

ARTICLE III : FURTHER 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.

2. This Briefing Paper is complementary to Briefing Paper No 12¹ which set out 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 controls of hazardous materials. International developments in respect of such controls are considered in this Briefing Paper.

3. There are a number of international control regimes relating to transfers of hazardous or dual-use materials. Of particular relevance in considering global regimes for chemical and biological materials is the regime for "banned and severely" restricted chemicals which has seen the introduction initially of a voluntary system of Prior Informed Consent (PIC) which is currently being transformed into an international legally binding system following the Conference of Plenipotentiaries on the Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade held on 10-11 September 1998 in Rotterdam, The Netherlands. Another regime that is currently being negotiated as part of the Biosafety Protocol is a system of Advance Informed Agreement (AIA) for the transfer of living modified organisms. Finally, as part of the United Nations Special Commission (UNSCOM) Ongoing Monitoring and Verification (OMV) scheme for Iraq, there is a world-wide system of notification of exports to and imports into Iraq which includes a wide range of dual purpose goods. Each of these is considered below.

4. It has become apparent that there is increasing awareness world-wide because of public health and environmental concerns of the need to control the transfer of such hazardous materials. This paper examines some of the current 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 other national, regional and international activities can be drawn upon to contribute to the strengthening of the BTWC.

Prior Informed Consent

5. **United Nations Consolidated List.** Following the growth in world trade in chemicals in the 1960s and 1970s, the Governing Council of the UN Environment Programme (UNEP) in

¹Graham S Pearson, *Article III : Some Building Blocks*, Briefing Paper No. 12, University of Bradford, October 1998. Available on <http://www.brad.ac.uk/acad/sbtwc>

1977 urged² Governments to take steps to ensure that potentially harmful chemicals, which are unacceptable for domestic purposes in the exporting country, are not permitted to be exported without the knowledge and consent of appropriate authorities in the importing country.

6. Some 5 years later, the United Nations General Assembly "*aware of the damage to health and the environment that the continued production and export of products that have been banned and/or permanently withdrawn on ground of human health and safetyis causing in the importing countries*" and "*considering that many developing countries lack the necessary information and expertise to keep up with developments in this field*" requested³ that the Secretary-General prepare and regularly update "*a consolidated list of products whose consumption and/or sale have been banned, withdrawn, severely restricted or not approved by Governments.*" This list is prepared⁴ and regularly updated jointly by the United Nations, the World Health Organization and the United Nations Environmental Programme/International Register of Potentially Toxic Chemicals (UNEP/IRPTC). This is part of a continuing effort in the United Nations system aimed at disseminating information internationally on products harmful to health and the environment. It provides information on restrictive regulatory decisions taken by Governments on pharmaceutical, agricultural and industrial chemicals, and consumer products. The Fourth Edition covers regulatory actions taken by 92 Governments on over 600 products. The introduction to the Fourth Edition⁴ notes that "*It is important to realize that all pharmaceutical and chemical products are potentially harmful if not correctly used.*" and that "*The list does not include many widely used industrial chemicals to which occupational exposure limits have been assigned by national authorities, and on which information is available in ILO (International Labour Organization) and UNEP/IRPTC publications.*"

7. In order to ensure that the list focusses on products harmful to health and the environment, criteria for the inclusion of products were developed in 1985 and transmitted to Governments for their comments. These criteria, revised in the light of the comments received, are reproduced in an Annex to the Consolidated List. Those for chemical products are "Banned", "Withdrawn" and "Severely restricted" which are defined as:

Banned - A product that has been prohibited for all uses nationally in one or more countries by final government regulatory action because of health or environmental reasons

Withdrawn - A product formerly in commerce that has been withdrawn for all uses nationally in one or more countries by final voluntary action of the manufacturer because of health or environmental reasons

Severely restricted - A product for which virtually all uses have been prohibited nationally in one or more countries by final government regulatory action because of health or environmental reasons, but for which certain specific uses remain authorized.

²United Nations Environment Programme, Governing Council decision 85(V), 25 May 1977.

³United Nations General Assembly, Resolution 37/137, *Protection against Products Harmful to health and the Environment*, 109th Plenary Meeting, 17 December 1982.

⁴United Nations Department of International Economic and Social Affairs, *Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or not Approved by Governments*, Fourth Edition, United Nations, New York, 1991.

8. **The London Guidelines.** UNEP in 1987 adopted⁵ the London Guidelines for the Exchange of Information on Chemicals in International Trade⁶ which were aimed at enhancing the sound management of chemicals through the exchange of scientific, technical, economic and legal information. Special provisions were included regarding *"the exchange of information on banned and severely restricted chemicals in international trade, which call for cooperation between exporting and importing countries, in the light of their joint responsibility for the protection of human health and the environment at the global level."* UNEP in adopting these guidelines also identified that additional measures were required to enable importing countries to give or withhold their consent to particular exports following receipt of adequate information from exporting countries and that such measures, based on the principle of prior informed consent should be incorporated in the London Guidelines as expeditiously as possible.

9. This principle of Prior Informed Consent (PIC) was incorporated⁷ in the amended London Guidelines⁸ in 1989. These provide a mechanism for importing countries to formally record and disseminate their decisions regarding the future importation of chemicals which have been banned or severely restricted in the exporting countries and outlines the shared responsibilities of importing and exporting countries and exporting industries in ensuring that these decisions are heeded. The Introduction to the Guidelines states that *"Although these Guidelines have not been prepared specifically to address the situation of developing countries, they nevertheless provide a framework for the establishment of procedures for the effective use of chemicals in these countries. Implementation of the Guidelines should thus help them to avoid serious and costly health and environmental problems due to ignorance about the risks associated with the use of chemicals, particularly those that have been banned or severely restricted in other States."*

10. The PIC procedure is being implemented jointly by the Food and Agriculture Organization (FAO) of the United Nations which leads for pesticides and UNEP through the IRPTC (International Register of Potentially Toxic Chemicals) which leads for chemicals. Each participating country - of which, by February 1998, there were 152 - nominates a Designated National Authority (DNA)⁹ to serve as a focal point for the operation of the PIC procedure. Some countries have designated one authority for all chemicals while others have designated two, one with responsibility for pesticides and the other for other chemicals. The DNA is generally a government department or office responsible for broad policy decisions with the authority to decide which chemicals may be used in the country. In the UK, it is the Chemicals and Biotechnology Division of the Department of the Environment while in the USA it is the Assistant Administrator, Prevention, Pesticides and Toxic Substances of the Environmental Protection Agency.

⁵United Nations Environment Programme, Proceedings of the Governing Council at its Fourteenth Session, UNEP/GC.14/26, 10 July 1987. Decision 14/27 of 17 June 1987.

⁶United Nations Environment Programme, Programme Matters, UNEP/GC.14/17, 2 April 1987, Annex IV: London Guidelines for the Exchange of Information on Chemicals in International Trade

⁷United Nations Environment Programme, Governing Council Decision 15/30 of 25 May 1989.

⁸United Nations Environment Programme, London Guidelines for the Exchange of Information on Chemicals in International Trade, Amended 1989.

⁹UNEP/FAO Register of Designated National Authorities for the Implementation of the Information Exchange and PIC Procedures of the London Guidelines and the International Code of Conduct, Geneva and Rome, February 1998. Available on the web at <http://irptc.unep.ch/pic/>

11. The functions of the DNA in respect of the import of banned or severely restricted chemicals are to receive information on exports from exporting States, to transmit requests for further information as required to exporting States, to advise and assist import control authorities, to strengthen national decision-making procedures and import control mechanisms, to ensure that decisions apply uniformly to all import sources and to domestic production of chemicals for domestic use, and to encourage that chemicals subject to PIC be purchased only from sources in exporting countries which are participants in that procedure. Insofar as exports of banned or severely restricted chemicals are concerned, the function of the DNA is to ensure the provision or transmittal of information on exports, to respond to requests for information from other States, especially as regards sources of precautionary information on the safe use and handling of the chemicals concerned, to communicate PIC decisions to their export industry, and to implement appropriate procedures, within their authority, designed to ensure that exports do not occur contrary to the PIC decisions of participating importing countries.

12. Participating countries provide information on control actions they have taken to ban or severely restrict chemicals by completing a Notification of Control Action form which gives competent authorities in other States the opportunity to assess the risks associated with the chemical and to make timely and informed decisions thereon having regard to local environmental, public health, economic and administrative conditions. The minimum information to be provided is the chemical identification/specification of the chemical, a summary of the control action taken and the reasons for it and whether additional information is available. The reasons supporting the control action should be based on a national review of scientific data, information or analysis which indicate that use under expected conditions within the country may give rise to an unacceptable risk to human health or the environment. Any chemical banned or severely restricted in at least one country after 1 January 1992 is eligible for inclusion in the PIC procedure; any chemicals banned or severely restricted prior to that date which have been the subject of control actions taken in 5 or more countries may also be eligible.

