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MAXIMIZING THE SECURITY AND IMPROVING OVERSIGHT OF PATHOGENIC MICROORGANISMS AND TOXINS

by Graham S. Pearson

REPORT* OF THE NATO ADVANCED RESEARCH WORKSHOP BLED, SLOVENIA: 19 - 21 JUNE 2003

Introduction

1. The NATO Advanced Research Workshop entitled "Maximizing the Security and Improving Oversight of Pathogenic Microorganisms and Toxins" was held in the Kompas Hotel, Bled, Slovenia on Thursday 19 June through Saturday 21 June 2003 under the co-directorship of Professor Dr. Borut Bohanec, Head of Centre for Plant Biotechnology, Biotechnical Facility, University of Ljubljana, Ljubljana, Slovenia and Professor Graham S. Pearson, Visiting Professor of International Security, Department of Peace Studies, University of Bradford, Bradford, UK. The objective of the Workshop was to examine how to maximize the security and control of access to pathogenic microorganisms and toxins and improve the oversight of such work and of genetic modification by building upon the existing biosafety requirements which are increasingly required for health and environmental reasons. The outcome of the Workshop is intended to help to promote understanding among national experts on how best to limit the availability of such materials for bioterrorism without inhibiting legitimate research and also to contribute to the preparation by the States Parties to the Biological and Toxin Weapons Convention for their meetings in August and November 2003 on the subject of security and oversight of pathogenic microorganisms and toxins.

2. The Workshop was attended by 36 individuals from 16 countries, of which 16 came from 6 of the original NATO countries (France, Germany, Italy, Netherlands, United Kingdom and United States) and 18 came from 8 of the new NATO countries and cooperation partners (Bulgaria, Czech Republic, Hungary, Poland, Russian Federation, Slovak Republic, Slovenia, and Ukraine) and one from each of Brazil and South Africa. Participants also came from several Intergovernmental Organizations (IGOs):

Food and Agriculture Organisation
Office International des Epizooties
World Health Organization
UNEP/GEF Project on Implementation of National Biosafety Frameworks
International Center for Genetic Engineering & Biotechnology

Over 60% of the participants came from the Ministries of Foreign Affairs and/or the MFA nominated experts from 13 of the 16 countries present:

Brazil
Bulgaria
Czech Republic

* This report is based on and developed from material that I presented in the final session of the Workshop giving my appreciation of the outcome of the Workshop. It represents my personal assessment of a lively, effective and enjoyable Workshop.

Germany
Hungary
Netherlands
Poland
Russian Federation
Slovak Republic
Slovenia
United Kingdom

3. At the Fifth Review Conference of the States Parties to the Biological and Toxin Weapons Convention (BTWC) it was agreed[1]:

> *To hold three annual meetings of the States Parties of one week duration each year commencing in 2003 until the Sixth Review Conference, to be held not later than the end of 2006, to discuss, and* ***promote common understanding and effective action*** *on:*
>
> > *i. The adoption of necessary, national measures to implement the prohibitions set forth in the Convention, including the enactment of penal legislation;*
> >
> > *ii. National mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins;*
> >
> > *iii. Enhancing international capabilities for responding to, investigating and mitigating the effects of cases of alleged use of biological or toxin weapons or suspicious outbreaks of disease;*
> >
> > *iv. Strengthening and broadening national and international institutional efforts and existing mechanisms for the surveillance, detection, diagnosis and combating of infectious diseases affecting humans, animals, and plants;*
> >
> > *v. The content, promulgation, and adoption of codes of conduct for scientists.*

and that *"Each meeting of the States Parties will be prepared by a two week meeting of experts."* The Workshop considered the second topic to be addressed in 2003, namely *"National mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins;"*.

4. The Workshop programme was divided into four sessions:

Session I Pathogenic Microorganisms and Toxins: Towards a Safer World

A. Security and Bioterrorism Concerns. In this session, the first presentation set out the background to and the planning for the forthcoming meetings in Geneva in August and November 2003 to address the topics agreed by the Fifth Review Conference of the Biological and Toxin Weapons Convention.

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

The second presentation provided an appreciation of the European responses to the threat of bioterrorism.

B. Public Health and Environmental Concerns. The first presentation set out the background to and the current status of the UNEP/GEF National Biosafety Frameworks Programme which is currently (as of 14 April 2003) involving 116 countries around the world. The second presentation considered the work of the International Centre for Genetic Engineering and Biotechnology on improving biosafety in its member States.

Session II Pathogenic Microorganisms and Toxins: Current & Future Standards

A. Biological Agent Standards and Regulations: Use, Containment and Access. Three presentations provided appreciations of pathogen control regulations from a European and UK perspective, and then biological agent standards and regulations from a Russian Federation and a Czech Republic point of view.

B. Security Controls and Regulations. The first presentation provided a summary of a recent survey of European Union security controls and regulations. This was followed by a presentation providing a Romanian perspective. The evolution of the United States select agent programme was then outlined and followed by a presentation providing a Brazilian perspective on security controls and regulations.

C. International Standards for Human, Animal & Plant Pathogens. The WHO prepared programme including biosecurity and biosafety was addressed first and followed by a presentation of the OIE International Health Standards for animal pathogens and then one outlining the FAO Food and Agriculture Biosecurity programme.

Session III Oversight of Dangerous Pathogens, Genetic Modification & Information

A. Genetic Modification. A European and UK perspective on the oversight of genetic manipulation was followed by a Slovenian perspective.

B. Oversight of Dangerous Pathogens. Presentations addressed the oversight and control of the new biotechnology and then a protective oversight approach to controlling work with dangerous pathogens.

C. Oversight of Information. The first presentation addressed the oversight of defence programme objectives and was followed by a presentation on addressing public concerns about biotechnology before a final presentation on striking the balance between transparency and security.

Session IV Maximizing the Security and Oversight of Pathogenic Microorganisms and Toxins

A. Achieving Enhanced Security and Oversight. This presentation took stock as to how best enhanced security and oversight might be achieved and ended by considering how the key issues addressed at the Workshop might best be embraced within the framework of the five subtopics identified by

Ambassador Tibor Toth for the experts meeting in August on security and oversight.

B. Conclusions: Issues of Particular Relevance for the BTWC Experts Meeting in Geneva in August 2003. The final presentation provided a summary of the key points that had emerged from the Workshop and an overall appreciation as to the common understandings that had emerged and how effective action might be taken to ensure that the experts meeting in Geneva made effective use of the time available.

5. Overall, the Workshop was particularly effective and timely as it enabled the participants to review and gain an appreciation of the current provisions for security and oversight of pathogenic microorganisms and toxins and thereby gain a perception of the common understandings and subsequent effective action that might emerge from the experts meeting to be held in Geneva in August 2003.

6. The spread of participants at the Workshop with over 60 per cent being experts coming from Ministries of Foreign Affairs or other government departments or agencies which would be involved in or providing technical advisers to the national delegations participating in the experts meeting was a key factor that made the Workshop especially valuable in aiding preparations for the experts meeting in August 2003 and the subsequent meeting of the States Parties in November 2003.

7. The key points emerging from the presentations and discussion in each of the main sessions of the Workshop are considered in turn. These all contributed to the development by the participants during the Workshop of their appreciation as to what the common understandings and effective action emerging from the experts meeting and the subsequent meeting of States Parties should be.

