

## **THE BTWC PROTOCOL: PROPOSED COMPLETE TEXT FOR AN INTEGRATED REGIME**

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### **Introduction**

1. The Ad Hoc Group of States Parties to the Biological and Toxin Weapons Convention have been engaged since 1995 in the negotiation of a legally-binding Protocol *to strengthen the effectiveness and improve the implementation* of the Biological and Toxin Weapons Convention (BTWC). The Ad Hoc Group successfully transitioned to negotiation of a rolling text of the Protocol in July 1997 and completion of the Protocol is now within reach<sup>1</sup>.

2. The Department of Peace Studies at the University of Bradford, Bradford, UK has been engaged since July 1997 in preparing Briefing Papers on the key Protocol issues to aid the delegations participating in the Ad Hoc Group: some 31 Briefing Papers had been prepared and distributed by July 2000. As the Articles in the Protocol have reached the stage at which they are largely agreed, Evaluation Papers have been prepared on the individual Articles; some 18 Evaluation Papers had been prepared and distributed by July 2000. These Evaluation Papers have addressed 19 of the 23 Articles in the Protocol and two Evaluation Papers have provided complete proposed clean texts; the first, Evaluation Paper No. 17, issued in March 2000 provided a complete text based on the February 2000 AHG/50 Protocol text<sup>2</sup> and the second, Evaluation Paper No. 18, issued in July 2000 provided a revised complete text based on the April 2000 AHG/51 Part I Protocol text<sup>3</sup>. All of these Briefing Papers and Evaluation Papers as well as the draft Protocol text and the Ad Hoc Group working papers are available on the Bradford website at <http://www.brad.ac.uk/acad/sbtwc>

3. During the March 2000 Ad Hoc Group session there was a useful step forward when the individual Friends of the Chair categorized the remaining square brackets in the text for which they are responsible into three categories:

- a. Category I: "Little controversy, relatively easy to resolve"
- b. Category II: "Medium level of disagreement"

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<sup>1</sup>Graham S. Pearson, The Protocol to the Biological Weapons Convention Is Within Reach, *Arms Control Today*, Vol. 30, No. 5, pp. 15-20, June 2000.

<sup>2</sup>United Nations, *Procedural Report of the Ad Hoc Group 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*, BWC/AD HOC GROUP/50 (Part I), 11 February 2000, Geneva.

<sup>3</sup>United Nations, *Procedural Report of the Ad Hoc Group 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*, BWC/AD HOC GROUP/51 (Part I), 6 April 2000, Geneva.

c. Category III: "Strong conceptual differences in views".

This categorization was made using the AHG/50 text<sup>4</sup> and was done electronically with the three categories of square brackets being marked in yellow, green and red respectively<sup>5</sup>.

4. At the next Ad Hoc Group session in July/August 2000, the Chairman engaged in a series of bilateral consultations with delegations on those issues that had been categorized as having "Strong conceptual differences in views". In 90 such bilaterals during the four week session, the Chairman carried out a conceptual exploration of possible future solutions in the following areas: Investigations; Compliance Measures and Objective Criteria; Transfers; Cooperation; Legal Issues and Issues related to the Organization. At the end of the session, the Chairman provided an overall oral summary regarding these consultations and encouraged delegations to consider all the various issues together so as to focus on the concessions that would be necessary to arrive at an agreed Protocol.

5. There has been continued widespread political pressure to see the completion of the Protocol by the Fifth Review Conference which will be held in November/December 2001. The Non-Aligned Movement Ministerial Meeting in Cartagena, Colombia on 8/9 April 2000 noted *"the progress made so far in negotiating a Protocol to strengthen the BWC and reaffirm the decision of the Fourth Review Conference urging the conclusion of the negotiations of the Ad Hoc Group as soon as possible, before the commencement of the Fifth Review Conference."* A month later, the NATO Foreign Ministers meeting in Florence, Italy on 24 May 2000 said *"we continue to regard as a matter of priority the conclusion of negotiations on appropriate measures, including possible verification measures and proposals to strengthen the convention to be included as appropriate in a legally binding instrument. We reiterate our commitment to efforts to achieve such an instrument as soon as possible before the 5th Review Conference of the BTWC in 2001."* The G8 Communiqué issued in Okinawa, Japan on 23 July 2000 said *"We commit ourselves to work with others to conclude the negotiations on the Verification Protocol to strengthen the Biological Weapons Convention as early as possible in 2001."*

6. This Evaluation Paper provides a revised proposed complete clean text for the Protocol which has been revised so as to show how the August 2000 AHG/52 Part I Protocol text<sup>6</sup> might be amended, taking into account the latest Part II proposals<sup>7</sup>, as well as considering the FOC "Strong conceptual differences in views" (Cat III) issues in order to arrive at a final complete text.

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<sup>4</sup>United Nations, *Procedural Report of the Ad Hoc Group 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*, BWC/AD HOC GROUP/50 (Part I), 11 February 2000, Geneva.

<sup>5</sup>A copy of the categorized version of AHG/50 is available at <http://www.brad.ac.uk/acad/sbtwc>

<sup>6</sup>United Nations, *Procedural Report of the Ad Hoc Group 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*, BWC/AD HOC GROUP/52 (Part I), 11 August 2000, Geneva.

<sup>7</sup>United Nations, *Procedural Report of the Ad Hoc Group 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*, BWC/AD HOC GROUP/52 (Part II), 16 August 2000, Geneva.

7. As in Evaluation Paper 17<sup>8</sup> and 18<sup>9</sup>, the proposed text is a consolidation and development from the previous Evaluation Papers and takes forward the ideas developed therein and in the Briefing Papers as well as taking into account the further development of the Protocol text in the Ad Hoc Group. The Briefing Papers have considered key issues being addressed by the Ad Hoc Group and have provided additional background information from which an analysis and appreciation have been developed of how the particular issue might be taken forward. In this Evaluation Paper a transparent approach has again been adopted for this clean text in which the additions to the latest Part I draft Protocol text are shown in **bold**. For improved clarity, as deletions generally occur only where there are additions, deletions are not normally indicated although the symbol † has been inserted, where appropriate, to mark larger deletions.

8. In developing this proposed complete text we continue to recognise that the States Parties to the BTWC in negotiating the Protocol have different aims and aspirations regarding the details of what should be incorporated into the eventual Protocol. The Ad Hoc Group has now been working for 5 years and since July 1997 in negotiating mode. By August 2000 it has held 20 sessions during which all the States Parties have gained an understanding of the backgrounds to these different aims and aspirations and have, in many areas, identified compromise measures and language which have been acceptable to the great majority, if not to all, of the States Parties. Any international treaty is the result of negotiation and all States Parties have to seek to accommodate, to the extent possible, the views of other States Parties. The aim is to arrive at a Protocol that satisfies at least the minimum security and economic interests of all States Parties. In this proposed text, we have again sought to introduce realism and to strike a balance between the different aspirations so as to achieve a worthwhile and valuable Protocol that will be acceptable to all States Parties as well as meet the majority of their individual objectives for the Protocol.

9. The use of deliberate disease as a weapon of war would cause immense damage to international peace and security and, in a world in which international trade and travel is becoming ever more important, it is vital to *strengthen the effectiveness and improve the implementation* of the BTWC through an effective Protocol, especially as we recognise that the 21st century is indeed the age of biotechnology which will bring benefits to developed and developing States worldwide, and if misused, could cause devastating harm and damage.

10. The requirement is therefore for a Protocol that will indeed strengthen the Convention yet will not result in an undue burden that is disproportionate to the benefits to peace and security. The negotiations over the past three years have seen the development and elaboration of a Protocol which would indeed be efficient and effective and, through its various measures, result in an integrated regime which would, over time, build confidence in compliance between States Parties as well as reinforce the norm that biological weapons are totally prohibited by all nations.

11. In preparing this proposed complete text, we have continued to adopt the principle of minimum change. In other words, "if it isn't broken, don't fix it!" It is, after all, unhelpful at this late stage of the negotiations to reopen issues which have been negotiated and have resulted in Part I text that is free from square brackets. However, where there are areas

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<sup>8</sup>Evaluation Paper No. 17, *The BTWC Protocol: Proposed Complete Text For An Integrated Regime*, March 2000 provided a proposed clean text based on the February 2000 draft protocol text in AHG/50 (Part I).

<sup>9</sup>Evaluation Paper No. 18, *The BTWC Protocol: Revised Proposed Complete Text For An Integrated Regime*, July 2000 provided a proposed clean text based on the April 2000 draft protocol text in AHG/51 (Part I).

where we judge that the Protocol language has been over-elaborated to such an extent that the Protocol is unduly restrictive and will, in our view, inhibit its effective implementation, then we have proposed amendments. We have also proposed amendments in a few places where in our judgement there is still a risk of the Protocol being too weak. We also recognise that there are a number of areas in which there are political realities which require certain elements to be incorporated into the Protocol in order to arrive at a complete text acceptable to all States Parties even though from a strictly technical point of view, these additional elements may contribute little to the effectiveness of the overall regime. Finally, we have offered occasional amendments for clarification of meaning where this remains obscure, and for internal consistency of expression within the Protocol.

12. In this Evaluation Paper, we first set out, in an introductory section, the overall approach that we have adopted in regard to the FOC Cat III "strong conceptual differences in views" issues. The text that has been assigned to Category III wherever it has been reproduced in the introductory section is highlighted in bold and, although the categorization was carried out by the FOCs using the Protocol text in AHG/50 (Part I), the location of the Cat III language in the latest Protocol text in AHG/52 (Part I) is provided for convenience. The introductory section is then followed by the proposed complete text which is based on the August 2000 AHG/52 (Part I) Protocol text. Footnotes inserted at the relevant point in the text indicate why particular language has been proposed. Reference is made in these footnotes, as appropriate, to the previous Evaluation Papers and to the Briefing Papers which are all available at the University of Bradford website at <http://www.brad.ac.uk/acad/sbtwc>

### **Category III Issues "Strong Conceptual Differences in Views"**

13. An analysis of the principal Cat III issues in the Preamble and the 23 Articles of the Protocol text for which there are "Strong conceptual differences in views" shows that, although these are interrelated and all are important issues, they can with advantage be further divided into three groups:

#### **A. Key Issues**

1. Red light/green light initiation procedure for investigations
2. Randomly-selected visits to all declared facilities
3. Thresholds
4. Modification, particularly to Article I, of the BTWC (*Protocol Art I General Provisions, Art II Definitions, Art XI Relationship of the Protocol to the BTWC*)
5. Transfer guidelines (Art III of the BTWC, non-impedance of economic and technological development issues)
6. Cooperation Committee role
7. Biodefence in Art VII of the Protocol
8. Clarification procedures regarding facilities that appear to meet the requirements for declaration and have not been declared

#### **B. Other Issues**

1. Declaration Triggers (BL-3, Work with Listed Agents, Other Production Facilities, Other Facilities, Outbreaks)
2. Date for initial declarations (1925/1946/1975)
3. "Testing and evaluation, production" information in declarations

4. Documentation availability during visits/investigations
5. Sampling during investigations
6. Access and Executive Council procedures for visits/investigations
7. Waiver of immunity for Director-General and Organization for the Prohibition of Biological Weapons (OPBW).

### C. Further Issues

1. Preambular language
2. Redress situation -- report to UN General Assembly/Security Council
3. Request for assistance being conditional on a simultaneous request for a field investigation.
4. Seat of the Organization
5. Executive Council representation from Asia/East Asia and the Pacific/West and South Asia
6. Dispute procedure
7. Frequency of Review Conferences (5/10 years)
8. Amendments to Annexes/Appendices
9. Entry into Force
10. Reservations

These issues are considered below in these three groups.

### A. Key Issues

14. **Red Light/Green Light Initiation Procedure for Investigations.** The Cat III language occurs in paragraph 26 of Article III. G subsection (F) on page 82 of AHG/52 and reads as follows:

*26. The investigation shall proceed [in the case of a request for a facility investigation] [if formally approved by at least a [two-thirds] [three-quarters] majority [present and voting] of the Executive Council] [unless the Executive Council decides by a three-quarters majority of [all] its members [present and voting] against carrying out the investigation] [and, in the case of a request for a field investigation, if formally approved by a simple majority of the Executive Council members present and voting].*

Investigations are the ultimate measure in the Protocol and, on the very rare occasions when they are requested, they do need to take place. These should have the presumption that they will occur<sup>10</sup> -- and the safeguards against abuse will be provided both by the Executive Council voting to **stop** an investigation and by the Executive Council deciding on redress should it conclude that there has been abuse. The reality is that such investigations -- as with challenge inspections or investigations of alleged use under the Chemical Weapons Convention (CWC) -- will be **extremely** infrequent -- and provisions already in the text, which mirror those in the CWC, to protect against abuse will suffice. Consequently, a red light initiation procedure is vital to ensure that the Protocol regime is a strong one. A simple green light initiation procedure is not equivalent to a simple red light procedure as the

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<sup>10</sup>Briefing Paper No. 15, *Non-Compliance Concern Investigations: Initiation Procedures*, October 1998 addressed the importance to the strength of the overall regime of investigations as the ultimate measure for which the presumption needed to be that they will indeed go ahead.

presumption is quite different -- and it continues to be apparent from the Organization for the Prohibition of Chemical Weapons (OPCW) experience under the CWC that a red light procedure provides a strong regime as it provides a presumption that should a challenge inspection be requested by a State Party then that inspection will take place.

**15. Randomly-Selected Visits to All Declared Facilities.** The Cat III language occurs in paragraph 10 of Article III D. Subsection II on page 40 of AHG/52 and relates to two points -- first regarding the facilities to receive the randomly selected visits "*to [declared] [biodefence and BL4] facilities.*" and second regarding the purpose of these visits and whether these are *[Promoting accuracy of declarations] [Promoting the accurate fulfilment of the declaration obligations under this Protocol]*. Infrequent randomly-selected visits to **all** declared facilities are necessary to ensure that declaration obligations are consistently fulfilled.<sup>11</sup> If such visits were to be limited to biodefence and BL-4 facilities then there would be very few visits to the majority of States Parties. The consequence would be that, should there be an investigation in one of those States Parties which has never been visited by the Technical Secretariat, there is a greater probability that the investigations may reach an incorrect conclusion because of a lack of understanding of the approaches to microbiology and biotechnology in that country. In addition, in regard to visits, it needs to be recognized that the frequency of such visits will be controlled effectively by the Conference of the States Parties through their annual scrutiny and approval of the programme and budget of the Protocol Organization, and it is unnecessary in the Protocol, as in the CWC, to specify an overall limit for the number of visits, of whatever type. Indeed, specification of such a limit in the Articles of the Protocol would be unwise as it would reduce flexibility and further it is inefficient as it removes any incentive for the future Organization to optimize its operations. Additional visibility of the planned visits could be achieved through the Director-General, every three months, notifying the Executive Council of the overall plan of visits for the forthcoming three months; the overall plan should not include sufficient detail to enable States Parties to identify which States Parties would receive a visit in the next quarter.

**16. Thresholds.** The Cat III language relating to thresholds includes all the language in Article III. C on pages 26 to 27 of AHG/52 and in Annex A.III on pages 158 to 162. Because of the nature of microorganisms and the ease with which they can be grown, there is less technical justification for thresholds in the BTWC Protocol than in the CWC.<sup>12</sup> However, as in the CWC, there is a need for quantitative information in the declarations made under the Protocol and there are therefore quantitative thresholds that will need to be exceeded in order for a declaration to be required. Consequently, reference has been included, where appropriate, to the need for declarations when the stated threshold capacities have been exceeded. There is no requirement, however, for the determination of individual thresholds for individual agents and toxins nor is there any requirement for the exceeding of a threshold to be notified to the Organization.

**17. Modification, particularly to Article I, of the BTWC (Protocol Art I General Provisions, Art II Definitions, Art XI Relationship of the Protocol to the BTWC).** The Cat

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<sup>11</sup>Briefing Papers No. 2, *The Necessity for Non-Challenge Visits*, September 1997, No. 10, *The Strengthened BTWC Protocol : An Integrated Regime*, July 1998, No. 18, *Visits: An Essential and Effective Pillar*, January 1999, No. 20, *Visits: An Essential Portfolio*, April 1999 and No. 26, *Visits: The Emerging Portfolio*, November 1999 have all addressed the importance of randomly-selected visits to ensure that declaration obligations are fulfilled consistently

<sup>12</sup>Organisation for the Prohibition of Chemical Weapons, *Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction*, Available on the web at <http://www.opcw.org>

III language relates to several elements of *Article I General Provisions* on page 12 of AHG/52, to definitions of biological and toxin weapons in *Article II Definitions* on page 15 and to the relationship of the Protocol to the Convention in paragraph 1 of Article XI on page 129 -- where the Cat III language is in the phrase that *This Protocol being [supplementary][and][additional] to the Convention*. The mandate for the Ad Hoc Group is *to strengthen the effectiveness and improve the implementation of the Convention* through the consideration of *appropriate measures, including possible verification measures, to strengthen the Convention to be included, as appropriate, in a legally binding instrument*. It is clear that the Ad Hoc Group has a mandate to develop a Protocol to strengthen the Convention -- but does **not** have a mandate to **amend** the Convention. Consequently, it is beyond the mandate of the Ad Hoc Group to propose language within the body of the Protocol which in any way amends the scope of the Convention. It is appropriate for the Preamble to set the Protocol in the wider framework of the Convention and its Review Conferences but care needs to be taken within the Protocol -- such as in *Article I General Provisions*, *Article II Definitions* or *Article XI Relationship of the Protocol to the Convention* -- not to amend the scope of the Convention. The place for considering an extended understanding of the Convention is in the Review Conferences of the Convention where such extended understandings can be and are reflected in the Final Declaration.

18. In respect of *Article II Definitions* there has long been a divergence of views as to what should be defined and what should not. There is general recognition that care needs to be taken to ensure that nothing in the Protocol might be perceived as modifying in any way the basic prohibitions in Article I of the Convention. There is also broad agreement that in order to avoid ambiguity there is a need for definition of some of the terms used in the language relating to the provision of declarations and in other measures. The approach adopted has been to limit definitions and objective criteria to those **necessary** for an unambiguous and effective Protocol. This is in accord with the mandate requirement for the consideration of definitions and objective criteria *where relevant for specific measures designed to strengthen the Convention*. We have retained some definitions in Article II and have transferred most of the definitions to a new subsection I to Annex A. As for the relationship in Article XI of the Protocol, we see no necessity to use either "supplementary" or "additional" and alternative language avoiding this is proposed.

19. **Transfer Guidelines (Art III of The BTWC, Non-Impedance of Economic and Technological Development Issues)**. The Cat III language relates to several elements of *Article III. F. Measures to Strengthen the Implementation of Article III* (of the Convention) on page 73 to 77 of AHG/52 as well as to language in Article VII Section (C) referring to maintenance of discriminatory measures or restrictions. As the mandate of the Ad Hoc Group is to consider measures *to strengthen the effectiveness and improve the implementation of the Convention* it is both appropriate and necessary to consider measures to strengthen Article III of the Convention. It needs to be appreciated that in order to permit a transfer, the State making a transfer will need to have confidence that the transfer to a State Party to the Protocol is:

- a. **only** being used for permitted purposes;
- b. **not** being retransferred, without approval, to another facility within the receiving State Party; or
- c. **not** being retransferred, without approval, to another State Party to the Protocol.

The requirements are thus three. First, that there should be **transparency** as to what the transferred materials and equipment are being used for. Secondly, that there should be **national internal** controls on the facilities within a State Party to the Protocol in which particular agents are handled and on transfers between such facilities. Thirdly, that there should be **national** controls of **interstate** transfers from the State Party to the Protocol to other States Parties. The Protocol regime will establish minimum standards for transfers and it will be a matter for individual States as to whether they decide that they need to adopt and implement higher standards. It is recognized that over time after the entry into force of the Protocol **for the requesting State**, the State making the transfer should gain greater transparency of activities in the requesting State together with greater confidence that the requesting State has indeed the appropriate **national internal and interstate controls** both in place and in operation and thus the transfer is more likely to be approved. Such confidence will over time decrease in regard to States not party to the Protocol and it is evident from the CWC experience that a regime in which transfers to non-States Parties to the Protocol become increasingly controlled and prohibited both contributes to enhancing the safety and security of States Parties to the Protocol and provides a strong incentive for non-States Parties to become party to the Protocol.<sup>13</sup>

20. **Cooperation Committee Role.** Whilst there is general agreement about the establishment of the Cooperation Committee, there is Cat III language in respect of some aspects relating to the Committee. Thus, in Art VII, para 14 on page 104 there is language that:

*14. [The members of the Committee shall be elected for a term of two years, on the basis of an equitable geographical distribution, in accordance with Article IX, paragraph ... of this Protocol]. [The Committee shall be a pluridisciplinary body open to the participation of all States Parties and shall comprise government representatives competent in the relevant fields of expertise.] The Committee may establish working groups on an ad hoc basis.*

and in para 17 on the same page that:

*17. The chairmanship of the Committee shall rotate annually between each regional group, as defined in Article IX, paragraph ..., represented in the Committee. [Decisions][Recommendations] shall be agreed [by consensus] [in the same manner as decisions by the Conference of State Parties in accordance with Article IX, paragraph ...].*

OR

*[The chairmanship of the Committee shall rotate annually between each regional group, as defined in Article IX, paragraph ..., represented in the Committee. Decisions on specific recommendations for inclusion in the report of the Committee to the Executive Council and the Conference of States Parties shall be agreed by consensus. Decisions on specific recommendations to the Executive Council pursuant to paragraph 10 shall be agreed by consensus.]*

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<sup>13</sup>Briefing Paper No. 28, *The BTWC Protocol: Improving the Implementation of Article III of the Convention*, January 2000 addressed measures to improve the implementation of Article III of the BTWC.



19. A Cooperation Committee open to the participation of all States Parties would rapidly become unwieldy as the number of States Parties to the Protocol grew. It is therefore appropriate to require membership to be drawn on an equitable geographical basis from among the States Parties to the Protocol. The requirement that the Committee be a pluridisciplinary body comprising government representatives competent in the relevant fields of expertise is a statement of the obvious as States Parties can be expected to appoint appropriate representatives -- after all, there is quite correctly no comparable specification for members of the Conference of the State Parties or for the Executive Council. As to decisions and recommendations, these should be taken by consensus.

20. **Biodefence in Art VII of the Protocol.** The Cat III language is in respect of all mentions of biodefence in Article VII. The measures in *Article VII Scientific and Technological Exchange for Peaceful Purposes and Technical Cooperation* are an important part of the Protocol contributing **both** to promoting technical cooperation between States Parties to the Protocol **and** to increasing transparency and enhancing confidence in compliance.<sup>14</sup> The breadth of activities covered in Article VII including surveillance and countering of infectious diseases, biosafety and good manufacturing practice is welcomed as it is recognized that the infrastructure required by States Parties to carry out such activities will indeed, over time, lead to increased transparency and enhanced confidence.<sup>15</sup> Nevertheless, it is important to avoid unnecessary duplication and for the Protocol Organization to concentrate on those measures for which it is particularly well fitted. It is inappropriate to address biodefence related activities in Article VII although in Article VI, it is appropriate to note that the States Parties may benefit from scientific and technological exchanges pursuant to the provisions of this Protocol, including Article VII thereof.

21. **Clarification Procedures Regarding Facilities that Appear to Meet the Requirements for Declaration and Have Not Been Declared.** The Cat III language appears in Article III. D. II subsection (B) and again in Article III. E. There is a need for a non-controversial, non-confrontational and non-accusatory clarification procedure in respect of any ambiguity, uncertainty, anomaly or omission in declarations whether of declared facilities and/or activities or of facilities and/or activities which should have been declared. Such clarification requests should be initiated by the Protocol Organization or at the request of a State Party. It is evident from the OPCW experience that there are numerous occasions on which clarification is needed of information provided in declarations received from States Parties.<sup>16</sup> Indeed, the Director-General of the OPCW in his address<sup>17</sup> to the Fifth Conference of the States Parties on 15 May 2000 spoke of "... *certain implementation-related*

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<sup>14</sup>Briefing Papers No. 6, *Article X : Some Building Blocks*, March 1998, No. 7, *Article X : Further Building Blocks*, March 1998, No. 8, *Article X : Pharmaceutical Building Blocks*, July 1998, No. 9, *Article X : Specific Measures to Achieve Implementation*, July 1998 and Briefing Paper No. 22, *Article VII Measures: Optimizing the Benefits*, July 1999 have set the Protocol in the context of other relevant international initiatives and demonstrated how technical exchange and technical cooperation can contribute to increasing transparency and enhancing confidence between States Parties.

<sup>15</sup>Briefing Paper No. 29, *Maximizing the Security Benefits from International Cooperation in Microbiology and Biotechnology*, July 2000 showed how the contributions from biosafety and good manufacturing practice as well as from Article VII measures contributed towards benefits from improved safety, environment, prosperity and security for all States Parties.

<sup>16</sup>See for example, John Gee, *The CWC at the Two-Year Mark: An Interview with Dr. John Gee*, Arms Control Today, April/May 1999, pp. 3 - 9. Organization for the Prohibition of Chemical Weapons, *OPCW Annual Report 1998*.

<sup>17</sup>OPCW, *Opening Statement by the Director-General to the Conference of the States Parties at its Fifth Session*, Conference of the States Parties, Fifth Session, 15 - 19 May 2000, C-V/DG. 11, 15 May 2000. Available at <http://www.opcw.org>

*inconsistencies and technicalities which, unfortunately, continue to occur. However, they are being addressed and corrected.*" The vast majority of these ambiguities, uncertainties, anomalies or omissions are resolved through correspondence or consultation with the State Party concerned. A visit to the facility and/or activity concerned may well be the most efficient and effective way of resolving the ambiguity, uncertainty, anomaly or omission. However, should a State Party consider that it has taken all reasonable steps to clarify the ambiguity, uncertainty, anomaly or omission then it can refuse the proposed clarification visit. Such refusals should be reported to the Executive Council. We recommend that declaration clarification procedures should apply both to declared facilities and/or activities **and** to facilities and/or activities that the Protocol Organization or a State Party believe appear to meet the requirements for declaration and have not been declared. Such procedures will add significantly to the increase of confidence by States Parties over time that other States Parties are in compliance with the Protocol. Consequently, resolution of such ambiguities, uncertainties, anomalies or omissions from declarations should not become blurred into the C3 (Clarification, Consultation and Cooperation) process of Article III. E which should be reserved as the first stage in addressing non-compliance concerns.

### **B. Other Issues**

**22. Declaration Triggers (BL-3, Work with Listed Agents, Other Production Facilities, Other Facilities, Outbreaks).** A balance has to be struck between those facilities of **most** relevance to the Convention and facilities of some relevance to the Convention. In considering declaration triggers and the associated declaration formats in Appendices A, B and C it is important to bear in mind the information available from the BTWC Confidence-Building Measures<sup>18</sup> on the numbers of biological defence facilities, maximum containment (BL-4) facilities and vaccine production facilities around the world as this gives a useful indication, even though only about half the States Parties have provided information, of which triggers and declaration formats will capture information from a greater number of States Parties. This information, based on the 1997 CBM responses, is provided in tabular form below:

State Party	Biological defence facility	Maximum containment (BL-4)	Vaccine production facility
Argentina			7
Australia	1	3	1
Austria		1	1
Belarus		1	
Belgium			1

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<sup>18</sup>Iris Hunger, *Article V: Confidence Building Measures*, in Graham S. Pearson & Malcolm R. Dando (eds), *Strengthening the Biological Weapons Convention: Key Points for the Fourth Review Conference*, Department of Peace Studies, University of Bradford, September 1996. Available on <http://www.brad.ac.uk/acad/sbtwc> Iris Hunger, *Private communication*, June 2000, Max Delbruck Centre for Molecular Medicine, Berlin.

State Party	Biological defence facility	Maximum containment (BL-4)	Vaccine production facility
Brazil			8
Bulgaria			1
Canada	1	2	2
China	1		7
Cuba		2	2
Czech Republic		2	3
Denmark			1
Finland	2	3	1
France	1	5	4
Germany	2	4	4
Hungary			3
India	1		19
Iraq			3
Italy	1	1	9
Japan		2	11
Mongolia		1	1
Netherlands	1	2	2
Norway	1		4
Poland		1	4
Romania			2
Russia	9	2	16
Slovak Republic		2	1
South Africa		1	2
South Korea			7
Spain	1	1	10
Sweden	1	2	1
Switzerland		2	1
Turkey			4
Ukraine			3
United Kingdom	1	6	4
United States	19	3	11
<b>Total Number of Facilities</b>	<b>43</b>	<b>49</b>	<b>162</b>
<b>Total Number of Countries</b>	<b>15</b>	<b>22</b>	<b>36</b>

From this, it is evident that biological defence facilities are only likely to be declared in a small number of countries (15), and that the addition of maximum containment facilities only increases the number of countries by six. It is only when vaccine production facilities are considered that the number of countries increases by another 15 to a total of 36. Given the Protocol objective of increasing transparency and building confidence between States Parties, triggers such as "Other Production Facilities" and "Work with Listed Agents and Toxins" are necessary in order to increase the distribution and spread of relevant declared facilities both within these countries and to additional countries.

The declaration triggers that are currently assigned to Cat. III are the following:

**a. BL-3 facilities.** The focus on containment facilities is seen as basically flawed as containment standards are primarily a manifestation of the more developed countries within which there is generally a developed national infrastructure which will monitor and inspect such maximum containment facilities. It is also a fact that countries which have in the past developed offensive biological weapons have done so without using containment facilities. Nevertheless, it is recognized that there is a perception that the capabilities in maximum containment (BL-4) facilities might be misused and therefore should be subject to appropriate compliance monitoring. However, we consider that high containment(BL-3) alone should not be a trigger for declarations and we have therefore deleted this as a stand-alone trigger.

**b. Work with Listed Agents.** There is a need for the declaration of facilities working on listed agents and toxins that also have one or more of the following characteristics:

- i. A certain scale of production capability
- ii. Work on certain types of genetic modification
- iii. Work on aerosolization.

**c. Other Production Facilities.** It would be illogical to require declaration of vaccine production facilities and not to require declaration of other production facilities although the requirement for declaration needs to be precise so that only the most relevant facilities are declared.

**d. Other Facilities.** There is a need for the declaration of facilities which

- i. Possessed aerosol test chambers for work with microorganisms and toxins
- ii. Possessed equipment for aerosol dissemination in the open air with a particle mass median diameter not greater than 10 microns
- iii. Conducted genetic modification within a high containment facility (BL-3) to enhance pathogenicity, virulence, stability or resistance to antibiotics or which altered the host range, the infection route or the ease of identification or diagnosis.

This declaration trigger might be combined with the trigger on work with listed agents and toxins.

**e. Disease Outbreaks.** There is a clear requirement for the future Protocol Organization to have background information on human, animal and plant disease profiles around the world. It is also apparent that information on outbreaks of disease is increasingly being reported both officially and unofficially at the national, regional and international level.<sup>19</sup> It is also evident that there is considerable variation between States in which diseases are reported nationally, regionally and internationally. Consequently, a requirement for States Parties to report on outbreaks of disease to the future BTWC Organization would necessarily result in different reports from different countries because of the different national reporting systems and would also be an unnecessary duplication of existing reporting systems. Our

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<sup>19</sup>Briefing Papers No. 21, *Outbreaks of Disease: Current Official Reporting*, April 1999, No. 23, *BTWC Security Implications of Human, Animal and Plant Epidemiology*, July 1999 and No. 24, *Outbreaks of Disease: Current European Reporting*, September 1999 have described current official disease surveillance reporting.

recommendation is that States Parties under the Protocol should be encouraged to improve their disease surveillance systems and their national, regional and international reporting of such information to organizations such as the WHO, FAO and OIE. In addition, provision of copies of such disease surveillance information, to the extent possible, to the future Protocol Organization would be encouraged.

It should be noted that in its consideration of Declaration Formats in the Appendices to the Protocol, the Ad Hoc Group is engaged in far more detailed elaboration than in the negotiation of the Chemical Weapons Convention where the detailed declaration formats were addressed in the PrepCom phase.

**23. Date for Initial Declarations (1925/1946/1975).** The draft Protocol contains alternative dates -- 17 Jun 1925 (the date of signature of the Geneva Protocol), 1 January 1946 (the date agreed by the States Parties at the Third Review Conferences for the information to be provided under the Confidence-Building Measures) and 26 March 1975 (the date of Entry into Force of the BTWC) -- for the initial declaration of past offensive programmes and an even wider range of dates -- of 1 January 1946, 26 March 1975, the date of Entry into Force for a State after 26 March 1975, 31 December 1991 and five years prior to the first annual declaration for that State Party -- for the initial declaration of past defensive programmes. In considering these dates, it is important to recall why these declarations of past offensive and defensive programmes are required -- to build confidence between and increase transparency within States Parties to the Protocol. As the States Parties to the Convention have already agreed that information shall be provided on both past offensive and past defensive programmes **since 1 January 1946**, and States Parties are already politically bound to provide this information, there is much logically to be said for adopting the same date, 1 January 1946, for the Protocol initial declarations. To adopt any later dates would be incompatible with the object and purpose of the Protocol whilst there is no compelling argument for the earlier date of 17 June 1925 especially given the uncertainty that information would be available in full from that earlier date. It is therefore recommended that the date of 1 January 1946 be adopted for the initial declarations and that, as has been the case with the information provided under the Confidence-Building Measures, individual States Parties can provide earlier information where that is available thereby providing a more complete appreciation of the past offensive and defensive programmes.

**24. Testing and Evaluation, Production Information in Declarations.** Whilst there is general agreement that research and development activities should be declared under the initial declarations of past offensive and defensive programmes and/or activities and under current declarations of defensive programmes and/or activities, there is Cat III language where the words "*testing or evaluation, and production*" occurs in the requirements for these declarations as for example in paragraph 7 (b) of Article III. D. subsection I. This general agreement on the declaration of research and development activities reflects the agreement that such declarations should be made under the politically-binding Confidence-Building Measures agreed by the States Parties at the Second and Third Review Conferences. As the **purpose** of **all** the declarations in the Protocol is to increase transparency in and confidence between States Parties, it is illogical to provide incomplete information on past offensive and defensive programmes and on current defensive programmes. The information provided should cover **all** the activities within these past and current programmes as comprehensive and complete information is vital to increasing transparency and assuring other States Parties that activities within a State Party are for permitted purposes. However, the requirement for such comprehensive and complete information should be tailored so as to

provide transparency and to build confidence -- it does not require and should not seek, for example, information about detailed performance capabilities of current biodefence equipment.

25. **Documentation Availability During Visits/Investigations.** There are differences in views about the availability of documentation during visits and investigations. For example, in respect of randomly-selected visits, there is Cat III language in Article III D. II in paragraph 35(c) that the visiting team may:

*[(c) Examine, with the consent of the visited State Party, documentation relevant to the mandate in order to facilitate the visiting team's understanding of the activities being conducted at the declared facility. The visited State Party shall endeavour to provide such documentation, or to provide alternative means to address the questions of the visiting team if provision of any documentation is denied;]*

In the context of facility investigations, there is Cat III language in Annex D. III para 46 on that:

*[46. If specific issues arise during the investigation, which in the opinion of the investigation team could be resolved by the examination of specific documentation and records not available at the investigated facility, the investigation team may request the receiving State Party to provide access to these specific documents and records for review at the investigated facility in accordance with the provisions of Article III, section G, subsection G.]*

26. As visits are non-confrontational measures aimed at building understanding and confidence, it is counter-productive to introduce elements that may impede the achievement of such goals. The language in the Protocol in paragraph 35 (c) is helpful in that it enables the visiting team to maximize the benefits from the visit whilst enabling the visited State Party to provide alternative means if, for some reason, it decides not to provide the documentation.

27. Insofar as the documentation in the context of facility investigations is concerned, it is in the interests of the investigated State Party to do all that it can to resolve any issues that arise during an investigation -- and the provisions in Article III, section G, subsection G include the option for the investigated State Party to provide alternative means should it decide not to provide full access to information.

28. **Sampling During Investigations.** In respect of investigations, there is Cat III language in respect of the detail regarding precisely where analysis of a sample shall take place -- thus there is Cat III language in Annex D I para 18 regarding *[Analysis [of a part of a sample] should, whenever possible, be carried out on the territory of the receiving State Party]*, in Annex D II Field Investigations para 44 regarding *Analysis [of one of the sealed duplicate samples referred to in paragraph 42] shall, whenever possible be carried out on the territory of the receiving State Party*, in Annex D. II para 47 regarding *samples shall be analysed in two designated and certified laboratories [in different States Parties]* and in Annex D. III Facility Investigations para 53 regarding *Where possible a sample [shall][may also] be analysed in an accredited and certified laboratory on the territory of the receiving State Party.*

29. In investigations, it is of crucial importance that the analytical results of samples shall be unequivocal and thus that the samples shall be analysed blind in designated and accredited laboratories in at least two States Parties with the possibility of further samples being analysed in a designated and accredited laboratory in a third State Party should the results from the first analyses be inconsistent. It is unsound and imprudent to suggest that samples from an investigation be analysed **only** in a designated and accredited laboratory in the receiving State Party -- and this would not be in the interests of the States Parties to the Protocol as it could bring the Protocol into disrepute.

30. In the context of sampling and analysis, attempts in the Protocol text to set deadlines, for example, for the carrying out of the analysis in the designated and certified laboratories in separate States Parties of samples taken during investigations are unwise as there can be no certainty that these designated and certified laboratories will have the capacity available to carry out these sample analyses within a set time. The Protocol regime will fall into disrepute if the analysis of samples is not carried out using the highest international standards.

31. **Access and Executive Council Procedures for Visits/Investigations.** There is Cat III language at various points in Article III and in Annex D relating to access, to the report of the visit/investigation and to Executive Council procedures. Thus, there is Cat III language in Art III D. II para 29 (f) that the visiting team shall:

*[(f) Have the right to state the relevance of questions asked by the visiting team and objected to by the visited State Party; the team leader may ask the visited State Party to reconsider its objection. The visiting team may note in the final report any refusal to permit interviews or to allow questions to be answered without any justification given for any such refusal by the visited State Party.]*

in paragraph 43 that:

*[The draft report shall also include an account of the degree and nature of access and the cooperation provided by the visited State Party in order to fulfil the visit mandate.]*

and in paragraph 46 that:

*[The Director-General may, with the consent of the visited State Party, provide copies of the final report, on request, to any other State Party.] [The Director-General shall, as a rule, provide copies of the final report, on request, to any other State Party, taking into account the provisions of Article IV, paragraph 4 (d) [, unless otherwise indicated by the visited State Party].]*

32. Likewise in Art III. G para 44, regarding access during investigations there is language that:

*[44. The investigation team may, during the course of the investigation, request the receiving State Party to provide access to a facility, building or other structure as objects of investigation within the area(s) designated for investigation [if the field investigation mandate already specifies that access to such a facility, building or other structure may be required, or] if access is required in order to fulfil the field investigation mandate. The investigation team shall, together with its request for access, provide the receiving State Party with information substantiating its request.*

and in para 52 regarding the review by the Executive Council of the final report of an investigation there is language that:

*[52. The Executive Council shall, in accordance with its powers and functions as determined in Article IX, section C, review and consider the final report of the investigation team as soon as it is presented, and address [and decide on] any concern as to whether:*

- (a) Any non-compliance has occurred;*
- (b) The request had been in accordance with the provisions of this Protocol;*
- (c) The right to request an investigation has been abused.]*

33. The access provided during visits and investigations is a crucial element of the Protocol regime as it is through access that transparency is demonstrated and confidence is built that the receiving State Party is in compliance with the Protocol and the Convention provisions. There are adequate provisions already in the Protocol to protect commercial proprietary information or national security information enabling the receiving State Party to use alternative means to meet the requirements of the visiting or investigating teams. It is important that the reports of visits and investigations include factual accounts of the access provided by the receiving State Party as this will facilitate the accurate appreciation by other States Parties of the effectiveness of the Protocol regime and, over time, build confidence. It should also be recalled that there are extensive provisions enabling the receiving State Party to review the report of the visit or investigation and to comment upon that report so that any inaccuracies can be readily countered and corrected. Consequently, reports of visits and investigations should be made available to other States Parties as it is through such reports that transparency is increased and confidence is built that the regime is being applied effectively and equitably to all States Parties.

34. **Waiver of Immunity for the Director-General and the OPBW.** The Cat III language originally in *Article IV Confidentiality Provisions* has now been removed and the whole question of the waiver of the immunity of the Director-General and the OPBW is now addressed in *Article IX The Organization in Section (E) Privileges and Immunities*. We recommend that the provisions for waiver of immunity for the Organization or the Director-General should be deleted as to retain such language is tantamount to an expression of no confidence in either the Organization or the Director-General. Absence of an explicit provision for waiver of the immunity of the Organization or the Director-General does not prevent the Conference of the States Parties from taking such action at some future date should it judge that this was necessary.

### ***C. Further Issues***

35. **Preambular language.** There was Cat III language in two places in the Preamble. The first is in paragraphs (9) and (10)

*[(9) Determined to achieve effective progress toward the prohibition and complete elimination of all types of weapons of mass destruction,*



***(10) Determined also to achieve effective progress toward general and complete disarmament under strict and effective international control,]***

**OR**

***[(9+10) Determined to act with a view to achieving effective progress toward general and complete disarmament under strict and effective international control, including the prohibition of all types of weapons of mass destruction,]***

and the second was in an earlier version of what is now paragraph (20 + 8) which is close to emerging from square brackets.

Our view, for the reasons developed in Evaluation Paper No. 15<sup>20</sup>, *Preamble*, March 2000, is that paragraphs (9) and (10) are acceptable as they stand as they are closely similar to the preambular language in the CWC and the BTWC and that the combined (9+10) could disappear. The reference to *complete elimination* in paragraph (9) should now be more acceptable following the 2000 NPT Review Conference which in the Final Document<sup>21</sup> in subpara 6 to paragraph 15 records:

*6. An unequivocal undertaking by the nuclear-weapon States to accomplish the total elimination of their nuclear arsenals leading to nuclear disarmament to which all States Parties are committed under Article VI.*

following the statement<sup>22</sup> by the five nuclear weapons States in which they state that:

*We reiterate our unequivocal commitment to the ultimate goals of the complete elimination of nuclear weapons and a treaty on general and complete disarmament under strict and effective control.*

**36. Redress Situation -- Report to UN General Assembly/Security Council.** In *Article V Measures to Redress a Situation and to Ensure Compliance* there is Cat III language in paragraph 4 concerning which United Nations body the issue should be brought to:

*4. The Conference or, alternatively, if the case is particularly grave and urgent, the Executive Council, may bring the issue, including relevant information and conclusions, to the attention of the [General Assembly [and] [or] the Security Council of the] [relevant organs of the] United Nations.*

Our view is that it should be brought to both the General Assembly and the Security Council in exactly the same way as for the CWC.

**37. Request for Assistance being Conditional on a Simultaneous Request for a Field Investigation.** In *Article VI Assistance and Protection against Biological and Toxin*

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<sup>20</sup>Graham S. Pearson & Nicholas A. Sims, *Preamble*, Evaluation Paper No. 15, University of Bradford, March 2000. Available at <http://www.brad.ac.uk/acad/sbtwc>

<sup>21</sup>Arms Control Today, *2000 NPT Review Conference Final Document*, Vol. 30, No. 5, pp. 28-34, June 2000.

<sup>22</sup>United Nations, *Letter dated 1 May 2000 from the representatives of France, the People's Republic of China, the Russian Federation, the United Kingdom of Great Britain and Northern Ireland and the United States of America addressed to the President of the 2000 Review Conference of the Parties to the Treaty on the Non-Proliferation of Nuclear Weapons*, NPT/CONF.2000/21, 1 May 2000.

*Weapons* there is Cat. III language in paragraph 10 which makes a request for assistance effectively conditional on a similar request for a field investigation.

*[Requests for assistance when a State Party considers that biological or toxin weapons have been used against it shall **[not be considered or otherwise acted upon by the Director-General or the Executive Council unless a field investigation request from the State Party making the Article VI request is submitted]** **[also be accompanied, either simultaneously or within [12] hours, by a request for a field investigation pursuant to Article III, section G].**]*

As there is no parallel requirement in the CWC, it is not apparent why assistance under the Protocol should be conditional. There is a failure to recognise that a State Party may well require assistance at a much earlier time, well before it has sufficient information to request a field investigation. Our advice is that this conditional linkage should disappear.

38. **Seat of Organization.** Article IX The Organization has paragraph 3 which states that 3. *The seat of the Organization shall be ...* as Cat III language as two bids from the Netherlands for The Hague and from Switzerland for Geneva have been lodged. The detailed bids have been called for by 13 October 2000 and it will become clear in due course which has been selected as the seat of the future Organization will be located.

39. **Executive Council representation from Asia/East Asia and the Pacific/West and South Asia.** The alternatives in paragraph 23 (b) of Article IX on page 116 for ... *States Parties from Asia* or ... *States Parties from East Asia and the Pacific* or ... *States Parties from West and South Asia* are all shown as Cat III language. This is primarily a matter for the countries in the region to resolve.

40. **Dispute Procedure.** In *Article XII Settlement of Disputes* there is Cat III language, highlighted in bold below, in paragraph 2 concerning the procedure to address disputes:

*The parties to a dispute **[shall]** **[may]** inform the Executive Council of the commencement of consultations, and shall keep the Executive Council informed of the actions being taken **[and their outcomes].***

Our recommendation is that in parallel with the CWC Article XIV requirement that *the States Parties involved shall keep the Executive Council informed of actions being taken* it would be logical under the Protocol to require that the parties shall inform the Executive Council of the commencement of their consultations and shall also inform the Executive Council of the outcomes.

41. **Frequency of Review Conferences (5/10 years).** In Article XIII Review of the Protocol, the alternatives of **[5][10]** years for the convening of the first Review Conference and the frequency of subsequent Review Conferences are shown as Cat III language. Our view is that the first Review of the Protocol should occur within 5 years after entry into force and subsequent Review Conferences should occur at 5 year intervals because this frequency has worked well for the BTWC and is also being used for the CWC -- and a first Review

Conference after 5 years is clearly not being regarded as too soon in the context of the CWC<sup>23</sup>.

42. **Amendments to Annexes/Appendices.** There is Cat. III language in Article XIV Amendments in both paragraph 1 and in paragraph 4 regarding proposals for changes in the technical sense of a simplified procedure, distinct from amendments, to Annexes and Appendices of the Protocol:

*[1. Any time after the entry into force of this Protocol any State Party may propose amendments to this Protocol or its Annexes or Appendices. Any State Party may also propose changes, in accordance with paragraph 4, to **[the Annexes and Appendices of this Protocol] [specified parts of this Protocol or its Annexes or to its Appendices].***

and

*4. In order to assure the viability and effectiveness of this Protocol, provisions in **[sections ... of the Annexes and Appendices] [the Appendices, sections ≡ of the Annexes, and those sections of Article III, section D, which are so identified in that Article,]** shall be subject to changes in accordance with paragraph 5, if the proposed changes are related only to matters of a technical or administrative nature.*

Our recommendation is that changes in this sense of a simplified procedure, distinct from amendments, should apply **only to specified** parts of the Protocol or its Annexes and Appendices, that **all** changes to Section I Lists and Criteria (Agents and Toxins) of Annex A should be made in accordance with paragraph 5 (thereby paralleling the CWC Article XV provisions in respect of the CWC Annex on Chemicals) and that changes should **not** apply to Annex D or to section I of Annex E (thereby paralleling the CWC Article XV provisions excluding parts of the Verification and the Confidentiality Annexes from the simplified procedure for changes).

