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# **Strengthening the Biological Weapons Convention**

## **Briefing Paper No 3 (Second Series)**

### **National Measures to Implement the Prohibitions in the BTWC**

**March 2003**

**Series Editors**

**Graham S Pearson and Malcolm R Dando**

Department of Peace Studies, University of Bradford

# **Strengthening the Biological Weapons Convention**

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Graham S. Pearson & Nicholas A. Sims

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Bradford, UK

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# NATIONAL MEASURES TO IMPLEMENT THE PROHIBITIONS IN THE BTWC

by Graham S. Pearson\* and Nicholas A Sims†

## Introduction

1. At the Fifth Review Conference of the States Parties to the Biological and Toxin Weapons Convention (BTWC) it was agreed<sup>1</sup>:

*To hold three annual meetings of the States Parties of one week duration each year commencing in 2003 until the Sixth Review Conference, to be held not later than the end of 2006, to discuss, and **promote common understanding and effective action** on:*

*i. The adoption of necessary, national measures to implement the prohibitions set forth in the Convention, including the enactment of penal legislation;*

*ii. National mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins;*

*iii. Enhancing international capabilities for responding to, investigating and mitigating the effects of cases of alleged use of biological or toxin weapons or suspicious outbreaks of disease;*

*iv. Strengthening and broadening national and international institutional efforts and existing mechanisms for the surveillance, detection, diagnosis and combating of infectious diseases affecting humans, animals, and plants;*

*v. The content, promulgation, and adoption of codes of conduct for scientists.*

and that "Each meeting of the States Parties will be prepared by a two week meeting of experts." This Briefing Paper considers the first topic to be addressed in 2003, namely "The adoption of necessary, national measures to implement the prohibitions set forth in the Convention, including the enactment of penal legislation;".

2. In Briefing Paper No. 2<sup>2</sup> it was noted that the annual meeting of States Parties would ideally develop a text that would integrate

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<sup>1</sup>United Nations, *Fifth Review Conference of the Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, Geneva, 19 November - 7 December 2001 and 11 - 22 November 2002, Final Document, BWC/CONF.V/17, 2002. Available at <http://www.opbw.org>

<sup>2</sup>Nicholas A. Sims, *The New Multilateral Process For The BTWC: Ambiguities And Opportunities*, University of Bradford, Department of Peace Studies, Briefing Paper No.2 (Second Series), January 2003, paragraph 19. Available at <http://www.brad.ac.uk/acad/sbtwc>

a. the States Parties' verdict on the experts' recommendations, commending those it felt able to approve as promoting best practice,

**and**

b. the relevant language in Final Declarations, arranged and tabulated by the secretariat for the meetings of experts and of States Parties.

3. This Briefing Paper provides an input to the meetings of experts and of the States Parties by first collecting the relevant language from Final Declarations regarding national measures and then providing an example, drawing on the legislation and other regulatory measures for one State Party, of the input on national measures that all States Parties should be able to make to the meetings. There is much to be said, as was noted in Briefing Paper No.2<sup>3</sup>, for States Parties providing their legislation, regulations and other measures of BTWC national implementation **prior** to the experts meeting.

### **The requirement for national measures**

4. Article IV of the Convention requires that:

*Each State Party to this Convention shall, in accordance with its constitutional processes, take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere.*

5. Article IV obliges each State Party to ensure national implementation in the broadest possible terms, as the scope clauses at the end of the Article spell out clearly. Although the word *legislation* does not appear in this Article, the commonest response to this obligation among those States Parties which have made known any response whatever (and they are thus far all too few) has been either to legislate in such a way as to give domestic legal effect to the prohibitions contained in Article I, or to determine on examination of their existing laws that no further specific legislation is necessary. In recent years a growing concern about bioterrorism has reinforced the case for enacting specific legislation, and also for strengthening such legislation as already exists. It has also given governments a greater sense of urgency, as it has come to be recognised that legislation to give domestic legal effect to BTWC prohibitions is a vital element in their efforts to counter terrorist threats. National implementation also embraces government decrees, regulations and administrative memoranda to law enforcement agencies, but little is yet known of what action, if any, States Parties have taken under those headings. It is understandable, therefore, that national implementation has come to be identified closely with the adoption of new legislation.

6. Such legislation ties the Convention into national legal systems in the clearest possible way. It contributes to the strengthening of compliance by expanding the constituency with an institutional interest in the success of the Convention. It also builds the treaty regime flowing from the Convention into normative structures at the national level, in the form of rules and expectations and procedures for upholding them. These rules, expectations and procedures in

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<sup>3</sup>Nicholas A. Sims, *The New Multilateral Process For The BTWC: Ambiguities And Opportunities*, University of Bradford, Department of Peace Studies, Briefing Paper No.2 (Second Series), January 2003, paragraph 15. Available at <http://www.brad.ac.uk/acad/sbtwc>

turn uphold their counterparts at the international level. They shore up the international treaty regime and help, even if only marginally, to ensure its survival by constituting one more obstacle which would have to be overcome if the Convention were to come under attack.

### **The evolution of common understandings**

7. Successive Review Conferences have seen the evolution of common understandings regarding Article IV. The first four Review Conferences reinforced Article IV with successive layers of consensually agreed language, as each Final Declaration built on its predecessor and added new material to the inherited paragraphs. This cumulative process records, reaffirms and extends the common understandings of States Parties with regard to the implications and implementation of Article IV.

8. In 1980 the First Review Conference the Article IV section of the Final Declaration<sup>4</sup> stated that:

*The Conference notes the provisions of Article IV, which requires each State Party to take any necessary measure to prohibit and prevent the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, within its territory, under its jurisdiction or under its control anywhere, and calls upon all States Parties which have not yet taken any necessary measures in accordance with their constitutional processes to do so immediately.*

*The Conference invites States Parties which have found it necessary to enact specific legislation or take other regulatory measures relevant to this Article to make available the appropriate texts to the United Nations Centre for Disarmament, for the purposes of consultation.*

The language in the second paragraph had resulted from proposals made by the United Kingdom, with Belgian and Finnish support.

9. In 1986 at the Second Review Conference, the language in the Article IV section of the Final Declaration<sup>5</sup> was extended to some four paragraphs:

*The Conference notes the importance of Article IV, under which each State Party shall, in accordance with its constitutional processes, take any necessary measures to prohibit or prevent any acts or actions which would contravene the Convention.*

*The Conference calls upon all States Parties which have not yet taken any necessary measures in accordance with their constitutional processes, as required by the Article, to do so immediately.*

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<sup>4</sup>United Nations, *The First Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, Geneva, 3–21 March 1980, Final Document, BWC/CONF.I/10, 21 March 1980, p. 7. Available at <http://www.opbw.org>

<sup>5</sup>United Nations, *The Second Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, Geneva, 8–26 September 1986, Final Document, BWC/CONF.II/13/11, 26 September 1986, pp. 4-5. Available at <http://www.opbw.org>

*The Conference notes that States Parties, as requested by the First Review Conference, have provided to the United Nations Department for Disarmament Affairs information on and the texts of specific legislation enacted or other regulatory measures taken by them, relevant to this Article. The Conference invites States Parties to continue to provide such information and texts to the United Nations Department for Disarmament Affairs for purposes of consultation.*

*The Conference notes the importance of:*

- *legislative, administrative and other measures designed effectively to guarantee compliance with the provisions of the Convention within the territory under the jurisdiction or control of a State Party,*
- *legislation regarding the physical protection of laboratories and facilities to prevent unauthorised access to and removal of pathogenic or toxic material, and*
- *inclusion in textbooks and in medical, scientific and military educational programmes of information dealing with the prohibition of bacteriological (biological) and toxin weapons and the provisions of the Geneva Protocol*

*and believes that such measures which States might undertake in accordance with their constitutional process would strengthen the effectiveness of the Convention.*

10. This therefore repeated the invitation first made at the First Review Conference<sup>6</sup> to

*States Parties which have found it necessary to enact specific legislation or take other regulatory measures relevant to this Article to make available the appropriate texts to the United Nations Centre for Disarmament, for [the] purposes of consultation.*

In addition, the Second Review Conference also repeated the 1980 call

*upon all States Parties which have not yet taken any necessary measures in accordance with their constitutional processes, **as required by the Article**, to do so immediately.*<sup>7</sup> [The words emphasised were added in 1986.]

