ARTICLE X : SOME BUILDING BLOCKS

by Graham S. Pearson

Introduction

1. The Ad Hoc Group (AHG) of the States Parties to the Biological and Toxin Weapons Convention (BTWC) has the consideration of measures to implement Article X of the Convention as an element of its mandate agreed by the Special Conference in September 1994. The AHG has considered how to address this at each of its substantive meetings with a Friend of the Chair, initially Ambassador Jorge Berguno of Chile and subsequently, Carlos Duarte of Brazil carrying out this responsibility. As progress is being made on the development of the rolling text for the Protocol to strengthen the Convention, it is timely to consider how the implementation of Article X might contribute to the strengthening of the effectiveness of the Convention.

2. This Briefing Paper considers some of the developments that have occurred nationally, regionally and internationally in respect of the use of bacteriological (biological) agents and toxins for peaceful purposes. It has become apparent that there is increasing awareness world-wide because of public health and environmental concerns of the need to control the handling, use, storage and transfer of such biological agents. This paper examines some of the current controls and regulations for biological agents and the international initiatives that are ongoing to strengthen biosafety around the world. These are seen as building blocks which might be considered from a point of view of strengthening the BTWC as well as contributing to the implementation of Article X although care will need to be taken in the Protocol for the AHG to avoid unnecessary duplication with other international activities. The challenging goal is to identify how these other national, regional and international activities can be utilised to contribute to the strengthening of the BTWC.

Ad Hoc Group

3. The Final Report of the Special Conference of States Parties to the BTWC in September 1994[1] stated that:

> *"the Conference, determined to strengthen the effectiveness and improve the implementation of the Convention and recognizing that effective verification could reinforce the Convention, decides to establish an Ad Hoc Group, open to all States Parties. The objective of this Ad Hoc Group shall be to consider appropriate measures, including possible verification measures, and draft proposals to strengthen the Convention, to be included, as appropriate, in a legally binding instrument, to be submitted for the consideration of the States Parties."*

It went on to say that *"In this context, the Ad Hoc Group shall, inter alia, consider:*

> ....

[1]United Nations, *Special Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, Final Report, BWC/SPCONF/1 Geneva, 19–30 September 1994.

- Specific measures designed to ensure effective and full implementation of Article X, which also avoid any restrictions incompatible with the obligations undertaken under the Convention, noting that the provisions of the Convention should not be used to impose restrictions and/or limitations on the transfer for purposes consistent with the objectives and the provisions of the Convention of scientific knowledge, technology, equipment and materials."

4. Article X of the BTWC[2] states that:

> *"(1) The States Parties to this Convention undertake to facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials, and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes. Parties to the Convention in a position to do so shall also cooperate in contributing individually or together with other States or international organisations to the further development and application of scientific discoveries in the field of bacteriology (biology) for the prevention of disease, or for other peaceful purposes.*
>
> *(2) This Convention shall be implemented in a manner designed to avoid hampering the economic or technological development of States Parties to the Convention or international cooperation in the field of peaceful bacteriological (biological) activities, including the international exchange of bacteriological (biological) agents and toxins and equipment for the processing, use or production of bacteriological (biological) agents and toxins for peaceful purposes in accordance with the provisions of the Convention."*

The Ad Hoc Group in its meetings has addressed Article X measures and a number of working papers have been provided on the subject of such measures. It is clear that in considering possible measures to strengthen the Convention and improve its effectiveness, it is necessary to do so in the light of the ongoing developments nationally, regionally and internationally in regard to the use of bacteriological (biological) agents for peaceful purposes. This Briefing Paper aims to contribute to this process.

The Use of Biological Agents for Peaceful Purposes

5. The past two decades has seen immense developments in the peaceful uses of biological agents in the field of biotechnology. The Final Declaration of the Fourth Review Conference[3] held on 25 November to 6 December 1996 in its statement of Article X declared that

> *"The Conference once more emphasizes the increasing importance of the provisions of Article X, especially in the light of recent scientific and technological developments in the field of biotechnology, bacteriological (biological) agents and toxins for peaceful applications, which have vastly increased the potential for cooperation*

[2]United Nations General Assembly, *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction,* Annex to Resolution 2826 (XXVI), 16 December 1991, General Assembly, Official Records: Twenty-Sixth Session, Supplement No. 29 (A/8429), New York, 1972.

[3]United Nations, Fourth Review Conference of the Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, *Final Declaration*, Final Report, BWC/CONF.IV/9, Geneva, 1996.

between States to help, promote economic and social development, and scientific and technological progress, particularly in the developing countries, in conformity with their interests, needs and priorities."

However, the past two decades have also seen an increased international awareness of the potential dangers to public health and to the environment. This was typified by the United Nations Conference on Environment and Development[4] held in Rio de Janeiro on 3 to 14 June 1992 which declared a series of Principles and agreed Agenda 21 which addressed the pressing problems of today and also aims at preparing the world for the challenges of the next century. It reflected a global consensus and political commitment at the highest level on development and environment cooperation.

6. **Agenda 21** includes one Chapter (16) entitled "Environmentally Sound Management of Biotechnology" -- throughout Agenda 21 the term "environmentally sound" means "environmentally safe and sound", in particular when applied to the terms "technology/technologies". Chapter 16 states[5] that

"Biotechnology is the integration of the new techniques emerging from modern biotechnology with the well-established approaches of traditional biotechnology. Biotechnology, an emerging knowledge-intensive field, is a set of enabling techniques for bringing about specific man-made changes in deoxyribonucleic acid (DNA), or genetic material, in plants, animals and microbial systems, leading to useful products and technologies....Nevertheless, it promises to make a significant contribution in enabling the development of, for example, better health care, enhanced food security through sustainable agricultural practices, improved supplies of potable water, ..."