43. **Entry into Force.** There is Cat III language *Article XX Entry into Force* in paragraph 1 regarding the conditions for entry into force:

*1. This Protocol shall enter into force 180 days after the deposit of instruments of ratification by **[45] [50] [65] [75] [...]** States **[, including the Governments of the Depositaries of the Convention,]** **[having advanced biological capabilities and technologies listed in Annex ...]** but not earlier than two years after its opening for signature.*

The paramount need is to achieve the earliest possible entry into force of the Protocol so that the strengthening of the regime can begin to benefit from the operation of the Organization. A requirement for a large number of ratification instruments before entry into force would delay the strengthening of the regime. With the Organization in existence, with full authority to implement and promote the Protocol, in accordance with Article IX, the Protocol in our judgement will gather momentum and the number of States Parties will increase significantly as confidence grows in the Organization and its operations. We therefore favour a simple

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<sup>23</sup>Organization for the Prohibition of Chemical Weapons, *Opening Statement by the Director-General to the Conference of the States Parties at its Fifth Session*, C-V/DG.11, 15 May 2000. Available at <http://www.opcw.org>

numerical condition for entry into force, with no requirement for particular ratifications within this number, which should be kept low. Our recommendation is thus that paragraph 1 should read as follows:

1. *This Protocol shall enter into force 180 days after the deposit of instruments of ratification by 20 States but not earlier than two years after its opening for signature.*

**44. Reservations.** There is Cat III language in *Article XXI Reservations* as follows:

*[The Articles of this Protocol [shall not be subject to reservations] [incompatible with its object and purpose or that of the Convention]. The Annexes and Appendices of this Protocol [shall not be subject to reservations] [incompatible with its object and purpose or that of the Convention].]*

Our advice is based on Evaluation Paper No. 6, *Article XXI: Reservations*, September 1999 as further developed in Evaluation Paper No. 17<sup>24</sup> when we recommended the following language for Article XXI:

*The Articles of and the Annexes and Appendices to this Protocol shall not be subject to reservations. In addition, no exceptions or conditions, however phrased or named, including interpretative statements or declarations, which purport to exclude or modify the legal effect of the provisions of the Articles and the Annexes and Appendices to this Protocol in their application to any State, may be made by any State upon signing, ratifying or acceding to this Protocol.*

The additional final sentence is necessary in order to prevent, as comprehensively as possible, any attempt to circumvent the ban on reservations by means of statements, declarations, exceptions or conditions which similarly purport to exclude or modify the legal effect of any part of the Protocol in its application to any State.

### **Proposed Complete Text**

45. The proposed complete text has been prepared to show how the April 2000 (AHG/51) Part I Protocol text might be amended to arrive at a final complete text. The proposals for further consideration made in the April 2000 (AHG/51) Part II text have been taken into account along with the amendments proposed in the previous Evaluation Papers in arriving at the complete text. Particular attention has been paid to language which had been categorized by the FOC as being in Cat. III "strong conceptual differences in views". New language is shown in bold and footnotes, where appropriate, explain the basis for the amended language.

46. The objective of the revised complete text is to introduce realism and to strike a balance between the different aspirations of the individual States Parties so as to arrive at an integrated, worthwhile and valuable Protocol that will be both acceptable to all States Parties, bring significant benefits to all States Parties and meet the majority, if not all, of their individual objectives for the Protocol.

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<sup>24</sup>Evaluation Paper No. 17, *The BTWC Protocol: Proposed Complete Text For An Integrated Regime*, March 2000 provided a proposed clean text based on the February 2000 draft protocol text in AHG/50 (Part I).

A PROTOCOL TO THE CONVENTION ON THE PROHIBITION OF THE  
DEVELOPMENT, PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL  
(BIOLOGICAL) AND TOXIN WEAPONS  
AND ON THEIR DESTRUCTION

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\*For clarity and to avoid confusion, the current Annex and Appendix designations have been retained although Annexes B, C, F and G and Appendices D and F have been deleted from this proposed complete text.

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\*For clarity and to avoid confusion, the current Annex and Appendix designations have been retained although Annexes B, C, F and G and Appendices D and F have been deleted from this proposed complete text.



## PREAMBLE<sup>25</sup>

The States Parties to this Protocol,

- (1)<sup>26</sup> Being Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, which was opened for signature on 10 April 1972, and entered into force on 26 March 1975, hereinafter referred to as the Convention,
- (2) Reaffirming the purposes laid down in the preamble to the Convention as well as their obligations under the Convention, and desiring to further its objectives,
- (3) Emphasizing that the principles and objectives of the Geneva Protocol of 1925 and the Convention represent an unequivocal determination for the sake of all humankind to exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons,
- (4) Mindful of their obligations under the Convention never in any circumstances to develop, produce, stockpile or otherwise acquire or retain microbial or other biological agents or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes or weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict,
- (5) Stressing the importance of the final declarations of successive Review Conferences of the Convention, and emphasizing, in particular, the unanimous reaffirmation that the use by States Parties, in any way and under any circumstances, of microbial or other biological agents or toxins, that is not consistent with prophylactic, protective or other peaceful purposes, is effectively a violation of Article I of the Convention,
- (6) Determined to implement all the provisions of the Convention in a comprehensive and balanced manner in order to maintain and enhance regional and international peace and security and promote international development,
- (7) Convinced that strengthening and enhancing the preamble and the provisions of the Convention, adopting specific measures to improve its implementation and effectiveness, and encouraging universal adherence to the Convention and this Protocol, will deliver significant benefits in terms of international security and development,
- (8) Determined to achieve effective progress toward the prohibition and complete elimination of all types of weapons of mass destruction,
- (9) Determined also to achieve effective progress toward general and complete disarmament under strict and effective international control, which is the ultimate objective of the efforts of States in the disarmament process,

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<sup>25</sup>The amendments made to the Preamble are based on the analysis in Evaluation Paper No. 15, *Preamble*, March 2000.

<sup>26</sup>Although in the final Protocol, the preambular paragraphs will not be numbered, the numbering has been retained here for convenience.

(10) Welcoming the entry into force of the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction, signed at Paris on 13 January 1993,

(11) Recognizing the significant advances in the field of biotechnology since the entry into force of the Convention, and the potential implications, both positive and negative, of these advances for the implementation and effectiveness of the Convention,

(12) Conscious of the apprehension arising from relevant scientific and technological developments as expressed by States Parties at Review Conferences of their use for purposes inconsistent with the objectives and the provisions of the Convention, **and of their reaffirmation that Article I covers all such developments,**

(13) Determined to ensure that all achievements in this field are used exclusively for the benefit of mankind,

(14) Reaffirming the obligation of each State Party to the Convention under Article III not to transfer to any recipient whatsoever, directly or indirectly, and not in any way to assist, encourage, or induce any State, group of States or international organizations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in Article I of the Convention,

(15) Concerned with the increasing gap between the developed and the developing countries in the field of biotechnology, genetic engineering, microbiology and other related areas,

(16) Desiring to promote international cooperation and exchange of bacteriological (biological) agents and toxins, and equipment, materials and scientific and technological information in the field of biotechnology for purposes not prohibited under the Convention to enhance the economic and technological development of all States Parties,

(17) Emphasizing the increasing importance of the implementation of the provisions of Article X of the Convention and the obligations of each State Party under that Article, as well as under this Protocol, especially in the light of recent scientific and technological developments in the field of biotechnology, bacteriological (biological) agents and toxins for peaceful purposes, which have vastly increased the potential for cooperation between States to help to promote economic and social development, and scientific and technological progress particularly in developing countries,

(18) Determined to promote international cooperation on all developments in the field of frontier science and high technology in areas relevant to the Convention, and urging **all States Parties** possessing advanced biotechnology and knowledge in such fields as medicine, public health and agriculture to adopt positive measures and to continue to promote technology transfer and cooperation on an equal and non-discriminatory basis, in particular with the developing countries, for the benefit of all mankind,

(19) Convinced that the most effective way to promote a world free of biological and toxin weapons is through strengthening the provisions of the Convention by the measures contained

in this Protocol, and through promoting universal adherence to the Convention and this Protocol;

(20) Further convinced that this will deliver significant benefits in terms of international security and development,

(21) Determined to strengthen and improve the effective implementation of the Convention,

Have agreed as follows:

## ARTICLE I

### GENERAL PROVISIONS<sup>27 28</sup>

1. Each State Party to this Protocol reaffirms its obligations under the Biological and Toxin Weapons Convention<sup>29</sup> **and in order to strengthen the effectiveness and improve the implementation of the Convention undertakes to implement measures, as set out in the Protocol**, which include, *inter alia*:

(a) Declarations to be submitted and visits to be conducted in accordance with Article III, section D of this Protocol;

(b) Investigations to be conducted in accordance with Article III, section G of this Protocol;

(c) Measures to be taken in accordance with Article VII of this Protocol to enhance compliance and ensure effective and full implementation of Article X of the Convention.

2. States Parties shall have the right to protect commercial proprietary information and national security information in accordance with the provisions of this Protocol. This right may not be invoked by a State Party to conceal evasion of its obligations nor to engage in activities prohibited under the Convention.

3. To enhance confidence in the continued compliance with the Convention by all States Parties, through increased transparency of relevant facilities and activities, information about the implementation of the measures set out in this Protocol shall be routinely provided, in accordance with the provisions of this Protocol:

(a) To States Parties;

(b) To the relevant organs of the Organization if it is considered that such information is necessary for the performance of functions entrusted to those organs.

4. Each State Party to this Protocol shall, in accordance with its constitutional and legal processes:

(a) Ensure that this Protocol and its national legislation are compatible with each other;

(b) Adopt the necessary measures to implement its obligations under this Protocol.

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<sup>27</sup>Our view is that the Protocol is concerned with strengthening the effectiveness and improving the implementation of the BTWC and, as such, is **not** the place to amend the basic obligations under the Convention. Such amendments are beyond the mandate of the Ad Hoc Group. The extension of the understanding among States Parties to the Convention of their obligations under the Convention is appropriate for consideration at the Review Conferences of the Convention.

<sup>28</sup>The text in AHG/52 (Part II) has been used as the baseline for this section.

<sup>29</sup>This is a Protocol to the BTWC and therefore references to the Geneva Protocol of 1925 are, with the sole exception of the reference in Article XI, inappropriate in the operative part, or Articles, of the Protocol. Such references are rightly made within the Preamble which sets the Protocol in the wider context (see Evaluation Paper No. 15, *Preamble*, March 2000).

5. All provisions under the Protocol shall apply to States Parties on an equal basis.
6. Without prejudice to their rights and obligations under Article V of the Convention, the States Parties to this Protocol undertake to consult one another and to cooperate in solving any problems which may arise in relation to the object and purpose of the Convention or the full and effective implementation of the measures set out in this Protocol by all States Parties, inter alia through the procedures for consultation, clarification and cooperation set out in Article III, section E of this Protocol.

ARTICLE II  
DEFINITIONS<sup>30</sup>

For the purposes of this Protocol:

1. "Bacteriological (biological) and toxin weapons" means **the following together or separately**<sup>31</sup>:

(1) **Microbial or other** biological agents or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;

(2) Weapons, equipment, or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

2. "Biological Agents" means

**Microbial or other biological agents or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;**

**(Biological agents and toxins which have been identified for the purpose of declarations under this Protocol are listed in Annex A.)**<sup>32</sup>

3. "Purposes not prohibited by the Convention" means

Any purpose, which has prophylactic, protective or other peaceful intention.

4. "Organization" means **the Organization for the Prohibition of Biological and Toxin Weapons established pursuant to Article IX of this Protocol.**<sup>33</sup>

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<sup>30</sup>As already noted above in respect of *Article I General Provisions*, the Protocol is concerned with strengthening the effectiveness and improving the implementation of the BTWC and, as such, is **not** the place to amend the understanding of the Convention. It is recalled that the mandate of the Ad Hoc Group required consideration *inter alia* of *definitions of terms and objective criteria ... where relevant for specific measures designed to strengthen the Convention*. Those definitions necessary for the effective implementation of Article III of the Protocol have been transferred to *Annex A. I. Definitions*.

<sup>31</sup>The formulation "*means the following together or separately*" is unambiguous and is preferred to the ambiguous language in AHG/52 that "*The term "Bacteriological(biological) and toxin weapons" together or separately shall be applied to the following*".

<sup>32</sup>This language reflects that in the CWC, *Article II Definitions and Criteria*, paragraph 2. The language in AHG/52 (Part I) is ambiguous as the formulation "For the purpose of implementing this Protocol, a list of biological agents [relevant to declarations] is contained in Annex A." undesirably extends the utility of the list of agents beyond declarations. The words proposed here avoid this ambiguity.

<sup>33</sup>This language reflects that in the CWC *Article II Definitions and Criteria*, paragraph 11.

## ARTICLE III

### COMPLIANCE MEASURES

#### A. LISTS AND CRITERIA (AGENTS AND TOXINS)

1. Each State Party shall **adopt the necessary measures to subject** agents and toxins **listed** in Annex A, section I, **to compliance measures as provided in Article III.**<sup>34</sup>
2. The Conference of States Parties shall, taking into account scientific and technical **developments**, and in accordance with **Article XIV**, examine proposals **relating to changes** whereby microbiological or other biological agents and toxins are to be included in or excluded from the lists, and shall take a decision thereon.

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<sup>34</sup>This text has been amended to reflect more closely the language in the CWC relating the Schedules of Chemicals to the verification measures as in the CWC Article VI, paragraph 2.

## B. EQUIPMENT

1. Each State Party shall **adopt the necessary measures to provide** information concerning equipment **listed** in Annex A, section II, **as required in the compliance measures provided in Article III.**
2. The Conference of States Parties shall, taking into account scientific and technical **developments, and in accordance with Article XIV,** examine proposals **relating to changes** whereby equipment is to be included in or excluded from the list, and shall take a decision thereon.



### C. THRESHOLDS<sup>35</sup>

**1. Each State Party shall adopt the necessary measures to provide information as required in the compliance measures provided in Article III. The information required for completion of the Declaration Formats specified in the Annexes referred to in Article III will include provision of information as to whether production capability exceeds certain specified threshold capacities. In addition, information shall be provided on aggregate quantities as specified in the Declaration Formats.**

**2. The Conference of State Parties shall, taking into account scientific and technical developments, and in accordance with Article XIV, examine proposals for changes whereby the threshold capacities and aggregate quantities specified in the Declaration Formats shall be increased, reduced or excluded and shall take a decision thereon.**

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<sup>35</sup>This text has been amended to make it clear that the completion of the Declaration Formats will require States Parties to provide information on whether specified threshold capacities are exceeded and on aggregate quantities. There is no requirement for the identification of specific quantities of individual listed agents as such quantities have no significance as the question of whether or not a particular quantity of a specific agent is of a type or quantity that has no justification for prophylactic, protective or other peaceful purposes. Judgement will depend on the specific individual circumstances.

## D. DECLARATIONS

### I. SUBMISSION OF DECLARATIONS

1. Each State Party shall declare to the Organization, regardless of the form of their ownership or control, all activities and facilities listed below which exist or existed on its territory or in any other place under its jurisdiction or control during the period specified.

†<sup>36</sup>

2. All declarations submitted in accordance with paragraph 1 above shall be submitted to the Organization, in accordance with the appropriate format in the Appendix, not later than 180 days after this Protocol enters into force for it and, in the case of annual declarations, **declarations for the previous calendar year shall be submitted** not later than 30 April<sup>37</sup> of each successive year thereafter. **The terms used in this section are defined in Annex A, section 1.**<sup>38</sup>

3.<sup>39</sup> The Executive Council may review periodically the declaration formats' structure and contents to ensure the effective implementation and operation of Article III, section D. Any State Party may propose modifications to the declaration formats which shall be subjected to review by the Executive Council. In reviewing the declaration formats, the Executive Council shall consider, *inter alia*, scientific and technological developments that may affect their operational structure and contents.

4. A State Party hosting a facility or facilities owned or controlled by another State Party, shall have the right to gain access to information and/or to receive such information required to fulfil its obligations under this section, from the other State Party.

#### INITIAL DECLARATIONS

##### (A) OFFENSIVE BIOLOGICAL AND TOXIN PROGRAMMES AND/OR ACTIVITIES CONDUCTED PRIOR TO THE ENTRY INTO FORCE OF THE PROTOCOL FOR EACH STATE PARTY

5. Each State Party shall declare, in accordance with paragraphs 1 and 2 above whether, at any time since 1 January 1946<sup>40</sup> until entry into force of the Protocol for that State Party, it

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<sup>36</sup>Paragraph 2 of AHG/52 (Part I) Article III D. Declarations section I has been deleted as this is addressed in Article III. H. Other Provisions.

<sup>37</sup>The choice of 30 April for the due date for submission of annual declarations is presumably to allow an appropriate period of time to enable declarations for the last calendar year to be compiled. In the CWC Verification Annex, the requirement for annual declarations requires that these be submitted "*not later than 90 days after the end of the previous calendar year.*" The additional words are required to make it unambiguous that the annual declaration is to provide a declaration for the previous calendar year.

<sup>38</sup>All definitions for use in Article III section D have been collected in Annex A section 1.

<sup>39</sup>Although it has been proposed that this paragraph is unnecessary because of the provisions of *Article XIV Amendments*, we recommend that it be retained as there is no specific mention in either Article XIV, or *Article IX The Organization* to review and amendment of declaration formats. Such periodical review is necessary to ensure that the Protocol declaration formats are kept up to date with developments.

<sup>40</sup>1 January 1946 is appropriate because it is the date which was agreed for the CBM F agreed at the Third Review Conference. As the Protocol is intended to strengthen confidence in compliance, it would be contrary to that stated objective to adopt a later date. An earlier date would be impractical as little information might be

has developed, produced, stockpiled or otherwise acquired or retained, and whether, during the same period, it has used:

- (a) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;
- (b) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict;

The State Party shall provide a summary<sup>41</sup> of any such programme(s) and/or activities, indicating work concerned performed concerning research and development, production, testing and evaluation, weaponization, and/or stockpiling of biological agents, toxins and/or weapons, equipment or means of delivery for hostile purposes or in armed conflict<sup>42</sup>. The State Party shall also provide a summary of activities performed to destroy such agents, toxins and/or weapons, equipment or means of delivery for hostile purposes or in armed conflict and/or to divert them to peaceful purposes. The declaration shall also include a list of all participating facilities and test ranges **indicating for each one whether it has been converted/dismantled or destroyed since 1 January 1946.**<sup>43</sup>

(B) DEFENSIVE BIOLOGICAL AND TOXIN PROGRAMMES AND/OR ACTIVITIES CONDUCTED PRIOR TO ENTRY INTO FORCE OF THE PROTOCOL FOR EACH STATE PARTY

6. Each State Party shall declare, in accordance with paragraphs 1 to 2 above, whether at any time since 1 January 1946<sup>44</sup> it has conducted programmes<sup>45</sup> and/or activities as part of any effort to directly protect or directly defend humans, animals or plants against the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict. If so, the State Party shall provide a summary<sup>46</sup> of:

- (a) The general objectives of activities that were part of such programmes and/or activities;

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available for the earlier years. In any event, adoption of a date of 1 January 1946 does not prevent States from making more comprehensive and informative declarations that provide information on earlier years as was done by some States in making declarations under CBM F.

<sup>41</sup>The word "*summary*" is important as this makes it explicit that excessive detail is not being sought in these declarations. It further implies that although the summaries should be as complete as possible, inadvertent omissions will not be regarded as a failure to make a complete declaration.

<sup>42</sup>The additional words "*equipment or means of delivery for hostile purposes or in armed conflict*" are necessary to avoid inadvertent exclusions.

<sup>43</sup>There is a logical argument that, in the interests of building confidence, this date should also be 1 January 1946. In addition, 1 January 1946 avoids uncertainties which would otherwise arise about what happened to facilities and test ranges mentioned in the 1 January 1946 declaration.

<sup>44</sup>1 January 1946 is appropriate because it is the date which was agreed for the CBM F agreed at the Third Review Conference. As the Protocol is intended to strengthen confidence in compliance, it would be contrary to that stated objective to adopt a later date.

<sup>45</sup>As the intention is to build confidence, the declaration should be comprehensive and should not omit any aspect. Omissions raise queries and potential concerns.

<sup>46</sup>The word "*summary*" is important as this makes it explicit that excessive detail is not being sought in these declarations. It further implies that although the summaries should be as complete as possible, inadvertent omissions will not be regarded as a failure to make a complete declaration.

- (b) Any research and development, testing or evaluation, and production<sup>47</sup> conducted as part of such programmes and/or activities that involved prophylaxis, pathogenicity/virulence, diagnostic techniques, detection, aerobiology, **medical**<sup>48</sup> treatment **or** toxinology, physical protection, and decontamination.

The State Party shall additionally declare information on such programmes and/or activities performed during the period from the date ten years prior to entry into force of the Protocol until entry into force for that State Party, as required in the appropriate format in the Appendix.

7. Each State Party shall declare any information that subsequently comes to its notice that would have been required to have been declared pursuant to paragraph 5 and 6 above had such information been known one year after this Protocol entered into force for that State Party, not later than 180 days after such information is discovered.

#### ANNUAL DECLARATIONS

##### (C) DEFENSIVE BIOLOGICAL AND TOXIN PROGRAMMES AND/OR ACTIVITIES CONDUCTED DURING THE PREVIOUS YEAR

8. Each State Party shall declare, in accordance with paragraphs 1 **and** 2 above, whether at any time during the previous calendar year **it has conducted**<sup>49</sup>:

(a) Activities<sup>50</sup> as part of programmes or any other efforts to protect or defend humans, animals, or plants against the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict. If so, it shall declare:

- (i) All such activities;
- (ii) The general objectives and main elements, and funding arrangements of such research and development, testing and evaluation, production programmes and/or activities;
- (iii) In summary form, the **work** conducted as part of such programmes and/or activities **including**<sup>51</sup> **the following:** prophylaxis, pathogenicity/virulence, diagnostic techniques, detection, aerobiology, medical treatment or toxinology, physical protection, and decontamination<sup>52</sup>;

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<sup>47</sup>As the intention is to build confidence, the declaration should be comprehensive and should not omit any aspect. Omissions raise queries and potential concerns.

<sup>48</sup>Amendment made for consistency with paragraph 8 (b) (iii) below.

<sup>49</sup>The requirement is for a simple unambiguous declaration that is clear and embraces all States Parties having defensive programmes.

<sup>50</sup>As the intention is to build confidence, the declaration should be comprehensive and should not omit any aspect. Omissions raise queries and give rise to potential concerns.

<sup>51</sup>This is needed to avoid limiting the summary to **only** the selection of topics identified.

<sup>52</sup>Production fermentation capacities is deleted as this is different in nature from the other listed topics.

(b) Declare all facilities where five<sup>53</sup> or more person years of technical and scientific effort were devoted to the programmes and/or activities specified in subparagraph (a) above. Where less than five facilities have to be declared, declare in addition all facilities where more than 10 per cent of the total scientific and technical person years were devoted by the State Party to such programmes and/or activities;

(D) VACCINE PRODUCTION FACILITIES

9. Each State Party shall declare, in accordance with paragraphs 1 **and 2** above, each facility which, during the previous calendar year with primary production containment produced with the use of fermenters and/or bioreactors, embryonated eggs or other means, or produced with the use of fermenters and/or bioreactors, embryonated eggs or other means and recovered by concentration or isolation, microorganisms or substances, causing a specific and protective immune response as an ingredient of:

(a) Any vaccine for humans for public use or for armed forces, or which was licensed, registered or otherwise approved by a component of the government of the State Party for distribution or sale;

(b) Any vaccine for animals for public use<sup>54</sup> or any vaccine for animals which was licensed, registered or otherwise approved by a component of the government of the State Party for distribution or sale.

(E) MAXIMUM BIOLOGICAL CONTAINMENT FACILITIES

10. Each State Party shall declare, in accordance with paragraphs 1 **and 2** above, all facilities designated as maximum biological containment.

†<sup>55</sup>

(F) PLANT PATHOGEN CONTAINMENT

11. Each State Party shall declare, in accordance with paragraphs 1 **and 2** above, all facilities designated as plant pathogen containment **facilities**.

(G) WORK WITH LISTED AGENTS AND/OR TOXINS

12. Each State Party shall declare, in accordance with paragraphs 1 **and 2** above, each facility which, during the previous calendar year, has conducted any of the following activities with agents and/or toxins listed in Annex A:

(a) Research and development performed in areas protected by high biological containment;

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<sup>53</sup>Detailed information on facilities where less than five or more person years of technical and scientific effort were devoted to the programmes and/or activities would run the risk of being an undue burden. The aim should be to declare all activities but to limit the detailed information to those with more than 5 person years of effort in those States Parties with relatively large defensive programmes whilst not excluding the need for declarations from States Parties with small defensive programmes.

<sup>54</sup>The words in AHG/52 "for public sale" or "that is available to the general public" are more limiting than the term in the earlier draft Protocol "for public use".

<sup>55</sup>High biological containment has been incorporated into (G) Work with Listed Agents and/or Toxins.

(b) Production of one or more agents and/or toxins listed in Annex A, using **the following techniques in which the stated threshold capacities are exceeded:**

(i) Any fermenter(s)/bioreactor(s) with a total internal volume of 50 litres or more; or

(ii) Continuous or perfusion fermenters/bioreactors with a flow rate capable of exceeding 2 litres an hour; or

(iii) A chemical reaction vessel or equipment used for recovery with a total internal volume of 50 litres or more; or

(iv) More than 2,000 embryonated eggs on an annual basis; or

(v) More than 1,000 litres of tissue culture or other medium on an annual basis;

(c) Modification of any nucleic acid sequence of agents, or coding for toxins, listed in Annex A;

(d) Insertion of a nucleic acid sequence coding from an agent or coding for any toxin listed in Annex A or coding for a toxic subunit of such a toxin, into any organism, resulting in a genetically modified organism with imposed disease-causing or toxic properties characteristic of one or more agents and/or toxins listed in Annex A or facilitating the production of any such toxin or its toxic subunit;

(e) Intentional aerosolization of any agent and/or toxin listed in Annex A or any work with aerosolized agents and/or toxins listed in Annex A in/by

(i) An explosive aerosol test chamber; or

(ii) A dynamic aerosol test chamber; or

(iii) A static aerosol test chamber; or

(iv) Open air; or

(v) Application to the respiratory tract of an animal;

(f) Maintenance of culture collections in maximum or high containment installations.

**Diagnostic facilities shall not be declared under this paragraph.**

**(H) OTHER PRODUCTION FACILITIES**

**13.** Each State Party shall declare, in accordance with paragraphs 1 **and** 2 above, each facility which, during the previous calendar year, under primary production containment

- (i) Produced; or
- (ii) Produced or recovered by concentration or isolation;

any microorganisms or other substances for use, directly or after chemical modification as an active ingredient in:

- (i) Any preparation, other than vaccine or food and beverages for humans and animals, for the prevention or treatment of disease in humans and animals; or
- (ii) Diagnostic reagents; or
- (iii) Biocontrol agents or plant inoculants;

using one of the following **in which the stated threshold capacities are exceeded**:

- (a) Any fermenter/bioreactor exceeding 300 litres in volume; or
- (b) Any continuous or perfusion fermenter/bioreactor with a flow rate exceeding 50 litres per hour; or
- (c) More than 15,000 embryonated eggs annually; or
- (d) More than 10,000 litres of tissue culture medium annually; or
- (e) More than 10,000 litres of growth medium annually.

**14.** A facility shall not be declared under paragraph **13** above if such production of microbial or biological agents or toxins was performed exclusively for:

- (a) Bioremediation or waste treatment; or
- (b) Manufacture for sale or use of soap, cosmetics, detergents, fertilizers, **non-biologically active ingredients of** pharmaceuticals, or foods or beverages for humans or animals; or
- (c) Research and development of the products listed in subparagraph (b) above; or
- (d) Teaching the manufacture of the products listed in subparagraph (b) above.

**(I) OTHER FACILITIES**

15. Each State Party shall declare, in accordance with paragraphs 1 **and** 2 above, each facility which, during the previous calendar year, conducted activities with any biological agent and/or toxin and which also:

(a) Possessed aerosol test chambers of 1 cubic metre or above for work with microorganisms or toxins;

(b) Possessed equipment with a capacity of 1 litre or more for aerosol dissemination in the open air with a particle mass median diameter not exceeding 10 microns excluding those for agricultural, health or environmental use;

(c) Conducted genetic modification to enhance pathogenicity, virulence, stability or resistance to antibiotics or chemical or physical methods of disinfection, or which altered the host range, the infection route or the ease of identification or diagnosis, within a high biological containment facility.

**(J) OTHER DECLARATIONS<sup>56</sup>**

16. Each State Party shall declare, in accordance with paragraphs 1 **and** 2 above, the following:

(a) All international transfers during the previous calendar year of agents and/or toxins, equipment listed in Annex A.

**(b) Declarations pursuant to Article III, section F.**

**(c) Declarations pursuant to Article VII and Appendix E.**

**(d) Declarations pursuant to Article X.**

(e) A list of the number, dates and titles of legislation, regulations, directives, orders or other administrative and legal measures that govern, regulate, provide guidance on or otherwise control:

(a) Access to buildings or other structures in which pathogens or toxins are being produced, handled or stored;

(b) Access to buildings or other structures or areas in which an outbreak of infectious disease affecting humans, animals or plants is suspected or is known to be occurring.

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<sup>56</sup> It is important to provide language in *Article III, Section D Declarations* which refers to all declarations required under the Protocol --this is achieved by Section *(J) Other Declarations* -- as such inclusion will bring all declarations within the provisions to ensure submission of declarations. It is evident from the experience under the CWC that States Parties have been very dilatory in meeting some of their declaration obligation.



**17. Each State Party shall provide to the relevant competent international body, such as the WHO, OIE and FAO, information, in accordance with the requirements of that international body on outbreaks of disease occurring on its territory. Should the State Party not be a member State of the WHO, OIE or FAO then it shall provide comparable information to the Organization.<sup>57</sup>**

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<sup>57</sup>Briefing Papers No. 21, *Outbreaks of Disease: Current Official Reporting*, April 1999, No. 24, *Outbreaks of Disease: Current European Reporting*, September 1999, and No. 23, *BTWC Security Implications of Human, Animal and Plant Epidemiology*, July 1999 have shown that there is no justification for dual reporting of outbreaks of disease. It is evident that reporting to the relevant international body -- WHO, OIE and FAO -- should be encouraged. Consequently, we recommend that reporting to the Organization only be made by States Parties who are not member States of the international bodies WHO, OIE and FAO.

## II. FOLLOW-UP AFTER SUBMISSION OF DECLARATIONS<sup>58</sup>

1. The Technical Secretariat shall receive, process, analyse, and store declarations submitted by States Parties in accordance with the provisions of this Protocol.

2. Upon receipt of a request by a State Party which has submitted its own declarations, the Director-General shall make available to that State Party in accordance with the provisions on confidentiality contained in Article IV and Annex E of this Protocol copies of the initial and/or annual declarations of other States Parties, as specified in the request. The Director-General shall simultaneously inform the State(s) Party(ies) concerned that copies of their declarations have been made available to the requesting State Party.

3. In order to increase confidence in the consistency of declarations submitted by States Parties and to encourage submission of comprehensive declarations, the Technical Secretariat shall:

(a) Process and analyse the declarations;

(b) Conduct a limited number per year of visits to facilities declared<sup>59</sup> pursuant to Article III, section D, subsection I, parts (C), (D), (E), (F), (G), (H) and (I) in accordance with the procedures set out in part A below;

(c) If it, in its analysis pursuant to paragraph 3 (a) above, identifies any ambiguity, uncertainty, anomaly or omission of a purely technical nature related solely to the content of the declaration, seek clarification from the State Party concerned, in accordance with the procedures set out in part B below;

(d) Provide technical assistance to States Parties to help them compile individual facility and national declarations including, if requested, by means of visiting a State Party, in accordance with the procedures set out in part C below.

4. A State Party which identifies any ambiguity, uncertainty, anomaly or omission in the declaration of another State Party may seek clarification from the State Party concerned, in accordance with the provisions of section E of this Article, or it may initiate the clarification process set out in part B below.

### Visit schedule

5. The total number of all visits conducted pursuant to this Article shall not exceed **100**<sup>60</sup> in each calendar year. The Third Conference of States Parties shall review the total numbers of visits in light of experience gained in the operation of this section.<sup>61</sup>

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<sup>58</sup>The text in AHG/52 (Part II) has been used as the baseline for this section.

<sup>59</sup>For the reasons set out in a number of Briefing Papers (No. 2, 10, 18, 20,25, 26), we consider that in order to build confidence in the consistency of declarations and to encourage submission of comprehensive declarations it is necessary that a limited number of randomly-selected visits are made to declared facilities each year.

<sup>60</sup>This figure is based on a realistic assessment of what the BTWC Organization will be able to carry out effectively each year. See Briefing Paper No. 20, *Visits: An Essential Portfolio*, April 1999, para 69.

<sup>61</sup>It is considered prudent to make provision for the overall number of visits conducted under the Protocol to be reviewed at the Third Conference of States Parties as it is clear that the States Parties will have more than enough control of the actual number in any year through their annual scrutiny and approval of the programme and budget of the BTWC Organization.

6. The quota for individual types of visits shall be as follows:

(a) The quota for visits pursuant to paragraph 3 (b) shall be half of the total for visits specified in paragraph 5;

(b) The quota for visits pursuant to paragraph 3 (d) and part C shall be one quarter of the total for visits specified in paragraph 5;

**(c) The quota for visits conducted pursuant to paragraph 3 (c) or 4 shall be the remainder of the total for visits specified in paragraph 5;<sup>62</sup>**

(d) Subject to the provisions in paragraph 5 above and subparagraph (e) below, the total number of visits conducted each year for each category of visits referred to in subparagraphs (a) and (b) above may exceed the quota allocated for the respective category of visit if the Executive Council deems it appropriate. In deciding on any reallocation, the Executive Council shall take into account the budget for visits and the objectives set forth in paragraph 3;

**(e) Should the quota for visits conducted pursuant to paragraph 3(c) or 4 under subparagraph (c) above be insufficient, then provision for additional visits in any year shall be made according to the following procedure.** The first visit in any year **additional to the quota in paragraph (c) above** resulting from the procedures set forth in paragraphs 3 (c) or 4 shall be deducted from the total number of visits conducted pursuant to paragraph 3 (b). Thereafter any visits required under paragraph 3 (c) or 4 shall be deducted alternately from the quotas allocated to visits conducted pursuant to paragraph 3 (d) and part C, and visits conducted pursuant to paragraph 3 (b).

#### Annual programme

7. At the end of each year, the Director-General shall prepare a visit schedule for the following year. States Parties shall, wherever possible, submit invitations for voluntary assistance visits and, where known, clarification visits volunteered, not later than 1 December each year to enable the Director-General to prepare the visit schedule for the subsequent year. On receipt of an invitation for such a visit, the Director-General shall include the visit in his/her schedule for visits for the following year. The Director-General shall submit the schedule containing the details for the voluntary assistance visits and voluntary clarification visits already known to the Executive Council at its first session of each year. If the number of invitations exceeds the ceiling prescribed above, the Director-General shall report this fact to the Executive Council at its first session of each year. If during the year, the numbers of invitations for voluntary assistance visits exceed the initial quota pursuant to paragraph 6, the Director-General shall report this fact to the Executive Council. The Director-General shall also include recommendations on the priority of each visit in light of the information submitted by the State Party and available resources.

8. The Executive Council shall decide on the programme for the year including, if necessary, how to proceed if the number of invitations exceeds the overall ceiling provided for in this section. The Director-General shall not later than seven days after the first session

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<sup>62</sup>The provisions made in AHG/52 (Part II) in paragraph 6 on page 21 are incomplete and are not self consistent.

of the Executive Council notify all States Parties of the schedule for the voluntary assistance visits and any outstanding visits pursuant to paragraphs 3 (c) and 4.

### Review of annual programme

9. The Director-General shall submit to the Executive Council every three months, or earlier if necessary, a report on the implementation of visits of each type and on outstanding invitations for voluntary assistance and voluntary clarification visits. If it judges it necessary, the Executive Council may decide to adjust the initial allocations, between the types of visits, specified in paragraph 6. The Director-General shall notify the Executive Council of any changes to the visit schedule at its next session.

9 *bis* If the procedure in paragraph 6 (e) above results in the number of visits of any type falling below the **quota** for that visit type, the Executive Council shall decide on any deductions or reallocations and make any readjustments as necessary.

### (A) VISITS

#### Purpose

10. The Technical Secretariat shall conduct visits pursuant to paragraph 3 (b) of this subsection, which shall be confidence-building in nature. These visits shall, through cooperation with the visited State Party, promote the overall objectives of the Protocol by:

(a) Increasing confidence in the consistency of declarations submitted by States Parties and encouraging submission of comprehensive declarations; and also by

(b) Enhancing transparency of facilities and helping the Technical Secretariat, subject to the provisions of this section, to acquire and retain a comprehensive and up-to-date understanding of the facilities and activities declared globally.

11. In addition, if so requested by the visited State Party in its acknowledgement of receipt of notification of the visit, the visit shall be extended by up to two working day. The purpose of any requested extension shall be for the visiting team to provide to the extent possible technical advice or information to the visited State Party and/or to visited facility personnel on any of the subjects listed in Article VII; or to provide any of the technical assistance and cooperation activities contained in programmes as specified in Article VII, section D. The resources required for this **extension**<sup>63</sup> of the visit shall be charged against the technical assistance portion of the budget of the Organization.

### Selection of facilities

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<sup>63</sup>It is only the additional resources for the extension of the visit that should be charged against the technical assistance portion of the budget of the Organization.

12. During each calendar year, the Technical Secretariat shall randomly select facilities to be visited from among those specified in paragraph 3 (b). The mechanism of random selection shall be weighted to ensure that:

(a) Visits are distributed as widely and equitably as possible among States Parties submitting declarations and among a broad range of types of eligible facilities;

(b) All States Parties submitting declarations are visited over time, but no State Party or individual facility receives an unreasonable number of visits taking into account, *inter alia*, the number of visits it has received in previous years;

(c) Prediction of when any particular facility will or will not be subject to a visit is precluded.

13. The method of selection, and in particular the provisions of subparagraph (a) below, shall be reviewed, and revised if necessary, by the Third Conference of States Parties, and may be adjusted by future Conferences of States Parties in the light of experience with implementation. The method of selection shall meet the following conditions, which may be revised by a Review Conference held pursuant to Article XIII:

(a) The probability of a State Party receiving a visit shall be proportional to the **ratio of the cube root of the number of declared facilities in that State Party to the cube root of the total number of facilities declared to the Organization**<sup>64</sup>;

(b) The maximum number of visits which a State Party may receive in any year shall be limited to a number proportional to the cube root of the number of declared facilities in that State Party. This maximum number shall be higher than the average number of visits expected in accordance with subparagraph (a), but shall be not more than 6 per cent of the total number of visits pursuant to paragraph 3 (b) carried out in that year;

(c) No State Party with declared facilities shall receive less than 0.5 per cent of the total number of visits pursuant to paragraph 3 (b) carried out in any five year period;

(d) No individual facility shall receive more than three visits pursuant to paragraph 3 (b) in any five year period.

#### Duration

14. Visits pursuant to this part may last up to two consecutive working days. This time excludes the inspection of approved equipment. The duration of the visit may be extended if the visited State Party and visiting team so agree.

15. If so requested by the State Party to be visited in its acknowledgement of receipt of notification of the visit, the visit shall be extended by up to two days for the visiting team to provide technical advice or information, or to provide any of the technical assistance and cooperation activities contained in the programmes as specified in Article VII, section D, requested by the State Party to be visited.

#### Equipment

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<sup>64</sup>These amendments have been introduced for clarity as a probability is a ratio not a number.

16. The visiting team shall bring to the visited facility only items from the list of approved equipment. The visiting team shall normally only bring to the visited facility items of equipment meeting the specifications for instant developing cameras, voice recorders, personal computers **and protective equipment**.<sup>65</sup> Instant developing cameras and voice recorders shall only be used for collecting factual information for the visit report. Instant developing cameras shall only be operated by the representatives of the visited State Party. The use and disposition of such equipment during the visit shall be at the discretion of the visited State Party. The bringing and use of additional items of approved equipment at the declared facility shall be with the agreement of the visited State Party.

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#### Administrative arrangements

17. The visited State Party shall provide or arrange for the amenities necessary for the visiting team such as communication means, interpretation services to the extent necessary for the performance of interviewing and other tasks, in-country transportation, working space, lodging, meals and urgent medical care. The visited State Party may, to the extent possible, provide approved equipment as requested by the visiting team. The visited State Party shall be reimbursed by the Organization for any assistance provided pursuant to this paragraph within 30 days after receipt of a detailed and validated claim from the visited State Party.

#### PRE-VISIT ACTIVITIES

##### Mandate

18. The Director-General shall issue a standard mandate for the visit. The mandate shall be confined to the purposes set out in paragraphs 10 and 11 of this subsection. The mandate shall contain:

- (a) The name of the visited State Party;
- (b) The name of the host State Party/State, if applicable;
- (c) The name and location of the facility to be visited;
- (d) The declaration submitted by the facility;
- (e) The names of the leader and other members of the visiting team;
- (f) The approved equipment to be used during the visit in accordance with paragraph 16 above;

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<sup>65</sup>The proposal that protective equipment should be provided by the visited State Party is unsound as the visiting team must be trained in, familiar with and have confidence in the use of protective equipment. It would be **unsafe** to have a situation under which the visiting team had to depend upon protective equipment provided by the visited State Party as they would be unfamiliar with such equipment and it is unreasonable to jeopardize the safety of the visiting team. There is no comparable provision in the CWC.

<sup>66</sup>Paragraph deleted as its provisions are unreasonable and unsafe for the reasons stated in the preceding note.

(g) Operational instructions to the visiting team necessary for the visiting team to fulfil its mandate;

**19.** If the visited State Party has requested in its acknowledgement of receipt of the visit notification, that the visiting team provide technical advice or information, or to provide any of the technical assistance and cooperation activities contained in the programmes as specified in Article VII, section D, such activities shall, as appropriate, be added to the visit mandate to be conducted at the end of the visit activities. The addendum to the visit mandate shall be made available to the State Party to be visited as soon as possible before the commencement of the visit.

**20.** The mandate for each visit shall be issued by the Director-General to the visiting team leader.

### Notification

**21.** The Director-General shall notify the State Party to be visited and, if applicable, the host State Party **10**<sup>67</sup> working days before the arrival of the visiting team at the point of entry, of its intention to conduct a visit to a declared facility; and at the same time, shall make available to the State Party to be visited the mandate for the visit. The State Party to be visited shall acknowledge receipt of the notification within 24 hours after receipt of the notification. The notification shall include:

- (a) The name of the State Party to be visited;
- (b) The name of the host State Party/State, if applicable;
- (c) The name and location of the facility to be visited;
- (d) The point of entry where the visiting team will arrive as well as the means of arrival;
- (e) The date and estimated time of arrival of the visiting team at the point of entry;
- (f) The names of the leader and of the other members of the visiting team;
- (g) The visit mandate;
- (h) Additional approved equipment the visiting team requests to bring to the visited facility pursuant to paragraph 16 above;
- (i) Information on the existing cooperation and assistance activities or programmes, if any, which the Technical Secretariat considers may be applicable to the facility to be visited and from which the facility could benefit.

**22.** In its acknowledgement of receipt, the State Party shall provide its response to the request for additional approved equipment and it may also indicate whether it requires technical advice and information and specify which technical assistance and cooperation activities contained in the programmes as specified in Article VII, section D, it requests to be

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<sup>67</sup>10 working days -- or two weeks -- is more appropriate than 14 working days.

provided by the visiting team, without prejudice to its right to request technical advice and information at any time during the visit which shall be provided after conclusion of the visit.

23. The State Party to be visited shall acknowledge receipt of the notification within 24 hours after receipt. Within three days of receipt, the State Party, as a rule, shall confirm acceptance of the dates proposed for the visit, but it may, in exceptional circumstances, propose alternative dates occurring within 30 days of receipt of the notification. The Technical Secretariat, as a rule, shall accept such proposed alternative dates, but may, if operational requirements so dictate, propose other dates occurring within 30 days of the issuing of the notification. If a State Party can not accept these dates, its proposed alternative dates shall be the dates for the visit.

#### Appointment of visiting team

24. The Director-General shall appoint the members of the visiting team from among only the full-time personnel of the Technical Secretariat designated in accordance with Annex D, section I, paragraphs 1 to 10, taking into account the specific nature of the facility to be visited. The members of the visiting team shall be selected on as wide an equitable geographical basis as possible. The Director-General shall limit the size of the visiting team to the minimum necessary for the proper fulfilment of the mandate. In any event the team shall not exceed four members. No national of the State Party to be visited, or, if applicable, the host State Party, shall be a member of the visiting team.

#### Designation of visited State Party representatives

25. The visited State Party may designate personnel to assist visited facility personnel, prepare for and host the visiting team. The visited State Party shall designate visited facility personnel to accompany the visiting team for the duration of the visit.

### ACTIVITIES UPON ARRIVAL OF THE VISITING TEAM

#### Inspection of approved equipment

26. The State Party to be visited shall have the right to inspect the equipment of the visiting team including the additional equipment the State Party to be visited approved, to ensure that it is properly sealed, appears on the list of approved equipment and conforms to the standards as set out in Annex D, section I. The visited State Party may exclude items of equipment that do not conform to the provisions set out in Annex D, section I, paragraph 40, as well as paragraph 16 above, and may retain them at the point of entry.

### CONDUCT OF THE VISIT

27. The visiting team and the visited State Party shall cooperate with each other to fulfil the mandate while protecting the interests of the visited State Party.

28. In this regard the visited State Party shall:

(a) Provide access to the visiting team to the facility to be visited. The nature and extent of access inside the facility shall be at the discretion of the visited State Party;



(b) Allow the visiting team to conduct the activities, described in paragraph 35 of this subsection, proposed by the visiting team as necessary to fulfil its mandate;

(c) Have the right to take measures to protect national security and commercial proprietary information;

(d) Have the right to object to questions posed to the facility personnel if those questions are deemed not relevant to the objectives of the visit mandate or compromise commercial proprietary or national security information;

(e) Make every reasonable effort to provide alternative means to allow the visiting team to fulfil its mandate if any of the activities proposed by the visiting team in accordance with paragraphs 34 and 35 are not possible.

29. The visiting team shall:

(a) Collect only that information necessary to carry out its mandate and treat any information, documents and data obtained during the visit, which contain commercial proprietary or national security information and which are identified as such by the visited State Party, as confidential and handle such information, documents and data in accordance with the confidentiality provisions of this Protocol;

(b) Arrange its activities so as to ensure the timely and effective discharge of its duties in accordance with the visit mandate in the least intrusive manner possible, and every reasonable effort shall be made to avoid inconvenience to the visited State Party and disturbance to the visited facility;

(c) Make every effort to avoid hampering or delaying the operation of the facility. In particular, the visiting team shall not operate any facility equipment;

(d) Strictly observe established safety and working practices at the facility, whether instituted for the protection of personnel, animals, plants, the environment or of the processes performed or their products;

(e) Provide the visited State Party with copies of all the information and data obtained during the course of the visit;

### Briefing

30. Upon arrival at the facility to be visited, the visiting team shall be briefed on the facility and the activities carried out there by a facility representative and, at their discretion, the representatives of the visited State Party. The facility representative may be supported by any other facility personnel, as required.