11. The Second Review Conference also took a modest step forward in regime-building for strengthening compliance with the Convention on the foundations of Article IV. It did so by widening, on the initiative of the then German Democratic Republic, the range of national

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<sup>6</sup>United Nations, *The First Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, Geneva, 3–21 March 1980, Final Document, BWC/CONF.I/10, 21 March 1980, p. 7. Available at <http://www.opbw.org> The intrusive the was deleted when the invitation was repeated in 1986 "for purposes of consultation," the Australian delegation, in editing the text for the Drafting Committee, having restored the original UK language at the request of its author.

<sup>7</sup>United Nations, *The Second Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, Geneva, 8–26 September 1986, Final Document, BWC/CONF.II/13/11, 26 September 1986, pp. 4-5. Available at <http://www.opbw.org>

implementation actions which were given international commendation. After repeating the invitations contained in the 1980 declaration as indicated above it added a new passage:

*The Conference notes the importance of*

- *legislative, administrative and other measures designed effectively to guarantee compliance with the with the provisions of the Convention within the territory under the jurisdiction or control of a State Party;*
- *legislation regarding the physical protection of laboratories and facilities to prevent unauthorised access to and removal of pathogenic or toxic material; and*
- *inclusion in textbooks and in medical, scientific and military educational programmes of information dealing with the prohibition of bacteriological (biological) and toxin weapons and the provisions of the Geneva Protocol*

*and believes that such measures which States might undertake in accordance with their constitutional process[es] would strengthen the effectiveness of the Convention.<sup>8</sup>*

12. In 1991, the Third Review Conference further developed the regime with the Article IV section of the Final Declaration<sup>9</sup> stating that:

*The Conference notes the importance of Article IV, under which each State Party shall, in accordance with its constitutional processes, take any necessary measures to prohibit or prevent any acts or actions which would contravene the Convention.*

*The Conference notes those measures already taken by some States Parties in this regard, for example the adoption of penal legislation, and reiterates its call to any State Party that has not yet taken any necessary measures to do so immediately, in accordance with its constitutional processes. Such measures should apply within the territory of a State Party, under its jurisdiction or under its control anywhere. The Conference invites each State Party to consider, if constitutionally possible and in conformity with international law, the application of such measures to actions taken anywhere by natural persons possessing its nationality.*

*The Conference notes the importance of:*

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<sup>8</sup>United Nations, *The Second Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, Geneva, 8–26 September 1986, Final Document, BWC/CONF.II/13/11, 26 September 1986, pp. 4-5. Available at <http://www.opbw.org> *Process* in the last line of this text seems to have been a typographic error in the Final Declaration carried through to the Final Document. It was corrected to *processes* when the 1986 text was repeated in 1991. The GDR proposal of 1986 (which used the plural *processes*) is reproduced in BWC/CONF.II/9 (22 September 1986), Annex, pp.16-17.

<sup>9</sup>United Nations, *The Third Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, Geneva, 9–27 September 1991, Final Document, BWC/CONF.III/23/Part II, 1992, pp.12-13. Available at <http://www.opbw.org> In this Briefing Paper by changing "States parties" to "States Parties", and by inserting capitals in the title of the BTWC, capitalization has been made consistent with UN practice as correctly applied in the Final Documents of 1980, 1986, 1996 and 2002.



- *Legislative, administrative and other measures designed effectively to enhance domestic compliance with the Convention;*
- *Legislation regarding the physical protection of laboratories and facilities to prevent unauthorized access to and removal of microbial or other biological agents, or toxins;*
- *Inclusion in textbooks and in medical, scientific and military educational programmes of information dealing with the prohibition of microbial or other biological agents or toxins and the provisions of the Geneva Protocol.*

*The Conference believes that such measures which States Parties might undertake in accordance with their constitutional processes would strengthen the effectiveness of the Convention.*

*The Conference notes that some States Parties, as requested by the Second Review Conference, have provided to the United Nations Department for Disarmament Affairs information on and texts of specific legislation enacted or other measures taken to assure domestic compliance with the Convention. The Conference invites these States Parties, and encourages all States Parties, to provide such information and texts in the future. In this regard the Conference welcomes agreement by the States Parties participating in the Third Review Conference to implement a new confidence-building measure entitled "Declaration of legislation, regulations and other measures". In addition, the Conference invites all States Parties to provide any useful information on the implementation of such measures.*

*The Conference welcomes regional measures such as the Mendoza Declaration as well as other initiatives dealing with the renunciation of weapons of mass destruction, including biological weapons, as concrete positive steps towards the strengthening of the Biological and Toxin Weapons Convention regime.*

13. The Third Review Conference thus continued the process of regime-building in this area, repeating the declarations of 1980 and 1986 and adding to them, notably, a new confidence-building measure entitled 'Declaration of legislation, regulations and other measures'.<sup>10</sup> The Annex contained the following on CBM "E":

6. *CONFIDENCE-BUILDING MEASURE "E"*

- *Declaration of legislation, regulations and other measures*

*At the Third Review Conference the States Parties agreed to implement the following:*

*As an indication of the measures which they have taken to implement the Convention, States Parties shall declare whether they have legislation, regulations or other measures:*

- (a) *to prohibit the development, production, stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons,*

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<sup>10</sup>BWC/CONF. III/22/Add. 2 (27 September 1991) pp 4-5, p 7.

*equipment and means of delivery, specified in Article I of the Convention, within their territory or anywhere under their jurisdiction or control;*

*(b) in relation to the export or import of micro-organisms pathogenic to man, animals and plants or of toxins in accordance with the Convention;*

*States Parties shall complete the attached form (Form E) and shall be prepared to submit copies of the legislation or regulations, or written details of other measures on request to the United Nations Department for Disarmament Affairs or to an individual State Party. On an annual basis States Parties shall indicate, also on the attached form, whether or not there has been any amendment to their legislation, regulations or other measures.*

Form E was elaborated as follows:

Form E

Declaration of legislation, regulations and other measures

<u>Relating to</u>	<u>Legislation</u>	<u>Regulations</u>	<u>Other measures</u>	<u>Amended since last year</u>
(a) <i>Development, production stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I</i>	YES/NO	YES/NO	YES/NO	YES/NO
(b) <i>Exports of micro-organisms* and toxins</i>	YES/NO	YES/NO	YES/NO	YES/NO
(c) <i>Imports of micro-organisms* and toxins</i>	YES/NO	YES/NO	YES/NO	YES/NO

14. The new CBM, labelled **E**, in the Annex<sup>11</sup> to the Final Declaration went beyond simply addressing those States Parties which **had** legislated or taken other implementing action in this area. It asked every State Party to complete a straightforward annual questionnaire answering four questions yes/no:

- do you have legislation?
- do you have regulations?
- do you have other measures?

\* Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

<sup>11</sup>United Nations, *The Third Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, Geneva, 9–27 September 1991, Final Document, BWC/CONF.III/23/Part II, 1992, Annex, pp.42-43. Available at <http://www.opbw.org>

- has there been any amendment since last year to your legislation, regulations or other measures?

These four questions were applied to three areas of policy, requiring twelve yes/no answers altogether. The first area of policy was the direct concern of Article IV with giving domestic legal effect to the prohibitions in Article I. The second and third were export and import control respectively, specified as the "*export or import of micro-organisms pathogenic to man, animals and plants or of toxins in accordance with the Convention.*" These export and import controls were of particular concern to the United Kingdom, which successfully proposed their insertion. The CBM would otherwise have been limited to making more universal and systematic the invitations issued in 1980, 1986 and 1991 with regard to giving domestic legal effect to the prohibitions in Article I, and sharing information. The CBM, however, shifts the emphasis from the sharing of texts -- although texts could still be requested -- to sharing information on the status of each State Party in terms of measures taken or not taken.

15. The information-sharing ambitions of the Third Review Conference in this area went further still. From 15 April 1992 States Parties, under Confidence-Building Measure **E**,

*shall be prepared to submit copies of the legislation or regulations or written details of other measures on request to the United Nations Department for Disarmament Affairs or to an individual State Party.*<sup>12</sup>

Each State Party can now, therefore, request these details **bilaterally** under the authority of the Third Review Conference, instead of depending solely upon the circulation of texts made available to the United Nations. This extension to provide for bilateral requests has not been recorded explicitly in any Final Declaration, but it is still one part of the politically binding requirement of CBM 'E'. It therefore represents one of the common understandings which have evolved out of Article IV. It could become more important as States Parties take a greater interest in the status and effectiveness of other States Parties' legislation, and whether it is sufficiently strong and comprehensive to contribute to security overall. They can check one another's legislative performance individually, and make their own assessment of its adequacy. The possibility of requesting these details bilaterally could be used to bring diplomatic pressure to bear on any State Party which was thought, by reason of the inadequacy of its national measures, to be leaving open loopholes which bioterrorists or others might exploit to the detriment of everyone's security. To "*be prepared to submit copies of the legislation or regulations or written details of other measures on request*" is to accept that these texts are of legitimate interest to individual States Parties and that their requests are in accord with the common understanding of what Article IV implies for each State Party.

