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ARTICLE III : SOME BUILDING BLOCKS

by Graham S. Pearson

Introduction

1. Article III of the Biological and Toxin Weapons Convention (BTWC) states 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 the Convention.

The Final Declaration¹ of the Fourth Review Conference of the BTWC held on 25 November to 6 December 1996 stated in respect of Article III that:

"The Conference notes the importance of Article III and welcomes the statements which States that have acceded to the Convention have made to the effect that they have not transferred agents, toxins, weapons, equipment, or means of delivery, specified in Article I of the Convention, to any recipient whatsoever and have not furnished assistance, encouragement, or inducement to any State, group of States or international organizations to manufacture or otherwise acquire them. The Conference affirms that Article III is sufficiently comprehensive to cover any recipient whatsoever at international, national or subnational levels.

The Conference notes that a number of States Parties stated that they have already taken concrete measures to give effect to their undertakings under this Article, and in this context also notes statements made by States Parties at the Conference about the legislative or administrative measures they have taken since the Third Review Conference. The Conference calls for appropriate measures by all States parties. Transfers relevant to the Convention should be authorized only when the intended use is for purposes not prohibited under the Convention.

The Conference discussed the question whether multilaterally-agreed guidelines or multilateral guidelines negotiated by all States Parties to the Convention concerning the transfer of biological agents, materials and technology for peaceful purposes for any purpose whatsoever might strengthen the Convention. In the development of implementation of Article III, the Conference notes 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. The Conference notes that these issues are being considered as part of the ongoing process of strengthening the Convention.

The Conference reiterates that the provisions of this Article should not be used to impose restrictions and/or limitations on the transfers for purposes consistent with

¹United Nations, *The Fourth Review Conference of the Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, Geneva 25 November - 6 December 1996, Final Report, BWC/CONF.IV/9, Geneva, 1996.

the objectives and the provisions of the Convention of scientific knowledge, technology, equipment and materials under Article X."

2. It is to be noted that the third paragraph of the Fourth Review Conference Final Declaration replaced the single sentence in the Third Review Conference Final Declaration² which stated simply that:

"The implementation of this Article with respect to such transfers should continue to be the subject of multilateral consideration."

The expanded consideration by the Fourth Review Conference reflected both the ongoing consideration by the Ad Hoc Group (AHG) addressing measures to strengthen the effectiveness and the implementation of the Convention and the concern expressed by the G7 Heads of State and Government in June 1996 in their declaration on terrorism³ when they stated that *"Special attention should be paid to the threat of utilization of nuclear, biological and chemical materials, as well as toxic substances, for terrorist purposes."*

3. This Briefing Paper considers the provisions for the strengthening of Article III in the current version of the draft Protocol for the strengthening of the BTWC being negotiated by the Ad Hoc Group in the light of some of the developments that have occurred nationally and regionally in respect of export controls of hazardous materials. Some international export control developments are considered in Briefing Paper No 13⁴ which complements this one. It has become apparent that there is increasing awareness world-wide, both from security considerations and from public health and environmental concerns, that the transfer of hazardous materials needs to be controlled. These two Briefing Papers examine some of the current national export controls and regulations for such materials and the international initiatives that are ongoing to strengthen these around the world. These are seen as building blocks which might be considered from a point of view of strengthening the BTWC as well as contributing to the implementation of Article III. The challenging goal is to identify how these national, regional and international export control activities can be drawn upon to contribute to the strengthening of the BTWC.

Ad Hoc Group

4. The Final Report of the Special Conference of States Parties to the BTWC in September 1994⁵ stated that:

*"the Conference, determined to strengthen the effectiveness and **improve the implementation of the Convention** and recognizing that effective verification could reinforce the Convention, decides to establish an Ad Hoc Group, open to all States Parties. The objective of this Ad Hoc Group shall be to consider appropriate*

²United 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 Report, BWC/CONF.III/23, Geneva 1992.

³United Nations, Letter dated 5 July 1996 from the Permanent Representative of France to the United Nations addressed to the Secretary-General, A/51/208, S/1996/543, 12 July 1996.

⁴Graham S Pearson, *Article III : Further Building Blocks*, Briefing Paper No. 13, University of Bradford, October 1998. Available on <http://www.brad.ac.uk/acad/sbtwc>

⁵United Nations, *Special Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, Final Report, BWC/SPCONF/1 Geneva, 19–30 September 1994.

measures, including possible verification measures, and draft proposals to strengthen the Convention, to be included, as appropriate, in a legally binding instrument, to be submitted for the consideration of the States Parties." [Emphasis added]

The Ad Hoc Group in its meetings has included consideration of measures to improve the implementation of Article III of the Convention. These have included measures for the declaration of transfers, guidelines for transfers, provisions for an investigation where there is a concern that a transfer has taken place in violation of Article III of the Convention, and for a Confidence-Building Measure. The following provisions are contained in the current version⁶ of the draft Protocol.

5. Declarations. Article III of the Protocol which addresses Compliance Measures contains in Section D Declarations the following language on transfers:

[(H) TRANSFERS

18. Each State Party shall declare annually all international transfers of listed agents or toxins, equipment [or means of delivery].

19. Each State Party declaring such transfers shall submit information according to the format in Annex...]

6. Transfer Guidelines. A subsequent section of Article III of the Protocol which addresses Compliance Measures is Section F Visits and Investigations which includes the following guidelines on transfers:

[II. [MEASURES TO STRENGTHEN THE IMPLEMENTATION OF ARTICLE III]

[1. States Parties, in order to ensure compliance with Article III of the BTWC, shall only transfer dual-use microbial and other biological agents, toxins and equipment for purposes not prohibited by the Convention, in accordance with the following guidelines.

2. In pursuance of paragraph 1, and recognizing that most of the agents, toxins, equipment and technologies are of a dual-use nature and with the objective of preventing dual-use items from being utilized for purposes prohibited by BTWC, the guidelines shall be as follows:

(a) Any request made by a State Party for the procurement of a specific agent/toxin reagent shall be accompanied by information on purpose, quantity required, site or facility for proposed use, quantity to be produced at the site or facility, place where intended to be stored and end-use certificate;

(b) Any request for transfer or procurement of equipment envisaged to be declared under CBMs, for use by a State participating in the compliance regime in a BL4 facility, including details of its proposed application and the site/facility for intended use, shall be intimated to [the BTWC Organization];

⁶United Nations, *Procedural Report of the Ad Hoc Group of the States Parties to the Convention on the prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, BWC/AD HOC GROUP/41, 16 July 1998.

(c) Any transfer of technology related to delivery systems, aerosol dispersion of toxins and pathogens, stabilization of agents/toxins to environmental stress shall be intimated to [the BTWC Organization];

(d) Transfer of agents, equipment and material shall not be allowed to non-States Parties of the compliance regime under the Convention without prior approval of [the BTWC Organization].]

[3. (a) To ensure compliance with Article III of the BTWC, [no] [each] State Party shall [only] authorize transfers to any recipient whatsoever, of microbial or other biological agents, or toxins whatever their origin or method of production, or equipment which [is capable of using such agents or toxins for hostile purposes] [can be used in contravention of Article I of the Convention], [unless that State Party has] [if it is] determined that these will be used solely for prophylactic, protective or other peaceful purposes.

(b) (i) Each State Party shall report to [the Organization] on the national laws and regulations it has adopted to implement Article III of the BTWC not later than [...] days after the entry into force of this Protocol for that State Party and whenever an amendment thereto is made.

(ii) Each State Party shall report to [the Organization] on its administrative and other national measures to implement Article III of the BTWC not later than [...] days after the entry into force of this Protocol for that State Party and whenever an amendment thereto is made.

[(iii) Such reports shall contain detailed information. If available, the information contained in these reports may be subject to examination during a visit under the Article I investigation procedures of this Protocol.]

[(c) No transfer of microbial or other biological agents or toxins, whatever their origin or method of production, or equipment which is capable of using such agents or toxins for [hostile purposes] [for purposes which would contravene Article I of the Convention], shall be allowed to non-States Parties of the Convention and the Protocol.]

[(d) Each State Party, in implementing these measures, shall ensure that they do not impede the peaceful economic and technological development of States.]]

[4. [Proposed] Transfer guidelines

(a) The provisions of the Convention shall not be used to impose restrictions and/or limitations on the transfer of scientific knowledge, technology, equipment and materials for purposes not prohibited under the Convention.

(b) In order to promote transparency in the biological trade, the States Parties may agree on arrangements for exchanging the end-user certificate related to biological exports in a manner that will entail no restrictions or impediments on access to biological materials, equipment or technological information by all States Parties. This would replace all existing ad hoc regulations in the biological trade at the time of entry into force of the Protocol for States Parties.