31. The briefing shall not exceed three hours. It shall include, *inter alia*:

(a) The scope and a general description of current declared activities of the facility including a description of the main scientific and technical information relating to the declared activity(ies), including written and visual documentation, if available, such as photographs, brochures, drawings, as appropriate;

(b) Short background description of the declared facility covering the date of establishment, current ownership, organizational structure and, wherever possible, general information on the declared facility's role within the overall structure of company or government agency or entity operating the declared facility; organizational structure of the facility and any previous uses or changes in ownership;

(c) General information on the physical layout, including laboratories, equipment and other relevant characteristics of the visited facility, including a map or sketch showing all structures and significant geographic features;

(d) Numbers and types of personnel involved in the declared activity(ies) and whether they are military or civilian, scientific or administrative;

(e) General information concerning the safety regulations in force, including rules of observation and quarantine and vaccination policy, and on any other regulatory frameworks which may apply;

(f) Indication of areas the visited State Party considers sensitive;

(g) General information on any relevant changes in activities or equipment at the facility since the submission of the most recent declaration;

(h) Explanation for any levels of containment and the rationale for operating or not operating at such levels; and for work involving listed agents and/or toxins, including main objectives and rationales;

(i) A description of the technical assistance and cooperation activities requested by the visited State Party pursuant to paragraph 22 above;

(j) General information on the method used for any treatment or disposal of waste or effluent from the declared facility;

(k) General information on any experimental animal usage related to the declared activities;

(l) The administrative and logistical arrangements necessary for the visit.

32. The visited facility shall provide to the visiting team a written summary of the key points of the briefing. It may also provide additional information, such as documentation related to either the briefing or tour, at its discretion. At its discretion, the visited facility may also provide in writing any additional information contained in the briefing. The visiting team may discuss with the visited State Party and the visited facility personnel the content of the briefing and any other information made available by the visited State Party and visited facility personnel.

### Tour of the visited facility

33. To complement the briefing, the visited State Party shall invite the visiting team to tour areas within the declared facility relevant to the visit mandate. All access during the tour shall be at the discretion of the visited State Party. The areas to be visited by the visiting team shall be determined by the visited State Party. The duration of the tour shall not exceed two hours.

### Visit plan

35.<sup>68</sup> After the briefing and the tour, the visiting team may propose to conduct one or more of the following activities in accordance with the provisions of paragraphs 27 to 29:

(a) Review and discuss with facility personnel the declaration and the information contained in the briefing and tour provided by the visited facility;

(b) Discuss, with the consent of the visited State Party, specific factual points, related to the visit mandate, on the activities of the declared facility as described in the facility declaration, briefing and tour, with facility personnel who are able to address those factual points. The visited State Party may make available national representatives to respond to questions on matters relating to national health and safety legislation and other regulatory matters, or to provide information on such matters. All discussions shall be conducted in the presence of representatives of the visited State Party. The visiting team shall only request information and data that are necessary for the fulfilment of the visit mandate;

(c) Review, with the consent of the visited State Party, documentation relevant to the mandate in order to facilitate further the visiting team's understanding of the declared activities as presented in the facility briefing, tour and declaration. The visited State Party, if it agrees to such a review, shall endeavour to provide such documentation, or to provide alternative means to address any questions raised by the visiting team pursuant to this paragraph;

(d) Visit, and revisit if necessary to ensure fulfilment of the mandate, parts of the facility mentioned in the briefing and where declared activities are conducted;

(e) At any time during the visit, the visited State Party may, at its own initiative or at the suggestion of the visiting team, grant the visiting team the opportunity to conduct other on-site activities. It may also offer additional rights of access that the visited State Party believes may help assist the visiting team to fulfil its mandate. Any such on-site activities or levels of access shall be subject to the provisions of paragraphs 27 to 29 above.

37. If any questions related to the visited State Party's declarations and briefing are identified during the visit, the visited State Party and the facility shall seek to resolve these cooperatively, with the assistance, if necessary, of the visiting team.

### Debriefing

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<sup>68</sup>This and subsequent paragraphs have not been renumbered in order to maintain correct cross references within other paragraphs of this section.

38. At the completion of the visit, the visiting team, facility personnel and visited State Party representatives shall meet to discuss the outcome of the visit and, if necessary, to confirm any details of fact for inclusion in the preliminary report which shall be a factual account of the visit. Such a meeting shall not take place if the visited State Party and the visiting team agree that it is not necessary.

## POST-VISIT ACTIVITIES

### Cooperation and assistance activities

39. If requested in accordance with paragraphs 11 and 15 above, after the conclusion of the other activities related to the visit, the visiting team shall provide the technical advice and information and any of the cooperation and assistance activities contained in the programmes specified in the addendum to the visit mandate pursuant to paragraph 20 above or requested during the visit.

### Preliminary report

40. Within 24 hours of the completion of the visit, the visiting team shall provide to the representatives of the visited State Party a preliminary report in written form. The preliminary report shall only contain a description of the visit activities and the factual findings of the visiting team. The preliminary report shall be signed by the visiting team leader. In order to indicate that he/she has taken note of the contents of the preliminary report, the representative of the visited State Party shall sign the preliminary report.

41. If, during the visit, the visited State Party has provided to the visiting team any information which the visited State Party has identified as commercial proprietary or national security information not already included in the declaration, the visited State Party may require that any such information shall not be included in the draft or final report.

### Departure

42. On completion of the debriefing and, if applicable, the relevant cooperation and assistance activities, the visiting team shall depart from the territory of the visited State Party as soon as possible.

## REPORTS

### Draft report

43. Not later than 14 days after the visit, the visiting team shall prepare a draft report which shall include the contents of the preliminary report and an account of the cooperation and assistance activities of the visiting team during the visit. At the request of the visited State Party, the draft report may identify technical recommendations and possible follow-up cooperation and assistance activities of the Organization. The report may also include comments from both the visited State Party and visiting team on the extent to which the information provided during the visit furthered the purpose of the visit as specified in paragraph 10 of this subsection.

44. The draft report shall immediately upon completion be submitted to the visited State Party. The visited State Party may make any comments or suggestions on the draft report to

ensure factual and technical accuracy and the full protection of commercial proprietary and national security information. The visited State Party may identify any information contained in the report that it considers confidential and to be handled as such. The visited State Party may also identify any information which due to its confidential nature, or because it is in the view of the visited State Party not related to the visit mandate, should not be included in the final report. Any such comments shall be submitted to the visiting team not later than seven days after receipt of the draft report.

45. The visiting team shall consider comments received from the visited State Party. In preparing the final report, the visiting team shall, as a rule, adjust the draft report to reflect those comments. If the visited State Party identifies any information as confidential, the visiting team shall remove such information from the report. The final report shall include as an annex all the comments made by the visited State Party on the draft report, unless otherwise requested by the visited State Party.

#### Final report

46. The final report shall be the draft report adjusted by the visiting team in accordance with paragraph 45. The visiting team shall submit the final report to the Director-General and the visited State Party not later than seven days after receipt of any comments from the visited State Party. The Director-General shall, as a rule, provide copies of the final report, on request, to any State Party, taking into account the provisions of Article IV, paragraph 4 (d).

47. If the Director-General considers it necessary that the visited State Party revise its declaration, the Director-General shall inform the State Party separately in writing of the reasons.

#### (B) DECLARATION CLARIFICATION PROCEDURES

46. Concerns related to the declaration of a State Party concerning any facility pursuant to Article III, section D, subsection (I), parts (C), (D), (E), (F), (G), (H) and (I) shall be resolved through the procedures set out in this section<sup>69</sup>. The State Party to which the concern is related may volunteer for the Technical Secretariat to conduct a visit in accordance with the provisions set out in this section to the facility in question with a view to resolving the concern.

#### Requests for clarification

47. When a State Party considers that there is an ambiguity, uncertainty, anomaly or omission in the declaration concerning any declared facility or activity of another State Party, or identifies any facility which it believes meets the criteria for declaration as set forth in Article III, section D, and that facility has not been included in the declaration(s) concerned, it may submit a request in writing to the Director-General to initiate the clarification procedures set out in this section on its behalf. The request shall include all relevant information on

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<sup>69</sup>Our recommendation is that clarification of any ambiguities, uncertainties, anomalies, or omissions relating to facilities that appear to meet the criteria for declaration but which have not been declared should be addressed through Declaration Clarification Procedures. See Briefing Paper No. 26 *Visits: The Emerging Portfolio*, November 1999, para. 43. Consequently, the process of consultation, clarification and cooperation in Article III, section E should be used to address any matter which may be raised relating to the object and purpose of the Convention, or the implementation of the provisions of this Protocol and to clarify and resolve any matter which may cause concern about possible non-compliance with the obligations of this Protocol or the Convention.

which it is based including, in the case of the possible omission of a facility from a declaration, the reasons why it is believed that the facility may be required to be declared and a delimitation of the location of the facility.

48. Any State Party which has not taken any necessary measures it may have been required to take in accordance with a decision of the Executive Council pursuant to part III of this section shall not have the right to seek clarification from another State Party under this section until any measures required pursuant to paragraphs 94 and 95 of this subsection are implemented.

49. Upon receipt of a request pursuant to paragraph 47 above, or if as a result of his/her analysis pursuant to paragraph 3 (a) above, the Director-General considers that there is an ambiguity, uncertainty, anomaly or omission of a purely technical nature related solely to the content of the declaration submitted by a State Party or identifies any facility which he/she believes meets the criteria for declaration as set forth in Article III, section D, and that facility has not been included in the declaration(s) concerned, the Director-General shall submit a written request for clarification to the State Party concerned (hereinafter referred to as the requested State Party). The request shall include all relevant information on which it is based including, in the case of the possible omission of a facility from a declaration, the reasons why it is believed that the facility may be required to be declared and a delimitation of the location of the facility.

#### Consultations including a consultative meeting

50. The requested State Party shall provide the clarification in writing to the Director-General not later than 20 days after receipt of the request. In cases where a State Party initiated the clarification procedures, such response shall be forwarded to the requesting State Party by the Director-General not later than 24 hours after its receipt by the Director-General.

51. If within 14 days of receipt of the written response either the requesting State Party, for reasons which it shall set out in writing to the Director-General, or the Director-General himself/herself considers that the written response does not resolve the matter, the Director-General shall submit to the requested State Party a written request for a consultative meeting between staff of the Technical Secretariat and representatives of the requested State Party, which may include representatives of the facility concerned, in order to resolve the matter.

52. Upon receipt of such a request, the requested State Party shall make arrangements for the consultative meeting. The consultative meeting shall take place at any location agreed by the Director-General and the requested State Party. Wherever possible, the consultative meeting shall take place in the capital or at any other location on the territory of the requested State Party, beginning not later than 10 days after receipt of the request for such a meeting, and its duration shall not exceed 48 hours.

53. In cases where a State Party initiated the clarification procedures, the Director-General shall inform the requesting State Party of the outcome of the consultative meeting not later than 24 hours after the end of that meeting.

54. Information regarding on-going or completed clarification procedures (consultations) conducted pursuant to this subsection, including requests for such consultations, and information resulting therefrom shall be restricted to the Technical Secretariat, the requested State Party, and, if applicable, the requesting State Party unless further release is expressly

authorized by the requested State Party without prejudice to the right of the requesting State Party to refer the issue to the Executive Council.

55. If a voluntary clarification visit is offered, the Director-General shall provide the members of the Executive Council with such information on a confidential basis. In the event of such a visit, information related to it shall be restricted to the members of the Executive Council, the Technical Secretariat, the requested State Party, and, if applicable, the requesting State Party unless further release is expressly authorized by the requested State Party. If an on-site activity occurs pursuant to the section, the final report of the visit shall only be distributed to the members of the Executive Council, the Technical Secretariat, the requested State Party, and, if applicable, the requesting State Party unless further release is expressly authorized by the requested State Party. Information that the requested State Party considers to be commercial proprietary information or national security information shall not be included in the final report.

#### VOLUNTARY CLARIFICATION VISIT

56. The visit shall be conducted in the least intrusive manner and shall as far as possible not affect or interrupt in any way the activities taking place in the facility. The inviting State Party and the visiting team shall cooperate with each other in the achievement of the objectives of the mandate.

##### Offering of a voluntary clarification visit

57. The requested State Party may, at its discretion and at any time during the clarification procedures, invite the Technical Secretariat to conduct a voluntary clarification visit to the facility in question which shall be conducted in accordance with the provisions set forth in paragraphs 72 to 93, with a view to resolving satisfactorily and expeditiously any matter which has been raised pursuant to paragraph 47 above.

58. The invitation to visit the facility shall be addressed to the Director-General in writing at any time during the consultations pursuant to paragraphs 47 to 52 above or as soon as possible, but in no case later than seven days after the completion of the consultative meeting pursuant to paragraph 51 above. The invitation shall be accompanied by an explanation for the invitation, the purpose of the proposed visit, the specific issue(s) to be clarified, the location of the facility to be visited and a diagram identifying and describing the specific place(s) and facility where the visit would occur.

59. The Director-General shall ensure that the visit request is acceded to, if necessary by making adjustments in the overall programme of visits for that year.<sup>70</sup>

60. The Director-General shall handle the invitation in accordance with the provisions set out in paragraphs 5 to 10 of this subsection. The Director-General and the inviting State Party shall decide by mutual consent on the time of the visit taking into account the overall visit schedule. If consensus cannot be reached on the dates for the visit, every effort shall be made by the Director-General and the State Party to be visited to make the visit possible at the earliest possible opportunity.

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<sup>70</sup>It is anticipated that the frequency of such visits will decline appreciably over time as States Parties resolve initial difficulties. See Briefing Paper No. 20, *Visits: An Essential Portfolio*, April 1999, para 74.

61. If offering a visit, the inviting State Party shall ensure necessary access to the facility so as to enable the visiting team to fulfil its mandate. The voluntary visit shall be conducted according to the procedures set forth in paragraphs 72 to 102 of this subsection. The inviting State Party may, at its discretion, offer additional access and rights to the visiting team.

62. In the event that a request for an investigation is submitted to the Director-General in connection with the same matter as a voluntary clarification visit invitation, the Director-General shall continue with the preparations for but not proceed with the voluntary visit, pending an Executive Council determination on the investigation request. If the Executive Council does not approve the investigation request, then the voluntary clarification visit shall proceed.

#### CONSULTATIVE MEETING FOLLOW-UP

63. If the requesting State Party **or the Director-General** considers that the consultative meeting has not resolved the matter, the Director-General shall submit a report to the Executive Council.

64. The requesting State Party, if applicable, shall inform the Director-General in writing within seven days after the conclusion of the consultative meeting if it believes that the consultative meeting has not resolved the issue. Any such proposal shall include an explanation of why the requesting State Party considers that the previously conducted clarification procedures have not resolved the matter.

65. If the condition set out in paragraph 63 applies, the Director-General shall request the requested State Party to offer a voluntary clarification visit within a specified time frame. He/she shall also submit a full report on the matter in writing to the Executive Council, including all relevant information pertaining to the implementation of the clarification procedures set out in this section.

#### Executive Council review

65*bis* If the Director-General has initiated a clarification process and considers that the consultative meeting has not resolved the matter, he/she shall submit a proposal to conduct a clarification visit within seven days after the conclusion of the consultative meeting. Any such proposal shall include an explanation of why the Director-General considers that the previously conducted clarification procedures have not resolved the matter.<sup>†71</sup>

66. If the requested State Party declines to offer a clarification visit, the Director-General shall inform the Executive Council which shall consider the matter at its next regular session and may decide, *inter alia*:

- (a) That no further action is justified;
- (b) To recommend further consultations with the requested State Party;
- (c) To request further information from the requested and/or requesting State(s) Party(ies);

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<sup>71</sup>There is no necessity to place the proposed visit on the agenda of the Executive Council unless the requested State Party declines to offer a clarification visit.



(d) To seek the assistance of other relevant international organizations in resolving the matter;

(e) To refer the matter to a special session of the Conference of States Parties;

(f) To request the requested State Party to offer a clarification visit within a specified time frame taking into account the specific circumstances of each case;

(g) By a majority of all its members present and voting, to initiate a clarification visit to be conducted according to the procedures set out in this subsection.

67. During the Executive Council's consideration of the matter, the requested and, if applicable, the requesting State Party shall have the right to participate in the discussions but shall not have the right to participate in any decision on further action.

#### Duration

68. The inviting State Party and the Director-General shall determine the duration of the visit, but in no case shall the duration exceed two days. The period of visit means the consecutive period of time from the arrival of the visiting team at the visited facility until the completion of their visit activities provided for in this section.

#### Equipment

69. The visiting team shall only bring to the visited facility equipment from the list of approved equipment. The items of approved equipment shall be kept to the minimum necessary and shall be included in the notification.

70. Any approved position-locating equipment shall be used only to confirm the location of the facility. Any approved photographic equipment and audio tape recording equipment shall be used only for collecting factual information for the visit report. The use of approved photographic equipment shall be at the discretion of the visited State Party and such equipment shall only be operated by the representatives of the visited State Party. The use and disposition of audio tape recording equipment or any additional items from the appropriate approved equipment list at the **visited** facility shall be with the agreement of the visited State Party.

#### Administrative arrangements

71. The visited State Party shall provide or arrange for the amenities necessary for the visiting team such as communication means, interpretation services to the extent necessary for the performance of interviewing and other tasks, in-country transportation, working space, lodging, meals and urgent medical care. The visited State Party may, to the extent possible, provide approved equipment on request to the visiting team. The visited State Party shall be reimbursed by the Organization for any assistance pursuant to this paragraph within 30 days after receipt of a detailed and validated claim from the visited State Party.

#### PRE-VISIT ACTIVITIES

#### Mandate

72. The Director-General shall issue a mandate for the visit which shall be limited to the clarification of the specific issue in the declaration of the requested State Party which was the subject of the prior consultations held pursuant to this **subsection**. The mandate shall be included in the notification of the visit made by the Director-General. The mandate shall be made available to the representative of the State Party to be visited immediately upon the arrival of the visiting team at the point of entry. The mandate shall contain at least the following:

- (a) The name of the visited State Party;
- (b) The name of the host State Party/State, if applicable;
- (c) The name and location of the facility to be visited specified as precisely as possible;
- (d) The objectives of the visit and the possible means to resolve the issue related to the declaration of the requested State Party which was the subject of the consultative meeting pursuant to **this subsection**;
- (e) The names of the leader and other members of the visiting team;
- (f) The list of approved equipment to be used during the visit pursuant to paragraphs 69 and 70 above;
- (g) The declaration submitted by the facility.

#### Notification

73. The Director-General shall notify the State Party to be visited and, if applicable the host State Party, confirming the visit not later than seven days in advance of the planned arrival of the visiting team at the point of entry. The notification shall include, *inter alia*:

- (a) The name of the State Party to be visited;
- (b) The name of the host State Party/State, if applicable;
- (c) The name and location of the facility to be visited;
- (d) The purpose of the visit and the specific issue(s) to be clarified;
- (e) The point of entry;
- (f) The means of arrival;
- (g) The date and estimated time of arrival of the visiting team at the point of entry;
- (h) The names of the leader and of the other members of the visiting team;
- (i) The visit mandate.

74. The State Party to be visited shall acknowledge receipt of the notification not later than 48 hours after receipt of such notification. The State Party shall confirm acceptance of the proposed dates for the visit or propose alternative dates occurring within seven days of the Director-General's proposed visit date. If the dates suggested by the State Party to be visited cannot be met by the Director-General, the original dates shall be the dates of the visit.

#### Appointment of visiting team

75. The Director-General shall appoint members of the visiting team from among only the full time personnel of the Technical Secretariat designated in accordance with Annex D, section I, taking into account the specific nature of the facility to be visited. Members of the visiting team shall be selected on as wide an equitable geographical basis as possible. The Director-General shall limit the size of the visiting team to the minimum necessary for the proper fulfilment of the mandate. In any event the team shall not exceed four members. No national of the requesting State Party, the visited State Party or, if applicable, the host State Party shall be a member of the visiting team.

#### Designation of visited State Party representatives

76. The State Party to be visited shall designate personnel to assist visited facility personnel prepare for and host the visiting team and to accompany the visiting team for the duration of the visit.

### ACTIVITIES UPON ARRIVAL OF THE VISITING TEAM

#### Inspection of approved equipment

77. The visited State Party shall have the right to inspect the equipment of the visiting team to ensure that it is properly sealed, appears on the list of approved equipment, and conforms to the standards as set out in Annex D, section I. The visited State Party may exclude equipment that does not conform to the provisions set out in Annex D, section I and may retain them at the point of entry for the duration of the visit.

### CONDUCT OF THE VISIT

78. The visiting team and the visited State Party shall cooperate with each other to fulfil the mandate while protecting the interests of the visited State Party.

79. For activities conducted pursuant to paragraphs 84 and 85 below, the rights and obligations of the visiting team and the visited State Party shall be the same as those provided pursuant to the access provisions set forth in paragraphs 29 to 36 of section G of this Article.

80. The sole purpose of such activities shall be to clarify the specific issue related to the requested State Party's declaration identified in the mandate.

#### Briefing

81. Upon arrival at the facility to be visited, the visiting team shall be briefed by the facility representatives and/or the representatives of the visited State Party. The briefing shall include the scope and a general description of activities of the facility relevant to the issue(s)

to be clarified as specified in the visit mandate, details of the physical layout and other relevant characteristics of the facility, including a map or sketch showing the relevant structures and significant geographic features. It shall include information concerning the safety regulations in force, including rules of observation and quarantine. It may also include an indication of areas the visited State Party considers sensitive or not related to the visit mandate. The briefing shall not exceed three hours.

82. The visited facility shall provide to the visiting team a written summary of the key points of the briefing. At their discretion, the visited facility may also provide in writing any additional information contained in the briefing. The visiting team may discuss with the visited State Party and the visited facility personnel the content of the briefing and any other information made available by the visited State Party and visited facility personnel.

83. The visited State Party may offer or the visiting team may request an orientation tour of areas within the facility relevant to the issue(s) to be clarified as specified in the visit mandate. The visiting team and the visited State Party shall discuss the arrangements for the tour. The scope and nature of the tour shall be at the discretion of the visited State Party. The orientation tour shall not exceed two hours.

84. After the briefing and any orientation tour, the visiting team shall, in consultation with the representatives of the visited State Party, prepare an initial visit plan and immediately make it available to the visited State Party. The visit plan shall specify the activities the visiting team proposes to carry out, including the specific areas of the facility to be visited and any proposals for the visiting team to subdivide. The visiting team may propose changes to the visit plan at any time to the visited State Party. Any changes to the visit plan made during the visit and any proposals for the visiting team to subdivide shall be agreed by the visited State Party.

85. One or more of the following activities may be conducted:

(a) Ask questions about the declaration relevant to the facility and on the issue to be clarified;

(b) With their consent, interview those individuals responsible, or their representatives, or other knowledgeable personnel in respect of the scientific, technical, medical, accounting or managerial activities relevant to the issue to be clarified as specified in the mandate. At the discretion of the visited State Party, the visiting team may interview other facility personnel who may be able to assist in clarifying the issue specified in the visit mandate. All interviews shall be conducted in the presence of representatives of the visited State Party, with the purpose of establishing relevant facts. The visiting team shall only request information and data which are necessary for the fulfilment of the visit mandate;

(c) Visually observe parts of the facility as well as equipment, relevant to the mandate.

86. The visited State Party may at the suggestion of the visiting team **invite** the visiting team, at any time during the visit, **to visit** any other on-site activities which the visited State Party believes may assist the visiting team to fulfil its mandate.

87. The visited State Party shall, at the request of the visiting team, make available documentation which in the judgement of the visited State Party and visiting team may help clarify the issue in the mandate. The nature and extent of any examination shall be agreed between the visited State Party and the visiting team.

## POST-VISIT ACTIVITIES

### Debriefing and preliminary findings

88. Upon completion of the visit the visiting team shall meet with representatives of the visited State Party and the visited facility at the visited facility to review the preliminary findings of the visiting team and to clarify any remaining ambiguities. The visiting team shall provide to the visited State Party its preliminary findings in written form, together with a list and copies of documents and other material obtained, that it proposes, subject to the agreement of the visited State Party, to remove from the facility. The document shall not contain any information or data unrelated to the issue to be clarified as stated in the visit mandate. It shall, as a rule, not contain information or data identified as confidential by the visited State Party and not related to the issue to be clarified as stated in the visit mandate. The document shall be signed by the visiting team leader. In order to indicate that the visited State Party has reviewed the contents of the document, the visited State Party representative shall countersign it. This meeting shall be completed not later than 24 hours after completion of the visit.

### Departure

89. On completion of the visit the visiting team shall depart from the territory of the visited State Party in the minimum time possible.

## REPORT

### Visit report

90. The visiting team shall prepare and process a draft report. The draft report shall be considered confidential. The draft report shall summarize the general activities undertaken during the visit and the factual findings of the visiting team. It shall only contain facts relevant to the clarification of the issue to be clarified as stated in the visit mandate. The draft report shall be submitted to the visited State Party not later than 14 days after the end of the visit. The visited State Party may submit to the visiting team any written comments on the draft report not later than 21 days after receipt of the draft report. In particular, it may identify any information and data which, in its view, should not be contained in the final version of the report, because it is considered to be not relevant to the issue to be clarified as stated in the visit mandate, or due to its confidential nature.

91. The visiting team shall consider any comments received from the visited State Party and incorporate those comments and, as a rule, remove any information and data as requested pursuant to paragraph 90 before submitting the draft final report to the Director-General and the visited State Party and, if applicable, the requesting State Party not later than seven days after receipt of such comments.

92. The visited State Party may submit further comments to the Director-General on the draft final report within 14 days after receipt of the draft final report. The Director-General

shall annex any such comments to the draft final report, which together shall become the final report. The Director-General shall provide copies of the final report to the visited State Party and, if applicable, to the requesting State Party.

93. The Director-General shall submit the final report to the Executive Council for its consideration when either:

(a) The Director-General or, if applicable, the requesting State Party consider that the matter to be clarified has not been resolved; or

(b) The clarification visit resulted from the provisions set forth in paragraph 66 above.

In all other cases, no further action shall be taken.

#### Executive Council review and decision on any follow-up action

94. The Executive Council shall, in accordance with its powers and functions, review the final report of the visiting team. In keeping with its powers and functions, the Executive Council may, if it considers that further action may be necessary, agree upon appropriate measures to redress the situation, which may include making recommendations to the States Parties involved.

95. The Director-General shall inform the visited State Party of the outcome of the review of the report and on any recommendation on any subsequent measures pursuant to paragraph 94 as soon as possible. If applicable, the Director-General shall also inform the requesting State Party of the outcome of the review of the report and on any subsequent recommendations pursuant to paragraph 94.

#### (C) VOLUNTARY ASSISTANCE VISITS

96. Each State Party may, through the Director-General, invite the Technical Secretariat to undertake a visit(s) to a facility(ies) on its territory or in any other place under its jurisdiction or control. In its invitation the State Party shall indicate the purpose(s) of the visit, which shall be to enhance transparency and promote confidence among States Parties and one or more of the following:

(a) To obtain relevant technical assistance and information;

(b) To obtain any of the technical assistance and cooperation activities contained in programmes **pursuant to** Article VII;

(c) To obtain from the Technical Secretariat technical advice or information on the implementation of the declaration obligations of this Protocol with respect to specific facilities.

#### Invitations for visits

97. Each invitation for a voluntary assistance visit shall be addressed to the Director-General and shall be accompanied by an explanation for the invitation and the purpose(s) of the proposed visit. The Director-General shall handle the invitations in accordance with the provisions set out in paragraphs 5 to 9 of this subsection.

98. The Director-General shall issue a mandate for each visit which shall be written in cooperation with the State Party to be visited.

99. The visited State Party and the visiting team shall cooperate with each other in the achievement of the objectives of the mandate.

100. The detailed arrangements for, and contents of, a voluntary visit, such as size and composition of the visiting team, duration of the visit, and procedures upon arrival of the visiting team at the point of entry, shall be agreed beforehand between the Director-General and the State Party to be visited.

101. The costs of scheduled voluntary assistance visits incurred by the Technical Secretariat shall be borne by the Technical Secretariat. The costs of voluntary assistance visits additional to those provided for in the initial schedule pursuant to paragraphs 5 and 6 shall be shared by the visited State Party and the Technical Secretariat.

102. A visit report, prepared jointly by the visiting team in consultation and cooperation with the visited State Party, shall be submitted to the Director-General not later than 14 days after the completion of the visit. The Director-General shall submit the report to the Cooperation Committee for consideration.

### III. MEASURES TO ENSURE SUBMISSION OF DECLARATIONS

1. As soon as possible after the deadline for the submission of the initial or annual declarations specified in paragraph 2 of section D, subsection I, of this Article has passed, the Director-General shall issue a written request to States Parties which have not submitted all their declarations, as required in section D, subsection I, of this Article, to submit the required declarations and/or a written explanation of why the submission of the declarations is delayed. Such declarations and/or explanation shall be submitted as soon as possible after receipt of the request.

2. On receipt of such an explanation, the Director-General may offer to provide assistance in the preparation of declarations in accordance with Article III, section D, subsection II and Article VII.

3. The Director-General shall provide a report to each regular session of the Conference of the States Parties, to each regular session of the Executive Council and to any special session, as appropriate, of the Executive Session on the status of the implementation of the declaration obligations set out in section D, subsection I, of this Article. The Director-General shall include in this report information relating to paragraphs 1 and 2 above.

4. Notwithstanding the action taken by the Director-General specified in paragraphs 1 to 3 above, if any State Party has not submitted its initial declarations by the expiry of a **one** year period, or its annual declarations by the expiry of a 6 month period, following the relevant deadline for submission established under paragraph 2 of section D, subsection I, of this Article, the State Party may not have access to the declarations of other States Parties. The Executive Council shall consider any explanations provided by the State Party and, if not satisfied, may decide whether to apply one or more of the following measures until the Director-General confirms receipt of the declarations concerned:

(a) The State Party may not invoke the declaration clarification procedure, as provided for in section D, subsection II, of this Article, or a facility investigation;

(b) The State Party may not request from the Technical Secretariat technical assistance under Article VII other than assistance in the preparation of declarations including the establishment and functioning of the National Authority;

(c) The State Party may not invoke those provisions on consultation, clarification and cooperation as provided for in section E of this Article which directly involve the Organization.

5. At any time the Executive Council may decide in light of the explanations submitted by the State Party concerned to suspend the operation of any of the measures in paragraph 4 and specify a prescribed time frame for remedial action. The Executive Council shall keep the operation of these provisions under review.

6. The State Party concerned may participate in any Executive Council consideration or review of the operation of these measures, but may not vote on the issue.

7. If a State Party has not submitted its initial declarations by the expiry of a two year period, or its annual declarations by the expiry of a 12 month period, following the relevant



deadline for submission established under paragraph 2 of section D, subsection I, of this Article, the following provisions shall apply until the Director-General confirms receipt of the declarations concerned:

(a) The State Party shall have no vote in the Conference of the States Parties;

(b) The State Party shall not be eligible for election as a member of the Executive Council or, if already a member of the Executive Council, shall be suspended from membership.

8. The Conference of States Parties shall consider the operation of these provisions. The Conference of States Parties may decide in light of the explanations submitted by the State Party concerned to suspend the operation of any of the measures in paragraph 7 and specify a prescribed time frame for remedial action.

9. The State Party concerned may participate in any Conference of States Parties consideration or review of the operation of these measures, but may not vote on the issue.

## E. CONSULTATION, CLARIFICATION AND COOPERATION

1. States Parties shall without prejudice to their rights and obligations under Article V of the Convention, and without prejudice to their right to request an investigation, consult and cooperate, directly among themselves, or through the Organization or other appropriate international procedures, including within the framework of the United Nations and in accordance with its Charter, on any matter which may be raised relating to the object and purpose of the Convention, or the implementation of the provisions of this Protocol and to clarify and resolve any matter which may cause concern about possible non-compliance with the obligations of this Protocol or the Convention.<sup>72</sup> For these purposes, States Parties shall follow, *inter alia*, one or more of the following procedures:

(a) Seek clarification from another State Party directly, or through the offices of a third State Party, or other appropriate international procedures. In the case of a written request for clarification, the requested State Party shall provide the clarification to the requesting State Party as soon as possible, but in any case not later than 15 days after receipt of the request. The requesting and requested States Parties may, if they agree, keep the Executive Council and Director-General informed of the request and the response;

(b) Submit a written request for clarification concerning another State Party, together with information upon which the request is made, to the Director-General. The Director-General shall immediately forward the request to the State Party concerned. The requested State Party shall provide the clarification to the Director-General as soon as possible, but in any case not later than 15 days after receipt of the request. The Director-General shall immediately forward the clarification to the requesting State Party. If agreed by both the requesting and requested States Parties, the Director-General shall keep the Executive Council and/or all other States Parties informed of the request and the basis for the request as well as the response;

(c) If the case is particularly serious, submit a written request for clarification concerning another State Party, together with information upon which the request is made, to the Executive Council which shall forward the request to the requested State Party through the Director-General not later than 24 hours after its receipt. The requested State Party shall provide the response to the Executive Council as soon as possible, but in any case not later than 15 days after receipt of the request. The Executive Council shall take note of the response and forward it to the requesting State Party not later than 24 hours after its receipt. The Executive Council shall inform without delay all other States Parties about any such request for clarification and the basis for this request as well as the response provided by the requested State Party.

2. For the purposes of obtaining further clarification, the Executive Council may call on the Director-General to consult the Scientific Advisory Board and/or establish a group of experts from the list of investigation personnel designated and approved in accordance with

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<sup>72</sup>Our recommendation is that clarification of any ambiguities, uncertainties, anomalies, or omissions relating to facilities that appear to meet the criteria for declaration but which have not been declared should be addressed through Declaration Clarification Procedures. See Briefing Paper No. 26 *Visits: The Emerging Portfolio*, November 1999, para. 43. Consequently, the process of consultation, clarification and cooperation in Article III, section E should be used to address any matter which may be raised relating to the object and purpose of the Convention, or the implementation of the provisions of this Protocol and to clarify and resolve any matter which may cause concern about possible non-compliance with the obligations of this Protocol or the Convention.

the procedures set out in Annex D, section I, to examine all available information and data relevant to the situation causing concern. The Scientific Advisory Board **or the group of experts** shall submit a factual report to the Executive Council on its findings as soon as possible; **if a final report cannot be submitted within 30 days, an interim report shall be provided.**

3. If, following receipt of the clarification obtained pursuant to paragraph 1, the requesting State Party considers that the response does not resolve the concern, and that it needs to seek further clarification, or if it has not received the clarification within the times specified in paragraph 1, or if the requested State Party makes it clear to the requesting State Party, that it will not provide the requested clarification, the requesting State Party may request in writing, providing reasons why the clarification does not resolve the concern:

(a) The Executive Council to obtain further clarification from the requested State Party or to obtain from the requested State Party the reasons as to why it has not provided the clarification as required under the provisions of this Article within the times specified in paragraph 1, or why the requested State Party will not provide the requested clarification; and/or

(b) A special session of the Executive Council in which States Parties involved that are not members of the Executive Council shall be entitled to take part. In such a special session the Executive Council shall consider the matter and may recommend to the States Parties involved any measure it deems appropriate to resolve the situation.

4. If the concern of a State Party about possible non-compliance has not been resolved within 60 days after the submission of the request for clarification to the Executive Council, and if the State Party believes its concern warrants urgent consideration, notwithstanding its right to request an investigation, it may request in writing a special session of the Conference of States Parties in accordance with Article IX. At such a special session, the Conference shall consider the matter and may recommend any measure it deems appropriate to resolve the situation.

5. The requested State Party may at any time during the consultation, clarification and cooperation process:

(a) Request the Executive Council to consider the matter on the basis of the information which was made available in the request as well as on information which has been made available by the requested State Party, and, if appropriate, also on the basis of information received from the Technical Secretariat based on the declarations submitted by the States Parties and any other relevant information which it has acquired in the performance of its functions;

(b) In the case of a concern involving compliance with the declaration obligations of this Protocol, request the Director-General to mandate the Technical Secretariat to conduct a visit for the sole purpose of resolving the concern. The visit shall be conducted according to the procedures for voluntary clarification visits set out in section D, subsection II of this Article;

6. If requested by all the States Parties concerned, other States Parties or relevant international organizations may undertake to assist in clarifying or resolving matters related

to a concern about non-compliance which has been raised as a matter for consultation, clarification and cooperation.

7. Nothing in the above arrangements shall prejudice States Parties' rights to arrange by mutual consent for any procedures among themselves.

## F. MEASURES TO STRENGTHEN THE IMPLEMENTATION OF ARTICLE III OF THE CONVENTION<sup>73</sup>

### (A) TRANSFERS

1. State Parties shall undertake all necessary measures to ensure that obligations under Article III of the Convention are implemented fully and effectively, consistent with the objectives and purposes of the Convention. **The implementation of such measures shall be aimed at ensuring that transfers of dual-use microbial and other biological agents, toxins and equipment will only be used for prophylactic, protective or other peaceful purposes.**

2. **The Organization shall assist States Parties to develop and implement procedures for transfers of dual-use microbial and other biological agents, toxins and equipment for peaceful purposes. The Organization may also provide a forum for consultation on matters related to the transfer of dual-use microbial and other biological agents, toxins and equipment for peaceful purposes and the implementation of Article III provisions of the Convention among the States Parties to the Protocol.**

3. **The Organization shall also develop a regime for transfers of dual-use microbial and other biological agents, toxins and equipment to States not party to the Protocol.**

### (B) TRANSFERS TO STATES PARTIES TO THE PROTOCOL

4. States Parties, in order to ensure compliance with Article III of the Convention **and with the objective of preventing dual-use items from being utilized for purposes prohibited by the Convention<sup>74</sup>**, shall only transfer **to other States Parties** dual-use microbial and other biological agents, toxins and equipment for purposes not prohibited by the Convention, in accordance with the following guidelines:

(a) Each State Party shall require that any request pursuant to the Convention for authorizing the transfer of an item **listed in Annex A** that could be used both for prophylactic, protective and other peaceful purposes, and for purposes prohibited by the Convention, hereafter referred to as a dual-use item, shall be accompanied by information on purpose, quantity required, site or facility for proposed use, quantity to be produced at the site or facility, place where intended to be stored and end-use certificate;

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(b) Any transfer of technology related to means of delivery, aerosol dispersion of toxins and pathogens, stabilization of agents/toxins to environmental stress shall be **notified** to the Organization;

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<sup>73</sup>The proposals for this Section are based upon the analysis in Briefing Paper No. 28, *The BTWC Protocol: Improving the Implementation of Article III of the Convention*, January 2000.

<sup>74</sup>Text from paragraph 3 of AHG/51 Part 1, Article III Section F.

<sup>75</sup>As has been argued in Briefing Papers, containment is not a necessary prerequisite for possible misuse of dual-use microbial and other biological agents, toxins and equipment.

(c) Any transfer of **equipment in the following categories** shall be **notified** to the Organization;

(i) Fermenters or bioreactors designed to prevent the release of aerosols with a total internal volume of 100 litres or more;

(ii) Aerosol chambers designed for use for the dissemination of aerosols of microorganisms or toxins;

(iii) Equipment designed for use in experimental aerobiology studies to generate aerosols of microorganisms or toxins;

(iv) Aerosol analytical equipment designed to determine the size of aerosol particles up to 20 microns in diameter that contain microorganisms or toxins.

(d) Each State Party shall take into account, as appropriate, the stated end-use of the transfer and any supporting information, the nature and implementation in the requesting State Party/State of measures to comply with the purposes of the Convention, and the extent to which those measures are effective in fulfilling the obligations of Article III and IV of the Convention.

**5.76 The end-user certificate to be provided in the request of the State Party for agents, toxins and equipment listed in Annex A shall state the following:**

(i) That they will only be used for purposes not prohibited under this Convention;

(ii) That they will not be retransferred without **prior** authorization from the supplier **State(s) Party(s)**;

(iii) Their types and quantities;

(iv) Their end-use(s); and

(v) The name and address(es) of the end-user(s).

**6.** In fulfilment of the obligation in paragraph **3** above each State Party shall take into account as appropriate the stated end-use of the transfer and any supporting information; the nature and implementation in the State Party requesting the transfer of the measures specified in paragraph **8** of this section; and the extent to which these measures are effective in fulfilling the obligations of Articles III and IV of the Convention.

#### (C) NOTIFICATIONS

**7.** In order to promote transparency and to enhance confidence-building among States Parties, each State Party shall, according to the standardized formats for reporting international transfers contained in Appendix G, notify the Technical Secretariat annually of

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<sup>76</sup>Text from paragraph 11(c) of AHG/51 Part 1, Article III Section F has been modified to be consistent with the end-use certificates required under the Chemical Weapons Convention (see Briefing Paper No. 28, *The BTWC Protocol: Improving the Implementation of Article III of the Convention*, January 2000, paragraphs 20 and 21).

any imports or exports of the following equipment which have been completed for prophylactic, protective or other peaceful purposes, during the previous calendar year:

(a) Fermenters or bioreactors designed to prevent the release of aerosols with a total internal volume of 100 litres or more for which the end-use indicated by the State Party requesting the transfer is use in a maximum biological containment laboratory or facility;

(b) Chambers designed for aerosol challenge testing with microorganisms or toxins, and having a capacity of one cubic metre or more.

**8.** Each State Party shall, in accordance with its national constitutional and/or legislative procedures, review and, if necessary, amend or establish any legislation, regulatory and/or administrative provisions to govern the transfer of agents, toxins, equipment and technologies relevant to the Convention in accordance with its obligations under the Convention and this Protocol. Each State Party shall notify the Technical Secretariat on the national laws, regulations and administrative measures it has adopted to implement Articles III and IV of the Convention **and Article X of this Protocol** not later than 180 days after entry into force of this Protocol for that State Party. **Each State Party shall also notify the Technical Secretariat of the national laws, regulations and administrative measures it has adopted to control the internal transfers of microbial or other agents and toxins within its territory.**<sup>77</sup> Each State Party shall submit to the Technical Secretariat annually any modifications or additions made to such national laws, regulations and administrative measures during the previous calendar year **together with reports on the national implementation of those laws, regulations and measures relating to interstate transfers.**

**9.** Following submission of the national reports pursuant to paragraph **7 and 8** above, States Parties may, if they deem it appropriate, consult and exchange among themselves further information on an ad hoc basis, in order to improve clarity and avoid discrepancies in the data and information reported.

**10.** Information submitted pursuant to paragraph **7 and 8** above shall be made available to States Parties on request.

#### **(D) TRANSFERS TO STATES NOT PARTY TO THE PROTOCOL**

**11.** States Parties, in order to ensure compliance with Article III of the Convention **and with the objective of preventing dual-use items from being utilized for purposes prohibited by the Convention**, shall only transfer **to States Parties to the Convention and not to the Protocol** dual-use microbial and other biological agents, toxins and equipment for purposes not prohibited by the Convention, in accordance with the guidelines specified above, and shall in addition:

(a) **Declare annually to the Technical Secretariat all transfers to States Parties to the Convention and not to the Protocol of microbial and other biological agents and toxins and equipment listed in Annex A. Such declarations shall provide**

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<sup>77</sup>A State Party in deciding whether or not to make a transfer needs to know about the laws and regulations within the recipient State Party in respect of **both** internal and interstate transfers.

information specifying which microbial and other biological agents, toxins and equipment have been transferred, the quantity, recipient and purpose.<sup>78</sup>

**12. Five years after entry into force of this Protocol, the Conference shall consider the need to establish other measures regarding transfers to States Parties to the Convention and not party to the Protocol of microbial or other biological agents or toxins, whatever their origin or method of production, or equipment or material which is capable of using such agents or toxins for purposes which would contravene Article I of the Convention.**

**13. No transfer of microbial or other biological agents or toxins, whatever their origin or method of production, or equipment or material which is capable of using such agents or toxins for purposes which would contravene Article I of the Convention, shall be allowed to non-States Parties of the Convention and the Protocol except for humanitarian purposes with the prior approval of the Organization or in emergency circumstances to provide humanitarian assistance. Any such transfers in emergency circumstances shall be notified within 30 days to the Organization.**

#### **(E) CONSULTATION, CLARIFICATION AND COOPERATION**

**10.<sup>79</sup> Pursuant to Article III, Section E. Consultation, Clarification and Cooperation, States Parties shall without prejudice to their rights and obligations under Article V of the Convention, or their rights and obligations under this Protocol, consult and cooperate, directly among themselves, or through the Organization, on any matter which may be raised relating to the object and purpose of the Convention, or the implementation of the provisions of this Protocol including those relating to this Article and to clarify and resolve any matter which may cause concern about possible non-compliance with the obligations of this Protocol.**

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<sup>78</sup>Text developed from language in the Chemical Weapons Convention (see Briefing Paper No. 28, *The BTWC Protocol: Improving the Implementation of Article III of the Convention*, January 2000, paragraphs 19, 20 and 21).

<sup>79</sup>This is based upon paragraph 1 of Article III, Section E Consultation, Clarification and Cooperation.



## G. INVESTIGATIONS<sup>80</sup>

### (A) TYPES OF INVESTIGATIONS

1. Each State Party shall have the right to request an investigation which shall be carried out for the sole purpose of determining the facts relating to a specific concern about possible non-compliance with the Convention by any other State Party.

2. Each State Party shall be under the obligation to keep all requests within the scope of the Convention and refrain from unfounded or abusive requests.

3. The requesting State Party shall specify in each request which one of the following types of investigations it is seeking:

(a) Investigations to be conducted in geographic areas where the release of, or exposure of humans, animals or plants to microbial or other biological agents and/or toxins has given rise to a concern about possible non-compliance under Article I of the Convention or use of biological weapons, hereinafter referred to as “field investigations”;

(b) Investigations of alleged breaches of obligations under Article I of the Convention, to be conducted inside the perimeter around a particular facility at which there is a substantive basis for a concern that it is involved in activities prohibited by Article I of the Convention, hereinafter referred to as “facility investigations”.

### (B) OUTBREAKS OF DISEASE

#### Exclusion of all outbreaks of disease which are due to natural causes

4. All outbreaks of disease which are due to natural causes do not pose a compliance concern under the Convention and shall not be a reason for an investigation of a non-compliance concern.

5. Nothing in this Protocol shall prejudice the right of a State Party to investigate, as per its national regulations, outbreaks of disease which occur on its territory or in any place under its jurisdiction or control, or if it so wishes, with the assistance of other State(s) and/or relevant international organizations.

#### Investigation of disease outbreaks relating to a specific concern about possible non-compliance with the Convention

6. If a State Party has a concern that an outbreak of disease is directly related to activities prohibited by the Convention, it shall have the right to request a field investigation to address the non-compliance concern. In accordance with the requirements of Annex D, section II, paragraphs 1 and 2, such request shall contain detailed evidence, and other information, and analysis substantiating why, in its view, it considers the outbreak of disease not to be naturally occurring and directly related to activities prohibited by the Convention. Information coming from the mass media or from private persons can not be considered as evidence on the basis of which the request shall be made. Relevant information from private

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<sup>80</sup>The text in AHG/52 (Part II) has been used as the baseline for this section.

persons who have direct knowledge of the alleged event(s) or of the results and/or details of any prior national or international investigation of the event(s) can be considered as evidence.