16. The Fourth Review Conference in 1996 in the Article IV section of the Final Declaration<sup>13</sup> continued to strengthen the regime by stating that:

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<sup>12</sup>United Nations, *The Third Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, Geneva, 9–27 September 1991, Final Document, BWC/CONF.III/23/Part II, 1992, pp.12-13. Available at <http://www.opbw.org>

<sup>13</sup>United Nations, *The Fourth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, Final Document, Geneva, 25 November - 6 December 1996, BWC/CONF.IV/9, 1996, Part II. pp. 17-18. Available at <http://www.opbw.org>

1. The Conference underlines the importance of Article IV. It reaffirms the commitment of States Parties to take the necessary national measures under this Article, in accordance with their constitutional processes. These measures are to ensure the prohibition and prevention of the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention anywhere within their territory, under their jurisdiction or under their control, in order to prevent their use for purposes contrary to the Convention. The States Parties recognize the need to ensure, through the review and/or adoption of national measures, the effective fulfilment of their obligations under the Convention in order, *inter alia*, to exclude use of biological and toxin weapons in terrorist or criminal activity.

2. The Conference notes those measures already taken by a number of States Parties in this regard, for example the adoption of penal legislation, and reiterates its call to any State Party that has not yet taken any necessary measures to do so immediately, in accordance with its constitutional processes. Such measures should apply within its territory, under its jurisdiction or under its control anywhere. The Conference invites each State Party to consider, if constitutionally possible and in conformity with international law, the application of such measures also to actions taken anywhere by natural persons possessing its nationality.

3. The Conference notes the importance of:

- Legislative, administrative and other measures designed to enhance domestic compliance with the Convention;

- Legislation regarding the physical protection of laboratories and facilities to prevent unauthorized access to and removal of microbial or other biological agents, or toxins;

- Inclusion in textbooks and in medical, scientific and military education programmes of information dealing with the prohibitions and provisions contained in the Biological and Toxin Weapons Convention and the Geneva Protocol of 1925.

4. The Conference believes that such measures which States Parties might undertake in accordance with their constitutional processes would strengthen the effectiveness of the Convention, as requested by the Second and Third Review Conferences.

5. The Conference notes that some States Parties, as requested by the Second Review Conference, have provided to the United Nations Department for Disarmament Affairs information on the texts of specific legislation enacted or other measures taken to assure domestic compliance with the Convention. The Conference invites these States Parties, and encourages all States Parties, to provide such information and texts in the future. In this regard the Conference welcomes information provided by States Parties in response to the confidence-building measure agreed to at the Third Review Conference entitled "Declaration of legislation, regulations and other measures". In addition, the Conference encourages all States Parties to provide any useful information on the implementation of such measures.

6. *The Conference encourages cooperation and initiatives, including regional ones, towards the strengthening and implementation of the Biological and Toxin Weapons Convention regime.*

7. *The Conference reaffirms that under all circumstances the use of bacteriological (biological) and toxin weapons is effectively prohibited by the Convention.*

17. The opening paragraph not only said that the Conference "*underlines the importance*" rather than, as at the Third Review Conference, "*notes the importance*" of Article IV but it went on, unlike the simple single sentence in the Third Review Conference, to set out what the "*necessary measures*" required under Article IV should be:

*These measures are to ensure the prohibition and prevention of the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention anywhere within their territory, under their jurisdiction or under their control, in order to prevent their use for purposes contrary to the Convention.*

and went on to stress the importance of national measures in excluding the use of biological or toxin weapons in terrorist or criminal activity:

*The States Parties recognize the need to ensure, through the review and/or adoption of national measures, the effective fulfilment of their obligations under the Convention in order, inter alia, to exclude use of biological and toxin weapons in terrorist or criminal activity.*

18. The second paragraph used identical language to that of the Third Review Conference to note those measures already taken by some States in regard to the implementation of Article IV, such as the adoption of penal legislation, and reiterated its call to any State Party that had not yet taken any necessary measures to do so immediately. Such measures should apply within the territory of a State Party, under its jurisdiction or under its control anywhere. The Conference also invited each State Party to consider the application of such measures to actions taken anywhere by natural persons possessing its nationality.

19. The third and fourth paragraphs also used identical language to that of the Third Review Conference in also noting the importance of:

- *Legislative, administrative and other measures designed to enhance domestic compliance with the Convention;*

- *Legislation regarding the physical protection of laboratories and facilities to prevent unauthorised access to and removal of microbial or other biological agents, or toxins;*

- *Inclusion in textbooks and in medical, scientific and military educational programmes of information dealing with the prohibition of microbial or other biological agents or toxins and the provisions of the Geneva Protocol of 1925.*

and that such measures would strengthen the effectiveness of the Convention.

20. The fifth paragraph also used identical language to that of the Third Review Conference in noting that some States Parties, as requested by the Second Review Conference (and before then by the First Review Conference), had provided to the United Nations Department for Disarmament Affairs information on and the texts of specific legislation enacted or other measures taken to assure domestic compliance with the Convention. The Conference invited these States Parties, and encouraged all States Parties, to provide such information and texts in the future. The Conference also welcomed the information provided by States Parties in response to the agreement by States Parties participating in the Third Review Conference to implement a new confidence-building measure entitled "*Declaration of legislation, regulations and other measures.*" In addition the Conference invited all States Parties to provide any useful information on the implementation of such measures.

21. The sixth paragraph reflected a similar sense to the language in the corresponding paragraph in the Third Review Conference but used different more general language referring to "*cooperation and initiatives*":

*The Conference encourages cooperation and initiatives, including regional ones, towards the strengthening and implementation of the Biological and Toxin Weapons Convention regime.*

22. The final paragraph was new, having no parallel in the Third Review Conference, with language reaffirming that use is effectively prohibited by the Convention:

*The Conference reaffirms that under all circumstances the use of bacteriological (biological) and toxin weapons is effectively prohibited by the Convention.*

#### **The developing regime for Article IV**

23. The developments thus far of the regime for Article IV over the first four Review Conferences can usefully be summarised in tabular form using **bold** text to highlight the developments in successive Final Declarations. First in regard to the fundamental requirement in Article IV:

Article IV	<i>Each State Party to this Convention shall, in accordance with its constitutional processes, take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere.</i>
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1st Review Conference	<p><i>The Conference notes the provisions of Article IV, which requires each State Party to take any necessary measure to prohibit and prevent the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, within its territory, under its jurisdiction or under its control anywhere, and <b>calls upon all States Parties which have not yet taken any necessary measures in accordance with their constitutional processes to do so immediately.</b></i></p>
2nd Review Conference	<p><i>The Conference notes <b>the importance</b> of Article IV, under which each State Party <b>shall</b>, in accordance with its constitutional processes, take any necessary measures to prohibit or prevent any acts or actions which would contravene the Convention.</i></p> <p><i>The Conference calls upon all States Parties which have not yet taken any necessary measures in accordance with their constitutional processes, as required by the Article, to do so immediately.</i></p>
3rd Review Conference	<p><i>The Conference notes the importance of Article IV, under which each State Party shall, in accordance with its constitutional processes, take any necessary measures to prohibit or prevent any acts or actions which would contravene the Convention.</i></p> <p><i><b>The Conference notes those measures already taken by some States Parties in this regard, for example the adoption of penal legislation, and reiterates its call to any State Party that has not yet taken any necessary measures to do so immediately, in accordance with its constitutional processes. Such measures should apply within the territory of a State Party, under its jurisdiction or under its control anywhere. The Conference invites each State Party to consider, if constitutionally possible and in conformity with international law, the application of such measures to actions taken anywhere by natural persons possessing its nationality.</b></i></p>