Chapter 16 sets out programme areas *"to foster internationally agreed principles to be applied to ensure the environmentally sound management of biotechnology, to engender public trust and confidence, to promote the development of sustainable applications of biotechnology and to establish appropriate enabling mechanisms, especially within developing countries, through the following activities:*

(a) Improving the availability of food, feed and renewable raw materials;

(b) Improving human health;

(c) Enhancing protection of the environment

(d) Enhancing safety and developing international mechanisms for cooperation;

(e) Establishing enabling mechanisms for the development and the environmentally sound application of biotechnology."

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[4]United Nations, *Report of the United Nations Conference on Environment and Development,* Rio de Janeiro, 3- 14 June 1992, A/CONF.151/26, 12 August 1992. See also *Earth Summit '92,* The United Nations Conference on Environment and Development, Rio de Janeiro 1992, Regency Press, London, 1992.

[5]United Nations, *Report of the United Nations Conference on Environment and Development,* Rio de Janeiro, 3- 14 June 1992, A/CONF.151/26, Volume II, Page 111, 13 August 1992.

7. Separate sections of Chapter 16 address each of the above. Section D on "Enhancing Safety and Developing International Mechanisms for Cooperation" in its Basis for Action[6] states that:

> *There is a need for further development of internationally agreed principles on risk assessment and management of all aspects of biotechnology which should build upon those developed at the national level.* ***Only when adequate and transparent safety and border-control procedures are in place will the community at large be able to derive maximum benefit from, and be in a much better position to accept the potential benefits and risks of, biotechnology.*** *Several fundamental principles could underlie many of these safety procedures, including primary consideration of the organism, building on the principle of familiarity, applied in a flexible framework, taking into account national requirements and recognizing that the logical progression is to start with a step-by-step and case-by-case approach, but also recognising that experience has shown that in many instances a more comprehensive approach should be used, based on the experiences of the first period, leading, inter alia, to streamlining and categorizing; complimentary consideration of risk assessment and risk management; and classification into contained use or release to the environment.* [Emphasis added].

There is thus a highly relevant, from a BTWC point of view, emphasis on "adequate and transparent safety and border-control procedures".

8. The objectives of Section D are set out as follows:

> *The aim of this programme area is to ensure safety in biotechnology development, application, exchange and transfer through international agreement on principles to be applied on risk assessment and management, with particular reference to health and environmental considerations, including the widest possible public participation and taking account of ethical considerations.*

The activities to achieve this objective are detailed and include the following:

> *Governments... should:*
>
> > *(a) Make the existing safety procedures widely available by collecting the existing information and adapting it to the specific needs of different countries and regions;*
> >
> > *(b) Further develop, as necessary, the existing safety procedures to promote scientific development and categorization in the areas of risk assessment and risk management (i****nformation requirements;*** *databases; procedures for assessing risks and conditions of release;* ***establishment of safety conditions; monitoring and inspections,*** *taking account of ongoing national, regional and international initiatives and avoiding duplication wherever possible);*
> >
> > *(c) Compile, update and develop compatible safety procedures into a framework of internationally agreed principles as a basis for guidelines to be*

[6]United Nations, *Report of the United Nations Conference on Environment and Development,* Rio de Janeiro, 3- 14 June 1992, A/CONF.151/26, Volume II, Page 123, 13 August 1992.

applied on safety in biotechnology, including consideration of the need for and feasibility of an international agreement, and promote information exchange as a basis for further development, drawing on the work already undertaken by international or other expert bodies; ....[Emphasis added]

Again from the BTWC point of view, the references to information requirements, establishment of safety conditions and monitoring and inspections are relevant.

9. **The Convention on Biological Diversity** (CBD)[7] was opened for signature at the United Nations Conference on Environment and Development in Rio de Janeiro in June 1992 and entered into force in December 1993. By 16 November 1997, this Convention had been ratified by 171 countries[8]. The Objectives of this Convention are set out in Article I as being

"...the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding."

The terms "biotechnology" and "technology" are defined in Article II as follows:

"Biotechnology" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

"Technology" includes biotechnology.

10. Various Articles of the CBD address topics of relevance to the strengthening of the BTWC and to Article X of the BTWC. Two particular ones are Article 16 "Access to and Transfer of Technology" and Article 19 "Handling of Biotechnology and Distribution of its Benefits".

11. Article 16 "Access to and Transfer of Technology" states in its first paragraph that:

"1. Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment."

In subsequent paragraphs it goes to recognize the need to protect information that is the subject of patents or intellectual property rights by saying:

"2. Access to and transfer of technology...to developing countries shall be provided and/or facilitated under fair and most favourable terms.... In the case of technology

[7]United Nations, *Convention on Biological Diversity,* opened for signature at Rio de Janeiro 5 June 1992, UNEP/CBD/94/1, Geneva, November 1994. Also available as HMSO, Cm 2127, January 1993.

[8]Convention on Biological Diversity, Ratification Status, available at http://www.biodiv.org/conv/ratify.html

subject to patents and other international property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights...."

and that

"3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology, which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary,..."

The final paragraph of Article 16 states that:

"5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall co-operate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives."

12. Article 19 "Handling of Biotechnology and Distribution of its Benefits" addresses the distribution of the benefits of biotechnology and goes on in its third and fourth paragraphs to address safety and transfer aspects:

"3. The Parties shall consider the need for and the 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*** *which may have adverse effect on the conservation and sustainable use of biological diversity."*

"4. Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide ***any available information about the use and safety regulations required by that Contracting Party in handling such organisms****, as well as available information on the potential adverse impact of the specific organisms concerned to the Contracting party into which those organisms are to be introduced."* [Emphasis added]

13. The implementation of the CBD has been taken forward by Conferences of the Parties which were required in accordance with Article 23 to meet not less than one year after the entry into force of the Convention and to keep under review the implementation of the Convention.

14. The first Conference of the Parties to the CBD was held in Nassau, Bahamas from 28 November to 9 December 1994. It decided to establish an Open-ended Ad Hoc Group of Experts on Biosafety with a mandate

"(a) to consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of safe transfer, handling and use of any living modified organism resulting from

biotechnology that may have an adverse effect on the conservation and sustainable user of biological diversity; and

(b) to consider existing knowledge, experience and legislation in the field of biosafety, including the views of Parties, subregional, regional and international organizations, with a view to presenting a report for consideration at 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 the modalities of a protocol."