7. The Executive Council shall not consider a request for a field investigation of an outbreak of disease, unless it determines that there is a basis for concern substantiated by detailed evidence, and other information, and analysis that the outbreak(s) of disease, is not naturally occurring and is directly related to activities prohibited by the Convention. The Executive Council, if it deems it appropriate for its consideration of the above request, shall also request from the most relevant international organization(s) such as, but not limited to, the WHO, OIE, FAO, all available information in its/their possession, that may be relevant to the outbreak. When a State Party requests a field investigation of an outbreak(s) of disease on the territory or in any place under the jurisdiction or control of another State Party, the State Party where the investigation is proposed to occur shall have the right to provide evidence, and other information, and analysis that indicates that the outbreak of disease is naturally occurring or otherwise unrelated to activities prohibited by the Convention. If deemed appropriate by the Executive Council as a matter of procedure under Article IX, paragraph 30, other State(s) Party(ies) may also provide information relevant to whether the outbreak(s) of disease is naturally occurring and/or whether it is related to activities prohibited by the Convention. All of the evidence, and other information, and analysis submitted, shall be taken into account by the Executive Council in its consideration of the investigation request in accordance with the request procedures of paragraphs 13 to 27 of this section.

#### Unusual outbreaks of disease

8. The diseases which are endemic in the region and present the expected epidemiological features shall not be considered as an unusual outbreak of disease. **Such** an outbreak of disease which appears to be unusual, **may** be investigated by the affected State Party.

#### (C) ALLEGED USE OF A BIOLOGICAL WEAPON

9. A State Party has a right to request a field investigation of an alleged use of a biological weapon if it believes that a biological weapon was used against it on the territory under its jurisdiction and control.

#### (D) CONSULTATION, CLARIFICATION AND COOPERATION

10. States Parties may, without prejudice to their right to request an investigation, and prior to the submission of any request for an investigation make use of and follow the relevant procedures set out in section E of this Article on consultation, clarification and cooperation in order to clarify and resolve satisfactorily any matter which may cause concern about possible non-compliance with the obligations of the Convention.

#### (E) INITIATION OF INVESTIGATIONS

11. An investigation may be requested to be conducted on the territory of a State Party, or in any other place under its jurisdiction or control, regardless of the form of ownership of the facility or the area subject to the investigation, in accordance with the provisions of this Protocol.

12. An investigation may also be requested to be conducted in any place on the territory of a non-State Party which is under its jurisdiction or control, if any State Party has a concern(s) that another State Party, which shall be identified in the request, is the alleged cause of the non-compliance concern. Upon receipt of such a request, the Director-General shall immediately contact the non-State Party concerned to seek:

(a) Its consent to the conduct of the investigation; and, subject to such consent

(b) Its agreement that the provisions of this Protocol governing the conduct of investigations shall apply to the investigation or, alternatively, its agreement to different procedures for the conduct of the investigation which the Director-General is satisfied would enable the facts relating to the specific concern about non-compliance raised in the request to be determined.

The Director-General shall inform the Executive Council and the requesting State Party of the outcome of such consultations as soon as possible.

13. Requests for investigations to be conducted in accordance with this Protocol shall be submitted in writing by the requesting State Party to the Executive Council and at the same time to the Director-General for processing in accordance with procedures as set out in paragraphs 19 to 27 of this section.

14. If, during the course of a field investigation, the investigation team has acquired information (as a result of the conduct of the activities specified in Annex D, section II, subsection D) indicating that a facility on the territory or in any other place under the jurisdiction or control of a State Party, is directly relevant to the alleged non-compliance concern that has been identified in the field investigation mandate, the investigation team leader shall provide a factual statement of the information and a factual description of how the information was obtained, to the receiving State Party. The receiving State Party may within 24 hours comment on the factual statement. The investigation team leader shall then submit the factual statement, description of how the information was obtained and the comments of the receiving State Party to the Executive Council through the Director-General.

15. Upon receipt of the information, the Executive Council shall provide the information to the receiving State Party, the requesting State Party, and, if appropriate, the State Party on whose territory or under whose jurisdiction or control the facility in question is located. Only these States Parties may submit a request for a facility investigation which involves this information. Such request shall be considered in accordance with the provisions contained in paragraphs 10 to 13 and 18 to 20 of this section.

16. The Executive Council's consideration of the information or any request for a facility investigation received from a State Party which received its information in accordance with paragraph 15 above and any decision made there-on shall be conducted in accordance with the provisions set out in paragraphs 19 to 27 of this section.

17. If the Executive Council decides that a facility investigation must be conducted, the investigation shall be conducted in accordance with the provisions for facility investigations set out in this section, and Annex D, sections I and III. The reports of the field and facility investigations shall be considered independently or simultaneously as determined by the Executive Council depending on the specific circumstances involved.

(F) INFORMATION TO BE SUBMITTED WITH A REQUEST FOR AN INVESTIGATION TO ADDRESS A CONCERN OF NON-COMPLIANCE WITH THE CONVENTION

18. A State Party requesting an investigation shall provide supporting evidence and other information required in accordance with the provisions set out in Annex D. All such evidence and other information shall be as precise as possible.

(G) FOLLOW-UP AFTER SUBMISSION OF AN INVESTIGATION REQUEST AND EXECUTIVE COUNCIL DECISION-MAKING

19. The Director-General, after receiving an investigation request, shall acknowledge receipt of it to the requesting State Party within two hours and shall provide a copy of the investigation request to the State Party sought to be investigated within six hours.

20. The Director-General shall ascertain within six hours after receipt of the investigation request whether the investigation request meets the requirements set out in paragraph 1 of section II of Annex D, for field investigations, and paragraph 1 of section III of Annex D, for facility investigations. If the Director-General is satisfied that the investigation request meets these requirements, he/she shall so inform the Executive Council immediately, and the State Party sought to be investigated and, if applicable, the potential host State Party/State, within six hours. If the Director-General determines that the investigation request does not meet these requirements, the Director-General shall so inform the Executive Council and the requesting State Party, and shall inform the requesting State Party of the reasons for this determination. The requesting State Party may submit a revised request, which shall be submitted and processed in the same way as an original request.

21. When the investigation request fulfils the requirements, the Director-General may begin with appropriate preparations for the investigation.

22. The Director-General, may upon receipt of an investigation request referring to an investigation area under the jurisdiction or control of a State Party, propose to the requesting State Party to immediately seek clarification from the State Party sought to be investigated in order to clarify and resolve the concern raised in the request. A State Party which receives a request for clarification pursuant to this paragraph shall provide the requesting State Party and the Director-General with explanations and with other relevant information as soon as possible but no later than 24 hours after receipt of the request for clarification without prejudice to its rights to provide additional relevant information during the entire process of the consideration of the investigation request by the Executive Council. Unless the requesting State Party considers the concern raised in the investigation request to be resolved and withdraws the request, the Executive Council shall take a decision on the request in accordance with paragraph 24.

23. The Executive Council shall begin its consideration of an investigation request immediately after it is informed by the Director-General, in accordance with paragraph 20, that the request meets the requirements and shall come to a conclusion on the request not later than **12** hours<sup>81</sup> after it is so informed. Upon the conclusion of the Executive Council's

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<sup>81</sup>This language reflects that of the CWC, Article IX, paragraph 17 as there is no logical reason for a longer delay.

consideration of an investigation request, the Director-General shall provide a copy of the request and the decision to all States Parties within 24 hours.

24. The investigation shall proceed unless the Executive Council decides by a three-quarters majority of all its members against carrying out the investigation<sup>82</sup>.

25. The State Party sought to be investigated shall have the right to inform the Executive Council about the nature of the facility or area indicated in the investigation request, and provide information to indicate why, in its view, this facility is unrelated to the Convention. It may also state, if it believes it necessary to do so, why in its view the investigation request is unfounded or abusive.

26. In its examination of the investigation request, the Executive Council shall consider all the evidence and other information as well as analysis provided by the requesting State Party and the State Party sought to be investigated, as well as any information resulting from any prior consultation or clarification process and may also take into account other relevant information available to it. In doing so, the Executive Council may also decide, without prejudice to the time-line set out in paragraph 23, to seek more information from the requesting State Party, the State Party sought to be investigated and from other relevant international organizations. If such information cannot be provided by other relevant international organizations within the time-line set out in paragraph 23, the Director-General shall inform the Executive Council as appropriate. In the case of the Executive Council not approving the request for investigation, it may recommend other actions to resolve the matter such as bilateral or multilateral consultations to resolve the issue.

27. The requesting State Party as well as the State Party sought to be investigated, and, if applicable, in the case of a request for a field investigation, the State Party identified in the request as the alleged cause of the non-compliance concern, may participate in the Executive Council's consideration of an investigation request, but shall not have the right to vote on the request, whether or not such States Parties are members of the Executive Council.

28. The investigation mandate shall be made available to the receiving State Party immediately after the mandate is issued to the investigation team by the Director-General which shall be no later than 12 hours before the team's arrival at the point of entry.

#### (H) ACCESS AND MEASURES TO GUARD AGAINST ABUSE DURING THE CONDUCT OF INVESTIGATIONS

##### General principles

29. The receiving State Party shall provide access to the investigation team within the areas specified in paragraphs 38 and 41 and at the same time have the right to take such measures it deems necessary in accordance with the provisions of this section to protect its national security interests and/or to protect confidential information and data (including commercial proprietary information) during an investigation within the relevant time frames specified in Annex D in accordance with the following:

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<sup>82</sup>The presumption should be that an investigation, once requested and meeting the requirements of Annex D, will take place unless the Executive Council votes to stop the investigation. See Briefing Paper No. 15, *Non-Compliance Concern Investigations: Initiation Procedures*, October 1998. This is vital for a strong Protocol as the ultimate measure available to the States Parties is the carrying out of an investigation.

(a) All such access shall be for the sole purpose of establishing facts relevant to the investigation mandate;

(b) The receiving State Party shall have the right to inform the investigation team about the areas, facilities or buildings which it considers sensitive and/or not related to the Convention;

(c) The nature and extent of access to a particular facility, place(s) or information within the areas specified in paragraphs 38 and 41 below, as set out in the mandate, shall be negotiated between the investigation team and the receiving State Party;

(d) The investigation team and the receiving State Party shall also negotiate the activities to be performed during the investigation; all activities shall be performed in accordance with the relevant provisions for these activities contained in Annex D, sections II and III;

(e) The receiving State Party shall have the right to make the final decision on the nature and extent of such access, taking into account its rights and obligations under this Protocol;

(f) In meeting the requirements to provide access, the receiving State Party shall be under the obligation to provide the greatest degree of access possible, taking into account any constitutional obligations it may have with regard to proprietary rights or searches and seizures;

(g) The receiving State Party shall make every reasonable effort to demonstrate its compliance with the Convention and, to this end, to enable the investigation team to fulfil its mandate.

30. The receiving State Party shall have the right to take measures, as it deems necessary to protect national security and/or to protect confidential information and data (including commercial proprietary information) in accordance with the provisions of this section and taking into account its obligations under this Protocol. Such measures may include but shall not be limited to the following:

(a) Removal of sensitive papers from office spaces and direct view;

(b) Shrouding of sensitive displays, stores, and equipment;

(c) Shrouding sensitive pieces of equipment, such as computer or electronic systems;

(d) Logging off of computer systems and turning off data indicating devices;

(e) Using random selective access techniques whereby the team is requested to select a given percentage or number of buildings of their choice to investigate; the same principle can apply to the interior and content of sensitive buildings or documents;

(f) Limiting the number of team members who have access to certain buildings, structures or places within the area specified in paragraphs 38 and 44;

- (g) Limiting the viewing angle;
- (h) Limiting the time investigation team members may spend in any area or building;
- (i) At any time during the investigation, notifying the investigation team of the products and processes which involve national security and/or the protection of confidential information and data (including commercial proprietary information) and its rights to safeguard it. It may request that if a specific piece of information is released to the team, it should be accorded the most stringent protection measures in conformity with the confidentiality provisions.

31. The receiving State Party may, in accordance with paragraph 29 and 30 above deny access to particularly sensitive buildings, structures or parts thereof not related to the investigation mandate, taking into account its obligations under this section.

32. If the receiving State Party provides less than full access to places, activities or information, it shall make every reasonable and feasible effort to provide alternative means to demonstrate compliance and to clarify the possible non-compliance concern that generated the investigation. The nature and extent of access, including any alternative means to demonstrate compliance, provided by the receiving State Party, and the extent to which this enabled the investigation team to fulfil its mandate, shall be recorded factually in the investigation report.

33. These provisions may not be invoked by the receiving State Party to conceal any evasion of its obligations not to engage in activities prohibited under the Convention.

34. In carrying out the investigation in accordance with the investigation mandate, the investigation team shall use only those methods necessary to provide sufficient relevant facts to clarify the concern about possible non-compliance with the provisions of the Convention, and shall refrain from activities not relevant thereto. It shall request, collect and/or document only such facts as are related to the investigation mandate, but shall neither seek nor document information which is clearly not related thereto, unless the receiving State Party expressly requests it to do so. Any material collected and subsequently found not to be relevant shall not be retained.

35. The investigation team shall conduct the investigation in the least intrusive manner possible consistent with the effective and timely implementation of its mandate. As a rule, it shall begin with the procedures it deems least intrusive and proceed to more intrusive procedures only as required to fulfil its mandate.

36. The investigation team shall take into consideration suggested modifications of the investigation plan and proposals which may be made by the receiving State Party, at any stage of the investigation, including the pre-investigation briefing, to ensure, *inter alia*, that sensitive equipment, information or places are protected. The investigation plan shall be handled in accordance with section II, paragraph 17, and section III, paragraph 30, of Annex D.

37. If the investigation team considers it necessary in order to fulfil its mandate, the investigation team shall have the right to request clarification in connection with ambiguities

that may arise during an investigation. Such requests shall be made promptly to or through the representative of the receiving State Party. The representative shall make every reasonable effort to provide the investigation team with such clarification as may be necessary to remove the ambiguity.

#### Field investigations

38. The receiving State Party shall provide access into the investigation area within **24** hours<sup>83</sup> after arrival at the point of entry in order to conduct activities pursuant to this Article and sections I and II of Annex D for the duration of the investigation as specified in Annex D, section II, paragraph 10.

39. The receiving State Party shall provide access in accordance with paragraph 29 of this section within the investigation area for the sole purpose of enabling the investigation team to conduct specific on-site activities identified in, and in accordance with, Annex D, section II, paragraphs 21 to 50. The extent and nature of access within the investigation area shall be negotiated between the investigation team and the receiving State Party in accordance with paragraphs 29 to 37 of this section. Such negotiated access in accordance with paragraphs 29 to 37 of this section, shall allow access to all humans, animals and/or plants that may have been affected by microbial or other biological agents or toxins directly related to the non-compliance concern being investigated.

40. The access provided for in these paragraphs shall not interfere or impede with any national measures taken to deal with the outbreak of disease.

#### Facility investigations

41. The receiving State Party shall provide access within the requested and, if different, final perimeter not later than **36** hours<sup>84</sup> after arrival at the point of entry pursuant to Annex D, section III, paragraph 5 for the conduct of activities pursuant to this Article and sections I and III of Annex D for the duration of the investigation as specified in Annex D, section III, paragraph 8.

#### (I) FINAL REPORT

42. The preparation and handling of the final report shall be conducted in accordance with Annex D.

#### (J) REVIEW AND CONSIDERATION OF THE FINAL REPORT

43. The Executive Council shall, in accordance with its powers and functions as determined in Article IX, section C, review and consider the final report of the investigation team as soon as it is presented, and address any concern as to whether:

- (a) Any non-compliance has occurred;

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<sup>83</sup>There is no logical reason for a longer delay.

<sup>84</sup>There is no logical reason for a longer delay.



- (b) The request had been in accordance with the provisions of this Protocol;
- (c) The right to request an investigation has been abused.

44. With respect to any concerns raised under paragraph 43 (c), one or more of the following factors could be taken into account, where relevant:

(a) Information relating to the investigated site available prior to the investigation request (the authenticity and reliability of any information would need to be carefully assessed);

(b) Whether any of the information submitted as part of the investigation request was shown to be false;

(c) Information from and/or outcome or results of prior consultations/clarifications relevant to the request, if applicable;

(d) Whether any investigation(s) (including any instituted under Article VI of the Convention) had previously been requested by the same State Party *vis-à-vis* the same investigated site, and if so, their number, frequency and outcome (including any follow-up action).

45. If the Executive Council reaches the conclusion, in keeping with its powers and functions, that there has been abuse, it shall consider and decide on, *inter alia*, whether:

(a) The requesting State Party shall bear some or all of the financial implications of the investigation, including those which have been borne by the receiving State Party;

(b) To suspend the right of the requesting State Party to request an investigation for a period of time, as determined by the Executive Council;

(c) To suspend the right of the requesting State Party to serve on the Executive Council for a period of time.

46. If the Executive Council reaches the conclusion, in keeping with its powers and functions, that further action may be necessary with regard to paragraph 43, it shall take the appropriate measures to redress the situation and to ensure compliance, including, if appropriate, specific recommendations to the Conference which shall consider the recommendations in accordance with Article IX and take the appropriate measures in accordance with Article V.

47. If the Executive Council reaches the conclusion, in keeping with its powers and functions, that further action may be necessary with regard to paragraph 43 (a), it shall distribute the investigation report to all States Parties before the next session of the Conference.

48. The receiving State Party, the requesting State Party and any other State Party that has been identified in an investigation request as the alleged cause of the non-compliance concern, shall have the right to participate in the review process in the Executive Council but shall have no vote.

49. The Executive Council shall inform the States Parties and the next session of the Conference of States Parties of the outcome of the process.

## H. ADDITIONAL PROVISIONS<sup>85</sup>

1. In the specific case of a declaration, a visit or an investigation provided for in this Article, in which more than one State Party/State is involved, the following provisions shall apply.

### (A) DECLARATIONS

2. In cases where the programmes and/or activities or facilities subject to declarations in accordance with the provisions of this Article exist/existed in places on the territory of a State Party, but which are/were under the jurisdiction or control of another State not party to the Protocol, the provision of paragraph 1, section D, of this Article shall not apply to that State Party. The State Party concerned shall seek confirmation from the State under whose jurisdiction or control the programmes and/or activities or facilities fall, whether they are subject to the provisions of paragraph 1, section D, subsection I, of this Article. If so, the State Party in its initial and annual declaration shall inform the Technical Secretariat of the existence of such programmes and/or activities or facilities on its territory.

3. In cases where the programmes and/or activities or facilities subject to declarations in accordance with the provisions of this Article exist/existed in places on the territory of a State Party, but which are/were under the jurisdiction or control of another State Party, the provision of paragraph 1, section D of this Article shall only apply to the latter State Party. The latter shall provide the former with information on the presence of such programmes and/or activities or facilities and with a copy of its declaration relating to such programmes and/or activities or facilities simultaneously with the submission of the declaration to the Organization. The State Party on whose territory aforementioned places are/were shall inform the Organization about the fact of the presence of such programmes and/or activities or facilities in cases where such fact of their presence is known to this State Party.

4. In cases where the programmes and/or activities or facilities which are subject to declarations in accordance with the provisions of this Article exist/existed in places on the territory or in any other place under the jurisdiction or control of a State Party, but are/were conducted or administered by another State Party, the former shall have the right to gain access to information and/or to receive such information required to fulfil its obligations under this section, from the latter State Party. The State Party on whose territory there exist programmes and/or activities or facilities subject to declarations shall seek confirmation from the State Party responsible for such programmes and/or activities or facilities whether it has fulfilled its obligations under the Protocol, and include in its own declarations a report to that effect.

### (B) VISITS

#### Visits on the territory of a host State Party

6. In cases where a facility of a visited State Party is located on the territory of a host State Party, the visited State Party and the host State Party shall cooperate and make arrangements to allow the visit to be conducted in accordance with the provisions of this Protocol.

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<sup>85</sup>The text in AHG/51 (Part II) has been used as the baseline for this section.

7. In the case of visits on the territory of a host State Party/State, the host State Party shall be notified by the Director-General in the same manner as the visited State Party is, and the host State should be notified in an appropriate manner. In this case, the visit mandate and notification shall contain the name of the host State Party/State.

### (C) INVESTIGATIONS

#### Access and conduct of investigations involving States other than the receiving State Party

9. In cases where a facility or area of a receiving State Party is located on the territory of a host State Party or where the transport from the point of entry to a facility or area subject to investigation requires transit through the territory of another State Party, the receiving State Party shall exercise the rights and fulfil the obligations concerning such investigations in accordance with this Protocol. The host State Party shall facilitate the investigation of that facility or area and shall provide for the necessary support to enable the investigation team to carry out its tasks in a timely and effective manner. States Parties through whose territory transit is required to a facility or area to be investigated of a receiving State Party, shall facilitate such transit.

10. In cases where a facility or area of a receiving State Party is located on the territory of a host State not party to this Protocol, the receiving State Party shall take all necessary measures to ensure that investigations of that facility or area can be carried out in accordance with the provisions of this Protocol. A State Party that has one or more facilities or areas on the territory of a host State not party to this Protocol shall take all necessary measures to ensure acceptance by the host State of the designated investigation personnel accepted by the receiving State Party in accordance with the provisions set out in Annex D, section I, paragraphs 2 to 16. If a receiving State Party is unable to ensure access, it shall demonstrate that it took all necessary measures to ensure access.

11. In cases where a facility or area sought to be investigated is located on the territory of a State Party, but in a place under the jurisdiction or control of a State not party to this Protocol, such a State Party shall take all necessary measures as would be required of a host State Party in accordance with the provisions of paragraph 9 above.

12. In cases where the investigation is related to paragraphs 9 to 11, the host State Party shall be notified by the Director-General in the same manner as the receiving State Party is, and the host State shall be notified in an appropriate manner. In this case, the investigation mandate and notification shall contain the name of the host State Party/State.

## ARTICLE IV<sup>86 87</sup>

### CONFIDENTIALITY PROVISIONS

1. The Organization shall conduct its activities provided for under this Protocol in the least intrusive manner consistent with the timely and efficient accomplishment of their objectives. It shall request only the information and data necessary to fulfil its responsibilities under this Protocol and shall use this data and information only for the purpose of this Protocol. It shall avoid, to the extent possible, any access to information and data not related to the aims of this Protocol. It shall take every precaution to protect the confidentiality of information on civil and military activities and facilities in the implementation of this Protocol and, in particular, shall abide by the confidentiality provisions set forth in this Protocol.
2. Each State Party shall have the right to take measures as it deems necessary to protect confidential information in accordance with the provisions of the Protocol.
3. The Director-General shall have the primary responsibility for ensuring the protection of all confidential information which comes into possession of the Technical Secretariat. Based on guidelines provided for within this Protocol, the Director-General shall establish and maintain stringent procedures governing the handling of confidential information by the Technical Secretariat which shall include measures to protect confidential information obtained in the course or as a result of on-site activities as well as the necessary procedures to be followed in case of breaches or alleged breaches of confidentiality to ensure effective protection against unauthorized disclosure. These procedures shall be approved and periodically reviewed by the Conference of the States Parties.
4. States Parties shall be entitled to receive in accordance with the relevant provisions of this Protocol the following data:
  - (a) The initial and annual declarations provided by States Parties on a reciprocal basis in accordance with Article III, section D;
  - (b) Reports on the activities of the Technical Secretariat as compiled and issued by the Director-General;
  - (c) Reports on investigations as well as observations and comments on these reports, if any, from the receiving States Parties in accordance with Article III, section G;
  - (d) Reports on visits in accordance with Article III, section D, subsection II;
  - (e) Annual declarations required under Article VII;
  - (f) Other information and data to be supplied to States Parties in accordance with the provisions of this Protocol.

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<sup>86</sup>The text in AHG/52 (Part II) has been used as the baseline for this section.

<sup>87</sup>The amendments made to Article IV and Annex E are based on the analysis in Evaluation Paper No. 16, *Article IV: Confidentiality Provisions*, March 2000.

Each State Party shall treat information and data received from the Organization in accordance with the level of confidentiality established for that information and data and shall treat it exclusively in connection with its rights and obligations under this Protocol and in accordance with its provisions.

5. The relevant organs and subsidiary organs of the Organization shall be entitled to receive from the Technical Secretariat information and data necessary for the performance of the functions entrusted to them by the provisions of this Protocol. The provision of any confidential information and data shall be strictly limited to the minimum necessary for the performance of these functions and shall be in conformity with the procedures established pursuant to paragraph 3.

6. Any State Party to this Protocol which considers that it has been affected by a breach of confidentiality or that its natural or legal persons have suffered from damage through such a breach may seek to settle the dispute in accordance with the provisions set forth in Article XII. In case a dispute related to confidentiality cannot be settled between the States Parties or between States Parties and the Organization directly, a commission for the settlement of disputes related to confidentiality (hereinafter referred to as "Confidentiality Commission"), set up as a subsidiary organ of the Conference in accordance with Article IX shall consider the case. The Confidentiality Commission shall have the powers and functions as set forth in this Protocol. The Commission shall be appointed by the Conference. Rules governing its composition and its operating procedures shall be adopted by the Conference.

## ARTICLE V<sup>88</sup>

### MEASURES TO REDRESS A SITUATION AND TO ENSURE COMPLIANCE

1. The Conference shall take the necessary measures, in accordance with paragraphs 2, 3 and 4, to ensure compliance with the Convention and this Protocol and to redress and remedy any situation which contravenes their provisions. In considering action pursuant to this paragraph, the Conference shall take into account all information and recommendations on the issues submitted by the Executive Council.
2. In cases where a State Party has been requested by the Conference or by the Executive Council, taking into account their respective powers and functions, to take measures to redress a situation raising problems with regard to its compliance, and where the State Party fails to fulfil the request within the specified time, the Conference may, upon the recommendation of the Executive Council, *inter alia*, restrict or suspend the State Party's rights and privileges under this Protocol until the Conference decides it has undertaken the necessary action to conform with its obligations under the Convention and this Protocol.
3. In cases where serious damage to the object and purpose of the Convention may result from non-compliance with the provisions of the Convention or this Protocol, in particular Article I of the Convention, the Conference may recommend to States Parties collective measures which are in conformity with international law and designed to ensure the fulfilment of the object and purpose of the Convention.
4. The Conference or, alternatively, if the case is particularly grave and urgent, the Executive Council, may bring the issue, including relevant information and conclusions, to the attention of the General Assembly and the Security Council of the United Nations.

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<sup>88</sup>The amendments made to Article V are based on the analysis in Evaluation Paper No. 8, *Article V: Measures to Redress a Situation and to Ensure Compliance*, November 1999.

## ARTICLE VI<sup>89</sup>

### ASSISTANCE AND PROTECTION AGAINST BIOLOGICAL AND TOXIN WEAPONS

1. For the purposes of this Article, “Assistance” means the coordination and delivery to States Parties of protection against biological and toxin weapons, including, *inter alia*, any of the following: detection equipment including biosensors; alarm equipment; protective equipment; decontamination equipment and decontaminants; prophylactic, diagnostic and/or therapeutic medical measures and materials, and/or advice on any of these protective measures.
2. Nothing in this Protocol shall be interpreted as impeding the right of any State Party to conduct research into, develop, produce, acquire, transfer or use means of protection against biological and toxin weapons, for purposes not prohibited under the Convention.
3. Each State Party undertakes to facilitate, and shall have the right to participate in the fullest possible exchange of equipment, material and scientific and technological information concerning means of protection against biological and toxin weapons **and to benefit from scientific and technological exchanges pursuant to the provisions of this Protocol, including Article VII thereof.**<sup>90</sup>
4. The Technical Secretariat shall establish, not later than 180 days after entry into force of this Protocol and maintain, for the use of any requesting State Party, a data bank containing freely available information concerning various means of protection against biological and toxin weapons as well as such information as may be provided by States Parties.
5. The Technical Secretariat shall also, within the resources available to it, and at the request of a State Party, provide expert advice and assist the State Party in identifying how its programmes for the development and improvement of a protective capacity against biological and toxin weapons could be implemented.
6. Nothing in this Protocol shall be interpreted as impeding the right of States Parties to request and provide assistance bilaterally and to conclude individual agreements with other States Parties concerning the emergency procurement of assistance.
7. Each State Party undertakes to provide assistance to the extent possible through the Organization and to this end may elect to take one or more of the following measures:
  - (a) To contribute to the voluntary fund for assistance to be established by the Conference at its first session;
  - (b) To conclude, if possible not later than 180 days after this Protocol enters into force for it, agreements with the Organization concerning the procurement, upon demand, of assistance;

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<sup>89</sup>The amendments made to Article VI are based on the analysis in Evaluation Paper No. 13, *Article VI: Assistance and Protection Against Biological and Toxin Weapons*, January 2000.

<sup>90</sup>This language makes it clear that States Parties to the Protocol can benefit from scientific and technological exchange under Article VII.



(c) To declare, not later than 180 days after this Protocol enters into force for it, the kind of assistance it might provide in response to an appeal by the Organization. If, however, a State Party subsequently is unable to provide the assistance envisaged in its declaration, it is still under the obligation to provide assistance in accordance with this Article.

8. Each State Party has the right to request and, subject to the procedure set forth in paragraphs 9, 10, 11 and 12 to receive assistance and protection against the use or threat of use of biological and toxin weapons if it considers that:

(a) Biological and toxin weapons have been used against it;

(b) It is threatened by imminent actions that are prohibited for States Parties by Article I of the Convention;

(c) It has credible reason to believe it is confronted by imminent actions or serious threat with respect to actions that are prohibited for States Parties by Article I of the Convention.

9. The request for assistance, substantiated by relevant information, shall be submitted to the Director-General, who shall transmit it immediately to the Executive Council and to all States Parties, requesting those States Parties which have volunteered assistance, in accordance with subparagraphs 7 (b) and (c) to begin preparations to dispatch emergency assistance in case of use of biological and toxin weapons, or humanitarian assistance in case of serious threat of use of biological and toxin weapons to the State Party concerned, not later than 12 hours after receipt of the request.

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10. The Director-General shall initiate, not later than 12 hours after receipt of a request for assistance, from a State Party, an examination of the request in order to provide foundation for further action by the Organization. The Director-General shall complete the examination within 72 hours and forward a report to the Executive Council and to States Parties. If necessary, the time required for completion of the examination may be extended by periods of 72 hours with reports being submitted at the end of each 72 hour period, to the Executive Council and to all States Parties. The examination shall, as appropriate and in conformity with the request and the information accompanying the request, establish relevant facts related to the request as well as make recommendations on the type and scope of supplementary assistance and protection needed. In the case of request for assistance when a State Party considers that biological or toxin weapons have been used against it, the Director-General shall, when possible, incorporate into the examination report relevant factual information from the affected area(s) and, as appropriate, progress reports from any investigation team which may be conducting a field investigation in the State Party concerned.

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<sup>91</sup>The language proposing that provision of assistance should be conditional on submission of a simultaneous request for a field investigation is deleted as it is not apparent why assistance under the Protocol should be conditional -- there is no parallel requirement in the CWC. Such a proposed conditionality fails to recognise that a State Party may well require assistance at a much earlier time, well before it has sufficient information to request a field investigation.

11. The Executive Council shall meet not later than 24 hours after receiving an examination report to consider the situation and shall take a decision by simple majority within the following 24 hours on whether to instruct the Technical Secretariat to provide supplementary assistance. The Technical Secretariat shall immediately transmit to all States Parties and relevant international organizations the examination report and the decision taken by the Executive Council. When so decided by the Executive Council, the Director-General shall provide assistance immediately. For this purpose, the Director-General may cooperate with the requesting State Party, other States Parties and relevant international organizations. The States Parties shall make the fullest possible efforts to provide assistance.

12. If the information available from the ongoing examination or other reliable sources would give sufficient proof that there are humans, animals or plants affected by the use of biological and toxin weapons and immediate action is indispensable, the Director-General shall notify all States Parties and shall take emergency measures of assistance, using the resources the Conference has placed at his/her disposal for such contingencies. The Director-General shall keep the Executive Council informed of actions undertaken pursuant to this paragraph.

## ARTICLE VII<sup>92</sup> <sup>93</sup>

### SCIENTIFIC AND TECHNOLOGICAL EXCHANGE FOR PEACEFUL PURPOSES AND TECHNICAL COOPERATION

#### (A) GENERAL PROVISIONS

1. Each State Party undertakes to implement specific measures, including those set out in this Article, designed to enhance compliance and ensure effective and full implementation of Article X of the Convention among the States Parties to the Protocol. The implementation of such measures shall be aimed at:

(a) Promoting scientific and technological exchanges and fostering international cooperation, as appropriate, on a multilateral, regional or bilateral basis, directly or through the Organization, in the field of peaceful bacteriological (biological) and toxin activities;

(b) Facilitating free trade and the fullest possible exchange in biological agents, toxins, equipment and materials for peaceful purposes in order to enhance the economic and technological development of States Parties and ensuring the right of States Parties to participate in such exchanges to the fullest extent possible;

(c) Avoiding hampering the economic and technological development of States Parties **by** any restrictions incompatible with the obligations undertaken under the Convention 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.

2. The Organization shall provide a forum for consultation and creation of opportunities for cooperation on matters related to the promotion of scientific and technological exchange in the field of peaceful bacteriological (biological) and toxin activities and review of the implementation **of this Article**<sup>94</sup> **by** the States Parties to the Protocol. The Organization shall also develop a framework for activities aimed at promoting scientific and technological cooperation and exchange and providing technical assistance, including Protocol implementation assistance, upon request, to States Parties, in particular to developing countries which are States Parties. Such a framework may include activities conducted in collaboration with relevant international organizations and agencies.

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<sup>92</sup>The text in AHG/52 (Part II) has been used as the baseline for this section.

<sup>93</sup>The amendments made to Article VII are based on the analyses in Briefing Papers No. 6 *Article X : Some Building Blocks*, March 1998, No. 7 *Article X : Further Building Blocks*, March 1998, No. 8 *Article X : Pharmaceutical Building Blocks*, July 1998, No. 9 *Article X : Specific Measures to Achieve Implementation*, July 1998 and No.22 *Article VII Measures: Optimizing the Benefits*, July 1999 as well as taking into account subsequent development of the text by the Ad Hoc Group.

<sup>94</sup>This review should address the implementation of all the provisions in Article VII of the Protocol.

(B) MEASURES TO PROMOTE SCIENTIFIC AND TECHNOLOGICAL EXCHANGES

3. Each State Party undertakes 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 and, in its implementation of these measures, to ensure that any transfers or exchanges of materials, equipment, technology, and any information pursuant to this Article shall take place in compliance with the provisions of Articles III and X of the Convention.

4. Each State Party shall promote and support, **as appropriate**<sup>95</sup> **and** in furtherance of any current endeavours relevant to and in accordance with the Convention, individually, jointly, through arrangements, with relevant international organizations and agencies<sup>96</sup>, or the institutional mechanisms provided for under section D of this Article:

(a) The publication, exchange and dissemination of information, including through workshops, training programmes and conferences, on current and recent developments, as well as on research and development on the peaceful uses of microorganisms and toxins, biosafety, †<sup>97</sup> biotechnology, good laboratory practice and current good manufacturing practice, and diagnosis, surveillance, detection, treatment and prevention of diseases caused by biological agents or toxins, in particular infectious diseases;

(b) The work of existing laboratories on the prevention, surveillance, detection and diagnosis of diseases caused by biological agents or toxins, in particular infectious diseases, to improve the capabilities of such laboratories and their effectiveness, through, *inter alia*, the provision of training and technical advice, equipment and reagents;

(c) The improvement and development of States Parties' capabilities, upon the specific request of the State Party concerned, in the surveillance, prevention, detection, diagnosis and treatment of diseases caused by biological agents or toxins, in particular infectious diseases, as an integral part of a global effort to improve the monitoring of emerging and re-emerging diseases in humans, animals and plants;

(d) The improvement and development of research capabilities in relevant fields of biosciences and biotechnology for peaceful purposes, through collaborative research programmes and projects, upon the specific request of the State Party concerned, in particular in the use of microorganisms and toxins for medical, agricultural, veterinary and industrial purposes;

(e) The establishment, operation and updating of biological databases including those maintained by the Technical Secretariat on information relevant to the purposes of the Convention as well as accessibility to such databases;

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<sup>95</sup>The qualification "*as appropriate*" is necessary as the efforts of each State Party cannot realistically be seen as being to promote and support each item listed.

<sup>96</sup>It is unnecessary to list the international organizations and agencies twice in the same Article. The list is retained in the most appropriate Section (D) *Cooperative Relationships with Other International Organizations and Among States Parties*.

<sup>97</sup>It is inappropriate to have specific mention of "*biodefence*" in Article VII. However, a cross reference in Article VI to the benefits to biodefence arising from technical cooperation under the Protocol is appropriate and has been inserted in Article VI.

(f) The monitoring, diagnosis, detection, prevention and control of outbreaks of diseases, and international cooperation on the research, development and production of vaccines;

(g) Transfer among States Parties of technology for the peaceful uses of genetic engineering, the prevention, diagnosis and treatment of diseases caused by biological agents or toxins, in particular infectious diseases, and for other relevant fields of biosciences and biotechnology for peaceful purposes;

(h) Participation at the bilateral, regional or multilateral levels in the application of biotechnology and scientific research and development, for the prevention, surveillance, detection, diagnosis and treatment of diseases caused by biological agents or toxins, in particular infectious diseases;

(i) The establishment and conduct of training programmes on the diagnosis, surveillance, detection, prevention and treatment of diseases caused by biological agents or toxins, in particular infectious diseases;

(j) The establishment of a framework amongst States Parties **to enhance the cooperative activities contained in this Article and pursuant to the Protocol;**

(k) Any other specific measure(s) approved by the Conference of States Parties on the further strengthening of the implementation of Article X of the Convention and this Article in accordance with Article IX.

(C) MEASURES TO AVOID HAMPERING THE ECONOMIC AND TECHNOLOGICAL DEVELOPMENT OF STATES PARTIES

5. Nothing in this Protocol shall prejudice the rights of States Parties to, individually or collectively, conduct research with, develop, produce, acquire, retain, transfer and use biological agents and toxins for peaceful purposes.

6. Each State Party shall:

(a) **Undertake not to establish, maintain or use**, either individually or collectively, any discriminatory measure(s), **including regimes, agreements or measures**, incompatible with the obligations undertaken under the Convention, which would restrict or impede trade and the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes, *inter alia*, in the fields of biological research, microbiology, biotechnology, genetic engineering, and their industrial, agricultural, medical, pharmaceutical applications, and other related areas for peaceful purposes;

†<sup>98</sup>

(b) Undertake to review periodically, and amend or adopt as necessary, national regulations governing exchanges and transfers of bacteriological (biological) agents and

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<sup>98</sup>The subparagraph in AHG/52 (Part I) has been deleted as it is always open to States Parties to adopt nationally any measures that they judge appropriate.

toxins, and equipment, materials and scientific and technological information for the use of such agents and toxins in order to ensure their consistency with the objectives and relevant provisions of the Convention and this Protocol. The first review **by the State Party** shall be completed no later than 180 days after the entry into force of this Protocol **for that State Party. The outcome of this review and of any subsequent reviews shall be reported annually to the Director-General.**<sup>99</sup> The Director-General shall collate on an annual basis and, for the information of States Parties, report on the implementation of this subparagraph. **The Conference of States Parties shall consider the report of the Director-General and may make recommendations to States Parties on the implementation of national regulations to ensure their consistency with the objectives and provisions of the Convention and this Protocol.**

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(D) INSTITUTIONAL MECHANISMS FOR INTERNATIONAL COOPERATION AND PROTOCOL IMPLEMENTATION ASSISTANCE

The Cooperation Committee

7. The Cooperation Committee (hereinafter referred to as “the Committee”), established by the Conference of States Parties in accordance with Article IX shall be a forum for consultation aimed at promoting the effective and full implementation among the States Parties to the Protocol of the provisions of Article X of the Convention and this Article. To this end, the Committee shall consult on and review activities fostering international cooperation and assistance and the fullest possible transfer and exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes. The Committee shall also contribute to the efforts by the Organization to develop a framework for activities aimed at promoting scientific and technological exchanges for peaceful purposes and technological cooperation for peaceful purposes.

8. The Committee shall review the implementation of measures, pursuant to section B of this Article, to promote scientific and technological exchanges and make recommendations thereon to the Conference of States Parties.

9. The Committee shall review and make recommendations to the Executive Council on:

(a) Cooperative relationships of the Organization with other international organizations and agencies, pursuant to section F of this Article;

(b) The programmes and activities of the Technical Secretariat, pursuant to this **Article**;

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<sup>99</sup>This sentence has been added to provide clarity and to require the necessary reporting to the Director-General of the outcomes of the reviews carried out by the State Party to enable the Director-General to discharge the requirement to provide an annual collation.

<sup>100</sup>This paragraph in AHG/52 (Part I) has been deleted as it is more appropriate for consideration under Section (E) of this Article.

(c) The use of a voluntary fund and/or contributions in activities relevant to this Article, as well as the operation of the regular budget where it relates to activities of the Organization in the implementation of this Article.

**10.** The Committee shall prepare an annual report on its activities, containing the results of its review of measures agreed upon or taken by the relevant organs of the Organization and its recommendations pursuant to paragraphs 7 to 9 above. The report shall be forwarded to the Executive Council for consideration, at its next regular session for any additional recommendations or comments it may wish to annex to the report. The report of the Committee, with any recommendations, comments or decisions annexed by the Executive Council, shall then be submitted to the Conference of States Parties.

**11.** The Committee shall submit a report to the Review Conference of States Parties to the Protocol on its work, including any summation of any recommendations it has made to the Executive Council and the Conference of States Parties, containing its proposals and recommendations on the further strengthening of the implementation of Article X of the Convention and this Article.

**12.** The Committee shall receive and consider the annual declarations submitted by States Parties in accordance with section H of this Article and Appendix E.

**13.** The members of the Committee shall be elected for a term of two years, on the basis of an equitable geographical distribution, in accordance with Article IX of this Protocol. The Committee may establish working groups on an ad hoc basis.

**14.** The Committee shall elaborate its rules of procedure and submit them to the Conference of States Parties for approval.

**15.** The Committee shall **initially** meet at least twice a year.<sup>101</sup> Additional meetings may be convened in accordance with the rules of procedure referred to in paragraph **13** above.

**16.** The chairmanship of the Committee shall rotate annually between each regional group, as defined in Article IX represented in the Committee. Decisions on recommendations shall be agreed by consensus.

#### Role of the Technical Secretariat

**17.** The Director-General, assisted by the Technical Secretariat, shall promote and facilitate scientific and technical cooperation and exchange among States Parties and shall develop a framework of programmes and activities to implement the decisions of the relevant organs of the Organization. The Technical Secretariat shall, where appropriate<sup>102</sup>:

(a) Provide information on the availability of and accessibility to publications and other publicly available forms of information containing the results of recent and current research programmes on the uses of bacteriological (biological) agents and toxins for industrial, pharmaceutical, medical and agricultural purposes;<sup>103</sup>

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<sup>101</sup>As the Cooperation Committee will make recommendations to the Executive Council, a requirement to hold a meeting immediately prior to the Conference of States Parties is not logical.

<sup>102</sup>The functions of the Technical Secretariat have been reordered.

<sup>103</sup>Previously (h)

(b) Promote the exchange, dissemination and the publication of information on research centres, current research and training programmes and conferences on the diagnosis, treatment and prevention of diseases caused by biological agents and toxins, in particular infectious diseases;<sup>104</sup>

(c) Convene regional or international seminars with a view to optimizing cooperation on the peaceful uses of bacteriological (biological) agents and toxins;

(d) Establish and maintain a network to facilitate contact and communications, using the available electronic systems between States Parties, other relevant international organizations and the Technical Secretariat, for the purposes of enabling and promoting scientific cooperation and exchange among States Parties;<sup>105</sup>

(e) Develop a framework, including through either a voluntary fund and/or voluntary contributions, for States Parties to support an international system for the global monitoring of emerging diseases in humans, animals and plants, and to support other specific programmes to improve the effectiveness of national and international efforts on the diagnosis, prevention and treatment of diseases caused by biological agents and toxins, in particular infectious diseases;<sup>106</sup>

(f) Implement at the request of States Parties, programmes of support and assistance for upgrading laboratories nominated for designation and certification pursuant to Annex D, section I, part B;<sup>107</sup>

(g) Implement programmes of support and assistance for designation and certification of laboratories pursuant to Annex D, section I, part B.<sup>108</sup>

**(h) Provide advice on the establishment and operation of collaborative vaccine research and development programmes,** and on the requirements for vaccine production facilities meeting †<sup>109</sup> Good Manufacturing Practice standards;<sup>110</sup>

(i) Advise and assist States Parties to promote the objective of, employment of personnel on a wide and equitable geographical basis, on the design and conduct of training programmes to help develop and enhance the expertise and skills necessary for their nationals to serve on the staff of the Technical Secretariat;<sup>111</sup>

(j) Conduct internship programmes for appropriately qualified personnel, on the basis of equitable geographical distribution, to optimize cooperation on the peaceful uses of

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<sup>104</sup>Previously (g)

<sup>105</sup>Previously (b)

<sup>106</sup>Previously (d)

<sup>107</sup>Previously (j)

<sup>108</sup>Previously k

<sup>109</sup>Limitation to "current" Good Manufacturing Practice standards is unnecessary. Provision of advice on Good Manufacturing Practice standards, present and future, is appropriate.

<sup>110</sup>Developed from previous (a)*bis* and (a) *ter*.

<sup>111</sup>Previously (e)



bacteriological (biological) agents and toxins and technical cooperation amongst the States Parties;<sup>112</sup>

(k) Promote cooperation amongst States Parties and provide information, upon request, on equipment and technology exchanges relevant to the peaceful uses of bacteriological (biological) agents and toxins including for the diagnosis, treatment and prevention of diseases caused by biological agents and toxins, in particular infectious diseases.<sup>113</sup>

#### Cooperation and assistance in the context of visits

**18.** If specifically requested by a State Party in the context of visits pursuant to Article III and of paragraph 2 of this Article, the visiting team shall provide information and advice on, and implement, where appropriate, any cooperation and assistance activities contained in programme(s) of the Organization in, *inter alia*:

- (a) Biosafety, including environmental protection and occupational health issues;
- (b) The principles of Good Laboratory Practice and †<sup>114</sup> Good Manufacturing Practice;
- (c) **Diagnostic techniques for infectious diseases** and the availability of vaccines and the possible timetable for the introduction of new vaccines;
- (d) The principles and requirements of national and international regulatory mechanisms governing the production, validation, marketing and sale of biological products for prophylactic, diagnosis and treatment of diseases caused by biological agents or toxins, in particular infectious diseases, and pharmaceutical products and vaccines;
- (e) Training requirements for facility and national regulatory personnel, and sources of such training;
- (f) The evaluation of the methodology underpinning the State Party's or facility's declaration process and the formulation of suggestions, if necessary, for methodological improvements to future declarations;
- (g) The provision of information, guidance or the identification of any specific training opportunities for facility personnel on efficient biosafety, occupational health and safety practices and environmental protection relevant to the facility. This may include facilitating contact with relevant international bodies;
- (h) The provision of information on publications and other publicly available forms of information containing current research programmes in the biosciences and biotechnology, conferences, research centres, information databases and other scientific and technological developments and activities about which the visiting team are cognizant of relevance to the Convention and facility;

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<sup>112</sup>Previously (f)

<sup>113</sup>Previously (i)

<sup>114</sup>Limitation to "current" Good Manufacturing Practice is unnecessary. Provision of advice on Good Manufacturing Practice, present and future, is appropriate.

