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GROUP ON BIOSAFETY
Sixth meeting
Cartagena, Colombia, 14-19 February 1999

Note from the Secretariat

Note by the Co-Chairs of Contact Group I: Programme of Work

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Note by the co chairs Contact Group 1: Programme of work.
(February 14, 1999)

INTRODUCTION.

The programme of work of CG1 consists of:
finalising the discussions on the "technical" working definitions of 'LMO', 'living organism', and 'modern biotechnology' presented in document BSWG/6/2;
- finalising the annexes presented document BSWG/6/2;
- developing any additional definition (e.g. 'release' and/or 'contained use'), annex and/or other item SWG1 of SWG2 may request from CG1.

Given that the results of the work of CG1 have to be translated and discussed by SWG1 at the latest on Thursday, February 18, the work of CG1 has to be finalised by Wednesday evening, February 17.

With a view to facilitating the work of CG1 in the limited time available, the co-chairs of CG1 have prepared this note. This note is based on the results of discussions with the other co-chairs, as well as on the results of informal meetings with NGOs and industry and on the many informal comments and suggestions received from participants of CG1, for which the co-chairs wish to express their appreciation.

Given the time available, the co-chairs of CG1 propose the following provisional agenda:

	morning	afternoon	evening
Sunday, February 14			definitions
Monday, February 15	definitions	annexes	annexes
Tuesday, February 16	annexes	annexes	definitions
Wednesday, February 17	definitions	annexes	annexes

Depending on developments during the negotiation process, this agenda may have to be revised.

As to the output of CG1, the extended Bureau wishes that in any case the technical working definitions and drafts for annexes presented in document BSWG/6/2 will be finalised before Wednesday evening.

The following text contains proposals for:
- the working definitions of 'LMO' and 'modern biotechnology',
- the terms identified by SWG1 as possibly requiring further development (i.e. 'contained use' and 'release'),
- the annexes.

TECHNICAL WORKING DEFINITIONS CONTAINED IN DOCUMENT BSWG/6/2

LMO

a. Working definition in BSWG/6/2
"LMO means any living organism containing a novel combination of genetic material obtained through the use of modern biotechnology."

b. Comments:
- the term used in the Jakarta decision is "LMOs resulting from modern biotechnology"; to avoid duplication, it is proposed to include this in the definition and not to refer to "resulting from modern biotechnology" throughout the text;
- depending on the interpretation of 'containing', the current definition could be explained such that when a person or an animal consumes an LMO apple, that person or animal would become an LMO because, be it only for a while, that person or animal would contain novel genetic combinations in its digestive tract; to avoid this, it is proposed that it is made clear in the definitions that the novel combinations have to be contained in the genetic material of the organism;
- to avoid misunderstandings, it should be made clear that the definition of LMO does not cover human beings.

c. Proposed definition:

"LMOs resulting from modern biotechnology means any living organism, other than humans, of which the genetic material contains a novel combination obtained through the use of modern biotechnology"

Living organism

No changes proposed.

Modern biotechnology

a. working definition in BSWG/6/2:
"Modern biotechnology means the application of *in vitro* nucleic acid techniques [and cell fusion techniques] that overcome natural physiological reproductive or recombination barriers, other than traditional breeding and selection."

b. comments:
- At BSWG5, there was long and intense the debate in CG1 whether, and to what extent, cell fusion techniques have to be included in the definition of 'modern biotechnology'. On the one hand arguments were presented stating that cell fusion techniques applied to date are an extension of traditional breeding techniques. On the other hand, arguments were presented stating that in the foreseeable future, cell fusion techniques might be used to produce organisms that could not be produced by traditional breeding techniques, e.g. fusion of plant cells beyond the botanical family. To assure that this protocol does not have to be changed in the near future to cover new applications, it is proposed to include cell fusion techniques

used to produce organisms that could not be produced by traditional breeding techniques;
- since footnotes will not be allowed in the final text, the footnote to the definition should best be reflected in the definition;
- possible confusion as to which the wording "other than" refers should be taken away.

c. proposed definition:

"Modern biotechnology means the application of *in vitro* nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, and fusion of eukaryotic cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and which are not techniques used in traditional breeding and selection."

OTHER TERMS IDENTIFIED BY SWG1.

Depending on the development of the negotiations, SWG1 may request that definitions are developed such as 'contained use' and/or 'release into the environment'.

It is proposed that until such request, the definitions of 'contained use' and 'release' of the UNEP International Technical Guidelines for safety in Biotechnology are used as working definitions.