(c) An end-user certificate may be required from the recipients stating, in relation to the transferred biological agents or toxins and equipment (to be identified as relevant by the Ad Hoc Group), the following:

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

(ii) That they will not be retransferred without receiving the authorization from the supplier(s);

(iii) Their types and quantities;

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

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

(d) States Parties shall resolve suspicions arising from such transfers through the process of consultation and clarification in accordance with Article V of the Convention.]]

7. Investigations. Although there is mention in two places of investigations where there is a concern that a transfer has taken place in violation of Article III, there is no specific language to elaborate such investigations. In Article III of the Protocol on Compliance Measures, Section F on Visits and Investigations in III. Investigations includes under

(A) TYPES OF INVESTIGATION

[(3) Investigations where there is a concern that a transfer has taken place in violation of Article III of the Convention.]

Space is also provided for an Annex C which has a blank page under the heading of:

[MEASURES TO STRENGTHEN THE IMPLEMENTATION OF ARTICLE III].

Provision is also made in Annex D Investigations which has a blank page under the heading of:

IV. [INVESTIGATIONS WHERE THERE IS A CONCERN THAT A TRANSFER HAS TAKEN PLACE IN VIOLATION OF ARTICLE III OF THE CONVENTION]

8. Confidence-Building Measures. Annex G of the draft Protocol contains various Confidence-Building Measures which include:

III. DATA ON TRANSFERS AND TRANSFER REQUESTS AND ON PRODUCTION

As this measure is under consideration as a mandatory one in the Compliance Measures Friend of the Chair discussions, it should be further studied in the light of the outcome of those discussions.

1. Collection and survey of national export and import data (e.g. government and industrial production statistics, culture collection records and other relevant information going beyond declaration requirements and to be provided voluntarily by States Parties).

2. Collection

2.1 States Parties are requested to provide relevant information.

2.2 BTWC Organization is to collect relevant information from publicly available sources.

2.3 Confidentiality concerns need to be considered.

3. Survey

3.1 Management, categorization and synthesis.

3.2 To be carried out by personnel with specific expertise, relying on information technology.

3.3 Survey will have to be focused.

4. Sources of information

4.1 Trade publications.

4.2 Specific statistical data.

4.3 Regulations and other measures (including control).

5. Information to be collected and surveyed

5.1 Key identifiers (triggers) should be used.

5.1.1 Same triggers as for transfer and production declarations.

5.1.2 Other possible triggers (e.g. for data collection under paragraph 2.2).

5.2 Information on

5.2.1 Suppliers and recipients.

5.2.2 Agents.

5.2.3 Equipment.

6. Modalities

6.1 States Parties are requested to provide information on an annual basis (collection of national data might require national regulation).

6.2 Organization is to collect and survey information continuously.

6.3 Information is to be provided

6.3.1 In one of the United Nations official languages.

6.3.2 In accordance with agreed format.

6.3.3 Preferably in computerized format (floppy disk).

9. Analysis. From examination of the successive versions of the draft Protocol it is evident that the language relating to measures to strengthen the implementation of Article III of the Convention has not received detailed consideration in recent sessions of the AHG. This

clearly reflects the sensitivity of the issue of export controls and the expressed contention that harmonization of export controls is hampering trade for peaceful purposes despite the lack of evidence to the contrary.⁷

National Controls of Transfers

10. Each State Party to the BTWC is required under the Convention to take appropriate national measures to implement their obligations under Article III. For the purposes of this Briefing Paper, the United Kingdom is used as an example of a State Party which meets this obligation through a system of export controls.

11. The UK political approach to export controls is summarised in a July 1998 White Paper on Strategic Export Controls issued by the UK Department of Trade and Industry in which the responsible Government Minister in her introduction⁸ states that:

"The power to control the export of goods and technology for strategic reasons is vital for any responsible Government committed to preventing the proliferation of weapons of mass destruction, protecting the security of the United Kingdom and of our EU partners and allies, and generally preventing armed aggression and internal repression."

The criteria applied to export controls by the UK were revised in July 1997 when the Foreign Secretary said⁹ that

*"Today I am announcing new criteria which the Government will apply to all licences for arms exports. They are **universal** criteria. They are not aimed at one country in particular, but **they will apply even-handedly to all countries.**"* [Emphasis added].

The statement sets out in detail the criteria to be used in considering export licence applications. Under the heading of the United Kingdom's international obligations, this states that an export licence should be refused if approval would be inconsistent with:

"a. The UK's international obligations and commitments to enforce United Nations, Organisation for Security and Co-operation in Europe and European Union arms embargoes, together with any national embargoes or other commitments regarding the application of strategic export controls;

*b. The UK's international obligations under the Nuclear Non-Proliferation Treaty, the **Biological Weapons Convention** and the Chemical Weapons Convention;*

*c. The UK's commitments to the international export control regimes--**the Australia Group, the Missile Technology Control Regime, the Nuclear Suppliers Group and the Wassenaar Arrangement;***

⁷Brad Roberts, *Article III -- Non-Transfer*, in Graham S Pearson & Malcolm R Dando (eds), *Strengthening the Biological Weapons Convention: Key Points for the Fourth Review Conference*, Quaker United Nations Office, Geneva, September 1996.

⁸Department of Trade and Industry, *Strategic Export Controls*, July 1998. Available on the web at <http://www.dti.gov.uk/export.control/stratex/>

⁹Robin Cook, Foreign Secretary, Statement to the House of Commons on export licensing, 28 July 1997. Available on the web at <http://www.dti.gov.uk/export.control/statement.htm>

d. The EU common criteria for arms exports, the guidelines for conventional arms transfers agreed by the permanent five members of the UN Security Council, and the OSCE principles governing conventional arms transfers;

e. The UK's commitment not to export all forms of anti-personnel land mines and their components." [Emphasis added]

12. The UK system of export controls for biological materials and equipment essentially comprises three elements:

- a. The control of biological agents "adapted for use in war" through the Export of Goods (Control) Orders EG(C)O,
- b. The control of a long list of human, animal and plant pathogens through the Dual Use and Related Goods (Export Control) Regulations DU(EC), and
- c. A catch-all provision which controls any goods which the exporter has reason to think may be associated with a weapon of mass destruction programme.

As might be expected the UK export controls have evolved over the years and have developed so as to take into account the former COCOM controls and more recently, the European Community regime for dual use goods. The EG(C)O have largely taken forward the previous COCOM controls into the Wassenaar Arrangement whilst the DU(EC) largely take forward the European Community regime for dual use goods. The various developments of the UK legislation can be listed under the two headings of Export Controls and Dual Use (with the dual use list including also the relevant European Union Regulations and Council Decisions):

Export Controls			Dual Use		
Title	Date	Type	Title	Date	Type
SI 1994/1191	24 Apr 1994	EG(C)O 94			
SI 1994/1632	17 Jun 1994	EG(C)O (A)			
SI 1994/2711	19 Oct 1994	EG(C)O (A3)			
			94/942/CFSP	19 Dec 1994	DUEC

			Regn 3381/94	19 Dec 1994	DUEC
			SI 1995/271	4 Feb 1995	DU(EC) 95
SI 1995/3249	14 Dec 1995	EG(C)O (A2)			
			96/613/CFSP	22 Oct 1996	DUEC
SI 1996/2663	18 Oct 1996	EG(C)O (A2)			
			SI 1996/2721	25 Oct 1996	DU(EC) 96
			97/100/CFSP	20 Jan 1997	DUEC
SI/1997/323	13 Feb 1997	EG(C)O (A)			
			SI/1997/324	13 Feb 1997	DU(EC)A
			SI/1997/1007	22 Mar 1997	DU(EC)A2
SI 1997/1008	19 Mar 1997	EG(C)O (A2)			
			97/419/CFSP	26 Jun 1997	DUEC
			SI 1997/1694	14 Jul 1997	DU(EC)A3
SI 1997/2758	19 Nov 1997	EG(C)O (A3)			
			SI 1997/2759	19 Nov 1997	DU(EC)A4
			98/106/CFSP	26 Jan 1998	DUEC
			SI 1998/272	11 Feb 1998	DU(EC)A
			SI 1998/899	26 Mar 1998	DU(EC)A2

13. Consequently UK export controls are detailed in the Export of Goods (Control) Order 1994 (together with its amendments) made under the Import, Export and Custom Powers (Defence) Act 1939¹⁰ and the Dual-Use and Related Goods (Export Control) Regulations (1996) which implement the European Community Council Regulation No 3381/94 setting up an EC regime for the control of exports of dual use goods. The Export of Goods (Control) Order 1994¹¹ prohibits the export of all goods specified in Schedule 1 to all destinations although:

"Nothing in this Order shall be taken to prohibit the exportation of ...any goods under the authority of a licence granted by the Secretary of State, provided that all conditions attaching to said licence are complied with".