(i) The provision of information and guidance as well as the identification of any specific training opportunities for facility personnel to facilitate the development, evaluation or licensing of products;

(j) The identification of national, regional and international sources of information for more detailed follow-up enquiries and specialized assistance on these topics.

#### Protocol implementation assistance

**19.** Upon a specific request by a State Party, the Technical Secretariat shall provide advice and assistance, either by itself or in cooperation with other States Parties on:

(a) The establishment and functioning of national authorities;

(b) The preparation of declarations required under Article III of this Protocol;

(c) The drawing up of internal legislation necessary under the provisions of this Protocol;

(d) The content and conduct of training courses and seminars for National Authority and declared facility personnel on the compilation of declarations and the planning and hosting of visits.

#### Requests for assistance

**20.** All requests for assistance by States Parties shall be submitted to the Director-General and shall include detailed information and reasons for the assistance sought. Where requests for assistance exceed the available resources of the Technical Secretariat, the Director-General shall take into the account one or more of the following factors:

(a) The effective implementation of this Protocol;

(b) The relative capacities and needs of individual States Parties, particularly of developing countries being States Parties;

(c) The specific details of each request;

(d) Whether the State Party seeking assistance has benefitted from technical and assistance programmes established by the Technical Secretariat within the last two years, and, if so, the financial extent of them;

(e) The extent to which the assistance requested would improve the operation and utility of existing national, regional and international efforts in the area of the assistance sought.

**(E) CONCERNS RELATED TO THE IMPLEMENTATION OF ARTICLE X OF THE CONVENTION AND THIS ARTICLE**

**21.** The Executive Council shall, in accordance with Article IX of the Protocol, consider concerns on the implementation of Article X of the Convention and this Article.

22. The State Party which raises concerns related to the implementation of Article X of the Convention and this Article shall provide the Executive Council with supporting evidence and other information substantiating its concerns. Any other State Party may provide relevant information to support or clarify the concern.

23. The Executive Council may make recommendations to the States Parties concerned on ways in which they may wish to resolve the situation. The Executive Council **may also, where appropriate,** bring the issue to the attention of the Conference of States Parties. The Conference of States Parties may make recommendations to the States Parties concerned on ways in which they may wish to resolve the situation.<sup>115</sup>

(F) COOPERATIVE RELATIONSHIPS WITH OTHER INTERNATIONAL ORGANIZATIONS AND AMONG STATES PARTIES

24. The Organization may, where appropriate, conclude agreements and arrangements pursuant to Article IX with relevant international organizations and agencies, including, but not limited to, the FAO, ICGEB, IVI, OIE, OPCW, UNEP, UNIDO, WHO, and the Secretariat of the CBD, taking into account their relevant competences and existing agreements, **as well as the activities of States Parties in order to avoid duplication as well as to ensure an effective and coordinated use of resources for the effective implementation of the measures identified in this Article. Such agreements and arrangements shall be** to enhance compliance and ensure effective and full implementation of Article X of the Convention and this Article in order to, *inter alia*:

- (a) Derive the greatest possible synergy in, and benefits from:
  - (i) The collection and dissemination of information on the peaceful uses of biological agents and toxins;
  - (ii) Sharing information on environmental release of genetically modified organisms;
  - (iii) †<sup>116</sup> Good Manufacturing Practice, Good Laboratory Practice, biological containment and other biosafety regulations and practices;
  - (iv) Facilitation of access to databases containing information on the peaceful uses of bacteriological (biological) agents and toxins, biosafety, and results of scientific research in the life sciences in areas of particular relevance to the Convention;
  - (v) The collection and dissemination of information on the diagnosis, surveillance, detection, treatment and prevention of diseases caused by biological agents or toxins, in particular infectious diseases;

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<sup>115</sup>This text has been developed from paragraph 23 and 23 *ter*.

<sup>116</sup>Limitation to "Current" Good Manufacturing Practice is unnecessary. Provision of advice on Good Manufacturing Practice, present and future, is appropriate. The abbreviations are deleted as there is no reference to them elsewhere in the Protocol.

- (vi) Regulations governing the handling, transportation, use and release of bacteriological (biological) agents and toxins;
- (vii)<sup>117</sup> Improving knowledge of relevant<sup>118</sup> national regulatory and administrative procedures and facilitating harmonization of such procedures;

(b) Coordinate its activities with those of international organizations and agencies on the peaceful uses of bacteriological (biological) agents and toxins, and on the diagnosis, detection, treatment and prevention of diseases caused by biological agents or toxins, in particular infectious diseases, and raise awareness of and facilitate access to those activities by States Parties to the Protocol;

(c)<sup>119</sup> Promote the establishment of a framework for multilateral cooperation among the States Parties, including exchange of information among scientists and technologists, with the aim of, *inter alia*:

- (i) Utilizing the scientific and technological capabilities, experience and know-how of States Parties;
- (ii) Assisting developing countries which are States Parties to strengthen their scientific and technological capabilities in the fields of biosciences, genetic engineering and biotechnology;
- (iii) Facilitate the provision of information and advice about relevant<sup>†120</sup> regulatory procedures on the peaceful uses of bacteriological(biological) agents and toxins.

**25.** The Conference of States Parties may consider and decide on possible ad hoc collaborative relationships with relevant non-governmental organizations for the purposes set out in paragraph **24** above<sup>121</sup>. Such consideration shall be preceded by detailed examination by the Executive Council, assisted, where necessary, by the Technical Secretariat, of the terms and conditions of the proposed agreements or arrangements, taking into account the qualification, competence, impartiality and sources of financing of the non-governmental organization(s) in question.

**26.** The Technical Secretariat shall maintain a record of cooperative activities with other relevant international organizations and agencies, pursuant to paragraph **24**, and shall make such a record available to States Parties on request, as well as to the Cooperation Committee.

**27.** The Technical Secretariat, including upon request by the Executive Council, after consultation with relevant international organizations and agencies with which the Organization has cooperative relationships, pursuant to paragraph **24**, may make recommendations, as appropriate, to the Cooperation Committee, the Executive Council or

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<sup>117</sup>Developed from the previous subparagraph (c) (ii) and (d).

<sup>118</sup>Limitation to "*existing*" is unnecessary.

<sup>119</sup>Developed from the previous subparagraph (c) (ii).

<sup>120</sup>Limitation to "*existing*" is unnecessary.

<sup>121</sup>This language enables the Conference of the States Parties to have the option, **where appropriate**, of entering into an ad hoc collaborative relationship with a relevant non-governmental organization.

the Conference of States Parties for further practical steps with a view to the effective implementation of the cooperative relationships envisaged in this section.

(G) SAFEGUARDS

**28.** The obligations set out in this Article are subject to, and limited by, the right of each State Party to protect commercial proprietary information and national security.

(H) DECLARATIONS

**29.** Each State Party shall submit a declaration annually to the Director-General, in accordance with the format set out in Appendix F, with a general description of measures taken, individually or together with other States and international organizations and agencies, in order to implement the provisions of Article X of the Convention and this Article. At the recommendation of the Cooperation Committee, the Director-General shall consider these declarations with the aim of suggesting specific practical steps for the enhanced effectiveness and improved implementation of Article X of the Convention and this Article. The Cooperation Committee shall receive and consider these declarations and any other suggestions, including those from the Director-General, in the preparation of its annual report to the Conference of States Parties, as specified under paragraph **10** of this Article.

## ARTICLE VIII

### CONFIDENCE-BUILDING MEASURES

**1. The States Parties undertake to submit full and timely declarations in respect of each of the confidence-building measures within the framework of the Convention, as agreed upon at the Second and Third Review Conferences and subsequent Review Conferences of the Convention.**

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<sup>122</sup>The language in AHG/52 (Part I), Article VIII inviting each State Party "at its own discretion" to provide information on disease outbreaks or on national legislation and regulations is a retrograde step as it is even less of a commitment than that already agreed by States Parties to the Convention at previous Review Conferences.

## ARTICLE IX<sup>123</sup>

### THE ORGANIZATION

#### (A) GENERAL PROVISIONS

1. The States Parties to this Protocol hereby establish the Organization for the Prohibition of Bacteriological (Biological) and Toxin Weapons (hereinafter referred to as “the Organization”) in order to strengthen the effectiveness and improve the implementation of the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (hereinafter referred to as “the Convention”) and to ensure the implementation of this Protocol, **including its provisions for international verification of compliance with it**, and to provide a forum for consultation and cooperation among States Parties.
2. All States Parties shall be members of the Organization. A State Party shall not be deprived of its membership in the Organization.
3. The seat of the Organization shall be ... .
4. There are hereby established as organs of the Organization: the Conference of the States Parties, the Executive Council and the Technical Secretariat.
5. Each State Party shall cooperate with the Organization in the exercise of its functions in accordance with this Protocol. States Parties shall consult directly among themselves or through the Organization or other appropriate international procedures, including procedures within the framework of the United Nations and in accordance with its Charter, on any matter which may be raised relating to the goal and purpose of the Convention or the implementation of this Protocol.
6. The Organization, as an independent body, shall seek to utilize existing expertise and facilities, as appropriate, and to maximize cost efficiencies, through cooperative arrangements with other international organizations as referred to in Article VII, section E, including, but not limited to, FAO, ICGEB, IVI, OIE, OPCW, UNEP, UNIDO, WHO. Such arrangements, excluding those of a minor and normal commercial and contractual nature, shall be set out in agreements to be submitted to the Conference of the States Parties for approval.
7. The costs of the activities of the Organization shall be met annually by the States Parties in accordance with the United Nations scale of assessments, adjusted to take into account differences in membership between the United Nations and the Organization.
8. A member of the Organization which is in arrears in the payment of its assessed contribution to the Organization shall have no vote in the Conference or the Executive Council, if the amount of its arrears equals or exceeds the amount of the contributions due from it for the preceding two full years. The Conference of the States Parties may, nevertheless, permit such a State Party to vote if it is satisfied that the failure to pay is due to conditions beyond the control of the member.

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<sup>123</sup>The amendments made to Article IX are based on the analysis in Evaluation Paper No. 14, *Article IX: The Organization*, January 2000.

(B) THE CONFERENCE OF THE STATES PARTIES

Composition, procedures and decision-making

9. The Conference of the States Parties (hereinafter referred to as “the Conference”) shall be composed of all States Parties. Each State Party shall have one representative in the Conference, who may be accompanied by alternates and advisers.

10. The initial session of the Conference shall be convened by the Depositary<sup>124</sup> no later than 30 days after the entry into force of this Protocol.

11. The Conference shall meet in regular sessions, which shall be held annually, unless it decides otherwise.

12. A special session of the Conference shall be convened:

(a) When decided by the Conference;

(b) When requested by the Executive Council; or

(c) When requested by any State Party and supported by a majority of the States Parties.

The special session shall be convened not later than 30 days after the decision of the Conference, the request of the Executive Council, or the attainment of the necessary support, unless specified otherwise in the decision or request.

13. The Conference may also be convened in the form of a Review Conference, in accordance with Article **XIII**.

14. The Conference may also be convened in the form of an Amendment Conference, in accordance with Article **XIV**.

15. Sessions shall take place at the seat of the Organization unless the Conference decides otherwise.

16. The Conference shall adopt its rules of procedure. At the beginning of each regular session, it shall elect its President and such other officers as may be required. They shall hold office until a new President and other officers are elected at the next session.

17. A majority of the States Parties shall constitute a quorum.

18. Each State Party shall have one vote.

19. The Conference shall take decisions on matters of procedure by a simple majority of members present and voting. Decisions on matters of substance shall be taken as far as possible by consensus. If consensus is not attainable when an issue comes up for decision, the President of the Conference shall defer any vote for 24 hours and during this period of

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<sup>124</sup>As in the analysis on Article XXII in Evaluation Paper No. 7, *Article XXII: Depositary/ies*, September 1999.



deferment shall make every effort to facilitate achievement of consensus, and shall report to the Conference before the end of this period. If consensus is not possible at the end of 24 hours, the Conference shall take a decision by a two-thirds majority of members present and voting unless specified otherwise in this Protocol. When the issue arises as to whether the question is one of substance or not, that question shall be treated as a matter of substance unless otherwise decided by the majority required for decisions on matters of substance.

#### Powers and functions

20. The Conference shall be the principal organ of the Organization. It shall consider any questions, matters or issues relevant to the provisions of this Protocol, including those relating to the powers and functions of the Executive Council and the Technical Secretariat, in accordance with this Protocol. It may make recommendations and take decisions on any questions, matters or issues relevant to the provisions of this Protocol raised by a State Party or brought to its attention by the Executive Council.

21. The Conference shall oversee the implementation of this Protocol, and review compliance with, the Convention and this Protocol and act in order to promote their object and purpose. It shall also oversee the activities of the Executive Council and the Technical Secretariat and may issue guidelines to either of them for the exercise of their functions.

22. The Conference shall:

(a) Consider and adopt the report of the Organization on the implementation of this Protocol and the programme and budget of the Organization, submitted by the Executive Council, as well as consider other reports;

(b) Decide on the scale of financial contributions to be paid by States Parties in accordance with paragraph 7;

(c) Elect the members of the Executive Council;

(d) Appoint the Director-General of the Technical Secretariat (hereinafter referred to as “the Director-General”);

(e) Consider and approve the rules of procedure of the Executive Council submitted by the latter;

(f) Establish such subsidiary organs, including the Cooperation Committee, as it finds necessary for the exercise of its functions in accordance with this Protocol;

(g) Consider and review scientific and technological developments that could affect the operation of this Protocol. In this context, the Conference may direct the Director-General to establish a Scientific Advisory Board to render specialized advice in areas of science and technology relevant to this Protocol to the Conference, the Executive Council or to States Parties. In that case, the Scientific Advisory Board shall be composed of independent experts and appointed, in accordance with terms of reference adopted by the Conference, on the basis of their expertise and experience in the particular scientific fields relevant to the implementation of this Protocol and on as wide an equitable geographic basis as possible;

(h) Take the necessary measures to ensure compliance with the Convention and this Protocol and to redress and remedy any situation that contravenes the provisions of the Convention and this Protocol, in accordance with Article V;

(i) Consider and approve at its first session any draft agreements, provisions, procedures, operational manuals, guidelines and any other documents;

(j) Consider and approve agreements or arrangements negotiated by the Technical Secretariat with States Parties, other States and international organizations to be concluded by the Executive Council on behalf of the Organization in accordance with paragraph 32 (k);

(k) Establish at its first session the Voluntary Fund in accordance with Article VI;

(l) Promote scientific and technological exchange for peaceful purposes and technical cooperation among States Parties in accordance with Article VII.

## (C) THE EXECUTIVE COUNCIL

### Composition, procedures and decision-making

23. The Executive Council shall consist of ... members<sup>125</sup>. Each State Party shall have the right, in accordance with the principle of rotation, to serve on the Executive Council. The members of the Executive Council shall be elected by the Conference for a term of two years. In order to ensure the effective functioning of this Protocol, due regard being specially paid to equitable geographical distribution, to the importance of the biotechnological industry and biotechnology related pharmaceutical industry sectors, as well as to political and security interests, the Executive Council shall be composed as follows:

(a) ... States Parties from Africa to be designated by States Parties located in this region. As a basis for this designation it is understood that, out of these ... States Parties, ... members shall be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data as well as with the highest number of declared facilities; in addition, the regional group shall agree also to take into account other regional factors in designating these ... members;

(b) ... States Parties from Asia to be designated by States Parties located in this region. As a basis for this designation it is understood that, out of these ... States Parties, ... members shall be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data as well as with the highest number of declared facilities; in addition, the regional group shall agree also to take into account other regional factors in designating these ... members;

OR

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<sup>125</sup>As noted in Evaluation Paper No. 14, *Article IX: The Organization*, January 2000, our recommendation is that the membership of the Executive Council should be kept as small as possible in order to maximise the effectiveness and efficiency of the Executive Council. We therefore recommend a total membership of 41 as with the OPCW.

(b) ... States Parties from East Asia and the Pacific to be designated by States Parties located in this region. As a basis for this designation it is understood that, out of these ... States Parties, ... members shall be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data as well as with the highest number of declared facilities; in addition, the regional group shall agree also to take into account other regional factors in designating these ... members;

(b) *bis* ... States Parties from West and South Asia to be designated by States Parties located in this region. As a basis for this designation it is understood that, out of these ... States Parties, ... members shall be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data as well as with the highest number of declared facilities; in addition, the regional group shall agree also to take into account other regional factors in designating these ... members;

(c) ... States Parties from Eastern Europe to be designated by States Parties located in this region. As a basis for this designation it is understood that, out of these ... States Parties, ... members shall be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data as well as with the highest number of declared facilities; in addition, the regional group shall agree also to take into account other regional factors in designating these ... members;

(d) ... States Parties from Latin America and the Caribbean to be designated by States Parties located in this region. As a basis for this designation it is understood that, out of these ... States Parties, ... members shall be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data as well as with the highest number of declared facilities; in addition, the regional group shall agree also to take into account other regional factors in designating these ... members;

(e) ... States Parties from among Western European and other States to be designated by States Parties located in this region. As a basis for this designation it is understood that, out of these ... States Parties, ... members shall be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data as well as with the highest number of declared facilities; in addition, the regional group shall agree also to take into account other regional factors in designating these ... members.

24. For the first election of the Executive Council ... members shall be elected for a term of one year, due regard being paid to the established numerical proportions as described in paragraph 23.

25. Each member of the Executive Council shall have one representative on the Executive Council, who may be accompanied by alternates and advisers.

26. The Executive Council shall elaborate its rules of procedure and submit them to the Conference for approval.

27. The Executive Council shall elect its Chairman from among its members.

28. The Executive Council shall meet for regular sessions. Between regular sessions it shall meet as may be required for the fulfilment of its powers and functions.

29. Each member of the Executive Council shall have one vote.

30. The Executive Council shall take decisions on matters of procedure by a majority of all its members. The Executive Council shall take decisions on matters of substance by a two-thirds majority of all its members unless specified otherwise in this Protocol. When the issue arises as to whether the question is one of substance or not, that question shall be treated as a matter of substance unless otherwise decided by the majority required for decisions on matters of substance.

#### Powers and functions

31. The Executive Council shall be the executive organ of the Organization. It shall carry out the powers and functions entrusted to it in accordance with this Protocol. It shall be responsible to the Conference. In so doing, it shall act in conformity with the recommendations, decisions and guidelines of the Conference and ensure their proper and continuous implementation.

32. The Executive Council shall:

- (a) Promote effective implementation of, and compliance with, this Protocol;
- (b) Supervise the activities of the Technical Secretariat;
- (c) Supervise the scientific and technological exchange for peaceful purposes and technical cooperation activities and measures stipulated in Article VII;
- (d) Facilitate cooperation among States Parties, and between States Parties and the Technical Secretariat, relating to the implementation of this Protocol through information exchanges;
- (e) Facilitate, as appropriate, consultation and clarification among States Parties in accordance with Article III, section E;
- (f) Receive, consider and take action on requests for, and reports on, visits and investigations in accordance with Article III, sections D and G;
- (g) Receive, consider and take necessary action on the recommendations made by the Cooperation Committee;
- (h) Make recommendations as necessary to the Conference for consideration of further proposals for promoting the object and purpose of this Protocol;
- (i) Cooperate with the National Authority of each State Party;
- (j) Consider and submit to the Conference the draft programme and budget of the Organization, the draft report of the Organization on the implementation of this Protocol, the

report on the performance of its own activities and such other reports as it deems necessary or that the Conference may request;

(k) Make arrangements for the sessions of the Conference, including the preparation of the draft agenda;

(l) Conclude, subject to prior approval of the Conference, agreements or arrangements with States Parties, other States and international organizations on behalf of the Organization and supervise their implementation; and

(m) Consider and recommend to the Conference for approval any new operational manuals and any substantive changes to the existing operational manuals that may be proposed by the Technical Secretariat.

33. The Executive Council may request a special session of the Conference.

34. The Executive Council shall consider concerns raised by a State Party regarding compliance and cases of possible non-compliance and abuse of the rights established by this Protocol. In doing so, the Executive Council shall consult with the States Parties involved and, as appropriate, request a State Party to take measures to redress the situation within a specified time. To the extent that the Executive Council considers further action to be necessary, it shall take, *inter alia*, one or more of the following measures:

(a) Notify all States Parties of the issue or matter;

(b) Bring the issue or matter to the attention of the Conference;

(c) Make recommendations to the Conference regarding measures to redress the situation and to ensure compliance in accordance with Article V.

The Executive Council may, in cases of particular gravity and urgency, bring the issue or matter, including relevant information and conclusions, directly to the attention of the United Nations General Assembly and the United Nations Security Council. It shall at the same time inform all States Parties of this step.

#### (D) THE TECHNICAL SECRETARIAT

35. The Technical Secretariat shall assist States Parties in the implementation of this Protocol. The Technical Secretariat shall assist the Conference and the Executive Council in the performance of their functions. It shall carry out the **compliance and other** functions entrusted to it by this Protocol, as well as those functions delegated to it by the Conference or the Executive Council in accordance with this Protocol.

36. The functions of the Technical Secretariat with regard to the implementation of **the Protocol including** Article III and the Annexes shall include, *inter alia*:

(a) Receiving, processing and analysing of declarations, and collecting, processing and analysing relevant epidemiological information, in accordance with the provisions of Article III, section D;

(b) Assisting the Executive Council in facilitating consultation, clarification and cooperation among States Parties;

(c) Processing, preparing, conducting and reporting on visits in accordance with the provisions of Article III, section D;

(d) Receiving requests for investigations to address non-compliance concerns, making technical evaluations of those requests, submitting the requests to the Executive Council for consideration, carrying out the preparations for, providing technical support during the conduct of, and conducting investigations in accordance with the provisions of Article III, section G, and of Annex D, and reporting the outcome to the Executive Council;

(e) Maintaining and updating a list of ad hoc experts as investigation personnel and notifying all States Parties of any additions to or alterations in the list in accordance with paragraphs 11 to 16 of Annex D, section I;

(f) Negotiating on behalf of the Organization, subject to the prior authorization of the Executive Council, draft agreements and arrangements, as appropriate, between the Organization and States Parties, other States and international organizations. Such draft agreements and arrangements shall be submitted to the Executive Council for consideration and to the Conference for approval;

(g) Assisting the States Parties through their National Authorities on other matters relating to the implementation of this Protocol.

37. The Technical Secretariat shall develop and maintain, subject to approval by the Executive Council and, if required, by the Conference, operational manuals in accordance with Article III and the Annexes. These manuals shall not constitute integral parts of this Protocol or the Annexes and may be changed by the Technical Secretariat. Such substantive changes shall be subject to approval by the Executive Council and, if required, by the Conference. The Technical Secretariat shall promptly inform the States Parties of any changes in the operational manuals.

38. The functions of the Technical Secretariat with regard to scientific and technological exchange for peaceful purposes and technical cooperation shall be, *inter alia*, to:

(a) Facilitate implementation of measures to promote scientific and technological exchanges in accordance with Article VII, section B;

(b) Facilitate implementation of measures to avoid hampering the economic and technological development of States Parties in accordance with Article VII, section C;

(c) Support the establishment and functioning of the institutional mechanisms for international cooperation and Protocol implementation assistance in accordance with Article VII, section D;

(d) Assist in the implementation follow-up of Article X of the Convention and Article VII of the Protocol in accordance with Article VII, section E;

(e) Promote and facilitate cooperative relationships with other international organizations and among States Parties in accordance with Article VII, section F;

(f) Promote the implementation of safeguards in accordance with Article VII, section G;

(g) Receive, consider and process declarations in accordance with Article VII, section H.

39. The functions of the Technical Secretariat with respect to administrative matters shall include, *inter alia*:

(a) Preparing and submitting to the Executive Council the draft programme and budget of the Organization;

(b) Preparing and submitting to the Executive Council the draft report of the Organization on the implementation of this Protocol and such other reports as the Conference or the Executive Council may request;

(c) Providing administrative and technical support to the Conference, the Executive Council and other subsidiary organs;

(d) Addressing and receiving communications on behalf of the Organization relating to the implementation of this Protocol;

(e) Carrying out the administrative responsibilities related to any agreements between the Organization and other international organizations; and

(f) Ensuring that the confidentiality provisions of the Protocol as applied to the Technical Secretariat are observed.

40. The Technical Secretariat shall promptly inform the Executive Council of any problems that have arisen with regard to the discharge of its functions that have come to its notice in the performance of its activities and that it has been unable to resolve through consultations with the State Party concerned.

41. The Technical Secretariat shall comprise a Director-General, who shall be its head and chief administrative officer, and such scientific, technical, administrative and other personnel as may be required. The Director-General shall be appointed by the Conference upon the recommendation of the Executive Council for a term of four years, renewable for only one further term.

42. The Director-General shall be responsible to the Conference and the Executive Council for the appointment of the staff and for the organization and functioning of the Technical Secretariat. Only citizens of States Parties shall serve as the Director-General or as members of the professional and clerical staff. In the employment of the staff and in the determination of the conditions of service, **the paramount consideration<sup>126</sup> shall be the**

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<sup>126</sup>Our analysis on pages 48 to 51 of Evaluation Paper No. 14, *Article IX: The Organization*, January 2000 has drawn attention to the great importance of restoring to paragraph 42 the fundamental principle of staffing the secretariats of international organizations which is expressed in Article 101.3 of the UN Charter and in the WHO

necessity of securing **and maintaining**<sup>127</sup> the highest standards of **professional expertise, experience**, efficiency, competence and integrity. **Due regard shall be paid to** the importance of selecting personnel on as wide an equitable geographic basis as possible. Recruitment shall be guided by the principle that the staff shall be kept to the minimum necessary for the proper discharge of the responsibilities of the Technical Secretariat.

43. The Director-General shall be responsible for the organization and functioning of the Scientific Advisory Board, referred to in paragraph 22 (g), and shall, in consultation with States Parties, appoint members of the Scientific Advisory Board, who shall serve in their individual capacity. The members of the Board shall be appointed on the basis of **their**<sup>128</sup> expertise in the particular scientific fields relevant to the implementation of this Protocol paying due regard to the importance of selecting personnel on as wide an equitable geographic basis as possible. The Director-General may also, as appropriate, in consultation with members of the Board, establish temporary working groups of scientific experts to provide recommendations on specific issues. In regard to the above, States Parties may, if they deem it necessary, submit lists of experts to the Director-General.

44. In the performance of their duties, the Director-General and the other members of the staff shall not seek or receive instructions from any government or from any other source external to the Organization. They shall refrain from any action that might reflect adversely on their positions as international officials<sup>129</sup> responsible only to the Organization.

45. Each State Party shall respect the exclusively international character of the responsibilities of the Director-General and the other members of the staff and shall not seek to influence them in the discharge of their responsibilities.

46. All requests and notifications by States Parties to the Organization shall be transmitted to the Director-General. Requests and notifications shall be in one of the official languages of this Protocol. In response the Director-General shall use the language of the transmitted request or notification.

#### (E) PRIVILEGES AND IMMUNITIES

47. The Organization shall enjoy on the territory and in any other place under the jurisdiction or control of a State Party such legal capacity and such privileges and immunities as are necessary for the exercise of its functions.

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Constitution, the CWC and the CTBT. That fundamental principle requires one set of criteria, namely securing the highest standards of professional expertise, experience, efficiency, competence and integrity, to be accorded priority, as the **paramount** consideration, while a secondary set of criteria receives **due regard**.

<sup>127</sup>Our analysis in paragraph 62 of Evaluation Paper No. 14, *Article IX: The Organization*, January 2000, which has been amplified slightly in the version available on the website <http://www.brad.ac.uk/acad/sbtwc>, notes that the WHO constitution emphasises the importance of ensuring that the efficiency and integrity of the secretariat *shall be maintained at the highest level* thereby avoiding the problems being faced by the OPCW in maintaining expertise and experience. A recent article entitled "*10 Suggestions to Strengthen UN*" (*Daily Yomiuri*, Tokyo, 3 February 2000) by Yasushi Akashi, a former UN Undersecretary-General, in point 5 emphasises the importance of enhancing the efficacy of the Secretariat and of the necessity of ensuring "*recruitment and retention of the highest caliber individuals*".

<sup>128</sup>To be consistent with paragraph 22 (g) of this Article.

<sup>129</sup>As noted in Evaluation Paper No. 14, *Article IX: The Organization*, January 2000, we recommend "*officials*" as in the UN Charter, Article 100.1 rather than "*officers*".



48. Delegates of States Parties, together with their alternates and advisers, representatives of members elected to the Executive Council, together with their alternates and advisers, the Director-General and the staff of the Organization shall enjoy such privileges and immunities as are necessary in the independent exercise of their functions in connection with the Organization.

49. The legal capacity, privileges and immunities referred to in this Article shall be defined in an agreement on the privileges and immunities of the Organization to be concluded between the Organization and the States Parties as well as in an agreement between the Organization and the State in which the Organization is seated. Such agreements shall be considered and approved in accordance with paragraph 22 (i) and (j).

50. The Organization shall not be held liable for any breach of confidentiality committed by members of the Technical Secretariat.<sup>130</sup>

51. The Director-General shall have the right to waive the immunity of any member of a team conducting on-site activities or the other staff of the Technical Secretariat in any case where, in his or her opinion, the immunity would impede the course of justice and can be waived without prejudice to the implementation of the provisions of this Protocol. Waiver of immunity from jurisdiction in respect of civil or administrative proceedings shall not be held to imply waiver of immunity in respect of the execution of the judgement, for which a separate waiver shall be necessary. Waiver shall always be express.

52. Notwithstanding paragraph 49, the privileges and immunities enjoyed by the members of a team conducting on-site activities shall be those set forth in this Article.

53. In deciding whether to waive immunity in cases of breach of confidentiality, the Director-General or the Conference of the States Parties, as appropriate, shall request and take into consideration the views of the Confidentiality Commission.

54. Following acceptance of the list of designated personnel as provided for in Annex D, section I, each State Party shall issue, not later than 30 days after acknowledgement of receipt of that list, or of changes thereto, in conformity with its national visa-related laws and regulations and upon application by any person from the list of designated personnel, multiple entry/exit and/or transit visas and other relevant documents to enable each member of an investigation or visit team to enter, to remain on, or to transit its territory for the sole purpose of carrying out on-site activities on the territory of the receiving State Party. Such documents issued by the receiving State Party shall be valid for at least two years after their provision and shall be reissued, if needed. These documents shall enable the investigation and visit personnel to remain on, or to transit its territory as long as is necessary for carrying out the investigation or visit activities.

55. To exercise their functions effectively, members of the team conducting on-site activities shall be accorded by the receiving State Party and the host State Party privileges and

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<sup>130</sup>Elaboration of language relating to the waiver of the immunity of the Organization is imprudent as it instills from the outset a sense of a lack of confidence in the Organization. This lack of confidence is further reinforced by language proposing limitations of the financial liability to 5 or 10 per cent of the annual budget of the Organization. Such language **is unnecessary** as it is always open to the Conference of the States Parties to take such a decision should it judge that the particular circumstances at some time in the future warrant such a step. Likewise, specific language on the waiver of the immunity of the Director-General is imprudent and unnecessary.

immunities as set forth in subparagraphs (a) to (i). Privileges and immunities shall be granted to members of the team conducting on-site activities for the sake of this Protocol and not for the personal benefit of the individuals themselves. Such privileges and immunities shall be accorded to them for the entire period between arrival on and departure from the territory of the receiving State Party and host State Party, and thereafter with respect to acts previously performed in the exercise of their official functions in accordance with their mandate.

(a) The members of the team conducting on-site activities shall be accorded the same inviolability as is enjoyed by diplomatic agents pursuant to Article 29 of the Vienna Convention on Diplomatic Relations of 18 April 1961.

(b) The living quarters and office premises occupied by the team conducting on-site activities carrying out investigation or visit activities pursuant to this Protocol shall be accorded the same inviolability and protection as are accorded to the premises of diplomatic agents pursuant to Article 30, paragraph 1, of the Vienna Convention on Diplomatic Relations.

(c) The papers and correspondence, including records, of the team conducting on-site activities shall enjoy the same inviolability as is accorded to all papers and correspondence of diplomatic agents pursuant to Article 30, paragraph 2, of the Vienna Convention on Diplomatic Relations. The team conducting on-site activities shall have the right to communicate with the Technical Secretariat, in accordance with the provisions of Annex D, section I.

(d) Samples carried by members of the investigation team and approved equipment carried by members of the team conducting on-site activities shall be inviolable subject to provisions contained in this Protocol and exempt from all customs duties.

(e) The members of the team conducting on-site activities shall be accorded the same immunities as are accorded to diplomatic agents pursuant to Article 31, paragraphs 1, 2 and 3, of the Vienna Convention on Diplomatic Relations.

(f) The members of the team conducting on-site activities carrying out prescribed activities pursuant to this Protocol shall be accorded the exemption from dues and taxes accorded to diplomatic agents pursuant to Article 34 of the Vienna Convention on Diplomatic Relations.

(g) The members of the team conducting on-site activities shall be permitted to bring into the territory of the receiving State Party or host State Party, without payment of any customs duties or related charges, articles for personal use, with the exception of articles the import or export of which is prohibited by law or controlled by quarantine regulations.

(h) The members of the team conducting on-site activities shall be accorded the same currency and exchange facilities as are accorded to representatives of foreign governments on temporary official missions.

(i) The members of the team conducting on-site activities shall not engage in any professional or commercial activity for personal profit on the territory of the receiving State Party or the host State.

**56.** When transiting the territory of States Parties other than the receiving State Party, the members of the team conducting on-site activities shall be accorded the same privileges and immunities as are enjoyed by diplomatic agents pursuant to Article 40, paragraph 1, of the Vienna Convention on Diplomatic Relations. Papers and correspondence, including records and samples and approved equipment, carried by the team conducting on-site activities, as well as samples carried by the investigation team, shall be accorded the privileges and immunities set forth in paragraph **55** (c) and (d).

**57.** Without prejudice to their privileges and immunities the members of the team conducting on-site activities shall be obliged to respect the laws and regulations of the receiving State Party or host State and, to the extent that is consistent with the mandate for on-site activities, shall be obliged not to interfere in the internal affairs of that State. If the receiving State Party or host State Party considers that there has been an abuse of privileges and immunities by the members of the team conducting on-site activities, consultations shall be held between the State Party and the Director-General to determine whether such an abuse has occurred and, if so determined, to prevent a repetition of such abuse.

**58.** Observers shall be accorded the same privileges and immunities accorded to members of the team conducting on-site activities pursuant to this section, except for those accorded pursuant to paragraph **55** (d).

## ARTICLE X<sup>131</sup>

### NATIONAL IMPLEMENTATION MEASURES

#### General undertakings

1. In addition to its obligations under the Convention, including Article IV, each State Party shall, in accordance with its constitutional and legal processes, take any measures required to implement its obligations under this Protocol. In particular, it shall where appropriate and necessary:

(a) Prohibit natural and legal persons anywhere on its territory or in any other place under its jurisdiction as recognized by international law from undertaking any activity prohibited to a State Party under the Convention †<sup>132</sup>, including enacting penal legislation with respect to such a prohibition;

(b) Prohibit natural and legal persons from undertaking any activity prohibited to a State Party under the Convention anywhere under its control; and

(c) Prohibit, in conformity with international law, natural persons possessing its nationality from undertaking any activity prohibited to a State Party under the Convention anywhere.

2. Each State Party may, where requested, cooperate with other States Parties and afford the appropriate form of legal assistance to facilitate the implementation of the obligations under paragraph 1.

3. Each State Party, during the implementation of its obligations under this Protocol, shall take all necessary steps to ensure the safety of people and to protect the environment, and may cooperate as appropriate with other States Parties in this regard.

#### Relations between the State Party and the Organization

4. In order to fulfil its obligations under this Protocol, each State Party shall designate or establish a National Authority and shall so notify the Organization upon entry into force of this Protocol for it. The National Authority shall serve as the national focal point for effective liaison with the Organization and with other States Parties.

5. Each State Party shall inform the Organization of the legislative and administrative measures taken pursuant to this Article.

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<sup>131</sup>The amendments made to this Article are based on the analysis in Evaluation Paper No. 2, *Article X: National Implementation Measures*, July 1999 taking into account subsequent development of the text by the Ad Hoc Group as well as of the previous Briefing Paper No 14, *National Implementation Measures: An Update*, October 1998 and Briefing Paper No.4, *National Implementation Measures*, January 1998.

<sup>132</sup>The reference to *Article I General Provisions* of the Protocol is, in our view, inappropriate because the Ad Hoc Group has a mandate to develop a Protocol to strengthen the Convention -- but does **not** have a mandate to **amend** the Convention (see paragraph 8 of this Evaluation Paper). Consequently, *Article I General Provisions* of the Protocol should not extend the prohibitions of the Convention and does not in this proposed complete text.

6. Each State Party undertakes to cooperate with the Organization in the exercise of all its functions and in particular to provide assistance to the Technical Secretariat in the discharge of its functions in accordance with the provisions of this Protocol.

ARTICLE XI<sup>133</sup>

RELATIONSHIP OF THE PROTOCOL TO THE BTWC

This Protocol to the Convention shall not be interpreted as in any way modifying or amending the Convention, or limiting or detracting from the rights and obligations assumed by any State under the Convention. The provisions under this Protocol shall apply only to States Parties to this Protocol.

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<sup>133</sup>The amendments made to this Article are based on the analysis in Evaluation Paper No. 9, *Article XI: Relationship of the Protocol to the BTWC and Other International Agreements*, November 1999.

## ARTICLE XII<sup>134</sup>

### SETTLEMENT OF DISPUTES

1. Disputes that may arise concerning the application, interpretation or implementation of the Convention and this Protocol shall be settled in accordance with the relevant provisions of the Convention and this Protocol and in conformity with the Charter of the United Nations and other rules of international law.
2. When a dispute arises between two or more States Parties, or between one or more States Parties and the Organization, relating to the application, interpretation or implementation of this Protocol, the parties concerned shall engage in consultations without delay with a view to the expeditious settlement of the dispute by negotiation or by other mutually agreed peaceful means of the parties' choice, including recourse to appropriate organs of this Protocol or other organs established and entrusted by the Executive Council or the Conference of States Parties with tasks related to the settlement of these disputes in conformity with Articles IV and IX, and referral to the International Court of Justice in conformity with the Statute of the Court. The parties to a dispute shall inform the Executive Council of the commencement of consultations, and shall keep the Executive Council informed of the actions being taken and their outcomes. The Executive Council may contribute to the settlement of a dispute by negotiation by whatever means it deems appropriate, including offering its good offices **and calling upon the States parties to a dispute to seek a settlement by negotiation or by other peaceful means of the parties' choice. It may recommend a time-limit for any agreed procedure.**
3. The Conference of States Parties shall consider questions related to disputes raised by States Parties, the Organization or brought to its attention by the Executive Council.
4. The Conference of States Parties and the Executive Council are separately empowered, subject to authorization from the General Assembly of the United Nations, to request the International Court of Justice to give an advisory opinion on any legal question arising within the scope of the activities of the Organization. An agreement between the Organization and the United Nations shall be concluded for this purpose in accordance with Article IX.
5. This Article is without prejudice to Articles III and V of this Protocol.
6. Nothing in this Article shall affect the right of two or more States Parties to clarify and resolve any dispute among themselves.

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<sup>134</sup>The amendments made to this Article are based on the analysis in Evaluation Paper No. 10, *Article XII: Settlement of Disputes*, November 1999.

ARTICLE XIII<sup>135</sup>

REVIEW OF THE PROTOCOL

1. The First Conference of States Parties to review the operation of the Protocol (hereinafter referred to as a “Review Conference”) shall be convened within 5 years after the entry into force of the Protocol with a view to assuring that the purposes of the Protocol are being realized.<sup>136</sup>
2. At intervals of 5 years thereafter, unless otherwise decided by a majority of States Parties to the Protocol, further such Review Conferences of the Protocol shall be convened with the same objective.
3. The Review Conferences shall take into account any new scientific and technological developments relevant to the Protocol.
4. The schedules of the Review Conferences shall be so decided as to coincide with the Review Conferences of the Convention.

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<sup>135</sup>The amendments made to this Article are based on the analysis in Evaluation Paper No. 11, *Article XIII: Review of the Protocol*, November 1999 taking into account subsequent development of the text by the Ad Hoc Group.

<sup>136</sup>Although a footnote (AHG/51 (Part I), page 129, footnote 55) indicates that the question of the location of the First Review Conference remains to be addressed after further consideration of the location of the Seat, we do not consider it either necessary or desirable to include the location of the Review Conferences in the text of the Protocol.



## ARTICLE XIV<sup>137</sup>

### AMENDMENTS

1. Any time after the entry into force of this Protocol any State Party may propose amendments to this Protocol or its Annexes or Appendices. Any State Party may also propose changes, in accordance with paragraph 4, to specified parts of this Protocol or its Annexes or to its Appendices. Proposals for amendments shall be subject to the procedures in paragraphs 2 and 3. Proposals for changes, as specified in paragraph 4, shall be subject to the provisions set out in paragraph 5.

2. Any proposal for an amendment shall be communicated to the Director-General. The proposed amendment shall be considered only by an Amendment Conference. The Director-General shall circulate the proposal to all States Parties and seek their views on whether an Amendment Conference should be convened to consider the proposal. If one-third or more of the States Parties notify the Director-General, not later than 30 days after the circulation of the proposal that they support the convening of an Amendment Conference, the Director-General shall convene such a Conference to which all States Parties shall be invited. The Amendment Conference shall be held immediately following a regular session of the Conference of States Parties unless all States Parties which support the convening of an Amendment Conference request that it be held earlier. In no case shall an Amendment Conference be held sooner than 60 days after the circulation of the proposed amendment. Amendments shall be adopted by the Amendment Conference by a positive vote of a majority of all States Parties with no State Party casting a negative vote.

3. Amendments shall enter into force for all States Parties 30 days after the deposit of the instruments of ratification or acceptance by all of the States Parties casting a positive vote at the Amendment Conference.

4. In order to assure the viability and effectiveness of this Protocol, provisions in the Appendices, the Annexes **other than Annex D and section I of Annex E**, and those sections of Article III, section D, which are so identified in that Article, shall be subject to changes in accordance with paragraph 5, if the proposed changes are related only to matters of a technical or administrative nature. **All changes to *Section I Lists and Criteria (Agents and Toxins)* of Annex A shall be made in accordance with paragraph 5. *Annex D Investigations* and *section I General Principles for the Handling of Confidential Information of Annex E Confidentiality Provisions* shall not be subject to changes in accordance with paragraph 5.**

5. Proposed changes referred to in paragraph 4 shall be made in accordance with the following procedures:

(a) The text of the proposed changes, together with supporting documentation, shall be transmitted to the Director-General. The Director-General shall promptly communicate any such proposal to all States Parties and the Executive Council. Any State Party and the Director-General may provide additional information to assist in the evaluation of the proposal;

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<sup>137</sup>The amendments made to this Article are based on the analysis in Evaluation Paper No. 12, *Article XIV: Amendments*, January 2000.

(b) Not later than 60 days after its receipt, the Director-General shall evaluate the proposal to determine all its possible consequences for the provisions and implementation of this Protocol and for the provisions and implementation of the Convention and shall communicate any such information to all States Parties and the Executive Council;

(c) The Executive Council shall examine the proposal, including whether the proposal fulfils the requirements of paragraph 4, in light of all the information available to it, and any specific guidelines or criteria for review specified in the article, annex or appendix to which the change is proposed. The Executive Council shall consider the proposal as a matter of substance. Not later than 90 days after its receipt, the Executive Council shall notify its recommendations, with appropriate explanations, to all States Parties for consideration. States Parties shall acknowledge receipt within 10 days;

(d) If the Executive Council recommends to all States Parties that the proposal be adopted, it shall be considered approved if no State Party objects to it within 90 days after receipt of the recommendation. If the Executive Council recommends that the proposal be rejected, it shall be considered rejected if no State Party objects to the rejection within 90 days after the receipt of the recommendation;

(e) If a recommendation of the Executive Council does not meet with the acceptance required under subparagraph (d), a decision on the proposal, including whether the proposal fulfils the requirements of paragraph 4, shall be taken as a matter of substance by a Conference of States Parties at its next session;

(f) The Director-General shall notify all States Parties of any decision under this paragraph;

(g) Changes approved under this procedure shall enter into force for all States Parties 180 days after the **date**<sup>138</sup> of notification by the Director-General of their approval unless another time period is recommended by the Executive Council or<sup>139</sup> decided by a Conference of States Parties.

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<sup>138</sup>"date" is used rather than "day" for consistency with Article XX paragraph 2 and with BTWC and CWC usage.

<sup>139</sup>"or" is appropriate as it avoids a situation in which any other time period has to have been recommended by the Executive Council.

## ARTICLE XV<sup>140</sup>

### DURATION AND WITHDRAWAL

1. This Protocol shall remain in force so long as the Convention is in force.
2. Each State Party to this Protocol shall, in exercising its national sovereignty, have the right to withdraw from this Protocol if it decides that extraordinary events, related to the subject matter of this Protocol, have jeopardized its supreme interests. It shall give notice of such withdrawal to the Depositary, all other States Parties to the Protocol, the Executive Council and the United Nations Security Council three months in advance. Such notice shall include a statement of the extraordinary events it regards as having jeopardized its supreme interests.
3. The withdrawal of a State Party from this Protocol shall not in any way affect its rights and obligations under other international legal instruments to which it is a party.
4. Any State Party that withdraws from the Convention shall be deemed to have withdrawn from this Protocol, irrespective of whether it has complied with the procedure set forth in paragraph 2 of this Article. The Protocol shall cease to be in force for such a State on the same day as the Convention ceases to be in force for it.

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<sup>140</sup>The amendments made to this Article are based on the analysis in Evaluation Paper No. 4, *Article XV: Duration and Withdrawal*, September 1999.

ARTICLE XVI<sup>141</sup>

STATUS OF THE ANNEXES AND APPENDICES

The Annexes and Appendices to this Protocol form an integral part of the Protocol. Any reference to this Protocol includes the Annexes and Appendices.

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<sup>141</sup>This Article was analysed in Evaluation Paper No. 3, *Articles XVI, XVII, XVIII, XIX and XXIII: Status of the Annexes and Appendices, Signature, Ratification, Accession and Authentic Texts*, September 1999.

ARTICLE XVII<sup>142</sup>

SIGNATURE

This Protocol shall be open for signature to all States Parties to the Convention, before this Protocol enters into force.

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<sup>142</sup>This Article was analysed in Evaluation Paper No. 3, *Articles XVI, XVII, XVIII, XIX and XXIII: Status of the Annexes and Appendices, Signature, Ratification, Accession and Authentic Texts*, September 1999.

ARTICLE XVIII<sup>143</sup>

RATIFICATION

This Protocol shall be subject to ratification by States Signatories according to their respective constitutional processes.

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<sup>143</sup>This Article was analysed in Evaluation Paper No. 3, *Articles XVI, XVII, XVIII, XIX and XXIII: Status of the Annexes and Appendices, Signature, Ratification, Accession and Authentic Texts*, September 1999.

ARTICLE XIX<sup>144</sup>

ACCESSION

Any State Party to the Convention which does not sign this Protocol before its entry into force may accede to it at any time thereafter.

