

**Biosafety Protocol Final Draft of Biosafety Protocol Approved at
Montreal Meeting On Biological Diversity Convention, Released Jan.
29, 2000 (Final Text)**

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1 **Biosafety Protocol Final Draft of Biosafety Protocol**
2 **Approved at Montreal Meeting On Biological Diversity**
3 **Convention, Released Jan. 29, 2000 (Final Text)**

4 The Parties to this Protocol, Being Parties to the Convention on Bio-
5 logical Diversity, hereinafter referred to as “the Convention”,

6 Recalling Article 19, paragraphs 3 and 4, and Articles 8(g) and 17
7 of the Convention,

8 Recalling also decision II/5 of 17 November 1995 of the Conference
9 of the Parties to the

10 Convention to develop a Protocol on biosafety, specifically focus-
11 ing on transboundary movement of any living modified organism
12 resulting from modern biotechnology that may have adverse effect
13 on the conservation and sustainable use of biological diversity, set-
14 ting out for consideration, in particular, appropriate procedures for
15 advance informed agreement,

16 Reaffirming the precautionary approach contained in Principle 15
17 of the Rio Declaration on Environment and Development,

18 Aware of the rapid expansion of modern biotechnology and the
19 growing public concern over its potential adverse effects on biolog-
20 ical diversity, taking also into account risks to human health,

21 Recognizing that modern biotechnology has great potential for hu-
22 man well-being if developed and used with adequate safety mea-
23 sures for the environment and human health,

24 Recognizing also the crucial importance to humankind of centres
25 of origin and centres of genetic diversity,

26 Taking into account the limited capabilities of many countries, par-
27 ticularly developing countries, to cope with the nature and scale
28 of known and potential risks associated with living modified organ-
29 isms,

30 Recognizing that trade environment agreements should be 11
31 mutually supportive with a view to achieving sustainable develop-
32 ment,

33 Emphasizing that this Protocol shall not be interpreted as implying 12
34 a change in the rights and obligations of a Party under any existing
35 international agreements,

36 Understanding that the above recital is not intended to subordinate 13
37 this Protocol to other international agreements,

38 Have agreed as follows: 14

39 **Article 1 - Objective** 15

40 In accordance with the precautionary approach contained in Prin- 16
41 ciple 15 of the Rio Declaration on Environment and Development,
42 the objective of this Protocol to contribute to ensuring an adequate
43 level of protection in the field of the safe transfer, handling and
44 use of living modified organisms resulting from modern biotechnol-
45 ogy that may have adverse effects on the conservation and sus-
46 tainable use of biological diversity, taking also into account risks to
47 human health, and specifically focusing on transboundary move-
48 ments.

49 **Article 2 - General Provisions** 17

50 1. Each Party shall take necessary and appropriate legal, adminis- 18
51 trative and other measures to implement its obligations under this
52 Protocol.

53 2. The Parties shall ensure that the development, handling, trans- 19
54 port, use, transfer and release of any living modified organisms are
55 undertaken in a manner that prevents or reduces the risks to biolog-
56 ical diversity, taking also into account risks to human health.

20 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
contentional 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.

21 4. Nothing in this Protocol shall be interpreted as restricting the
right of a Party to take action that is more protective of the conser-
vation 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 its other obligations under international law.

22 5. The Parties are encouraged to take into account, as appropri-
ate, available expertise, instruments and work undertaken in in-
ternational fora with competence in the area of risks to human
health.

23 **Article 3 - Use of Terms**

24 For the purposes of this Protocol:

25 (a) "Conference of the Parties" means the Conference of the Par-
ties to the Convention.

26 (b) "Contained use" means any operation, undertaken within a fa-
cility, 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.

27 (c) "Export" means intentional transboundary movement from one
Party to another Party.

(d) "Exporter" means any legal or natural person, under the juris- 28
diction to the Party of export, who arranges for a living modified
organism to be exported.

(e) "Import" means intentional transboundary movement into one 29
Party from another Party.

(f) "Importer" means any legal or natural person, under the juris- 30
diction of the Party of import, who arranges for a living modified
organism to be imported.

(g) "Living modified organism" means any living organism that pos- 31
sesses a novel combination of genetic material obtained through
the use of modern biotechnology.

(h) "Living organism" means any biological entity capable of trans- 32
ferring or replicating genetic material, including sterile organisms,
viruses and viroids.

(i) "Modern biotechnology" means the application of: (i) In vitro nu- 33
cleic acid techniques, including recombinant deoxyribonucleic acid
(DNA) and direct injection of nucleic acid into cells or organelles, or
(ii) Fusion of cells beyond the taxonomic family that overcome nat-
ural physiological reproductive or recombination barriers and that
are not techniques used in traditional breeding and selection.