Session I Pathogenic Microorganisms and Toxins: Towards a Safer World

8. *A. Security and Bioterrorism Concerns.* The opening presentation[†] of the Workshop by Ambassador Tibor Tóth, Chairman of the 2003 meetings of the experts and States Parties to the Biological and Toxin Weapons Convention set out the five thematic subtopics for the topic *ii. National mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins;* to be addressed, it was proposed, on successive days in the second week of the meeting in August 2003. The presentation also indicated the items that might be included in each subtopic:

a. Legal, Regulatory & Administrative.

- Approaches for ensuring security and oversight of pathogenic microorganisms and toxins
- Classification and risk assessment
- Include health & safety legislation here

b. Facilities and Equipment

[†] Presented in the absence of Ambassador Tibor Tóth by the co-Director of the Workshop, Graham S. Pearson.

• Physical security and equipment to ensure security of pathogenic microorganisms and toxins within facilities
• Containment equipment, facility design & security arrangements

c. Personnel and handling

• Measures to ensure safety of personnel
• Measures to prevent unintentional exposure and unauthorized access
• Handling -- Good Manufacturing Practice, Good Laboratory Practice and good science standards

d. Transport

• Intra and inter-facility transport of pathogenic microorganisms and toxins
• Transboundary transport of pathogenic microorganisms and toxins

e. Accountability, licensing and accreditation

• Overarching issues
• Applicable to both individuals and facilities

It was emphasised that the aim of the subtopics was to structure the use of the limited time available and was not intended to restrict discussions. The subtopics were intended as a framework and were not exhaustive.

9. The presentation made it clear that input papers were being requested from States Parties by 25 July 2003 that might provide:

• An overview of national measures for security and oversight, **or**

• Papers approaching the issues from a thematic perspective grounded in national perspectives.

In addition, States Parties were being invited to make 15 minute presentations detailing their experience from a thematic perspective, preferably tailored to subtopics.

10. In the subsequent discussion at the Workshop, a number of points were made:

a. It was important for the experts meeting to focus on *"promote common understanding and effective action"* as required by the mandate as it was the *"effective action"* on which the success of the experts meeting and the subsequent States Parties meeting would be judged.

b. There also needed to be a clearer view about what was going to be achieved through the expert meetings and the meeting of States Parties and the process onward to 2006.

c. Chairman's observations or findings could be a solution as there was a need to avoid negotiation. It was noted that the International Conference on the Security of

Radioactive Sources held in Vienna on 10 to 13 March 2003 had concluded[2] with *"Findings of the President of the Conference"* which outlined *"a number of findings to promote greater international cooperation in addressing the security concerns raised by insufficiently controlled radioactive sources, to the need to identify those sources which pose the greatest risks and to the need for strong national action by all States to minimize those risks..."* -- and that this might provide a useful model for the BTWC meetings.

d. It would be important at the experts meeting to avoid focussing solely on human pathogens as animal and plant pathogens must also be addressed. Likewise, care need to be taken to ensure that toxins are also addressed as they are part of the mandate.

e. The Workshop would provide an opportunity to consider how best to address the key issues relating to security and oversight of pathogenic microorganisms and toxins within the five subtopics identified by Ambassador Tóth.

11. The second presentation by a representative of the Institute for the Security and Protection of the Citizen, Ispra, Italy which is one of the institutes of the Joint Research Centre (JRC) of the European Commission addressed ongoing European Union initiatives for the security of the citizen. This outlined the activities being taken by the JRC to support the EU initiative to have a coordinated response to the threat of nuclear, biological or chemical terrorism through the coordination of all scientific knowledge and information that would underpin sound decision-making regarding protective and preventive measures, as well as response measures in case of emergency.

12. In the subsequent discussion, concern was expressed that overemphasis on bioterrorism such as that being seen in the United States could be counter-productive and could stimulate terrorist interest in such activities. Indeed, it was recognized that it could possibly stimulate the interest of States in exploring whether bioterrorism might be a useful tool for achieving its objectives. There was consequently much to be said for recognizing that deliberate outbreaks of disease would have similar effects to naturally occurring outbreaks of disease and that consequently responses to deliberate outbreaks could usefully be developed from and embedded in the responses to natural outbreaks. It was also noted that useful lessons can be learnt from the responses to recent disease outbreaks such as BSE in the UK, to food and mouth outbreaks in livestock in the UK and to the recent SARS outbreak in Canada.

13. *B. Public Health and Environmental Concerns.* The UNEP/GEF (United Nations Environment Programme/Global Environment Facility) National Biosafety Frameworks programme was outlined[3]. Its aim is to enable States to comply with the Cartagena Protocol on Biosafety which addresses the *"safe transfer, handling and use of living modified organisms."* The key elements of the National Biosafety Framework are:

- Legal instruments
- Administrative systems
- Risk assessment and management

[2]IAEA, International Conference on the Security of Radioactive Sources, Vienna, 10 -- 13 March 2003. *Findings of the President of the Conference,* available at http://www.iaea/worldatom/Press/Focus/RadSources/PDF/findings.pdf

[3]Further information is available at http://www.unep.ch/biosafety

• Systems for public participation

There are two phases in the UNEP/GEF programme -- the first to help States develop their National Biosafety Frameworks and the second to help States implement their National Biosafety Frameworks. The implementation programme focusses on the following elements:

• Policy on biosafety
• Regulatory regime
• System to handle requests
• Monitoring and inspections
• Public information

In addition, support is being given to the biosafety clearing house in order to promote the exchange of experience on issues of relevance to the national biosafety frameworks..

14. It was apparent that the infrastructure being developed within States and the issues being addressed through the UNEP/GEF programme are similar to those which are required for effective security and oversight of pathogenic microorganisms and toxins. There would therefore be advantages in the experts group meeting in August being aware of the ongoing UNEP/GEF initiatives although it needs to be emphasised that the emphasis of the UNEP/GEF programmes are on the implementation of the Cartagena Protocol on Biosafety and consequently on *"safe transfer, handling and use of living modified organisms"* -- and not on unmodified microorganisms.

15. The next presentation outlined the Global Biosafety initiatives of the International Centre for Genetic Engineering and Biotechnology (ICGEB). The biosafety unit of ICGEB has been engaged in a number of activities[4]:

• Dissemination of information
  - Biosafety bibliographic database
  - Risk assessment searching mechanism
  - Webpages and Biosafety news

• Capacity building
  - Biosafety annual workshops
  - Biosafety outstation
  - Cooperation and training with member State biosafety authorities in biosafety and risk assessment

• International cooperation
  - Voluntary code of conduct for the release of organisms into the environment (1991)
  - Cooperation with UNIDO, UNESCO, UNEP, FAO and CBD/SBSTTA/Biosafety clearing house
  - Participation in IANB (Interagency Network for Biosafety)

A new ICGEB Biosafety outstation is scheduled to become operational in October 2003 which will be engaged on research and definition of appropriate procedures for risk assessment (horizontal gene flow, persistency, allergies, induction of resistance,

[4]Further information is available at http://icgeb.org/biosafety

susceptibility, etc) as well as other biosafety related work such as definition of new protocols for the identification of GMOs in food, feed, seeds and their products.

16. Insofar as the forthcoming BTWC experts activities in regard to security and oversight is concerned, it was suggested that ICGEB could contribute in the following ways:

> • *Databases.* ICGEB could develop a new bibliographic database, as a "clone" of the biosafety database, containing scientific literature dedicated to the safe handling of pathogens.
> • *Training.* Specific curricula could be developed by ICGEB for the training of scientists, especially from developing countries, which could also take advantage of the new biosafety outstation.
> • *Code of conduct.* Specific collaboration with the UNDDA and involvement of the Interacademy Panel.