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<sup>144</sup>This Article was analysed in Evaluation Paper No. 3, *Articles XVI, XVII, XVIII, XIX and XXIII: Status of the Annexes and Appendices, Signature, Ratification, Accession and Authentic Texts*, September 1999.

## ARTICLE XX<sup>145</sup>

### ENTRY INTO FORCE

1. This Protocol shall enter into force 180 days after the deposit of instruments of ratification by **20** States<sup>146</sup> but not earlier than two years after its opening for signature.
2. For States whose instruments of ratification or accession are deposited subsequent to the entry into force of this Protocol, it shall enter into force on the 30th day following the date of deposit of their instrument of ratification or accession.

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<sup>145</sup>The amendments made to this Article are based on the analysis in Evaluation Paper No. 5, *Article XX: Entry into Force*, September 1999.

<sup>146</sup>The paramount need is to achieve the earliest possible entry into force of the Protocol so that the strengthening of the regime can begin to benefit from the operation of the Organization. A requirement for a large number of ratification instruments before entry into force would delay the strengthening of the regime. With the Organization in existence, with full authority to implement and promote the Protocol, in accordance with Article IX, the Protocol in our judgement will gather momentum and the number of States Parties will increase significantly as confidence grows in the Organization and its operations. We therefore favour a simple numerical condition for entry into force, with no requirement for particular ratifications within this number, which should be kept low, at 20. A figure of 20 corresponds to a delay of entry into force of two years based on the CWC ratification experience.

<sup>147</sup>The third paragraph in Article XX in AHG/52 (Part I) is an unnecessary statement as it is a statement of the obvious. It is best deleted.



## ARTICLE XXI<sup>148</sup>

### RESERVATIONS

The Articles of **and** the Annexes and Appendices **to**<sup>149</sup> this Protocol shall not be subject to reservations. **In addition, no exceptions or conditions, however phrased or named, including interpretative statements or declarations, which purport to exclude or modify the legal effect of the provisions of the Articles and the Annexes and Appendices to this Protocol in their application to any State, may be made by any State upon signing, ratifying or acceding to this Protocol.**<sup>150</sup>

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<sup>148</sup>The amendments made to this Article are based on the analysis in Evaluation Paper No. 6, *Article XXI: Reservations*, September 1999.

<sup>149</sup>"to" is preferred to "of" as this is then consistent with Article XVI which defines the status of the Annexes and Appendices "**to this Protocol**" [Emphasis added].

<sup>150</sup>There is a need for this additional sentence in order to prevent, as comprehensively as possible, any attempt to circumvent the ban on reservations by means of statements, declarations, exceptions or conditions which similarly purport to exclude or modify the legal effect of any part of the Protocol in its application to any State.

ARTICLE XXII<sup>151</sup>

DEPOSITARY

The Secretary-General of the United Nations is hereby designated as the Depositary of this Protocol and shall, *inter alia*:

(a) Promptly inform all signatory and acceding States of the date of each signature, the date of deposit of each instrument of ratification or accession and the date of the entry into force of this Protocol, and of the receipt of other notices;

(b) Transmit duly certified copies of this Protocol to the governments of all signatory and acceding States; and

(c) Register this Protocol pursuant to Article 102 of the Charter of the United Nations.

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<sup>151</sup>The amendments made to this Article are based on the analysis in Evaluation Paper No. 7, *Article XXII: Depositary/ies*, September 1999.

ARTICLE XXIII<sup>152</sup>

AUTHENTIC TEXTS

1. This Protocol, the Arabic, Chinese, English, French, Russian and Spanish texts of which are equally authentic, shall be deposited with the Secretary-General of the United Nations.
2. IN WITNESS THEREOF the undersigned, being duly authorized to that effect, have signed this Protocol.

Done at ... on ... .

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<sup>152</sup>This Article was analysed in Evaluation Paper No. 3, *Articles XVI, XVII, XVIII, XIX and XXIII: Status of the Annexes and Appendices, Signature, Ratification, Accession and Authentic Texts*, September 1999.

## ANNEXES<sup>153</sup>

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<sup>153</sup>For clarity and to avoid confusion, the current Annex designations have been retained although Annexes B, C, F and G have been deleted from this proposed complete text. For example, this retention of the Annex designation has obviated the need to modify all cross references to Annex D to read Annex B with the potential for confusion amongst a readership that is accustomed to Annex D being the Annex on Investigations.

## A. DECLARATIONS

### I. DEFINITIONS<sup>154</sup>

#### (A) DEFINITIONS FOR THE PURPOSES OF ARTICLE III

1. Facility means

Any room(s), laboratory(ies), buildings, or parts of buildings, or other structures either at a fixed location or mobile which can be used to conduct activity(ies) in the field of biology related to the Convention. Such a facility may have an identifiable boundary and/or a single operational control.

2. Site means

The location and integration of one or more facilities within a geographically and/or physically defined area which may have an identifiable boundary, which can not be smaller than a building.

3. The receiving or visited State Party and the host State Party

The receiving or visited State Party means the State Party on whose territory or in any other place under whose jurisdiction or control an investigation or a visit is proposed, taking place or has been completed. In the specific case where an investigation or a visit is proposed, taking place or has been completed on the territory of a State Party/State, but in a place under the jurisdiction or control of another State Party/State, the former State Party/State shall not be the “receiving or visited State Party”, but shall be defined as the “host State Party/State of a visit or an investigation”.

#### DEFINITIONS FOR THE PURPOSES OF ARTICLE III, SECTION D ON DECLARATIONS AND DECLARATION FORMATS:

4. Biological defence programme and/or activities (against biological and toxin weapons) means

Programme and/or activities designed to detect and/or assess the impact of any use of microbial or other biological agents or toxins for hostile purposes or in armed conflict, and/or to prevent, reduce and/or neutralize the impact of biological and toxin weapons on humans, animals or plants.

5. Biological defence facility means

Facility which works in a biological defence programme and/or activities.

6. High biological containment (BL-3 - WHO and OIE classification) means

Any room or suite of rooms, laboratory(ies) or other buildings or structures with the following features:

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<sup>154</sup> This is based on language transferred from Article II Definitions in AHG/52 (Part II).

(a) Designed or used to handle and work with biological agents causing disease and known or suspected to meet either:

- (i) The classification criteria of Risk Group 3 human pathogens, as determined by each State Party for itself and specified in the 1993 WHO Laboratory Biosafety Manual; or
- (ii) The classification criteria of Group 3 animal pathogens, as determined by each State Party for itself and specified in the Amendment to the International Animal Health Code adopted by the International Committee of the OIE during its 66th General Session, 1998; or

(b) Any room or suite of rooms, laboratory(ies) or other buildings or structures which meet(s) the requirements specified in the 1993 WHO Laboratory Biosafety Manual with respect to the maintenance of negative air pressure to the environment, access control and the rendering safe of exhaust air and of contaminated material and waste, including effluents by HEPA filtration, steam sterilization, incineration or other physical or chemical means.

7. Maximum biological containment (BL-4 - WHO and OIE classification) means

Any room or suite of rooms, laboratory(ies) or other buildings or structures with the following features:

(a) Designed or used to handle and work with biological agents causing disease and known or suspected to meet either:

- (i) The classification criteria of Risk Group 4 human pathogens, as determined by each State Party for itself and specified in the 1993 WHO Laboratory Biosafety Manual; or
- (ii) The classification criteria of Group 4 animal pathogens, as determined by each State Party for itself and specified in the Amendment to the International Animal Health Code adopted by the International Committee of the OIE during its 66th General Session, 1998; or

(b) Any room or suite of rooms, laboratory(ies) or other buildings or structures with the following features, in addition to the features specified for high biological containment (BL-3 - WHO classification):

- (i) Controlled access. Entry and exit of personnel and supplies must be through an airlock or pass-through system. On entering, personnel must put on a complete change of clothing; before leaving, they should shower before putting on their street clothing;
- (ii) Controlled air system. Negative pressure must be maintained in the facility by a mechanical, individual, inwardly directed, HEPA-filtered supply, and an exhaust air system with HEPA filters in the exhaust and, where necessary, in the intake;

(iii) Decontamination of effluents. All fluid effluents from the facility, including shower water, must be rendered safe before final discharge;

(iv) Sterilization of waste and materials. A double-door, pass-through autoclave must be available;

(v) An efficient primary containment system must be in place. For work with human pathogens or zoonoses, primary containment must be provided by use of, one or more of the following: (i) Class III biological safety cabinets, or (ii) positive-pressure ventilated suits. In the latter case a special chemical decontamination shower must be provided for personnel leaving the suit area. For work with animal pathogens, primary containment must be provided by use of Class III biological safety cabinets;

(vi) Airlock entry ports for specimens and materials.

8. Plant pathogen containment means

Any laboratory or other building or structure specifically designed and used to handle and work with plant pathogens and pests that are of economic importance to a specific area endangered thereby, and not yet present there, or present but not widely distributed and which are also being controlled by official regulatory measures. Such a design includes access control through a vestibule bounded by outer and inner doors, hand washing facilities, the ability to apply negative or positive pressure to the environment, the exhaust air sterilized by HEPA filtration, incineration, or other physical or chemical means and the ability to control the internal temperature. Decontamination of all waste is achieved by a suitable chemical or physical process before exhausting into a public or communal system.

9. Diagnostic facility means

Facility which tests only samples for the purpose of diagnosis of subclinical, clinical, or latent infection or intoxication in humans, animals or plants; or for the purpose of analysis of microbial or toxin contamination in food, water, soil and air by means of detection, isolation, and/or identification of microbial or other biological agents or toxins and serology.

10. Genetic modification means

A process of arranging and manipulating nucleic acids of an organism and microorganisms to produce novel molecules or to add to them new characteristics or to modify the original characteristics.

11. Primary production containment means

Features in any system of equipment for the production of microbial or other biological agents, or toxins, that are designed to separate the production process from the environment thereby preventing release that could compromise the health of workers or cause other harm to the product or the environment. Sample collection, addition of material, transfers to another system, and final discharge of exhaust gases, effluents and wastes, are performed so as to prevent such release. Before discharge, exhaust gases, effluents and wastes from the system should be decontaminated by appropriate physical or chemical means.

12. Vaccine means

Preparations, including live-attenuated, killed or otherwise modified microorganisms or components obtained from organisms, including inactivated toxins and nucleic acids, which, when introduced by any routes into a human being or animal, induces in it a specific immune response for prophylaxis or protection against infectious disease(s) or intoxication.

13. Production means

Cultivation of replicative biological agents by any means, or synthesis, or biosynthesis, or extraction of non-replicative biological agents including toxins.

14. Aerobiology means

The study of or work with aerosols of materials comprising biological agents and toxins or simulants in a facility or open air.

15. Simulants of biological agents and toxins mean

Substances of biological, chemical or other origin which, due to their characteristics are used for research on the properties of biological agents or toxins.

16. Plant inoculant means

Any formulation containing a pure or predetermined mixture of microorganisms which alter the properties of plants or crops.

17. Biocontrol agent means

A living organism or biologically active substance originated from such organism used for the prevention, elimination or reduction of plant diseases and pests or unwanted plants.



## II. LISTS AND CRITERIA (AGENTS AND TOXINS)

1. The list of agents and toxins following below is for use with Article III.
2. The following criteria were used for developing the list of agents and toxins and , *inter alia*, these criteria as well as the additional factors in subparagraphs (b) and (c) shall be used in reviewing any proposed modifications to the list:
  - (a) The potential of individual agents and toxins for use as weapons, †<sup>155</sup>
  - (b) Scientific and technological developments that may affect the potential of individual agents or toxins for use as weapons;
  - (c) Effects of potential inclusion or exclusion of an agent or toxin in the list on scientific and technical research and development.
3. Any State Party may propose modifications to the list. The Executive Council shall review such proposed modifications to the list of agents and toxins. Any changes to the list shall be made in accordance with Article XIV.
4. The list is not exhaustive, it does not exclude the relevance for the Protocol of unlisted microbial or other biological agents or toxins. †<sup>156</sup>
5. Pathogens causing zoonotic diseases appearing in one section of the list shall also apply to the other sections.

### A. HUMAN AND ZOONOTIC PATHOGENS

#### Viruses

1. Crimean-Congo haemorrhagic fever virus
2. Eastern equine encephalitis virus
3. Ebola virus
4. Sin Nombre virus
5. Junin virus
6. Lassa fever virus
7. Machupo virus
8. Marburg virus
9. Rift Valley fever virus
10. Tick-borne encephalitis virus
11. Variola major virus (Smallpox virus)
12. Venezuelan equine encephalitis virus
13. Western equine encephalitis virus
14. Yellow fever virus
15. Monkeypox virus

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<sup>155</sup>The specific list in paragraph 2 (a) of AHG/52 (Part II) is excluded as they are not objective criteria.

<sup>156</sup> The additional words "*which potentially can be used as weapons or vectors*" in AHG/52(Part II) in paragraph 4 are unnecessary and are deleted

## Bacteria<sup>157</sup>

1. *Bacillus anthracis*
2. *Brucella melitensis*
3. *Burkholderia (Pseudomonas) mallei*
4. *Burkholderia (Pseudomonas) pseudomallei*
5. *Francisella tularensis tularensis*
6. *Yersinia pestis*
7. *Coxiella burnetii*
8. *Rickettsia prowazekii*
9. *Rickettsia rickettsii*

## B. ANIMAL PATHOGENS<sup>158 159</sup>

1. Foot and mouth disease virus
2. Vesicular stomatitis virus
3. **Swine vesicular disease**
3. Rinderpest virus
4. Peste des petits ruminants virus
5. Contagious bovine (pleuropneumonia)/*Mycoplasma mycoides var. mycoides*<sup>160</sup>
6. **Lumpy skin disease**
7. Bluetongue virus
8. **Sheep pox and goat pox**
9. African horse sickness virus
10. African swine fever virus
11. Classic swine fever virus (Hog cholera virus)
12. Avian influenza virus (Fowl plague virus)

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<sup>157</sup>In accordance with standard international practice, the names of bacteria and rickettsiae are written in italic script.

<sup>158</sup>The animal pathogens have been selected as those which appear on the OIE List A Diseases which are defined as "*transmissible diseases which have the potential for very serious and rapid spread, irrespective of national borders, which are of major socio-economic or public health consequences and which are of major importance in the international trade of animals and animal products.*" Reports of disease outbreaks are required to be submitted to OIE. Consequently, selection of these diseases correspond to diseases for which OIE member States already have infrastructure for disease surveillance and reporting. The subdivision of animal pathogens in AHG/51 (Part I) is not necessary and could be counter-productive particularly if the disease were to appear in another species. If it is retained then paragraph 6 above should be broadened by the deletion of the words "*causing zoonotic diseases*".

<sup>159</sup>There is no logic for reducing the list of animal pathogens below those which appear on the OIE List A Diseases.

<sup>160</sup>In accordance with standard international practice, the names of bacteria are written in italic script.

### 13. Newcastle disease virus

#### C. PLANT PATHOGENS<sup>161 162</sup>

1. *Dothistroma pini* (*Scirrhia pini*)
2. *Erwinia amylovora*
3. *Ralstonia solanacearum*
4. *Puccinia graminis*
5. Sugar cane Fiji disease virus
6. *Tilletia indica*
7. *Xanthomonas albilineans*
8. *Xanthomonas campestris* pv *citri*
9. *Sclerotinia sclerotiorum*
10. *Peronospora hyoscyami* de Bary f.sp. *tabacina* (Adam) *skalicky*
11. *Claviceps purpurea*

#### D. TOXINS

##### Bacteriotoxins

1. Botulinum toxins
2. *Clostridium perfringens*<sup>163</sup> toxins
3. Staphylococcal enterotoxins
4. Shigatoxins

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<sup>161</sup>The list of plant pathogens in AHG/52 (Part I), page 147, has been analysed with the aid of information from the IPPO (International Plant Protection Organization) from the International Plant Protection Convention Database concerning the geographic spread of these diseases. This analysis shows that reports of the listed plant diseases come from the following regions of the world:

#### C. PLANT PATHOGENS

1. *Colletotrichum coffeanum* var. *virulans* Africa
2. *Dothistroma pini* (*Scirrhia pini*) Europe, Asia, Africa, North America, South America, Oceania
3. *Erwinia amylovora* Europe, Asia, Africa, North America, South America, Oceania
4. *Ralstonia solanacearum* Asia, Africa, Europe, North America, Central America, Caribbean, South America, Oceania
5. *Puccinia graminis* Europe, Asia, , North America, South America, Oceania
6. Sugar cane Fiji disease virus Asia, Africa, Oceania
7. *Tilletia indica* Asia, South America
8. *Xanthomonas albilineans* Asia, Africa, South America, Oceania
9. *Xanthomonas campestris* pv *citri* Asia, Africa, South America, Oceania
10. *Sclerotinia sclerotiorum* Europe, Asia, Africa, North America, South America, Oceania
11. *Peronospora hyoscyami* de Bary f.sp. *tabacina* (Adam) *skalicky* Europe, Africa, North America, South America, Oceania
12. *Claviceps purpurea* Europe, Asia, Africa, North America, South America

As *Colletotrichum coffeanum* var. *virulans* only occurs in a single region, this has been deleted. Selection of the other diseases correspond to diseases for which IPPC member States already have infrastructure for disease surveillance and reporting. The subdivision of plant pathogens in AHG/51 (Part I) is not necessary and could be counter-productive particularly if the disease were to appear in another species. If it is retained then paragraph 6 above should be broadened by the deletion of the words "*causing zoonotic diseases*".

<sup>162</sup>In accordance with standard international practice, the names of bacteria and fungi are written in italic script.

<sup>163</sup>In accordance with standard international practice, the names of bacteria are written in italic script.

### Phycotoxins

1. Anatoxins
2. Ciguatoxins
3. Saxitoxins

### Mycotoxins

1. Trichothecene toxins

### Phytotoxins

1. Abrins
2. Ricins

### Zootoxins

1. Bungarotoxins

### III. LIST OF EQUIPMENT

The list of equipment **following below is for use with Article III<sup>164</sup> including *inter alia* its use as** a component of the reporting format<sup>165</sup> for facilities declared pursuant to Article III, section D.

1. Aerosol chambers (either static, dynamic or explosive).
2. Equipment designed or used to generate aerosols of microorganisms or toxins and simulants.
3. Aerosol analytical equipment to determine the size of particles up to 20 micrometers in diameter.
4. Fermenters/bioreactors for batch operation with a volume over **50 litres**<sup>166</sup>.
5. Equipment for continuous or perfusion growth of microorganisms with a **flow rate capable of exceeding 2 litres an hour**.<sup>167</sup>
6. Self-sterilizable centrifuges for continuous or semi-continuous operation with a throughput capacity of over 100 litres per hour.
7. Cross-flow or tangential filtration equipment with a filter area of over 5 square metres.
8. Freeze-drying equipment with a condenser capacity of over 5 kg of ice in 24 hours.
9. Cell disruption equipment capable of continuous operation without the release of aerosols with a flow rate greater than 10 litres per hour.
10. Spray drying equipment.
11. Drum drying equipment.
12. Biological safety cabinets Class III or Class I with accessories for conversion to Class III.
13. Flexible film isolators or other cabinets with air handling characteristics equivalent to Class III and anaerobic boxes.
14. Biological safety cabinets Class II.
15. Equipment for microencapsulation of microorganisms or toxins.

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<sup>164</sup>The list of equipment has utility principally as a component of the reporting format for facilities declared pursuant to Article III, section D and also for other purposes under Article III such as for declarations of transfers and as an illustrative list in the context of a facility investigation.

<sup>165</sup>A version of this equipment list is included in this Evaluation Paper as an addendum to Appendix C Facilities.

<sup>166</sup>Amended to be consistent with the capacity in Article III. D, section I.

<sup>167</sup>Amended to be consistent with the capacity in Article III. D, section I.

16. Automatic DNA sequencing equipment.
17. Automatic DNA synthesizer.
18. Automatic peptide sequencing equipment.
19. Automatic peptide synthesizer.
20. Milling equipment having a capacity of milling grain with mass median diameter less than 10 micrometres.
21. Plant inoculation cabinets/chambers providing quarantine.
22. Cabinets/chambers designed or used for rearing insects.

## ANNEX D. INVESTIGATIONS<sup>168</sup>

### I. GENERAL PROVISIONS

#### (A) DESIGNATION OF INVESTIGATION PERSONNEL

1. The personnel of an investigation team shall consist of investigators and, as necessary, investigation assistants. The Director-General shall only designate properly qualified investigation personnel from the appointed full time staff of the Technical Secretariat or ad hoc experts, nominated by States Parties in accordance with paragraphs 10 to 15 of this section, to carry out field investigations. In the employment of the staff and in the determination of the conditions of service due regard shall be paid to the necessity of securing the highest standards of efficiency, competency and integrity and the importance of selecting personnel on as wide an equitable geographic basis as possible. No national of the requesting State Party or the receiving State Party shall be a member of an investigation team.

#### Designation of full time investigation personnel

2. The Technical Secretariat shall recruit candidates for appointment as investigation personnel to its full time staff on the basis of their expertise and experience relevant to the purpose of investigations of non-compliance concerns.

3. Not later than 30 days after the entry into force of this Protocol, the Technical Secretariat shall communicate in writing to all States Parties an initial list of the names, nationalities, dates and places of birth, gender, passport numbers and ranks of the persons proposed for designation as investigation personnel by the Technical Secretariat, as well as a description of their qualifications and professional experience.

4. Each State Party shall acknowledge receipt of this initial list of investigation personnel proposed for designation, within 24 hours of receipt thereof. Any investigator or investigation assistant included in this list shall be regarded as accepted unless a State Party, not later than 30 days after acknowledgment of receipt of the list, declares its non-acceptance in writing. The State Party may include the reason for the objection. In the case of non-acceptance, the proposed investigator or investigation assistant shall not participate in investigation activities either (i) on the territory of a State Party that has declared its non-acceptance, or (ii) in any other place under the jurisdiction or control of a State Party that has declared its non-acceptance. The Technical Secretariat shall immediately confirm receipt of the notification of non-acceptance. The Technical Secretariat shall, as necessary, submit further proposals in addition to the initial list.

5. Additions or changes to the list of investigation personnel shall be effected according to the procedures set out in paragraphs 3 and 4 above.

6. The Technical Secretariat shall keep the list of investigation personnel up to date and notify all States Parties of any additions, deletions or changes to the list.

7. A State Party that has been notified of an investigation shall not seek the removal from the investigation team of any of the investigation personnel named in the investigation mandate. A State Party shall have the right at any other time, to object to any member of the

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<sup>168</sup>The text in AHG/52 (Part II) has been used as the baseline for this Annex.

investigation personnel who has already been accepted. It shall notify the Director-General of its objection in writing and may include the reason for the objection. The Director-General shall within 12 hours of receipt of the objection, acknowledge receipt thereof. Such objection shall come into effect upon receipt by the State Party of the Director-General's acknowledgement.

8. The number of investigation personnel accepted by a State Party for designation shall be sufficient to allow for availability of appropriate numbers of investigation personnel.

9. If, in the opinion of the Director-General, the non-acceptance by a State Party of proposed investigation personnel impedes the designation of a sufficient number of investigation personnel or otherwise hampers the effective fulfilment of the tasks of the Technical Secretariat for the purposes of investigations, he/she shall take the matter up with the State Party concerned. If the matter remains unresolved he/she shall then refer the issue to the Executive Council.

#### Designation of ad hoc experts as investigation personnel

10. Not later than 30 days after the entry into force of this Protocol, the Technical Secretariat shall communicate the necessary qualifications, professional experience and an indication of the minimum number of experts in each category to be included on the list of investigation personnel for utilization on an ad hoc basis as investigators during field investigations.

11. Ad hoc experts, meeting the requirements as communicated pursuant to paragraph 10, shall be nominated by States Parties. Such nominations shall be submitted by States Parties to the Director-General within 30 days after receipt of the communication and shall include the names, nationalities, dates and places of birth, gender, passport numbers, qualifications and professional experience of the ad hoc experts they nominate for designation as investigation personnel. The Director-General may seek further nominations, and additional nominations may also be submitted by States Parties, at any time. Such nominations shall be circulated to States Parties in accordance with the provisions of paragraphs 3 to 9 above.

12. Not later than 120 days after the entry into force of this Protocol, the Director-General shall communicate to each State Party the list of ad hoc personnel in accordance with the provisions for the list of investigation personnel as set out in paragraphs 3 to 9 of this section.

13. In the event that necessary expertise is not available within the Technical Secretariat and ad hoc experts are required for the conduct of a field investigation, such experts shall be selected from the designated list of ad hoc personnel by the Director-General in accordance with the provisions of paragraph 42 of this section. A nominated ad hoc expert shall not be appointed as an investigation team leader.

14. When assigned for a field investigation team the personnel on the list of ad hoc personnel shall be considered members of the staff of the Technical Secretariat and as such subject to all provisions, applicable to such personnel, contained in this Protocol. A State Party that has been notified of an investigation shall not seek the removal from the investigation team of any of the investigation personnel named in the investigation mandate.

15. Each State Party shall promptly notify the Technical Secretariat if an ad hoc expert nominated by it can no longer fulfil the duties of investigation personnel. Any ad hoc expert



appearing on the list of designated investigation personnel, may also withdraw from the list by informing the Director-General in writing.

### Training

16. The Technical Secretariat shall ensure that all members of the designated investigation personnel are properly trained to conduct investigations. The Technical Secretariat shall conduct such training and it may coordinate, in agreement with States Parties offering training, a schedule for such training.

### (B) DESIGNATION AND CERTIFICATION OF LABORATORIES

17. The Director-General shall utilize only properly designated and certified laboratories for off-site analyses of samples.

18. The criteria, including the proficiency standards, and procedures required for designation and certification of laboratories shall be approved by the first Conference of States Parties.

19. Not later than 30 days after the conclusion of the first Conference of States Parties, or after the accession of a State Party to the Protocol, the Technical Secretariat shall communicate to the States Parties the criteria, including the proficiency standards, and procedures required for the designation and certification of laboratories as approved by the first Conference of States Parties.

20. States Parties, wishing to do so, shall, within 60 days after receiving the communication of the criteria, including the proficiency standards, and procedures required for the designation and certification of laboratories, provide an initial list of laboratories nominated for designation and certification.

21. Nominated laboratories shall be designated and certified by the Director-General in accordance with the provisions contained in paragraphs 18 to 20 above. The Director-General shall not later than 30 days after the completion of the designation and certification process, communicate a list of all the designated and certified laboratories to all States Parties.

22. The Director-General may terminate the designation and certification of a laboratory on the request of the nominating State Party or if such a laboratory falls below the required proficiency standards.

23. Further laboratories may, when necessary, be designated and certified in accordance with the procedures referred to in paragraphs 18 to 20 above. The designation and certification of each laboratory shall be subject to renewal every three years.

24. In the designation and certification of laboratories, the Director-General shall pay due regard to the necessity of equitable geographic distribution of designated laboratories. At the request of a State Party, the Technical Secretariat shall assist in the upgrading of a laboratory(ies) nominated for designation and certification. The cost of upgrading the nominated laboratories shall be borne by the State Party concerned, and/or by the Technical Secretariat within available resources when possible.

25. In order to ensure the security and confidentiality of samples being analysed, the Director-General shall enter into specific agreements with designated and certified laboratories as soon as possible after the designation and certification of each laboratory. A designated and certified laboratory shall not be used for the analysis of samples until such an agreement has been concluded with the laboratory.

(C) STANDING ARRANGEMENTS

Point(s) of entry

26. Each State Party shall designate its point(s) of entry and shall supply the required information to the Technical Secretariat not later than 30 days after this Protocol enters into force for it. These point(s) of entry shall be such that the investigation team can reach any investigation area from at least one point of entry within 24 hours. Locations of point(s) of entry shall be provided to all States Parties by the Director-General.

27. Each State Party may change its point(s) of entry by giving notice of such change to the Director-General. Changes shall become effective 30 days after the Director-General receives such notification, to allow appropriate notification to all States Parties.

28. If the Director-General considers that there are insufficient point(s) of entry for the timely conduct of investigations or that changes to the point(s) of entry proposed by a State Party would hamper such timely conduct of investigations, **he/she**<sup>169</sup> shall enter into consultations with the State Party concerned to resolve the problem.

Arrangements for use of non-scheduled aircraft

29. Where timely travel to the point of entry is not feasible using scheduled commercial flights, an investigation team may utilize non-scheduled aircraft. Not later than 30 days after this Protocol enters into force for it, each State Party shall inform the Technical Secretariat of the diplomatic clearance number for non-scheduled aircraft or appropriate procedures and measures to facilitate the arrival and handling of non-scheduled aircraft transporting an investigation team and equipment necessary for investigation. Aircraft routings shall be along established international airways that are agreed upon between the State Party and the Director-General as the basis for such procedures.

30. When a non-scheduled aircraft is used, the Technical Secretariat shall provide the receiving State Party with the proposed flight plan for the aircraft's flight from the last airfield prior to entering the airspace of the State in which the investigation site is located to the point of entry, not less than six hours before the scheduled departure time from that airfield. Such a plan shall be filed in accordance with the procedures of the International Civil Aviation Organization applicable to civilian aircraft. The Technical Secretariat shall include in the remarks section of each flight plan the diplomatic clearance number or details concerning the appropriate procedures and measures to facilitate the arrival of the non-scheduled aircraft and the appropriate notation identifying the aircraft transporting the investigation team and equipment necessary for the investigation.

31. Not less than three hours before the scheduled departure of the investigation team from the last airfield prior to entering the airspace of the State in which the investigation is to

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<sup>169</sup>"he/she" is consistent with "Director-General" earlier in the sentence.

take place, the receiving State Party or host State Party/State shall ensure that the flight plan filed in accordance with paragraph 30 is approved, so that the investigation team may arrive at the point of entry by the estimated arrival time.

32. The receiving State Party shall provide parking, security protection, servicing and fuel as required by the Technical Secretariat for the aircraft of the investigation team at the point of entry when such aircraft is owned or chartered by the Technical Secretariat. Such aircraft shall not be liable for landing fees, departure tax, and similar charges. The Technical Secretariat shall bear the cost of such fuel, parking, security protection and servicing.

#### Administrative arrangements

33. The receiving State Party shall provide or arrange for the amenities necessary for the investigation team such as transport, communications means, interpretation, working space, lodging, meals and emergency medical care. In this regard, the receiving State Party shall be reimbursed by the Organization for all such costs incurred by the investigation team within 30 days after receipt of a detailed notification claim for such costs from the receiving State Party.

#### Approved investigation equipment

34. The approved investigation equipment for use during on-site investigations, which shall be commercially available to all States Parties of the Protocol as well as the specifications for this equipment shall be approved by the Conference of States Parties at its first session. These specifications shall take account of safety and confidentiality factors bearing in mind the type of location where such equipment could be used.

35. The Technical Secretariat shall, as appropriate, update the list of equipment. The updated list shall be considered and approved by the Conference.

36. The Technical Secretariat shall ensure that all types of approved equipment are available for on-site investigations when required. When required for an on-site investigation, the Technical Secretariat shall duly certify that the equipment has been calibrated, maintained and protected. To facilitate the checking of the equipment at the point of entry by the receiving State Party, the Technical Secretariat shall provide documentation and attach seals to authenticate the certification.

37. Any permanently held equipment shall be in the custody of the Technical Secretariat. The Technical Secretariat shall be responsible for the maintenance and calibration of such equipment.

38. Subject to paragraph 39, there shall be no restriction by the receiving State Party on the investigation team bringing into the investigation site such equipment on the list which the Technical Secretariat has determined to be necessary to fulfil the investigation requirements. The investigation team shall take into account local regulations having an effect on the use of specific pieces of equipment when such equipment is being used during an investigation. The receiving State Party shall include the details of such regulations in the pre-investigation briefing.

39. The receiving State Party shall have the right, without prejudice to the prescribed time frames, to inspect the equipment in the presence of investigation team members at the point

of entry, i.e. to check the identity of the equipment brought in or removed from the territory of the receiving State Party or the host State. To facilitate such identification, the Technical Secretariat shall attach documents and devices to authenticate its designation and approval of the equipment. The investigation of the equipment shall also ascertain to the satisfaction of the receiving State Party that the equipment meets the description of the approved equipment specified in the mandate for the particular type of investigation. The receiving State Party has the right to exclude equipment not meeting that description or equipment without the above-mentioned authentication documents and devices. The inspection of investigation equipment shall not exceed four hours.

40. In cases where the receiving State Party agrees to provide, at the request of the Technical Secretariat, investigation equipment, or the investigation team finds it necessary to use equipment available on site not belonging to the Technical Secretariat and requests the receiving State Party to enable the team to use such equipment, the receiving State Party shall attempt to meet the request to the extent it can. The investigation team shall have the right to observe and confirm the calibration of such equipment. The receiving State Party shall be reimbursed for the cost of making the equipment available and for any calibration thereof required by the investigation team.

41. In cases where the receiving State Party offers to provide equipment, available on site, the investigation team may accept the offer. The investigation team shall have the right to observe and confirm the calibration of such equipment. Any calibration required by the investigation team and the use of the equipment shall be at the cost of the receiving State Party.

#### (D) PRE-INVESTIGATION ACTIVITIES

##### Assignment of investigation team

42. The Director-General shall determine the size of the investigation team and select the proper qualified members to conduct the specific type of investigation requested in the investigation request on as wide an equitable geographic basis as possible taking into account the circumstances of the particular request. Members of the investigation team shall be selected from the investigation personnel designated in accordance with paragraphs 2 to 15 above. The size of the investigation team shall be kept to the minimum necessary for the proper fulfilment of the investigation mandate.<sup>170</sup> The Director-General may at his/her discretion alert potential members of the investigation team, as soon as possible after receipt of the investigation request, of the possibility that they may be required for an investigation.

43. The Director-General may extend the size of the investigation team and in agreement with the receiving State Party.

##### Observer

44. The requesting State Party may, subject to the agreement of the receiving State Party, send a representative who may be a national either of the requesting State Party or of a third State Party, to observe the conduct of an investigation. The receiving State Party shall as a

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<sup>170</sup>It is unnecessary and unwise to specify an upper limit for the size of investigation team as the size necessary will depend upon the particular circumstances of the investigation.

rule, accept the proposed observer, but if the receiving State Party exercises a refusal, that fact shall be recorded without comment in the final report.

45. The receiving State Party shall notify its acceptance or non-acceptance of the proposed observer to the Director-General.

46. The requesting State Party shall liaise with the Director-General to coordinate the arrival of the observer at the same point of entry as the investigation team within a reasonable period of the investigation team's arrival.

47. The observer shall have the right throughout the period of investigation to be in communication with the embassy or other official representation of the requesting State Party located in the receiving State Party, or in the case of absence of an embassy or other official representation, with the requesting State Party itself. The receiving State Party shall, to the extent possible, provide means of communication to the observer.

48. The observer shall have the right to arrive at the investigation area/alternative or final perimeter, whichever occurs first, with the investigation team and to have access to and within the investigation area/alternative or final perimeter, whichever occurs first, as granted by the receiving State Party.

49. The observer shall have the right to make recommendations concerning the conduct of the investigation. The investigation team leader shall be under no obligation to act upon any recommendations of the observer.

50. Throughout the investigation, the investigation team shall keep the observer informed about the conduct of the investigation and the factual findings.

51. Throughout the investigation, the receiving State Party shall provide or arrange for the amenities necessary for the observer similar to those enjoyed by the investigation team as described in paragraph 33. All costs in connection with the stay of the observer on the territory of the receiving State Party, shall be borne by the requesting State Party.

#### Dispatch/arrival of investigation team

52. The Director-General shall dispatch an investigation team as soon as possible after an investigation request has been received and processed in accordance with the provisions of Article III, section G, paragraphs 19 to 27. The investigation team shall arrive at the point of entry specified in the request in the minimum time possible in accordance with the provisions contained in Article III, section G, and this Annex.

53. In the case of field investigations, the Director-General may, in exceptional cases and after prior consultation with the receiving State Party, dispatch an element of the investigation team assigned in accordance with paragraph 42 above, later than the rest if the time period for the deployment of the full team cannot be achieved simultaneously.

#### (E) CONDUCT OF INVESTIGATION

##### Communications

54. The members of the investigation team shall have the right at all times during the investigation to communicate with each other. For this purpose they may use their own duly approved and certified equipment with the consent of the receiving State Party and in full compliance with the relevant regulations of the receiving State Party, if the receiving State Party can not provide them with the necessary telecommunication equipment. Members of the investigation team shall have the right to communicate at all times with the Technical Secretariat, using their own duly approved and certified equipment to the extent that the receiving State Party can not provide them with the required telecommunication equipment meeting the same specifications as for the similar approved and certified equipment. In doing so, the members of the investigation team shall be under the obligation not to communicate any information or data not related to the investigation mandate.

55. The members of the investigation team shall, unless authorized by the Director-General, be prohibited at all times from communicating directly or indirectly on any matter related to the investigation with any person or institution other than the members of the investigation team or the Technical Secretariat.

#### Orientation overflight

56. Upon the request of the investigation team, the receiving State Party may provide an overflight over the investigation area or the facility to be investigated during the investigation for the purposes of providing the investigation team with a general orientation of the investigation area or the facility to be investigated.<sup>†171</sup>

#### (F) POST-INVESTIGATION ACTIVITIES

##### Preliminary findings

57. Upon completion of the investigation, the investigation team shall meet with the receiving State Party to review the team's preliminary findings and to clarify any remaining ambiguities. The team shall provide to the receiving State Party its preliminary findings in written form having taken into account the provisions of Annex E, together with a list and copies of written information and data gathered and other material intended to be taken off site, and any samples proposed to be removed from the site. This document shall be signed by the team leader. In order to indicate that the receiving State Party has taken notice of the contents of the initial findings, the representative of the receiving State Party shall countersign the document. This meeting and these procedures shall be completed not later than 24 hours after completion of the on-site activities.

58. In accordance with the access provisions contained in Article III, section G, subsection H, the receiving State Party may request that restrictions be placed on the removal of specific samples, documents or other materials, if it deems this necessary to protect commercial proprietary or national security information.

59. The receiving State Party may also draw to the attention of the investigation team any information in the preliminary findings which, in its view, is unrelated to the investigation. In such cases the receiving State Party shall have the right to request that such information is

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<sup>171</sup>The additional text in AHG/52 (Part II) excluding any mention or comment on the absence of an overflight is an unnecessary impairment of the ability of the investigation team to provide an effective report.

deleted. If the investigation team does not agree to the deletion of such information, it shall be handled as confidential.

60. Further to the provisions of paragraph 57 above the investigation team shall, upon request, supply copies of all information and data recorded during the investigation to the receiving State Party.

#### Departure

61. Upon completion of the post-investigation activities, the investigation team and the observer shall leave the territory of the receiving State Party as soon as possible. The receiving State Party shall do everything in its power to provide assistance and to ensure the safe conduct of the investigation team, equipment and baggage to the point of exit. Unless agreed otherwise by the receiving State Party and the investigation team, the point of exit shall be the same as the point of entry used.

#### (G) MEASURES TO GUARD AGAINST ABUSE DURING AN INVESTIGATION

62. In carrying out the investigation in accordance with the investigation mandate, the investigation team shall use only those methods provided for in this Protocol which are necessary to provide sufficient relevant facts to clarify the concern about possible non-compliance described in the investigation mandate and shall refrain from activities not relevant thereto.

63. It shall collect and document such facts as are related to the possible non-compliance concern described in the investigation mandate but shall neither seek nor document information which is clearly not related thereto, unless the receiving State Party expressly requests it to do so. Any material collected and subsequently found not to be relevant shall not be retained.

## II. FIELD INVESTIGATIONS

### (A) INVESTIGATION REQUEST

Evidence, including information and analysis to be submitted with a request for an investigation

1. A request for an investigation under paragraph 3 (a) of Article III, section G, for an event(s) which has given rise to a concern about non-compliance shall include the following information:

(a) Name of the State Party/State on whose territory or in any other place under whose jurisdiction or control the alleged event(s) has taken place;

(b) A description of the alleged event(s), including all available information on:

(i) The use or release of microbial or other biological agent(s) or toxin(s) for other than peaceful purposes; and/or

(ii) Weapons, equipment or means of delivery used in the alleged event(s);

(iii) The circumstances under which the alleged event(s) took place;

(iv) The suspected cause and/or perpetrator of the alleged event(s);

(c) To the extent possible, the date and time, when the alleged event(s) took place and/or became apparent to the requesting State Party and, if possible, the duration of that alleged event(s);

(d) The area requested to be investigated in accordance with paragraph 3 below;

(e) Whether any victims are humans, animals or plants as well as an indication of numbers affected and a description of the consequences of exposure, and if so:

(i) Symptoms and/or signs of the disease;

(ii) All available epidemiological data relevant to the disease outbreak;

(f) For requests involving outbreaks of disease, detailed evidence, and other information, and analysis, including detailed information on events and/or activities which substantiate its view that an outbreak of disease (a) is not naturally occurring, and (b) is directly related to activities prohibited by the Convention;

(g) Information from and/or the outcome or results of any prior consultations/clarifications relevant to the request.

2. In addition to the information to be supplied with a request pursuant to paragraph 1, other types of information may also be submitted as appropriate and to the extent possible including, *inter alia*:



(a) Reports of any internal investigation including results of any laboratory investigations;

(b) Information on the initial treatment and the preliminary results of the treatment of the disease;

(c) A description of the measures taken to prevent the spread of the disease outbreak and to eliminate the consequences of the alleged event(s), and their results in the affected area, if available;

(d) Any request for specific assistance submitted separately in accordance with the provisions contained in Article VI, paragraph 9;

(e) Any other corroborative information, including affidavits of eye witness accounts, photographs, samples or other physical evidence which in the course of internal investigations have been recognized as being related to the alleged event(s).

#### Investigation area

3. The investigation area identified in paragraph 1 (d) above, shall:

(a) Be kept to the minimum size necessary consistent with the requirements for an effective and timely investigation of the specific non-compliance concern contained in subparagraph 1 (b) above;

(b) Be finite and identified as precisely as possible by providing the geographic coordinates, specified to the nearest second if possible, or other alternative measures, as well as a map specifying the identified area and the geographic characteristics of the area;

(c) Not exceed 1,500 square kilometres **in size** in case of human disease and 15,000 square kilometres **in size** in case of animal and plant disease;

(d) Be no larger than the evidence provided can reasonably justify;

(e) Not cross any international borders.

4. For the purposes of the investigation mandate the Director-General shall designate the investigation area on a map by geographic coordinates specified to the nearest second. The designation shall be based on the investigation area identified by the requesting State Party in the investigation request, subject to guidelines received from the Executive Council.

#### (B) PRE-INVESTIGATION ACTIVITIES

##### Notification of investigation

5. The Director-General shall, not less than 12 hours prior to the arrival of the investigation team at the point of entry, notify the receiving State Party of the impending investigation. The Director-General shall also notify other States Parties if access to their territories might be required during the investigation.

6. The notification made by the Director-General under the provisions of paragraph 5 shall include, *inter alia*:

- (a) Name of the receiving State Party/State;
- (b) Name of the requesting State(s) Party(ies) if not the same as the name of the receiving State Party;
- (c) The nature of the alleged event(s) to be investigated as determined from the investigation request;
- (d) The point of entry where the investigation team will arrive as well as the means of arrival;
- (e) The date and estimated time of arrival of the investigation team at the point of entry;
- (f) If using a non-scheduled aircraft, the standing diplomatic clearance number or the appropriate information required by the receiving State Party to facilitate the arrival and handling of the non-scheduled aircraft;
- (g) Location and characteristics of the area where the incident(s) of non-compliance is alleged to have taken place;
- (h) A description of any effects on humans, animals or plants;
- (i) A list of the approved equipment that will accompany the investigation team;
- (j) A list of approved equipment which the Director-General requests the receiving State Party to consider to make available to the investigation team for use during the investigation in accordance with section I, paragraph 41 of this Annex;
- (k) A list of laboratory facilities and other support which the Director-General requests, if applicable, the receiving State Party to provide to the investigation team for use during the investigation if available and possible;
- (l) The investigation mandate;
- (m) The names of the leader and the other members of the investigation team.

7. The receiving State Party shall acknowledge receipt of the notification of the impending investigation not later than one hour after receipt of such a notification.

8. The receiving State Party shall indicate not later than six hours after receipt of the notification, which of the requested equipment, laboratory facilities and other support will be supplied.

#### Investigation mandate

9. The investigation mandate, issued in accordance with Article III, section G, paragraph 28, shall contain at least the following:

- (a) The name of the receiving State(s) Party(ies);
- (b) The nature of the alleged event(s) to be investigated as determined from the investigation request, including any effects on humans, animals or plants;
- (c) The investigation area designated in accordance with paragraph 4 of this section;
- (d) Specified investigation objectives to be accomplished by the investigation team;
- (e) The planned types of activities, operational instructions and any other identifiable tasks of the investigation team;
- (f) Any transit or basing points to be used by the investigation team, as appropriate;
- (g) The names of the leader and of the other members of the investigation team;
- (h) The list of approved equipment that will accompany the investigation team;
- (i) The estimated time necessary to conduct the investigation.

#### Duration of an investigation

10. The investigation shall not exceed 30 days unless an extension is authorized by the Executive Council.<sup>172</sup> The estimated period of the investigation shall be indicated in the investigation mandate and updated, within the time frame specified above, by the investigation team in full consultation with the receiving State Party after the pre-investigation briefing. The investigation team shall make every effort to conduct the investigation in the shortest time possible. The period of investigation means the period from the end of the point of entry procedures until the departure of the investigation team from the point of exit.

#### (C) ACTIVITIES UPON ARRIVAL OF THE INVESTIGATION TEAM

##### Transportation from the point of entry

11. The receiving State Party shall transport the investigation team together with its equipment to the location within the investigation area indicated by the investigation team as the starting point of the investigation as soon as possible, but in any case shall ensure their arrival at that location not later than **24** hours after the arrival of the investigation team at the point of entry.

12. The host State Party/State shall as necessary assist in the transportation of the investigation team and its equipment.

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<sup>172</sup>An extension that is authorized by the Executive Council should not also require to be agreed upon by the receiving State Party.

### Pre-investigation briefing

13. The investigation team shall be briefed by representatives of the receiving State Party with the aid of maps and other documentation as appropriate. The briefing shall include, *inter alia*, relevant natural terrain features, safety aspects, prevailing disease profiles in the area to be investigated which the receiving State Party considers relevant to the briefing, possible routes and means of transport to the area, logistical arrangements for the investigation, details of equipment and/or laboratory facilities provided on request of the Director-General and any other relevant information.

14. If the case so warrants, the receiving State Party shall have the right to inform the investigation team during the pre-investigation briefing or at any time during the investigation about the place or places which it considers sensitive or not related to the Convention and therefore subject to the access provisions in Article III, section G, subsection H.

15. The receiving State Party may provide additional information that became available after the request was made or that does not appear on the investigation mandate.

16. The pre-investigation briefing shall not exceed three hours.

### Investigation plan

17. After the pre-investigation briefing the investigation team shall prepare an initial investigation plan to serve, *inter alia*, as a basis for logistic and safety arrangements. This plan shall at least contain the activities to be carried out by the team, logistic requirements of the team and provisional timings of the activities and requirements. The investigation team shall, as appropriate, modify the investigation plan taking into account any comments by the receiving State Party. This plan shall be made available to the receiving State Party prior to the commencement of the investigation. The preparation of the investigation plan shall not exceed two hours.