13. Once a chemical has been identified for inclusion in the PIC procedure, a Decision Guidance Document (DGD) is prepared by FAO/UNEP and sent to each participating country (through the DNAs) together with an Importing Country Response form. The DGD provides a summary of toxicological and environmental characteristics, known usage, possible exposure routes, measures to reduce exposure and regulatory actions taken by some countries to ban or severely restrict the chemical, with corresponding reasons for their actions. The DGD is intended to help Governments assess the risks connected with the handling and use of the chemical and to make more informed decisions about future import and use taking into account local conditions. The DNA then completes an Importing Country Response form indicating whether to accept import, refuse import or allow import under certain conditions. The response is sent to the FAO/UNEP Secretariat who summarize the import decisions and circulate these to DNAs every six months¹⁰. Governments of exporting countries shall, upon receipt of importing countries decisions, transmit them to their industry. In addition, this information is also included in the regular updates of the Consolidated List of Products whose Consumption and/or Sale have been Banned, Withdrawn or Severely Restricted.

14. The aim of the PIC procedure is to ensure that a banned or severely restricted chemical is not exported without the consent of the importing country. The Guidelines require that if

¹⁰FAO/UNEP Joint Programme for the Operation of Prior Informed Consent(PIC), Import Decisions from participating countries as of 30 June 1996, PL 32/23, 31 July 1996.

an export is planned of a chemical banned or severely restricted in the exporting State, then the exporting State should ensure that the DNA of the importing State is provided with relevant information to remind the importing State of the original notification by the exporting State of control action and to alert it to the fact that an export is planned. The minimum information to be provided is a copy of the information provided at the time of notification of the control action, the indication that an export of the chemical will occur and an estimate of the quantity to be exported annually as well as any shipment-specific information that might be available. Such information is to be provided to the State of final destination and to UNEP/IRPTC. It is also clear that the PIC procedure is applied to chemicals that have multiple use. For example, the six monthly PIC circular¹¹ of import decisions for some chemicals has in the column headed "Final Decision on Import" the words "Prohibit for plant protection use" and then in the column headed "Conditions for Import" has the words "For uses other than plant protection, written authorization is required for import".

15. The banned and severely restricted chemicals thus far subject to the PIC procedure are pesticides and industrial chemicals; last September five organophosphates -- methamidophos, methyl parathion, monocrotophos, parathion and phosphamidon -- were added to some 17 pesticides and 5 industrial chemicals which were already the subject of DGDs.¹¹ In some cases, a specific chemical is the subject of a DGD such as fluoroacetamide, parathion or ethylene oxide, whilst other DGDs apply to a group of chemicals such as mercury compounds and polychlorinated biphenyls (PCB), except mono- and dichlorinated.

16. **EU Regulation.** In the European Union, a legally binding Council Regulation (EEC) No 2455/92 was adopted¹² in 1992 which requires exporters of chemicals which are banned or severely restricted in the European Union to provide information to importing countries about these chemicals. This regulation implements the UNEP/FAO PIC scheme in the EU. Member Governments of the EU are legally required, as well as formally committed, to implement EEC Regulations. Consequently it is a legal requirement for an exporter to provide the designated national authority of the Member State in which he is located with information about the export from the Community to a third country for the first time of a chemical subject to the Regulation no later than 30 days before the export is due to take place. The designated national authority has then to ensure that the appropriate authorities of the country of designation receive notification at least 15 days before export; copies of the notification are to be copied to the Commission which shall forward it to the designated national authorities of the other Member States and to UNEP/IRPTC. The notification provides information about the identity of the chemical, information on precautions to be taken, summary of the regulatory restrictions and the reasons for them, the expected date of first export, country of designation, use category (whether plant protection product, industrial chemical or consumer chemical) and the estimated amount of the chemical to be exported to the destination country in the next year. The regulation requires the exporter to comply with the decision of the country of destination participating in the PIC procedure.

¹¹FAO/UNEP Joint Programme for the Operation of Prior Informed Consent, Update on Implementation as of 30 June 1996. FAO/UNEP, Prior Informed Consent, *News & Highlights*, Rome 23 September 1997. Available on the web at <http://irptc.unep.ch/pic/>

¹²Council Regulation (EEC) No 2455/92 of 23 July 1992 concerning the import and export of certain dangerous chemicals, Official Journal of the European Communities, L251, Volume 35, 29 August 1992, pp 13-22. See also European Chemicals Bureau, Informing the Importer, Guide to Council Regulation (EEC) No 2455/92 concerning the import and export of certain dangerous chemicals, 1996.

17. **The Rio Summit.** The United Nations Conference on Environment and Development held in Rio de Janeiro from 3 to 14 June 1992 (the Earth Summit) proclaimed a set of Principles¹³ which were amplified in a series of Chapters and programme areas; for each the bases for action, objectives, activities and means of implementation are addressed. These include:

Chapter 19 Environmentally sound management of toxic chemicals, including prevention of illegal international traffic in toxic and dangerous products.

Within these chapters there are areas addressing the protection of people and the environment such as:

Expanding and accelerating international assessment of chemical risks (Chapter 19, Section A)

Information exchange on toxic chemicals and chemical risks (Chapter 19, Section C)

Prevention of illegal international traffic in toxic and dangerous products (Chapter 19, Section F)

18. Of particular interest, are various sections of Chapter 19 (*Prevention of illegal international traffic in toxic and dangerous products*). Thus Section C on information exchange has the objectives of promoting intensified exchange of information on chemical safety, use and emissions among all involved parties and of achieving "by the year 2000, as feasible, full participation in and implementation of the PIC procedure, including possible mandatory applications through legally binding instruments". Section F notes that there is currently no global international agreement on traffic in toxic and dangerous products (toxic and dangerous products are those that are banned, severely restricted, withdrawn or not approved for use or sale by Governments to protect public health and the environment). However, it was noted that there was international concern that illegal international traffic in these products is detrimental to public health and the environment, particularly in developing countries as acknowledged by the General Assembly in resolutions 42/183 and 44/226¹⁴. It went on to say that further strengthening of international and regional cooperation is needed to prevent illegal transboundary movement of toxic and dangerous products. The following activities are detailed:

Governments, according to their capacities and available resources and with the cooperation of the United Nations and other relevant organizations, as appropriate should:

a Adopt, where necessary, and implement legislation to prevent the illegal import and export of toxic and dangerous products

¹³United Nations, *Report of the United Nations Conference on Environment and Development*, Rio de Janeiro, 3- 14 June 1992, A/CONF.151/26, 12 August 1992. See also *Earth Summit '92*, The United Nations Conference on Environment and Development, Rio de Janeiro 1992, Regency Press, London, 1992.

¹⁴United Nations General Assembly, *Traffic in and disposal, control and transboundary movements of toxic and dangerous products and wastes*, Resolution 44/226, 85th Plenary Meeting, 22 December 1989.

b. Develop appropriate national enforcement programmes to monitor compliance with such legislation, and detect and deter violations through appropriate penalties.

19. **A legally binding PIC procedure.** The UNEP Governing Council at its meeting in May 1991 adopted¹⁵ resolution 16/35 on Toxic Chemicals requesting further urgent action be taken to strengthen the legal basis of the amended London Guidelines taking into consideration experience gained in the implementation of the Guidelines and the PIC procedure. At the UNEP meeting in May 1995, resolution 18/12 was adopted¹⁶ to develop an internationally legally binding instrument for the application of the PIC procedure. This resolution followed consideration of a report¹⁷ by the Executive Director of UNEP which noted that one of the objectives of programme area C of Chapter 19 of Agenda 21 was to achieve by 2000 full participation in and implementation of the PIC procedure, including possible mandatory applications through legally binding instruments. Resolution 18/12 authorised UNEP in conjunction with FAO to convene *"an intergovernmental negotiating committee with a mandate to prepare a legally binding instrument for the application of the prior informed consent procedure for certain hazardous chemicals in international trade."* The resolution also called for the convening of *"a diplomatic conference for the purpose of adopting and signing an internationally legally binding instrument for the application of the prior informed consent procedure for certain hazardous chemicals in international trade, preferably not later than early 1997."*

20. The first meeting of the intergovernmental negotiating committee for an international legally binding instrument for the application of the PIC procedure was held¹⁸ in Brussels in March 1996 under the chairmanship of Ms Rodriguez of Brazil. This session made rapid progress, agreed quickly on the rules of procedure, and completed a preliminary review of a draft outline of the future agreement. The second meeting was held in September 1996 in Nairobi, Kenya which made further progress producing 24 pages of draft Convention text with most of the articles having been extensively discussed. Further development of the text of the Protocol took place at the third meeting was held in May 1997 in Geneva and the fourth meeting held in October 1997 in Rome and was finalized at the fifth meeting held in March 1998 in Brussels¹⁹. Five meetings each of one week has seen the agreement of a Convention of 30 Articles and 5 Annexes. A diplomatic conference, the Conference of Plenipotentiaries on the Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, hosted by the Government of the Netherlands, was held in Rotterdam on 10 - 11 September 1998 to officially adopt and sign the new Convention.