Session II Pathogenic Microorganisms and Toxins: Current & Future Standards

17. *A. Biological Agent Standards and Regulations: Use, Containment and Access.* The opening presentation provided an appreciation of pathogen control regulations from a European and UK perspective. The European Directive 2000/54/EC[5] lays down the minimum provision to be applied in this respect within the European Community. The implementation of this Directive in the United Kingdom is carried out through the Control of Substances Hazardous to Health Regulations 2002[6] which are intended to protect both workers and others who may be exposed from work activities to the risks of hazardous substances. The Directive requires the classification of biological agents, assessment of the risk associated with them, notification of initial and subsequent use to the competent authority -- which in the UK is the Health and Safety Executive (HSE) -- and the maintainance of a list of workers exposed to the agent and requirements for the training of those working with biological agents. In the national implementation in the UK, there is also a requirement to notify the competent authority (the HSE) of the consignment of Hazard Group 4 biological agents; an extended subsequent use notification requirement of all Hazard Group 3 and a few hazard Group 2 agents; and a requirement to ensure that procedures are in place to deal with accidents, incident and emergencies.

18. It was noted that such health and safety legislation has limitations in that it only applies to work activities and it does not cover animal and plant pathogens. In the UK, toxins are also covered by Control of Substances Hazardous to Health Regulations 2002, by the Control of Major Accident Hazards (COMAH) regulations and the Advisory Committee on Toxic Substances. Insofar as steps to improve the security of pathogens are concerned, it was suggested that there should be efforts towards international legislation, that there should be wide stakeholder involvement -- so that all involved in considering the security of pathogens whether government, industry or academia are engaged -- and that the emphasis should be on agreeing principles rather than lists of biological agents although it was recognised that lists can be valuable in implementing legislation. It was also noted that non legally binding options -- such as guidelines and codes of conduct can be effective.

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[5]European Community, *Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work*, Official Journal of the European Communities, L.262/21, 17 October 2000. Available at http://europa.eu.int

[6]United Kingdom, *Control of Substances Hazardous to Health Regulations, 2002*, Statutory Instrument S.I. 2002/2677. Available at http://www. opbw.org

19. In discussion about future legislation and guidance, it was noted that bad legislation and bad regulations add no value. It was important to avoid a multiplicity of regulations aimed at different objectives as this could lead to confusion of those who are required to implement the regulations.

20. Subsequent presentations provided appreciations of biological agent standards and regulations from Russian Federation, Czech Republic, and Ukrainian perspectives. These provided valuable insights into the different national approaches to address security and oversight of pathogenic microorganisms and toxins and showed that there was much similarity between the approaches adopted in these countries. Thus in Russia, it was noted that strict government control is exercised over the handling of listed pathogens and toxins. Government Act No 869 enacted in 1992 has provisions aimed at registration of and limiting access to certain potentially dangerous biological agents and chemicals. All facilities handling dangerous pathogens and agents are registered with registration requiring standard conditions of safety and security and transfers are prohibited unless the recipient is similarly registered. Any registered government or commercial facilities are monitored by government officials and authorities responsible for ensuring the security of handling of listed materials.

21. In the Czech Republic, Act No. 281/2002 of 30 May 2002 and Decree No 474/2002 of 1 November 2002 set out measures related to the implementation of the Biological and Toxin Weapons Convention which includes licensing conditions for those handling highly hazardous agents and toxins as well as for those exporting or importing such agents and toxins. Such licensing and subsequent monitoring is carried out by the State Office for Nuclear Safety which is designated as the national office responsible for the implementation of and compliance with the BTWC. The Czech Republic Act limits exportation and importation of highly hazardous agents to and from States Parties to the BTWC. The highly hazardous biological agents and toxins are listed in Annex 1 to the decree while the hazardous biological agents and toxins, on which annual declarations are required, are listed in Annex 2. The highly hazardous biological agents and toxins listed comprise:

1. Human pathogens and animal pathogens transmissible to humans
   22 viruses
   11 bacteria
   4 rickettsiae
2. Animal pathogens
   14 viruses
   1 mycoplasma
3. Plant pathogens
   3 fungi
4. Toxins
   19 toxins
5. Genetically modified organisms
   Two categories

22. In the Ukraine, regulations control access to and work with biological agents and toxins. These stem from a regulation on procedure of storage, work and transfer of cultures of bacteria, viruses, rickettsiae, fungi, protozoa, mycoplasma, bacterial toxins and poisons of biological origin which was enacted in 1979. This requires strict accounting of materials and safety of work in laboratories as well as controlling transfers within the Ukraine and across its borders. State Sanitary Rules set out the procedure for granting permission to work with

microorganisms in groups I - IV of pathogenicity and with recombinant DNA -- it was noted that in the Ukraine, Group I pathogenic agents are those presenting the greatest danger (plague, viruses of Lassa, Ebola, Marburg, Hunan, Machupo, Crimea-Congo. smallpox, monkey virus). Permission to work with pathogenic microorganisms is given by the regime commissions which implement the national regulations.

23. In discussion, it was noted that there are clearly common approaches being adopted both in the United States through its select agent programme and in several European countries to the registering/approval/licensing of facilities and of personnel working with listed/select/ highly hazardous agents. There was thus a common understanding that nationally facilities and personnel working with listed/select/highly hazardous biological agents and toxins needed to be registered and approved. A further common understanding related to the controls and approval of transfers both nationally and internationally of listed/select/highly hazardous biological agents and toxins.

24. *B. Security Controls and Regulations.* The first presentation outlined a survey which had been carried out by Germany of the EU countries in which a questionnaire consisting of 71 questions addressing the BTWC prohibitions, export controls, handling of biological agents and toxins, and other issues had been circulated and answered, by most, but not yet all of the EU countries. This survey had identified some broad conclusions and recommendations which were summarised as:

• Prohibitions	-- Should be according to BTWC Article I
• Agents	-- Classification into risk groups
• Facilities	-- Licensing according to biosecurity standards
	-- Internal and external controls
• Activities	-- Risk assessment
	-- Licensing according to risks
	-- Internal and external controls
• Access	-- Scrutiny of personnel
	-- Professional competence
• Transfer	-- Only between licensed/controlled facilities
	-- Documentation of transfers
	-- End-user certificate for licensed exports
	-- Catch all clause
• Transport	-- According to international standards
• Scientific reports	-- No restriction

25. In discussion, it was noted that a key requirement is how to ensure that legislation is being enforced as legislation alone is not the solution. It was also recognized that coordination is essential between the different government departments and authorities in order to ensure consistency.

26. A subsequent presentation provided a Romanian perspective on security controls and regulations which demonstrated how Romania implemented export controls of biological agents and toxins and of biological equipment nationally so as to harmonise these with the Australia Group lists and with the European Community regulations.

27. The next presentation addressed the evolution of the United States Select Agent Program. Prior to the select agent rule which became effective on 15 April 1997, there were no requirements for facilities within the United States transferring certain human pathogens to be

licensed, registered and identified nor were there requirements for tracking and verification of such transfers. The United States Antiterrorism and Effective Death Penalty Act of 1996 required the Secretary of Human Health Services (HHS) through regulation to maintain a list of biological agents that have the potential to pose a severe threat to public health and safety and to establish procedures for the transfer of the listed biological agents, including measures to ensure proper training and appropriate skills of those handling such agents and proper laboratory facilities to contain and dispose of agents. Under the select agent rule between 15 April 1997 and 11 March 2003, 355 facilities were registered and about 30% of the registered facilities were inspected. More than 4,000 transfer records were received.