4th Review Conference	<p>1. The Conference <b>underlines</b> the importance of Article IV. <b>It reaffirms the commitment of States Parties to take the necessary national measures under this Article, in accordance with their constitutional processes. These measures are to ensure the prohibition and prevention of the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention anywhere within their territory, under their jurisdiction or under their control, in order to prevent their use for purposes contrary to the Convention. The States Parties recognize the need to ensure, through the review and/or adoption of national measures, the effective fulfilment of their obligations under the Convention in order, <u>inter alia</u>, to exclude use of biological and toxin weapons in terrorist or criminal activity.</b></p> <p>2. The Conference notes those measures already taken by a number of States Parties in this regard, for example the adoption of penal legislation, and reiterates its call to any State Party that has not yet taken any necessary measures to do so immediately, in accordance with its constitutional processes. Such measures should apply within its territory, under its jurisdiction or under its control anywhere. The Conference invites each State Party to consider, if constitutionally possible and in conformity with international law, the application of such measures also to actions taken anywhere by natural persons possessing its nationality.</p>
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24. Secondly, in regard to the provision of texts of legislation and other regulatory measures for the purposes of consultation:

1st Review Conference	<p>The Conference invites States Parties which have found it necessary to enact specific legislation or take other regulatory measures relevant to this Article to make available the appropriate texts to the United Nations Centre for Disarmament, for the purposes of consultation.</p>
2nd Review Conference	<p>The Conference <b>notes that</b> States Parties, as requested by the First Review Conference, <b>have provided to the United Nations Department for Disarmament Affairs information on and the texts of specific legislation enacted or other regulatory measures taken by them, relevant to this article.</b> The Conference invites States Parties to <b>continue to provide such information and texts to the United Nations Department for Disarmament Affairs for purposes of consultation.</b></p>



3rd Review Conference	<p><i>The Conference notes that <b>some States Parties</b>, as requested by the Second Review Conference, have provided to the United Nations Department for Disarmament Affairs information on and texts of specific legislation enacted or other measures taken to <b>assure domestic compliance with the Convention</b>. The Conference invites <b>these States Parties, and encourages all States Parties</b>, to provide such information and texts <b>in the future</b>. <b>In this regard the Conference welcomes agreement by the States Parties participating in the Third Review Conference to implement a new confidence-building measure entitled "Declaration of legislation, regulations and other measures"</b>. <b>In addition, the Conference invites all States Parties to provide any useful information on the implementation of such measures.</b></i></p>
4th Review Conference	<p><i>5. The Conference notes that some States Parties, as requested by the Second Review Conference, have provided to the United Nations Department for Disarmament Affairs information on the texts of specific legislation enacted or other measures taken to assure domestic compliance with the Convention. The Conference invites these States Parties, and encourages all States Parties, to provide such information and texts in the future. In this regard the Conference welcomes <b>information provided by States Parties in response to the confidence-building measure agreed to at the Third Review Conference entitled "Declaration of legislation, regulations and other measures"</b>. In addition, the Conference encourages all States Parties to provide any useful information on the implementation of such measures.</i></p>

25. Thirdly, in regard to the wider range of national implementation actions which were given international commendation first at the Second Review Conference:

2nd Review Conference	<p><i>The Conference notes the importance of</i></p> <ul style="list-style-type: none"> <li>- <i>legislative, administrative and other measures designed effectively to guarantee compliance with the with the provisions of the Convention within the territory under the jurisdiction or control of a State Party;</i></li> <li>- <i>legislation regarding the physical protection of laboratories and facilities to prevent unauthorised access to and removal of pathogenic or toxic material; and</i></li> <li>- <i>inclusion in textbooks and in medical, scientific and military educational programmes of information dealing with the prohibition of bacteriological (biological) and toxin weapons and the provisions of the Geneva Protocol</i></li> </ul> <p><i>and believes that such measures which States might undertake in accordance with their constitutional process would strengthen the effectiveness of the Convention.</i></p>
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3rd Review Conference	<p><i>The Conference notes the importance of:</i></p> <ul style="list-style-type: none"> <li>- <i>Legislative, administrative and other measures designed effectively to enhance domestic compliance with the Convention;</i></li> <li>- <i>Legislation regarding the physical protection of laboratories and facilities to prevent unauthorized access to and removal of microbial or other biological agents, or <b>toxins</b>;</i></li> <li>- <i>Inclusion in textbooks and in medical, scientific and military educational programmes of information dealing with the prohibition of microbial or other biological agents or toxins and the provisions of the Geneva Protocol.</i></li> </ul> <p><i>The Conference believes that such measures which States Parties might undertake in accordance with their constitutional processes would strengthen the effectiveness of the Convention.</i></p>
4th Review Conference	<p><i>3. The Conference notes the importance of:</i></p> <ul style="list-style-type: none"> <li>- <i>Legislative, administrative and other measures designed to enhance domestic compliance with the Convention;</i></li> <li>- <i>Legislation regarding the physical protection of laboratories and facilities to prevent unauthorized access to and removal of microbial or other biological agents, or toxins:</i></li> <li>- <i>Inclusion in textbooks and in medical, scientific and military education programmes of information dealing with the prohibitions <b>and provisions contained in the Biological and Toxin Weapons Convention</b> and the Geneva Protocol of 1925.</i></li> </ul> <p><i>4. The Conference believes that such measures which States Parties might undertake in accordance with their constitutional processes would strengthen the effectiveness of the Convention, <b>as requested by the Second and Third Review Conferences.</b></i></p>

26. Finally, on cooperation and initiatives, including regional ones, which appeared first at the Third Review Conference:

3rd Review Conference	<i>The Conference welcomes regional measures such as the Mendoza Declaration as well as other initiatives dealing with the renunciation of weapons of mass destruction, including biological weapons, as concrete positive steps towards the strengthening of the Biological and Toxin Weapons Convention regime.</i>
4th Review Conference	<i>6. The Conference <b>encourages cooperation and initiatives, including regional ones</b>, towards the strengthening <b>and implementation</b> of the Biological and Toxin Weapons Convention regime.</i>

There was also a single paragraph on use which first appeared at the Fourth Review Conference:

4th Review Conference	<i>7. The Conference reaffirms that under all circumstances the use of bacteriological (biological) and toxin weapons is effectively prohibited by the Convention.</i>
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### The New Process

27. The above is thus the background to the new process under which the expert meeting and the meeting of States Parties in 2003 will consider:

*i. The adoption of necessary, national measures to implement the prohibitions set forth in the Convention, including the enactment of penal legislation;*

28. This topic addresses a number of useful elements:

a. The **adoption** of such measures. For an effective regime to implement the BTWC, it is vital that **all** States Parties have indeed adopted such measures. The experience of the CWC is such that it is probable that only some of the States Parties will have adopted such measures. This element should be extended to consider the provision of assistance to States Parties in their adoption of necessary measures -- and attention might usefully be directed to examining the potential for a model law that addresses both national measures required for the BTWC and the measures required for the Cartagena Protocol on Biosafety -- the model law developed by the OPCW and the Association of Caribbean States to implement the CWC and the Rotterdam Prior Informed Consent Convention is a useful precedent. In addition, given the international concerns about terrorism and the need for strengthened national anti-terrorism legislation, this could provide another model whereby both the BTWC prohibitions and those for anti-terrorism might be addressed in a composite national measure.

b. National measures to implement the **prohibitions** set forth in the Convention. There are essentially two sets of **prohibitions** which need to be addressed -- those in Article I and those in Article III. The prohibitions that need to be addressed are not limited just to the language in these Articles -- attention needs to be given to ensuring that the scope of the prohibitions is effective in addressing the extended understandings agreed by successive Review Conferences. Thus the Final

Declaration<sup>14</sup> of the Fourth Review Conference in regard to Article III *affirms that Article III is sufficiently comprehensive to cover any recipient whatsoever at international, national or subnational levels* and goes on in regard to its implementation to note *that States Parties should also consider ways and means to ensure that individuals or subnational groups are effectively prevented from acquiring, through transfers, biological agents and toxins for other than peaceful purposes.*

c. The **effectiveness** of these national measures. The next element is to address what national measures are **necessary** to implement these prohibitions effectively -- and to ensure that these national measures are effective in their comprehensive capturing of the prohibitions. These national measures need to apply to national biodefence programmes and there must be no exclusions of military personnel or of military programmes.

d. The **applicability** of such national measures. The Convention requires that such measures should apply within its territory, under its jurisdiction or under its control anywhere. In addition, it should be recalled that the Final Declaration of the Fourth Review Conference had invited *each State Party to consider, if constitutionally possible and in conformity with international law, the application of such measures also to actions taken anywhere by natural persons possessing its nationality.*

e. Inclusion of the enactment of **penal legislation**. Successive Review Conferences have adopted language that encourages States Parties to consider penal legislation -- for example, the Fourth Review Conference Final Declaration language in the Article IV section states that *"The Conference notes those measures already taken by a number of States Parties in this regard, for example the adoption of penal legislation, and reiterates its call to any State Party that has not yet taken any necessary measures to do so immediately, in accordance with its constitutional processes."* [Emphasis added]

## **Input on national measures**

29. This section of the Briefing Paper provides an example, by drawing on the legislation and other regulatory measures for one State Party, of the input on national measures that all States Parties should be able to make, preferably **prior**, to the expert meeting to be held in 2003. The essential elements for effective national legislation and regulation include the following:

- a. The enactment of the basic prohibitions of the BTWC into national legislation;
- b. Regulatory measures relating to biological agents and toxins; such measures are likely to include considerations relating to health and safety, to those working with the biological agents and toxins, to security of the biological agents and toxins, to protection of the environment, and to control of transfers, both nationally and internationally. Many such regulatory measures will have been adopted primarily for

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<sup>14</sup>United Nations, *The Fourth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, Final Document, Geneva, 25 November - 6 December 1996, BWC/CONF.IV/9, 1996, Part II. pp. 16-17. Available at <http://www.opbw.org>

reasons unconnected with the implementation of the BTWC yet they contribute directly to the effective national implementation of the Convention.