14. Part II of Schedule 1 of this Order is entitled *"Goods capable of being used in relation to chemical, biological or nuclear weapons and related missiles"* and states that:

1. Goods of a description specified in paragraph 2 below are prohibited to be exported --

(a) if the exporter knows that they are intended or likely to be used in --

*(i) the development, production, handling, operation, delivery, detection, identification or storage of any chemical or **biological** weapon;*

¹⁰United Kingdom, *An Act to provide for controlling the importation, exportation and carriage coastwise of goods and the shipment of goods as ships' stores;.... The Import, Export and Customs Powers (Defence) Act, 1939*, Chapter 69, 1st September 1939, Her Majesty's Stationery Office.

¹¹United Kingdom, *The Export of Goods (Control) Order 1994*, Statutory Instrument, 1994 No. 1191, 24 April 1994.

(ii) *the disposal of waste arising out of the development or production of any chemical or **biological** weapon;*
 (iii) *the development, production, handling, operation, delivery, detection, identification or storage of any vaccine, toxoid, protein or immunoglobulin for protection against, or the treatment of the harmful effects of any chemical or **biological** weapon;...*

(b) where the exporter knows or has grounds for suspecting that they might be used for any purpose referred to in sub-paragraph (a) above, unless he has made all reasonable enquiries as to their proposed use and satisfied himself that the goods will not be so used.

2. (a) *Any chemical, **toxin, microorganism or other biological agent**;*
 (b) *Any vaccine, toxoid, protein or immunoglobulin capable of being used for protection against, or treatment of, any harmful effect of any chemical, **toxin, microorganism or other biological agent**;*
 (c) *Any equipment (including clothing), software or materials capable of being used in the development, production, handling, operation, delivery, detection, identification or storage of any of the substances specified in sub-paragraph (a) or (b) above;*
 ...
 (f) *technology the information in which includes information relating to any goods in sub-paragraphs (a) to (e) above. [Emphasis added]*

15. Part III of Schedule 1 of this Order details in various groups and categories the goods of which the export is prohibited under the Order. There are three particular groups and categories of relevance to biological and toxin weapons:

Group 1 Military, Security and Para-Military Goods and Arms, Ammunition and Related Material

Group 3 Industrial Goods

Category 1 Materials, Chemicals, Microorganisms & Toxins
 Category 2 Materials Processing

The Explanatory Note to SI 1994/1191 provides a useful clarification of the 5 character entry references used to identify specific goods eg 1C351 in which the first character indicates the generic category eg 1 Materials, Chemicals, Microorganisms & Toxins, the second character indicates a sub-category eg C Materials and *"the third character indicates the origin of the control:*

0 controls which former COCOM members have agreed to maintain for strategic reasons;
1 controls agreed in the Missile Technology Control Regime (MTCR);
2 controls agreed in the Nuclear Suppliers Group (NSG);
3 controls agreed in the Australia Group (AG) (which aims to limit the proliferation of chemical and biological weapons);
9 other controls;

and the last two characters are used to identify the explicit item."

16. Group 1 includes the following:

ML 7 Toxicological agents, riot control agents and related equipment, components, material and technology as follows:

a. Biological agents and radioactive materials adapted for use in war to produce casualties in humans or animals, degrade equipment or damage crops or the environment, and chemical warfare (CW) agents;...

d. Equipment specially designed or modified for the dissemination of the materials or agents specified in head a. above and specially designed components therefor;

e. Goods specially designed or modified for defence against materials or agents specified in head a. above and specially designed components therefor;

f. Goods specially designed or modified for the detection or identification of materials or agents specified in head a. above and specially designed components therefor;...

i. Technology as follows:

1. Technology for the development, production or use of goods specified in heads a. to f. above [Emphasis added]

17. Category 1 of Group 3 includes the following:

1C351 Human pathogens, zoonoses and toxins, as follows:

a. Viruses, 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, as follows:

1. Chikungunya virus;
2. Congo-Crimean haemorrhagic fever virus;
3. Dengue fever virus;
4. Eastern equine encephalitis virus;
5. Ebola virus;
6. Hantaan virus;
7. Junin virus;
8. Lassa fever virus;
9. Lymphocytic choriomeningitis virus;
10. Machupo virus;
11. Marburg virus;
12. Monkey pox virus;
13. Rift Valley fever virus;
14. Tick-borne encephalitis virus (Russian Spring-Summer encephalitis virus);
15. Variola virus;
16. Venezuelan equine encephalitis virus;
17. Western equine encephalitis virus;

18. White pox;
19. Yellow fever virus;
20. Japanese encephalitis virus;

b. Rickettsiae, 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, as follows:

1. *Coxiella burnetii*;
2. *Bartonella quintana* (*Rochalimaea quintana*, *Rickettsia quintana*);
3. *Rickettsia prowasecki*;
4. *Rickettsia rickettsii*;

c. Bacteria, 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, as follows:

1. *Bacillus anthracis*;
2. *Brucella abortus*;
3. *Brucella melitensis*;
4. *Brucella suis*;
5. *Chlamydia psittaci*;
6. *Clostridium botulinum*;
7. *Francisella tularensis*;
8. *Burkholderia mallei* (*Pseudomonas mallei*);
9. *Burkholderia pseudomallei* (*Pseudomonas pseudomallei*);
10. *Salmonella typhi*;
11. *Shigella dysenteriae*;
12. *Vibrio cholerae*;
13. *Yersinia pestis*;

d. "Toxins", as follows, and "sub-unit of toxins" thereof:

1. Botulinum toxins;
2. *Clostridium perfringens* toxins;
3. Conotoxin;
4. Ricin;
5. Saxitoxin;
6. Shag toxin;
7. *Staphylococcus aureus* toxins;
8. Tetrodotoxin;
9. Verotoxin;
10. Microcystin (Cyanginosin);

except:

Any goods specified in this entry in the form of a vaccine.

1C352 Animal pathogens, as follows:

a. Viruses, 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, as follows:

1. African swine fever virus;
2. Avian influenza virus, which are:
 - a. Uncharacterised; or
 - b. Defined in EC Directive 92/40/EC (O.J. L.16 23.1.92 p.19) as having high pathogenicity, as follows:
 1. Type A viruses with an IVPI (intravenous pathogenicity index) in 6 week old chickens of greater than 1.2; or
 2. Type A viruses H5 or H7 subtype for which nucleotide sequencing has demonstrated multiple basic amino acids at the cleavage site of haemagglutinin;
3. Bluetongue virus;
4. Foot and mouth disease virus;
5. Goat pox virus;
6. Porcine herpes virus (Aujeszky's disease);
7. Swine fever virus (Hog cholera virus);
8. Lyssa virus;
9. Newcastle disease virus;
10. Peste des petits ruminants virus;
11. Porcine enterovirus type 9 (swine vesicular disease virus);
12. Rinderpest virus;
13. Sheep pox virus;
14. Teschen disease virus;
15. Vesicular stomatitis virus;

b. *Mycoplasma mycoides*, 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 *Mycoplasma mycoides*.

except:

Any goods specified in this entry in the form of a "vaccine".

1C353 Genetically-modified microorganisms, as follows:

- a. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences associated with pathogenicity of organisms specified in heads a. to c. of entry 1C351 or entries 1C352 or 1C354;
- b. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the "toxins" specified in head d. of entry 1C351.

1C354 Plant pathogens, as follows:

a. Bacteria, whether natural, enhanced or modified, either in the form of "isolated live cultures" or as material which has been deliberately inoculated or contaminated with such cultures, as follows:

1. *Xanthomonas albilineans*;
2. *Xanthomonas campestris* pv. *citri* including strains referred to as *Xanthomonas campestris* pv. *citri* types A,B,C,D,E or otherwise classified as *Xanthomonas citri*, *Xanthomonas campestris* pv. *aurantifolia* or *Xanthomonas campestris* pv. *citrumelo*;

b. Fungi, whether natural, enhanced or modified, either in the form of "isolated live cultures" or as material which has been deliberately inoculated or contaminated with such cultures, as follows:

1. *Colletotrichum coffeanum* var. *virulans* (*Colletotrichum kahawae*);
2. *Cochliobolus miyabeanus* (*Helminthosporium oryzae*);
3. *Microcyclus ulei* (syn. *Dothidella ulei*);
4. *Puccinia graminis* (syn. *Puccinia graminis* f. sp. *tritici*);
5. *Puccinia striiformis* (syn. *Puccinia glumarum*);
6. *Magnaporthe grisea* (*pyricularia grisea/pyricularia oryzae*).

1C992 Vaccines for protection against either of the following:

- a. *Bacillus anthracis*; or
- b. botulinum toxin.

1E001 Technology required for the development or production of goods specified in...sub-categories 1B or 1C.