In addition, the Conference of the Parties also decided to establish a panel of 15 Government-nominated experts assisted by UNIDO, UNEP. FAO and WHO to prepare a background document for consideration by the Open-ended Ad Hoc Group of Experts. The panel met in Cairo from 1 to 5 May 1995 and produced a report[9] which noted the specific provision made for "Environmentally Sound Management of Biotechnology" in Chapter 16 of Agenda 21 remarking that:

> "The contribution that safety in biotechnology can make to the successful global development of the technology depends on the extent of international information exchange, cooperation, harmonization, and agreement, and on the extent to which countries are able to take advantage of mechanisms for safety."

The report went on to note that

> *"The development of new techniques of genetic modification in the early 1970s prompted a thorough discussion on safety in biotechnology which resulted in a number of national and international recommendations, guidelines and legislation. By the mid 1980s it was widely considered that recombinant DNA techniques were an extension of conventional genetic procedures and that* ***organisms produced by this technology present risks that can be the same in kind as those posed by any other organism.*** *It was also recognised that the potential benefits of biotechnology were increased because the new molecular techniques allowed a greater diversity of genes to be introduced into organisms. However, it was considered that it would be appropriate to develop the technology in a precautionary manner.*
>
> *Modern biotechnology has now been developed and applied for over 20 years under contained conditions and over eight years for applications in the environment. Given the rapid development of the use of this technology and taking into account the knowledge and experience gained so far, an international framework to provide for safety in biotechnology, as called for in Agenda 21, was now opportune."* [Emphasis added]

15. The panel reviewed existing international and regional guidelines/agreements on biosafety and identified needs for additional action in several areas such as the need for immediate action by countries which have not adopted specific regulations for biosafety or have not used existing legislation to promulgate regulations for biosafety. Furthermore, whilst some efforts art regional harmonization have been undertaken or are underway, such regional harmonization was not occurring on a global basis and the panel felt that such action

[9]Convention on Biological Diversity, *Report of the Open-Ended Ad Hoc Group of Experts on Biosafety*, UNEP/CBD/COP/2/7, 3 August 1995: Annex IV, Report of the Panel of Experts on Biosafety.

should be initiated in those regions where it has not yet begun. The panel drew several main conclusions which included the following:

> *"The Panel strongly believes that capacity building is essential to ensure adequate capacities to implement effectively biosafety regulations at the national level in a way which also promotes safe development in the field of biotechnology."*

and

> *"The Panel also strongly believes that immediate action is needed to excess existing biosafety frameworks including their ability to address the movement of LMOs [living modified organisms] across national boundaries and to address other related transboundary issues. The Panel finds that such issues are best addressed by an appropriate international framework."*

16. The panel report was considered by the Open-ended Ad Hoc Group of Experts on Biosafety which met in Madrid from 24 to 28 July 1995/ Its report[10] was considered by the second Conference[11] of the Parties to the CBD when they met in Jakarta on 6 to 17 November 1995 which agreed Decision II/5 stating that the Conference of the Parties

> *"1. Decides to seek solution to the above mentioned concerns* [about safety in biotechnology] *through a negotiation process to develop in the field of safe transfer, handling and use of living modified organisms, a protocol on biosafety, specifically focussing on transboundary movement, of any living modified organisms 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;*
>
> *2. Decides to establish an Open-ended Ad Hoc Working Group under the Conference of parties which shall operate in accordance with the terms of reference in the annex to this decision;"*

The annex states that the "Ad Hoc Working Group should endeavour to complete its work in 1998."

17. This decision also stressed the importance of the urgent finalisation of the United Nations Environmental Programme International Technical Guidelines on Safety on Biotechnology noting that *"guidelines on biosafety...may be used as an interim mechanism during the development of the protocol and to complement it after its completion, for the purposes of facilitating the development of national capacities to assess and manage risks, establish adequate information systems and develop expert human resources in biotechnology."*

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[10]Convention on Biological Diversity, *Report of the Open-Ended Ad Hoc Group of Experts on Biosafety,* UNEP/CBD/COP/2/7, 3 August 1995.

[11]Convention on Biological Diversity, *Report of the Second Meeting of the Conference of the Parties to the Convention on Biological Diversity,* Jakarta, 6 - 17 November 1995, UNEP/CBD/COP/2/19 dated 30 November 1995.

18. The Open-ended Ad Hoc Working Group met for the first time in Aarhus, Denmark from 22 to 26 July 1996 and reported[12] to the Third meeting of the Conference of the Parties to the CBD which met in Buenos Aires, Argentina on 4 - 15 November 1996. The Conference of the Parties in its decision III/20[13] affirmed its *"support for a two track approach through which the promotion of the application of the UNEP Technical Guidelines for Safety in Biotechnology can contribute to the development and implementation of a protocol on biosafety, without prejudicing the development and conclusion of such a protocol"* and decided that *"two meetings of the Open-ended Ad Hoc Working Group would be held in 1997 and that a sufficient number of meetings will be held in 1998 to allow the Working Group to complete its work in 1998."*

19. **Advance Informed Agreement/Biosafety Protocol.** Two meetings of the Open-ended Ad Hoc Working Group on Biosafety were held in 1997 both in Montreal, Canada. The first was on 12 to 16 May 1997[14] and the second on 13 to 17 October 1997[15] at which the draft protocol was further developed. In order to complete the work on the draft protocol by the end of 1998, three meetings are planned:

a. An eight day working meeting from 9 to 18 February 1998 in Montreal

b. A two-week meeting in the second half of July 1998

c. A one-week meeting at the beginning of December 1988 to be followed by a two-day (Monday-Tuesday) extraordinary meeting of the Conference of Parties

The consolidated text of the draft articles for the "Biosafety Protocol" is provided as an Annex to the Report of the Third Meeting; it comprises some 43 Articles together with Annexes. It is interesting to note the approach being adopted is different from using square brackets in that a number of Options are simply listed under each heading. Thus there are 5 Options listed for the Title of the protocol and for the Preamble, nine unanswered questions appear first and are followed by the text for three options. It has to be said that the square bracket approach is much easier to assimilate than that of complete alternative texts.