### ***National Legislation***

30. An example of this is the United Kingdom's Biological Weapons Act<sup>15</sup> enacted in 1974 which sets out that:

*No person shall develop, produce, stockpile, acquire or retain--*

*(a) any biological agent or toxin of a type and in a quantity that has no justification for prophylactic, protective or other peaceful purposes; or*

*(b) any weapon, equipment, or means of delivery designed to use biological agents or toxins for hostile purposes or in armed conflict.*

It goes on to define biological agent and toxin by stating that:

*In this section--*

*"biological agent" means any microbial or other biological agent; and  
"toxin" means any toxin, whatever its origin or method of production.*

and then setting out the penalty that:

*Any person contravening this section shall be guilty of an offence and shall, on conviction on indictment, be liable to imprisonment for life.*

31. It will be noted that the language used in the Biological Weapons Act very closely parallels that in Article I of the Convention:

### ***Article I***

*Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain:*

*(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.*

32. The Australian Crimes (Biological Weapons) Act 1976<sup>16</sup> also uses language that is closely similar to that in Article I of the Convention to set out the prohibition that:

*It is unlawful to develop, produce, stockpile, acquire or retain:*

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<sup>15</sup>United Kingdom, Biological Weapons Act 1974. Available at <http://www.opbw.org>

<sup>16</sup>Australia, Crimes (Biological Weapons) Act 1976. Available at <http://www.opbw.org>

(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; or*

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

### **Regulatory Measures**

33. A comprehensive tabulation of UK legislative and regulatory measures relating to the Biological and Toxin Weapons Convention was provided in a tabulation submitted by the Foreign & Commonwealth Office to the House of Commons Select Committee on Foreign Affairs and published in the Report of that committee issued on 3rd December 2002<sup>17</sup>. The 10 page tabulation sets out legislative and regulatory measures for some 71 activities under the following headings:

BTWC	12 activities
Export Controls	9 activities
Handling of Agents and Toxins	28 activities
Genetic Work	10 activities
Other Issues	12 activities

Most of the specific pieces of legislation or regulatory measures referred to in the tabulation are available on the web<sup>18</sup>. In this Briefing Paper, the principal measures relating to the handling of biological agents, to genetic work and to export controls are outlined below.

### **Regulatory Measures: Handling of Biological Agents**

34. It needs to be recognised that the regulations relating to pathogens that can cause human disease are aimed at protecting the health of those working with such agents and of those who may be exposed to such agents because of such work activities. The regulations relating to animal and plant pathogens are aimed at preventing the spread of such diseases in the country and at preventing their release into the environment.

35. **Human pathogens.** An example of the regulatory measures regarding human pathogens is the United Kingdom Control of Substances Hazardous to Health Regulations, 2002<sup>19</sup>. The regulations are intended to protect both workers and others who may be exposed from work activities from the risks of hazardous substances. In the context of the regulations, hazardous substances are anything which can harm health if they are not adequately controlled. Consequently, all pathogens and toxins are covered by these regulations.

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<sup>17</sup>United Kingdom, House of Commons, Foreign Affairs Committee, *The Biological Weapons Green Paper*, First Report of Session 2002-03, issued 3rd December 2002, pp. Ev 25 -- 34. Available at <http://www.publications.parliament.uk/pa/cm200203/cmselect/cmcaff/150/150.pdf>

<sup>18</sup>See, for example, under national legislation implementation on <http://www.opbw.org>

<sup>19</sup>United Kingdom, Control of Substances Hazardous to Health Regulations, 2002, Statutory Instrument S.I. 2002/2677. Available at <http://www.opbw.org>

36. The development of these regulatory measures in respect of biological agents was addressed in paragraphs 5 to 13 of a Briefing Paper issued in March 1998<sup>20</sup>. The 2002 COSHH regulations define biological agent as:

*"biological agent" means a micro-organism, cell culture or human endo-parasite, whether or not genetically modified, which may cause infection, allergy, toxicity or otherwise create a hazard to human health"*

The basic approach in regard to substances hazardous to health, including biological agents, adopted in the COSHH regulations comprises of the following elements:

- a. Assessment of risk to health created by work involving substances hazardous to health;
- b. Prevention or control of exposure to substances hazardous to health;
- c. Use of control measures, etc;
- d. Maintenance, examination and testing of control measures;
- e. Monitoring of exposure at the workplace
- f. Health surveillance
- g. Information, instruction and training for persons who may be exposed to substances hazardous to health;
- h. Arrangements to deal with accidents, incidents and emergencies;

Additional requirements apply to work with biological agents including:

- a. Classification of biological agents;
- b. Special control measures for laboratories, animal rooms and industrial processes;
- f. List of employees exposed to certain biological agents (in Group 3 and Group 4);
- g. Notification of the use of biological agents (in Groups 2, 3 and 4);
- h. Notification of the consignment of biological agents (in Group 4);

37. Biological agents are categorized into four hazard Groups:

**Group 1** - unlikely to cause human disease;

**Group 2** - can cause human disease and may be a hazard to employees; it is unlikely to spread to the community and there is usually effective prophylaxis or treatment available;

**Group 3** - can cause severe human disease and may be a serious hazard to employees; it may spread to the community, but there is usually effective prophylaxis or treatment available;

**Group 4** - causes severe human disease and is a serious hazard to employees; it is likely to spread to the community and there is usually no effective prophylaxis or treatment available.

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<sup>20</sup>Graham S. Pearson, Article X: Further Building Blocks, University of Bradford, Department of Peace Studies, Briefing Paper No.7 (First Series), March 1998, paragraph 5 - 13. Available at <http://www.brad.ac.uk/acad/sbtwc>

An approved list of the categorisation to be applied to biological agents is issued by the Health and Safety Executive<sup>21</sup>.

38. The regulations also set out the minimum requirements for containment measures in facilities and laboratories handling such biological agents as follows:

- (a) level 2 for activities which involve working with a Group 2 biological agent;
- (b) level 3 for activities which involve working with a Group 3 biological agent;
- (c) level 4 for activities which involve working with a Group 4 biological agent;
- (d) level 2 for laboratories which do not intentionally propagate, concentrate or otherwise increase the risk of exposure to a biological agent but work with materials in respect of which it is unlikely that a Group 3 or Group 4 biological agent is present;
- (e) level 3 or 4, where appropriate, for laboratories which do not intentionally propagate, concentrate or otherwise increase the risk of exposure to a Group 3 or Group 4 biological agent but where the employer knows, or it is likely, that such a containment level is necessary; and
- (f) level 3 for activities where it has not been possible to carry out a conclusive assessment but where there is concern that the activity might involve a serious health risk for employees.

The basic requirement is thus that the containment level must match the hazard grouping of the agent as a minimum.