18. Category 2 of Group 3 includes the following:

2B352 Equipment capable of use in biological manufacturing, as follows;

a. Containment facilities at Containment Level (ACDP) 3 or 4, and related equipment, as follows:

1. Facilities that meet the criteria for Containment Level 3 or 4 ...
2. Independantly ventilated protective full or half suits;
3. Biological safety cabinets or isolators, which allow manual operations to be performed within, whilst providing an environment equivalent to Class III biological protection;
In this sub-head, 'isolators' include flexible isolators, dry boxes, anaerobic chambers and glove boxes.

b. Fermenters, bioreactors, chemostats and continuous-flow systems, capable of operation without the propagation of aerosols, having all the following characteristics:

1. Capacity of 300 litres or more;
2. Double or multiple sealing joints within the steam containment area; and
3. Capable of in-situ sterilization in a closed state;

c. Centrifugal separators or decanters, capable of continuous separation without the propagation of aerosols, having all the following characteristics:

1. Flow rate exceeding 100 litres per hour;
2. Components of polished stainless steel or titanium;
3. Double or multiple sealing joints within the steam containment area; and
4. Capable of in-situ sterilization in a closed state;

d. Cross-flow filtration equipment, designed for continuous separation without the propagation of aerosols, having both of the following characteristics:

1. Equal to or greater than 5 square metres; and
2. Capable of in-situ sterilization;

e. Steam sterilizable freeze drying equipment with a condenser capacity exceeding 50kg of ice in 24 hours and less than 1,000 kg of ice in 24 hours;

f. Chambers designed for aerosol challenge testing with pathogenic microorganisms or toxins and having a capacity of 1 m³ or greater.

2E001 Technology required for the development of goods specified in sub-categories 2A, **2B** or 2D

2E002 Technology required for the production of goods specified in sub-categories 2A, **2B** or 2D

19. The terms 'microorganisms' and 'toxins' are defined in the Export of Goods (Control) Order 1994 as follows:

'Microorganisms' means bacteria, viruses, mycoplasma, 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;

'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 seed stocks of microorganisms;

20. Some eight months later, the European Union on 19 December 1994 established a community regime for dual-use goods through Council Regulation 3381/94¹² and the associated Council decision 94/242/CFSP¹³. Annex I to the Council decision sets out the list of dual-use goods. As might be expected, this in respect of biological materials and equipment is very closely similar to the list in Schedule 1 of the Export of Goods (Control) Order 1994 although without the category 1C992 'Vaccines for protection against either bacillus anthracis or botulinum toxin'.

¹²European Union, *Council Regulation (EC) No 3381/94 of 19 December 1994 setting up a Community regime for the control of exports of dual-use goods*, Official Journal, No L 367/1 - 8, 31 December 1994.

¹³European Union, *Council Decision of 19 December 1994 on the joint action adopted by the Council on the basis of Article J.3 of the Treaty on European Union concerning the control of exports of dual-use goods*, 94/942/CFSP, Official Journal, No L 367/8 - 163, 31 December 1994.

21. These were given effect in the UK through the Dual-Use and Related Goods (Export Control) Regulations 1995 (Statutory Instrument SI 1995/271)¹⁴ which were subsequently replaced by the Dual-Use and Related Goods (Export Control) Regulations 1996¹⁵. The latter also gave effect to the amendment of Council Decision 94/942/CFSP by Council Decision 96/613/CFSP¹⁶. The Dual-Use Regulations 1996 include the following catch-all provisions relating to dual-use and related goods:

(2) Subject to the provisions of these Regulations -

(a) goods of a description specified in Schedule 2 hereto are prohibited to be exported as therein provided;

(b) goods other than dual-use goods which

(i) the exporter (or, if the exporter is not within the United Kingdom, any agent of his within the United Kingdom concerned in the exportation or intended exportation) has been informed by a competent authority are or may be intended, wholly or in part, to be used in connection with the development, production, handling, operation, maintenance, storage , detection, identification or dissemination of chemical, biological or nuclear weapons or the development, production, maintenance or storage of missiles capable of delivering such weapons, or

(ii) the exporter knows are intended, wholly or in part, to be used in connection with one of the activities referred to in sub-paragraph (i) above, or

(iii) the exporter has grounds for suspecting might be used, wholly or in part, in connection with an activity referred to in sub-paragraph (i) above unless he has made all reasonable enquiries as to their proposed use and satisfied himself that they will not be so used,

are prohibited to be exported to any destination;

(c) dual-use goods which the exporter has grounds for suspecting might be used, wholly or in part, in connection with an activity referred to in sub-paragraph (b)(1) above, unless he has made all reasonable enquiries as to their proposed use and satisfied himself that they will not be so used, are prohibited to be exported to any destination not in a Member State; and

(d) the following goods are prohibited to be exported to a destination in a Member State:

¹⁴United Kingdom, *The Dual-Use and Related Goods (Export Control) Regulations 1995*, Statutory Instrument, 1995 No. 271, 4 February 1995.

¹⁵United Kingdom, *The Dual-Use and Related Goods (Export Control) Regulations 1996*, Statutory Instrument, 1996 No. 2721, 25 October 1996.

¹⁶European Union, *Council Decision of 22 October 1996 amending Decision 94/942/CFSP on the joint action adopted by the Council on the basis of Article J.3 of the Treaty on European Union concerning the control of exports of dual-use goods*, 96/613/CFSP, Official Journal, No L 278/1-215, 30 October 1996.

(i) all goods specified in Schedule 3 hereto; and

(ii) any--

(aa) goods of a description specified in Annex I to the Decision or Schedule 2 hereto, or

(bb) dual-use goods which are not of a description specified in Annex I to the Decision but for the export of which from the European Community an authorisation is required in accordance with Article 4(1) of the Regulation,

in respect of which in either case the exporter knows at the time of export that the final destination of those goods is outside the European Community and no processing or working is to be performed on those goods in any Member State to which they are exported; and this sub-paragraph, "processing or working" has the same meaning as in Article 24 of Council Regulation (EEC) No.2913/92 establishing the Community Customs Code.

(3) Subject to the provisions of these Regulations, paragraph (2) above does not prohibit export of any goods in relation to which a licence has been granted by the Secretary of State provided that all conditions attaching to said licence are complied with.

22. In respect of biological materials, the Dual-Use Regulations 1996 saw the inclusion in Schedule 2 of the following:

1C992 The export of goods specified in this entry is prohibited to any destination

Vaccines for protection against either of the following:

- a. bacillus anthracis; or
- b. botulinum toxin.

Although this would appear to prohibit such exports to any destination, it is clear from paragraph (3) reproduced above that goods can be exported provided that an export licence has been granted.

23. Subsequent amendments to the Dual-Use and Related Goods (Export Control) Regulations have implemented subsequent changes made by Council Decisions. In respect of biological materials, the Dual-Use and Related Goods (Export Control) (Amendment No. 3) Regulations 1997 implemented Council Decision 97/419 which added "Aflatoxins" as a new entry (d.11) to 1C351 d.

24. The Export of Goods (Control) Orders reflecting their COCOM origins and the Wassenaar Arrangement focus more on weapons or on materials "**adapted for war**". Consequently, the Export of Goods (Control) (Amendment No. 2) Order 1996¹⁷ which harmonised the UK controls with the Wassenaar Arrangement includes the following, which

¹⁷United Kingdom, *The Export of Goods (Control) (Amendment No. 2) Order 1996*, Statutory Instrument, 1996 No. 2663, 18 October 1996.

uses language closely similar to that in Group 1 of the earlier Export of Goods (Control) Order 1994¹⁸:

*ML 7 ...**Toxicological agents**, "tear gases", related equipment, components, materials and "technology" as follows:*

*a. **Biological agents** and radioactive materials "**adapted for use in war**" to **produce casualties in humans or animals**, degrade equipment or **damage crops or the environment**, and chemical warfare (CW) agents...*

d. Equipment specially designed or modified for the dissemination of the materials or agents specified in entry ML 7.a and specially designed components therefor;...

e. "Goods" specially designed for defence against materials specified in entry ML 7.a and specially designed components therefor;...

f. "Goods" specially designed for the detection or identification of materials specified in entry ML 7.a and specially designed components therefor;...
[Emphasis added]

Notes make it clear that equipment or "goods" not specially designed or modified for military purposes are not included. The term "adapted for use in war" is defined in the Order as:

"adapted for use in war" means any modification or selection (such as altering purity, shelf life, virulence, dissemination characteristics, or resistance to ultra violet (UV) radiation) designed to increase the effectiveness in producing casualties in humans or animals, degrading equipment or damaging crops or the environment.