20. The language for the Objective of the Protocol in Article 1 is presented as 8 options; some of these emphasise that "the objective of this Protocol is to promote the safe transboundary movement of living modified organisms resulting from modern biotechnology" whilst others emphasise that "the objective of this Protocol is to ensure the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effect on the environment". Articles 3 to 10 all relate to the Advance Informed Agreement (AIA) procedure and its requirements for notification and decision. There is also an intention that the AIA procedure should be carried out in a transparent manner and Article 22 addresses "Public Awareness/Public Participation" although the 5 options listed range from "No provisions necessary" through to options in which "each Contracting Party shall

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[12]Convention on Biological Diversity, *Elaboration of a Protocol on Biosafety,* Progress Report, UNEP/CBD/COP/3/27, 16 September 1996.

[13]Convention on Biological Diversity, *Report of the Third Meeting of the Conference of the Parties to the Convention on Biological Diversity*, Buenos Aires, Argentina, 4 - 15 November 1996, UNEP/CBD/COP/3/38 dated 11 February 1997.

[14]Convention on Biological Diversity, Report of the Second Meeting of the Open-ended Working Group on Biosafety, UNEP/CBD/BSWG/2/6, 16 May 1997.

[15]Convention on Biological Diversity, Report of the Third Meeting of the Open-ended Working Group on Biosafety, UNEP/CBD/BSWG/3/6, 17 October 1997.

take appropriate measures to ensure to the extent practicable, that the public has appropriate access to information related to the implementation of this protocol, whilst respecting confidential commercial information" to an option which would "provide the public which is likely to be affected by any activity or product involving modified living organisms, an opportunity for public hearings in the process of approving the release, transfer or use, contained or otherwise, of such living modified organisms".

21. **UNEP International Technical Guidelines for Safety in Biotechnology.** A joint initiative taken by the UK and the Netherlands following the Rio summit in June 1992 has been to develop guidelines on safety in biotechnology. These guidelines were then taken forward by UNEP and developed into their International Guidelines. These are the second approach endorsed by the Committee of Parties to the CBD in parallel with the Biosafety Protocol; namely for the finalisation and application of the UNEP International Technical Guidelines for Safety in Biotechnology. This was promoted by the decision 18/36 on Biosafety made by the Governing Council of UNEP on 26 May 1995[16] which affirmed the

> *"desirability of the United Nations Environment Programme contributing to international efforts on biosafety while avoiding duplication with other international activities currently being undertaken by other organizations....*
>
> > *1. Welcomes the United Nations Environment Programme initiative to hold consultations on International Technical Guidelines for Safety in Biotechnology and Related Capacity-Building Requirements;*
> >
> > *2. Notes with appreciation that three regional expert consultations on International Technical Guidelines for Safety in Biotechnology and Related Capacity-Building Requirements have so far been held and that further regional consultations are planned;....*
> >
> > *4. Endorses and supports United Nations Environment Programme sponsorship of regional consultations on International Technical Guidelines for Safety in Biotechnology and Related Capacity-Building Requirements...."*

22. The International Guidelines were adopted by a meeting of the Global Consultation of Government-designated Experts held in Cairo, Egypt from 11 to 14 December 1995 and issued by UNEP[17]. The foreword to the International Guidelines by Elizabeth Dowdeswell, Executive Director of UNEP, emphasises the linkage between the application of the Guidelines and the capacity-building that is essential for their implementation as being both obvious and inevitable. It goes on to say that:

> *"Indeed, it is vital and urgent for countries and regions to acquire the various relevant capacities to implement the Guidelines. Neither these Guidelines or the biosafety protocol currently under development will in or of themselves ensure safety in biotechnology development, research and application. Consequently, the national and regional capacity-building programmes that are necessary for the effective implementation of these Guidelines should be formulated and given adequate*

[16]United Nations Environment Programme, *Proceedings of the Governing Council at its Eighteenth Session,* Nairobi, 15 - 26 May 1995, UNEP/GC. 18/40, 13 June 1995.

[17]United Nations Environment Programme, *UNEP International Technical Guidelines for Safety in Biotechnology*, UNEP Nairobi, Kenya.

technical and financial support on a priority basis. Founded on sound scientific principles, their implementation needs to be undertaken with technical competence, logical consistency and judicious urgency."

" UNEP has formulated such a programme as part of its 1996-1997 programme of work. It incorporates components and proposals for funding by, among others, the Global Environment facility (GEF), through which developing countries and countries with economies in transitions will receive the technical and financial support to develop and/or strengthen their national biosafety frameworks which will permit the effective implementation of these Guidelines and any future international agreement on biosafety within a harmonized regional and global context."

23. The Foreword goes on to outline essential elements of the role of the national biosafety frameworks:

"The development of the national biosafety frameworks called for in the Guidelines will entail technical and financial support to Governments and relevant in-country or regional entities. Such support is essential in order to:

** Establish or strengthen national authorities or national institutional biosafety mechanisms;*

** Review national legislative, administrative and policy measures on biosafety;....*

** Enhance public awareness of biotechnology risks... through initiatives involving the community at large, policy makers, legislators, administrators, the private sector and the biotechnology industry;"*

24. The Preface to the guidelines makes it clear that they have been developed on the basis of common elements and principles derived from relevant existing regional and international instruments and national regulations and guidelines. The Introduction sets the scene, using language that is closely similar to that in the report of the Open-ended Ad Hoc Group of Experts which met in Cairo from 1 to 5 May 1995 (see para 14 above), noting that:

"The development of new techniques of genetic modification in the early 1970s prompted a thorough discussion on safety in biotechnology which resulted in a number of national and international recommendations, guidelines and legislation. By the mid 1980s it was widely considered that recombinant DNA techniques were an extension of conventional genetic procedures and that ***organisms produced by this technology presented risks that were similar in kind to those posed by any other organism.*** *But, while it was also recognised that the potential benefits of biotechnology were greater because of the new molecular techniques which allowed a greater diversity of genes to be introduced into organisms, the relative lack of experience with such organisms nevertheless indicated that it would be appropriate to develop the technology in a precautionary and judicious manner.* [Emphasis added]

The Introduction states that "The Guidelines address the human health and environmental safety of all types of applications of biotechnology, from research and development to commercialization of biotechnological products containing or consisting of organisms with novel trait(s)."