¹⁵United Nations Environment Programme, Proceedings of the Governing Council at its Sixteenth Session, UNEP/GC.16/27, 30 June 1991. Decision 16/35 of 31 May 1991.

¹⁶United Nations Environment Programme, Proceedings of the Governing Council at its Eighteenth Session, UNEP/GC.18/40, 13 June 1995. Decision 18/12 of 26 May 1995.

¹⁷United Nations Environment Programme, Policy Issues, UNEP/GC.18/7, 27 February 1995.

¹⁸United Nations Environment Programme/Food and Agriculture Organization of the United Nations, Report of the Intergovernmental Negotiating Committee for an Internationally Legally Binding Instrument for the Application of the Prior Informed Consent Procedure for certain Hazardous Chemicals and Pesticides in International Trade on the Work of its First Session, UNEP/FAO/PIC/INC.1/10, 21 March 1996. Available on the web at <http://irptc.unep.ch/pic/>

¹⁹United Nations Environment Programme/Food and Agriculture Organization of the United Nations, Report of the Intergovernmental Negotiating Committee for an Internationally Legally Binding Instrument for the Application of the Prior Informed Consent Procedure for certain Hazardous Chemicals and Pesticides in International Trade on the Work of its Fifth Session, UNEP/FAO/PIC/INC.5/3, 17 March 1998. Available on the web at <http://irptc.unep.ch/pic/>

21. The new Convention will enter into force when 50 countries have ratified. The Preamble recognizes that "trade and environmental policies should be mutually supportive" to achieve sustainable development. The treaty aims at protecting "human health, including the health of consumers and workers, and the environment." It requires that harmful pesticides and chemicals that have been banned or severely restricted in at least two countries shall not be exported unless explicitly agreed by the importing country. The information about the new Convention states that "As a first among the multilateral environmental agreements, Governments have agreed to continue to implement the voluntary PIC procedure using the new procedures of the Convention until the Convention formally enters into force" thereby avoiding any break in the implementation of the PIC procedure. The 27 chemicals currently subject to the voluntary PIC procedure will be carried forward into the legally binding Convention. Under the treaty, exporting countries will be legally bound to inform importing countries about exports of chemicals banned or severely restricted in the exporting country. This export notification will be required prior to the first export and be repeated for the first export each year. Countries that ratify the treaty will be obliged to enforce the agreement at national level and to create enforcement mechanisms that will control commercial exports and exporters. In developing countries and countries in transition, technical assistance shall be promoted for the development of the infrastructure and the capacity necessary to manage chemicals.

22. The Convention contains provisions for the *exchange of information* among Parties and provides for a *national decision-making process* regarding import and compliance by exporters with these decisions. The provisions regarding information exchange include:

- * The requirement for a Party to inform other Parties of each ban or severe restriction on a chemical it implements nationally;
- * The possibility for a developing country Party or a Party with an economy in transition to inform other Parties that it is experiencing problems caused by a severely hazardous pesticide formulation under conditions of use in its territory;
- * The requirement for a Party that plans to export a chemical that is banned or severely restricted for use within its territory, to inform the importing Party that such export will take place, before the first shipment and annually thereafter;
- * The requirement that an exporting Party, when exporting chemicals that are to be used for occupational purposes, shall ensure that a safety data sheet that follows an internationally recognized format, setting out the most up-to-date information available, is sent to the importer;
- * The requirement that exports of chemicals included in the PIC procedure and other chemicals that are banned or severely restricted domestically, when exported, are subject to labelling requirements that ensure adequate availability of information with regard to risks and/or hazards to human health or the environment.

Decisions taken by the importing Party must be trade neutral; that is, if the Party decides it does not consent to accepting imports of a specific chemical, it must also stop domestic production of the chemical for domestic use or imports from any non-party.

23. The proformas²⁰ for the "Notification of Control Action to Ban or Severely Restrict a Chemical" , for "Information Regarding Export" and for "Importing Country Response" set out the information required. Notification of Control Action forms requires information on the identity of the chemical, the major use categories within the agricultural, industrial and consumer use sectors, the uses controlled and the uses still allowed together with the reasons for taking the control action relevant to human health and the environment. The Export form likewise requires information on the identity of the chemical, the use categories in the country of export and information regarding the intended use in the country of import together with estimated annual quantities. The Importing Country Response requires information on the identity of the chemical and on the status of the use of the chemical -- is it registered or approved, is it currently used, is it currently imported, is it currently manufactured? -- as well as the final or interim decision regarding import. The proformas are completed by the designated national authorities and are copied to the PIC Convention Secretariat which at intervals circulates collated information to the States Parties. The Convention in Article 14 on Information Exchange specifically states that certain information shall not be regarded as confidential for the purpose of the PIC Convention: the information provided in the Notification of Control Action forms and information on pesticides to be controlled, information provided in safety data sheets, information on precautionary measures and the summary results of the toxicological and ecotoxicological tests.

Analysis

24. The PIC Convention has functioned through a voluntary procedure involving 152 countries which has controlled the export and import of "restricted and severely banned chemicals". The procedures have been legally binding within the European Union since 1992 and are being transformed now into a legally binding Convention. The information required on, the transparency of and the control of the uses of chemicals provide a useful model which might be helpful in considering measures to improve the implementation of Article III of the BTWC.

Advance Informed Agreement

25. The past decade has seen an increasing awareness of the importance of protecting health and the environment. This was highlighted by the holding of the UN Conference on Environment and Development²¹ in Rio de Janeiro in June 1992 (the Earth Summit) which saw the adoption of a set of Principles, Agenda 21 and the opening for signature the Convention on Biological Diversity (CBD)²². The Principles are amplified in a series of Chapters and programme areas which include "*Chapter 16 Environmentally sound management of biotechnology*" which has a section (D) on "*enhancing safety and developing international mechanisms for cooperation.*" This states that:

"there is a need for further development of internationally agreed principles of risk assessment and management of all aspects of biotechnology, which should build upon those developed at the national level. Only when adequate and transparent

²⁰Available on the web at <http://irptc.unep.ch/pic/>

²¹United Nations, *Report of the United Nations Conference on Environment and Development*, Rio de Janeiro, 3- 14 June 1992, A/CONF.151/26, 12 August 1992. See also *Earth Summit '92*, The United Nations Conference on Environment and Development, Rio de Janeiro 1992, Regency Press, London, 1992.

²²Convention on Biological Diversity, opened for signature at Rio de Janeiro 5 June 1992, HMSO, Cm 2127, January 1993. Also available as United Nations, UNEP/CBD/94/1, Geneva, November 1994.

safety and border-control procedures are in place will the community at large be able to derive maximum benefit from, and be in a much better position to accept the potential benefits and risks of, biotechnology." [Emphasis added].

26. The desirability of trans-border controls was echoed in the legally binding CBD which entered into force in December 1993. Paragraph 3 of Article 19 on Handling of Biotechnology and Distribution of its Benefits states that:

"The Parties shall consider the need for an modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity." [Emphasis added]

27. In November 1995 an open-ended Ad Hoc Working Group was set up to negotiate in:

"the field of the safe transfer, handling and use of living modified organisms, a protocol on biosafety, specifically focusing on transboundary movement, of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity..." [Emphasis added].

Its first meeting²⁶ was held in July 1996 when an Advance Informed Agreement (AIA) procedure was identified as a key component of the protocol. The third Conference of Parties to the Convention on Biological Diversity held in Buenos Aires, Argentina on 4 to 15 November 1996 urged the Ad Hoc Working Group on Biosafety to complete its work on developing a protocol in 1998 as a matter of urgency; four further meetings of the Ad Hoc Working Group have been held in May 1997, October 1997, February 1998 and August 1998.

28. At the fourth meeting of the Conference of Parties to the CBD held on 4 - 15 May 1998, Decision IV/3²³ was agreed which decided that the final meeting of the Open-ended Ad Hoc Working Group on Biosafety and an extraordinary meeting of the Conference of the Parties to adopt the Protocol on Biosafety would be held in February 1999. The decision also determined that the Protocol should be opened for signature at the Headquarters of the United Nations in New York no later than three months from the date of its adoption by the Conference of the Parties.