(j) "Regional economic integration organization" means an organi- 34
zation constituted by sovereign States of a given region, to which
its member States have transferred competence in respect of mat-
ters governed by this Protocol and which has been duly authorized,
in accordance with its internal procedures, to sign, ratify, accept,
approve or accede to it.

(k) "Transboundary movement" means the movement of a living 35
modified organism from one Party to another Party, save that for the
purposes of Article 17 and 24 transboundary movement extends to
movement between Parties and non-Parties.

36 **Article 4 - Scope**

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

38 **Article 5 - Pharmaceuticals**

39 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

40 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 organisa-
tions.

41 **Article 6 - Transit And Contained Use**

42 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
of this Protocol, regarding the transit through its territory of a spe-
cific 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.

43 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 7 - Application Of The Advance Informed Agreement
Procedure**

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

46 2. "Intentional introduction into the environment" in paragraph 1
above does not refer to living modified organisms intended for di-
rect use as food or feed, or for processing.

47 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.

48 4. The advance informed agreement procedure shall not apply
to the intentional transboundary movement of living modified or-
ganisms 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.

Article 8 - Notification

49 1. The Party of export shall notify, or require the exporter to en-
sure notification in writing to, the competent national authority of
50 the Party of import prior to the intentional transboundary movement

of a living modified organism that falls within the scope of the Article 7, paragraph 1. The notification shall contain, at a minimum, the information specified in Annex I.

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

52 **Article 9 - Acknowledgement Of Receipt Of Notification**

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

54 2. The acknowledgement shall state:

55 (a) The date of receipt of the notification;

56 (b) Whether the notification, prima facie, contains the information referred to in Article 8;

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

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

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

60 **Article 10 - Decision Procedure**

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

62 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 63

(b) After no less than ninety days without a subsequent written consent. 64

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: 65

(a) Approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism; 66

(b) Prohibiting the import; 67

(c) Requesting additional relevant information in accordance with its domestic regulatory framework or Annexes I and II; 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 68

(d) Informing the notifier that the period specified in this paragraph is extended by a defined period of time. 69

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. 70

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. 71

6. Lack of scientific certainty due to insufficient relevant scientific information and acknowledge 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, 72

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 minimize such potential adverse effects.

73 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.

74 **Article 11 - Procedure for Living Modified Organisms Intended for Direct use as Food or Feed, or for Processing**

75 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 III. The Party shall provide a written copy of the information 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.

76 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.

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

78 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 79 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 of a Party with an economy in transition may, in the absence of the domestic regulatory framework 80 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 II; 81 and

(b) A decision made within a predictable timeframe, not exceeding 82 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. 83

8. Lack of scientific certainty due to insufficient relevant scientific 84 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 minimize such potential adverse effects.

85 9. A Party may indicate its needs for financial and technical assistance and capacity-building with respect to living modified organisms for direct use as food or feed, or for processing. Parties shall cooperate to meet these needs in accordance with Article 22 and 28. 93

86 **Article 12 - Review Of Decisions**

87 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 organisms referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.

88 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:

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

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

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

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

Article 13 - Simplified Procedure

1. A Party of import may, provide 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: 94

(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: such notifications may apply to subsequent similar movements to the same Party; and 95

(b) Imports of living modified organisms to it to be exempted from the advance informed agreement procedure. 96

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 in the information specified in Annex I. 97

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. 99

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 entry into force of this Protocol. 100

3. The provisions of this Protocol shall not affect intentional trans- 101

boundary movements that take place pursuant to such agreements and arrangements as between the parties to those agreements or arrangements.

102 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.

103 **Article 15 - Risk Assessment**

104 1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex II and taking into account recognized 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.

105 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 assessments.

106 3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires.

107 **Article 16 - Risk Management**

108 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 risk to human health, within the territory of the Party of import. 109

3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring risk assessments to be carried out prior to the first release of a living organism. 110

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. 111

5. Parties shall cooperate with a view to: 112

(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 113

(b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits. 114

115 **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 organizations, when it knows of an occurrence under its jurisdiction resulting in a release that leads or may lead to an unintentional transboundary movements of a living modified organism that is likely to have significant 116

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.

117 2. Each Party shall, no later than the date of entry into force of the 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.

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

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

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

121 (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;

122 (d) Any other relevant information; and

123 (e) A point of contact for further information.

124 4. In order to minimize any significant adverse effect on 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.