25. The Guidelines comprise some six chapters and seven Annexes:

I. Introduction

II. General Principles and Considerations

III. Assessment and Management of Risks

IV. Providing for Safety: Mechanisms at National and Regional Level

V. Providing for Safety: Mechanisms at International Level using Information Supply and Exchange

VI. Capacity-Building

One Annex addresses "Possible Mechanisms for Providing Information to the Public".

26. Although it is clear that the Guidelines were prepared to focus primarily on living modified organisms, the General Principles and Considerations make it clear that the basis for safety in biotechnology rests on the characteristics of the basic organisms together with consideration of the newly introduced traits. Annex 3 of the International Guidelines is entitled "Risk Assessment: Examples of Points to Consider, as Appropriate" which makes it clear that:

> *The impacts to be considered include those on human health, agricultural production, other organisms and the quality of the environment.*

It goes on to outline the information required for a scientifically sound risk assessment which includes

> "INFORMATION RELATING TO THE ORGANISM WITH NOVEL TRAITS
>
> *Characteristics of the organism from which the organism with novel traits is derived:*
>
> The relevant biological, physiological and genetic and environmental characteristics of the recipient/parental/host organism include, as appropriate:
>
> * the name and identity of the organism
>
> * pathogenicity, toxicity and allergenicity (in the case of micro-organisms it should be noted that there are internationally accepted classification lists for human pathogens. Similar lists exist at national level for plant and animal pathogens);...
>
> INFORMATION RELATING TO THE INTENDED USE
>
> CHARACTERISTICS OF THE POTENTIAL RECEIVING ENVIRONMENT"

27. The Chapter on Mechanisms at National and Regional Level emphasises the importance of establishing, designating or strengthening "national and/or regional authorities/national institutional mechanisms for oversight and/or control of the use of organisms with novel

traits." It notes that "the authority or mechanism should have, or have access to, the relevant scientific and technical knowledge and experience." It says that:

> *"Effective oversight mechanisms require that: a risk assessment has been done; or the organism has been exempted from oversight on the basis of experience and knowledge; relevant users supply to the authority/national institutional mechanism all required relevant information or appropriate references; users record the outcome of relevant activities and inform the authority/national institutional mechanism of the outcome when required. In particular, they should provide relevant information if there is an unexpected or adverse effect on human health or environmental impact during, or as a result of, the notified use."*

It goes on to say that "Mechanisms for oversight and/or control can include prior notification to the authority/national institutional mechanism of contained use facilities and certain contained uses and releases of organisms with novel traits." If such prior notification is required, then "such notification may or may not require a positive decision from the authority/national institutional mechanism before the notified use can proceed." The Chapter then addresses public participation:

> *"As set out in Agenda 21 and relevant provisions of the Convention on Biological Diversity, authorities/national institutional mechanisms are responsible for* ***encouraging public participation by allowing access to information on which decisions are based****, whilst respecting confidential commercial information."* [Emphasis added]

28. The Chapter on Mechanisms at International Level focuses on information exchange and supply. It states that "Countries are encouraged to participate in the exchange of general information about national biosafety mechanisms...". It goes on to note that "Countries, organizations and companies will wish to be aware of which countries have adopted similar measures to those set down in these guidelines to facilitate the exchange of mutually acceptable data and assessments. This form of information exchange can be carried out through direct information exchange, as well as through the creation of an international register or database." The chapter then addresses the supply of information related to transboundary transfer of organisms with novel traits outlining the information to be provided and the concept of the advance informed agreement process.

29. The nineteenth meeting of the UNEP Governing Council in Nairobi, Kenya in January/February 1997 agreed Decision 19/16 on biosafety. This welcomed the adoption of the UNEP International Technical Guidelines for Safety in Biotechnology and also welcomed the decisions taken by the Conference of the Parties to the Convention on Biological Diversity by which the Conference affirmed its support for the two track approach through which the promotion of the application of the UNEP International Technical Guidelines for Safety in Biotechnology can contribute to the development and implementation of a protocol on biosafety. It urged:

> *"Governments to promote safety in biotechnology at the regional and global levels by contributing relevant information to the International Register on Biosafety of the United Nations Environment Programme and by using all available mechanisms, drawing attention to the International Register, to implement the international information exchange provisions of the UNEP International Technical Guidelines for*

Safety in Biotechnology, particularly with regard to the exchange of general information about national biosafety mechanisms..."

It then requested that the Executive Director of UNEP

...continue to promote the implementation of the UNEP International Technical Guidelines for Safety in Biotechnology , particularly in the developing countries, by carrying out such activities at the internatiuonal, subregional and regional levels developed in consultation with the involved parties and organizations.....

...explore with other United nations and international bodies the mutual sharing of information about organisms with novel traits that is contained in international databases and the rationalization of these databases, in order to avoid the duplication of sources of information and the need for multiple entry of data.

30. **Analysis.** It is thus apparent that the UNEP International Technical Guidelines for Safety in Biotechnology are being widely promoted and are seen as being complementary to the Biosafety Protocol which whilst particularly addressing advance informed agreement for transboundary transfers also includes Articles on Risk Assessment, Risk Management, Minimum National Standards and on Information Sharing/Biosafety Clearing House. Although all of this is aimed at micro-organisms with novel traits, the risks are all based primarily on the baseline micro-organism and how the novel traits amend the risks. Internationally, there is a move, certainly for micro-organisms with novel traits, towards information exchange and for information supply should such micro-organisms be transferred from one country to another. There is also clear encouragement for the provision of information to the public, whilst protecting commercial confidential information. All of this helps to build confidence nationally, regionally and internationally that such micro-organisms are being handled, used and transferred in safe ways for permitted purposes -- and in this way contributes to building confidence in compliance with the BTWC.