29. Consequently, it is clear that the negotiations to develop a protocol to ensure that living modified organisms are handled safely, used and transferred without danger to human health and to the environment is close to completion.

30. As might be expected, the requirements of the Biosafety Protocol are still being finalized. However, it is clear that the Protocol will include provisions for an Advanced Informed Agreement (AIA) procedure to be applied to the transboundary transfer of living modified organisms (LMOs). Article 4 of the draft Protocol²⁴ addresses the notification procedure for

²³United nations Environment Programme, Convention on Biological Diversity, Fourth Conference of Parties, Bratislava, Slovakia, 4 - 15 may 1998, *Decision IV/3. Issues related to Biosafety*, Available on the web at <http://www.biodiv.org/cop4/FinalRep-/3.html>

²⁴United Nations Environment Programme, *Report of the Fourth Meeting of the Open-ended Ad Hoc Working Group on Biosafety*, Montreal, 5-13 February 1998, UNEP/CBD/BSWG/4/4, 13 February 1998.

AIA which requires, prior to the transboundary movement of LMOs, the provision of specific information to the appropriate authority of the importing State. The information to be provided is specified in Annex I of the Protocol as:

- a. *Designation [and classification of biosafety levels] of LMO(s) [or products thereof].*
- b. *Name and address of the exporter.*
- c. *Name and address of the importer.*
- d. *Common name, taxonomic status, [source and characteristics] of recipient organism [and donor organism].*
- e. *Centre of origin/genetic diversity [if known] relevant to the organism that has been modified.*
- f. *Description of DNA/RNA fragment(s)/traits introduced or modified and resulting characteristics of the LMO [or products thereof]*
- g. *Intended use of the LMO [or products thereof] [if known].*
- h. *Quantity of LMOs [or products thereof] to be transferred or volume and physical state of culture.*
- i. *A [known and available] risk assessment report [carried out on the LMO [or products thereof] in question] in accordance with the risk assessment parameters as stated in Annex II of this Protocol.*
- j. *Suggested methods to ensure safe handling, storage, transport and use, including packaging, [labelling,] documentation, disposal and contingency procedures.*
- k. *Intended date[s] of [first] [transfer] [movement].*
- l. *Declaration that the information is [factually] correct.*

Article 5 of the draft Protocol addresses the response to AIA notification which includes, in the current draft, the provision for the importing Party to inform the notifier whether further information in accordance with Annex II Risk Assessment is required. Annex II sets out in considerable detail the information required for carrying out the risk assessment.

Analysis

31. It is evident that a legally binding Protocol to address transboundary transfers of living modified organisms is close to completion which is likely to have similar requirements for information exchange and decision prior to first import to those of the PIC Convention. The Biosafety Protocol again provides a further model which might be helpful in considering measures to improve the implementation of Article III of the BTWC.

Import/export system for Iraq.

32. Following the Gulf War of 1990/1991, the United Nations Security Council adopted Resolution 687²⁵ which required *inter alia* the removal or destruction of Iraqi weapons of mass destruction as well as measures to prevent their reconstruction, under the supervision of

²⁵United Nations Security Council, *Security Council Resolution establishing detailed measures for a cease fire, including deployment of a United Nations Observer Unit; arrangements for demarcating the Iraq-Kuwait borders; the removal or destruction of Iraqi weapons of mass destruction and measures to prevent their reconstitution, under the supervision of a Special Commission and Director General of the IAEA; and creation of a compensation fund to cover direct loss and damage resulting from Iraq's invasion of Kuwait*, S/RES/687(1991) 3 April 1991.

a special commission (UNSCOM) and the Director General of the IAEA. This Resolution includes the requirement for:

"... the Secretary-General, in consultation with the Special Commission, to develop a plan for the future ongoing monitoring and verification of Iraq's compliance with this paragraph, to be submitted to the Council for approval within one hundred and twenty days of the passage of this resolution;"

33. At the beginning of October 1991, the Secretary General transmitted²⁶ to the Security Council the plan for the future monitoring and verification of Iraq's compliance with the destruction or removal of weapons specified in Security Council Resolution 687 (1991). This plan included:

specific provisions for the monitoring and verification, from within Iraq, of any eventual import by Iraq.

and went on to note that:

The efficacy of these provisions would be enhanced if they were complemented by transparency and timely information as regards any future sale or supply by other States to Iraq of relevant items with dual use....The Plan ...contains in its annexes lists of items relevant to the monitoring and verification, from within Iraq, of prohibited items as well as items with dual use. These should be taken into account in the development of a mechanism related to the sale or supply of items to Iraq by other countries.

These plans was approved by the Security Council a week later when Resolution 715 (1991) was adopted²⁷ on 11 October 1991. The Resolution *inter alia* requested that "*a mechanism for monitoring any future sales or supplies by other countries to Iraq of items relevant to the implementation of section C of resolution 687(1991) and other relevant resolutions, including the present resolution and the plans approved hereunder*" be developed.

34. This mechanism was developed during the following years and in March 1996 the United Nations Security Council adopted Resolution 1051²⁸ which approved an export/import monitoring mechanism to monitor Iraq's exports and imports of dual-purpose capabilities to ensure that Iraq does not reconstitute its programs for weapons of mass destruction. The resolution recognised that the export/import mechanism was not a regime for international licensing, but rather for the timely provision of information by States in which companies were located which were contemplating sales of supplies to Iraq of items covered by the plans for ongoing monitoring and verification. The mechanism would not impede Iraq's legitimate right to import and export for non-proscribed purposes, items and technology necessary for the promotion of its economic and social development. The resolution "*calls upon all States to adopt as soon as possible such measures as may be necessary under their national*

²⁶United Nations Security Council, *Report of the Secretary General submitting the plan, revised pursuant to the adoption of Security Council resolution 707(1991), for future monitoring and verification of Iraq's compliance with the destruction or removal of weapons specified in Security Council resolution 687(1991)*, S/22871/Rev.1, 2 October 1991.

²⁷United Nations Security Council, *Security Council Resolution approving the plans submitted by the Secretary-General and the Director General of the IAEA*, S/RES/715(1991), 11 October 1991.

²⁸United Nations, Security Council Resolution 1051(1996), S/RES/1051(1996), 27 March 1996.

procedures to implement the mechanism." The resolution also affirmed that the mechanism approved was without prejudice to and shall not impair the operation of existing or future non-proliferation agreements or regimes on the international or regional level including arrangements referred to in Resolution 687 (1991), nor shall such agreements or regimes impair the operation of the mechanism. The mechanism would enter into force for Iraq not later than 60 days after the adoption of the resolution.

35. The mechanism²⁹ requires the timely notification by all States of any items identified in the plans³⁰ for ongoing monitoring and verification. Both Iraq and the Governments of suppliers are required to provide these notifications in advance of shipment. If an item, the import of which should have been notified under the mechanism, but was not, is found in Iraq, the import would constitute a case of non-compliance with the monitoring regime established by the plans for ongoing monitoring and verification. The strong presumption would be that the item had been procured for prohibited purposes and so, as such, would be subject for disposal by UNSCOM/IAEA. The resolution approves the establishment of a joint UNSCOM/IAEA unit at UN headquarters to operate the regime. States are called upon to adopt national measures to implement the mechanism as soon as possible.³¹ This export/import regime is designed to complement the ongoing monitoring and verification system as required under Security Council resolution 715 (1991).

36. In September 1996, the Secretary-General wrote³² to the President of the Security Council to advise the Security Council that 1 October 1996 would be the effective date from which states would provide notification of exports to Iraq as required under the export/import mechanism approved in Resolution 1051 (1996). As sanctions on Iraq have not been lifted, the export-import mechanism was able to initially start functioning at what could be described as a pilot scale level, through the export-import requests arising from UNSCR 986 (1995) which allows a limited amount of Iraqi oil to be sold for food for humanitarian purposes; by April 1997, some six months experience had been gained largely for dual-purpose chemical and biological-related materials and equipment. This had involved some 30 transactions, each of which can involved a number of different items and different delivery dates, associated with some 80 notification forms. This export-import mechanism has shown that exports of sensitive of dual-use items can be made to Iraq as the ongoing monitoring and verification (OMV) system provides UNSCOM and the exporting states with confidence that what has been exported will not be misused.