25. Insofar as the implementation of these export controls are concerned, the UK has essentially three types of export licence:

a. **Standard Individual Export Licences.** A separate licence is applied for each export or group of exports. Open licences are now used wherever it is possible.

b. **Open Individual Export Licences (OIELs).** This allows the licensee to make multiple shipments of a range of goods to several destinations, normally without specifying particular consignees. An OIEL must not be used in relation to the export of goods for purposes associated with weapons of mass destruction or missiles for their delivery. In addition, an OIEL requires *inter alia* that an end-user undertaking that shipments are not intended for re-export to a non-eligible destination must be obtained from all consignees.

c. **Open General Export Licences (OGELs).** This allows the export of the goods specified in the OGEL to specified destinations. Most OGELs list the goods to which they apply in a Schedule that is part of the licence and a separate specific Schedule lists the countries to which the OGEL applies. OGELs are currently available for export of a large range of controlled dual-use goods to countries closely

¹⁸United Kingdom, *The Export of Goods (Control) Order 1994*, Statutory Instrument, 1994 No. 1191, 24 April 1994.

allied to the UK and to non-EU members of the international proliferation and arms control regimes. Many OGELs require the exporter to register with the UK Department of Trade and Industry if they intend to export goods under an OGEL.

In addition, there is an overall requirement for an export licence if the End-Use Control is relevant. This control is designed to help prevent the proliferation of weapons of mass destruction and requires that a licence must be applied for if the exporter has either been informed by the authorities or the exporter knows or suspects that the goods are intended or likely to be used in connection with weapons of mass destruction or missiles capable of delivering them. The exporter is responsible for determining the need for a licence under the "end-use" control as the exporter knows the capabilities of their products, their customers and potential customers and the circumstances of any particular order.

26. One OGEL relates to Dual Use Goods¹⁹. This states that:

"goods specified in Part A of Schedule 1 hereto...may be exported from the United Kingdom, or from any other member State by any person established in the United Kingdom, to any destination in any country specified in Schedule 2 hereto."

Part A of Schedule 1 covers *"Goods specified in any entry in Annex I to Council Decision 94/942/CFSP"* -- thereby covering all the goods listed in the Export of Goods (Control) Order 1994²⁰ and reproduced above in paragraphs 15 to 18 -- and Schedule 2 lists as permitted destinations:

Australia, Canada, Japan, New Zealand, Norway, Switzerland, USA

Export is also permitted to other States within the European Community. The OGEL (Dual Use Goods) also states that the authorisation is subject to various conditions including one that

the goods shall not be exported

(i) if the exporter has been informed by a competent authority that the goods are or may be intended, wholly or in part, to be used in connection with the development, production, handling, operation, maintenance, storage, detection, identification or dissemination of chemical, biological or nuclear weapons,...;

(ii) if the exporter knows they are intended, wholly or in part, to be used in connection with one of the activities referred to in sub-paragraph (i) above; or

(iii) if the exporter has grounds for suspecting that they might be used, wholly or in part, in connection with an activity referred to in sub-paragraph (i) above, unless he has made all reasonable enquiries as to their proposed use and satisfied himself that the goods will not be so used;

¹⁹United Kingdom, Open General Export Licence (Dual-Use Goods) dated 20 January 1998 granted by the Secretary of State. Available on the web at <http://www.dti.gov.uk/export.control>

²⁰United Kingdom, *The Export of Goods (Control) Order 1994*, Statutory Instrument, 1994 No. 1191, 24 April 1994.

27. **Proposed revised UK legislation.** In addition, the UK is currently considering revision of its legislation regarding Strategic Export Controls with a view to new primary legislation to replace the powers in the Import, Export and Customs Powers (Defence) Act 1939²¹, which is limited only to control of physical exports and not to modern means of transferring information, and for an export licensing system and procedures suitable for the post cold war era. A White Paper was issued in July 1998 setting out proposals for a new legislative framework for strategic export controls and improvements to export licensing procedures.²² This proposes the strengthening of the existing legislation in respect of chemical weapons and of biological weapons so as to enable action to be taken, where appropriate, against anyone found to be deliberately helping in any way, a weapons of mass destruction programme.

28. The specific proposals in respect of chemical weapons note that the Chemical Weapons Act 1996 (CWA) which implemented the Chemical Weapons Convention in the United Kingdom made it an offence for any person²³ in the UK or any UK person overseas to develop, produce, use, possess or participate in the transfer of a chemical weapon anywhere in the world or to engage in military preparations or preparations of a military nature, intending to use a chemical weapon anywhere in the world. It is also an offence at common law to aid, abet, counsel or procure such activity, but not if that activity is carried out by a foreigner overseas as it is not an offence in UK law for a foreigner to undertake such activity overseas. The new proposal is that it should in addition be made an offence for anyone in the UK or a UK person abroad to aid, abet, counsel or procure a foreigner overseas to develop, produce or use a chemical weapon. Consideration is also being given to whether it would be appropriate to make it an offence for anyone in the UK or a UK person abroad to aid, abet, counsel or procure a foreigner overseas to engage in military preparations or preparations of a military nature, intending to use a chemical weapon. The White Paper notes that it would not be necessary to make it an offence to aid, abet, counsel or procure a foreigner overseas to possess or participate in the transfer of such a weapon as it would be enough to prosecute someone for participation in a transfer under the CWA.

29. The White Paper goes on to note that offences relating to other weapons of mass destruction (i.e. nuclear and biological weapons)²⁴ are currently not as comprehensive as those contained in the CWA. It states that the Government considers that there is a strong case in principle for creating prohibitions in relation to biological and nuclear weapons which are equivalent to the current prohibitions in the CWA and the extension outlined above. This is on the basis that biological and nuclear weapons (with the exception of those in the five official nuclear weapons states) are, like chemical weapons, subject to international agreements outlawing them.

30. In addition, the White Paper indicates that there is also concern that a UK person or company, might, without being directly involved in an attempt to produce a weapon of mass destruction, nevertheless, provide a service or information which could assist such a

²¹United Kingdom, *An Act to provide for controlling the importation, exportation and carriage coastwise of goods and the shipment of goods as ships' stores;.... The Import, Export and Customs Powers (Defence) Act, 1939*, Chapter 69, 1st September 1939, Her Majesty's Stationery Office.

²²Department of Trade and Industry, Strategic Export Controls, July 1998. Available on the web at <http://www.dti.gov.uk/export.control/stratex/>

²³By person is meant natural or legal person - i.e. either an individual or a corporate body.

²⁴The UK Biological Weapons Act 1974 makes it an offence for any person to develop, produce, stockpile, acquire or retain (i.e. possess) a biological weapon in the UK. The UK Nuclear Explosions (Prohibitions and Inspections) Act 1998 makes it an offence knowingly to cause a nuclear weapon test explosion or any other nuclear explosion either in the UK or outside the UK if done by UK nationals or companies.

programme. Although existing end-use control is intended to prevent the export of equipment which might be used in such programmes, it is considered that it would be desirable to introduce measures to prevent other ways in which such programmes might be given assistance, such as the transfer of technological information by intangible means or provision of technical services. Consequently, it is proposed to make it an offence to do something that would promote or facilitate the development or production of weapons of mass destruction either if the Government has informed someone that what he is doing poses such a risk or if someone knows by other means or has grounds for suspecting that a particular course of action might assist such a programme. It is further proposed that this new offence should apply to certain means of delivery of weapons of mass destruction, namely ballistic and cruise missiles capable of ranges of at least 300 km.

31. Another proposal relates to the collection of information from exporters to enable the UK to meet its reporting obligations under international agreements. The White Paper notes that the UK currently has reporting obligations under the United Nations Conventional Arms Register and the Wassenaar Arrangement and considers that a statutory requirement for exporters to provide relevant information is essential to ensure the accuracy and completeness of the UK's reports to international bodies. It is proposed that the new legislation should enable the UK Government to require the reporting of information needed to meet international obligations and that this should be framed in such a way that it will allow the UK to meet any future commitments on reporting to international bodies that it may enter into.

Analysis

32. The UK system of export controls for biological materials and equipment is thus comprehensive and comprises three elements:

- a. The control of biological agents "adapted for use in war" through the Export of Goods (Control) Orders,
- b. The control of a long list of human, animal and plant pathogens through the Dual Use and Related Goods (Export Control) Regulations, and
- c. A catch-all provision which controls any goods which the exporter has reason to think may be associated with a weapon of mass destruction programme.

Regional Controls of Transfers

33. It is apparent from the account of the UK export control regime that this has closely reflected that of the European Union for dual-use goods. In considering regional controls of transfers, the European Union regime is first addressed and then two other wider arrangements -- those of the Australia Group and of the Wassenaar Arrangement -- are considered.

34. **European Union.** The European Union has established a regime for the control of exports of dual-use goods through a Council Decision 94/942/CFSP²⁵ and a Council

²⁵European Union, *Council Decision of 19 December 1994 on the joint action adopted by the Council on the basis of Article J.3 of the Treaty on European Union concerning the control of exports of dual-use goods*, 94/942/CFSP, Official Journal, No L 367/8 - 163, 31 December 1994.