28. Following the 11 September attacks, the USA Patriot Act signed on 23 October 2001 and the Public Health, Security and Bioterrorism Preparedness and Response Act of 2002 have significantly amended and extended the earlier select agent provisions. In particular, comparable regulatory authorities have been granted to the US Department of Agriculture (USDA) for biological agents and toxins that present a severe threat to plant or animal health, or animal or plant products[7]. USDA and HHS are required to coordinate on "overlap" agents regulated by both agencies. The principal extensions to the select agent programme[8] are:

- Registration is required for **possession**, use and transfer
- Requirements for safety and for **security**
- Database checks are to be made by the Department of Justice on
    - Entity and the individual
    - Restricted persons (as required under the USA Patriot Act)
- Exemptions to the rule have been narrowed
- Sensitive information required is protected from disclosure
- Additional criminal penalties
- Possession of select agents are to be immediately notified.

The list of select agents and toxins has been updated[9] and regulates toxins based on potency and quantity. Under the new rule, this list will be reviewed and updated as necessary every two years.

29. Thus far, some 463 entities have registered under the select agent program; of these about 33% are registered with HHS, 44% with USDA and the balance of 83% with overlap agents. About 45% of these applications have come from commercial entities, 35% from academia and 15% from government of which about half are from the Department of Defence. It was noted that there are no exemptions for Federal or military facilities from the select agent rule.

30. Two categories of work currently require prior approval from the HHS Secretary:

- Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire this naturally.

[7]The complete list of agents subject to the select agent rule by HHS and USDA is available at http://www.cdc.gov/od/sap/docs/salist.pdf

[8]The Interim Final Rule for the Possession, Use and Transfer of Select Agents and Toxins was published in *The Federal Register* on 13 December 2002. It is available at http://www.cdc.gov/od/sap/docs/42cfr73.pdf

[9]The complete list of agents subject to the select agent rule by HHS and USDA is available at http://www.cdc.gov/od/sap/docs/salist.pdf

• Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins.

Additional categories of work are being considered for addition to the list of those requiring prior approval:

• Increase virulence or pathogenicity
• Change the natural mode of transmission, route of exposure or host range
• Result in the deliberate transfer of a drug resistance trait or toxin-producing capability to a microorganism by means that do not involve recombinant DNA techniques.

In discussion, it was noted that the microbiological community in the United States has been very supportive of the select agent rule and program.

31. The next presentation considered security controls and regulations from a Brazilian perspective. This emphasised the chapeau to the topics to be addressed by the BTWC expert and States Parties meetings which stated that they were *"to discuss, and promote common understanding and effective action on"* the topics. It was evident that the success of the meetings would be judged by whether *"effective action"* resulted. The presentation then set out the principles that need to be followed in developing *"national mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins."* These include:

• Designation of a national authority
• Define a list of pathogenic microorganisms and toxins and critical equipment subject to control
• Establish legislation on biosecurity of facilities (possession, acquisition, stockpiling), and on transport of listed pathogenic microorganisms and toxins and critical equipment
• Import/export control, including licensing of international transfers
• Oversight of dangerous activities

32. The presentation included the elements that should be included under each of the above. For example, in regard to the legislation and regulation on biosecurity of facilities, the following elements need to be considered:

• Establish legislation on biosecurity of facilities (possession, acquisition, stockpiling), and on transport of listed pathogenic microorganisms and toxins and critical equipment
  -- Registration (facilities, carriers, personnel)
  -- Licensing (activities)
  -- Tagging of equipment
  -- Chain of custody for domestic transfers or movements
  -- Permission for transfers (only between licensed institutions using registered carriers)

• Regulation on biosecurity of facilities that have listed pathogenic microorganisms and toxins and critical equipment
  -- Registration of personnel
  -- Requirements for physical security

- Security doors
- Secured areas
- Camera
- Logging of entering of personnel, removal or destruction of listed agents or critical equipment
- Inventory of listed agents or critical equipment

33. Insofar as common understandings and effective action are concerned, it was suggested that at national level States Parties should identify and evaluate national mechanisms and activities taking into account the realities of the situation with the State in respect of:

- Constitutional processes which can differ in concept and enforcement.
- Threat analysis, based on national perceptions, geography, neighbourhood, allies, capabilities, etc
- Risk assessment, including identification, analysis, evaluation, perception and communication aspects.

At the international level, States Parties could also decide on:

- A mechanism to ensure and oversee the implementation of national measures
- To collect and disseminate information
- To promote cooperation
- To resolve ambiguities and to act in the case of suspicious unlawful activities.

34. In discussion, it was noted that such an approach which set out principles based on national experience would be of particular value to the forthcoming BTWC experts meetings and the subsequent States Parties meeting rather than one which simply elaborated national legislation and regulations. It was recognised also that the list of agents is something that needs to be determined nationally as it needs to reflect national sensitivities and vulnerabilities. It was also noted that there were benefits in focussing on the oversight of "activities" involving listed agents and toxins as "activities" was an all-embracing term rather than using terms such as "research" or "development" which could be quite differently interpreted in different countries.

35. *C. International Standards for Human, Animal & Plant Pathogens.* The first presentation gave an outline of the WHO's activities to assist countries to manage biological threats. It was noted that the preamble to the WHO constitution of 1948 says that "The States Parties to this Constitution declare, in conformity with the Charter of the United Nations, that the following principles are basic to the happiness, harmonious relations and **security** of all peoples." [Emphasis added] and that Article 2 (d) states that the WHO shall "...furnish appropriate technical assistance and, in emergencies, necessary aid upon request or acceptance of Governments" -- and thus that WHO may be required to provide assistance to health emergencies that might be caused by deliberate attacks using chemical or biological materials. The WHO response is based on a three pillar approach:

- Containing known risks
- Respond to the unknown
- Improve preparedness

In addition, it was noted that the WHO Biosafety Programme has as its overall goal the reduction, to the extent possible, of the spread of disease caused by accidents or inappropriate

handling or usage of pathogenic microorganisms. One product is the WHO Laboratory Biosafety Manual[10]. Progress is also being made towards the revision of the International Health Regulations which is taking into account the experience recently gained in dealing with the SARS outbreaks[11].

36. The second presentation addressed the Office International des Epizooties (OIE) programme on Animal Pathogens and Animal Health Standards. This outlined the objectives and organization of the OIE which currently has 164 member countries. It went on to describe the operation of the OIE Information System, which aims to promote transparency and knowledge of the global animal disease situation, and drew the following conclusions:

- The recent episodes of emerging and re-emerging animal and human diseases have emphasised the important role of the OIE's world-wide disease information system.
- The disruption to trade caused by such diseases and the resulting social, economic, food security and food safety implications in one location have broad implications on global trade that affect all countries.
- The OIE, together with FAO, are currently actively engaged in improving the capacity of National Veterinary Services Surveillance and Information Systems.
- The OIE has adopted new 'standards' for the quality of veterinary services and their disease notification systems and improved its own information system in order to provide early and accurate epidemiological information on a world-wide basis, in particular through its Early Warning System.

37. From the point of view of the deliberate attack of animals, it was observed that:

- Many countries share a common concern about the natural occurrence or deliberate misuse of pathogenic biological agents that could affect public health, food and agriculture.
- Existing methods of disease prevention and containment, regulations, guidelines and standards are being extended at both national and international levels to improve the ability of countries to prevent, manage and recover from natural, accidental or deliberate introduction of animal diseases.
- If the OIE standards and its network of disease surveillance and reference laboratories are correctly implemented by member countries, the threat of bioterrorism could be better managed.
- There are, at present, substantial differences between countries in the perception of national threats from the deliberate use of pathogenic biological agents.