37. The note³³ by the Executive Chairman of UNSCOM which forwarded the revised detailed annexes listing the items relevant to the export/import mechanism states that

²⁹United Nations Security Council, Letter from the Chairman of the Sanctions Committee to the President of the Security Council forwarding a proposal for a mechanism to monitor Iraq's exports and imports of dual-use capabilities, S/1995/1017, 7 December 1995

³⁰United Nations Security Council Resolution 715(1991), S/RES/715(1991), 11 October 1991 approved the plans submitted in S/22871/Rev. 1, 2 October 1991 and S/22872/Rev. 1, 20 September 1991. These plans were updated in S/1995/208, 17 March 1995 and a compendium of terms was provided in S/1996/303.

³¹Information from the News Chronology, Chemical Weapons Convention Bulletin, No. 32, June 1996, p. 28.

³²United Nations Security Council, *Letter dated 24 September 1996 from the Secretary-General and the Director general of the International Atomic Energy Agency to the President of the Security Council*, S/1996/805, 30 September 1996.

³³United Nations Security Council, Plan for Future Ongoing Monitoring and Verification of Iraq's Compliance with Relevant Parts of Section C of Security Council Resolution 687 (1991), Revised Annexes II, III, and IV, S/1995/208, 17 March 1995.

"in the course of developing the mechanism, it became clear that, for the annexes to the plan to serve, as intended, as lists of items to be reported by the exporting countries to the Special Commission and IAEA, it was necessary to elaborate upon generic descriptions in those Annexes so that customs and control authorities would know precisely what items should be subject to notification."

The detailed lists for biological materials and equipment specified in the detailed annexe are reproduced as an Annex to this Briefing Paper. As might be expected, these are even more comprehensive than the lists of biological materials and agents in the UK national and the European Union and Australia Group listings³⁴.

Analysis

38. The export/import mechanism that exists for imports of dual-use items to Iraq embraces a much broader range of dual-purpose items than those controlled by the UK, the European Union and the Australia Group export control regimes. As the Security Council Resolution called upon *"all States to adopt as soon as possible such measures as may be necessary under their national procedures to implement the mechanism"* , it would be reasonable to assume that a number of States have already taken steps to set up the necessary national infrastructure to implement this export/import mechanism. This would appear to be even more relevant to the strengthening of Article III of the BTWC than either the PIC Convention or the Advanced Informed Agreement mechanisms.

Conclusions

39. In considering both Briefing Paper No 12 and this Briefing Paper, it is evident that arrangements are 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. In addition, there are also international export/import mechanisms that have been in operation on a voluntary basis for "banned and severely restricted chemicals" for a number of years and are now becoming the subject of a legally binding Convention, are being negotiated for living modified organisms and are in operation under UN Security Council Resolution 1051 (1996) for a wide range of biological materials and equipment of direct relevance to the BTWC. These various regimes and mechanisms 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.

³⁴These listings are reproduced in Graham S Pearson, *Article III : Some Building Blocks*, Briefing Paper No. 12, University of Bradford, October 1998. Available on <http://www.brad.ac.uk/acad/sbtwc>

ANNEX: SCR 1051 (1996) EXPORT/IMPORT MECHANISM
(Detailed biological materials and equipment as listed in S/1995/208, 17 March 1995)

Revised annex III to the Special Commission's Plan

Provisions related to biological items

1. The following list contains equipment* , biological material and other items capable of being used for the development, production or acquisition of biological and toxin weapons or of a biological and toxin weapons capability and, therefore, subject to monitoring and verification in accordance with paragraphs 34 to 38 of the Plan:

- 1.1 microorganisms, ³⁵ other organisms and toxins Including purified or crude material. meeting the criteria for risk groups IV, III and II according to the classification in the World Health Organization (WHO) Laboratory Biosafety Manual (Geneva 1993, second edition), and genetic material for such toxins;
- 1.2 detection and assay systems for risk groups IV, III, and II microorganisms and toxins, or for genetic material, including immunological assays, gene probe assays and other specific detection systems;
- 1.3 equipment designed or accepted for use for processing, handling, transporting or storing microorganisms, their products or components, including toxins, or other biological material including foodstuffs, including:
 - 1.3.1 centrifugal separators or decanters for continuous or semi-continuous operation;
 - 1.3.2 continuous flow centrifuge rotors;
 - 1.3.3 plate press filter separators;
 - 1.3.4 cross-flow or tangential filtration equipment with a filter area of 0.5 square metres or greater;
 - 1.3.5 spray drying equipment;
 - 1.3.6 freeze-drying (lyophilisation) equipment with a condenser capacity greater than 1 kg of ice per 24hours;
 - 1.3.7 pressure cell disruption equipment or continuous flow ultrasonic cell disruption equipment;
 - 1.3.8 chromatography equipment for preparative separations;

*"Equipment" means complete systems and any components or reagents thereof.

³⁵ For the purposes of the Plan, full lists of the microorganisms, other organisms and toxins concerned have been enumerated in two lists, one covering risk groups IV and III (List 1), the other covering risk group II (List 2). These lists are contained in an Explanatory Note which follows on the appendix to this annex.

- 1.3.9 pharmaceutical milling equipment;
- 1.3.10 drum drying equipment;
- 1.3.11 jacketed vessels; and
- 1.3.12 control units, valves and filters for the above types of equipment;
- 1.4 biohazard containment equipment and decontamination equipment, including:
 - 1.4.1 facilities, rooms or other enclosures meeting the physical containment criteria for P3 or P4 (BL3, BL4, L3, L4) biological containment as defined in the WHO Laboratory Biosafety Manual and using laminar or turbulent air flow clean air conditions as specified for pharmaceutical, biotechnology, vaccine or other applications;
 - 1.4.2 biological safety cabinets meeting Class I, II and III containment standards, as defined in the WHO Laboratory Biosafety Manual;
 - 1.4.3 safety cabinets allowing manual or remote operations to be performed within at Class I, II or III biological containment levels, including flexible film isolators, rigid isolators, dry boxes, glove boxes, anaerobic chambers, interconnected cabinet lines, isolator lines and secondary containment systems designed to enclose fermenters or downstream processing equipment;
 - 1.4.4 rubber gloves specifically designed for use with safety cabinets and biological safety cabinets;
 - 1.4.5 autoclaves, with an internal volume of 0.3m^3 or more, designed to sterilise infectious material;
 - 1.4.6 other waste disposal systems for infectious material, such as liquid waste treatment systems, solid waste treatment systems, liquid waste disposal systems, solid waste disposal systems and incinerators; and
 - 1.4.7 positive pressure air-fed suits, half suits, helmets and respirators;
- 1.5 equipment designed or accepted for use for the microencapsulation of living microorganisms, their products or components including toxins, or other biological material;
- 1.6 complex media for the growth of risk groups IV, III and II microorganisms;
- 1.7 fermentation vessels (including bioreactors, chemostats and continuous flow systems), orbital or reciprocal shakers and shaking incubators designed or accepted for use for the cultivation of microorganisms or

eukaryotic cells or for the production of toxins, and components therefor, including control units for fermenters and other vessels;

- 1.8 recombinant nucleic acids (DNA and RNA), equipment and reagents³⁶ for their isolation, characterization or production and equipment and reagents for the construction of synthetic genes, including nucleic acid sequencing equipment, nucleic acid synthesizers, electroporation or biolistics equipment, thermal cyclers, electrophoresis equipment, transilluminators, automatic work stations and automatic data collection systems, and components therefor, including derivatized solid supports for solid phase nucleotide synthesis;
- 1.9 equipment for the release and/or dispersal into the environment or into cabinets, chambers, rooms or other enclosures of biological material and equipment capable of being modified for such use, excluding devices designed for personal use in self-administered prophylactic or therapeutic preparations by inhalation, but including crop sprayers, aircraft sprayers and tanks, other sprayers capable of chassis mounting and tanks, jet engine disseminators, aerosol disseminators, droplet disseminators, dry powder disseminators (including dry aerosol disseminators, venturi air movers and nebulisers), mist generators and foggers, including pulse jet disseminators;
- 1.10 equipment designed or accepted for use for studying the aerobiological characteristics or aerosols of microorganisms, their components including toxins, or other biological material and equipment capable of being modified for such use, including aerosolization containers (drums, cabinets, chambers, rooms or other enclosures), nose-only aerosolization equipment and aerodynamic particle-sizing equipment;
- 1.11 equipment for breeding of vectors of human, animal or plant diseases;
- 1.12 vaccines for risk groups IV, III, and II microorganisms, whether for use with humans or animals and whether licensed, unlicensed or experimental;
- 1.13 documents,³⁷ information, software or technology for the design, development, use, storage, manufacture, maintenance or support of items listed in the preceding subparagraphs of this paragraph, or of biological weapons or any component thereof, or of biological and training activities or defence; and
- 1.14 munitions, rockets or missile warheads Delivery systems are addressed in annex IV. capable of disseminating biological weapons agents.