Regulation EC 3381/94²⁶ which constitute an integrated system involving the Council, the Commission and the Member States. The preamble to the Regulation makes it clear that *"an effective system of export control on dual-use goods on a common basis is also necessary to ensure that the international commitments of the Member States and the European Union, especially on non-proliferation, are complied with"*. The Regulation sets out the Community system of export controls for dual-use goods which are defined as:

(a) 'dual-use goods' shall mean goods which can be used for both civil and military purposes;

The system requires an authorization for the export of the dual-use goods listed in Annex 1 to the Council Decision 94/942/CFSP. In addition, Articles 4 and 5 of the system enable Member States to prohibit or subject to authorization of the export of dual-use goods **not** listed in Annex 1 to 94/942/CFSP. The Regulation requires the keeping by exporters of detailed records which must enable the following to be identified:

- *the description of the dual-use goods,*
- *the quantity of the dual-use goods,*
- *the name and address of the exporter and of the consignee,*
- *where known, the end-use and end-user of the dual use goods.*

35. The Council Decision 94/942/CFSP comprises five Annexes of which Annex 1 is the "List of Dual-Use Goods" which comprises a number of categories:

L 367/11 - 30	Definition of terms in this Annex
L 367/31 - 39	Category 0 Nuclear materials, Facilities and Equipment
L 367/40 - 57	Category 1 Materials, Chemicals, 'Microorganisms' and 'Toxins'
L 367/58 - 80	Category 2 Materials Processing
L 367/81 - 94	Category 3 Electronics
L 367/95 - 103	Category 4 Computers
L 367/104 - 111	Category 5 Telecommunications and Information Security
L 367/112 - 131	Category 6 Sensors and Lasers
L 367/132 - 137	Category 7 Navigation and Avionics
L 367/138 - 143	Category 8 Marine
L 367/144 - 153	Category 9 Propulsion Systems, Space Vehicles and Related Equipment

Within each Category there are a number of sections

- A Equipment, Assemblies and Components
- B Test, Inspection and Production Equipment
- C Materials
- D Software
- E Technology

²⁶European Union, *Council Regulation (EC) No 3381/94 of 19 December 1994 setting up a Community regime for the control of exports of dual-use goods*, Official Journal, No L 367/1 - 8, 31 December 1994.

As each item is numbered, an item can be referenced by a number such as '1 C 351' which refers to category 1, section C, item 351.

36. Biological materials. In respect of materials of relevance to the BTWC, the definitions of terms in Annex 1 of 94/942/CFSP include:

187. 'Microorganisms' (1 2) means bacteria, viruses, mycoplasma, 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.

188. 'Toxins' (1 2) 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 seed stocks of 'microorganisms'.

The (1 2) indicates that the term is used in Categories 1 and 2 of Annex 1.

37. The materials listed in Category 1 are

- 1 C 351 Human pathogens, zoonoses and 'toxins'
- 1 C 352 Animal pathogens
- 1 C 353 Genetically-modified 'microorganisms'
- 1 C 354 Plant pathogens

These are the same as those listed above in paragraph 17.

38. In Category 2 are listed the following biological equipment

2 B 352 *Biological equipment as follows;*

a. complete biological containment facilities at P3, P4 containment level

b. fermenters, capable of operation without the propagation of aerosols, having all the following characteristics:

- 1. capacity of 300 litres or more*
- 2. double or multiple sealing joints within the steam containment area; and*
- 3. capable of in-situ sterilization in a closed state;*

Technical note: Fermenters include bioreactors, chemostats and continuous-flow systems

c. centrifugal separators, capable of continuous separation without the propagation of aerosols, having all the following characteristics:

- 1. flow rate exceeding 100 litres per hour;*
- 2. components of polished stainless steel or titanium;*
- 3. double or multiple sealing joints within the steam containment area; and*
- 4. capable of in-situ sterilization in a closed state;*

Technical note: Centrifugal separators include decanters.

d. cross-flow filtration equipment, designed for continuous separation without the propagation of aerosols, having both of the following characteristics:

- 1. equal to or greater than 5 square metres.*
- 2. capable of in-situ sterilization.*

e. steam sterilizable freeze drying equipment with a condenser capacity exceeding 50kg of ice in 24 hours and less than 1000 kg of ice in 24 hours.

f. equipment that incorporates or is contained in P3 or P4 containment housing, as follows,

- 1. individually ventilated protective full or half suits;*
- 2. biological safety cabinets or isolators which allow manual operations to be performed within, whilst providing an environment equivalent to Class III biological protection;*

Note: In this entry, isolators include flexible isolators, dry boxes, anaerobic chambers and glove boxes.

g. chambers designed for aerosol challenge testing with pathogenic 'microorganisms' or 'toxins' and having a capacity of 1 m³ or greater.

The Technology section of this category also includes

2 E 301 *'Technology' required for the 'use' of goods specified in 2 B 350 to 2 B 352.*

39. The European Community regime has been updated by subsequent Council Decisions (96/613/CFSP, 97/100/CFSP, 97/419/CFSP and 98/106/CFSP) which have not changed the lists of biological materials apart from the addition of "aflatoxins" in 97/100/CFSP. The biological equipment listing was modified by 96/613/CFSP which modified and tightened some of the wording so that this now reads (changes shown in bold) as:

2 B 352 ***Equipment capable of use in handling biological materials as follows;***

a. complete biological containment facilities at P3, P4 containment level

*b. fermenters, capable of **cultivation of pathogenic "microorganisms", viruses or capable of toxin production**, without the propagation of aerosols, **and having a total capacity of 100 litres or more.***

Technical note: Fermenters include bioreactors, chemostats and continuous-flow systems

c. centrifugal separators, capable of continuous separation without the propagation of aerosols, having all the following characteristics:

1. *flow rate exceeding 100 litres per hour;*
2. *components of polished stainless steel or titanium;*
3. *double or multiple sealing joints within the steam containment area; and*
4. *capable of in-situ sterilization in a closed state;*

Technical note: Centrifugal separators include decanters.

d. cross-flow filtration equipment, designed for continuous separation without the propagation of aerosols, having both of the following characteristics:

1. *equal to or greater than 5 m²; and*
2. *capable of in-situ sterilization.*

e. steam sterilizable freeze drying equipment with a condenser capacity exceeding 50kg of ice in 24 hours and less than 1000 kg of ice in 24 hours.

f. equipment that incorporates or is contained in P3 or P4 containment housing, as follows,

1. *individually ventilated protective full or half suits;*
2. *biological safety cabinets or isolators which allow manual operations to be performed within, whilst providing an environment equivalent to Class III biological protection;*

Note: In 2B352.f.2, isolators include flexible isolators, dry boxes, anaerobic chambers and glove boxes.

g. chambers designed for aerosol challenge testing with 'microorganisms' or 'toxins' and having a capacity of 1 m³ or greater.

40. Australia Group. Another harmonized set of export controls which includes countries beyond the European Community is that provided by the Australia Group.²⁷ This first met in 1985 to constrain the trade in the technologies and materials of chemical warfare. It was created in response to the rapid proliferation of chemical weapons during that period, their use in the Iran-Iraq war, and the long drawn out process of negotiating the Chemical Weapons Convention (CWC). It is known as the Australia Group because it is chaired by Australia and meets in the Australian Embassy in Paris. The Group has no charter or constitution. It operates by consensus. In 1990, its purview expanded to include biological weapons and it began to develop guidelines relevant to biological weapons and in 1991, 1992, and 1993 finalized a set of lists of controlled technologies and materials. Its now annual meetings focus on sharing information about national export controls, considering proposals for "harmonization" -- the adoption of common controls by all members on chemical precursors, equipment, biological weapons related materials and considering other measures to address chemical and biological weapons proliferation and use. In tandem with export controls, the Australia Group has periodically used warning mechanisms to sensitize its public to potential risks relating to chemical and biological weapons proliferation. The Group has issued an

²⁷A useful account of the Australia Group is provided by the US Arms Control and Disarmament Agency Fact Sheet available on the web at <http://www.acda.gov/factshee/wmd/cw/aus496.htm> and the press release issued after the Australia Group meeting held on 6 to 9 October 1997 available on the web at <http://www.acda.gov/factshee/wmd/cw/agmtg.htm>

informal "warning list" of dual-use materials and equipment. Member States develop and share the warning lists with their relevant industries and ask industry to report on any suspicious transactions. In more recent years, its work has focused on implementation and enforcement. Its membership has steadily increased since 1985 and the number of participating States is now 30, with the inclusion of a number of countries from Central Europe and one from South America.²⁸ Requests by other States to join the Group are considered on a case by case basis.

41. The current Australia Group list²⁹ for biological materials and equipment is, as might be expected, closely similar to the list in the European Union dual use control regime. The Australia Group control and warning lists for biological equipment are as follows:

LIST OF DUAL-USE BIOLOGICAL EQUIPMENT FOR EXPORT CONTROL

1. Complete containment facilities at P3, P4 containment level

Complete containment facilities that meet the criteria for P3 or P4 (BL3, BL4, L3, L4) containment as specified in the WHO Laboratory Biosafety manual (Geneva, 1983) are subject to export control.