## (D) CONDUCT OF INVESTIGATION

### Situation report

18. The investigation team shall, not later than 24 hours after its arrival on the territory of the receiving State Party, in consultation with the receiving State Party send a situation report to the Director-General. It shall in consultation with the receiving State Party send further investigation progress reports as necessary.

19. The situation report may indicate any urgent need related to the matter under investigation for technical, medical, veterinary or agronomic assistance and any other relevant information. The progress reports may indicate any further need for assistance that might be identified during the course of the investigation.

### Implementation by the investigation team of specific on-site activities

20. All on-site activities shall be conducted in accordance with the access provisions contained in Article III, section G, subsection H.

## Interviewing

### Interviewing of eye witnesses

21. The investigation team may interview persons, with their explicit consent, who witnessed or could provide information on a specific incident or series of incidents, that could be relevant to the investigation. The interview shall take place in the presence, and if possible and appropriate with the assistance, of representatives of the receiving State Party, unless the individual concerned indicates otherwise.
22. The investigation team may seek information relevant to the investigation which is necessary to fulfil their investigation mandate. If required, interpretation shall be provided by the investigation team or, where requested, by the receiving State Party.

### Interviewing of humans who may have been exposed to BTW or owners of plants or animals which may have been exposed to BTW

23. The investigation team may interview humans, with their explicit consent, who may have been exposed in order to establish how the exposure affected them. In the case of animals or plants which may have been exposed, the investigation team may interview the persons responsible for the animals or plants, with their consent, in order to establish how the exposure affected such animals or plants. Interviews shall be conducted in the presence, and if possible and appropriate with the assistance, of representatives of the receiving State Party, unless the individual concerned indicates otherwise.
24. The investigation team shall seek only information which is relevant to the investigation and necessary to fulfil their investigation mandate. If required, interpretation shall be provided by the investigation team or, where requested, by the receiving State Party.

### Interviewing of other individuals

25. The investigation team may interview other individuals, such as national/local government officials, personnel of any relevant medical, veterinary, pharmaceutical, agricultural institutions or facilities, with their explicit consent, in the presence, and if possible and appropriate with the assistance, of a representative of the receiving State Party, unless the individual concerned indicates otherwise, in order to obtain information relevant to the investigation.
26. The investigation team shall only seek information which is relevant to the investigation and necessary to fulfil the investigation mandate. If required, interpretation shall be provided by the investigation team or, where requested, by the receiving State Party.
27. The receiving State Party, or the person being interviewed, shall have the right to object to questions they deem not relevant to the investigation or impinge on sensitive national security or commercial proprietary data. If the investigation team leader nonetheless continues to believe that these questions are relevant and should be answered, he/she may submit them in writing to the receiving State Party for reply, together with an explanation of their relevance to the investigation. The investigation team may note in its report any refusal by the receiving State Party to permit interviews or to allow questions to be answered and any explanations provided by the receiving State Party in this regard.

28. Interviews shall be conducted in such a way as to avoid unduly hindering the work of the personnel interviewed. The investigation team shall, where relevant, give advance notice of the proposed timings of any requested interviews with specific individuals. The receiving State Party may make proposals for the timings of such interviews.

#### Interviewing of individuals not available in the investigation area

29. If the investigation team, during the course of the investigation establishes that any person(s) who meet the criteria for interviewing set out in paragraphs 21, 23 and 25 above, but not present in the area of investigation during the investigation, the interviewing of whom is required to fulfil its mandate, it may indicate such individuals<sup>173</sup> to the receiving State Party. The investigation team shall provide the receiving State Party with the etiological and/or epidemiological information indicating why such interviews are necessary to fulfil its mandate. The receiving State Party shall enable the investigation team to conduct such interview(s). Such interviews shall be conducted in accordance with the provisions contained in paragraphs 21 to 28 above.

#### Visual observation

30. The investigation team may observe visually the area identified in the investigation mandate in order to obtain information relevant to the investigation. All necessary precautions shall be taken to ensure the health and safety of the investigation team. The investigation team shall be accompanied by representatives of the receiving State Party. Approved equipment shall be used in accordance with the access provisions contained in Article III, section G, subsection H.

#### Disease/intoxication-related examination

31. Appropriately qualified medical members of the investigation team may conduct medical examinations of persons affected or exposed, with their informed written consent or with the informed written consent of their family or legal representatives. The purpose of such examinations shall be to enable the investigation team to make a diagnosis and/or determine whether exposure has occurred.

32. Appropriately qualified members of the investigation team may conduct disease/intoxication-related examinations of animals and/or plants affected or exposed, with relevant explicit consent where possible and appropriate, of the legal owners of the animals and/or plants. The purpose of these examinations shall be to enable the investigation team to make a diagnosis and/or determine whether exposure has occurred.

33. The investigation team may, where necessary and applicable, take body samples from affected persons or animals as well as samples of affected or exposed plants in order to diagnose, confirm a clinical diagnosis of the disease or determine whether exposure has occurred. In the case of persons affected this shall be with the informed written consent or with the informed written consent of the family or legal representative of the person affected. The receiving State Party shall receive duplicate samples for its own analysis.

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<sup>173</sup>The normal place of residence of such individuals is immaterial. They may, for example, be individuals who happened to be in the area of investigation at the time of the event being investigated.

34. The investigation team may observe, participate in or conduct post mortem examinations where relevant, with the informed written consent by the family or the legal representative of the deceased.

35. The investigation team may when necessary examine laboratory animals, existing samples taken from laboratory animals or take samples from such animals with the consent of the legal owners.

36. All medical information, including samples and other material taken from humans, shall be accorded the most stringent protection measures by the investigation team and all laboratories involved in the investigation.

37. If the investigation team, during the course of the investigation, establishes that any affected or exposed persons or animals not present in the investigation area, **for which** the medical or veterinary examination or taking of body samples is required for the fulfilment of its mandate, it may indicate such persons or animals to the receiving State Party. The receiving State Party shall enable the investigation team to conduct such medical or veterinary examination and/or taking of body samples. Such activities shall be conducted in accordance with the provisions contained in paragraphs 31 to 36 above. The investigation team shall provide the receiving State Party with the etiological and/or epidemiological information which necessitates such activities.

#### Sampling and identification

38. The investigation team may, where appropriate and it considers necessary, take environmental samples, samples of munitions and devices or remnants of munitions and devices relevant to the investigation mandate. Any such samples shall be analysed for the presence of specific biological agents or toxins.

39. Samples shall be taken in the presence of a representative of the receiving State Party. The investigation team may request the receiving State Party to assist in the collection of samples under the supervision of members of the investigation team. The investigation team may also request the receiving State Party, where necessary and appropriate, to take relevant control samples from areas immediately adjacent to the locations under investigation. The receiving State Party shall receive duplicate samples for its own analysis.

**40.**<sup>174</sup> The Director-General shall have the primary responsibility for the security, integrity and preservation of samples and for ensuring that the confidentiality of samples transferred for off-site analysis is protected. The Director-General shall, in any case:

(a) Establish a stringent regime governing the collection, handling, storage, transport and analysis of samples;

(b) Select from among the designated and certified laboratories those which shall perform analytical or other functions in relation to the investigation;

(c) **Ensure that all samples shall be analyzed in two designated and certified laboratories, one of which may be within the receiving State Party;**<sup>175</sup>

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<sup>174</sup>Previously paragraph 42 on page 94 of AHG/52 (Part II). Reordered for greater clarity.

<sup>175</sup>Duplicate analysis of all samples in two designated and certified laboratories is essential.

(d) Ensure that there are procedures for the safekeeping and maintaining of the integrity of sealed duplicate samples for further clarification if necessary;

(e) Ensure the expeditious processing of the analysis of samples;

(f) Be accountable for the safety of all samples.

41. The investigation team may analyse samples using any methods specifically designed or approved for use in such investigations, and available to the investigation team. At the request of the investigation team, the receiving State Party shall, to the extent possible, provide assistance for the analysis of samples, using locally available resources. If the receiving State Party itself performs analyses, the investigation team or some member especially assigned by the team leader shall be present **throughout**.<sup>176</sup> All sampling shall be conducted according to procedures and methods so as to ensure that the desired samples taken are not contaminated and taken with due regard to health and safety considerations.

42. When it is not possible to carry out the analysis on the territory of the receiving State Party, the investigation team may remove samples for analysis in designated and certified laboratories. Representatives of the receiving State Party shall have the right to accompany all samples and observe any analysis and the subsequent destruction. Any unused samples or portions thereof, remaining after analysis has been completed, shall be returned to the receiving State Party.

43. When off-site analysis is to be performed, the samples shall be analysed in different designated and certified laboratories in separate States Parties. The Director-General shall ensure the expeditious processing of the analysis.

44. The receiving State Party shall receive duplicate samples for its own analysis. The receiving State Party and the investigation team shall also receive sealed duplicate samples for safekeeping and use if necessary for further clarification.

45. If further clarification of analytical results becomes necessary, then the sealed duplicate samples shall be used for this purpose. The seals of these samples shall be broken in the presence of both the investigation team and representatives of the receiving State Party. The analysis of these samples shall also take place in the presence of the investigation team and representatives of the receiving State Party.

46. Any unused samples or portions thereof, remaining after the investigation has been completed and that have not been destroyed, shall be returned to the receiving State Party.

#### Collection and examination of background information and data

47. The investigation team may with the assistance of the receiving State Party:

(a) Obtain and examine epidemiological data which it deems relevant to the investigation mandate. Such data may include data on the prevalence of a disease, an

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<sup>176</sup>It is essential that the investigation team or a member of it shall be present **throughout** not just during all the analytical processes.



epidemic or other disease outbreaks, and any preliminary identification and diagnosis of the event(s) that has given rise to the investigation as well as data on immunization programmes;

(b) Examine all medical, public and occupational health records and data which it deems relevant to the investigation mandate. Access to individual medical records shall be by the informed written consent of the individual concerned, or the family or legal representative where appropriate;

(c) Examine other documentation and records, such as those on veterinary or agricultural matters, which it deems relevant to the investigation mandate.

48. The investigation team may request copies of any documentation or data relevant to the investigation request for inclusion in the final report or to assist in its preparation. The reason for any objection given by the receiving State Party shall be put in writing for inclusion in the investigation report. Documentation and data requested by the investigation team and identified as confidential by the receiving State Party shall be treated in accordance with the confidentiality provisions of this Protocol.

49. Any documents or data collected and subsequently identified by the receiving State Party not to be relevant to the investigation mandate, shall be returned to the receiving State Party by the investigation team. Any documentation or data identified by the receiving State Party as in its view not being relevant to the investigation mandate shall be identified as such in the final report.

#### Extension of investigation area

50. If during the course of the investigation the investigation team considers it necessary to extend the area of investigation, it may request the receiving State Party for such extension. In its request, the investigation team shall indicate the requested extended area on a map by geographic coordinates specified to the nearest second. It shall also provide the receiving State Party with the reasons for the request and if the receiving State Party agrees with the request, the investigation area shall be extended as requested.

51. If agreement is not reached in 24 hours, the investigation team leader shall submit the issue to the Executive Council through the Director-General. The Director-General shall submit to the Executive Council a written request to extend the investigation area which shall include the evidence, including information and scientific and technical analysis providing a substantive basis for the request as well as all the information in the original request submitted to the receiving State Party. The Director-General shall also transmit a copy of the request to the receiving and requesting States Parties simultaneously with the submission of the request to the Executive Council. The Executive Council shall decide to approve the extension of the investigation area by a simple majority of its members. The requesting or receiving State Party or, if applicable, the State Party identified in the request as the alleged cause of the non-compliance concern, may participate in any Executive Council deliberations in this regard. If the requesting or receiving State Party or, if applicable, the State Party identified in the request as the alleged cause of the non-compliance concern, is a member of the Executive Council, such State Party shall not have the right to vote on the request of the Director-General request.

52. If during an investigation the investigation team considers it necessary to extend the investigation to a neighbouring State Party/State, the investigation team shall notify the

Director-General. The Director-General shall inform the Executive Council. On the basis of that information and/or any other information, any State Party may request in accordance with Article III, section G, paragraphs 6 to 18 that a separate investigation be conducted on the territory of a State Party identified by the Director-General in the submission to the Executive Council. In the case of a non-State Party, the Director-General shall immediately contact that non-State Party in accordance with the procedure set out in Article III, section G, paragraph 12.

#### Preliminary findings and departure

53. The post-investigation activities relating to preliminary findings and departure of the investigation team shall be conducted in accordance with paragraphs 57 to 60 of section I of this Annex.

#### (E) REPORTS

##### Interim investigation report

54. An interim investigation report shall be made available to the receiving State Party not later than 30 days after completion of the investigation.

55. The interim investigation report shall summarize the factual findings of the investigation. In addition, the report shall include a description of the investigation process, tracing its various stages, with special reference to:

(a) The activities conducted by the investigation team and its factual findings, particularly with regard to the concern regarding possible non-compliance as expressed in paragraph 1, subparagraph (b);

(b) The locations and times of any sampling and on-site analysis;

(c) Supporting evidence such as the records of interviews, the results of disease/intoxication-related examinations and epidemiological and scientific analyses, and the documents examined by the investigation team;

(d) Any information that the investigation team in the course of its investigation collected, that might serve to help in the identification of the origin of any biological agent or toxin found during the course of the investigation such as, *inter alia*, chemical composition and the presence of inert materials in the case of possible toxin weapons and serological or molecular sequence evidence in the case of infectious agents;

(e) The report shall also present such environmental and historical information as is available on the previous presence of the alleged agent in the region;

(f) An account of the assistance and its timeliness, provided by the host State Party/State;

(g) The result of any completed laboratory investigations and sampling and identification;

(h) A factual description by the investigation team of the degree and nature of access and cooperation granted by the receiving State Party and the extent to which this enabled the investigation team to fulfil its mandate.

56. The receiving State Party shall have the right to the following, which shall be communicated to the investigation team within 10 days after receipt of the interim report from the investigation team:

(a) Identify any information and data not related to the non-compliance concern(s) contained in the investigation mandate which in its view, due to its confidential nature, should not be contained in the final version of the report. The investigation team shall consider these observations and, as a rule, should remove that information and data as requested;

(b) Comment on the contents of the interim investigation report. The investigation team shall refer to the comments of the receiving State Party in the final version of the report and, wherever possible, incorporate them before submitting the final report to the Director-General.

#### Laboratory reports

57. Laboratory analysis and identification of biological agents and/or toxins shall be reported by the laboratory by means of the following types of reports:

(a) Initial laboratory report. An initial laboratory report shall be made available to the leader of the investigation team by the laboratory as soon as possible after receipt of the sample(s) and shall indicate initial findings, contain a differential diagnosis, give an estimate of the duration of further work as well as a plan for the conduct of further analysis and tests.

(b) Intermediate laboratory report. The laboratory shall make an interim laboratory report to the leader of the investigation team if it has not finalized its work after 30 days since the initial report. It shall contain details of progress of work and the final plan for future work.

(c) Final laboratory report. The laboratory shall make a final report of its findings to the leader of the investigation team as soon as it has finalized its work, **which should not be**<sup>177</sup> later than six months after receipt of the sample(s). The final laboratory report shall contain a description of the work done and a complete diagnosis or identification of an agent or agents. If it was not possible to make a positive diagnosis or identification, the report shall state that fact and give an explanation as to why it was not possible to make a final diagnosis or identification.

58. If there is any discrepancy in the laboratory reports, the investigation team shall submit a duplicate sample to another designated and certified laboratory for analysis.

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<sup>177</sup>It would be unwise to include a deadline of six months as AHG/52 (Part II) does as there can be **no** certainty that the designated and certified laboratories will have the capacity available to carry out and complete the work required by the Organization within six months. The Protocol will come into disrepute if the quality of the analytical results of samples from investigations is not of the highest international standard.

59. The laboratory reports shall be completed as soon as possible but **should** not **be**<sup>178</sup> later than six months after the conclusion of the on-site investigation for inclusion in the draft final report.

#### Final report

60. A draft final report which shall contain the interim investigation report, the comments of the receiving State Party and the laboratory reports shall be made available to the receiving State Party by the leader of the investigation team not later than 10 days after receipt of the final laboratory report(s). The receiving State Party may provide written comments on the draft final report which shall be communicated to the investigation team leader within **7** days after receipt of the draft final report. Any written comments that the receiving State Party may wish to make concerning the contents and findings of the draft final report, shall be attached as an annex to the final version of the draft report. The draft final report together with its annexes shall become the final report.

61. The final report shall be transmitted to the Director-General not later than 14 days after the completion of the investigation for further handling in accordance with Article III, section G.

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<sup>178</sup>Amended for consistency with paragraph 57 (c).

### III. FACILITY INVESTIGATIONS

#### (A) INVESTIGATION REQUEST

##### Information to be submitted with a request for an investigation

1. Requests for facility investigations under paragraph 3 (b) of Article III, section G, for an event(s) which has given rise to a concern about non-compliance shall at least include the following information:

(a) Name of the State Party on whose territory or in any other place under whose jurisdiction or control the alleged non-compliant activity has taken place;

(b) A description of the specific event(s) or activity(ies) which gave rise to a non-compliance concern, including specific information regarding the development, production, stockpiling, acquisition or retention of:

(i) Microbial or other biological agents or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;

(ii) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict;

(c) The name, if known, or other form of identification and location(s) of the facility where the alleged non-compliant activity(ies) took place. This shall include as much detail as possible including a site diagram, indicating boundaries as well as the requested perimeter, related to a reference point with geographic coordinates, specified to the nearest second, if possible, or other alternative measures;

(d) The approximate period during which the non-compliant event(s) or activity(ies) is alleged to have taken place;

(e) Information from and/or the outcome or results of any prior consultations/clarifications or any other prior investigations relevant to the request.

2. In addition to the information to be supplied with a request pursuant to paragraph 1, other relevant information should also be submitted as appropriate and to the extent possible including, *inter alia*:

(a) Whether the facility concerned has been declared under the Protocol; and any information included in or absent from the declaration relevant to the allegations; if not, any information to suggest that the facility concerned should have been declared under the Protocol;

(b) Details of the ownership and/or operator of the facility concerned.

##### Requested perimeter

3. The requested perimeter identified in paragraph 1 (c) above, shall:

- (a) Where possible, run at least 10 metres outside any buildings or other structures;
- (b) Not cut through existing security enclosures; and
- (c) Where possible, run at least 10 metres outside any existing security enclosures that the requesting State Party wishes to include within the requested perimeter.

4. If the requested perimeter does not conform with the specifications of paragraph 3, it shall be re-drawn by the investigation team in consultation with the receiving State Party to ensure that it conforms with that provision.

## (B) PRE-INVESTIGATION ACTIVITIES

### Notification of investigation

5. The Director-General shall, not less than 12 hours before the planned arrival of the investigation team at the point of entry, notify the receiving State Party, of the impending investigation. This notification shall include, *inter alia*:

- (a) Name of the receiving State Party;
- (b) Name of the requesting State Party;
- (c) The name, if known, and location of the facility to be investigated;
- (d) The point of entry where the investigation team will arrive as well as the means of arrival;
- (e) The date and estimated time of arrival of the investigation team at the point of entry;
- (f) If using a non-scheduled aircraft, the standing diplomatic clearance number or the appropriate information required by the receiving State Party to facilitate the arrival and handling of the non-scheduled aircraft;
- (g) The names of the leader and of the other members of the investigation team;
- (h) The investigation mandate.

6. The receiving State Party shall acknowledge receipt of the notification of the impending investigation not later than one hour after receipt of such a notification.

### Investigation mandate

7. The investigation mandate, issued in accordance with Article III, section G, paragraph 28, shall contain at least the following:

- (a) The name of the receiving State Party;

- (b) The non-compliance concern(s) that gave rise to the investigation request;
- (c) The location and requested perimeter of the investigation site specified on a map, taking into account all information on which the request was based;
- (d) The names of the leader of and of the other members of the investigation team;
- (e) The list of approved equipment that will accompany the investigation team;
- (f) Operational instructions and any other identifiable tasks;
- (g) The planned types of activity of the investigation team;
- (h) Specified objectives to be accomplished by the investigation team;
- (i) Point of entry to be used by the investigation team;
- (j) The estimated time necessary to conduct the investigation.

#### Duration of an investigation

8. The period of the investigation shall not exceed 84 consecutive hours, unless extended by agreement with the receiving State Party. The period of investigation shall be the period from provision of access to the investigation team within the requested or if different final perimeter, exclusive of time spent on presentation of the preliminary findings.

#### Monitoring of perimeter

9. Not later than 12 hours after receiving the notification in accordance with paragraph 5 of this section, the receiving State Party shall begin collecting factual information of all vehicular exit activity from all exit points for all land, air and water vehicles of the perimeter as determined in accordance with paragraphs 3 and 4 of this section. This obligation may be met by collecting factual information in the form of traffic logs, photographs or video recordings.

10. Upon the investigation team's arrival at the alternative or final perimeter, whichever occurs first, it shall have the right to begin implementing exit monitoring procedures in order to secure the alternative or final perimeter whichever occurs first. Such procedures shall include the identification of vehicular exits and the making of traffic logs.

11. The investigation team may inspect, in accordance with the access provisions contained in Article III, section G, subsection H, vehicular traffic exiting the perimeter. The receiving State Party shall make every reasonable effort to demonstrate to the investigation team that any vehicle, subject to inspection, to which the investigation team is not granted full access, is not being used for purposes related to the possible non-compliance concern(s) as stated in the investigation mandate. Personnel and **personal** vehicles entering and personnel and personal vehicles exiting shall not be subject to inspection.

12. The investigation team may, under the supervision of a representative(s) from the receiving State Party and/or the facility, take photographs and make video recordings of exit traffic which are deemed relevant to the investigation mandate by the investigation team. The

photographs and video recordings shall be safeguarded by the investigation team and the receiving State Party, which at the end of the investigation shall take a joint decision about their relevance to the investigation mandate. All photographs and video recordings not relevant to the investigation mandate shall remain with the receiving State Party. Other procedures for exit monitoring shall be agreed upon by the investigation team and the receiving State Party. The investigation team has the right to go, under escort, to any other part of the perimeter to check that there is no other exit activity.

13. All activities for securing the perimeter and exit monitoring shall take place within a band around the outside of the perimeter, not exceeding 45 metres in width, measured outward.

14. The application of the above procedures may continue for the duration of the investigation, but shall be conducted in such a manner as to ensure the least possible hampering or delaying of the normal operation of the facility.

### (C) ACTIVITIES UPON ARRIVAL OF INVESTIGATION TEAM

#### Alternative determination of final perimeter

15. At the point of entry, if the receiving State Party is unable to accept the requested perimeter, it shall propose an alternative perimeter as soon as possible, but in any case not later than 24 hours after the arrival of the investigation team at the point of entry. In case of differences of opinion, the receiving State Party and the investigation team shall engage in negotiations with the aim of reaching agreement on a final perimeter.

16. The alternative perimeter shall be designated as specifically as possible in accordance with paragraph 3. It shall include the whole of the requested perimeter and, as a rule, bear a close relationship to the requested perimeter, taking into account natural terrain features and man-made boundaries. It shall normally run close to the surrounding security barrier if such a barrier exists. The receiving State Party shall seek to establish such a relationship between the perimeters by a combination of at least two of the following means:

(a) An alternative perimeter that shall not extend to cover an area significantly greater than that of the requested perimeter;

(b) An alternative perimeter that is where possible a short, uniform distance from the requested perimeter;

(c) At least part of the requested perimeter is visible from the alternative perimeter.

17. If the alternative perimeter is acceptable to the investigation team, it shall become the final perimeter and the investigation team shall be transported from the point of entry to that perimeter in accordance with paragraphs 23 and 24 of this section.

19. If a final perimeter is not agreed, the perimeter negotiations shall be concluded as early as possible, but in no case shall they continue for more than 3 hours after the arrival of the investigation team at the point of entry. If no agreement is reached, the receiving State Party shall transport the investigation team to a location at the alternative perimeter.



20. If the receiving State Party deems it necessary, such transportation may begin before the expiry of the time period specified for the perimeter negotiations in paragraph 19. Transportation shall, in any case, be completed not later than **12** hours after the arrival of the investigation team at the point of entry.

21. The receiving State Party shall provide the investigation team with prompt access to the alternative perimeter to facilitate negotiations and agreement on the final perimeter and access within the final perimeter.

22. If no agreement is reached within **three** hours after the arrival of the investigation team at the alternative perimeter, the alternative perimeter shall be designated the final perimeter.

#### Transportation from the point of entry

23. The receiving State Party shall transport the investigation team together with its equipment, to the alternative or final perimeter, whichever occurs first, as soon as possible, but in any case shall ensure their arrival at that location not later than **12** hours after the arrival of the investigation team at the point of entry.

24. The host State Party/State shall as necessary assist in the transportation of the investigation team and its equipment.

#### Pre-investigation briefing

25. The receiving State Party shall provide a pre-investigation briefing to the investigation team prior to granting it access. The briefing shall include the scope and a general description of the activities conducted at the facility to be investigated as well as details of the physical layout and other relevant characteristics of the area within the perimeter, including either a map or sketch, whichever is available, showing all structures and significant geographic features. The investigation team shall also be briefed on the availability of personnel and records which may be relevant to the investigation mandate. The briefing shall also include information concerning the safety or other relevant regulations including, where applicable, rules of observation and quarantine, in force at the facility. The briefing may, at the discretion of the receiving State Party, include an orientation tour of the area within the perimeter. The investigation team shall provide information on the vaccination status of the team members at the pre-investigation briefing. The duration of the briefing shall not exceed three hours unless agreed to by the investigation team and the receiving State Party.

26. If the case so warrants, the receiving State Party shall have the right to inform the investigation team during the pre-investigation briefing or at any time during the investigation about the areas, facilities or buildings which it considers sensitive or not related to the Convention and therefore subject to the access provisions in Article III, section G, subsection H.

#### Initial investigation plan

27. After the pre-investigation briefing the investigation team shall prepare on the basis of information available and appropriate to it an initial plan for the conduct of the investigation. This plan shall outline the specific activities the investigation team plan to carry out and

specific areas within the perimeter, documentation and personnel to which access is desired. Other information such as approximate timings and the sequence of activities may also be included in the plan.

28. The investigation team shall take into account the areas, facilities, buildings or documentation which the receiving State Party considers sensitive or not related to the Convention, in accordance with paragraph 26 above, in the preparation of the investigation plan. The investigation team shall also take into account any measures, in accordance with the provisions contained in Article III, section G, subsection H, indicated by the receiving State Party and may make proposals concerning the implementation of these measures.

29. The investigation team shall indicate in the initial plan the number of personnel responsible for perimeter activities. The investigation team shall also include in its initial plan an indication whether it plans to divide into subgroups. It shall not divide into more than two subgroups unless otherwise agreed by the receiving State Party.

30. The initial plan shall be made available to the receiving State Party prior to the commencement of the investigation. The investigation team shall, as appropriate, modify the plan and consider any comments by the receiving State Party. During the investigation, the investigation team may revise the initial plan as it deems necessary, taking into account any comments by the receiving State Party and information required during the investigation. Any revision of the initial investigation plan shall be made available to the receiving State Party.

31. The preparation of the initial investigation plan, including the consideration of the receiving State Party shall not exceed two hours.

#### (D) CONDUCT OF INVESTIGATION

##### Implementation by the investigation team of specific on-site activities

32. All on-site activities shall be conducted in accordance with the access provisions contained in Article III, section G, subsection H.

##### Interviewing

33. The investigation team may interview any relevant personnel of the facility with their explicit consent in the presence of representatives, which may include a legal advisor and/or a senior member of the facility staff, of the receiving State Party with the purpose of establishing relevant facts. They shall only request information and data which are necessary for the fulfilment of the investigation mandate.

34. The receiving State Party shall have the right to object to questions posed to the facility personnel if it deems that those questions are not relevant to the investigation or impinge on sensitive national security or commercial proprietary data. If the investigation team leader nonetheless continues to believe that these questions are relevant and should be answered, he/she may submit them in writing to the receiving State Party for reply, together with an explanation of their relevance to the investigation. The investigation team may note in its report any refusal by the receiving State Party to permit interviews or to allow questions to be answered and any explanations given.

35. Interviews shall be conducted in such a way as to avoid unduly hindering the work of the facility. The investigation team shall give advance notice of interview requests.

#### Visual observation

36. The investigation team may visually observe the interior and exterior of those buildings and structures which are relevant to the investigation mandate within the investigated facility.

#### Identification and examination of equipment

37. The investigation team may identify and examine only equipment relevant to the investigation mandate at the investigated facility. In the identification and examination of equipment considered key equipment by the investigation team, it may make use of, but not be limited to, the list of equipment contained in Annex A.

38. The investigation team may also note the size and quantity of equipment in the facility, or the absence of any equipment, and compare this with information provided in facility declarations where appropriate.

#### Determination of the quantity of biological material

39. The investigation team may consider the quantity of material containing biological agents in terms of weight, volume, name of agent and the concentration of such agent, when required to fulfil its mandate.

#### Examination of documentation and records

40. The investigation team may only when required to fulfil its mandate, examine documentation, electronically held data, manuals and records available at the facility, relevant to the investigation mandate concerning, *inter alia*, the supply and consumption of media and the design or operation of equipment, receipt and transfer of biological agents and toxins. The receiving State Party may assist the investigation team by providing the relevant documentation and records to the investigation team to discharge its functions in accordance with the investigation mandate.

41. The receiving State Party may, in accordance with Article III, section G, subsection H, protect documentation, electronically held data, manuals and records.

42. The investigation team may request copies of documentation or printouts of records. The investigation team and the Technical Secretariat shall, if so required by the receiving State Party, treat as confidential such documents and print-outs or records and any other information obtained as a result of access to documentation and records, and shall handle them accordingly. Documents and printouts may be removed from the facility only with the permission of the receiving State Party.

43. The examination of documentation and records shall be conducted in such a way as to minimize disruption to the normal work of the facility.

44. The investigation team may, with the consent of the receiving State Party, obtain information on relevant health, safety or other regulatory procedures or financial regulations,

to serve as background information which may assist the investigation team to understand documents and records examined.

45. If specific issues arise during the investigation, which in the opinion of the investigation team could be resolved by the examination of specific documentation and records not available at the investigated facility, the investigation team may request the receiving State Party to provide access at the investigated facility, to these specific documents and records for review at the investigated facility in accordance with the provisions of Article III, section G, subsection H.

#### Examination of medical records

46. The investigation team may, in discharging its mandate and with the consent of the receiving State Party, obtain access to medical and occupational health records and data of the facility or such regulations being applied at the facility. Access to such data shall be at the discretion of the receiving State Party. The receiving State Party shall, however, endeavour to provide the greatest degree of access possible to such data. The receiving State Party may maintain the anonymity of data. Access which may require scrutiny of individual medical records in which the identity of an individual may be revealed, shall be by the informed written consent of the individual. If a request for access to medical and occupational health data is refused, the receiving State Party shall provide a written explanation to the investigation team leader.

#### Examination of clinical and pathological samples

47. The investigation team may with the permission of the receiving State Party examine analytical data related to clinical and pathological samples relevant to the investigation mandate taken previously by the facility.

#### Sampling and identification

48. The investigation team may, with the permission of the receiving State Party, obtain samples and test these for the presence of specific biological agents or toxins in order to address a specific non-compliance concern contained in the investigation mandate.

49. Sampling shall only be used when the investigation team comes to a conclusion based on information obtained from the briefing and/or the application of the other measures in this section during the investigation which suggest that sampling might provide significant information necessary for the fulfilment of the investigation mandate. Where possible, specific tests shall be used to identify specific agents, strains or genes.

50. The receiving State Party shall have the right to take measures, in accordance with the access provisions contained in Article III, section G, subsection H, to protect national security and confidential proprietary information such as requiring the use of specific tests or on-site analysis or, if necessary, to refuse a sample. In the latter case the receiving State Party shall be under the obligation to make every reasonable effort to demonstrate that the requested sample is unrelated to the non-compliance concern(s) contained in the investigation mandate.

51.<sup>179</sup> The Director-General shall have the primary responsibility for the security, integrity and preservation of samples and for ensuring that the confidentiality of samples transferred for off-site analysis is protected. The Director-General shall, in any case:

(a) Establish a stringent regime governing the collection, handling, storage, transport and analysis of samples;

(b) Select from among the designated and certified laboratories those which shall perform the analytical functions in relation to the investigation;

(c) **Ensure that all samples shall be analysed in two designated and certified laboratories, one of which may be within the receiving State Party;**<sup>180</sup>

(d) Ensure that there are procedures for the safekeeping and maintaining of the integrity of sealed duplicate samples for further clarification if necessary.

52. Representatives of the receiving State Party shall take samples at the request of the investigation team and in their presence. If so agreed, the investigation team may take samples itself. Where possible, samples shall be analysed on-site. The investigation team may test samples using any methods approved by the Technical Secretariat for use in such investigations. At the request of the investigation team, the receiving State Party shall to the extent possible provide assistance for the analysis of samples on site, using locally available resources. In the event that it is agreed between the investigation team and the receiving State Party, that the receiving State Party itself performs analyses, this shall be done in the presence of members of the investigation team.

53. If on-site analysis is impossible, the investigation team may request the removal of samples for analysis in laboratories selected in accordance with paragraph 51 (b) above. Where possible, samples shall be analysed in an accredited and certified laboratory on the territory of the receiving State Party. The receiving State Party shall have the right to take measures necessary to ensure that commercial proprietary or national security information would not be jeopardized by the off-site analysis of samples. If the removal of samples is agreed, the receiving State Party shall have the right to accompany the sample and observe any analysis and its subsequent destruction.

54. When off-site analysis is to be performed, samples shall be analysed in at least two designated and certified laboratories. The Technical Secretariat shall ensure the expeditious processing of the analysis. The samples shall be accounted for by the Technical Secretariat.

55. The receiving State Party shall receive duplicate samples, for its own analysis. The receiving State Party and the investigation team shall also receive sealed duplicate samples for safekeeping and use if necessary for further clarification.

56. If further clarification of analytical results becomes necessary then the sealed duplicate samples shall be used for this purpose. The seals of these samples shall be broken in the presence of both the investigation team and representatives of the receiving State Party. The analysis of these samples shall also take place in the presence of the investigation team and representatives of the receiving State Party.

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<sup>179</sup>Previously paragraph 53 on page 109 of AHG/52 (Part II). Reordered for greater clarity.

<sup>180</sup>Duplicate analysis of all samples in two designated and certified laboratories is essential.

57. Any unused samples or portions thereof, remaining after the investigation has been completed and that have not been destroyed shall be returned to the receiving State Party.

58. The receiving State Party shall have the right to offer a sample for analysis in accordance with the provisions in paragraphs 51 to 59 of this section at any time in order to help resolve the non-compliance concern(s) contained in the investigation mandate.

59. Any on-site sampling and analysis shall be conducted in such a way as to avoid any adverse impact on the normal work of the facility and any consequent loss of production.

#### (E) POST-INVESTIGATION ACTIVITIES

##### Preliminary findings and departure

60. The post-investigation activities relating to preliminary findings and departure of the investigation team shall be conducted in accordance with paragraphs 57 to 60 of section I of this Annex.

#### (F) REPORTS

##### Interim investigation report

61. An interim investigation report shall be made available to the receiving State Party not later than 14 days after completion of the on-site part of the investigation. The interim investigation report shall summarize the factual findings of the investigation. In addition, the report shall include a description of the investigation process, tracing its various stages, with special reference to:

(a) The activities conducted by the investigation team and its factual findings, particularly with regard to the concern regarding possible non-compliance as expressed in subparagraph 1 (b);

(b) The positions and times of any sampling and on-site analysis;

(c) Supporting evidence such as records of perimeter monitoring activities, the records of on-site activities conducted by the investigation team;

(d) Any information that the investigation team in the course of its investigation collected, that might serve to help in the identification of any biological agent or toxin found during the course of the investigation such as, *inter alia*, chemical composition and the presence of inert materials in the case of possible toxin weapons and serological or molecular sequence evidence in the case of infectious agents;

(e) The results of any completed laboratory investigations and sampling and identification;

(f) A factual description by the investigation team of the degree and nature of access and cooperation granted by the receiving State Party and the extent to which this enabled the investigation team to fulfil its mandate;

(g) An account of the assistance and its timeliness, provided by the host State Party/State, if applicable.

62. The receiving State Party shall have the right to the following, which shall be communicated to the investigation team within **10**<sup>181</sup> days after receipt of the interim report from the investigation team:

(a) Identify any information and data not related to the non-compliance concern(s) contained in the investigation mandate which in its view, due to its confidential nature, should not be contained in the final version of the report. The investigation team shall consider these observations and, as a rule, should remove that information and data as requested;

(b) Comment on the contents of the interim report. The investigation team shall refer to the comments of the receiving State Party in the final version of the report and, wherever possible, incorporate them before submitting the final report to the Director-General.

#### Laboratory reports

63. Laboratory analysis and identification of biological agents and/or toxins shall be reported by the laboratory by means of the following types of reports:

(a) Initial laboratory report. An initial laboratory report shall be made available to the leader of the investigation team by the laboratory as soon as possible after receipt of the sample(s) and shall indicate initial findings, give an estimate of the duration of further work as well as a plan for the conduct of further analysis and tests.

(b) Intermediate laboratory report. The laboratory shall make an interim laboratory report to the leader of the investigation team if it has not finalized its work after 30 days since the initial report. It shall contain details of progress of work and the final plan for future work.

(c) Final laboratory report. The laboratory shall make a final report of its findings to the leader of the investigation team as soon as it has finalized its work, but **should not be**<sup>182</sup> later than six months after receipt of the sample(s). The final laboratory report shall contain a description of the work done and an identification of an agent or agents. If it was not possible to make a positive identification, the report shall state that fact and give an explanation as to why it was not possible to make a positive identification.

64. If there is any discrepancy in the laboratory reports, the investigation team shall submit a duplicate sample to another designated and certified laboratory for analysis.

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<sup>181</sup>The shorter time is necessary in order not to delay the overall timescale for reporting.

<sup>182</sup>It would be unwise to include a deadline of six months as AHG/52 (Part II) does as there can be **no** certainty that the designated and certified laboratories will have the capacity available to carry out and complete the work required by the Organization within six months. The Protocol will come into disrepute if the quality of the analytical results of samples from investigations is not of the highest international standard.

65. The laboratory reports shall be completed as soon as possible but **should** not **be**<sup>183</sup> later than six months after the conclusion of the on-site investigation for inclusion in the draft final report.

#### Final report

66. A draft final report which shall contain the interim investigation report, the comments of the receiving State Party and the laboratory reports shall be made available to the receiving State Party by the leader of the investigation team not later than 10 days after receipt of the final laboratory report(s). The receiving State Party may provide written comments on the draft final report which shall be communicated to the investigation team leader within **10** days after receipt of the draft final report. Any written comments that the receiving State Party may wish to make concerning the contents and findings of the draft final report, shall be attached as an annex to the final version of the draft report. The draft final report together with its annexes shall become the final report.

67. The final report shall be transmitted to the Director-General not later than 14 days after receipt of written comments from the receiving State Party for further handling in accordance with Article III, section G.

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<sup>183</sup>Amended for consistency with paragraph 63 (c).



## E. CONFIDENTIALITY PROVISIONS<sup>184 185</sup>

### I. GENERAL PRINCIPLES FOR THE HANDLING OF CONFIDENTIAL INFORMATION

#### (A) THE PROCEDURES GOVERNING THE HANDLING OF CONFIDENTIAL INFORMATION

1. In order to establish and maintain the procedures governing the handling of confidential information by the Technical Secretariat pursuant to Article IV, an appropriate unit of the Technical Secretariat (hereinafter referred to as “the Confidentiality Unit”) under the direct responsibility of the Director-General shall be charged with overall supervision of the administration of confidentiality provisions.

2. In selecting personnel for the Confidentiality Unit due regard shall be paid to the necessity of securing the highest standards of efficiency, competence and integrity, and the importance of selecting personnel on as wide an equitable geographic basis as possible.

3. The procedures governing the handling of confidential information pursuant to Article IV shall be considered and approved by the Conference pursuant to Article IX, paragraph 22 (i). The Organization shall not process, handle or distribute information or data supplied to it in confidence by States Parties until the procedures have been approved by the Conference **at its first session**.<sup>186</sup>

4. The Executive Council shall establish a sub-committee in accordance with its rules of procedure to monitor and make recommendations to the Conference on the application of the confidentiality provisions of this Protocol and the procedures governing the handling of confidential information pursuant to Article IV.

5. The Director-General shall report annually to the Conference on the implementation of the confidentiality provisions of this Protocol and the procedures governing the handling of confidential information pursuant to Article IV by the Technical Secretariat.

#### (B) THE ESTABLISHMENT OF A CLASSIFICATION SYSTEM

6. A classification system shall be introduced, which shall provide for clear criteria ensuring the inclusion of information into appropriate categories of confidentiality and the justified durability of the confidential nature of information. While providing for the necessary flexibility in its implementation, the classification system shall protect the right of States Parties providing confidential information. The classification system shall be considered and approved by the Conference pursuant to Article IX.

7. Each State Party from which information was received or to which information refers shall have the right, in consultation with the Confidentiality Unit as the State Party may consider appropriate, to classify such information in accordance with the classification system. Any such classification shall be binding for the Organization.

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<sup>184</sup>The amendments made to Annex E are based on the analysis in Evaluation Paper No. 16, *Article IV: Confidentiality Provisions*, March 2000.

<sup>185</sup>The text in AHG/52 (Part I) as amended in AHG/52 (Part II) has been used as the baseline for this Annex.

<sup>186</sup>It is important that such procedures **are approved** by Conference at its first session.

(C) CRITERIA FOR CLASSIFICATION AS CONFIDENTIAL

8. The essential factors to be considered in determining the classification of an item of information are as follows:

(a) The degree of potential damage which its disclosure could cause to a State Party, a natural or legal person of a State Party, or to the Protocol or the Organization; and

(b) The degree of potential advantage its disclosure could offer to a State, or to a natural or legal person.

(D) ACCESS TO CONFIDENTIAL INFORMATION

9. Access to confidential information shall be regulated in accordance with its classification and shall be on a need-to-know basis.

10. Not less than 30 days before an employee is given clearance for access to confidential information that refers to activities on the territory or in any other place under the jurisdiction or control of a State Party, the State Party concerned shall be notified of the proposed clearance. The proposal shall be regarded as accepted unless the State Party declares within 30 days its non-acceptance in writing. Individuals on the list of designated personnel as provided for in Annex D, section I, paragraphs 1 to 16 after acceptance by States Parties, shall be deemed to have fulfilled this requirement.

11. Members of the Confidentiality Commission, the Executive Council Sub-Committee on Confidentiality, the Scientific Advisory Board or any other body established in accordance with the provisions of this Protocol shall be granted access to information and data classified as confidential when necessary for the performance of their specific functions. In case such access is requested, it shall be strictly limited to the minimum necessary for the effective performance of those functions and shall be granted only on specific approval by the Director-General<sup>†187</sup> as well as on the basis of a specific secrecy agreement and in conformity with the procedures governing the handling of confidential information pursuant to Article IV.

11. Each access to confidential information at the Technical Secretariat shall be recorded on file when accessing and exiting. This record shall be retained for 10 years.

12. To the greatest extent consistent with the effective implementation of the provisions under this Protocol, confidential information shall be handled and stored by the Technical Secretariat in a form that precludes direct identification of the facility to which it pertains.

(E) OBLIGATIONS FOR INTENDED RELEASE OF CONFIDENTIAL INFORMATION

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<sup>187</sup>It would be invidious were a situation to arise in which a particular State Party were to object to certain information being provided to a specific member of a body established under this Protocol. The operation of the Organization under such circumstances would be ineffective and would fall into disrepute. It would be imprudent and unwise to allow the language relating to explicit consent of the State Party concerned to remain.

13. No confidential information obtained by the Technical Secretariat in connection with the implementation of this Protocol shall be published or otherwise released, except as follows:

(a) Any information may be released with the express consent of the State Party from which the information was received and the State Party to which the information refers;

(b) Information classified as confidential shall be released by the Organization only through procedures which ensure that the release of information only occurs in strict conformity with the needs of this Protocol. Such procedures shall be considered and approved by the Conference pursuant to Article IX.

## II. CONDITIONS OF STAFF EMPLOYMENT RELATING TO THE PROTECTION OF CONFIDENTIAL INFORMATION

### (A) GENERAL REQUIREMENTS

1. Conditions of staff employment shall be such as to ensure that access to and handling of confidential information shall be in conformity with the procedures governing the handling of confidential information pursuant to Article IV.
2. Each position in the Technical Secretariat shall be governed by a formal position description that specifies, inter alia, the scope of access to confidential information, if any, needed in that position.
3. In the discharge of their functions, staff members of the Technical Secretariat shall only request information and data which are necessary to carry out their duties and avoid to the extent possible any access to information and data unrelated to the discharge of their duties. They shall not make any records of such information collected incidentally and not related to the requirements of their duties.

### (B) INDIVIDUAL SECRECY AGREEMENTS

4. The Director-General and the other members of the staff shall enter into individual secrecy agreements with the Technical Secretariat in which each staff member shall agree not to disclose during the period of employment and for an unlimited period after termination of the staff member's functions, to any unauthorized State, organization or person any confidential information coming to the staff member's knowledge in the performance of official duties, unless the information has been declassified or officially released by the Organization.

### (C) CODE OF CONDUCT

5.†<sup>188</sup> **The Director-General may publicly release information that is not designated as confidential and that falls into one of the following categories:**

**(a) General information on the implementation of the Protocol which does not contain information relating specifically to any State Party. This excludes specific information about inspection activities being conducted in or planned for a State Party. The types of information which may be released publicly under this provision shall be set out in a list approved by the Conference;**

**(b) Factual organizational information about the Organization, except for information that relates to the security of the Organization, or to personnel matters and the privacy of the staff of the Secretariat; or**

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<sup>188</sup>The Protocol language in Annex E of AHG/52 (Part I) is unduly and unnecessarily restrictive as it could well result in the future BTWC Protocol Organization being perceived as a secretive organization and certainly one whose benefits for global security and peace and international cooperation are little recognised. Such a perception will not be in the long term interests of the Protocol regime, of the future Organization or of its States Parties. We recommend that paragraph 5 be amended as shown to parallel the OPCW Policy on Confidentiality guidelines on the public release of information and requiring the Director-General to prepare a Media and Public Affairs Policy for approval by the Conference at its first session.

**(c) Information referring to a State Party, which is unclassified and which that State Party has specifically requested or consented to be publicly released.**

**All contact between the Technical Secretariat staff members and the media or any individual who is not employed or contracted by the Organization nor authorised by a State Party in relation to the implementation of the Protocol shall be subject to a Media and Public Affairs Policy which the Director-General shall submit to the Conference for approval at its first session.**

6. In order to avoid unauthorized disclosures, staff members shall be appropriately advised and reminded about confidentiality considerations and of the possible penalties that they would incur in the event of improper disclosure.

7. In evaluating the performance of staff members of the Technical Secretariat, specific attention shall be given to the employee's record regarding protection of confidential information.

**(D) OBLIGATIONS OF OBSERVERS AND THE REQUESTING STATE PARTY SENDING AN OBSERVER**

8. The requesting State Party shall ensure that an observer sent in accordance with Annex D, section I, subsection D, complies with and is individually bound by all relevant provisions of this Protocol. If any confidential information is disclosed to or acquired by the observer, in addition to and without diminishing the observer's own individual responsibility, the requesting State Party shall also become responsible for the handling and protection of that information in accordance with this Protocol.