2. The initial information under paragraphs 35 and 36 of the Plan to be provided not later than 30 days after the adoption of the Plan by the Security Council shall cover the period from 1 January 1986. Subsequent information shall be provided each 15 January and 15 July and shall cover the six-month period prior to the provision of the information.

³⁶ Including dimethoxytrityl (DMT)-ribonucleosides and dimethoxytrityl (DMT)-deoxyribonucleosides.

³⁷ "Documents" means blueprints, plans, diagrams, models, formulae, tables, engineering designs or specifications, manuals or instructions, and any database or software concerning risk groups IV, III and II microorganisms, toxins and genetic material, except those generally available to the public.

Notifications under paragraph 38 (a) of the Plan shall be provided not later than 60 days in advance.

3. Whenever the information that Iraq is required to provide under section D of the Plan and this annex is equal to nil, Iraq shall provide nil returns.

4. The information on each site or facility³⁸ to be provided under section D of the Plan shall include the following:

- 4.1 the name of the site or facility and of the owner, company, or enterprise operating the facility;
- 4.2 the location of the site or facility (including the address, geographic coordinates to the nearest second, and a site diagram. Each diagram shall be drawn to scale and shall indicate the boundaries of the site or facility, all road and rail entrances and all structures, indicating their purpose and any structure number. If the site or facility is located within a larger complex, the diagram shall specify the exact location of the site or facility within the larger complex);
- 4.3 the sources and amounts of financing of the site or facility and of its activities;
- 4.4 the main purpose of the site or facility, including research, development, use, production, storage, testing, import and export;
- 4.5 the level of protection, including, as applicable, the number and size of maximum containment or containment laboratories (units);
- 4.6 scope and description of activities, including, as applicable, a list of types and quantities of microorganisms, toxins or vaccines and equipment and other items specified in paragraph 1 of this annex;
- 4.7 a list of microorganisms and toxins, equipment and vaccines imported or isolated for the use of the site or facility, or exported, indicating the supplier or recipient countries involved;
- 4.8 the date when the planned activities, as described in paragraphs 35 (a) to 35 (g) of the Plan, are to begin at the site or facility; and
- 4.9 the number of scientifically trained personnel and their main areas of responsibility.

5. Information on imports to be provided under paragraphs 35 (g) and 38 (a) of the Plan shall cover the items listed in the appendix to this annex and shall, for each import into Iraq, specify:

³⁸ Including sites or facilities involved in the import, export or storage of the equipment, biological material and other items specified in paragraph 1 of this annex.

- 5.1 types and quantities of microorganisms, other organisms, toxins, genetic material or vaccines;
- 5.2 quantities of any equipment, facilities, information, software, technology or other items specified in the appendix to this annex;
- 5.3 country of export and the specific exporter;
- 5.4 point or port and time of entry into Iraq;
- 5.5 site or facility where it is to be used and purpose of its use; and
- 5.6 name of the specific importing organization in Iraq.

6. The information under paragraph 37 of the Plan shall be provided within seven days of the occurrence and the standardized form contained in section III of the annex on confidence-building measures in document BWC/CONF.III/23/II shall be utilized as appropriate.

7. Iraq shall, not later than each 15 April, provide to the Special Commission the copies of the declarations, information and data that Iraq has sent to the Centre for Disarmament Affairs of the United Nations Secretariat pursuant to the agreements on confidence-building measures, including the exchange of information and data, reached at the Third 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 (document BWC/CONF.III/23/II and its annex on confidence-building measures).

APPENDIX

Items to be reported under paragraphs 35 (g) and 38 (a) of the Plan and paragraph 5 of its annex III

1. Risk groups IV and III³⁹. microorganisms,⁴⁰. other organisms, toxins,⁴¹ or genetic material.
2. Biohazard containment and decontamination items as follows:
 - 2.1 facilities, rooms or other enclosures:
 - (a) meeting the physical containment criteria for P3 or P4 (BL3, BL4, L3, L4) biological containment as specified in the WHO Laboratory Biosafety Manual (Geneva,1993); and
 - (b) constructed such that the number of particles of 0.5 microns in diameter in the contained air does not exceed 35,000 particles per cubic metre;
 - 2.2 biological safety cabinets meeting Class I, II, or III standards⁴² as specified in the WHO Laboratory Biosafety Manual, including flexible film isolators, dry boxes, glove boxes, anaerobic chambers, interconnected cabinet lines, isolator lines and secondary containment systems designed to enclose fermenters or downstream processing equipment, and specially designed components therefor;

³⁹ For the purposes of the Plan, full lists of the microorganisms, other organisms and toxins concerned have been enumerated in two lists, one covering risk groups IV and III (List 1), the other covering risk group II (List 2). These lists are contained in an Explanatory Note which follows on the appendix to this annex

⁴⁰ "Microorganisms" means bacteria, viruses, mycoplasmas, rickettsiae or fungi, whether natural, enhanced or modified, either in the form of isolated live cultures, including live cultures in dormant form or in dried preparations, or as material including living material which has been deliberately inoculated or contaminated with such cultures

⁴¹ Including purified or crude material

⁴² The specifications for Class I, II and III biological safety cabinets in the WHO Laboratory Biosafety manual are:

Class I cabinet: an open-fronted, ventilated cabinet for personal protection with an unrecirculated inward air flow away from the operator. It is fitted with a HEPA filter to protect the environment from discharge of microorganisms;

Class II cabinet: an open-fronted, ventilated cabinet for personal, product and environmental protection, which provides an inward air flow and HEPA-filtered supply and exhaust air. There are two main variations: the Class IIA type recirculates 70 per cent of the air; the Class IIB type recirculates 30 per cent of the air; and

Class III cabinet: a totally enclosed, ventilated cabinet which is gastight and is maintained under negative air pressure. The supply air is HEPA-filtered and the exhaust air is passed through two HEPA filters in series. Work is performed with attached long-sleeved gloves.

- 2.3 HEPA filters;⁴³
 - 2.4 rubber gloves specially designed for use with safety cabinets and biological safety cabinets;
 - 2.5 autoclaves designed to sterilise infectious material, with an internal volume equal to or greater than 0.3 cubic metres, and specially designed components therefor; and
 - 2.6 positive pressure air-fed suits, half suits, helmets and respirators, and specially designed components therefor.
3. Fermentation equipment, as follows:
- 3.1 fermenters, bioreactors, chemostats, and continuous flow fermentation systems and specially designed components therefor;
 - 3.2 other vessels suitable for use for the cultivation of microorganisms or eukaryotic cells or for toxin production, capable of operating without the propagation of aerosols, and capable of in situ steam sterilisation in the closed state, and specially designed components therefor;
 - 3.3 orbital or reciprocal shakers with a total flask capacity greater than 5 litres, and specially designed components therefor; and
 - 3.4 shaking incubators with a total flask capacity greater than 5 litres, and specially designed components therefor.
4. Equipment usable for processing, handling, transporting or storing microorganisms, their products or components excluding personal and household equipment, but including toxins, or other biological material (including foodstuffs), as follows, and specially designed components therefor:
- 4.1 centrifugal separators or decanters for continuous or semi-continuous operation;
 - 4.2 continuous flow centrifuge rotors;
 - 4.3 plate press filter separators;
 - 4.4 cross-flow and tangential filtration equipment with a filter area equal to or greater than 0.5 m²;
 - 4.5 spray drying equipment;
 - 4.6 freeze-drying (lyophilisation) equipment with a condenser capacity greater than 1 kg of ice in 24 hours;

⁴³ The WHO Laboratory Biosafety Manual defines HEPA filters as high efficiency particulate air filters. They should conform to national standards and not more than three particles should be recovered when the filter is challenged with a dose of 100,000 particles.

- 4.7 pressure cell disruption and continuous flow ultrasonic cell disruption equipment;
 - 4.8 chromatography columns with internal volumes greater than 2 litres, and specially designed end pieces and flow adaptors for such columns;
 - 4.9 milling equipment capable of producing particle sizes of 10 microns or less;
 - 4.10 drum drying equipment; and
 - 4.11 jacketed vessels.
5. Formulated powdered complex media or concentrated liquid complex media for growth of microorganisms.
6. Detection and assay systems for microorganisms, toxins, or genetic material in List 1 and specially designed reagents therefor, as follows:
- 6.1 immunological assay systems;
 - 6.2 gene probe assay systems; and
 - 6.3 biological agent detection systems designed for biological defence or civil defence applications.
7. Equipment and reagents for use in molecular biology research, as follows, and specially designed components therefor:
- 7.1 nucleic acid sequencing equipment;
 - 7.2 nucleic acid synthesizers;
 - 7.3 electroporation or biolistics equipment;
 - 7.4 thermal cyclers;
 - 7.5 specially designed automatic data collection systems;
 - 7.6 transilluminators;
 - 7.7 electrophoresis equipment;
 - 7.8 derivatized solid supports for solid phase nucleotide synthesis;
 - 7.9 dimethoxytrityl (DMT)-ribonucleosides; and
 - 7.10 dimethoxytrityl (DMT)-deoxyribonucleosides.

