBD/ExCOP/1/3 CORR. 1 Report of the Extraordinary Meeting of the Conference of the Parties for the adoption of the Protocol Biosafety (Corrigendum)

## **APPENDIX VI: TERMS OF REFERENCE FOR THE OPEN-ENDED AD HOC WORKING GROUP (FROM COP DECISION II/5)**

1. The Open-ended Ad Hoc Working Group should be composed of representatives, including experts, nominated by Governments and regional economic integration organisations.
2. The Open-ended Ad hoc Working Group shall, in accordance with operative paragraph 1 of the present decision:
  - (a) elaborate, as a priority, the modalities and elements of a protocol based on appropriate elements from Sections I, II and III, paragraph 18 (a), of Annex I of the report of the Open-ended Ad Hoc Group of Experts on Biosafety;
  - (b) consider the inclusion of the elements from Section III, paragraph 18 (b), and other elements, as appropriate;
3. The development of the draft protocol shall, as a priority:
  - (a) elaborate the key concepts and terms that are to be addressed in the process;
 

include consideration of the form and scope of advance informed agreement procedures;

identify relevant categories of LMOs resulting from modern biotechnology.
4. The protocol will have to reflect that its effective functioning requires that Parties establish or maintain national measures, but the absence of such national measures should not prejudice the development, implementation and scope of the protocol.
5. The protocol will take into account the principles enshrined in the Rio Declaration on Environment and Development and, in particular, the precautionary approach contained in Principle 15 and will:
  - (a) not exceed the scope of the Convention;
  - (b) not override or duplicate any other international legal instrument in this area;
  - (c) provide for a review mechanism;
  - (d) be efficient and effective and seek to minimise unnecessary negative impacts on biotechnology research and development and not to hinder unduly access to and transfer of technology.
6. The provisions of the Convention will apply to the protocol.
7. The process will take into full account the gaps in the existing legal framework identified through analysis of existing national and international legislation.
8. The process shall be guided by the need for all Parties to cooperate in good faith and to participate fully, with a view to the largest possible number of Parties to the Convention ratifying the protocol.
9. The process will be carried out on the basis of the best available scientific knowledge and experience, as well as other relevant information.
10. The process of developing a protocol should be conducted as a matter of urgency by an open-ended ad hoc group, which will report on progress to each subsequent meeting of the Conference of the Parties. The Open-ended Ad Hoc Working Group should endeavour to complete its work in 1998.