It was noted out that the OIE, as the international reference scientific organization for animal health issues and zoonoses, had not remained oblivious to this situation and plans were being made to organize an international Conference on 'Emergency management preparedness and response' with the participation of the 164 Member Countries of the OIE. The ultimate goal of the OIE is to protect and improve public and animal health conditions in all countries, while facilitating and protecting international trade.

[10]The full text of the Second Edition (Revised) Interim Guidelines. 2003 is available at http://www.who.int/csr/resources/publications/biosafety/Labbiosafety.pdf

[11]See report WHA.A56/48 submitted to the May 2003 World Health Assembly and the resolution WHA 56.29 agreed by the World Health Assembly on 28 May 2003. Available at http://www.who.int

38. The third presentation addressed the Food and Agriculture Organization (FAO) Biosecurity programme. This pointed out that biosecurity in the FAO describes the concept, process and objective of managing -- in a holistic manner -- biological risks associated with food and agriculture, with "agriculture" used in its broadest sense to include agronomy, livestock husbandry, forestry, fisheries and related environmental dimensions. Biosecurity is regarded as an objective that is a key requirement for public welfare and requires consideration of why we regulate, what we regulate, how we regulate, who regulates, and who pays. It includes the generation and sharing of scientific knowledge and includes ethical considerations, such as transparency of decision-making, public participation, confidence and trust, and responsibility and vigilance in protecting society. It was considered that effective biosecurity is a societal value and underwrites public confidence in the food and agriculture sector, and in its products.

39. Effective biosecurity needs to be able to change to meet current challenges which includes the following:

- Increased trade and expanding markets
- Expanding risks, including those associated with deliberate attacks
- Advances in modern biotechnology
- Advances in information technology
- Modernisation of the legislative and regulative frameworks
- The need for holistic systems with rationalisation between Ministries and national bodies
- Environmental awareness
- Resources needed to meet national and international obligations
- Capacity building

40. Improvements in ensuring effective biosecurity could be achieved through enhancing functional aspects such as strengthening cohesion and synergy across sectors, legislative consistency across sectors, rationalization in areas such as risk management, border control, surveillance and incursion response, increased public accountability and increased transparency. Biosecurity management involves an iterative process with a number of phases:

- Pre-risk / Establishment of process and procedures
- Surveillance
- Management and eradication
- Risk communication throughout.

41. Better biosecurity was already being addressed through the harmonization and integration of:

- Authority
- Legislation and regulations
- Technical approach/es
- Administrative functions
- Information exchanges

International standards were being developed and institutionalization of the national capabilities so that areas of potential overlap and conflict could be identified and resolved.

42. Insofar as deliberate attacks using pathogens -- or biological weapons -- are concerned, these were receiving increasing international attention and importance. They should, however, be regarded as an a component of biosecurity and addressed within the existing framework using existing resources and expertise thereby minimizing additional demands on resources. Consequently, in considering how to improve security, the approach should be to improve existing mechanisms such as regulations and to strengthen existing functional systems such as surveillance, monitoring and reporting. Communication and information exchange are of particular importance. Throughout it is important to have regulations and procedures that are feasible to implement and are cost effective. In discussion, several practical considerations were recognised which included pathogens that affect both humans and animals, pathogens that produce toxins, the difference between a pure strain at one extreme and the presence of a trace in a product at the other, the need to consider vectors/insects and to ensure that measures taken are compatible with other Conventions and national obligations. The essential underlying requirement is for a national capability to achieve effective biosecurity.

Session III Oversight of Dangerous Pathogens, Genetic Modification & Information

43. *A. Genetic Modification.* The first presentation provided a European and UK perspective on the oversight of genetic manipulation which began by providing definitions of some of the terms used in the national and regional regulations such as genetic modification, organism, microorganism, contained use and deliberate release. The current European directives are 2001/18/EC[12] on the deliberate release to the environment of genetically modified organisms (GMOs) and 98/81/EC[13] on the contained use of genetically modified microorganisms (GMMs). It was noted that in regard to contained use, the requirement is for a risk assessment to be made of the contained use activity in order to assign it to the appropriate classification. Notification is required to the competent authority -- which in the United Kingdom is the Health & Safety Executive -- and consent is required for Class 3 (moderate risk) and Class 4 (high risk) activities. In the UK the European Directive for Contained Use is transposed into national law through the GMO (Contained Use) Regulations 2000[14] which differs from the EC Directive in three aspects:

- Extends to genetically modified organisms (plants and animals in containment) as well as to genetically modified microorganisms

- Increases information requirements through a public register in line with UK's open government policy

- Requires the establishment of genetic modification safety committees to advise on risk assessments.

The UK regulations have as its chief aims the protection of workers in genetic modification containment facilities and the prevention of organisms escaping and affecting the

[12]European Community, *Council Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EC*, Official Journal L 106, 17/04/2001, pp. 1 - 39. Available at http://europa.eu.int

[13]European Community, *Council Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified microorganisms*, Official Journal L 330, 05/12/1998, pp. 13 - 31. Available at http://europa.eu.int

[14]United Kingdom, *Genetically Modified Organisms (Contained Use) Regulations 2000*, Statutory Instrument S.I. 2000/2831. Available at http://www.hmso.gov.uk

environment or humans outside the containment facility. It was observed that the objective of biocontainment is to prevent the unwanted accidental release of genetically modified organisms -- and not biosecurity as it is not trying to prevent unauthorised access into containment facilities or unauthorised acquisition of genetically modified organisms.

44. In regard to the oversight of genetic modification in contained use, it was noted that a permissive regime is operated in regard to genetic modification work presenting moderate or high risks and that both the European Directive and the UK regulations include requirements for the disclosure of information. This emphasis on the public availability of information is in line with the Cartagena Protocol on Biosafety and, within Europe, the Aarhus Convention[15]. Although there had been some reconsideration within the UK following 11 September 2001 as to precisely what information should be included in the public register which had resulted in a number of activities and their locations being removed[16] from the register as a biosecurity measure, attention continued to be given to balancing the demands for transparency with the need for security.

45. In discussion, improvement of security and oversight of genetically modified microorganisms was seen as requiring international effort so as to extend national and regional standards and approaches more widely. A point was also noted about the need to ensure that regulatory controls are effective in regard to the buying and selling of biological material over the internet. Finally, a code of conduct for the scientific community could help to improve self regulation.

46. A second presentation provided a Slovenian perspective on the oversight of genetic modification. This made it clear that in Slovenia the national Management of Genetically Modified Organisms (GMOs) Act of 2002 which applied to microorganisms, plants and animals implemented in Slovenia the requirements of the European Community directives 98/81/EC and 2001/18/EC as well as of the Cartagena Protocol on Biosafety. The national legislation embraces contained use, deliberate release and the placing on the market of GMOs. It also regulates the import and export of GMOs. For those activities assessed as presenting a moderate or high risk, there is a requirement for a public hearing prior to contained use. Public hearings are also required for deliberate release into the environment or for placing GMOs on the market. It was thus evident that the approach taken to oversight of genetic modification in Slovenia was closely similar to that taken within the European Union.