### III. PROCEDURES IN CASE OF BREACHES OR ALLEGED BREACHES OF CONFIDENTIALITY

#### (A) OBLIGATION FOR INQUIRY

1. The Director-General shall promptly initiate an inquiry when there is **sufficient** indication that obligations concerning the protection of confidential information have been violated. The Director-General shall also promptly initiate an inquiry if an allegation concerning a breach of confidentiality is made by a State Party.

2. In case of an allegation of a breach of confidentiality, States Parties and/or staff members which are named in the allegation or which might be involved in the alleged breach shall be informed of that allegation immediately. The Director-General shall hold consultations with the concerned States Parties in the course of the inquiry.

3. States Parties shall, to the extent possible, cooperate with and support the Director-General in conducting an inquiry of any breach or alleged breach of confidentiality and in taking appropriate action in accordance with applicable laws and regulations in case a breach has been established.

4. An inquiry shall result in a written report, which shall remain confidential and be subject to the application of the need-to-know principle. The Director-General shall, upon request, provide the report to the States Parties concerned. The results of the inquiry shall be reported to the Conference of the States Parties in a form from which specific confidential material has been removed to ensure that confidential information connected with a breach is not further disclosed beyond its authorized scope of access, and to respect those elements of the privacy of the individual staff members not relevant to the case.

#### (B) INTERIM MEASURES

5. The Director-General may take interim measures any time after the commencement of the inquiry in order to prevent further damage. These measures may include withdrawal of personnel concerned from specific functions, denial of access to certain information and, in serious cases, temporary suspension, pending completion of procedures contained in this section.

#### (C) MEASURES IN CASE OF BREACHES OR ALLEGED BREACHES

6. In case of a breach or an alleged breach of confidentiality by an agent or official of a State Party or by a staff member of the Technical Secretariat, consultations shall be held between the States Parties concerned or between the Organization and States Parties concerned to address the case. If such consultations are not concluded to the satisfaction of the parties involved within 60 days, each State Party shall have the right to initiate the proceedings of the Confidentiality Commission to consider the case. The Commission shall seek to settle the case through mediation, inquiry, conciliation, arbitration or other peaceful means. The Commission may request the Director-General to submit the result of the inquiry carried out pursuant to paragraph 1 above.

7. If the inquiry pursuant to paragraph 1 establishes that there has been a breach of confidentiality by a staff member of the Technical Secretariat, the Director-General shall

impose appropriate disciplinary measures. In such cases, the provisions on privileges and immunities contained in Article IX of this Protocol shall apply.

## APPENDICES<sup>189</sup>

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<sup>189</sup>For clarity and to avoid confusion, the current Appendix designations have been retained although Appendices D and F have been deleted from this proposed complete text. Appendix F has been deleted as this is not intended to form part of the Protocol as it is a *List of Approved Investigation/Visit Equipment* to be approved by the Conference of the States Parties.



DECLARATION FORMATS

INITIAL DECLARATIONS

APPENDIX A

DECLARATIONS OF OFFENSIVE AND/OR DEFENSIVE BIOLOGICAL AND TOXIN PROGRAMMES AND/OR ACTIVITIES CONDUCTED PRIOR TO ENTRY INTO FORCE OF THE PROTOCOL FOR EACH STATE PARTY

1. Name of State Party:

.....

2. Date of entry into force of the Protocol for the State Party:

.....

3. Date of initial declaration:

.....

PART A

PAST BIOLOGICAL OFFENSIVE PROGRAMMES **AND/OR** ACTIVITIES <sup>190</sup>

1. At any time since **1 January 1946**<sup>191</sup> have you conducted any activities as specified in Article III, section D, subsection I, paragraph 5?

YES / NO

2. Indicate the years of operation of the programme(s) and/or activities during the declarable period:

.....

3. Indicate whether any research and development activities or other work<sup>192</sup> on microbial or other biological agents or toxins were carried out for hostile purposes or for use in armed conflict:

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<sup>190</sup>This is a key initial declaration that will contribute immensely to increasing transparency and building confidence between States Parties as it is uncertainty about past offensive programmes and/or activities and the facilities which were engaged therein that is one of the greatest contributors to mistrust and lack of confidence between States Parties.

<sup>191</sup>The operative date of 1 January 1946 is adopted because this is the agreed operative date for Confidence-Building Measure F which continues to be politically binding on the States Parties to the Convention. The choice of a later date would contradict the aim and purpose of the Protocol to increase transparency and build confidence between States Parties.

Research and development	YES / NO
Studies on pathogenicity/virulence	YES / NO
Studies on antibiotic resistance	YES / NO
Environmental stability studies on microbes	YES / NO
Studies on toxicity	YES / NO
Studies in toxinology	YES / NO
Aerobiology studies including open air release	YES / NO
Vector transmission studies	YES / NO
Genetic modification studies	YES / NO
Testing and evaluation	YES / NO
Production	YES / NO
Stockpiling	YES / NO
Other acquisition	YES / NO
Weaponization	YES / NO

4. Give a summary of each subject indicated as “YES” in paragraph 3 above:

.....  
.....  
.....

5. Indicate whether any research and development activities or other work was carried out on equipment or means of delivery for microbial or other biological agents or toxins for hostile purposes or for use in armed conflict:

Research and development	YES / NO
Testing and evaluation	YES / NO
Production	YES / NO
Stockpiling	YES / NO
Other acquisition	YES / NO

6. Give a summary of each subject indicated as “YES” in paragraph 5 above:

.....  
.....  
.....

---

<sup>192</sup>As the purpose of the initial declaration is to increase transparency and build confidence between States Parties it is essential that the declarations are comprehensive and separately include not only research and development but also testing and evaluation as well as production.

7. Have any microbial or other biological agents or toxins ever been used for hostile purposes or in armed conflict?

YES / NO

8. If “YES” in paragraph 7, give a summary of each case indicating the agent(s), date(s) and place(s):

.....  
.....  
.....

9. List all facilities, including their addresses, activities and purposes, that participated in the programme(s) **and/or** activities and indicate which had been destroyed when and how it was done. Describe what was done with all the facilities that were not destroyed:

.....  
.....  
.....

10. Was any maximum containment facility constructed for use in the biological offensive programme(s) **and/or** activities?

YES / NO

If yes, indicate the floor area of each facility:

.....

11. List all test ranges, including their addresses, activities and purposes, used in the programme(s) **and/or** activities and give a description including dates of the dismantling or conversion of each:

.....  
.....  
.....

12. Indicate what all the converted facilities and test ranges are presently being used for:

.....  
.....  
.....

13. List all microbial or other biological agents and/or toxins worked with, developed, produced, otherwise acquired, stockpiled or weaponized:

.....  
.....  
.....

14. If agents and/or toxins were produced, indicate the cumulative amount of each agent and toxin produced since **1 January 1946**:

.....  
.....  
.....

15. If agents and/or toxins were stockpiled, indicate the cumulative amount of each agent and toxin stockpiled since **1 January 1946**:

.....  
.....  
.....

16. Indicate which produced or otherwise acquired, stockpiled or weaponized agents and/or toxins listed in paragraph **13** above were destroyed, how, where and when it was done. Give a summary of what was done with those not destroyed:

.....  
.....  
.....

17. Give a summary of the destruction or conversion of the equipment or means of delivery described in paragraph **6** above:

.....  
.....  
.....

18. State the present status of the data, video recordings, etc. obtained when the programme(s) **and/or** activities was in operation:

.....  
.....  
.....

PART B

DECLARATION OF DEFENSIVE BIOLOGICAL AND TOXIN PROGRAMMES AND/OR ACTIVITIES CONDUCTED PRIOR TO ENTRY INTO FORCE OF THE PROTOCOL FOR EACH STATE PARTY<sup>193</sup>

1. At any time in the period since **1 January 1946**<sup>194</sup> but before the entry into force of the Protocol for your State Party, have you conducted programmes and/or activities as specified in Article III, section D, subsection I, paragraph 7?

YES / NO

If yes, complete the remainder of this format.

2. Indicate the period(s) of any such programmes and/or activities during the declaration period:

.....

3. Give a summary of the general objectives of any such programmes and/or activities:

.....  
.....  
.....

4. Indicate by ticking the appropriate box whether any work was carried out in the following areas<sup>195</sup>:

---

<sup>193</sup> As for past offensive programmes, this is another key initial declaration that will contribute immensely to increasing transparency and building confidence between States Parties as uncertainty about past defensive programmes and/or activities and the facilities which were engaged therein that contributes to mistrust and lack of confidence between States Parties.

<sup>194</sup>The operative date of 1 January 1946 is adopted because this is the agreed operative date for Confidence-Building Measure F which continues to be politically binding on the States Parties to the Convention. The choice of a later date would contradict the aim and purpose of the Protocol to increase transparency and build confidence between States Parties.

<sup>195</sup>As the purpose of the initial declaration is to increase transparency and build confidence between States Parties it is essential that the declarations are comprehensive and separately include not only research and development but also testing and evaluation as well as production.

Work area	Research and development	Testing or evaluation	Production other than in research, development, testing or evaluation
Detection or diagnosis			
Decontamination			n.a.
Prophylaxis against disease			
Physical protection			n.a.
Treatment of disease			
Pathogenicity or virulence			n.a.
Genetic modification			n.a.
Other characteristics of agents			n.a.
Toxinology*			n.a.
Toxicity other than relating to toxins			n.a.
Aerobiology			n.a.
Vector (e.g. insect) ecology			n.a.
Fermentation			

\* Toxinology is the study of toxins.

5. Summarize the principal objectives of and the work performed in the programmes and/or activities indicated in question 4 above, including a description of any significant changes in direction during the declaration period and the reasons for them. (Examples of changes may be starting/terminating work in areas denoted in question 4):

.....  
.....  
.....

6. Indicate which of the types of work performed in the programmes and/or activities indicated in question 4 above are carried on in programmes and/or activities conducted since entry into force of the Protocol for your State Party, by means of an asterisk against the appropriate entry in question 4.

7. For the programmes and/or activities indicated in question 4 above, indicate:

(a) The types of pathogens and/or toxins worked on (tick any that apply):

Human or zoonotic pathogens:

... Bacteria ... Viruses ... Fungi ... Others

Animal pathogens:

... Bacteria ... Viruses ... Fungi ... Others

Plant pathogens:

... Bacteria ... Viruses ... Fungi ... Others

Toxins: ...

(b) All agents and/or toxins listed in Annex A that were worked on:

.....

(c) Whether any such agents and/or toxins were worked on in any of the following types of organization (tick any that apply):

Organizations in the declaring State Party:

... Industry ... Academia  
... Government ministry/department/agency other than defence or military

Organizations in another State or State Party, working under contract or through collaboration:

... Industry ... Academia  
... Government ministry/department/agency other than defence or military

(d) The affiliation of sources of funding that applied at any time during the declaration period (tick any that apply):

- |                          |   |                          |        |                          |           |
|--------------------------|---|--------------------------|--------|--------------------------|-----------|
| <input type="checkbox"/> | Defence Ministry/Department/Agency          | <input type="checkbox"/> | wholly | <input type="checkbox"/> | partially |
| <input type="checkbox"/> | Other government ministry/department/agency | <input type="checkbox"/> | wholly | <input type="checkbox"/> | partially |
| <input type="checkbox"/> | Non-government                              | <input type="checkbox"/> | wholly | <input type="checkbox"/> | partially |
| <input type="checkbox"/> | International organization                  | <input type="checkbox"/> | wholly | <input type="checkbox"/> | partially |

8. Provide the names and postal addresses of all facilities which made substantial contributions to the programmes and/or activities and indicate which, if any, are still involved in a current programme:

Name	Postal address	Whether still active in the programmes and/or activities (YES / NO)

9. Indicate whether the programmes and/or activities were supported by outdoor studies of biological aerosols or their simulants:

YES / NO

10. Indicate whether vaccine or vaccine ingredients causing a specific and protective immune response were produced for armed forces or public use or storage:

YES / NO

11. Briefly describe any significant changes during the declaration period, and the reasons for them, in respect of the following:

(a) Sources of funding:

.....

(b) Organizational structure:

.....

(c) Number and types of personnel:

.....



ANNUAL DECLARATIONS

APPENDIX B

DECLARATION OF DEFENSIVE BIOLOGICAL AND TOXIN PROGRAMMES  
AND/OR ACTIVITIES CONDUCTED DURING THE PREVIOUS YEAR

1. Name of State Party:

.....

2. This declaration relates to the calendar year:

.....

3. At any time in the declaration year, have you conducted any programmes and/or activities as specified in Article III, section D, subsection I, paragraph 8?

YES / NO

If yes, complete the remainder of this format<sup>196</sup>.

4. Did any of the programmes and/or activities continue until the end of the declaration year:

YES / NO

5. Describe the general objectives of any such programmes and/or activities specified in Article III, section D, subsection I, paragraph 8 (50 lines or less):

.....  
.....  
.....

6. Indicate by ticking the appropriate box whether any work has been carried out in the following areas<sup>197</sup>:

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<sup>196</sup>A single format for the declaration of current biological defence programmes and/or activities will suffice. It is important to recognize that the number of States Parties which have declared biological defence programmes and facilities under the Confidence-Building Measures, based on the 1997 declarations, is small. In the 1997 declarations, some 43 facilities were declared as biodefence facilities: 32 were in Western countries (19 in the USA), 1 in China, 1 in India, 9 in Russia.

<sup>197</sup>As the purpose of the declaration is to increase transparency and build confidence between States Parties it is essential that the declarations are comprehensive and separately include not only research and development but also testing and evaluation as well as production.

Work area	Research and development	Testing or evaluation	Production other than in research, development, testing or evaluation
Detection or diagnosis			
Decontamination			n.a.
Prophylaxis against disease			
Physical protection			n.a.
Treatment of disease			
Pathogenicity or virulence			n.a.
Genetic modification			n.a.
Other characteristics of agents			n.a.
Toxinology*			n.a.
Toxicity other than relating to toxins			n.a.
Aerobiology			n.a.
Vector (e.g. insect) ecology			n.a.
Fermentation			

\* Toxinology is the study of toxins.

7. Summarize the principal objectives of and the work performed in the programmes and/or activities in the areas indicated in question 6 above:

.....  
.....  
.....

As an aggregate for the programmes and/or activities in the areas indicated in question 6 above, state for the reporting period:

8. Funding

- (a) The total funding:

.....

(b) Affiliation of sources of funding (tick all that apply):

- |                       |   |                       |        |                       |           |
|-----------------------|---|-----------------------|--------|-----------------------|-----------|
| <input type="radio"/> | Defence Ministry/Department/Agency              | <input type="radio"/> | wholly | <input type="radio"/> | partially |
| <input type="radio"/> | Other government ministry/department/<br>agency | <input type="radio"/> | wholly | <input type="radio"/> | partially |
| <input type="radio"/> | Non-government                                  | <input type="radio"/> | wholly | <input type="radio"/> | partially |
| <input type="radio"/> | International organization                      | <input type="radio"/> | wholly | <input type="radio"/> | partially |

(c) Whether aspects of the work were conducted under contract with, or by, any of the following types of organization (tick any that apply):

- Industry     Academia  
 Government ministry/department/agency other than defence or military

If yes, indicate the percentage of the total funding that was expended in such organizations for this purpose (Estimates of percentages shall be rounded up to the nearest whole number):

- Less than 5%     5-25%     26-50%     51-75%     76-100%

Summarize the objectives of any such work:

.....  
 .....  
 .....

9. For the personnel employed, including those contracted for more than six months:

(a) Indicate the total number of personnel:

- 1-10     11-25     26-100     101-500     greater than 500

(b) Indicate the total person years of work (Where a fraction of a person year is involved, this shall be rounded up to the nearest whole number):

- 1-10     11-25     26-100     101-500     greater than 500

(c) Give a detailed break-down of the following personnel categories taking part in the activities and/or programmes:

	Scientific personnel including engineers	Technical assistance personnel
Military personnel		
Civilian personnel		

Contract personnel*		
* Contract employees who have worked for more than six months in the reporting period.		

10. Indicate:

- (a) The types of pathogens and/or toxins worked on (tick any that apply):

Human or zoonotic pathogens:

... Bacteria ... Viruses ... Fungi ... Others

Animal pathogens excluding zoonotic pathogens:

... Bacteria ... Viruses ... Fungi ... Others

Plant pathogens:

... Bacteria ... Viruses ... Fungi ... Others

Toxins: ...

- (b) All agents and/or toxins listed in Annex A which were worked on, and for each indicate whether any genetic modification was performed:

Agent	Genetic modification performed (YES / NO)
...	...
...	...

In any such work, indicate any agents and/or toxins listed in Annex A which were worked on in any of the following types of organization:

Organizations in the declaring State Party:

Industry: agent(s): .....

Academia: agent(s): .....

Government ministry/department/agency other than defence or military:  
agent(s): .....

Organizations in another State or State Party, working under contract or through collaboration:

Industry: agent(s): .....

Academia: agent(s): .....

Government ministry/department/agency other than defence or military:  
agent(s): .....

- (c) Whether fermenters/bioreactors exceeding 25 litres in volume were used to produce pathogens, toxins or simulants:

YES / NO

If yes, indicate the types of products made and the purpose:

Type of product	Purpose
...	...
...	...
...	...

Were any such fermenters/bioreactors located in any of the following types of organization (tick any that apply):

Organizations in the declaring State Party:

... Industry    ... Academia  
... Government ministry/department/agency other than defence or military

Organizations in another State or State Party, working under contract or through collaboration:

... Industry    ... Academia  
... Government ministry/department/agency other than defence or military

- (d) Whether vaccine or vaccine ingredients causing a specific and protective immune response were produced for the general public or for armed forces:

YES / NO

If yes, provide the names of the facilities involved:

.....

- (e) Whether the programmes and/or activities were supported by outdoor studies of biological aerosols or their simulants:

YES / NO

Were any such outdoor studies performed in any of the following types of organization (tick any that apply):

Organizations in the declaring State Party:

- ... Industry    ... Academia
- ... Government ministry/department/agency other than defence or military

Organizations in another State or State Party, working under contract or through collaboration:

- ... Industry    ... Academia
- ... Government ministry/department/agency other than defence or military

11. Provide a list of all biological defence facilities for which a declaration format (Appendix C) has been provided (tick the appropriate box):

Name of biological defence facility	A declaration format has been provided (Appendix C)
...	
...	

12. Provide a diagram of the organizational structure of the declared programmes and/or activities, describing the reporting relationships including all the facilities mentioned in question 11 above:

.....

13. Describe the national publication policy for the declared programmes and/or activities:

.....  
.....  
.....

## APPENDIX C<sup>198</sup>

### FACILITIES<sup>199</sup>

#### Guidelines for completing the declaration format

1. The facility declaration format requires information on facilities meeting the criteria set out in one or more of the declaration triggers of the Protocol. Such facilities are referred to throughout the format as the “declared facility”. The format is to be utilized by declared facilities to report activities captured by declaration triggers.

2. The design of the format takes account of the differing sizes, complexities and scope of facilities satisfying the requirements of one or more of the Protocol declaration triggers. It is recognized that in some cases the room(s), laboratory(ies), buildings, or parts of buildings, or other structures which can be or is used to conduct activity(ies) related to the Convention that satisfy the requirements of the trigger - and that therefore are to be the declared facility - may involve only part of a building. Indeed, the facility declarable under the Protocol may be at a location with a large number of other facilities engaging in activities that are not declarable.

3. The facility declaration format is designed to cover this range of possibilities. The facility to be declared is the combination of room(s), laboratory(ies), buildings, or parts of buildings, or other structures which can be or is used to conduct activity(ies) related to the Convention which carried out activities during the reporting calendar year that satisfied the requirements of a specific declaration trigger. Where that exact same combination of rooms etc. also satisfies a different trigger, such a combination shall be declared as the same facility (i.e. as a single facility). When the combination of room(s), laboratory(ies), buildings, or parts of buildings, or other structures which can be or is used to conduct activity(ies) related to the Convention that satisfies a different trigger is not identical, it shall be treated as a separate declarable facility.

4. When scientific/technical activities which may require declaration under a particular trigger are conducted in different parts of a location, for example in different buildings and/or departments at a university campus or at a commercial installation operated by a single company, and they share one or more room(s), laboratory(ies), buildings, or parts of buildings, or other structures which can be or is used to conduct activity(ies) related to the Convention they shall be considered as a single facility for the purpose of determining whether a declaration should be made. Scientific/technical activities at the same location that meet the criteria of one or more declaration triggers but do not share one or more room(s), laboratory(ies), buildings, or parts of buildings, or other structures which can be or is used to conduct activity(ies) related to the Convention shall be considered as separate facilities for the purpose of declaration.

---

<sup>198</sup>The text in AHG/51 (Part 2) has been used as the baseline for this section.

<sup>199</sup>It is useful to recall the information provided in the introductory section of this Evaluation Paper which shows that, based on the 1997 CBM information, there were biological defence facilities in only 15 countries, maximum containment facilities in a further 6 countries and vaccine production facilities in a further 15 countries resulting in a total of 36 countries. Given the Protocol objective of increasing transparency and building confidence between States Parties, it is apparent that the triggers "*Other Production Facilities*" and "*Work with Listed Agents and Toxins*" are necessary to increase the distribution and spread of relevant declared facilities both within these countries and to additional countries.

5. Each declared facility shall answer the questions in sections A and B and, according to the trigger(s)<sup>200</sup> involved, the following questions in section C:

<u>Trigger that applies</u>	<u>Questions to be answered in section (C)</u>
Vaccine production facility	29
Maximum biological containment facility	30
Work with listed agents and/or toxins	31
Other production facility <sup>201</sup>	32
Other <b>facility</b> <sup>202</sup>	33
Biological defence facility	34, 35 and 36

Reporting period

This declaration covers the calendar year: .....

INTRODUCTION

(i) Declaration trigger(s) that apply to the facility

Submit a copy of the facility declaration format for each facility satisfying the requirements of one or more of the declaration triggers identified below. Indicate which of the declaration triggers is applicable to this facility, by ticking the appropriate triggers below and indicating the approximate percentage of the total work of the declared facility that relates to each trigger:

	Approximate percentage (in person-years)
Vaccine production facility	...
Maximum biological containment facility	...
Work with listed agents and/or toxins	...
Other production facility	...
Other <b>facility</b>	...
Biological defence facility	...

(A) GENERAL INFORMATION

<sup>200</sup>For consistency with Article III. D. I, the stand-alone trigger of high containment (BL-3) facilities has been deleted throughout.

<sup>201</sup>Amended to be consistent with Article III. D. I.

<sup>202</sup>Amended to be consistent with Article III. D. I.



Name and address

1. Name of the declared facility:
2. Address of the declared facility:
3. Postal address of the declared facility, if different:
4. Building details for the declared facility.

State, as appropriate, building name(s): .....

building number(s): .....

room number(s): .....

floor level(s): .....

Diagram/location<sup>203</sup>

5. Fixed facilities. Provide the following:

- (a) An orientation map (with scale, and a key explaining any abbreviations and symbols) of the location of the declared facility, including the following elements:
  - (i) The principal natural and/or man-made topographical features surrounding the declared facility, e.g., major highways or roads, including access roads to the facility, mountain(s), rivers (minimum size of area represented by the map should be approximately 1 square kilometre);
  - (ii) Direction of true north;

(b) A facility diagram. The purpose of the facility diagram is to graphically indicate the location of the declared facility. The facility diagram can be one or multiple diagrams and should include the entire declared facility, with boundaries of the declared facility building(s), room(s) or other structures, as appropriate, clearly marked. The facility diagram shall include geographic coordinates of a designated reference point within 100 metres of the declared facility, accurate to one second, a key with an explanation of all abbreviations and symbols, and an indication of the scale of the diagram.

6. Mobile facilities.

- (a) List the locations at which the declared facility was operated:  
.....
- (b) Indicate where the declared facility was normally kept, if different from above:

---

<sup>203</sup>As there is no requirement to identify the specific purpose of the buildings within the declared facility, there is no necessity to exclude the locations of animal holding areas from such maps (cf. Note 115 on page 251 of AHG/52 (Part I)).

.....

Owner

7. Name:

.....

8. Affiliation (tick all that apply):

- Ministry/Department/Agency of Defence       wholly  partially
- Other government ministry/department/  
agency       wholly  partially
- Non-government       wholly  partially

Operator(s) (Only provide details if different from the owner)

9. Name(s):

.....

10. Affiliation(s) (tick all that apply):

- Ministry/Department/Agency of Defence       wholly  partially
- Other government ministry/department/  
agency       wholly  partially
- Non-government       wholly  partially

Funding

11. Estimate the funding levels for the current biological defensive programme work at the declared facility:

.....

12. Affiliation of sources of funding (tick all that apply):

- Ministry/Department/Agency of Defence       wholly  partially
- Other government ministry/department/  
agency       wholly  partially
- International organization (UN agencies,etc)       wholly  partially
- Other non-government       wholly  partially
- Defence Ministry/Department/Agency  
of another State Party/State       wholly  partially
- Other government ministry/department/  
agency of another State Party/State       wholly  partially

(a) Identify the primary sponsor of or source of funding for declared activities at the declared facility (tick which applies):

- Defence Ministry/Department/Agency

- o Other government ministry/department/agency
- o International organization (UN agencies, etc.)
- o Other non-government
- o Defence Ministry/Department/Agency of another State Party/State
- o Other government ministry/department/agency of another State Party/State

Personnel

13. Indicate the number of person-years of technical and scientific staff directly involved in the declared activities at the declared facility (include on-site contractors):

\_\_\_ 0 - 10      \_\_\_ 11 - 25      \_\_\_ 26 - 50      \_\_\_ greater than 50

(a) Indicate the percentage of these personnel who hold, as their highest qualification, a diploma, bachelors degree or technical degree in the life sciences, chemistry, engineering or physics (estimates of percentages shall be rounded up to the nearest whole number):

\_\_\_ none                      \_\_\_ 1 - 25 per cent                      \_\_\_ 26 - 50 per cent  
 \_\_\_ 51 - 75 per cent      \_\_\_ 76 - 100 per cent

(b) Indicate the percentage of these personnel who received a higher or advanced degree in the life sciences, chemistry, engineering or physics (estimates of percentages shall be rounded up to the nearest whole number):

\_\_\_ none                      \_\_\_ 1 - 25 per cent                      \_\_\_ 26 - 50 per cent  
 \_\_\_ 51 - 75 per cent      \_\_\_ 76 - 100 per cent

(c) Are†<sup>204</sup> active duty military involved in the declared activity?

YES/NO

If yes, indicate the percentage of person-years that are involved:

\_\_\_ up to 10      \_\_\_ 11 - 50      \_\_\_ 50 -200      \_\_\_ greater than 200

(d) Are full-time civilian Defence Ministry/ Department/Agency employees (include on-site contractors) involved in the declared activity?

YES/NO

If yes, indicate the number of person-years that are involved:

---

<sup>204</sup>The term "full-time" is best deleted as it is ambiguous -- full-time in the declared activities or full-time active duty?

\_\_\_ up to 10    \_\_\_ 11 - 50    \_\_\_ 50 -200    \_\_\_ greater than 200

(B) SCIENTIFIC AND TECHNICAL INFORMATION

14. Summarize the scope and outcome of the work at the declared facility (10 lines or less):

.....  
 .....  
 .....

15. Indicate by ticking the appropriate box whether any work was carried out in the following areas<sup>205</sup>. Work performed only in order to establish and carry out routine procedures or to maintain safety at the declared facility shall not be reported.

Work area	Research and development	Testing and evaluation	Production other than for research, development, testing or evaluation
Detection, identification and diagnosis			
Decontamination, disinfection and pest control			
Prophylaxis			
Physical protection			
Medical or veterinary treatment			
Genetic modification			
Insect/pest control for use in agriculture/horticulture			
Characteristics of biological agents or toxins:			
pathogenicity/virulence		n.a.	n.a.
toxinology*		n.a.	n.a.
environmental stability		n.a.	n.a.
antimicrobial resistance		n.a.	n.a.

<sup>205</sup>As the purpose of the declaration is to increase transparency and build confidence between States Parties it is essential that the declarations are comprehensive and separately include not only research and development but also testing and evaluation as well as production.

Aerobiology			n.a.
Vector (insect) ecology			n.a.
Plant pathology			n.a.
n.a. = not applicable * Toxinology is the study of toxins.			

16. Summarize the principal objectives of and the work performed in the areas indicated in question 15 above.

17. Was high biological containment, as defined by the Protocol, used for declared activities within the declared facility?

YES / NO

18. If yes, specify the floor area of the working areas by indicating which range applies:

\_\_\_ up to 30 sq.m. \_\_\_ 30 to 100 sq.m. \_\_\_ 100 to 500 sq.m. \_\_\_ over 500 sq.m.

19. Were the following types of waste from declared activities at the declared facility, rendered safe by decontamination or sterilization prior to release or removal from the facility:

Effluent from hand-washing sinks or showers?	YES/NO
Waste from fermenters?	YES/NO
Waste from down-stream processing?	YES/NO
Air exhausted from working cabinets?	YES/NO
Air exhausted from rooms?	YES/NO

20. If the declared facility included room(s) for holding and/or working with live animals under maximum biological containment or high biological containment, indicate which applies:

Maximum biological containment (BL-4 ) YES / NO

High biological containment (BL-3 ) YES / NO

21. Answer the questions about equipment at the declared facility, to be found in the attached Addendum<sup>206</sup>.

22. Were culture media used at the declared facility?

<sup>206</sup>The Addendum includes, in a simple tabular form, the information required on equipment previously contained in Annex A II List of Equipment in AHG/51 (Part I).

YES / NO

If yes, indicate which range applies:

up to 1,000 litres     1,000-10,000 litres     over 10,000 litres

23. Were embryonated eggs used to culture microorganisms at the declared facility?

YES / NO

If yes, indicate which range applies:

1 - 10,000 eggs     10,000 - 100,000 eggs     over 100,000 eggs

24. Indicate the types of pathogens and/or toxins worked on (tick any that apply):

Human or zoonotic pathogens:

Bacteria     Viruses     Fungi     Others

Animal pathogens excluding zoonotic pathogens:

Bacteria     Viruses     Fungi     Others

Plant pathogens:

Bacteria     Viruses     Fungi     Others

Toxins:

25. Indicate whether any agents and/or toxins listed in Annex A were transferred outside the declared facility for any of the following purposes:

To perform further studies in research and development, testing or evaluation?	YES / NO
For larger scale production?	YES / NO
For downstream processing?	YES / NO
For animal studies?	YES / NO
For aerobiology studies?	YES / NO

26. Were there any areas which required specific vaccination of personnel to enable them to enter?

YES / NO

If yes, list the vaccines that applied:

.....

27. Was the declared facility supported at the same location or elsewhere by:
- A fixed outdoor site or fixed grid that is designed, intended and used for outdoor studies of biological aerosols? YES / NO
  - An experimental facility for animals, or an animal holding facility? YES / NO
  - A waste decontamination facility? YES / NO
  - A facility for larger scale production, or for downstream processing? YES / NO

28. Indicate the publication policy for work at the declared facility:
- Publishing in the open literature and/or at open scientific/technical meetings YES / NO
  - Scientific/technical reports on limited distribution only YES / NO
  - No publications or reports YES / NO

(C) ADDITIONAL INFORMATION

29. Vaccine production

If the declared facility produced microorganisms or substances causing specific and protective immune responses as ingredients of vaccines and/or vaccines, provide the following information:

- (a) List the microorganisms or substances causing specific and protective immune responses as vaccine ingredients, produced:

Ingredient	Intended for (tick which applies)		Disease against which the vaccine is directed	Highest level of containment used in any production	
	Human vaccine	Animal vaccine		High	Maximum

- (b) If the declared facility also produced vaccines, list and estimate the total quantity of vaccine produced (tick the appropriate box):

Intended for	Highest level of containment used in any production		Quantity of vaccine ingredients produced (Litres of culture or of bulk working suspension)		
	BL3	BL4	up to 1,000	1,000 to 10,000	above 10,000
Humans					
Animal 1...					

(c) List the vaccines produced:

Vaccine	Intended for use with (tick which applies)		Disease against which the vaccine is directed	Production objectives*
	Humans	Animals		

\* Production objectives: A - Public sale or use; B - Defence ministry/department/agency; C - Both

(d) Estimate the total quantity of vaccine produced (tick the appropriate box):

Vaccine intended for use with	Disease against which the vaccine is directed	Registration/licence/authorisation number	Production objective*	Aggregate number of doses** produced		
				up to 100,000	100,000 to 5,000,000	above 5,000,000
Humans						
Animal 1..						
Animal 2..						
....						

\* Production objectives: A - Public sale or use; B - Defence ministry/department/agency; C - Both

\*\* State the number of doses produced in terms of the estimated dose for adults even if a vaccine is intended for use with children or immature animals.



30. Maximum biological containment

If the declared facility satisfied the requirements of the declaration trigger for maximum biological containment, provide the following information:

- (a) Estimate the total floor area of the BL4 containment area, by indicating which range applies:

up to 30 sq.m.      **30** to 100 sq.m.      100 to 500 sq.m.      over 500 sq.m.

- (b) Indicate the number of units within the working containment area (tick which applies):

1 - 3                      4 - 6                      More than 6

- (c) Does the declared facility have any unit(s) for the management and/or treatment of patients as part of the structure of the containment area?

YES / NO

- (d) Indicate whether work in these laboratories was carried out on:

Human pathogens	YES / NO
Zoonotic pathogens	YES / NO
Other animal pathogens	YES / NO

- (e) Indicate any agents and/or toxins listed in Annex A on which work was carried out:

.....  
.....  
.....

- (f) Was any genetic modification, as defined in Article II, conducted within the containment area?

YES/NO

- (g) Method/system of decontamination of the biocontainment area(s) (check all that apply):

Formaldehyde/paraformaldehyde	YES / NO
Ultraviolet light	YES / NO
Steam	YES / NO
Chlorine/perchlorate	YES / NO
Hydrogen peroxide	YES / NO
Washdown	YES / NO
Other, specify: .....	

**31. Work with listed agents and/or toxins**

Did the declared facility satisfy the requirements of the declaration trigger for work with listed agents and or toxins?

YES / NO

If yes, indicate which activities<sup>208</sup> it has conducted:

- (a) Production of one or more agents and/or toxins listed in Annex A, using:
- (i) Any fermenter(s)/bioreactor(s) with a total internal volume of 50 litres or more YES / NO
  - (ii) Continuous or perfusion fermenters/bioreactors with a flow rate capable of exceeding 2 litres an hour YES / NO
  - (iii) A chemical reaction vessel or equipment used for recovery with a total internal volume of 50 litres or more YES / NO
  - (iv) More than 2,000 embryonated eggs on an annual basis YES / NO
  - (v) More than 1,000 litres of tissue culture or other medium on an annual basis YES / NO
- (b) Intentional aerosolization of any agent and/or toxin listed in Annex A in:
- (i) A static aerosol test chamber YES / NO
  - (ii) An explosive aerosol test chamber YES / NO
  - (iii) A dynamic aerosol test chamber that has a total volume exceeding 5 m<sup>3</sup> YES / NO

If yes, provide the following information:

Agent	Estimated amount produced (litres of culture or of working suspensions of agents)		
	[a to b]	[b to c]	[above c]

<sup>207</sup>High biological containment deleted for consistency with Article III. D, section I.

<sup>208</sup>Amended to be consistent with the capacity in Article III. D, section I.

Toxin	Estimated amount produced (dry or wet packed weight in grams)		
	[a to b]	[b to c]	[above c]

- (c) Did the facility conduct insertion of any nucleic acid sequence coding for any pathogenicity/virulence factor or for any toxin or subunit of any toxin, into an agent listed in Annex A?

YES / NO

If yes, name the agent(s) and the toxin(s) and give a short description of the purpose:

.....  
.....  
.....

- (d) Did the facility conduct insertion of any nucleic acid sequence coding for any pathogenicity/virulence factor from an agent or toxin listed in Annex A, or for a subunit of such toxin into any microorganism, resulting in a genetically modified organism with disease-causing or toxic properties?

YES / NO

If yes, name both organisms or toxins and give a short description of the purpose:

.....  
.....  
.....

- (e) Did the facility conduct intentional aerosolization of any agent and/or toxin listed in Annex A or any work with aerosolized agents and/or toxins listed in Annex A?

YES / NO

If yes, name the agent(s) or toxin(s) and give a short description of the purpose:

.....  
.....  
.....

- (f) Did the facility conduct the administration of any agent and/or toxin listed in Annex A to animals via the respiratory tract?

YES / NO

If yes, name the agent(s) or toxin(s) and give a short description of the purpose:

.....  
.....  
.....

**32. Other production**

Did the facility produce any products for distribution, sale, or public or general use, either directly or after further processing, formulation or packaging?

YES / NO

If yes,

(a) Indicate the type(s) of product produced. If more than one product applies, indicate with an asterisk which type constituted the major activity in terms of amount of product:

- Medicine
- Antimicrobial
- Pesticides
- Plant inoculants
- Enzymes
- Fine chemicals
- Proteins other than enzymes
- Peptides or amino acids
- Nucleic acids or genetic elements
- Microorganisms for use in biotransformation processes
- Other, specify: .....

(b) State if any of these products were produced in areas protected by high biological containment:

YES / NO

(c) State the approximate aggregate total amount produced in ranges:

up to x kg dry weight      x to y kg dry weight      above y kg dry weight

(d) If the declared facility included room(s)/other enclosure(s) with quarantine for plants or plant pathogens, specify the floor area of the working areas, excluding shower areas, by indicating which range applies:

up to 30 sq.m.      30-100 sq.m.      over 100 sq.m.

(e) Did the facility produce plant inoculants and/or biological control agent(s) inside a plant quarantine capability?

YES / NO

If yes,

(i) Indicate which was produced:

.....  
.....  
.....

(ii) State the approximate aggregate total amount produced in ranges:

up to x kg dry weight      x to y kg dry weight      above y kg dry weight

**33. Other facilities**

(a) Possession of aerosol chambers.

Did the facility possess aerosol chambers?

YES / NO

(b) Possession of aerosol generation equipment.

Did the facility possess aerosol generation equipment?

YES / NO

(c) Conducting genetic modification.

Did the facility conduct genetic modification?

YES / NO

Agent or toxin concerned	Indicate if under high biological containment level	Indicate if under maximum biological containment level

(d) Conducting open-air dispersion of aerosols.

Name of facility, place (site) where work was conducted to generate the aerosols:

.....

Indicate the type of terrain in which the work was conducted:

Natural terrain:

- Flat YES / NO
- Vegetation-covered YES / NO
- Mountainous YES / NO
- Aquatic YES / NO
- Combined YES / NO

Artificial (cultivated) terrain:

- Residential YES / NO
- Industrial YES / NO
- Combined YES / NO
- Model of residential/industrial complex YES / NO

Indicate the biological agents and/or toxins, or simulants, employed in generating the aerosols:

- Listed biological agents YES / NO
- Listed toxins YES / NO
- Other pathogenic microorganisms YES / NO
- Simulants YES / NO

Indicate the state of the material containing the biological agent or toxin which was used to generate the aerosol:

- Dry YES / NO
- Wet YES / NO

Indicate the size of the areas where specific work was carried out with the use of the aerosol (strike out where not applicable):

Up to 1 sq km      From 1 to 10 sq km      More than 10 sq km

Indicate whether or not animals were used in the work:

YES / NO

Number of specific experiments/hours/days spent disseminating the aerosols:

.....

Indicate the purposes of the work carried out (briefly):

.....

.....

**34. Biodefence facilities**

Diagram/location

For current biological defence facilities only: In addition, provide the general boundary of the site within which the declared biological defence facility is located, including all major access routes:

.....

**35.** Were vaccines or vaccine ingredients causing a specific and protective immune response produced?

YES / NO

**36.** If the declared facility satisfied the requirements of the declaration trigger for biological defence facilities in accordance with Annex ..., answer the following:

(a) Did declared activities at the declared facility include work on pathogenicity?

YES / NO

If yes, summarize the aims and objectives of biological defence work on pathogenicity at the declared facility (10 lines or less):

.....

.....

.....

(b) Did declared activities at the declared facility include work on virulence?

YES / NO

If yes, summarize the aims and objectives of biological defence work on virulence at the declared facility (10 lines or less):

.....  
.....  
.....

(c) Did declared activities at the declared facility include work on aerobiology?

YES / NO

If yes, summarize the aims and objectives of biological defence work on aerobiology at the declared facility (10 lines or less):

.....  
.....  
.....

(d) Did declared activities at the declared facility include work on toxinology?

YES / NO

If yes, summarize the aims and objectives of biological defence work on toxinology at the declared facility (10 lines or less):

.....  
.....



ADDENDUM TO APPENDIX C

EQUIPMENT INFORMATION

- The following table shall be completed by inserting a  $\checkmark$  in the appropriate boxes.
- When any one of the following five types of equipment, 1, 2, 4, 21 and 22 (shown by a \* in the "Present" box) is present, then additional information as detailed below the table shall be provided.

Equipment	Not present	Present	Utilized	Utilized in primary containment	Utilized in high containment	Utilized in maximum containment
1. Aerosol chambers (either static, dynamic or explosive) (i) Static tests		*				
(ii) Explosive tests		*				
(iii) Dynamic tests		*				
2. Equipment designed or used to generate aerosols of microorganisms or toxins and simulants.		*				
3. Aerosol analytical equipment to determine the size of particles up to 20 micrometers in diameter.						
4.(a) Fermenter(s)/bioreactor(s) with a total/internal volume exceeding 50 litres <sup>209</sup> .		*				
4.(b) Chemical reactor(s) with a total/internal volume exceeding 50 litres <sup>210</sup> .						
5. Equipment for continuous or perfusion growth of microorganisms with a volume over 50 litres.						
6. Continuous or semi-continuous centrifuge(s) that are self-sterilizable with throughput capacity greater than 100 litres per hour.						

<sup>209</sup>Amended to be consistent with the capacity in Article III. D, section I.

<sup>210</sup>Amended to be consistent with the capacity in Article III. D, section I.

Equipment	Not present	Present	Utilized	Utilized in primary containment	Utilized in high containment	Utilized in maximum containment
7. Cross-flow/tangential filtration equipment with a filter area of over 5 square metres.						
8. Freeze-dryer(s) with a condenser capacity of over 5 kg of ice in 24 hours.						
9. Cell disruption equipment capable of continuous operation without the release of aerosols with a flow rate greater than 10 litres per hour.						
10. Spray dryer(s).						
11. Drum dryer(s).						
12. Biological safety cabinets Class III or Class I with accessories for conversion to Class III.						
13. Flexible film isolators or other cabinets with air handling characteristics equivalent to Class III and anaerobic boxes.						
14. Biological safety cabinets Class II.						
15. Microencapsulation equipment.						
16. Automatic DNA sequencing equipment.						
17. Automatic DNA synthesizer.						
18. Automatic peptide sequencing equipment.						
19. Automatic peptide synthesizer.						
20. Milling equipment having a capacity of milling grain with mass median diameter less than 10 micrometres.						

Equipment	Not present	Present	Utilized	Utilized in primary containment	Utilized in high containment	Utilized in maximum containment
21. Plant inoculation cabinets/chambers providing quarantine.		*				
22. Cabinets/chambers designed or used for rearing insects.		*		Used in quarantine		

### ADDITIONAL INFORMATION

#### 1. Aerosol chambers (either static, dynamic or explosive):

What is the volume of the chamber(s) present and/or utilized

##### (i) Static

- Less than 0.2 cubic metres
- Equal to or greater than 0.2 but less than 5 cubic metres
- Equal to or greater than 5 but less than 30 cubic metres
- Equal to or greater than 30 but less than 100 cubic metres
- Equal to or greater than 100 cubic metres

##### (ii) Explosive

- Less than 0.2 cubic metres
- Equal to or greater than 0.2 but less than 5 cubic metres
- Equal to or greater than 5 but less than 30 cubic metres
- Equal to or greater than 30 but less than 100 cubic metres
- Equal to or greater than 100 cubic metres

##### (iii) Dynamic

- Less than 0.2 cubic metres
- Equal to or greater than 0.2 but less than 5 cubic metres
- Equal to or greater than 5 but less than 30 cubic metres
- Equal to or greater than 30 but less than 100 cubic metres
- Equal to or greater than 100 cubic metres

#### (b) Indicate the type(s) of activities conducted by or in these aerosol systems or chambers.

- Study of aerosol properties

- Study using aerosol flows
- Explosive/shock wave dissemination of aerosols
- Study of the properties of agents or toxins
- Studies with the use of experimental animals
- Other (specify) .....

2. Equipment designed or used to generate aerosols of microorganisms or toxins and simulants.

(a) Form of source material used to generate aerosol(s) (check all that apply):

- Liquid
- Powder

(b) Mass median diameter of aerosol particles generated (check all that apply):

- Less than 10 micrometres
- Equal to or greater than 10 but less than 20 micrometres
- Equal to or greater than 20 micrometres

(c) For which purpose was the equipment used:

- Aerosol chambers
- Open-air release
- With experimental animals

4. Aggregate fermenters/bioreactors capacity.

(a) Volume range.

Specify which range applies:

- Less than 100 litres      Yes / No
- Equal to or greater than 100 but less than 1,000 litres
- Equal to or greater than 1,000 but less than 10,000 litres
- Equal to or greater than 10,000 but less than 100,000 litres
- Equal to or greater than 100,000 litres

(b) Specify the volume of the largest fermenter/bioreactor.

21. Plant inoculation cabinets/chambers providing quarantine.

Total cabinet/chamber working volume range

- Less than 1 cubic metre
- Equal to or greater than 1 but less than 3 cubic metres
- Equal to or greater than 3 cubic metres

22. Cabinets/chambers designed or used for rearing insects.

(a) Total cabinet/chamber working volume range

\_\_\_ Less than 3 cubic metres  
\_\_\_ Greater than 3 cubic metres

## APPENDIX E

### INFORMATION TO BE PROVIDED IN THE DECLARATIONS REQUIRED **PURSUANT TO** ARTICLE VII

1. A general description of measures taken to facilitate the fullest possible exchange of equipment, materials and scientific and technological information for the use of the bacteriological (biological) agents, toxins for peaceful purposes.
2. A general description of measures taken to further the development and application of scientific discoveries in the field of bacteriology (biology) for the prevention of disease or for other peaceful purposes.
3. A general description of any other measure that the State Party has taken to implement Article X of the Convention and Article VII of the Protocol.
4. A general description of the outcome of any review undertaken on the existing national trade legislation or regulations, in accordance with section C, paragraph 7 (c) of Article VII.

APPENDIX H

STANDARDIZED FORMATS FOR REPORTING  
INTERNATIONAL TRANSFERS OF EQUIPMENT

Each State Party shall use the following formats for the implementation of its obligations under Article III, section F, paragraph 4.

(A) ANNUAL REPORTS ON IMPORTS

1. Name of the importing country: .....

2. National Authority: .....

A	B	C	D	E	F	G
Type of equipment	Final exporter State	Number of items	State of origin (if not exporter)	State of trans-shipment (if any)	Type of the facility for intended use	Specificities of the equipment and proposed application (optional)

(B) ANNUAL REPORT ON EXPORTS

1. Name of the exporting country: .....

2. National Authority: .....

A	B	C	D	E	F	G
Type of equipment	Final importer State	Number of items	State of origin (if not exporter)	State of trans-shipment (if any)	Type of the facility for intended use	Specificities of the equipment and proposed application (optional)