*2. Fermenters**

Fermenters capable of cultivation of pathogenic micro-organisms, viruses or for toxin production, without the propagation of aerosols, and having all the following characteristics:

(a) capacity equal to or greater than 100 litres;

**Sub-groups of fermenters include bioreactors, chemostats and continuous-flow systems.*

*3. Centrifugal Separators**

Centrifugal separators capable of the continuous separation of pathogenic micro-organisms, without the propagation of aerosols, and having all the following characteristics:

(a) flow rate greater than 100 litres per hour;

(b) components of polished stainless steel or titanium;

(c) double or multiple sealing joints within the steam containment area;

(d) capable of in-situ steam sterilization in a closed state.

**Centrifugal separators include decanters.*

²⁸Participating countries are: Argentina, Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Poland, Portugal, Republic of Korea, Romania, Slovak Republic, Spain, Sweden, Switzerland, United Kingdom, and United States. The European Community Commission attend as an Observer.

²⁹United States Arms Control & Disarmament Agency, *Australia Group Export Controls On Materials Used In The Manufacture Of Chemical And Biological Weapons, Control List Of Dual-Use Chemicals: Commercial And Military Application*, available on the web at <http://www.acda.gov/factshee/wmd/bw/auslist.htm>

4. Cross-flow Filtration Equipment

Cross-flow filtration equipment capable of continuous separation of pathogenic microorganisms, viruses, toxins and cell cultures without the propagation of aerosols, having all the following characteristics:

- (a) equal to or greater than 5 square metres;*
- (b) capable of in-situ sterilization.*

5. Freeze-drying Equipment

Steam sterilizable freeze-drying equipment with a condenser capacity greater than 50 kgs of ice in 24 hours and less than 1000 kgs of ice in 24 hours.

6. Equipment that incorporates or is contained in P3 or P4 (BL3, BL4, L3, L4) containment housing, as follows:

- (a) Independently ventilated protective full or half suits;*
- (b) Class III biological safety cabinets or isolators with similar performance standards.*

7. Aerosol inhalation chambers

Chambers designed for aerosol challenge testing with microorganisms, viruses or toxins and having a capacity of 1 cubic metre or greater.

WARNING LIST

The experts propose that the following items be included in awareness raising guidelines to industry:

1. Equipment for the micro-encapsulation of live micro-organisms and toxins in the range of 1-10 um particle size, specifically:

- (a) Interfacial polycondensers;*
- (b) Phase separators.*

2. Fermenters of less than 100 litre capacity with special emphasis on aggregate orders or designs for use in combined systems.

3. Conventional or turbulent air-flow clean-air rooms and self-contained fan-HEPA filter units that may be used for P3 or P4 (BL3, BL4, L3, L4) containment facilities.

42. The Australia Group control and warning lists for biological materials are as follows:

a. Human Pathogens and Toxins

AUSTRALIA GROUP LIST OF BIOLOGICAL AGENTS FOR EXPORT CONTROL CORE LIST[†]

Viruses

- V1. Chikungunya virus*
- V2. Congo-Crimean haemorrhagic fever virus*
- V3. Dengue fever virus*
- V4. Eastern equine encephalitis virus*
- V5. Ebola virus*
- V6. Hantaan virus*
- V7. Junin virus*
- V8. Lassa fever virus*
- V9. Lymphocytic choriomeningitis virus*
- V10. Machupo virus*
- V11. Marburg virus*
- V12. Monkey pox virus*
- V13. Rift Valley fever virus*
- V14. Tick-borne encephalitis virus (Russian Spring-Summer encephalitis virus)*
- V15. Variola virus*
- V16. Venezuelan equine encephalitis virus*
- V17. Western equine encephalitis virus*
- V18. White pox*
- V19. Yellow fever virus*
- V20. Japanese encephalitis virus*

Rickettsiae

- R1. Coxiella burnetii*
- R2. Bartonella Quintana (Rochalimea quintana, Rickettsia quintana)*
- R3. Rickettsia prowasecki*
- R4. Rickettsia rickettsii*

Bacteria

- B1. Bacillus anthracis*
- B2. Brucella abortus*
- B3. Brucella melitensis*
- B4. Brucella suis*
- B5. Chlamydia psittaci*
- B6. Clostridium Botulinum*
- B7. Francisella tularensis*
- B8. Burkholderia mallei (pseudomonas mallei)*
- B9. Burkholderia pseudomallei (pseudomonas pseudomallei)*
- B10. Salmonella typhi*
- B11. Shigella dysenteriae*
- B12. Vibrio cholerae*
- B13. Yersinia pestis*

[†]Except where the agent is in the form of a vaccine.

Genetically Modified Micro-organisms

G1. Genetically modified micro-organisms or genetic elements that contain nucleic acid sequences associated with pathogenicity and are derived from organisms in the core list.

G2. Genetically modified micro-organisms or genetic elements that contain nucleic acid sequences coding for any of the toxins in the core list, or their subunits.

Toxins as follow and subunits thereof^{††} :

- T1. Botulinum toxins*
- T2. Clostridium perfringens toxins*
- T3. Conotoxin*
- T4. Ricin*
- T5. Saxitoxin*
- T6. Shiga toxin*
- T7. Staphylococcus aureus toxins*
- T8. Tetrodotoxin*
- T9. Verotoxin*
- T10. Microcystin (Cyanginosin)*
- T11. Aflatoxins*

WARNING LIST^{†††}

Viruses

- WV1. Kyasanur Forest virus*
- WV2. Louping ill virus*
- WV3. Murray Valley encephalitis virus*
- WV4. Omsk haemorrhagic fever virus*
- WV5. Oropouche virus*
- WV6. Powassan virus*
- WV7. Rocio virus*
- WV8. St. Louis encephalitis virus*

Bacteria

- WB1. Clostridium perfringens^{**}*
- WB2. Clostridium tetani^{**}*
- WB3. Enterohaemorrhagic Escherichia coli, serotype 0157 and other verotoxin producing serotypes*
- WB4. Legionella pneumophila*
- WB5. Yersinia pseudotuberculosis*

^{††}Excluding immunotoxins.

^{†††}Except where the agent is in the form of a vaccine.

^{**}The Australia Group recognizes that these organisms are ubiquitous, but, as they have been acquired in the past as part of biological weapons programs, they are worthy of special caution.

Genetically Modified Micro-organisms

WG1. Genetically modified micro-organisms or genetic elements that contain nucleic acid sequences associated with pathogenicity and are derived from organisms in the warning list.

WG2. Genetically modified micro-organisms or genetic elements that contain nucleic acid sequences coding for any of the toxins in the warning list, or their subunits.

Toxins as follow and subunits thereof^{†††} :

- WT1. Abrin*
- WT2. Cholera toxin*
- WT3. Tetanus toxin*
- WT4. Trichothecene mycotoxins*
- WT5. Modeccin*
- WT6. Volkensin*
- WT7. Viscum Album Lectin 1 (Viscumin)*

b. Animal Pathogens

AUSTRALIA GROUP LIST OF ANIMAL PATHOGENS FOR EXPORT CONTROL^{††††}

Viruses

- AV1. African swine fever virus*
- AV2. Avian influenza virus^{***}*
- AV3. Bluetongue virus*
- AV4. Foot and mouth disease virus*
- AV5. Goat pox virus*
- AV6. Herpes virus (Aujeszky's disease)*
- AV7. Hog cholera virus (synonym: Swine fever virus)*
- AV8. Lyssa virus*
- AV9. Newcastle disease virus*
- AV10. Peste des petits ruminants virus*
- AV11. Porcine enterovirus type 9 (synonym: swine vesicular disease virus)*
- AV12. Rinderpest virus*
- AV13. Sheep pox virus*
- AV14. Teschen disease virus*
- AV15. Vesicular stomatitis virus*

Bacteria

- AB3. Mycoplasma mycoides*

^{†††}Excluding immunotoxins.

^{††††}Except where the agent is in the form of a vaccine.

^{***}This includes only those Avian influenza viruses of high pathogenicity as defined in EC Directive 92/401EC: "Type A viruses with an IVPI (intravenous pathogenicity index) in 6 week old chickens of greater than 1.2, or Type A viruses H5 or H7 subtype for which nucleotide sequencing has demonstrated multiple basic amino acids at the cleavage site of haemagglutinin."