39. The COSHH 2002 requirements for containment levels include requirements regarding access and safe storage of biological agents as follows:

Containment measure	2	3	4
Access to be restricted to authorised persons only	Yes	Yes	Yes, via air-lock key procedure
Safe storage of biological agents	Yes	Yes	Yes, secure storage

40. The requirement for keeping a list of employees exposed to agents in Group 3 and Group 4 is detailed as follows:

***List of employees exposed to certain biological agents***

*4. - (1) Subject to sub-paragraph (2), every employer shall keep a list of employees exposed to a Group 3 or Group 4 biological agent, indicating the type of work done*

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<sup>21</sup>The latest approved list took effect from 1 February 2000 and is available in Health and Safety Executive, Advisory Committee on Dangerous Pathogens, *Second supplement to: Categorisation of biological agents according to hazard and categories of containment*. 2000. Available at <http://www.hse.gov.uk/hthdir/noframes/biolhaz.htm>



*and, where known, the biological agent to which they have been exposed, and records of exposures, accidents and incidents, as appropriate.*

*(2) Sub-paragraph (1) shall not apply where the results of the risk assessment indicate that -*

- (a) the activity does not involve a deliberate intention to work with or use that biological agent; and*
- (b) there is no significant risk to the health of employees associated with that biological agent.*

*(3) The employer shall ensure that the list or a copy thereof is kept available in a suitable form for at least 40 years from the date of the last entry made in it.*

*(4) The relevant doctor referred to in regulation 11, and any employee of that employer with specific responsibility for the health and safety of his fellow employees, shall have access to the list.*

*(5) Each employee shall have access to the information on the list which relates to him personally.*

41. The requirement for notification of first use is set out as follows:

#### ***Notification of the use of biological agents***

*5. - (1) Subject to sub-paragraphs (7) and (8), an employer shall not use for the first time one or more biological agents in Group 2, 3 or 4 at particular premises for any of the activities listed in paragraph 3(3) unless he has -*

- (a) notified the Executive in writing of his intention to do so at least 20 working days in advance, or such shorter period as the Executive may allow;*
- (b) furnished with that notification the particulars specified in sub-paragraph (5); and*
- (c) received the acknowledgement required by sub-paragraph (4).*

*(2) Subject to sub-paragraphs (7) and (9), an employer shall not use a biological agent which is specified in Part V of this Schedule, except where the use of that agent has been notified to the Executive in accordance with sub-paragraph (1), for any of the activities listed in paragraph 3(3) unless he has -*

- (a) notified the Executive in writing of his intention to do so at least 20 working days in advance, or such shorter period as the Executive may allow;*
- (b) furnished with that notification the particulars specified in sub-paragraph (5); and*
- (c) received the acknowledgement required by sub-paragraph (4).*

*(3) The Executive may accept a single notification under sub-paragraph (2) in respect of the use of more than one biological agent by the same person.*

*(4) Upon receipt of the notification required by sub-paragraph (1) or (2), the Executive shall, within 20 working days -*

- (a) send to the notifier an acknowledgement of receipt; or*
- (b) if the notification does not contain all of the particulars specified in sub-paragraph (5) -*
  - (i) inform the notifier in writing of the further particulars required, and*
  - (ii) within 10 working days of receipt of those further particulars, send to the notifier an acknowledgement of receipt.*

*(5) The particulars to be included in the notification referred to in sub-paragraphs (1) and (2) shall be -*

- (a) the name and address of the employer and the address of the premises where the biological agent will be stored or used;*
- (b) the name, qualifications and relevant experience of any employee of that employer with specific responsibility for the health and safety of his fellow employees;*
- (c) the results of the risk assessment;*
- (d) the identity of the biological agent and, if the agent does not have an approved classification, the Group to which the agent has been assigned; and*
- (e) the preventive and protective measures that are to be taken.*

*(6) Where there are changes to processes, procedures or the biological agent which are of importance to health or safety at work and which render the original notification invalid the employer shall notify the Executive forthwith in writing of those changes.*

*(7) Sub-paragraphs (1) and (2) shall not apply in relation to a biological agent where an intention to use that biological agent has been previously notified to the Executive in accordance with the Genetically Modified Organisms (Contained Use) Regulations 2000.*

*(8) The requirement in sub-paragraph (1) to notify first use of a biological agent in Group 2 or 3 shall not apply to an employer whose only use of that agent is in relation to the provision of a diagnostic service provided that use will not involve a process likely to propagate, concentrate or otherwise increase the risk of exposure to that agent.*

*(9) The requirement in sub-paragraph (2) to notify use of a biological agent specified in Part V of this Schedule shall not apply to an employer whose only use of that agent is in relation to the provision of a diagnostic service provided that use will not involve a process likely to propagate, concentrate or otherwise increase the risk of exposure to that agent.*

42. The requirement for notification of the consignment of biological agents is set out as:

***Notification of the consignment of biological agents***

*6. - (1) An employer shall not consign a Group 4 biological agent or anything containing, or suspected of containing, such an agent to any other premises, whether or not those premises are under his ownership or control, unless he has notified the Executive in writing of his intention to do so at least 30 days in advance or before*

*such shorter time as the Executive may approve and with that notification has furnished the particulars specified in sub-paragraph (4).*

*(2) Sub-paragraph (1) shall not apply where -*

- (a) the biological agent or material containing or suspected of containing such an agent is being consigned solely for the purpose of diagnosis;*
- (b) material containing or suspected of containing the biological agent is being consigned solely for the purpose of disposal; or*
- (c) the biological agent is or is suspected of being present in a human patient or animal which is being transported for the purpose of medical treatment.*

*(3) Where a Group 4 biological agent is imported into Great Britain, the consignee shall give the notice required by sub-paragraph (1).*

*(4) The particulars to be included in the notification referred to in sub-paragraph (1) shall be –*

- (a) the identity of the biological agent and the volume of the consignment;*
- (b) the name of the consignor;*
- (c) the address of the premises from which it will be transported;*
- (d) the name of the consignee;*
- (e) the address of the premises to which it shall be transported;*
- (f) the name of the transport operator responsible for the transportation;*
- (g) the name of any individual who will accompany the consignment;*
- (h) the method of transportation;*
- (i) the packaging and any containment precautions which will be taken;*
- (j) the route which will be taken; and*
- (k) the proposed date of transportation.*

**43. Animal pathogens.** Different regulations apply in regard to animal and plant pathogens where the aim is to protect livestock and plants in the UK from disease. The development of these regulatory measures in respect of animal pathogens was addressed in paragraphs 14 to 16 of a Briefing Paper issued in March 1998<sup>22</sup>. The Specified Animal Pathogens Order (SAPO) 1998<sup>23</sup> entered into force on 1 April 1998 prohibits any person in Great Britain from having in his possession any specified animal pathogen or any carrier in which he knows such a pathogen is present except under the authority of a licence issued in writing by the appropriate Minister. The specified animal pathogens are those organisms listed in the Order causing serious epidemic diseases of farm livestock. The definition of disease is extended so as "*to comprise any disease of animals and poultry which may be caused by one or more specified animal pathogens.*" The specified animal pathogens include the following:

*Bacillus anthracis*  
*Brucella melitensis*  
*Brucella ovis*

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<sup>22</sup>Graham S. Pearson, Article X: Further Building Blocks, University of Bradford, Department of Peace Studies, Briefing Paper No.7 (First Series), March 1998, paragraph 14 - 16. Available at <http://www.brad.ac.uk/acad/sbtwc>

<sup>23</sup>United Kingdom, The Specified Animal Pathogens Order 1998, Statutory Instrument S.I. 1998/463. Available at <http://www.opbw.org>

*Brucella suis*  
*Eastern & Western equine encephalomyelitis viruses*  
*Foot and mouth disease virus*  
*Newcastle disease virus*  
*Rabies virus*  
*Rift Valley Fever virus*  
*Rinderpest virus*  
*Sheep pox and goat pox virus*  
*Venezuelan equine encephalomyelitis virus*

44. Laboratories holding and working with specified animal pathogens are subject to inspection to ensure that the containment conditions meet the requirements for the category of pathogen being held. Such inspections will be made prior to a licence being issued for the specified animal pathogen. These are categorized according to the risk that they pose to livestock and the environment. These categories are **not complementary** to the hazard groups for human pathogens (see para 35 above) which are for the protection of employees. The animal pathogen categories are for the purpose of protecting animal health from escapes of organisms from a laboratory and **not** protection of workers in that laboratory. The categories are:

- Group 1:** Disease-producing organism which are enzootic and do not produce notifiable disease.
- Group 2:** Disease producing organisms which are either exotic or produce notifiable disease, but have a low risk of spread from the laboratory.
- Group 3:** Disease producing organism which are either exotic or produce notifiable disease and have a moderate risk of spread from the laboratory.
- Group 4:** Disease producing organisms which are either exotic or produce a notifiable disease and have a high risk of spread from the laboratory.

