MEETING 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/MSP/2005/MX/INF.1 13 April 2005

ENGLISH ONLY

Third Meeting Geneva, 5-9 December 2005

Meeting of Experts Geneva, 13-24 June 2005 Item 5 of the provisional agenda

Consideration of the content, promulgation, and adoption of codes of conduct for scientists

Existing Codes of Conduct which Refer to Biological and Toxin Weapons

Background Paper prepared by the Secretariat¹

INTERGOVERMENTAL AND INTERNATIONAL ORGANIZATIONS

<u>United Nations and Specialised Agencies</u>

- 1. There are already efforts being made within the United Nations framework to develop a code of conduct for scientists. It would appear that from its inception such a code was designed to reference unconventional weapons including biological and toxin weapons.
- 2. In October 2001 the United Nations Secretary-General (UNSG) established The Policy Working Group on the United Nations and Terrorism using precedents established in United Nations Security Council (UNSC) Resolutions 1368 (2001) and 1373 (2001), as well as United Nations General Assembly (UNGA) Resolution 56/1. The Policy Working Group on the United Nations and Terrorism compiled a Report addressing long-term strategic goals and recommendations for countermeasures aimed at preventing terrorism (Annex to A/57/273, S/2002/875). This report included Recommendations 10 and 21, which state:

Recommendation 10

the activities of the United Nations related to the fight against terrorism should be promoted through, inter alia:

GE.05-61231

_

¹/ This background paper has been prepared at the request of the Chairman. The contents of the paper are intended to be indicative rather than exhaustive, and to provide an overview and starting point for States Parties who may wish to conduct further research. Comments, additions and corrections from States Parties are welcome.

- (i) Public information regarding the work of the Counter-Terrorism Committee, including the dissemination of positive examples of its work such as the assistance provided by the Committee and donors, and advances in regional cooperation;
- (ii) Dissemination of the work of United Nations agencies on the broad range of problems that relate to terrorism, including giving greater prominence to the work undertaken by the United Nations Educational, Scientific and Cultural Organization and other organizations of the United Nations system in respect of educational initiatives, such as curricula reform, that aim to increase understanding, encourage tolerance and respect for human dignity, while reducing mutual mistrust between communities in conflict. Elements of the United Nations system which address the issue of education should meet to determine how best to mount a coherent worldwide programme to assist countries in which the educational systems need support or that are under the control of groups advocating terror;
- (iii) Promotion of the role of international law in combating terrorism.

Recommendation 21

Relevant United Nations offices should be tasked with producing proposals to reinforce ethical norms, and the creation of codes of conduct for scientists, through international and national scientific societies and institutions that teach sciences or engineering skills related to weapons technologies, should be encouraged. Such codes of conduct would aim to prevent the involvement of defence scientists or technical experts in terrorist activities and restrict public access to knowledge and expertise on the development, production, stockpiling and use of weapons of mass destruction or related technologies.

- 3. Following submission and adoption of the Report and its Recommendations to the UNGA and the UNSC (2002), the Report was transmitted to all the Organizations and Specialized Agencies of the United Nations system. At the invitation of the Director-General of the United Nations Educational, Scientific and Cultural Organization (UNESCO), an Inter-Agency Consultative Meeting was held at UNESCO head quarters in Paris, on 26 February 2003, specifically to discuss Recommendations 10 and 21 of the Report. In attendance at this meeting were representatives of the member organisations, including:
 - (i) United Nations Educational, Scientific and Cultural Organization,
 - (ii) The Chief Executives Board,
 - (iii) United Nations Department of Political Affairs,
 - (iv) The Office of the High Commissioner for Human Rights,
 - (v) United Nations Development Programme,
 - (vi) United Nations Relief and Works Agency for Palestine Refugees in the Near East,
 - (vii) International Labour Organization, and
 - (viii) The United Nations University (UNU).
- 4. One of the outcomes of this UN Inter-Agency meeting was a general recommendation towards encouraging ethical codes of conduct for scientists and engineers and promoting ethics of science education and awareness. In addition, it was recommended that existing relevant bodies such as COMEST [UNESCO's World Commission on the Ethics of Scientific Knowledge and Technology] could in particular play a decisive role in fostering a continued dialogue on

education and ethics of science, also recommending the specific involvement of the COMEST together with ICSU in the field of the responsibility of scientists.