47. *B. Dangerous Pathogens.* A presentation emphasised the extremely rapid growth of new biology and the correspondingly rapid rate of production of new knowledge. The developments in understanding the nervous system and in understanding pathogenesis were used as examples of the new biology which could be misused. Possible approaches to preventing abuse could include:

- Classification of results prone to be abused
- Voluntary restriction of dissemination of results by journals, individual scientists etc
- International regulation of dual use science
- Scientific codes of conduct and promotion of norms

[15]United Nations Economic Commission for Europe, *Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters*, done at Aarhus, Denmark, on 25 June 1998. Available at http://www.unece.org/env/pp/cep43e.pdf

[16]United Kingdom, *Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2002*, Statutory Instrument S.I. 2002/63. Available at http://www.opbw.org and at http://www.hmso.gov.uk

• Universality and support for international treaties -- BWC, CWC ...
• Transparency in biotechnology, biodefence, chemical defence

It was observed in conclusion that effective prevention of abuse will require sustained efforts and multiple approaches:

• Promotion of transparency
• Promotion of norms and professional codes of conduct
• Support of international treaties
• Increased internationalization of biotechnology and pharmaceutical sciences
• Eliminating the root causes of terrorism.

48. A second presentation outlined a protective management scheme for dangerous pathogens and toxins. This noted that the most immediate and most probable sources of threat would involve known pathogens against which it was suggested that consequence management could in principle be effective. However, a less immediate and less probable but far more severe threat would involve the deliberate development of a new pathogen optimized for mass destruction. This led to the assumptions that national security measures of classification and export control would not be expected to be effective in restricting access to fundamental scientific information enabling the creation of a mass destruction pathogen. Consequently, it was argued that the most promising alternative approach would be a protective oversight process based on peer review procedures and that this would have to be explored and probably attempted. A central problem for such protective oversight would be how to ensure that exploratory research for permitted purposes was conducted while preventing its misuse for destructive application.

49. In considering protective oversight the following principles were proposed:

• Involvement of the scientific community on a global basis vital

• Should be based on principles of competent peer review

• Should be calibrated to the degree of danger

• A sensibly restrictive definition of extraordinarily dangerous research activity is required

• International licensing of all individuals and institutions engaged in such activity is required

• Prior review and continuous monitoring of specific research projects in the extraordinarily dangerous category is required

• Harmonized national registration and reporting rules for research of lesser but significant danger

• Appropriate rules needed for access to research results in both categories.

50. It was concluded that systematic transparency needs to be established at the international level of all research in the extremely dangerous category. However, it was observed that research involving most of the current select agents could be handled under national regulations provided that harmonized standards are established internationally. It was also recognized that achieving international oversight and national harmonization would require extensive legal specification and institutional development for which there are currently few precedents. However, it was predicted that current attitudes regarding protective oversight schemes were likely to evolve under the pressures of future developments and appreciations of the risks posed by dangerous pathogens.

51. *C. Oversight of Information.* The first presentation addressed the oversight of defence programme objectives and was followed by a presentation on addressing public concerns about biotechnology before a final presentation on striking the balance between transparency and security. Concerns about defence programme objectives had arisen in the autumn of 2001 when three United States biodefence programmes had been identified which would certainly have provoked political reaction had they been in other States Parties. These three programmes were:

- Project Clear Vision involving a BW bomblet (CIA)
- Project Jefferson involving genetically modified anthrax (DIA)
- Project Bacchus involving the purchase and construction of a small BW production facility (DTRA).

It was noted that although the confidence-building measures (CBMs) agreed by the States Parties at the Second Review Conference in 1986 and extended at the Third Review Conference in 1991 require declarations of biological defence research and development programmes, these three US programmes were not included in the US declarations in 2001 and 2002. It was, however, observed that the modalities agreed for the CBM declarations were such that a considerable amount of information is provided on national biological defence programmes and facilities by those States Parties which provide comprehensive declarations -- and that such information does contribute to transparency and thereby to building confidence in compliance. It was concluded that the CBM declaration requirements do provide useful insight into national capabilities and facilities including biodefence programmes. However, complete and timely CBM declarations are required from **all** States Parties.

52. In regard to biological defence programmes and facilities, it was concluded that making such CBM declarations available on the internet, as has been done by Australia which puts its whole CBM declaration on the web, would demonstrate transparency and would enable other States Parties and independent analysts to carry out consistency checks between the information in the CBM declaration and other publicly available information.

53. The second presentation examined approaches that could be taken to addressing public concerns about biotechnology. This recognised that public concerns have been raised about the potential of using biotechnology for human cloning and more recently about genetically modified foods. A similar concern could arise in regard to the potential misuse of biotechnology to carry out deliberate attacks to cause harm to humans, animals or plants. Taking genetically modified foods as an example, public concerns related to aspects such as toxicity, allergenicity, environmental damage and the potential uncontrollable effects of genes released into the environment. Useful lessons can be drawn from the continuing debate

about genetically modified organisms that could be applied equally to concerns about the misapplication of biotechnology to attack humans, animals and plants. It is important to distinguish the real and actual threat to human health and the environment from the perceived or feared threats. It is necessary to consider how public attitudes towards toxins and biohazards are created as well as to address who should take responsibility for correct and accurate provision of information and education of the public.

54. The third presentation addressed striking a balance between transparency and security. This noted that although transparency was a frequently used term in arms control, it was rarely defined. A dictionary definition was:

> *The state of being transparent -- candid, open or frank, easy to see through, understand, or recognise, obvious.*

Transparency was of particular importance in regard to biological and toxin weapons arms control as so much of the technology was dual-use. Nevertheless, it was recognised that transparency cannot be applied to all aspects of defence and industrial activity as some aspects need to remain secret. For example, vulnerabilities and detailed capabilities need to be protected and information that could assist proliferation should not be disseminated. The key question relates to where to draw the line between what is revealed and what is protected. In judging how to address this, it needs to be recognised that not everything has to be kept secret. It is also necessary to consider what the objective of transparency is. It is not for its own sake but for building confidence and to reduce the chances that an activity may be misinterpreted. It is also important to recognise that it is not necessary to know everything in order to understand or to recognise what is being done. Much can be gained from examining the consistency of various pieces of information.

55. It was noted that much information is currently available from sources such as the annual CBM declarations made by States Parties, company annual reports and information on company websites, official government reports, national regulatory requirements, scientific publications, and scientific and industry conferences. The quality and quantity of the information available from such sources was, however, variable. In considering the balance between transparency and security, it was observed that the recent increased concern about terrorism was leading to a move away from greater transparency thus reversing the previous trend towards increased transparency. Attention was being given to what information should be published -- the statement on biodefence and biosecurity published in *Nature* in February 2003 was noted -- with consideration being given to self-censorship of research publications which could assist proliferation -- a requirement which was being underlined by the technology transfer regulations being implemented within Europe -- and to codes of conduct for those in the biological sciences.

56. It was concluded that the distinction between State and non-State actor level needs to be recognised in regard to both capability and intent. However, in considering how to strike the balance between transparency and security, a pragmatic approach needs to be adopted as the risk will vary over time. Transparency should provide enough detail to acquire an understanding and build confidence yet not provide sufficient detail to expose vulnerabilities or to aid proliferation.