45. **Plant pathogens.** The aim of British legislation is to prevent the importation into Great Britain of any plant pathogen or pest that is not already established in Great Britain. The development of these regulatory measures in respect of plant pathogens was addressed in paragraphs 17 to 22 of a Briefing Paper issued in March 1998<sup>24</sup>. Official controls that apply to the import, movement, and keeping of plants, plant pests and other material such as soil are laid down in the Plant Health (Great Britain) Order 1993<sup>25</sup> which entered into force on 1 June 1993 and prohibits the importing into Great Britain from a third country any infected plants or plant pests. Plant pests are defined in the Order as:

*""Plant pest" means pests of and harmful organisms liable to infect plants or plant products which belong to the animal or plant kingdoms, or which are viruses, mycoplasmas or other pathogens and includes genetically modified plant pests."*

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<sup>24</sup>Graham S. Pearson, *Article X: Further Building Blocks*, University of Bradford, Department of Peace Studies, Briefing Paper No.7 (First Series), March 1998, paragraph 17 - 22. Available at <http://www.brad.ac.uk/acad/sbtwc>

<sup>25</sup>United Kingdom, *The Plant Health (Great Britain) Order 1993*, Statutory Instrument S.I. 1993/1320. Available at <http://www.brad.ac.uk/acad/sbtwc>

The controlled pathogens and pests may only be imported into Great Britain for experimental purposes under a licence issued by the appropriate Minister.

46. Applications for a licence are required to be submitted at least one month before the licence is required. Issue of the licence will be subject, if necessary, to a prior inspection of the premises in which the material is to be kept. The licence will prescribe conditions that are designed to ensure that the material imported, moved or kept does not pose a risk to plant health. These will include instructions for the safe transport of licensed material, where and how it should be contained and arrangements for its safe disposal. After issue of a licence, licensed premises will be visited to monitor compliance with licence terms and conditions. The frequency of such visits will be influenced by factors such as the plant health risk associated with the type of material imported or kept. It is clear from the Order that an inspector on entering premises *"may take with him such other persons, including, but not limited to, representatives of the European Commission, and such equipment and vehicles as are necessary for the exercise of his powers..."*. The inspector also has rights to sample as the Order states that

*"an inspector ... may at all reasonable times ... for any other purpose of this Order, including checking compliance with it, enter any premises, examine and mark any part of the premises or any objects on the premises and examine, take samples of, photograph or mark any plant pest, plant, plant product or other object or anything which has been or may have been in contact therewith;"*

47. The Order also requires that an official register be kept containing the name and address of each business, individual or other organisation which applies for registration. Such organisations on the register are required to keep records and these are to be inspected at least once in each calendar year.

48. It is also made clear that although licensed material may be provided to persons or organizations within Great Britain who hold a relevant DEFRA (Department of the Environment, Food and Rural Affairs) licence, such material must not be made available to other persons or organisations without written agreement from the Plant Health Division for DEFRA who will make arrangements for the issue of phytosanitary certificates or plant passports or for endorsement of letters of authority.

49. The Order also lays down the requirements for the movement of otherwise prohibited material. The principal requirement is for a letter of authority to accompany all material imported under licence; this letter of authority is issued by the relevant Ministry, DEFRA. Where material covered by a licence and a letter of authority is imported from another member state in the European Community, it is the responsibility of the licensee, where possible, to have the letter of authority endorsed by the plant health authorities in that member state. In addition, the European Community measures require that in the case of certain plants, plant products and other objects originating in the Community, the material must be accompanied by a plant passport issued under the authority of the plant health services of the exporting member state; the plants to which this requirement applies are listed in Schedule 5, Part A of the Plant Health Order 1993. If certain plants, plant products or other objects are to be introduced from a third country (ie a country outside the Community) then the material must be accompanied wherever possible by a phytosanitary certificate issued in the country of origin; the plants to which this requirement applies are listed in Schedule 5, Part B of the Plant Health Order 1993.

50. The Order also includes the prohibition of the import, movement or keeping of any plant pest which has been genetically modified and any plant material that has been modified such that it contains material derived from a plant pest. Genetically modified plant pests are defined in the Order as:

*"genetically modified plant pest" means a plant pest, the genetic component of which has been modified, and includes -*

- a. organisms and material which contain such a plant pest or parts thereof, and*
- b. any other modified organisms likely to be injurious to plants..."*

The legislation also prohibits any activity that involves genetic modification of a plant pest as it states that:

*"No person shall without the authority of an inspector engage in any activity which involves genetic modification of a plant pest or engage in any activity which to his knowledge involves genetically modified plant pests."*

### ***Regulatory Measures: Security of Biological Agents***

51. Additional requirements addressing the security of biological agents were enacted in the United Kingdom in the *Anti-Terrorism, Crime and Security Act 2001*<sup>26</sup> which includes as *Part 7 Security of Pathogens and Toxins*. This includes the following elements:

- a. Duty to notify Secretary of State before keeping or using any dangerous substance;
- b. Power to require information about security of dangerous substances;
- c. Power to require information about persons with access to dangerous substances;
- d. Duty to comply with security directions;
- e. Duty to dispose of dangerous substances;
- f. Denial of access to dangerous substances;

Part 7 sets out the pathogens and toxins to which these requirements apply as being those pathogens and toxins listed in Schedule 5 to the Act and includes provision for the Secretary of State to add any pathogen or toxin to that Schedule if he is satisfied that the pathogen or toxin is capable of endangering life or causing serious harm to human health. The term "dangerous substance" is defined as meaning anything which consists of or includes a substance for the time being mentioned in Schedule 5 as well as anything which is infected with or otherwise carries any such substance.

52. The Act also includes the power to extend the requirements to animal or plant pathogens, pests or toxic chemicals. This extension may be exercised in relation to any pathogen or pest only if the Secretary of State is satisfied that there is a risk that the pathogen or pest is of a description that could be used to cause:

- a. widespread damage to property;

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<sup>26</sup>United Kingdom, *Anti-Terrorism, Crime and Security Act 2001*. Available at <http://www.opbw.org> and at <http://www.legislation.hmso.gov.uk/acts/acts2001/10024>

- b. significant disruption to the public; or
- c. significant alarm to the public.

In respect of chemicals, this extension may be exercised in relation to any chemical only if the Secretary of State is satisfied that the chemical is capable of endangering life or causing serious harm to human health.

53. The detailed provisions include the following:

- a. The notification before keeping or using any dangerous substance must:
  - (a) identify the premises in which the substance is kept or used;
  - (b) identify any building or site of which the premises form part;
- b. The information about security of dangerous substances includes both
  - (a) measures taken to ensure the security of any building or site of which the premises form part; and
  - (b) measures taken for the purpose of ensuring access to the substance is given only to those whose activities require access and only in circumstances that ensure the security of the substance.
- c. The information required about persons with access to dangerous substances includes a list of-
  - (a) each person who has access to any dangerous substance kept or used there;
  - (b) each person who, in such circumstances as are specified or described in the notice, has access to such part of the premises as is so specified or described;
  - (c) each person who, in such circumstances as are specified or described in the notice, has access to the premises; or
  - (d) each person who, in such circumstances as are specified or described in the notice, has access to any building or site of which the premises form part.
- d. Denial of access to dangerous substances. The provisions set out that "*the Secretary of State may give directions to the occupier of any relevant premises requiring him to secure that the person identified in the directions:*
  - (a) *is not to have access to any dangerous substance kept or used there;*
  - (b) *is not to have, in such circumstances (if any) as may be specified or described in the directions, access to such part of the premises as is so specified or described;*
  - (c) *is not to have, in such circumstances (if any) as may be specified or described in the directions, access to the premises; or*
  - (d) *is not to have, in such circumstances (if any) as may be specified or described in the directions, access to any building or site of which the premises form part."*

### ***Regulatory Measures: Genetic Modification***

54. An example of the regulatory measures relating to genetic modification are the UK Genetically Modified Organisms (Contained Use) Regulations 2000<sup>27</sup> which entered into force on 15 November 2000 and UK Genetically Modified Organisms (Deliberate Release) Regulations 2002<sup>28</sup> which entered into force on 17 October 2002. These Regulations implemented in the United Kingdom the corresponding EC Directives.