5. The meeting also recalled the *Declaration on Science and the Use of Scientific Knowledge* made at the World Conference on Science in 1999. This declaration states:

A free flow of information on all possible uses and consequences of new discoveries and newly developed technologies should be secured, so that ethical issues can be debated in an appropriate way. Each country should establish suitable measures to address the ethics of the practice of science and of the use of scientific knowledge and its applications. These should include due process procedures for dealing with dissent and dissenters in a fair and responsive manner. The World Commission on the Ethics of Scientific Knowledge and Technology of UNESCO could provide a means of interaction in this respect.

- 6. UNESCO's role is understood to be to enhance existing efforts to develop a code of conduct for scientists and not to create a novel or parallel mechanism. To this end, the establishment of an inter-agency working group that would report to the Executive Committee on Peace and Security was suggested. COMEST is meeting in March 2005 to discuss these issues and to amend work from 2003 on this topic. Whilst work was being undertaken to specifically address biology and the life sciences, UNESCO appears to be moving towards developing a framework declaration on ethical principles (ethics of science) rather than focusing specifically on biotechnology, bioterrorism and biological weapons.
- 7. UNESCO is not the only member of the United Nations family to have acted upon Recommendation 21. In 2003, the Under-Secretary-General for Disarmament formally requested the International Centre for Genetic Engineering and Biotechnology (ICGEB), under the Cooperation Agreement between the two organizations, to assist the United Nations Secretariat in implementing this recommendation. The ICGEB initiated a series of consultations with various National Academies of Science. The result was to be a draft *Code of Conduct for Scientists in Relation to the Safe and Ethical Use of Biological Sciences*. Building blocks, which could form the underlying principles of such a code, were presented to the Meeting of States Parties in December 2004. These included:
 - (i) The extraordinary opportunities derived from knowledge and the technologies recently developed or foreseeable in the near future;
 - (ii) The dual-use potential of these technologies (i.e. that they could potentially be used for both peaceful and prophylactic purposes and, with a hostile intent, in the development, production, stockpiling or use of biological and toxin weapons);
 - (iii) The ethical implications of work in the life sciences, namely the duty to society and humankind to ensure such activities are aimed only at advancing knowledge and at bringing benefit to humankind and the environment;
 - (iv) Personal benign intent does not absolve a responsibility to understand the possible hostile utilisation of available technologies;
 - (v) The moral duty of scientists, in particular those who work with pathogenic microorganisms or with dangerous toxins, to adopt the use of best practices to ensure high standards of professionalism, safety and security, so as to minimise the risk of intentional or unintentional damage;

- (vi) To raise, at the appropriate level, suspicions over the possible hostile use of research;
- (vii) To adopt a holistic view of scientific process through an awareness that experimentation performed upstream or downstream of a given scientific project may orient it in a very different manner, possibly even within a hostile context;
- (viii) Oversight of research and the evaluation of projects or publications forms an integral part of educational curricula and institutional regulations and it is an individual and collective duty to become familiar and respect such principles and precautions;
- (ix) Self-governance by scientists should ensure that preventing the hostile or unethical use of the biological sciences takes precedence over obligations derived from other commitments, such as professional or military duties.
- (x) Scientists must strive to know, diffuse and teach national and international legislation, regulations and guidelines prohibiting the development, production, acquisition, transfer, stockpiling and use of biological and toxin weapons, in particular through the Biological Weapons Convention; and
- (xi) Scientists must act to raise public awareness of the universal prohibition against the use of biological and toxin weapons and the need for a universal prohibition on the hostile use of the biological sciences incorporating proscription, prosecution and punishment.

World Health Organization (WHO)

- 8. The first edition of the WHO *Laboratory biosafety manual* (LBM) published in 1983, encouraged the WHO Member States to accept and implement basic concepts in biological safety and to develop national codes of practice for the safe handling of pathogenic microorganisms in laboratories within their geographical borders. The LBM provides a set of best practice scientific guidelines and is revised according to periodic risk assessments. The second edition of the LBM was published in 1993. The third edition, published in 2004 (http://www.who.int/csr/resources/publications/biosafety/en/Biosafety7.pdf), provides a reference for nations to assist them in developing and establishing national codes of practice for securing microbiological assets, yet ensuring their availability for clinical, research and epidemiological purposes. The third edition also introduces the concept of biosecurity and addresses new threats to public health from deliberate misuse and release of microbiological agents and toxins.
- 9. The chapter on Laboratory biosecurity:
 - (i) Refers to institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins;
 - (ii) In addition to biosafety risk assessment, threat assessments are necessary to address the potential diversion or misuse of pathogenic agents or toxins stored in laboratories;
 - (iii) Requires input from scientific directors, principal investigators, biosafety officers, laboratory scientific staff, maintenance staff, administrators, information technology staff, and law enforcement agencies and security staff if appropriate;
 - (iv) Establish an institutional laboratory biosecurity protocol that takes into account identifying, reporting, investigating and remediating breaches in laboratory biosecurity, including discrepancies in inventory results;