Once the SWG1 has decided which term(s) it wishes to be defined, CG1 will discuss these definitions further.

Contained use:

"Contained use means any operation involving organisms which are controlled by physical barriers or a combination of physical and/or chemical and/or biological barriers which limit their contact with, or their impacts on, the potentially receiving environment, which includes humans."

Release into the environment:

"Release into the environment means any use of organisms that is not a contained use".

ANNEXES

Based on the annexes contained in document BSWG/6/2, the co chairs submit the proposals contained in Annexes I and II hereafter for consideration in CG1.

In these proposals, the following format is used paragraph by paragraph, the existing text is presented in normal text, followed by a proposal in italics, in which bold printing indicates elements (such as "products thereof") which are dependent on the outcome of the negotiations in the relevant SWG's.

Annex I - INFORMATION REQUIRED IN NOTIFICATION FOR ADVANCE INFORMED AGREEMENT

(a) Name and identity [and domestic classification of biosafety level, if any, in the exporting country] of the LMO(s) [or products thereof].

(a) Name and identity of the LMO(s) ***[or products thereof].***

(b) Name, address and contact details of the [exporter] [applicant].

(b) Name, address and contact details of the exporter

(c) Name, address and contact details of the [importer] [receiving company/institution/individual].

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

(d) Intended date[(s)] of the transboundary movement, if known.

(d) Intended date(s) of the transboundary movement, if known.

[(e) Taxonomic status, common name, point of collection or acquisition and characteristics of recipient or parental organism(s) related to biosafety.

(f) Centre(s) of origin/genetic diversity, if known, of the recipient and/or parental organism(s). [A description of the habitats where the organism may persist or proliferate.]

(g) Taxonomic status, common name, point of collection or acquisition and characteristics of donor organism(s) related to biosafety.

(h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the LMO [or products thereof].

(i) Intended use of the LMO [or products thereof].

(j) Quantity or volume of LMOs [or products thereof] to be transferred.]

(k) [A [known and available] risk assessment report carried out in accordance with Annex II of the Protocol].

(k) A risk assessment report including the relevant information in accordance with Annex II.

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

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

(m) Regulatory status of the LMO [or product thereof] in question within the exporting state (e.g. whether it is prohibited in the state of export, whether there are other restrictions, or whether it has been approved for general release). If the LMO [or product thereof] is banned in the state of export, the reason(s) for such a ban.

*(m) Regulatory status of the LMO **[or product thereof]** in question within the exporting state (e.g. whether it is prohibited in the state of export, whether there are other restrictions, or whether it has been approved for general release). If the LMO **[or product thereof]** is banned in the state of export, the reason(s) for such a ban.*

(n) [The result of any notification to other Governments by the [exporter] [applicant] regarding the LMO [or product thereof] and the purpose thereof.]

*(n) The result of any notification to other Governments by the exporter regarding the LMO **[or product thereof]** and the purpose thereof.*

[Declaration that the above-mentioned information is factually correct.]

[the responsibility for the accuracy of the information is covered in the provisions of the Protocol].

Annex II - RISK ASSESSMENT*

Objective

The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects [of the transboundary movement] [, handling and use] of LMOs [or products thereof] on the conservation and sustainable use of biological diversity in the [potential] receiving environment [, taking also into account the risk to human health] [and socio-economic considerations].

The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of LMOs **[or products thereof]** on the conservation and sustainable use of biological diversity in the potential receiving environment, taking also into account the risk to human health **[and socio-economic considerations]**.

Use of risk assessment

The results of risk assessment are used by, inter alia, competent authorities with respect to informed decision making on transboundary movement [, handling and use] of LMOs [or products thereof].

Risk assessment under this Protocol is, inter alia, used by competent authorities to make informed decisions regarding LMOs ***[or products thereof].***

General principles

[The guiding principle of risk assessment is the precautionary approach]. [Based on the precautionary approach,] risk assessment should be carried out in a scientifically sound and transparent manner.

Based on the precautionary principle, 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.

Risks associated with the transboundary movement [,handling and use] of the LMO [or products thereof] should be considered in the context of the risks posed by using the non-modified recipients or parental organisms in the [potential] receiving environment.

Risks associated with LMOs ***[or products thereof]*** *should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the potential receiving environment.*

Risk assessment should be carried out on a case-by-case basis. This means that the required information may vary from case to case, depending on the LMOs concerned, their [intended] use and the [potential] receiving environment.

[removed to Points to consider]

Lack of scientific knowledge or consensus may contribute to uncertainty regarding the level of risk. [This should not be interpreted as indicating [a risk,] an absence of risk, or an acceptable risk].