Session IV Maximizing the Security and Oversight of Pathogenic Microorganisms and Toxins

57. *A. Achieving Enhanced Security and Oversight.* This presentation took stock as to how best enhanced security and oversight might be achieved and ended by considering how the key issues addressed at the Workshop might best be embraced within the framework of the five subtopics identified by Ambassador Tibor Toth for the experts meeting in August on security and oversight. It started by considering which pathogenic microorganisms and toxins needed to be addressed from a security and oversight viewpoint. It was important to determine which biological agents and toxins are to be covered. One approach might be to consider only the WHO/OIE Group 4 pathogens whilst another approach might consider which microorganisms present a real concern to a particular State Party -- and might include agents such as anthrax, cholera, salmonella, brucella and plant pathogens. The question as to which toxins needed to be included also had to be addressed. It was recognised that each State Party needed to nationally address what its agents of concern were -- and that in so doing it was important to consider animal and plant pathogens as well as human pathogens and toxins.

58. The next stage is to consider what needs to be controlled in regard to security and oversight of the agents of concern:

- Access
- Transfers
  - -- domestic
  - -- international
- Physical protection -- biocontainment
- Activities

It was noted that although legislation provides the primary method to provide security and oversight, other important measures include physical security, peer oversight, and training and education.

59. In considering national legislation, it was observed that there may be several different legislative measures that are relevant to the security and oversight of pathogenic microorganisms and toxins including measures addressing:

- Human health and safety
- Animal health and safety
- Plant health and safety
- Genetic engineering
- Non-proliferation
- Anti-terrorism

60. In regard to non-proliferation and anti-terrorism legislation, a number of aspects need to be considered:

- Legal interaction
  - -- it is important that different legislation is complementary and that there are no contradictions between different elements of legislation and also that there are no loopholes. The administrative burden also needs to be considered.

- Extent of legislation
  - -- what should and what should not be included -- agents, facilities, activities -- with attention again been given to ensuring that there are no loopholes.

• Implementation

-- attention needs to be given to whether the requirement is for notification or for prior approval, ensuring that the security and oversight requirements avoid hampering health and safety activities, the capabilities required to implement the legislation, and which agencies are to provide the control and oversight -- with particular attention being paid to who does what and when. Training and education are also vital -- both for those enforcing the legislation and those in academia, government and industry who are required to comply with the legislation.

61. The presentation concluded by considering the security and oversight topics that had been identified and addressed at the Workshop and examining how these could best be incorporated within the framework that Ambassador Tibor Tóth had proposed to the States Parties:

a. Legal, Regulatory & Administrative.

b. Facilities and Equipment

c. Personnel and handling

d. Transport

e. Accountability, licensing and accreditation

62. The various security and oversight topics were collected within the outline as follows:

a. Legal, Regulatory & Administrative.

-- Agents of concern need to be identified nationally as clearly as possible to avoid loopholes. The aim should be for as small a burden as possible -- and thus to minimize the hampering of permitted legitimate activities.
-- A wide range of legislation is possible addressing agents, facilities and activities. Close coordination is needed to ensure that legislation is complementary and that the administering agencies coordinate their activities so that overlap is minimized.
-- Legislation needs to be practically implementable and include provisions for inspections of facilities and activities when necessary.
-- Legislation needs to contain penal clauses.

b. Facilities and Equipment

-- Building design requirements primarily for biocontainment
-- Guidelines
-- Licensing

c. Personnel and handling

-- Peer oversight -- based on awareness and knowledge
-- Education and training

-- Protective oversight and management of biotechnology
-- Licensing

d. Transport

-- Regulation of transfers both nationally and internationally

e. Accountability, licensing and accreditation

-- Facilities and individuals -- listed agents and toxins
-- Prior permission for specified work
-- Use term "activities" rather than "research" which has different interpretations in different countries
-- Licensing versus Registration
-- Registration with notification versus prior approval

Conclusions

63. *B. Conclusions: Issues of Particular Relevance for the BTWC Experts Meeting in Geneva in August 2003.* The final presentation provided a summary of the key points that had emerged from the Workshop leading to an overall appreciation as to the common understandings that had emerged and how effective action might be taken to ensure that the experts meeting in Geneva made effective use of the time available. This overall appreciation is outlined below.

Common Understandings: General

64. There was widespread agreement at the Workshop that Ambassador Tóth should focus more attention on *"discuss and promote common understanding and effective action"* that is required by the mandate for the annual meetings. It was noted that the success of the annual meetings would be judged by whether or not there was *"effective action."* This phrase was especially important and needs to be borne in mind in considering the experts meeting in August in Geneva. There was a strong feeling that Ambassador Tóth should put more focus on the outcome of the expert meeting and how this might facilitate the subsequent States Parties meeting in November to achieve an effective outcome.

65. Ambassador Tóth's request for a thematic approach to be taken by States Parties in their presentations to the experts meeting was strongly endorsed. The presentations by States Parties should set out the principles and core requirements which might form the basis of common understandings, and, ideally, effective action subsequently by individual States Parties. **Presentations** should **not** detail national laws, regulations and structure, which should be provided in background papers circulated to the States Parties but **instead** should be generic presentations addressing the sub-topic theme. They should identify **core** elements.

Common Understandings: Security

66. It is clear that there are common approaches adopted regionally and more widely in several areas:

a. Safety in storage, handling and use of pathogenic microorganisms and toxins;

b. Safety in handling and use of genetically modified microorganisms

c. Such safety includes biocontainment and thus physical security of the microorganisms

67. More recently, it is evident that attention has been given in several countries to:

a. Security in regard to access to and acquisition of listed/select/highly hazardous agents

b. Controls/registration/licensing of facilities and individuals involved in activities with listed/select/highly hazardous agents

c. Controls of transfers, both within and between countries, of listed/select/highly hazardous agents

Common Understandings: Oversight

68. It is evident that the consideration given to oversight of pathogenic microorganisms and toxins is much less developed than that given to security.

69. Oversight is necessary of legislation and regulations and of their implementation and enforcement.

• Badly drafted and unfocussed legislation and regulations, and unenforced legislation and regulations are counter-productive.

• An oversight forum of legislation and regulations involving government, industry and academia can be effective and is valuable.

70. **Oversight of the purpose of the work.** The need for such oversight has been fuelled by concerns about the mousepox and synthetic polio virus experiments and also by concerns about some US DOD activities. Improved transparency of biological defence activities could be achieved by universal application of the existing CBMs if all States Parties complete these fully and submit them annually. The publication nationally of the biodefence CBMs on the internet, as has been done by Australia, would be a valuable step forward to reduce concerns about defence programme activities.

71. The balance between transparency and security requires consideration. It was concluded that adequate transparency can be achieved without jeopardizing security as adequate transparency does not require complete transparency.

72. **Prior approval of work.** It was noted that prior approval is already required in some areas of work:

• Animal experimentation in the UK which requires licensing and approval of the facility, licensing of the individual and licensing of the project before work can start.

• Genetic manipulation in the higher risk categories (III and IV) which requires prior approval primarily from the point of view as to whether it is safe to carry out the work within the proposed facility.

• Certain types of work (transfer of drug resistance traits and transfer of toxin producing capabilities) require prior approval in the US select agent programme. Additional categories requiring prior approval are likely to be added to the select agent programme in 2004.

Prior approval of extremely dangerous experiments involving pathogenic microorganisms is probably going to be necessary. This could be a national approval scheme to internationally agreed standards regarding transparency.

Effective Action (to maximize the effectiveness of the meeting of experts)

73. The meeting of experts addressing the topic *ii. National mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins;* will have only five days to address security and oversight. Representatives could be present from 146 States Parties but more realistically are likely to come from 50 to 60 States Parties. The NATO ARW involved 36 experts from 16 countries and was a tightly structured 3 days which made full use of all the allotted time, starting and finishing on time. If common understandings and effective action are to emerge from the experts meeting at Geneva it will need to be tightly yet **flexibly** structured and run making full use of all the allotted time.