- (v) Training is recommended for all personnel (in addition to biosafety training) and should include a review of relevant national standards and institutional specific procedures;
- (vi) Includes an assessment of the professional and ethical suitability for working with dangerous pathogens of all personnel who have regular authorized access to sensitive materials.
- 10. In 2004, the Programme for Preparedness for Deliberate Epidemics within the Department for Communicable Diseases Surveillance and Response (CSR) of the WHO, in collaboration with other WHO departments and non-WHO experts, worked on a background paper entitled *Life science research Opportunities and risks for public health: Mapping the issues*. This paper aims at engaging dialogue with WHO Member States, the public health and life science communities, international and non-governmental organizations, the private and security sectors on the implications that life science research may have for global health security. The objectives are to raise awareness on these issues in order to protect public health, to safeguard the public health benefits of life science research and to emphasize the public health perspective of such issues in order to promote health equity. In collaboration with international organizations and other entities, the project is expected to engage dialogue on such issues through a study group and regional activities to be conducted in 2005 and 2006.

Other International Organizations

- 11. Other International Organizations have also engaged in the process of developing Codes of Conduct for Scientists. The International Committee of the Red Cross (ICRC) has developed a series of general principles which it believes should underpin any such code. These include:
 - (i) <u>Conflict of interest</u> Preventing advances in the life sciences from being used for poisoning and deliberate spread of infectious disease must always take precedence over personal, commercial or security interests.
 - (ii) <u>Legal responsibilities</u> Research and its application must always be compatible with respect for, and promotion of, national and international laws.
 - (iii) <u>Diligence</u> Undertaking well-intentioned research does not justify neglect of possible hostile use of the outcome.
 - (iv) Governance of research and publication Knowledge gained from research must ultimately become universal for the progress of science; however, the potential for hostile use of some advances in life science and biotechnology may pose a fundamental dilemma about how and when knowledge is made accessible to others.
 - (v) <u>A culture of transparency</u> Transparency and a culture of dialogue together constitute the most important element in minimising the risk that advances in life sciences will be turned to hostile use.
 - (vi) <u>Increasing speed of advances</u> The increasing power and variety of advances in life sciences must be matched by commensurate objective assessments of risk and closer vigilance.

- (vii) A "web of prevention" Minimising the risk of poisoning and deliberate spread of infectious disease require a range of synergistic measures and so is, by necessity, a multidisciplinary endeavour.
- (viii) <u>Voicing concern</u> Those working in life sciences who voice concern and take responsible action require and deserve political and professional support and protection.
- (ix) <u>Specific characteristics of biological weapons</u> Because of their particular characteristics, preventing the development, proliferation and use of biological weapons requires a very different approach to preventing the development, proliferation and use of chemical weapons.
- (x) <u>"Dual use"</u> Some materials and technologies more than others lend themselves to poisoning and deliberate spread of infectious disease.
- (xi) <u>Diffusion of materials and technologies</u> Materials and technologies associated with the life sciences can diffuse rapidly.
- 12. The ICRC has stopped short of using these principles to develop a code of conduct, but have used them to suggest a number of action points which could be considered during the development of such a code:
 - (i) Encourage education of scientists from undergraduate level onwards about pertinent ethical issues.
 - (ii) Develop and promote professional ethics and adhere to agreed codes of conduct that may be voluntary, professional or enforced as appropriate.
 - (iii) Encourage education of scientists from undergraduate level onwards about relevant national and international laws.
 - (iv) Work with government officials to prevent biological or chemical weapons from being developed, produced, transferred or used and call for governments to fully uphold, implement and strengthen existing and pertinent laws.
 - (v) Be diligent in safeguarding legitimate research, whether in academia, industry or defence from being used for any hostile purpose, including the development of chemical or biological weapons.
 - (vi) Raise concerns with policy-makers and institutions about existing regulations which may not be adequate for safeguarding legitimate research.
 - (vii) Maintain an open dialogue about and, if possible, define what constitutes 'dangerous' research.
 - (viii) Build a regime of governance of potentially dangerous research and its subsequent publication.
 - (ix) Create and promote a working culture of dialogue and transparency between colleagues about the nature of research undertaken.
 - (x) Be vigilant with respect to scientific advances that could facilitate poisoning and the deliberate spread of infectious disease.
 - (xi) Discuss mechanisms that could ensure that the divide between advances in science and advances in its governance and applicable law is minimised.
 - (xii) Encourage and participate in multidisciplinary dialogue and action about the prevention of poisoning and deliberate spread of infectious disease.