31. **Regional Safety in Biotechnology Meetings.** There has been reference above to UNEP Governing Council decisions which endorsed and supported United Nations Environment Programme sponsorship of regional consultations on International Technical Guidelines for Safety in Biotechnology and Related Capacity-Building Requirements. There have been a series of such Regional Consultations:

a. African Regional Conference for International Cooperation on Safety in Biotechnology, 11 - 14 October 1993, Harare, Zimbabwe;

b. Biodiversity and Harmonization of Biosafety of the Countries of the CORECA, 28 February - 3 March 1995, San Jose, Costa Rica;

c. Asia-Pacific Workshop on Safety in Biotechnology, 6 - 8 March 1995, Bangkok, Thailand;

d. Central and Eastern European Conference for Regional and International Cooperation on Safety in Biotechnology, 4 - 6 September 1995, Keszthely, Hungary;

e. Second Central and Eastern European Conference for Regional and International Cooperation on Safety in Biotechnology, 16 - 18 October 1996, Smolenice, Slovak Republic.

Most if not all of these have been organized with the support of the Netherlands Ministry of Housing, Spatial Planning and the Environment and several have been supported by the UK Department of the Environment and the Austrian Federal Ministry of the Environment, Youth and Family Affairs.

32. **African Regional Conference.** This Conference was attended by 50 participants from 11 African countries and 20 international experts who discussed how to ensure international cooperation on the safe application of biotechnology. The Conference was organised into four main sections:

1. General Introduction which set the overall scene

2. Existing Safety Mechanisms which included OECD, EEC and several national presentations

3. National and Regional Needs, Constraints and Priorities

4. National and Regional Implementation

The proceedings[18] of the Conference provide a useful overview of both the current state of the art in developed countries and in developing countries in Africa with papers on Zimbabwe, Kenya, South Africa, Uganda and Tanzania. Other papers address the OECD, the EEC, Latin-America and North America. It is clear that there is a common goal that is internationally seeking to improve the provisions for safety in biotechnology.

33. A useful summary is provided by the Conference Statement which stated that:

> *The aim of the Conference was to contribute to international cooperation on safety in biotechnology, with specific attention to national implementation, regional and international cooperation and harmonization.*

It went on to say that

> *The Conference concluded that safety in biotechnology should be considered in the development and application of biotechnology in the countries of Southern and Eastern Africa, as a matter of urgency.... The participants wish to urge the Governments of Southern and Eastern Africa to facilitate and give priority to biotechnology policies including safety mechanisms in each of the countries. Safety mechanisms should include guidelines and/or regulations, as well as biosafety committees at the national and institutional level, and should be adapted to specific national circumstances.*

The limitation to Southern and Eastern Africa reflected the geographical location of the 11 African countries which participated.

[18]Proceedings African Regional Conference for International Cooperation on Safety in Biotechnology, 11 - 14 October 1993, Harare, Zimbabwe.

34. Other Regional Workshops were held in Cartagena, Columbia and in San Jose, Costa Rica.

35. **Asia-Pacific Workshop.** This Conference was attended by 67 participants from 16 counties in the Asia - Pacific region together with experts from the Netherlands, UK, Zimbabwe and the United Nations. The structure was similar to that of the African Regional Conference in that it was divided into some six sections:

I. State of the Art of Biotechnology and Biosafety in Asia-Pacific;

II. Regional Cooperation on Safety in Biotechnology;

III. International Harmonization of Biosafety Regulation and its Importance to Developing Countries;

IV. Risk Assessment and Risk Management in Biotechnology;

V. Computer Demonstration on Risk Assessment and BINAS;

VI. Working Groups on Case Studies.

The proceedings[19] of the Conference provide a useful overview of both the current state of the art in the countries in Asia-Pacific with separate papers on ASEAN countries, Thailand, Philippines, Indonesia, Malaysia, Australia, Japan, Pakistan, Singapore and Vietnam. Other papers address the situation in Southern Africa, North America, Latin America and Europe. It is again clear that there is a common goal that is internationally seeking to improve the provisions for safety in biotechnology.

36. The final recommendations adopted by the participants at the workshop for taking forward biosafety in the region noted that

> *The aim of the workshop was to contribute to international cooperation on safety in biotechnology, with specific attention to national implementation, regional and international cooperation and harmonization.*

and the recommendations included:

> ** Promote harmonised or equivalent approaches to risk assessment and risk management at the regional and international level;*
>
> ** Promote the adoption of guidelines and/or the amendment of existing legislation if appropriate...;*
>
> ** Ensure that appropriate information is provided to national authorities about organisms derived from modern biotechnology and the potential receiving environment;*
>
> ** Promote the development of mutually acceptable data;*

[19]Proceedings Asia-Pacific Workshop on Safety in Biotechnology, 6 - 8 March 1995, Bangkok, Thailand.

** Promote an effective and attractive information programme on safety in biotechnology for dissemination to the public;*

36. **Central and Eastern European Conference.** This Conference was attended by 36 experts from 10 Central and Eastern European countries together with 27 experts from Africa, Asia, Latin America, Central America, North America and Europe and from UNEP and the OECD. The structure was again similar to that of the other regional conferences with three sections:

* Sharing knowledge and experience with regional cooperation on safety in biotechnology and with mechanisms for safety in biotechnology;

* Addressing national and regional approaches of risk assessment, risk management and regional cooperation;

* Implementation.

The proceedings[20] contain papers on the state of the art in biosafety in Central and Eastern Europe, Southern Africa, Asia, North America, Latin America and the Caribbean, and Europe together with individual papers on Albania, Austria, Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Russian Federation, Slovak Republic, Slovenia and Ukraine.