74. **IGOs.** It also became apparent during the NATO ARW that although the activities and expertise of the IGOs provide an important background to the experts meeting in Geneva, none of the IGOs are directly mandated to address the topic being addressed by the experts meeting and it was evident that they do not have the resources to devote to preparing presentations for the experts meeting in August. Although the IGOs are keen to assist they are seeking to have a much clearer statement as to what they are being expected to provide to assist the States Parties to the BTWC. In addition, it was apparent that the time needed for any IGO to make a presentation and to subsequently answer questions could be about 45 minutes for a presentation, 45 minutes for discussion thus making huge hole in the available time at the experts meeting. At the outset of the NATO ARW, it had been expected that it would be possible able to identify some of the most relevant IGOs to make presentations to the experts meeting in Geneva in August 2003. However, views changed significantly during the Workshop. It was concluded at the end of the ARW that the IGOs should **not** be invited to make presentations to the experts meeting but **instead** to be invited to provide background documentation that could be circulated to the States Parties experts.

75. **Thematic Presentations.** Making the most effective use of the time allotted to security and oversight will require **flexibility.** Based on the presentations and discussions at the ARW, it seemed that it was possible to develop a feel for the thematic presentations by States Parties that could facilitate arriving at common understandings within the framework proposed by Ambassador Tóth.

a. **Legal, Regulatory & Administrative.** Two topics were identified for thematic presentations:

a. Agents of concern. A thematic paper and presentation could usefully set out the approach that could be followed nationally by States Parties in developing a national control list of "agents of concern" to prevent the misuse of such agents by individuals within the State.

This thematic paper could start by recognizing that the term "pathogenic microorganisms and toxins" is very broad and includes many microorganisms and toxins which pose little hazard. The principles of risk assessment applicable to human, animal and plant pathogenic microorganisms and toxins in order to draw up the national list of "agents of concern" should be set out and should be broader than just the inherent properties of the agent.

b. *Legislation addressing the security of "agents of concern."* This thematic presentation could start by recognising that in most States Parties there will already be existing legislation to protect public, animal and plant health and the environment. This could set out the required physical containment and access control for the various categories of pathogenic microorganisms and toxins. Although these are primarily intended to ensure that the agents do not escape and are not inadvertently released, they should already include many of the requirements to provide physical security and access control to prevent unauthorized access to or acquisition of the agents of concern. This thematic presentation could then continue to address the importance of good legislation, coordination between the various government agencies involved -- which are frequently different for human, animal and plant pathogens -- enforcement, and the requirement for such legislation to have penal clauses.

b. **Facilities and Equipment.** The standards and guidelines for containment equipment, facility design and security arrangements are already well established with various internationally used standards and guidelines (such as those by the WHO (Laboratory Biosafety Manual, Second Edition, 1993), OIE and the US CDC/NIH guidelines (BMBL, 4th Edition, 1999)). This is an area that was discussed in detail by the Ad Hoc Group during its deliberations and is a topic that needs little debate at the experts meeting in August 2003. The common understanding that emerges should be the use of existing standards which a country can nationally upgrade if it feels such upgrading to be necessary -- for example to handle specific pathogenic microorganisms under a higher biosafety level.

c. **Personnel and handling.** There is considerable overlap between this topic and that of accountability, licensing and accreditation and it would be more logical to address these two topics **together**.

d. **Transport**. Two topics were identified for consideration here:

a. *Transport details.* The standards for the physical containers to be used for the transfer of pathogenic microorganisms and toxins both nationally and internationally are already set out and are largely internationally agreed. There might be advantages from a "smart" container (as in the nuclear arena) for transfers of "agents of concern". This topic should require little debate at the experts meeting in August 2003.

b. *Transfer requirements.* A thematic paper and presentation dealing with transfers could usefully start by noting that countries have long had measures in place to prevent unwanted diseases, in humans, animals and plants, from entering the country. Consequently, there is generally a much wider list of pathogenic microorganisms on which import controls have long been present. Likewise, within countries, there are frequently tight controls on internal transfers especially of plant and animal diseases. Consequently, when considering the list of "agents of concern" there are frequently national controls already in place for imports and for transfers within a country. The controls on the transboundary transfers of "agents of concern" are required by States Parties to meet their obligations under Article III of the BTWC and are also required frequently for human, animal and plant health reasons. There can be administrative benefits in adopting the same list of "agents of concern" for control of transfers both within a country and transboundary.

e. **Accountability, licensing and accreditation.** As "personnel and handling" overlaps considerably with this topic, these can usefully be taken **together**. Three key thematic issues were identified:

a. *Registration, licensing, approval of facilities handling agents of concern.* A thematic paper and presentation could address the central principles to be followed in establishing a national scheme for the registration, licensing and approval of facilities holding and handling "agents of concern." This needs to set out the authorities carrying out such registration and approval, the duration for which such registration, licensing or approval is given and the approaches to and frequency of inspection of such facilities.

b. *Registration, licensing, approval of individuals handling agents of concern.* A thematic paper and presentation could address the central principles to be followed in establishing a national scheme for the registration, licensing and approval of individuals holding and handling "agents of concern." This needs to set out the authorities carrying out such registration and approval, the duration for which such registration, licensing or approval is given and the approaches to screening of the individuals, the training and competence of such individuals. Good science standards and code of conduct and ethical considerations could all be included.

c. *Registration, licensing, approval of activities involving agents of concern.* A thematic paper and presentation could address the central principles to be followed in establishing a national scheme for the registration, licensing and approval of activities involving "agents of concern." This needs to set out the authorities carrying out such registration and approval, the duration for which such registration, licensing or approval is given and the approaches to and operation of a permissive or prior approval system for particular activities considered to pose a high risks.

76. **Indicative Outline.** The above analysis indicates that a **rigid** schedule in August allotting one day to each subtopic may not make most effective use of the available time. It would be much better to simply provide an **indicative** outline of how the subtopics might be

addressed and an indication of the estimated duration for each subtopic along the following lines:

a. Legal, Regulatory & Administrative. (1.5 days)

b. Facilities and Equipment (1/2 day)

d. Transport (1/2 day)

c. Personnel and handling) Taken together (2 days)
e. Accountability, licensing and accreditation)

Chairman's observations (1/2 day)

77. **Terminology.** For effective use of the limited time available for the experts meeting in Geneva, it will be important to avoid sidetracks and confusion resulting from the different meanings of some of the terms used in the discussions. At the ARW it became clear that there are different meanings and understandings for the following terms:

a. *Biosafety*. This is frequently used to mean the policies, practices and equipment to prevent biological agents harming humans, animal or plants or the environment. However, with the advent of the Cartagena Protocol on Biosafety, the term biosafety is sometimes used to refer to the procedures relating to living modified organisms.

b. *Biosecurity.* It was pointed out that in some languages, such as French, the same word is used for biosafety and biosecurity. The term biosecurity also has a particularly wide meaning in respect of FAO activities.

c. *Deliberate release.* In the BTWC arena, this term is usually used to relate to a deliberate release by terrorists or by State Action. There is another meaning -- a planned deliberate release -- in the context of the European wide directives relating to the deliberate release of genetically modified organisms or microorganisms.

There could be benefit in a common understanding being agreed prior to the start of the experts meeting in August as to what the terms "biosafety", "biosecurity" and "deliberate release" will mean during the experts meeting. Alternatively, each State Party should be asked to make it clear what is meant by the terms in their papers or presentations.