- (xiii) Make the risks of poisoning and deliberate spread of infectious disease comprehensible to actors in related fields and explore ways to work in cooperation to reduce the risks.
- (xiv) Work with the media with these principles of practice and action points in mind.
- (xv) Encourage people who work in the life sciences to voice concern about issues relating to poisoning and the deliberate spread of infectious disease.
- (xvi) Ensure that adequate mechanisms exist for voicing such concerns without fear of retribution.
- (xvii) Develop and promote awareness of the specific risks of the development, proliferation and use of biological weapons and promote preventive strategies.
- (xviii) Be vigilant with respect to and maintain a dialogue about the 'dual-use' phenomenon.
- (xix) Ensure materials and technologies are transferred in a manner that minimises the risk of their use for poisoning and deliberate spread of infectious disease while maximising their potential benefit for humanity.

PROFESSIONAL ORGANISATIONS, ASSOCIATIONS, BODIES AND INSTITUTIONS

- 13. Many of the professional organisations, associations and bodies identified by the Secretariat which possessed codes of conduct available to the Secretariat, did not refer to biological and toxin weapons and as a result are considered in BWC/MSP/2005/MX/INF.2.
- 14. At least one international federation, the World Medical Association (WMA), has taken action on this issue. Although the WMA has not formally adopted a code of conduct for its members, in Washington, USA in 2002, the General Assembly of this federation adopted a declaration on the topic, which according to the organization's website, should be considered a policy document and therefore of particular relevance to its members. This document has become known as the Washington Declaration (http://www.wma.net/e/policy/b1.htm). The Washington Declaration notes:

...there is a need for the creation of and adherence to a globally accepted ethos that rejects the development and use of biological weapons

On the basis of this need, the World Medical Association urged:

...all who participate in biomedical research to consider the implications and possible applications of their work and to weigh carefully in the balance the pursuit of scientific knowledge with their ethical responsibilities to society

Members of this organization are presumably expected to comply with this request and for practical purposes this should be considered a codification of expected conduct.

15. On the national level, a limited number of professional organisations do have codes of conduct that do refer to biological and toxin weapons. For example, the Code of Ethics of the Australian Society for Microbiology (http://www.theasm.com.au/) requires *each member... not to engage knowingly in research for the production or promotion of biological warfare agents.*

16. The months prior to the Meeting of Experts will also witness the creation of a new body, the International Council for the Life Sciences (ICLS), whose founders describe it as:

...an action-oriented forum where members will discuss responsible, ethical, and sound business and scientific practices. ICLS members will address key issues such as biosafety, biosecurity and other key issues with each other and government representatives

The ICLS was due to be launched on 14 April 2005 at The World Life Sciences Forum BioVision. It is expected that companies, organizations, and others will commit themselves to the charter of the International Council for the Life Sciences. On 25 May 2005, the ICLS is expecting to hold a Convening Conference on at which members will begin to plan its operation and initial work plan. Although the charter does not appear to be currently available, the founder's website (http://www.cbaci.org/nonp/projects.html) notes:

Extraordinary advances in biotechnology have brought enormous benefits to medicine, public health, the food industry, agriculture, and industrial processes. At the same time, the risks to public safety and security from the misuse of this technology have increased. These risks are best represented as a spectrum, ranging from emerging and re-emerging infectious disease through accident and misadventure to deliberate misuse. In order for the full humanitarian and economic benefit arising from the advances in the life sciences to be realized, it is essential that all these concerns are explicitly recognized and managed.

COMMERCIAL AND INDUSTRIAL ORGANISATIONS, ASSOCIATIONS, BODIES AND INSTITUTIONS

Biotechnology

17. A number of the international, regional and national biotechnology federations and associations identified, which possessed codes of conduct available to the Secretariat, included specific mention of biological weapons. These included:

AusBiotech, Ltd.

http://www.ausbiotech.org/code of conduct.asp

EuropaBio

http://www.europabio.org/ethics and dialogue.htm

BIOTECanada

http://www.biotech.ca/EN/ethics.html

Biotechnology Industry Organization

http://www.bio.org/news/features/20011105.asp

These codes of conduct adopt a similar approach in considering biological and toxin weapons, and opt for a general prohibition on the development of these weapons, as opposed to a detailed set of behavioural controls to prevent such development taking place.