37. The Conference Statement noted that there was consensus on a number of important issues and said that

Recognizing

- The potential of biotechnology to contribute to sustainable development in fields such as food production, health care, and environmental protection;
- The importance of adequate biosafety mechanisms;
- The need for capacity-building on safety in biotechnology in the countries of Central and Eastern Europe, to facilitate, among others, compliance with international obligations;
- The effectiveness and catalytic effect of internationally coordinated actions;
- The importance of raising awareness in the scientific community and with policy makers regarding safety in biotechnology;
- The importance of addressing public information and perception.

The participants recommended

....

- The harmonization of approaches in biosafety, including:
** regulatory frameworks and technical guidelines on the basis of internationally accepted guidelines*

[20]Proceedings Central and Eastern European Conference for Regional and International Cooperation in Safety on Biotechnology, 4 - 6 September 1995, Keszthely, Hungary.

** work towards mutual acceptability of data, including harmonised lists of classified organisms;*

- National and regional efforts:

** to increase the awareness and knowledge of the scientific community and policy makers regarding safety in biotechnology;*

** strengthening relevant training programmes for authorities and scientists;*

** addressing public perception of biotechnology;*

- That these activities should be coordinated on a regional basis through a regional mechanism, which should facilitate information exchange, capacity building and training programmes.

38. **Second Central and Eastern European Conference.** This was attended by 39 experts from 13 Central and Eastern European countries together with 13 experts from Europe, North America, UNEP, industry and the Biotechnology Advisory Commission of the Stockholm Environment Institute. The proceedings[21] contain papers from Central and Eastern Europe presenting progress reports on the state of the art of biotechnology and biosafety in Albania, Belarus, Bulgaria, Czech Republic, Latvia, Lithuania, Poland, Russian Federation, Slovak Republic, Slovenia, Ukraine and the Federal Republic of Yugoslavia. A useful summary table[22] is included on the progress of legislation (as of October 1996) in the Central and Eastern European countries:

Parameter\Country	**A**	**BG**	**BL**	**Cz**	**H**	**LA**	**LI**	**PL**	**RO**	**RU**	**SK**	**SL**	**U**	**YU**
Biodiversity Convention	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Gene Law		x		x?						x				
Biotechnology Committee		x	x	x				x	x	x	x	x		
EU member														
associate		x		x	x			x	x		x			
declaration						x	x							
OECD member				x	x			x						
associate			x											
declaration										x				
National system registration				x						x				
guidelines		x							x					
permits		x						x						

[21]Proceedings 2nd Central and Eastern European Conference for Regional and International Cooperation on Safety in Biotechnology, 16 - 18 October 1996, Smolenice, Slovak Republic.

[22]Tomasz Twardowski & Stanislaw Bielecki, *State of the Art in Biosafety in Central and Eastern Europe (Results from Country Reports)*, Proceedings 2nd Central and Eastern European Conference for Regional and International Cooperation on Safety in Biotechnology, 16 - 18 October 1996, Smolenice, Slovak Republic, 11 - 15.

Releases of GMO plants animals		x		x	x		x	x					

x - done; x? - partially done

The paper notes that contained use experiments and contained use for commercial production using genetically modified organisms are not included in the table.

39. Another paper[23] compares the regulatory structures and practices in the EU member countries in October 1996. The summary table reproduced below notes that Greece and Luxembourg did not respond although data are included for Norway and Switzerland:

Country	Implementation of Directive 90/220	Competent Authorities	Number in Competent Authority	Budget US $	Advisory Body	Public Participation *
Belgium	law, decrees in preparation	Mins of Agric, Health & Env	6	200,000	Yes	No (inf only)
Denmark	by law and statutory orders	EPA	4	Not known	No	Yes
Germany	by law	Robt Koch Institute, local States	many	No special budget	Yes	Yes
Spain	by law	Min of Env, Health, Agric	10	300,000	Yes	No
France	by law, 11 decrees	Min of Agric, Env	3	1,000,000 inc salaries	Yes	No (inf only)
Ireland	by law	EPA	10	60,000 Irish £s	Yes	No (inf only)
Italy	by law	Min of Health	3	50,000	Yes	If necessary
Netherlands	by decree	Min of Env	6	1,000,000	Yes	Yes
Austria	by law, 1 decree	Min of Health, Science, Env	6	100,000	Yes	Yes
Portugal	by decree	Min of Env	1	Not known	No	No

[23]Helmut Gaugitsch, *A Comparison of Regulatory Structures and Practices in the EU Member Countries (Results from a Questionnaire),* Proceedings 2nd Central and Eastern European Conference for Regional and International Cooperation on Safety in Biotechnology, 16 - 18 October 1996, Smolenice, Slovak Republic, 17 - 19.

Finland	by law and regulation	Board for Gene Tech	7	200,000	Yes	No (inf only)
Sweden	by law and regulation	many	15	Not known	Yes	No (inf only)
UK	by law and regulation	Dept of Env, HSE	8	1,500,000	Yes	No (inf only)
Norway	by law and regulation	Min of Env	5	Not known	Yes	If necessary
Switzerland	by law and regulation	Federal Office of Env, Health, Agric, Vet	2	200,000	Yes	No

* Public participation indicates whether such participation in the handling of notifications is a legal requirement.