Genetically-modified Micro-organisms

AG1. Genetically modified micro-organisms or genetic elements that contain nucleic acid sequences associated with pathogenicity and are derived from organisms in the list.

c. Plant Pathogens

AUSTRALIA GROUP CONTROL LIST OF PLANT PATHOGENS FOR EXPORT CONTROL

CORE LIST

Bacteria

PB1. Xanthomonas albilineans

PB2. Xanthomonas campestris pv. citri

Fungi

PF1. Colletotrichum coffeanum var. virulans (Colletotrichum Kanawae)

PF2. Cochliobolus miyabeanus (Helminthosporium oryzae)

PF3. Microcyclus ulei (syn. Dothidella ulei)

PF4. Puccinia graminis (syn. Puccinia graminis f. sp. tritici)

PF5. Puccinia striiformis (syn. Puccinia glumarum)

PF6. Pyricularia grisea/Pyricularia oryzae

Genetically-modified Micro-organisms

PG1. Genetically-modified micro-organisms or genetic elements that contain nucleic acid sequences associated with pathogenicity derived from the plant pathogens identified on the export control list.

ITEMS FOR INCLUSION IN AWARENESS RAISING GUIDELINES

Bacteria

PWB1. Xanthomonas campestris pv. oryzae

PWB2. Xylella fastidiosa

Fungi

PWF1. Deuterophoma tracheiphila (syn. Phoma tracheiphila)

PWF2. Monilia rorei (syn. Moniliophthora rorei)

Viruses

PWV1 Banana bunchy top virus

Genetically-modified Micro-organisms

PWGI Genetically-modified micro-organisms or genetic elements that contain nucleic acid sequences associated with pathogenicity derived from the plant pathogens identified on the awareness raising list.

43. The Wassenaar Arrangement. In 1994 the cold war-vintage Coordinating Committee on Export Controls (COCOM) formally ceased to function. It had brought together the Western countries with the aim of restricting the transfer of militarily-sensitive materials to the Soviet Union. At the Vancouver Summit in 1993, Presidents Clinton and Yeltsin agreed that the previous COCOM regime should be replaced by a new non-discriminatory arrangement which would include Russia as a participant. Representatives of Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Poland, Portugal, the Russian Federation, the Slovak Republic, Spain, Sweden, Switzerland, Turkey, the United Kingdom, and the United States met in Wassenaar, the Netherlands on 18 and 19 December 1995 and agreed to establish *The Wassenaar Arrangement on Export Controls for Conventional Arms and Dual-Use Goods and Technologies* ³⁰. This Arrangement is designed to promote transparency, exchange of views and information as well as greater responsibility in transfers of conventional arms and dual-use goods and technologies. Its purpose³¹ includes:

It complements and reinforces, without duplication, the existing control regimes for weapons of mass destruction and their delivery systems, as well as other internationally recognised measures designed to promote transparency and greater responsibility, by focussing on the threats to international and regional peace and security which may arise from transfers of armaments and sensitive dual-use goods and technologies where the risks are judged greatest.

This arrangement is also intended to enhance co-operation to prevent acquisition of armaments and sensitive dual-use items for military end-uses, if the situation in a region or the behaviour of a state is, or becomes, a cause for serious concern to the Participating States.

There are currently some 33 Participating States drawn from Western, Central, and Eastern Europe, North and South America, and Asia.³² The Arrangement which has a small Secretariat in Vienna, Austria, began operations in September 1996.

44. The Arrangement is open on a global and non-discriminatory basis to prospective adherents that comply with the agreed criteria³³ which state that:

³⁰The Wassenaar Arrangement, *Final Declaration*, 19 December 1995. Available on the web at <http://www.wassenaar.org/docs/findecl.html>

³¹The Wassenaar Arrangement, *Initial Elements*, as adopted by the Plenary of 11-12 July 1996. Available on the web at <http://www.wassenaar.org/docs/IE96.html>

³²The Participating States in the Wassenaar Arrangement are: Argentina, Australia, Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Poland, Portugal, the Republic of Korea, Romania, the Russian Federation, Slovak Republic, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom, and United States. See Public Statement, Wassenaar Arrangement on Export Controls for Conventional Arms and Dual-Use Goods and Technology, 10 December 1997. Available on the web at http://www.wassenaar.org/docs/press_3.html

When deciding on the eligibility of a state for participation, the following factors, inter alia, will be taken into consideration, as an index of its ability to contribute to the purposes of the new arrangement:

§ Whether it is a producer/exporter of arms or industrial equipment respectively;

§ Its non-proliferation policies and its appropriate national policies including:

§ Adherence to non-proliferation policies, control lists and, where applicable, guidelines for the Nuclear Suppliers Group, the Missile Technology Control Regime and the Australia Group; and through adherence to the Nuclear Non-Proliferation Treaty, the Biological and Toxicological (sic) Weapons Convention, the Chemical Weapons Convention and (where applicable) START 1, including the Lisbon Protocol;

§ Its adherence to fully effective export controls.

45. Participating States undertake to:

"exchange, on a voluntary basis, information that will enhance transparency, will lead to discussions among all Participating States on arms transfer, as well as on sensitive dual-use goods and technologies, and will assist in developing common understandings of the risks associated with the transfer of these items. On the basis of this information, they will assess the scope for coordinating national control policies to combat these risks."

46. As might be expected, the Wassenaar *"List of Dual-use Goods and Technologies and Munitions List"* ³⁴ contains elements that closely reflect those in the UK Export of Goods (Control) Order 1996. The Wassenaar Munitions List includes:

*ML 7 ...**Toxicological agents**, "tear gases", related equipment, components, materials and "technology" as follows:*

*a. **Biological agents** and radioactive materials "**adapted for use in war**" to produce casualties in humans or animals, degrade equipment or damage crops or the environment, and chemical warfare (CW) agents;...*[Emphasis added]

d. Equipment specially designed or modified for the dissemination of the materials or agents specified in entry ML 7.a. and specially designed components therefor;...

³³The Wassenaar Arrangement, *Initial Elements*, as adopted by the Plenary of 11-12 July 1996. Available on the web at <http://www.wassenaar.org/docs/IE96.html>

³⁴The Wassenaar Arrangement, *List of Dual-use Goods and Technologies and Munitions List*, WA List (97)1, 19 December 1997.

*e. Equipment specially designed for defence against materials specified in entry ML 7.a. and specially designed components therefor;
Note ML 7.e. includes protective clothing.*

f. Equipment specially designed for the detection or identification of materials specified in entry ML 7.a. and specially designed components therefor;...

N.B. For civil gas masks and protective equipment see also entry I. A. 4. on the Dual-Use List.

The term "adapted for use in war" is defined as:

"adapted for use in war" means any modification or selection (such as altering purity, shelf life, virulence, dissemination characteristics, or resistance to UV radiation) designed to increase the effectiveness in producing casualties in humans or animals, degrading equipment or damaging crops or the environment.

47. The List of Dual-Use Goods includes:

1. A. 4. Protective and detection equipment and components not specially designed for military use, as follows:

*a. Gas masks, filter canisters and decontamination equipment therefor designed or modified for **defence against biological agents** or radioactive materials "adapted for use in war" or chemical warfare (CW) agents and specially designed components therefor;*

*b. Protective suits, gloves and shoes specially designed or modified for **defence against biological agents** or radioactive materials "adapted for use in war" or chemical warfare (CW) agents;*

*c. Nuclear, biological and chemical (NBC) detection systems specially designed or modified for **defence against biological agents** or radioactive materials "adapted for use in war" or chemical warfare (CW) agents and specially designed components therefor; [Emphasis added]*

Note 1. A. 4 does not control:

a. Personal radiation monitoring dosimeters;

b. Equipment limited by design or function to protect against hazards specific to civil industries, such as mining, quarrying, agriculture, pharmaceuticals, medical, veterinary, environmental, waste management, or to the food industry.

48. The Wassenaar Arrangement's specific information exchange requirements include semi-annual notifications of arms transfers as well as transfers or denials of transfers of controlled dual-use items as such denial reporting helps to bring to the attention of members the transfers that may undermine the objectives of the arrangement. Information exchanged can also include any other matters relevant to the Wassenaar Arrangement goals that individual Participating States wish to bring to the attention of other members. The Annexes

to the Initial Elements set out the details of the specific information exchange on dual-use goods and technologies which states that:

"The content of denial notifications...will be based on, but not be limited to, the following indicative or illustrative list:

- § From (country)
- § Country of destination
- § Item number on the Control List
- § Short description
- § Number of licences denied
- § Number of units (quantity)
- § Reason for denial."

Analysis

49. It is thus apparent that national export controls for biological materials and equipment are harmonized both regionally as within the European Union and more widely through the Australia Group and the Wassenaar Arrangement.

Conclusions

50. Arrangements are clearly already in place within countries such as the United Kingdom for the monitoring and control of exports of biological materials and equipment which enable the United Kingdom to meet its obligations under Article III of the BTWC. These control regimes have been harmonized within the European Union and also more widely through the Australia Group and the Wassenaar Arrangement. These measures provide a useful basis which could with advantage be drawn upon in devising appropriate measures to strengthen the implementation of Article III in the Protocol being negotiated by the AHG to strengthen the BTWC.