- 18. The Codes of Conduct of AusBiotech and EuropaBio state [w]*e oppose the use of biotechnology to make any weapons and will not develop or produce biological weapons.*
- 19. The Code of Conduct of BIOTECanada goes a little further by stating:

We oppose the use of biotechnology to develop weapons. We support Canadian government policy that clearly and unequivocally states Canada does not at any time intend to develop, produce, acquire, stockpile or use chemical or biological agents of weapons.

20. Similarly the code of the Biotechnology Industry Organization (which is based in the United States of America) states that the BIO has:

...a long-standing policy of opposing the use of biotechnology to develop weapons of any sort that contain pathogens or toxins aimed at killing or injuring humans, crops or livestock. We support the Biological Weapons Convention, a treaty signed by the United States and many other nations banning development and use of biological weapons. We will not undertake any research intended for use in developing, testing or producing such weapons.

Pharmaceutical Research and Manufacturing

- 21. At the global level, this industry is represented by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). Although neither the IFPMA nor its members appear to have codes of conduct which refer to biological and toxin weapons (and are therefore considered in BWC/MSP/2005/MX/INF.2) some other large pharmaceutical research and manufacturing entities do have such codes. For example, the Wellcome Trust, an independent charity (based in the United Kingdom) which funds research to improve human and animal health, published a position statement on bioterrorism and biomedical research in November 2003 (http://www.wellcome.ac.uk/doc_WTD002767.html). This position statement included a number of decisions taken by the trust in regards to the research it funds, thus binding the conduct of not only those it employs but also those receiving its funding. These included:
 - (i) To ensure that the research the Trust funds is in line with its mission and of the highest scientific quality, all Trust-funded research is independently peer reviewed by experts. Reviewers are required to consider whether the proposed methodology is appropriate for achieving the stated objective and they may raise any ethical or safety concerns that they have regarding a particular application. The Trust will develop specific guidance for reviewers and applicants on the issues addressed in this statement [dual-use potential of biomedical research];
 - (ii) As a condition of grant support, institutions in receipt of Wellcome Trust funds are responsible for ensuring that they comply fully with the requirements of all regulatory authorities for the storage, use and transfer of harmful biological materials, and any additional provisions to safeguard security that may be specified by such authorities. Institutions also accept full responsibility for the management, monitoring and control of all research work funded by grants, and for ensuring that permanent and temporary staff and students employed to undertake such work receive training appropriate to their duties.

- (iii) The Wellcome Trust Sanger Institute (WTSI) ensures that it meets the requirements of all regulatory authorities, and that any ethical implications are considered through appropriate mechanisms in developing its research programme. With regard to its work on pathogen genomics, the WTSI has robust mechanisms in place to ensure compliance with relevant regulatory instruments for safe use, security and transfer of the agents and genetic materials derived from them.
- (iv) The Trust has established a Standing Advisory Group on Ethics (SAGE) to consider and advise the Trust on any major ethical issues associated with applications for funding that cannot be addressed through the standard procedures of local ethical review, and the Home Office Inspectorate (for animal experiments) or Research Ethics Committee (in the case of studies involving human subjects).
- (v) If a situation arose where concerns had been raised that an application had a serious risk of misuse associated with it, and such concerns could not be resolved through these mechanisms, then the Trust would not fund that application. The Trust would anticipate, however, that such circumstances would be extremely rare.
- 22. The policy statement continues by addressing directly the topic to be considered at the 2005 Meeting of Experts and Meeting of States Parties by noting:
 - (i) In order to promote best practice in the conduct of research and maintain public trust, the Trust considers that the international scientific community must take proactive steps to ensure that its members are aware of potential risks and concerns relating to terrorist misuse of research, and of the regulatory and ethical responsibilities that they hold.
 - (ii) The Trust considers that the development of a 'code of conduct' for scientists could play an important role in this regard.
 - (iii) It is essential that the international scientific community engages effectively with society in addressing these risks. The Trust is committed to fostering public engagement on the issues raised by advances in biomedical science, and will consider how it can work in partnership with other organisations to engage the public on the issues addressed in this statement.
 - (iv) The Trust considers that the risks associated with the potential misuse of scientific research for terrorist purposes must ultimately be addressed internationally, and that efforts to raise awareness and develop best practice amongst the research community will need to be implemented globally in order to be effective. The further development of processes to build international consensus on these issues will therefore be crucial.