8. Equipment capable of dispersing aerosols at a flow rate exceeding 1 litre of liquid suspension per minute or 10 g of dry material per minute, as follows, and specially designed components therefor:

- 8.1 crop sprayers;
- 8.2 aircraft sprayers and associated spray tanks;
- 8.3 other sprayers, capable of chassis mounting, and associated spray tanks;
- 8.4 jet engine disseminators;
- 8.5 aerosol disseminators;
- 8.6 droplet disseminators;
- 8.7 dry powder disseminators ⁴⁴
- 8.8 mist generators; and
- 8.9 foggers

9. Equipment usable in the study of aerosols, as follows, and specially designed components therefor:

- 9.1 aerosolization drums, cabinets, chambers, rooms or other enclosures;
- 9.2 nose-only aerosolization equipment but not devices for personal prophylaxis or therapy for medical conditions; and
- 9.3 aerodynamic particle-sizing equipment.

10. Equipment designed for the microencapsulation of living organisms, their products or components including toxins, or other biological material.

11. Vaccines for microorganisms or toxins in List 1, whether for use with humans or animals and whether licensed, unlicensed or experimental.

12. Documents ⁴⁵, information, software or technology for the design, development, use, storage, manufacture, maintenance or support of entries 1 to 11 above, or of biological weapons or any component thereof, or of biological defence and training activities or defence.

⁴⁴Including dry aerosol disseminators, venturi air movers and nebulisers.

⁴⁴Including pulse jet disseminators.

⁴⁵"Document" means blueprints, plans, diagrams, models, formulae, tables, engineering designs or specifications, manuals or instructions, and any database or software pertaining to microorganisms, toxins and genetic material of List 1 items except those containing information generally available to the public.

13. Munitions, rockets and missile warheads⁴⁶ capable of disseminating biological weapons agents.

⁴⁶Delivery systems are addressed in annex IV.

EXPLANATORY NOTE

UNSCOM Biological Lists based on the classification in the World Health Organization (WHO) Laboratory Biosafety Manual

LIST 1 - Risk Groups IV and III Microorganisms,⁴⁷ other Organisms and Toxins

1.1 Bacteria

- 1.1.1 Bacillus anthracis
- 1.1.2 Bacillus cereus
- 1.1.3 Bacillus subtilis
- 1.1.4 Bacillus megaterium
- 1.1.5 Bacillus thuringensis
- 1.1.6 Brucella abortus
- 1.1.7 Brucella melitensis
- 1.1.8 Brucella suis
- 1.1.9 Chlamydia psittaci
- 1.1.10 Clostridium botulinum
- 1.1.11 Clostridium perfringens
- 1.1.12 Francisella tularensis
- 1.1.13 Pseudomonas mallei
- 1.1.14 Pseudomonas pseudomallei
- 1.1.15 Salmonella typhi (Salmonella enterica var typhi)
- 1.1.16 Serratia marcescens
- 1.1.17 Shigella dysenteriae
- 1.1.18 Vibrio cholera
- 1.1.19 Yersinia pestis (Yersinia pseudotuberculosis var pestis)
- 1.1.20 Xanthomonas albilineans
- 1.1.21 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

1.2 Mycoplasma

- 1.2.1 Mycoplasma mycoides

1.3 Rickettsiae

- 1.3.1 Coxiella burnetii
- 1.3.2 Rickettsia prowasecki
- 1.3.3 Rickettsia quintana
- 1.3.4 Rickettsia rickettsii

1.4 Viruses

⁴⁷The items in this list do not conform fully with the criteria for risk groups IV and III according to the classification in the 1983 World Health Organization (WHO) Laboratory Biosafety Manual but should be considered as doing so for the purposes of ongoing monitoring and verification activities in Iraq.

- 1.4.1 African swine fever virus
- 1.4.2 Avian influenza virus
- 1.4.3 Bluetongue virus
- 1.4.4 Chikungunya virus
- 1.4.5 Congo-Crimean haemorrhagic fever virus
- 1.4.6 Dengue fever virus
- 1.4.7 Eastern equine encephalitis virus
- 1.4.8 Ebola virus
- 1.4.9 Foot and mouth disease virus
- 1.4.10 Goat pox virus
- 1.4.11 Hantaan virus
- 1.4.12 Human influenza
- 1.4.13 Japanese encephalitis virus
- 1.4.14 Junin virus
- 1.4.15 Lassa fever virus
- 1.4.16 Lymphocytic choriomeningitis virus
- 1.4.17 Lyssa virus
- 1.4.18 Machupo virus
- 1.4.19 Marburg virus
- 1.4.20 Monkey pox virus
- 1.4.21 Newcastle disease virus
- 1.4.22 Peste des petits ruminants virus
- 1.4.23 Porcine herpes virus (Aujeszky's disease)
- 1.4.24 Rift Valley fever virus
- 1.4.25 Rinderpest virus
- 1.4.26 Sheep pox virus
- 1.4.27 Swine fever virus (Hog cholera virus)
- 1.4.28 Swine Vesicular disease (Porcine enterovirus type 9)
- 1.4.29 Teschen disease virus
- 1.4.30 Tick-borne encephalitis virus (Russian Spring-Summer encephalitis virus)
- 1.4.31 Variola virus
- 1.4.32 Venezuelan equine encephalitis virus
- 1.4.33 Vesicular stomatitis virus
- 1.4.34 Western equine encephalitis virus
- 1.4.35 White pox virus
- 1.4.36 Yellow fever virus

1.5 Toxins

- 1.5.1 Abrin
- 1.5.2 Botulinum toxins
- 1.5.3 Clostridium perfringens toxins
- 1.5.4 Conotoxin
- 1.5.5 Diphtheria exotoxin
- 1.5.6 Microcystins (Cyanginosins)
- 1.5.7 Modeccin
- 1.5.8 Pseudomonas exotoxin

- 1.5.9 Ricin ⁴⁸
- 1.5.10 Saxitoxin ⁷²
- 1.5.11 Shiga toxin
- 1.5.12 Staphylococcus aureus toxins
- 1.5.13 Tetrodotoxin
- 1.5.14 Verotoxin
- 1.5.15 Volkensin

- 1.6 Fungi
 - 1.6.1 Colletotrichum cof feanum var. virulans
 - 1.6.2 Cochliobolus miyabeanus (Helminthosporium oryzae)
 - 1.6.3 Magnaporthe grisea (Pyricularia grisea/Pyricularia oryzae)
 - 1.6.4 Microcyclus ulei (syn. Dothidella ulei)
 - 1.6.5 Puccinia graminis (syn. Puccinia graminis f. sp. tritici)
 - 1.6.6 Puccinia striiformis (syn. Puccinia glumarum)

- 1.7 Other organisms
 - 1.7.1 Eukaryotic (non-microbial) organism which produce any listed toxin.

- 1.8 Genetically modified microorganisms, other organisms and genetic material
 - 1.8.1 The above listed microorganisms when they have been genetically modified.
 - 1.8.2 Other genetically modified microorganisms or genetic material that contain nucleic acid sequences derived from any of the listed microorganisms, or that contain nucleic acid sequences associated with pathogenicity determinants of any listed microorganism; or that contain nucleic acid sequences associated with any listed toxin.
 - 1.8.3 Genetically modified variants of eukaryotic (non-microbial) organisms which produce any listed toxin.

⁴⁸ Items 1.5.9 and 1.5.10 are prohibited to Iraq save under the procedure of special exceptions provided for in paragraph 32 of the Plan.