55. The contained use regulations set out the requirements for:

- a. Risk assessment and notification of activities involving genetic modification which include:
  - i. Notification of the intention to use premises for the first time for activities involving genetic modification;
  - ii. Notification of class 2 activities involving genetic modification of micro-organisms;
  - iii. Notification of class 3 or 4 activities involving genetic modification of micro-organisms;
- b. Conduct of activities involving genetic modification which includes containment and control measures for activities involving genetic modification of micro-organisms;

The classes of activity involving genetic modification are set out as:

- **Class 1.** Activities of no or negligible risk for which containment level 1 is appropriate to protect humans and the environment.
- **Class 2.** Activities of low risk for which containment level 2 is appropriate to protect humans and the environment.
- **Class 3.** Activities of moderate risk for which containment level 3 is appropriate to protect humans and the environment.
- **Class 4.** Activities of high risk for which containment level 4 is appropriate to protect humans and the environment.

56. The notification of the intention to use premises for the first time in activities involving genetic modification requires that no such use shall take place until an acknowledgement has been received from the competent authority of the notification. In regard to notifications to carry out class 2 activities, an acknowledgement is required from the competent authority, whilst in respect of notifications to carry out class 3 or 4 activities, prior written consent is required from the competent authority.

57. The regulations also require that a person who undertakes an activity involving genetic modification shall ensure that:

- a. the exposure of humans and the environment to genetically modified micro-organisms is reduced to the lowest level that is reasonably practicable; and
- b. harm to humans arising from an activity involving genetic modification of organisms other than micro-organisms is reduced to the lowest level that is reasonably practicable;

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<sup>27</sup>United Kingdom, Genetically Modified Organisms (Contained Use) Regulations 2000, Statutory Instrument S.I. 2000/2831. Available at <http://www.hmso.gov.uk>

<sup>28</sup>United Kingdom, Genetically Modified Organisms (Deliberate Release) Regulations 2002, Statutory Instrument S.I. 2002/2443. Available at <http://www.opbw.org> and at <http://www.hmso.gov.uk>



It goes on to require that for any activity involving genetic modification of micro-organisms, the measures to be taken to comply with the above requirement shall include the general principles of good microbiological practice and of good occupational safety and hygiene as detailed in Schedule 7 to the regulations.

58. The regulations also require that a register be maintained of genetic modification activities which shall be open for inspection by members of the public. Provisions are included for the exclusion of certain information regarded as confidential from this register. In addition, an amendment<sup>29</sup> to the regulations which entered into force on 8th February 2002, provides for information to be made confidential in the interests of national security and thus excluded from the public register.

### ***Regulatory Measures: Export Controls***

59. Article III of the BTWC requires that:

*Each State Party to this Convention undertakes 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 this Convention.*

Successive Review Conferences have emphasised the importance of this Article and at the Fourth Review Conference, the States Parties in the Article III section of the Final Declaration<sup>30</sup> stated that:

*The Conference affirms that Article III is sufficiently comprehensive to cover any recipient whatsoever at international, national or subnational levels.*

60. There is thus a clear requirement for States Parties to take national measures to control transfers and thereby meet their obligations in Article III of the Convention. In the United Kingdom, this is achieved through the implementation of the European Council Regulation (EC) 1334/2000<sup>31</sup> which set up a community wide regime for the control of exports of dual-use items and technology. This Regulation as well as imposing controls on the export of dual-use equipment also imposes controls on exports of certain dual-use technology and in particular the technology required for the development, production or use of listed items. This also introduces a licensing requirement on both physical and electronic transfers of information. It includes an "end-use" control which applies to any dual-use items not included in the Annex to the Regulation where the exporter is informed by the Government are or may be intended for use in connection with a weapons of mass destruction or related missile programme. This WMD end-use control applies to both physical and electronic transfers of technology as well as to exports of goods. It should be noted that there are no

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<sup>29</sup>United Kingdom, Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2002, Statutory Instrument S.I. 2002/63. Available at <http://www.opbw.org> and at <http://www.hmsso.gov.uk>

<sup>30</sup>United Nations, *The Fourth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, Final Document, Geneva, 25 November - 6 December 1996, BWC/CONF.IV/9, 1996, Part II. p. 17. Available at <http://www.opbw.org>

<sup>31</sup>European Community, *Council Regulation (EC) No 1334/2000 of 22 June 2000 setting up a Community regime for the control of exports of dual-use items and technology*. Available at <http://www.opbw.org>

exemptions for information in the public domain or for basic scientific research with respect to the end-use control since all European Member states agreed that deliberately to send to a known WMD proliferator even a published book or article which might be of use to that WMD programme should require a licence.

61. The national implementation of this regime in the United Kingdom is currently through the Export of Goods (Control) Order of 1994<sup>32</sup> and the Dual-Use Items (Export Control) Regulations 2000<sup>33</sup> and its subsequent amendments in which the term "microorganisms" is defined as follows:

*"microorganisms" means bacteria, viruses, mycoplasmas, rickettsiae, chlamydiae or fungi, whether natural, enhanced or modified, either in the form of isolated live cultures or as material including living material which has been deliberately inoculated or contaminated with such cultures.*

and toxins as:

*"toxins" means toxins in the form of deliberately isolated preparations or mixtures, no matter how produced, other than toxins present as contaminants of other materials such as pathological specimens, crops, foodstuffs or seedstocks of microorganisms.*

The approach taken in the United Kingdom was outlined in considerable detail in Briefing Paper No. 12 (First Series)<sup>34</sup> of October 1998. It was noted in Briefing Paper No. 12 that the UK was currently considering revision of its legislation regarding Strategic Export Controls with a view to new primary legislation. It has subsequently been decided to introduce new primary legislation which was adopted by the passage of the Export Control Act 2002<sup>35</sup> on 24 July 2002. Action is currently being taken to introduce the secondary legislation to strengthen and modernise the United Kingdom's export control regime which will also include controls on transfers of technology by intangible means and on the provision of technical assistance abroad. It should be noted that there are no exemptions for information in the public domain or for basic scientific research with respect to the end-use control since all European Member states agreed that deliberately to send to a known WMD proliferator even a published book or article which might be of use to that WMD programme should require a licence.

## Conclusions

62. This Briefing Paper provides an input to the meetings of experts and of the States Parties by first collecting the relevant language from Final Declarations regarding national measures and analysing its progressive evolution theme by theme. It is strongly recommended that this language from previous Review Conference Final Declarations should be used as the basis for the *"conclusions or results"* of the experts meeting and the subsequent meeting of the States Parties. Those meetings will thereby be enabled to take forward the cumulative

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<sup>32</sup>United Kingdom, Export of Goods (Control) Order 1994, Statutory Instrument S.I. 1994/1191, 24 April 1994. Available at <http://www.opbw.org> and at <http://www.hmso.gov.uk>

<sup>33</sup>United Kingdom, Dual-Use Items (Export Control) Regulations 2000, Statutory Instrument S.I. 2000/2620, 20 September 2000. Available at <http://www.hmso.gov.uk>

<sup>34</sup>Graham S. Pearson, *Article III: Some Building Blocks*, University of Bradford, Department of Peace Studies, Briefing Paper No.12 (First Series), October 1998, paragraphs 10 - 32. Available at <http://www.brad.ac.uk/acad/sbtwc>

<sup>35</sup>United Kingdom, Export Control Act 2002. Available at <http://www.hmso.gov.uk>

process of regime-building, through recording agreements among States Parties on common understandings with regard to the implications and implementation of Article IV. Having established this basis, recommendations should be added for promoting best practice, as evaluated by the new process. This will necessarily involve pooling the implementation experience of States Parties, as well as examining the text of their national measures, in the light of the need to capture comprehensively the BTWC prohibitions and to make them effective.

63. The Briefing Paper then provides an example, drawing largely on the legislation and other regulatory measures for one State Party, of the input on national measures that all States Parties should be able to make to the meetings. It is evident that in addition to national measures enacting the basic prohibitions of the BTWC into national legislation most States Parties will also have regulatory measures relating to biological agents and toxins; such measures are likely to relate to health and safety, to those working with the biological agents and toxins, to security of the biological agents and toxins, to protection of the environment, and to control of transfers, both nationally and internationally. Many such regulatory measures will have been adopted primarily for reasons unconnected with the implementation of the BTWC yet they contribute directly to the effective national implementation of the Convention and ensure that the prohibitions of Article III are implemented in addition to those of Article I. Consequently, all States Parties will have examples of national measures - - whether legislation, regulations or other measures -- which contribute to the effective implementation of the Convention and thus will contribute to the meetings in 2003 of the experts and of the States Parties. It is strongly recommended that all States Parties provide information and copies of their legislation, regulations and other measures of BTWC national implementation to the Secretariat in Geneva **prior** to the experts meeting.