Lack of scientific knowledge or consensus may contribute to uncertainty regarding the level of risk.

This should not be interpreted as indicating a risk, an absence of risk, nor as an acceptable risk.

Methodology

To fulfil its objective, risk assessment entails, as appropriate, the following steps:

1. an identification of any characteristics associated with the [novel [base sequences of the genetic material] [compositions] [combinations]] of the LMO [or products thereof] that may have adverse effects on biological diversity in the [potential] receiving environment[, taking also into account the risk to human health][and socio-economic considerations];

*1. an identification of any characteristics of the LMO **[or products thereof]** associated with the novel genetic combinations that may lead to adverse effects on biological diversity in the potential receiving environment, taking also into account the risk to human health **[and socio-economic considerations]**;*

2. an evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the receiving environment to the LMO [or products thereof];

*2. an evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the potential receiving environment to the LMO **[or products thereof];***

3. an evaluation of the consequences should these adverse effects being realized;

4. an estimation of the overall risk posed by the LMO [or products thereof] based on the evaluation of the likelihood and consequences of the identified adverse effects; and

4. an estimation of the overall risk posed by the LMO [or products thereof] based on the evaluation of the likelihood and consequences of the identified adverse effects being realised; and

5. a recommendation as to whether or not the risks are acceptable or manageable [, including, where necessary, identification of strategies to manage these risks and minimise the likelihood of adverse consequences].

5. a recommendation as to whether or not the risks are acceptable or manageable , including, where necessary, identification of strategies to manage these risks.

[Risk assessment can take into account expert scientific and technical advice [and guidelines developed by relevant international organizations]].

[removed to general principles]

Points to consider

Risk assessment should be carried out on a case-by-case basis. This means that the required information may vary from case to case, depending on the LMOs concerned, their [intended] use and the [potential] receiving environment.

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 LMOs concerned, their intended use and the potential receiving environment.

Risk assessment may require more specific information about individual topics, which may be identified and requested during the assessment process, while other topics may not be relevant in some instances.

Risk assessment may require further information about specific topics, which may be identified and requested during the assessment process, while information on other topics may not be relevant in some instances.

Depending on the case, risk assessment therefore takes into account the relevant technical and scientific details regarding:

[Characteristics of recipient or parental organism(s)]
The biological, physiological, genetic and ecological characteristics of the recipient/parental organism [related to biosafety] [necessary to conduct the risk assessment].

Characteristics of recipient or parental organism(s), including information on taxonomic status, common name, origin, centre(s) of origin/genetic diversity, if known, and a description of the habitat where the organism may persist or proliferate

[Characteristics of donor organism(s)]

The characteristics of the donor organism(s) [necessary to conduct the risk assessment] [including, in particular, pathogenicity and toxicity].

Characteristics of donor organism(s), including taxonomic status, common name, origin, and - in particular - pathogenicity and toxicity.

[Characteristics of the vector]

The characteristics of the vector, including its sources and host ranges.

Characteristics of the vector, including its origin and host range.

- [Characteristics of the inserts]

Characteristics of the nucleic acid or modification introduced.

Characteristics of the nucleic acid and/or modification introduced, including the techniques used.

[Characteristics of the LMO [or products thereof]]

The known differences between the LMO [or products thereof] and its recipient/parental organism [or products thereof] in any biological, physiological, genetic or ecological characteristic.

*Characteristics of the LMO [or products thereof], identifying the differences between the relevant characteristics of the LMO **[or products thereof]** and its recipient/parental organism **[or products thereof]**;*

[Information relating to intended use]

Information relating to the [intended] use of the LMO [or products thereof], including new or changed use compared to the unmodified recipient or parental organism.

*Information relating to the intended use of the LMO **[or products thereof]**, including quantity or volume of LMOs **[or products thereof]**;*

[Receiving environment]

Information on the location, geographical, climatic and ecological characteristics of the [potential] receiving environment.

information on the location, geographical, climatic and ecological characteristics, including relevant information on biodiversity and centres of origin, of the potential receiving environment.

[Resuscitated organism]

[Characteristics of resuscitated organism(s) and gene(s) and fossil DNA sequences.]

[Safety considerations for human and animal health]

[Information on the impact of the LMO on human and animal health]

[Socio -economic considerations]

[Socio-economic considerations] [Information on the potential impacts on the socio-economical patterns of the importing country, especially on traditional practices and national programs on sustainable agriculture.]

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* further discussion will be given to the question whether "should" will be replaced by "shall".