Article 18 - Handling, Transport, Packaging And Identification

125

126 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 the Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant intentional rules and standards.

127 2. Each Party shall take measures to require that at a minimum documentation accompanying;

128 (a) Living modified organism that are intended for direct use as food or feed, or for processing, clearly identifies them as "may contain" living modified organisms and as 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 entry into force of this Protocol.

129 (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

130 (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.

131 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.

132 **Article 19 - Competent National Authorities And National Focal Points**

133 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 authorized to act on its behalf with respect to those functions. A Party may designate a single entity to fulfill the functions of both focal point and competent national authority.

134 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. 135

Article 20 - Information-Sharing and the Biosafety Clearing-House 136

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: 137

(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and 138

(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 or origin and centres of genetic diversity. 139

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 also 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. 140

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: 141

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

143 (b) Any bilateral, regional and multilateral agreements and arrange-
ments;

144 (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 appropri-
ate, relevant information regarding products thereof, namely, pro-
cessed materials that are of living modified organism origin, con-
taining detectable novel combinations of replicable genetic material
obtained through the use of modern biotechnology;

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

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

147 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 at its first meeting, and kept under review thereafter.

148 **Article 21 - Confidential Information**

149 1. The Party of import shall permit the notifier to identify informa-
tion 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. Jus-
tification shall be given in such cases upon request.

150 2. The Party of import shall consult the notifier if it decides that

information identified by the notifier as confidential does not qual-
ify 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 deci-
sion prior to disclosure.

3. Each Party shall protect confidential information received under 151
this Protocol, including any confidential information received in the
context of the advance informed agreement procedure of the Proto-
col. 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 in-
formation in connection with domestically produced living modified
organisms.

4. The Party of import shall not use such information for a commer- 152
cial purpose, except with the written consent of the notifier.

5. If a notifier withdraws or has withdrawn a notification, the Party 153
of import shall respect the confidentiality of commercial and indus-
trial 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 informa- 154
tion shall not be considered confidential:

(a) The name and address of the notifier; 155

(b) A general description of the living modified organism or organ- 156
isms;

(c) A summary of the risk assessment of the effects on the conserva- 157
tion and sustainable use of biological diversity, taking also into
account risks to human health; and

(d) Any methods and plans for emergency response. 158

159 **Article 22 - Capacity-Building**

160 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 organizations and, as appropriate, through facilitating private sector involvement.

161 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 knowhow 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.

162 **Article 23 - Public Awareness And Participation**

163 1. The Parties shall:

164 (a) Promote and facilitate public awareness, education and participating 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.

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.

Article 25 - Illegal Transboundary Movements

1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing 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.

173 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.

174 3. Each Party shall make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements pertaining to it.

175 **Article 26 - Socio-Economic Considerations**

176 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.

177 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.

178 **Article 27 - Liability And Redress**

179 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.

Article 28 - Financial Mechanism and Resources

180 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. 181

182 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.

183 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.

184 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.

185 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.

186 6. The developed country Parties may also provide, and the devel-

oping 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 multilateral, bilateral and regional channels.

187 **Article 29 - Conference of the Parties Serving as the Meeting
of the Parties**

188 1. The Conference of the Parties shall serve as the meeting of the
Parties to this Protocol.

189 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.

190 3. When the Conference of the Parties serves as the meeting of the
Parties to this Protocol, any member of the bureau of 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.

191 4. The Conference of the Parties serving as the meeting of the Par-
ties to this Protocol shall keep under regular review the implemen-
tation of this Protocol and shall make, within its mandate, the de-
cisions necessary to promote its effective implementation. It shall
perform the functions assigned to it by this Protocol and shall:

192 (a) Make recommendations on any matters necessary for the im-
plementation of this Protocol;

193 (b) Establish such subsidiary bodies as are deemed necessary for
the implementation of this Protocol;

194 (c) Seek and utilize, where appropriate, the services and coop-

eration of, and information provided by, competent international
organizations and intergovernmental and non-governmental bod-
ies;

(d) Establish the form and the intervals for transmitting the informa- 195
tion to be submitted in accordance with Article 33 of this Protocol
and consider such information as well as reports submitted by any
subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol 196
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 imple- 197
mentation of this Protocol.

5. The rules of procedure of the Conference of the Parties and fi- 198
nancial rules of the Convention shall be applied, mutatis mutadis,
under this Protocol, except as may be otherwise decided by con-
sensus 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 199
the meeting of the Parties to this Protocol shall be convened by
the Secretariat in conjunction with the first meeting of the Confer-
ence of the Parties that is scheduled after the date of the entry into
force of this Protocol. Subsequent ordinary meetings of the Confer-
ence 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 Confer-
ence of the Parties serving as the meeting of the Parties to this
Protocol.