40. The Conference Statement noted that considerable progress had been made in the implementation of some aspects of biosafety in biotechnology in the region of Central and Eastern Europe. The participants recommended:

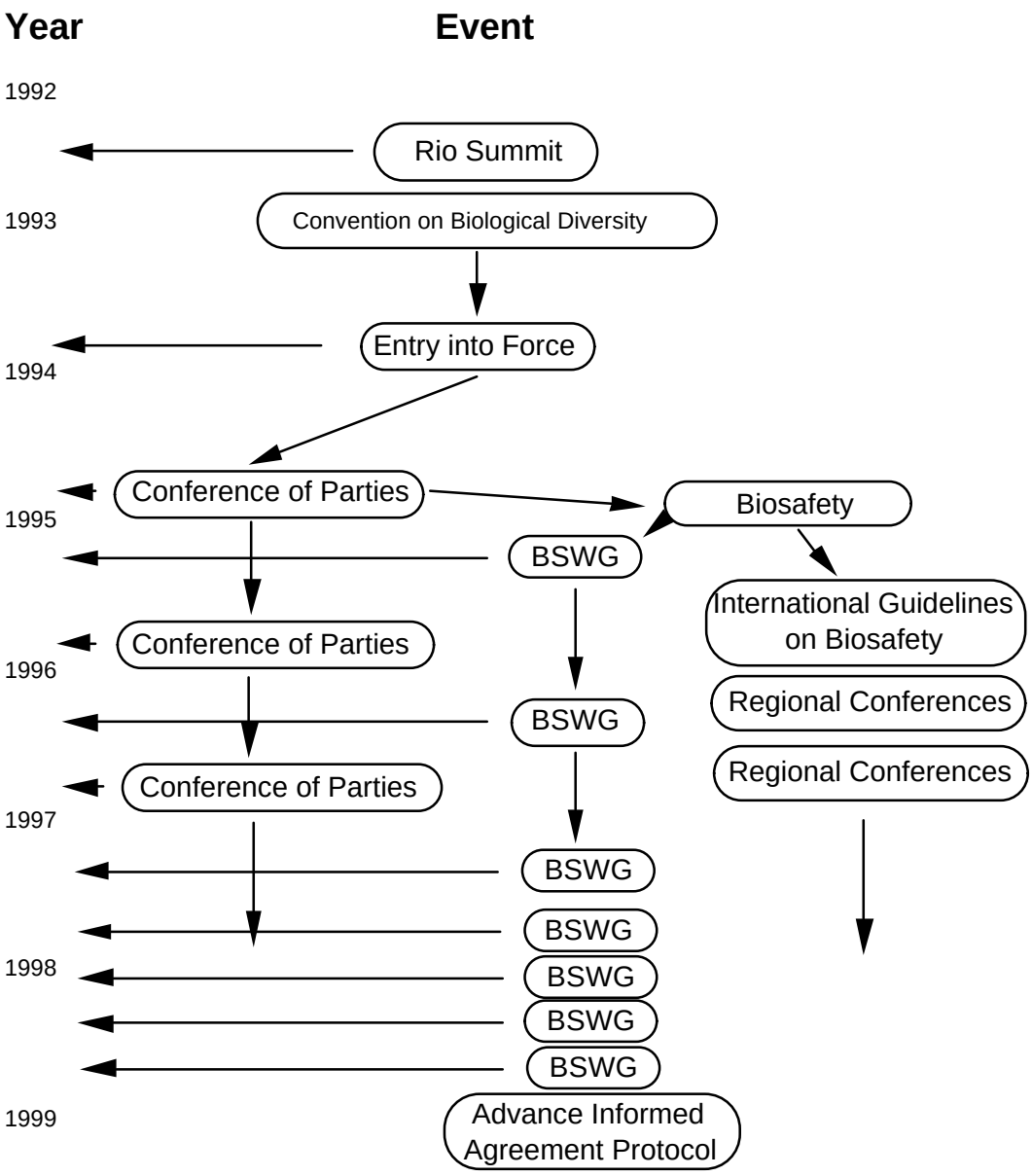
> ** To continue and strengthen regional cooperation on biosafety...*
> ** To implement adequate and flexible biosafety mechanisms in the countries of the region as soon as possible in order to take full advantage from the potentials of biotechnology;*
> ....
> ** that UNEP should continue its valuable role in promoting implementation of biosafety mechanisms in Central and Eastern Europe using the UNEP Guidelines as a model and promoting capacity building.*

The UNEP contribution to this Conference emphasised the importance of capacity building setting out the requirements for capacity building at both the national and international level. It also outlined a regulatory concern without offering solutions by noting that

> *"A large number of countries have no national safety frameworks regulating living modified organisms resulting from biotechnology. The situation has led to regulatory concerns in many countries....Some feel that advances in techniques and ideas for application are proceeding in the absence of appropriate regulatory mechanisms. Biotechnology industry feels that too much attention is being paid to remote and negligible risks, and that excessive regulation could limit biotechnology research and application. Questions arise regarding the capacity of existing regulatory approaches and institutions to address issues related to safety in biotechnology."*

Discussion and Conclusions

40. It is therefore apparent that following the Rio Summit in June 1992 and the entry into force of the Convention on Biological Diversity in December 1993, there is immense ongoing international activity in all regions of the world to improve biosafety in biotechnology and to build capacity. An overall appreciation of this is shown by the figure below which indicates the inter-relationship betwen the various activities.



These are all driven by an international awareness of the potential dangers to the environment and to public health that may result from the release of micro-organisms with novel traits into the environment. The international strategy has been to pursue a two-track approach -- first to adopt and apply the UNEP International Technical Guidelines for Safety in Biotechnology and second to carry forward the negotiations for a Biosafety Protocol which are planned to be completed in 1998.

41. There is an awareness in all of these activities of the importance of raising public awareness of the measures being adopted to protect the environment and public health and so to address the public perception of biotechnology. Whilst these initiatives go under the heading of biosafety or safety in biotechnology, they are all focussed on safety issues related to living modified organisms. It is, however, clearly recognised that the risks posed by modified organisms are similar in kind to those posed by any other organism and are thus based on those posed by the parent or baseline organism and the nature of the novel traits that have been introduced into that organism. Consequently, the basic framework for biosafety should be based on that for unmodified organisms.

42. The developments to establish information exchange and advance informed agreement prior to transborder transfers of living modified organisms are such that they will contribute to increased international transparency and to improved public confidence that such organisms are being handled and used safely without undue risk to the environment or to public health. Such improved transparency and enhanced confidence that such organisms are being used safely for permitted purposes can contribute to improving international confidence that States are in compliance with the BTWC. These activities to enhance biosafety in biotechnology should be regarded as building blocks that can be drawn upon in devising measures to strengthen the implementation of the BTWC.