LIST 2 - RISK GROUP II MICROORGANISMS, ⁴⁹OTHER ORGANISMS AND TOXINS

(A) HUMAN AND ANIMAL PATHOGENS

Bacteria

Actinobacillus actinomycetemcomitans
Actinomadura madurae
Actinomadura pelletieri
Actinomyces gerencseriae
Actinomyces israelii
Actinomyces pyogenes
Actinomyces spp
Arcanobacterium haemolyticum (Corynebacterium haemolyticum)
Bacteriodes fragilis
Bartonella bacilliformis
Bordetella bronchiseptica
Bordetella parapertussis
Bordetella pertussis
Borrelia burgdorferi
Borrelia duttonii
Borrelia recurrentis
Borrelia spp
Brucella canis
Campylobacter jejuni
Campylobacter spp
Cardiobacterium hominis
Chlamydia pneumoniae
Chlamydia trachomatis
Clostridium tetani
Corynebacterium diphtheriae
Corynebacterium minutissimum
Corynebacterium spp
Edwardsiella tarda
Ehrlichia sennetsu (Rickettsia sennetsu)
Ehrlichia spp
Elkenella corrodens
Enterobacter aerogenes/cloacae
Enterobacter spp
Enterococcus spp
Erysipelothrix rhusiopathiae
Escherichia coli (except non-pathogenic strains)
Flavobacterium meningosepticum
Fluoribacter bozemanii (Legionella)

⁴⁹ The items in this list do not conform fully with the criteria for risk group II according to the classification in the 1983 World Health Organization (WHO) Laboratory Biosafety Manual but should be considered as doing so for the purposes of ongoing monitoring and verification activities in Iraq.

Fusobacterium necrophorum
Gardnerella vaginalis
Haemophilus ducreyi
Haemophilus influenzae
Haemophilus spp
Helicobacter pylori
Klebsiella oxytoca
Klebsiella pneumoniae
Klebsiella spp
Legionella pneumophila
Legionella spp
Listeria ivanovii
Morganella morgani
Mycobacterium africanum
Mycobacterium chelonae
Mycobacterium fortuitum
Mycobacterium kansasii
Mycobacterium leprae
Mycobacterium malmoense
Mycobacterium marinum
Mycobacterium microti
Mycobacterium scrofulaceum
Mycobacterium simiae
Mycobacterium szulgai
Mycobacterium tuberculosis
Mycobacterium ulcerans
Mycobacterium xenopl
Mycoplasma pneumoniae
Neisseria gonorrhoeae
Neisseria meningitidis
Nocardia asteroides
Nocardia brasiliensis
Nocardia farcinica
Nocardia nova
Nocardia otitidiscaviarum
Pasteurella multocida
Peptostreptococcus anaerobius
Plesiomonas shigelloides
Porphyromonas spp
Proteus mirabilis
Proteus penneri
Proteus vulgaris
Providencia alcalifaciens
Providencia rettgeri
Providencia spp
Pseudomonas aeruginosa
Rhodococcus equi
Salmonella arizonae
Salmonella enteritidis
Salmonella typhimurium
Salmonella paratyphi A,B,C

Salmonella (other serovars)
Serpulina spp
Shigella boydii
Shigella flexneri
Shigella sonnei
Staphylococcus aureus
Streptobacillus moniliformis
Streptococcus pneumoniae
Streptococcus pyogenes
Streptococcus spp
Treponema carateum
Treponema pallidum
Treponema pertense
Treponema spp
Vibrio parahaemolyticus
Vibrio spp
Yersinia pseudotuberculosis
Yersinia spp

Rickettsia

Rickettsia akari
Rickettsia canada
Rickettsia conorii
Rickettsia montana
Rickettsia spp
Rickettsia typhi (Rickettsia mooseri)
Rickettsia tsutsugamushi

Viruses

Absettarov
Acute haemorrhagic conjunctivitis virus
Adenoviridae
Astroviridae
Australia encephalitis (Murray Valley encephalitis)
BK and JC viruses
Buffalo pox virus
Bunyamwera virus
California encephalitis virus
Central European tick-borne encephalitis virus
Coltivirus
Coronaviridae
Cow pox virus
Coxsackie viruses
Cytomegalovirus
Echo viruses
Elephant pox virus
Epstein-Barr virus
Hantaviruses
Hanzalova

Hazara virus
Hepatitis A virus (human enterovirus type 72)
Hepatitis B virus
Hepatitis C virus
Hepatitis D virus (Delta)
Herpes virus simiae (b virus)
Herpes simplex viruses types 1 and 2
Herpesvirus varicella-zoster
Human B-lymphotropic virus
Human Papillomaviruses
Human Parvovirus (B19)
Human Rotaviruses
Hypr
Influenza viruses types A,B and C
Kumlinge
Kyananur Forest
Louping Ill
Measles virus
Milkers' node virus
Mopeia virus and other Tacaribe viruses
Mumps virus
Norwalk virus
Omsk
Orbiviruses
Orf virus
Oropouche virus
Other Bunviridae known to be pathogenic
Other Caliciviridae
Other Flaviviruses known to be pathogenic
Other Hantaviruses
Parainfluenza viruses types 1 to 4
Polioviruses
Powassan
Prospect Hill virus
Puumala virus
Rabbit pox virus
Reoviruses
Respiratory syncytial virus
Rhinoviruses
Rocio
Sandfly fever
Seoul virus
St. Louis Encephalitis
Tick-borne Orthomyxoviridae: Dhori and Thogoto viruses
Toscana virus
Vaccinia virus
Wesselsbron virus
West Nile fever virus
Yatapox virus (Tana & Yaba)

(B) OTHER ANIMAL PATHOGENS

Actinomyces spp
African horse sickness virus
Anaplasma marginale
Avian encephalomyelitis virus
Avian infectious bronchitis virus
Avian infectious laryngotracheitis virus
Avian leucosis virus
Babesia spp
Bacteroides nodosus
Bordetella bronchiseptica
Borrelia anserina
Bovine malignant catarrhal fever virus
Bovine virus diarrhoea virus
Campylobacter fetus
Canine distemper virus
Caprine arthritis/encephalitis virus
Clostridium chauvoei
Clostridium spp
Coccidia spp
Cochliomyia hominivorax
Corynebacterium pseudotuberculosis
Cordaria ruminantium
Cysticercus bovis
Cysticercus cellulosae
Dermatophilus congolensiae
Duck hepatitis virus
Duck virus enteritis virus
Echinococcus spp
Enzootic bovine leucosis virus
Equine herpesvirus 3
Equine infectious anaemia virus
Equine influenza virus type A
Equine rhinopneumonitis virus
Erysipelou rhusiopathiae
Fowl pox virus
Haemophilus equigenitalium
Haemophilus paragallinarum
Histoplasma jaraiinosom
Horse pox virus
Hypoderma spp
Infectious arteritis virus
Infectious bovine rhinotracheitis virus
Infectious bursal disease virus
Leishmania spp
Leptospira spp
Listeria monocytogenes
Lumpy skin disease virus
Maedi-visna virus
Marek's disease virus
Mycobacterium avium

Mycobacterium bovis
Mycobacterium paratuberculosis
Mycoplasma agalactiae
Mycoplasma capricolum var capripneumoniae
Mycoplasma gallisepticum
Myxomatosis virus
Nairobi sheep disease virus
Pasteurella haemolytica
Pasteurella multocida
Pasteurella tularensis
Porcine enteroviruses
Psoroptes ovis
Rabies and rabies related viruses
Salmonella abortus equi
Salmonella abortus ovis
Salmonella gallinarum
Salmonella pullorum
Salmonella spp
Sheep pulmonary adenomatosis virus
Streptococcus equi
The agent of Bovine Spongiforme encephalopathy
The agent of porcine reproductive respiratory syndrome
The agent of scrapie
The agents of horse mange
Theileria spp
Toxoplasma gondii
Transmissible gastroenteritis virus
Trichinella spiralis
Trichomonas fetus
Trypanosoma evansi
Trypanosoma spp
Viral haemorrhagic disease of rabbits virus

(C) PLANT PATHOGENS

Citrus greening bacterium
Citrus tristeza closterovirus
Fusarium oxysporum f.sp. albedinis
Glomerella gossypii
Phymatotrichopsis omnivora
Pseudomonas solanacearum Race 2
Thecaphora solani
Tilletia indica
Xanthomonas oryzae pvs oryzae & oryzicola
Tricothecene-producing fungi including:
Fusarium poae
Fusarium sporotrichioides
Fusarium tricinctum
Micronectriella nivalis, anamorph

Microdochium nivale (Syn. Fusarium nivale)

(D) TOXINS

Toxins other than specified on List 1 with a molecular weight of more than 250 daltons.

(E) OTHER ORGANISMS

Eukaryotic (non-microbial) organisms which produce any toxin.

(F) GENETICALLY MODIFIED MICROORGANISMS, OTHER ORGANISMS AND GENETIC MATERIAL

1. The above listed microorganisms when they have been genetically modified.
2. Other genetically modified microorganisms or genetic material that contain nucleic acid sequences derived from any of the listed microorganisms, or that contain nucleic acid sequences associated with pathogenicity determinants of any listed microorganism; or that contain nucleic acid sequences associated with any listed toxin.
3. Genetically modified variants of eukaryotic (non-microbial) organisms which produce any toxin as above.