7. Extraordinary meetings of the Conference of the Parties serving 200
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.

201 8. The United Nations, its specialized 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 Convention 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.

202 **Article 30 - Subsidiary Bodies**

203 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, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.

204 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.

205 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.

Article 31 - Secretariat

207 1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.

208 2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, mutatis mutandis, to this Protocol.

209 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.

Article 32 - Relationship With The Convention

211 Except as otherwise provided in this Protocol, the provisions of the Convention relating to its Protocols shall apply to this Protocol.

Article 33 - Monitoring And Reporting

213 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.

214 **Article 34 - Compliance**

215 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.

216 **Article 35 - Assessment And Review**

217 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.

218 **Article 36 - Signature**

219 This Protocol shall be open for signature at Nairobi by States and regional economic integration organizations from 15 to 26 May 2000, and at United Nations Headquarters in New York from 5 June 2000 to 4 June 2001.

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 organizations that are Parties to the Convention. 221

2. This Protocol shall enter into force a State or regional economic integration organization 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 organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Protocol enters into force for that State or regional economic integration organization, whichever shall be the later. 222

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization. 223

Article 38 - Reservations

No reservations may be made to this Protocol. 224 225

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 Depository. 226 227

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depository, or on such later date as may be specified in the notification of the withdrawal. 228

229 **Article 40 - Authentic Texts**

230 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.

231 **Annex I - Information Required In Notifications Under Articles
8, 10 And 13**

232 (a) Name, address and contact details of the exporter.

233 (b) Name, address and contact details of the importer.

234 (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.

235 (d) Intended date or dates of the transboundary movement, if
known.

236 (e) Taxonomic status, common name, point of collection or acqui-
sition, and characteristics of recipient organism or parental organ-
isms related to biosafety.

237 (f) Centres of origin and centers of genetic diversity, if known, of
the recipient organism and/or the parental organisms and a de-
scription of the habitats where the organisms may persist or prolif-
erate.

238 (g) Taxonomic status, common name, point of collection or acquisi-
tion, and characteristics of the donor organism or organisms related
to biosafety.

239 (h) Descripton of the nucleic acid or the modification introduced,
the technique used, and the resulting characteristics of the living
modified organism.

240 (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 trans- 241
ferred.

(k) A previous and existing risk assessment report consistent with 242
Annex II.

(l) Suggested methods for safe handling, storage, transport and 243
use, including packaging, labelling, documentation, disposal and
contingency procedures, where appropriate.

(m) Regulatory status of the living modified organism within the 244
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 or-
ganism 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 245
other States regarding the living modified organism to be trans-
ferred.

(o) A declaration that the above-mentioned information is factually 246
correct.

Annex II - Risk Assessment Under Article 15 247

Objective 248

1. The objective of risk assessment, under this Protocol, is to iden- 249
tify and evaluate the potential adverse effects of living modified or-
ganisms on the conservation and sustainable use of biological di-

versity in the likely potential receiving environment, taking also into account risks to human health.

250 Use of risk assessment

251 2. Risk assessment is, inter alia, used by competent authorities to make informed decisions regarding living modified organisms. General principles

252 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 organizations.

253 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.

254 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.

255 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.

256 Methodology

257 7. The process of risk assessment may on the one hand give rise

to a need for further 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 realized, 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 realized;

(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 realized;

(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

266 9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

267 (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 origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

268 (b) Donor organism or organisms. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organism;

269 (c) Vector. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

270 (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;

271 (e) Living modified organism. Identify 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;

272 (f) Detection and identification of the living modified organism. Suggested detection and identification methods and their specificity, sensitivity and reliability;

273 (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

274 (h) Receiving environment. Information on the location, geograph-

265 ical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.

Annex III - Information Required For Living Modified Organisms Intended For Direct Use As Food Or Feed, Or For Processing Under Article 11

275 (a) The name and contact details of the applicant for a decision for domestic use 276

(b) The name and contact details of the authority responsible for the decision. 277

(c) Name and identify of the living modified organism. 278

(d) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism. 279

(e) Any unique identification of the living modified organism. 280

(f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety. 281

(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. 282

(h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety. 283

(i) Approved uses of the living modified organism. 284

(j) A risk assessment report consistent with Annex II of this Protocol. (k) Suggested methods for safe handling, storage, transport 285

and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

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